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ENVIRONMENTAL HEALTH IN INTERNATIONAL AND EU LAW

CURRENT CHALLENGES AND LEGAL RESPONSES

Edited by
Stefania Negri



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Environmental Health in International and EU Law
Current Challenges and Legal Responses



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Foreword

The World Health Organization has long recognised the important influence that environmental integrity has on human health and development. We know from WHO's most recent environmental burden of disease assessment that at least 12.6 million people die each year because of preventable environmental causes. This is almost a quarter of all annual deaths globally.

Air pollution kills approximately 7 million people a year. Climate change exacerbates existing health threats from extreme weather events to undernutrition and infectious disease and threatens the existence of some small island States and habitability of low-lying areas. Both of these are integrally connected to wider environmental degradation, including the degradation of life in the oceans, and the loss of biodiversity.

The good news is that today we have more knowledge, evidence, and understanding than ever before about how and through what pathways climate and environmental change impact health. We know which sector policies and interventions effectively address environmental root causes of disease (e.g., energy, transport, housing, and agriculture) and in which settings (e.g., cities, workplaces, and homes) these interventions will likely have the greatest impact. We also know many of the co-benefits to health, the environment, and the economy that could accrue with a more integrated approach to development policy and planning.

This knowledge needs to be translated into policy and legislations who can promote and protect health. The World Health Organization welcomes this book and believes it can serve as the basis for future collaboration and dialogue between the health professionals, the environmental and the law communities for the promotion of climate and environmental legislation that puts public health outcomes at the centre of law and regulations.

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Introduction

Environmental health addresses the physical, chemical and biological factors external to a person and all the related behaviours.¹ It comprises those aspects of human health and disease that are determined by environmental risks, encompassing also the assessment and control of environmental factors that have the potential to adversely affect human health.²

The global dimension of environmental health impacts is impressive. The report issued by the World Health Organization in 2016 on *Preventing Disease through Healthy Environments: A Global Assessment of the Burden of Disease from Environmental Risks*³ states that 23% of global deaths and 26% of deaths among children under age 5 – that is to say an estimated 12.6 million deaths every year – are due to preventable environmental risk factors such as air, water and soil pollution, chemical exposures, climate change, and ultraviolet radiation. It is estimated that these environmental hazards contribute to 101 diseases and injuries out of the 133 diseases or disease groups listed in the Global Health Observatory.⁴ In particular, 8.2 million environmental-related deaths are due to non-communicable diseases, including stroke, heart disease, cancers and chronic respiratory diseases, which are the top five causes of deaths. Children under 5 and older adults between 50 and 75 are most affected by the detrimental effects of environmental degradation, while low- and middle-income countries bear the greatest share of environmental disease. The report argues that environmental health interventions can make a valuable and sustainable contribution towards reducing the global disease burden, improving the well-being of people worldwide and achieving all Sustainable Development Goals, many of which are closely interlinked with the environmental and social determinants of health.⁵

The protection of public health from environmental harm is clearly a major concern in international environmental law.⁶ The importance of safeguarding human

¹ Annette Prüss-Ustün, Jennyfer Wolf, Carlos Corvalán, Robert Bos, Maria P Neira, *Preventing Disease through Healthy Environments: A Global Assessment of the Burden of Disease from Environmental Risks* (WHO 2016) 3.

² WHO Europe, *European Charter on Health and the Environment*, 1989; see also *Environment and Health. The European Charter and Commentary*, 1990, 18.

³ Prüss-Ustün and others (n 1).

⁴ *ibid* at 11.

⁵ *ibid* at 95.

⁶ See Makane Moïse Mbengue and Susanna Waltman, 'Health and International Environmental Law' in Gian Luca Burci and Brigit Toebe (eds), *Research Handbook on Global Health Law* (Edward

health in the context of environmental protection is evidenced by several multilateral environmental agreements (MEAs), whose stated aim is the dual protection of both health and the environment. They include the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes,⁷ the Rotterdam Convention on Hazardous Chemicals and Pesticides,⁸ the Stockholm Convention on Persistent Organic Pollutants,⁹ and the Minamata Convention on Mercury.¹⁰ These treaties establish an international regime for the control of cross-border movements and international trade in toxic and bio-accumulative products and substances, creating an integrated system of protection of human health from the damages caused by exposure to such harmful agents.

Air pollution is a major threat to public health owing to the severe respiratory (lung diseases and cancer) and cardiovascular diseases caused by air pollutants (both outdoor and indoor). Its death toll is estimated in 7 million deaths every year. The impact of air pollution on human health is currently at the top of the WHO agenda and was discussed in the first global conference on air pollution, climate change and human health, organised by the WHO in collaboration with the United Nations Environmental Programme (UNEP), the World Meteorological Organization and the Secretariat of the Framework Convention on Climate Change.¹¹ In this field, there are several important agreements combating air pollution and protecting health, first and foremost the Convention on Long-Range Transboundary Air Pollution and its eight protocols, negotiated by the United Nations Economic Commission for Europe.¹² These treaties aim to improve air quality at the local, national and regional levels, gradually reducing and preventing air pollution through the identification of specific measures aimed to cut noxious emissions.

In the field of water pollution and waterborne diseases due to unsafe or contaminated drinking, bathing and washing water, the UNECE Protocol on Water and Health is of special significance.¹³ The Protocol deals with the management of water

Elgar Publishing 2018) 197; see also Stefania Negri, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale* (Giappichelli 2018) 177-179; ILA, Committee on Global Health Law, Sydney Conference Report 2018, Section IV, paras 31-43 (by Stefania Negri).

⁷ Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, Basel, 22 March 1989, in force as of 5 May 1992, ratified by 186 States and the European Union.

⁸ Rotterdam Convention on Hazardous Chemicals and Pesticides (PIC Convention), Rotterdam, 10 September 1998, in force as of 24 February 2004, ratified by 160 States and the European Union.

⁹ Stockholm Convention on Persistent Organic Pollutants (POP Convention), Stockholm 22 May 2001, in force as of 17 May 2004, ratified by 182 States and the European Union.

¹⁰ Minamata Convention on Mercury, Kumamoto, 10 October 2013, in force as of 16 August 2017, ratified by 111 States and the European Convention.

¹¹ See at <www.who.int/airpollution/events/conference/en/>.

¹² Convention on Long-Range Transboundary Air Pollution, Geneva, 13 November 1979, in force as of 16 March 1983, ratified by 50 States and the European Union.

¹³ UNECE Protocol on Water and Health to the 1992 Convention on the Protection and Use of

resources and access to drinking water and its aim is to protect human health, prevent the spread of infectious diseases and diseases associated with water through better management of water resources and the protection of aquatic ecosystems.

The conservation and sustainable use of biodiversity and health are also inextricably linked, as the Convention on Biological Diversity¹⁴ and its Protocols exemplify. The preamble to the Convention recognises the importance of biodiversity to meet the health needs of the growing world population, while article 8 requires the Parties to take measures to regulate, manage and control the risks to human health posed by the use and release of leaving modified organisms resulting from biotechnology. The same concern for potential adverse health effects of modern biotechnologies is equally echoed in the preamble and several provisions of the Cartagena Protocol on Biosafety, which impose on the Parties the obligation to adopt necessary and appropriate preventive and risk assessment measures.¹⁵ Also relevant is the Nagoya Protocol on Access to Genetic Resources.¹⁶ The preamble to the Protocol explicitly acknowledges the importance of genetic resources for public health as well as the importance of ensuring access to human pathogens for public health preparedness and response purposes; it provides regulatory instruments to promote an effective and equitable international access to pathogens and the sharing of related benefits (including through the development of specific international instruments), the assessment of the existence of emergencies that threaten human health and the promotion of international collaboration.¹⁷

Last but not least, the impact of climate change on global health is considered the greatest challenge of the 21st century, threatening access to clean air, safe drinking water, nutritious food supply and safe shelter. It is currently the object of scientific investigation aimed at clarifying its negative effects, also in terms of increased spread of new pathogens that lead to the multiplication of infectious diseases.¹⁸ According

Transboundary Watercourses and International Lakes, London, 17 June 1999, in force as of 4 August 2005, ratified by 26 States.

¹⁴ Convention on Biological Diversity, Nairobi, 5 June 1992, in force as of 29 December 1993, ratified by 195 States and the European Union.

¹⁵ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 29 January 2000, in force as of 11 September 2003, ratified by 170 States and the European Union.

¹⁶ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Nagoya, 29 October 2010, in force as of 12 October 2014, ratified by 118 States and the European Union.

¹⁷ In a recent study by the WHO Secretariat, the implications of the application of the Protocol for the sharing of influenza and non-influenza pathogens are explored and it is concluded that the Protocol can play an important role also in support of the *Pandemic Influenza Preparedness Framework* and the *Global Influenza Surveillance and Response System*: see WHO, *Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications*, Study by the Secretariat, 18 November 2016 <www.who.int/influenza/pip/2016-review/NagoyaStudyAdvanceCopy_full.pdf>; see also *Review of the Pandemic Influenza Preparedness Framework*, Report by the Director-General, EB140/16, 29 December 2016, Annex: Report of the 2016 PIP Framework Review Group.

¹⁸ See WHO, COP24 Special Report: Health and Climate Change, 2018 <www.who.int/global

to the WHO, a highly conservative estimate of 250.000 additional deaths each year is projected between 2030 and 2050. In this respect, the first relevant global treaty is the Vienna Convention for the Protection of the Ozone Layer,¹⁹ which acknowledges the risks posed to human health by modifications of the ozone layer and sets the general obligation to protect both health and the environment against the adverse effects of such modifications as resulting from human activities. The United Nations Framework Convention on Climate Change²⁰ requires the Parties to commit to minimise the adverse effects of climate change on public health and on the quality of the environment, while the preamble to the Paris Agreement clearly emphasises the relationship between climate change and the right to health.²¹

Moving to the regional context and focusing on the European Union as a key global player in the protection of health and the environment, it is well known that EU law provides a rich legal framework that includes a wealth of legislative acts relevant to environmental health issues of both European and global concern.²²

Apart from the abundant legislation put in place pursuant to articles 168 and 191 of the Treaty on the Functioning of the European Union,²³ which has resulted in overall reduced air, water and soil pollution,²⁴ several EU acts have been adopted in order to implement the provisions of the MEAs to which the Union has adhered. Suffice it to mention that in execution of the Basel, Rotterdam, Stockholm and Minamata Conventions the EU adopted the directives on waste disposal and e-waste,²⁵

change/publications/COP24-report-health-climate-change/en/>; Health, environment and climate change, Draft WHO global strategy on health, environment and climate change: the transformation needed to improve lives and well-being sustainably through healthy environments, Report by the Director-General, A72/15, 18 April 2019.

¹⁹ Convention for the Protection of the Ozone Layer, Vienna, 22 March 1985, in force as of 22 September 1998, ratified by 197 States and the European Union. The Preamble to the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer (equally recognises 'that world-wide emissions of certain substances can significantly deplete and otherwise modify the ozone layer in a manner that is likely to result in adverse effects on human health and the environment').

²⁰ United Nations Framework Convention on Climate Change, New York, 9 May 1992, in force as of 21 March 1994, ratified by 196 States and the European Union.

²¹ Paris Agreement, Paris, 12 December 2015, in force as of 4 November 2016, ratified by 185 States and the European Union.

²² See William Onzivu, 'European Environmental Health Law' in André den Exter (ed), *European Health Law* (Maklu 2017) 77.

²³ Article 168, para 1, of the TFEU provides that 'Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health', while article 191, para 1, states that 'Union policy on the environment shall contribute to the pursuit of the following objectives: - preserving, protecting and improving the quality of the environment; - protecting human health (...)'.

²⁴ See at <https://ec.europa.eu/environment/index_en.htm>.

²⁵ Especially relevant is the Framework Directive on Waste Disposal, Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives; Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

the REACH,²⁶ PIC²⁷ and POP Regulations²⁸ and the new Mercury Regulation.²⁹ Echoing the dual purpose characterising the corresponding international conventions, the declared objective of these acts ‘is to ensure a high level of protection of human health and the environment’ in Europe.

One last consideration concerns the fact that environmental health is a dynamic and evolving field. In fact, while there is strong scientific evidence of the negative impact on the global burden of disease of well-defined hazards such as air, water and soil pollution, chemical exposure and ultraviolet radiation, not all environmental risk factors can be grasped with full detail, especially emerging threats posed by climate change, loss of biodiversity and the effects of biotechnologies, electromagnetic fields and antimicrobial resistance.³⁰

In consideration of such complexities, and consistent with the “One Health approach”, the present book aims to offer a broad and systematic overview of the interactions between public health and environmental protection and the legal responses provided by international and EU law to prevent the health hazards associated with massive pollution, degradation of ecosystems and climate change.

This book gathers the scientific results of the research project “New frontiers in environmental health” developed within the framework of the activities of the *Jean Monnet Chair in European Health, Environmental and Food Safety Law* (2016-2019), co-funded by the Erasmus+ programme of the European Union. It builds on the expertise of a large international network of academics collaborating with the “Observatory on Human Rights: Bioethics, Health, Environment”, which is based at the Law School of the University of Salerno. Leading experts in the field and younger

²⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

²⁷ Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (RECAST); Commission Delegated Regulation (EU) 2019/330 of 11 December 2018 amending Annexes I and V to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals.

²⁸ Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC; Commission Regulation (EU) No 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III; Commission Regulation (EU) No 756/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes IV and V.

²⁹ Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury and repealing Regulation (EC) No 1102/2008.

³⁰ See, eg, Antimicrobial resistance from environmental pollution among biggest emerging health threats, says UN Environment <www.unenvironment.org/news-and-stories/press-release/antimicrobial-resistance-environmental-pollution-among-biggest>, 5 December 2017.

researchers discuss both traditional and new or emerging environmental health challenges from multiple legal perspectives, integrating human rights, ethics, investments, trade, energy, food safety and emergencies. I am extremely grateful to all of them for their excellent contribution to the book and for their confidence in this project.

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Part I

Environmental Health at the Intersection of Ethical, Human and Economic Values



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Chapter 1

[Human] Values and Ethics in Environmental Health Discourse and Decision-Making: The Complex Stakeholder Controversy and the Possibility of “Win-Win” Outcomes

Anja Matwijkiw* and Bronik Matwijkiw**

1. *Introduction: Shareholder and Non-Shareholder Stakeholders*

Descriptively, real-world facts about the link between the mode of production and its effects on the environment speak their own clear language. In 2018, *Deutsche Welle* reported that:

Plastic now pollutes our entire Planet.
Governments are trying to tackle the environmental catastrophe... and this is hurting some businesses.
It is all proving that the move away from waste is going to be a struggle.
The move will save a lot of money in the long run, but big business is only interested in profits. Shareholders focus on the short-term.
And... we are forever encouraged to consume.¹

Making money is the centerpiece of corporate responsibility, according to Milton Friedman. Thus, the (value) clash between environmental concerns and the business-as-usual view goes to the very core of the controversy and conflict that this chapter

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Disclaimer: All views expressed in this chapter are the sole responsibility of the authors.

¹ Ben Fajzullin, ‘Made in Germany – Away from Waste’ *Deutsche Welle* (25 December 2018) <www.dw.com/en/made-in-germany-away-from-waste/av-46862971>.

addresses, as will be explicated in the following paragraphs and sections. At the same time, the complexity of the stakeholder divide is such as to give rise to a number of crucial mergers, meaning that critical questions about the depth and relevancy of their differences may be inescapable.

Stakeholder doctrine or theory has a very recent origin in that R. Edward Freeman's *Strategic Management: A Stakeholder Approach* (1984) is commonly construed as the alternative to Friedman and similar *laissez-faire* capitalists who support a Privatize-Deregulate-Decentralize program. Referring explicitly to Freeman as "the father of stakeholder theory", Norman E. Bowie contrasts Freeman's approach to business management with so-called "stockholder theory".² Like Freeman's stakeholder theory, this concerns the parties, be they individuals or groups, which deserve recognition and consideration for the specific objective of managing the business. However, unlike the broad criteria that theorists like Freeman adopt and endorse, the relevant defenders of traditional business interests take a "narrow" view by virtue of ascribing primacy to investors, ie stockholders or shareholders as stakeholders.³ Therefore, the responsibilities of managers consist first and foremost in acting as *their* agents. In the event that there are no monetary or market interests at stake, the profit *versus* humanity tension comes to define the relationship between shareholders and those (non-shareholders) who *cannot be counted* as stakeholders on narrow terms. Broad stakeholder theory opposes this, in part, because the implied exclusivity makes it impossible to account for the modern business environment as an empirical phenomenon.⁴ Thus, managers must and, *mutatis mutandis*, should be broad or holistic in their approach and outlook, in effect, to avoid being left behind. Realistically and pragmatically, they should consider *anybody who can affect or is affected* by the activity or policy of the business, firm, corporation or organization as stakeholders.⁵ Besides real-world necessity and effectiveness as regards the goal of doing and staying in business successfully, a broad approach and outlook also secures an idealist component, though; and this commits managers to manage the business on the basis of values, including values that derive from singular and substantive morality (cf ethics). Unlike the narrow stakeholder version's declared respect for ethical customs and the deconstruction of value objectivity that results from an analysis of the Privatize-Deregulate-Decentralize program, broad stakeholder theorists do *not* reduce all (market) preferences to wants, nor do they accept the consequences of such a *meta*-strategy, inter alia, the idea that important values like freedom are linked with subjectivist and/or relativist philosophies that, in turn, explain why that particular individ-

² Norman E Bowie, 'Foreword' in Abe J Zakheim and others (eds) *Stakeholder Theory. Essential Readings in Ethical Leadership and Management* (Prometheus Books 2008) 9, 12.

³ *ibid* 9. Note that the primacy is predicated on risk-taking. See generally Milton Friedman, *Capitalism and Freedom* (40th, University of Chicago Press 2002) (1962).

⁴ R Edward Freeman, *Strategic Management: A Stakeholder Approach* (Pitman 1984) 38.

⁵ *ibid* 25, 46.

ual or that particular group are owed rights that match liberal or libertarian perceptions – whereas yet other rights (allegedly) fall outside the domain of valid claims. The main point is that the broad line of reasoning has a universal and humanistic foundation for freedom and liberty (although the objects of the rights permit second-order diversity or variation); and reapplies this across the value-spectrum. Furthermore, broad stakeholder theorists are skeptical about the (narrow) private/public contrast as a phenomenon that imputes an inevitable value clash, *as if* the interests of the government or, even more broadly, the community are bound to pull in the opposite direction of *our* good; with stakes in autonomy (as opposed to hegemony), self-determination (as opposed to Big Government) and non-interference (as opposed to third-party control) and, on the other and broad side of the divide, welfare (as opposed to (in)human vulnerability through unmet basic human needs), solidarity (as opposed to strict individualism and/or group egoism), and cooperation (as opposed to competition over scarce resources).

In the case of both versions of stakeholder theory, however, a certain “missing link” can be observed.⁶ More precisely, to make the leap from business management to international law, stakeholder theory has to be supplemented with additional premises to make transferrable frameworks possible, even if these do not provide exhaustive accounts of the realm. Since neither narrow nor broad stakeholder theory was originally designed to accommodate general jurisprudence, it is hardly surprising that such a (re)constructivist effort can only be stretched so far. That said, attempts to formulate a “stakeholder jurisprudence” have to contain answers to *at least some* of the key questions with which legal experts access their discipline’s interpretative platform.⁷ The list includes inquiries into philosophical topics like: (1) “What is international law?” thereby inquiring about international law’s nature and origin and, *ipso facto*, its sources of norm-creation and, as an aspect of this, the difference (if any) between legislation and adjudication;⁸ (2) “Wherein lies international law’s purpose?” thereby inquiring about necessary and immanent properties; (3) “Are moral principles condi-

⁶ Anja Matwijkiw and Bronik Matwijkiw, ‘The Missing Link in Stakeholder Theory: A Philosophical Framework’ (2014) 28 *International Journal of Applied Philosophy* 125.

⁷ For the authors’ formulation of stakeholder jurisprudence, see Anja Matwijkiw and Bronik Matwijkiw, ‘From Business Management to Human Rights: The Adoption of Stakeholder Theory’ (2010) XIII *Journal of The Indiana Academy of the Social Sciences* 46; Anja Matwijkiw and Bronik Matwijkiw, ‘Stakeholder Theory and Justice Issues: The Leap from Business Management to Contemporary International Law’ (2010) 10 *International Criminal Law Review* 143; Anja Matwijkiw and Bronik Matwijkiw, ‘Stakeholder Theory and the Logic of Value Concepts: Challenges for Contemporary International Law’ (2011) 7 *International Studies Journal* 19; Anja Matwijkiw and Bronik Matwijkiw, ‘A Stakeholder Approach to International Human Rights: Could the Trend Become a Tragedy?’ (2013) 84 *Revue Internationale de Droit Pénal* 405; Anja Matwijkiw and Bronik Matwijkiw, ‘February 14, 2014: The Three-Year Anniversary. Bahrain and the Precarious Diplomacy of Responsibility-Ascriptions: Values and Philosophical Aspects of Interpretation’ (2015) 14 *Global Community YILJ* 63.

⁸ Answers like “International law is not really law” are possible. Such skepticism can be found in legal positivism.

tions for the legal validity of the system of international norms?” thereby inquiring about that same system’s legitimacy and/or authority in a manner that may or may not debunk the distinction between conceptual and normatively-substantive questions;⁹ (4) “What is the relationship between international law and national law?” thereby inquiring about international law’s status, in addition to its (possible) distinctiveness or unique character; (5) “What are the limits for state sovereignty?” thereby inquiring about the constituent elements of international jurisdiction, something which, in turn, gives rise to questions about; (6) the scope of responsibility-ascriptions and accountability-securing strategies in the event of norm-violation (tribunals, courts, etc) and – in the cases where the accused are found guilty of crimes – questions about the consequences that attach or should attach, namely; (7) “What are the offenders’ debts and just deserts?” thereby inquiring about the victim-satisfaction that is owed under international law, together with the legal/moral need for punishment (cf retribution), or alternatively; (8) the provision of non-punitive measures that secure future peace and security as goals, inter alia, deterrence, rehabilitation of offenders, and social reconciliation, thereby also inquiring about the stakes of the community and, furthermore; (9) the rationale for generalized consideration, an aspect which may not only draw on law and morality, but also on democracy, thereby extending the inquiry to questions about; (10) global(-ization) imperatives for the regulation of the behavior of states, such as “Does participatory politics constitute a requirement at the national and international level?”¹⁰

Yet other questions are possible. However, the list is more than enough to show that while the method and subject-matter of legal doctrine differ, there is nevertheless room for a number of stakeholder relevant observations and reflections, if not overlaps, as regards the kind of insights that theorists provide. Certainly, the United Nations (UN) converted to the stakeholder-terminology two decades ago, and at a point in time where the organization also highlighted a dual rule of law concept – as an anti-dote to both political tyranny and structural violence (cf economic inequities). The latter type of violations or deprivations may even be listed as “root-causes” of serious wrongdoing and antitheses to democracy.¹¹ Furthermore, ideas about “higher values and principles” have found their way into the UN’s perception of fairness and conse-

⁹This entails a response to the separation thesis for law and (normatively-)substantive morality or ethics. Traditionally, exponents of legal positivism endorse the separation whereas advocates of natural law doctrine oppose it.

¹⁰It is possible to promote the strategy of inclusiveness and cooperation at home and, at the same time, ascertain and/or accept that certain states act as a “directorate” of the international community, eg, ‘formed by the permanent members of the Security Council (or some of them)...’ This step is inconsistent with the “integrated approach”, a legal doctrine which relies on cooperation outside of the United Nations (Chapter VII) Charter system. See Giuliana Ziccardi Capaldo, ‘The Law of the Global Community: An Integrated System to Enforce “Public” International Law’ (2001) 1 *Global Community YILJ* 71, 85-86, 119; Terry Macdonald, *Global Stakeholder Democracy: Power and Representation Beyond Liberal States* (OUP 2008).

¹¹Kofi Annan, Report of the Secretary-General to the Security Council, *The Rule of Law and Transitional Justice in Conflict and Post-Conflict Societies*, 3-4, UN Doc. 5/2004/616 (Aug. 3, 2004).

quently *broadened* this, from a formal and procedural matter in rule-application to a (substantive) “fair laws” requirement.¹² While raising the bar with the use of ethics, the UN has also inserted political ideology. With performance as an integral aspect of legitimacy, it holds that the rule of law, democracy, and “all human rights and fundamental freedoms for all” reinforce each other – without any exceptions made, *inter alia*, for gender “empowerment”, “employment” or the “right to development”, which entails inclusive economic growth and the eradication of poverty.¹³ The UN’s Global Compact also distills the essence of stakeholder direction-posts like “sustainability” (cf principle 7 (businesses should support a precautionary approach to environmental challenges), principle 8 (businesses should undertake initiatives to promote greater environmental responsibility), and principle 9 (businesses should encourage the development and diffusion of environmentally friendly technologies)).¹⁴ Important interests in health are wedged between such broad notions of corporate *social* responsibility and the fear of ecocide.

In the light of this, concepts like “abuse and exploitation” and, moreover, “terrorism” cannot but assume connotations that go beyond the set of values that otherwise still appears to constitute the rights-paradigm, *viz.*, “life, liberty, physical integrity and security” defined as stakes in (narrow) freedom and survival (through non-interference).¹⁵ Although some trends in legal doctrine gravitate towards liberal *cum* narrow outlooks, interpretations of international criminal law (ICL) as a branch of public international law (PIL) do not warrant an uncritical repetition of H.L.A. Hart’s duty-fixation in national (criminal) law, especially because *jus cogens* crimes qualify as instances of basic human rights violations.¹⁶ Hence, proscriptions from

¹² M Cherif Bassiouni, *Crimes Against Humanity: Historical Evolution and Contemporary Application* (CUP 2011) 16; UNGA, Declaration of the High-level Meeting of the General Assembly on the Rule of Law at the National and International Levels, para 2, A/RES/67/1 (Nov. 30, 2012) [hereinafter 2012 Rule of Law Declaration].

¹³ 2012 Rule of Law Declaration (n 12) paras 7-8, 16.

¹⁴ The Ten Principles of the Global Compact are derived from respectively the *Universal Declaration of Human Rights*, the *International Labour Organization’s Declaration on Fundamental Principles and Rights at Work*, the *Rio Declaration on Environment and Development*, and the *United Nations Convention Against Corruption*. See UN, Global Compact <www.unglobalcompact.org/what-is-gc/mission/principles>; Jeremy L Caradonna, *Sustainability: A History* (OUP 2014) 89-112 (for ‘Eco-Warriors: The Environmental Movement and the Growth of Ecological Wisdom’ – which captures the broad and critical messages to narrow capitalism from the 1960s to the 1970s).

¹⁵ 2012 Rule of Law Declaration (n 12), paras 17, 26; M Cherif Bassiouni, *The Protection of Human Rights in the Administration of Criminal Justice: A Compendium of United Nations Norms and Standards* (Brill 1994) xxvi.

¹⁶ American Legal Process Theory (ALPT) is one example of a general jurisprudence trend that aims to halt boldness as far as rights are concerned by precluding economic/social claims from recognition. See Anja Matwijkiw and Bronik Matwijkiw, ‘The Unapologetic Integration of Ethics: Stakeholder Realignments in the light of Global Law and Shared Governance Doctrine. – Distilling the Essence of Giuliana Ziccardi Capaldo’s Jurisprudential Paradigm-Shift’ (2016) 15 Global Community YILJ 885, 900-901; Anja Matwijkiw, ‘A Philosophical Perspective on Rights, Accountability and Post-Conflict Justice. – Setting up the Premises’ in M Cherif Bassiouni (ed), *Post-Conflict Justice* (Brill 2002) 155-199.

“core international crimes” (cf genocide, crimes against humanity (CAH – which include apartheid), war crimes, and crime of aggression) give rise to rights on account of their nature and/or harmful consequences in the event of breaches.¹⁷ Furthermore, instead of *aut dedere aut judicare*, the relevant preemptory norms and corresponding non-derogable *obligatio erga omnes* may be paired with non-traditional measures and strategies for post-conflict justice management, eg, context-specific memorialization and vetting. Obviously, the narrow stakeholder version’s subjectivism and/or relativism are suitable for this application, although the broad theory can integrate such non-universal philosophies while also placing limits on their mandate and scope.

The unregulated autonomy parameter follows in the wake of the separation thesis between business and government. However, this thesis also entails spill-over effects for law and substantive morality. This is to say that the minimal state arguments that narrow stakeholder theorists advance (ideo)logically imply that the law functions as a non-paternalist instrument, whereas the broad doctrine requires, *per* Louis Henkin’s terminology, “public welfare” measures of positive protection for those who are unable to provide for their own basic needs.¹⁸ An analogous concept of justice, at least if construed broadly, results in a model of economic/social performance that covers both the national and international levels. To the extent that stakeholder theorists’ may and may not also draw on the interest-incommensurability thesis, the belief that stakes S come with a cancellation effect on stakes S’ cannot be ignored. As it happens, the narrow version invokes the thesis, whereas the broad alternative rejects it. Narrowly therefore, economic/social rights are *at the cost of* civil/political rights, which is tantamount to a Nationalize-Regulate-Centralize outcome. Broadly, civil/political rights mix negative *and* positive features for their protection, thereby practically invalidating any conclusions about necessary choices between different types of values. Furthermore, if values are put on a formula for rights and corresponding duties, stakeholder theorists may and may not proceed in accordance with the so-called logical correlativity thesis.¹⁹ Consequently, stakeholder theorists may and may not

¹⁷ The International Criminal Court (ICC), as established under the Rome Statute, accommodates complementarity, universal jurisdiction and cooperation in connection with core international crimes while reaching the compromise whereby ‘the ICC wields no primary jurisdiction over national courts. Instead, States are vested with the primary responsibility, or right, to prosecute such crimes. The ICC can only assume jurisdiction if national systems are “unwilling or genuinely unable to carry out the investigation or prosecution”’. See Sascha DD Bachmann and Eda N Nwibo, ‘Pull and Push – Implementing the Complementarity Principle of the Rome Statute of the ICC Within the African Union: Opportunities and Challenges’ (2018) 43 *Brooklyn Journal of International Law* 457, 463; Rome Statute of the ICC, 17 July 1998, 2187 UNTS 3-9, 13-16, corrected by *procès-verbaux* of 16 January 2002 (entered into force on 1 July 2002), arts 6-8, 17, 19; M Cherif Bassiouni, ‘Universal Jurisdiction for International Crimes: Historical Perspectives and Contemporary Practice’ (2001) 42 *Virginia Journal of International Law* 81, 156 (for universal jurisdiction as an “unsettled question”).

¹⁸ Louis Henkin and others, *Human Rights* (Foundation Publishers 1999) 285.

¹⁹ A critical review of each thesis’ application is provided in Matwijkiw and Matwijkiw, *A Stakeholder Approach to International Human Rights* (n 7); Joel Feinberg, *Social Philosophy* (Prentice Hall 1973) 61 (for logical correlativity).

agree that values *cum* rights depend upon duties for their existence *in the first instance*. If so, rights *per se* have no (separate) conceptual and normative pull, which causes a comparative and serious devaluation of course that is difficult, if not impossible, to square with the UN's strategy of accentuating "human rights" and, furthermore, of presupposing interdependency across the entire spectrum of values.

Notwithstanding, the following tentative conclusion stands: that talk about stakeholder jurisprudence is narrowly/broadly meaningful in the context of PIL on condition that this realm exhibits features that connect with a particular outlook and approach to values. Although the main test is about rights, stakeholder theorists and practitioners may also be identified through references and applications of ideas and beliefs that, *per* M. Cherif Bassiouni's terminology, are not "value-neutral".²⁰ While the two main versions of stakeholder theory are different in many respects, they also share a number of significant similarities – some of which constitute foundational premises. Eg, both narrow and broad versions entail a commitment (i) to the values that underpin the free market system, and (ii) to the belief that the distinction between the economic and political domains is not a static dichotomy. Admittedly, the pro-Friedmanian framework aims to emancipate interests in freedom of association, private property (rights) and profit-maximization outcomes (cf business-as-usual) from the agenda of those in power. If corporate social responsibility in terms of realizing the common good were to be decreed by political controllers, the implied no-choice position of utilitarianism would count as an inappropriate economic freedom-deprivation. However, if the (*per* Friedman's outlook) "impersonal" market forces are left intact, a responsibility to obey the law-that-is, to avoid fraud and deception and to non-interference with preferences in general would secure the voluntarism that the narrow ideal (of the minimal state) is premised on and which, if only over time, is more likely than not *to generate* political and civil freedoms *cum* rights as safeguards against totalitarianism.²¹ While the concept of the law-that-is undoubtedly paves a path towards legal positivism and, *ipso facto*, a Westphalian notion of international law and international relations that revolves around sovereignty and state-centricity, the narrowness of the liberty that is valued entails, of course, credentials-checking that can substantiate that same narrowness. Apart from its deference to capitalist desires, the narrow stakeholder theory is *not* willing to negotiate economic/social rights that transcend (the narrow subclass of) market freedoms. The framework that best matches this (exclusivist) perception can be found in Hart's Classical Choice Theory of Rights.

²⁰ M Cherif Bassiouni, 'Accountability for Violations of International Humanitarian Law and Other Serious Violations of Human Rights' (2001) 1 Global Community YILJ 22.

²¹ Friedman (n 3) 7, 20, 119.

2. *Rights Stricto Sensu: Meta-Freedom to (Ab)use One's Power to Eliminate Values*

Narrow stakeholder theorists home in on rights the object and indeed objective of which is to secure freedom and autonomy as (higher) values on behalf of individuals as national citizens. Therefore, Hart's Classical Choice Theory of Claim-Rights is well-suited for the purpose of conceptualization. According to the theory in question, the holder of a claim-right, *viz.*, a right *stricto sensu*, is a "small-scale sovereign" who has (i) a bilateral liberty to waive the primary duty or leave it in existence as he chooses (cf discretionary powers) and, if the primary duty is breached, (ii) enforce the secondary duty, eg, by suing for compensation (cf remedial powers) just as the right-holder may (iii) choose to waive the secondary duty.²² Thus, the implied credentials-checking is such as to make it hold that rights are consequences. In order for A to have a claim-right, there must – as a logically necessary condition – exist at least one other person or party, B, who has a duty toward A (cf logical correlativity thesis). This is the order of the relevant values. Furthermore, the right-holders present themselves as the parties who, by definition, must be in control of the correlative duties. Therefore, in the event of scarcity, there would be no rights that correspond to duties to render aid and assistance. As it happens, there would be no real economic/social rights in *any set of circumstances* because, as explained by Joel Feinberg, the availability of resources here and now at time T may change in tomorrow's world. It is the lack of a guarantee of fulfilment that disqualifies economic/social claims as candidates for status as rights *stricto sensu*.²³ As a premise, it holds that economics determine ethics. The premise in question can be subsumed under economic realism as a position. Theoretically, the premise is sometimes generalized to the Ought Implies Can Principle, thereby making it evident that "money matters" reasoning constitutes a trump. Both advocates of classical liberalism and neo-liberalism, that is, libertarianism apply it in credentials-checking.

For the purpose of self-identification, Friedman sees himself as a defender of classical liberalism.²⁴ However, Friedman's position can (more correctly) be classified as libertarianism for the following reasons. First, to violate the rights of stockholders or shareholders for generalized consideration is inexcusable. Second, even if rights translate into a compatriot version of the concentric-circle conception (because relativism and legal positivism together imply nationalism), the government has no jurisdiction over the assets that belong to individual citizens. A redistribution of resources is wrong.²⁵ Consequently, the issue of freedom *versus* welfare boils down to a distinc-

²² HLA Hart, 'Bentham on Legal Rights' in AWB Simpson (ed), *Oxford Essays in Jurisprudence* (Clarendon Press 1973) 192.

²³ Feinberg (n 19) 84-97.

²⁴ Friedman (n 3) 5-6.

²⁵ *ibid* 107.

tion between justice (= a capitalist free society) and injustice (= a socialist welfare state). The premise that permeates the implied liberal democracy *versus* economic “democracy” argument, namely the idea that it is not possible to have both freedom and welfare (cf interest-incommensurability thesis) cannot but have an unhappy outcome. This is to say that there is no choice in the matter after all. And the conclusion stands. Alan Gewirth, one of the most ardent defenders of a double-aspect notion of agency, presents arguments to demonstrate that the individual is bound to contradict himself if he were to reason that there are no rights to freedom *and* well-being, and yet well-being loses out on comparison. Unlike freedom, well-being is a value that requires resources. In spite of his support of welfare liberalism, Gewirth views freedom as a negative concept because it imposes negative duties of non-interference. On the other hand, well-being is a positive right that entails positive duties to do or to deliver something, eg, assistance to those in need.²⁶

Transferring strict individualism to states and international relations, the (collective) right to development would have to be dismissed or denied by analysts, especially because of the economic harm and imbalance in the current distribution of autonomy/sovereignty it (the “right”) necessarily causes and inflicts. Furthermore, developed nations would no longer be able to rely on the Principle of Mutual Benefit (cf voluntary cooperation) under international law, but instead unfair laws would undermine the *status quo* by demanding that national governments act on the basis of (alleged) “socially desirable goals”, such as the eradication of poverty, or preventable diseases, or pollution, or all of these as a package-solution.²⁷ However deserving on the basis of merit, winners would be made to sacrifice for the sake of realizing goals/values that *they* say compel *us* to make certain decisions about *our* successful way – to *their* advantage. Replacing free competition with market corrections is not consistent with capitalism’s individual freedom under individual responsibility prescription – a minimal state arrangement that also helps to protect against uniformity and promote liberal plurality and diversity. What is more, dominion and imperialist conquest are not precluded by the narrow outlook. Unlike the broad goal of social viability, narrow stakeholder theory is geared towards a type of continued survival that does *not* presuppose interdependency. If anything, this enhances the risk of zero-sum game outcomes in connection with the Principle of Mutual Benefit. There is no reason to seek a negotiated compromise. Instead, there is a strong incentive to “leave them to their own devices” while we pursue our own rational self-interest. As it happens, there is no alternative. The pursuit of rational self-interest is a market force. A short-term gain is preferable to a “bad deal”, ie, a policy of social equalization where the 2nd sentence of thermodynamics may come to apply in economics and politics, meaning that generosity and solidarity will not even the playing field (but instead

²⁶ Alan Gewirth, *Reason and Morality* (University of Chicago Press 1978) 340.

²⁷ For the “normative dimension” of corporate social responsibility (doctrine), see Andrew Crane and others, *The Oxford Handbook of Corporate Social Responsibility* (OUP 2008) 201.

universalize the “status” as non-winners). Capitalism does not attempt to negate the class society. It is through *its* dynamics that wealth is created. In turn, this is why (narrow) risk-taking and innovation cannot and indeed should not be stigmatized as *a priori* suspect in comparison to considerations having to do with vulnerability and sustainability. Eg, if climate change poses environmental health issues at the national and international levels, it may be the new technology of private business entrepreneurs that “saves the world”, and *not* OSHA regulations (cf United States measures) or signatures on the Paris Agreement (cf international measure) or, for that matter, all the concerned members of the (national and international) civil society who may criticize business for its “greed” and “immoral profit”.²⁸ Even utilitarian thinkers like Peter Singer advocate effective altruism as a business strategy.²⁹

In all circumstances, considerations having to do with environmental health issues revolve around the notion of harm which, in turn, introduces a variable in the stakeholder equation.³⁰ Ideas about “global warming” expresses a perspective.

3. *Fairness through Broadness: Rights- and Stakeholder-Inclusion*

Besides market freedoms, the narrow rights-typology is limited to civil/political rights and, even more narrowly for fundamental or basic rights, to life, liberty and security *on condition* that the arrangement is the outcome of negotiation in accordance with preferences. The role of the minimal state is to ‘protect our freedom both from the enemies outside our gates and from our fellow-citizens ... [and to] preserve law and order’,³¹ but paradoxically enough it may be doomed to failure through its lack of protective measures in situations where autonomy is exercised in ways that adversely affect liberty, physical integrity and security, thereby *discounting* the values to the extent that no-rights outcomes are unavoidable. Self-regarding decisions that backfire on the premises of liberalism by virtue of ending that particular individual’s status as an end in himself (in practice) are too extremist to match the dignity and respect constellation in international (human rights) law. Counterproductive exercise of freedom goes to the core of the profit *versus* humanity tension, with examples like slavery-related practices, human, sex and organ trafficking, and transplant tourism.³²

²⁸ The anti-business perspective relies on “normative and ethical” egalitarianism whereby the state should (re)distribute resources in accordance with (basic) needs. For Friedman, it is not possible to be ‘both an egalitarian, in this sense, and a liberal’. See Friedman (n 3) 161, 195.

²⁹ Peter Singer, *The Most Good You Can Do: How Effective Altruism Is Changing Ideas about Living Ethically* (Yale University Press 2016).

³⁰ Friedman (n 3) 3 (‘... what one man regards as good, another may regard as harm’), 12 (for Friedman’s embryonic notion of a marketplace of ideas).

³¹ *ibid* 2.

³² Anja Matwijkiw and Bronik Matwijkiw, ‘Biolaw Stakes, Activist Jurisprudence, and (Presumed)

The main point is that free will and consent have to be disqualified as criteria for credentials-checking concerning the most basic stakes.³³ Regarding other-regarding violations like environmental crimes (cf ecocide), the individual responsibility clause has also been challenged in the context of an analysis of CAH, partly in an attempt to establish basic and broader rights to life and health.³⁴ For example, Stefania Negri argues that the current obstacles for recognizing environmental crimes in terms of CAH can and indeed should be overcome. Empirically, the relevant crimes take place during times of peace as well as times of war and conflict. Furthermore, ecocide during times of peace is often ‘a crime without intent as it occurs as a byproduct of industrial and other activity’ just as it is “associated with” the activity of states.³⁵ Unfortunately, the Rome Statute currently makes the progressive step of analogous norm-recognition impossible because the elements of CAH, *expressis verbis*, include *mens rea*. Therefore, impunity as opposed to accountability is secured on behalf of states and corporations. Another obstruction consists in the fact that environmental destruction currently can only be subsumed under “war crimes” (cf Article 8 (b VI)). To make ecocide applicable in times of peace requires, therefore, CAH status.

The question is, of course, how much of an advantage, if any, the broad stakeholder version accomplishes once a(n alternative) framework for rights has been added? Since Freeman’s critical reaction against Friedman is *not* driven by ideologically antagonistic sentiments, the broad version does not entail any political-economic revolution for ‘[i]t is decidedly not a form of socialism’.³⁶ That granted, the broad responsibility to balance the different interests of the different stakeholders resonates with advocates of “*hypernorms*” which function as global limits on capitalism and which render it impermissible to let corporate (state or other) activities trump the important rights of others *unless* these others participate in the decision-making.³⁷ Besides the Principle of Corporate Rights (PCR) that incorporates central aspects of Immanuel Kant’s philosophy, ethics also accommodates consequentialism. Under the Principle of Corporate Effects (PCE), the corporation and its managers should be held accountable for the effects of their actions on others whose stakes are reciprocal, thereby arriving at a balanced judgment on the basis of interdependence. Cutting across the Respect Principle (from Kant) and the Harm Principle, PCR and PCE summarize the implicit social contract. Additional norms that are ascribed status as

Limits for Protected Interests’ in Anja Matwijkiw (ed) (special issue entitled) Paving the BioLaw Path in International Criminal Law (2017) 17 International Criminal Law Review 1070.

³³ Stefania Negri, *New Frontiers of International Justice: Crimes against the Environment and Public Health*, keynote speech at the Conference *International Justice: A Work in Progress*, Indiana University Northwest, 8 November 2018 (for the irrelevancy of the victim’s consent under current international law).

³⁴ *ibid.*

³⁵ *ibid.*

³⁶ R Edward Freeman and others, *Stakeholder Theory. The State of the Art* (CUP 2010) 230.

³⁷ *ibid.*

ideals are: the (P1) Principle of Corporate Legitimacy and the (P2) Stakeholder Fiduciary Principle. Like the PCR and the PCE, the contents of these do not diverge from the requirements of Kantianism and consequentialism, which are pitted together as working rules although they derive from two different traditions in general ethics. Notwithstanding, P1 and P2 give rise to tension. On the basis of the premise that the purpose of the firm, business, organization (or state) is to be a vehicle for the coordination of interests, the conclusion under P1 is that stakeholders have inalienable rights, thereby making the implicit social contract consistent with natural law theory as a position within general jurisprudence. However, the same conclusion is counteracted by (a) a rights-reduction of participation to simply “being heard”, and (b) a corresponding duty-reduction toward claimants – from safeguarding the long-term stakes of each group – to “paying attention” to those stakes. Accepting the reality of conflict under P2, fiduciary is construed as *prima facie* and, subsequently, management should act in the long-term interests of the corporation “when the interests of the group outweigh the interests of the individual parties to the collective contract”.³⁸ In this way, P2 may require the survival of the corporation at the expense of the stakes of individual claimants, however deserving. It follows that the vulnerability factor from Friedman’s radical market approach reappears in Freeman’s idealism. Voluntary cooperation may be inseparable from unfairness. In other words, it may be false that it is, borrowing Freeman’s own wording, “through the firm” that stakeholders make themselves better off.³⁹ At worst, Kantianism is sacrificed in favour of libertarianism or consequentialism as an instance of utilitarianism. In either case, justice has not been done. It makes no difference, if the principles are applied to the relationship between governments and their citizens. However, the broad version’s potential relapse to libertarianism poses a greater transfer challenge than utilitarianism, which is already embedded in rights-restricting clauses, albeit the position cannot actually extinguish values *per se*.⁴⁰

While humanistic in nature, the broad idea of natural law imputes no absolutism whereby any (business, legal, etc) (norm-)reality that discords with higher *cum* moral values or principles ceases to be in force descriptively as well as prescriptively. Rather, the moderate natural law argument is that discourse, decision-making and practices must and, *mutandis mutandis*, should be grounded in “good reason”, in “multi-fiduciary” considerations that go beyond profit, thereby *benefitting non-shareholder* stakeholder interests while complying with the (corporate) responsibility to shareholders.⁴¹ The natural environment, *qua* a nonhuman entity, so some stakeholder theorists maintain, should also be recognized as a stakeholder constituency, in part,

³⁸ William Evan and R Edward Freeman, ‘A Stakeholder Theory of the Modern Corporation: Kantian Capitalism’ in Tom Beauchamp and Norman E Bowie (eds), *Ethical Theory and Business* (Prentice Hall 1988) 100.

³⁹ *ibid* 103.

⁴⁰ Matwijkiw and Matwijkiw, *A Stakeholder Approach to International Human Rights* (n 7) 420–421.

⁴¹ Freeman and others, *Stakeholder Theory. The State of the Art* (n 36) 198, 203.

because it lacks the political-economic voice to express its interests, but also on account of its inherent moral worth.⁴² A win-win situation accommodates the natural environment – for its own sake.⁴³ The community, which is inserted into the broad stakeholder equation together with the government and, in principle, any other party whose welfare is substantially affected, is equally defined by “intrinsically superior” stakes – that therefore warrant consideration and recognition.⁴⁴ Nature *versus* humanity strategies and outcomes are as pragmatically defeatist as they are ethically absurd. Thus, interdependency, *mutual* sustainability, and *mutual* responsiveness to needs positively reinforce each other, thereby also validating claims about subsistence (in addition to survival through non-interference) as a matter of (broad) rights that are anchored in ethics as the First Pillar of law. Given that the serious and negative effects of climate change encompass threats to the health of the planet and the human species, inter alia, in terms of accessibility to drinking water, food scarcity and increased prices of the essentials for subsistence, broad stakeholder theory’s conceptual flexibility seems crucial.⁴⁵ Certainly, outlooks that void social/economic rights with economic realism entail such blatant contradictions of international law that they have to be classified, at best, as inaccurate and outdated responses and, at worst, as reflections of aversions to humanity-centricity, shared community values and collective enforcement strategies for human rights, as defended by modern supporters of global constitutionalism and governance.

After this, the credentials for rights cannot but invoke minimal decency in the context of universalism. More precisely, it seems that the best framework is provided by the Modern Interest Theory of Rights. On Neil MacCormick’s premises, the concept of a benefit is a necessary condition. The claim to treatment T constitutes a right *if and only if* the object of the right in question advances important interests of the stakeholder constituency, C, on the supposition that T is normally a good for each and every member of C. Eg, judged by the general norm for humanity, fulfillment of basic needs secures wellbeing and welfare in terms of a benefit and, therefore, economic/social human rights clearly and unambiguously qualify as candidates for recognition. However, the concept of a benefit is not sufficient. The object of the right must also promote the good of the intended beneficiary as an end in himself. Therefore, rights-recognition incorporates respect. *Only if* the interest in welfare is promoted for the right reason, is it correct that “X’s claim-right to T has been established”.⁴⁶ On behalf of basic stakes in

⁴² *ibid* 208-209.

⁴³ Broadly, biolaw stakes ‘extend the interpretation of the human organism and its vital processes and capabilities to aspects that concern the fundamental conditions for humanity and the natural environment within which “our own kind” exists, such as consciousness-formation that avoids alienation, inter-species associations and, even more broadly, love, creativity, and the (search for) meaning with human life’. See Matwijkiw and Matwijkiw, *Biolaw Stakes* (n 32) 1074.

⁴⁴ *ibid* 1079.

⁴⁵ See generally Paul R Epstein and Dan Ferber, *Changing Planet, Changing Health* (University of California Press 2011).

⁴⁶ Neil MacCormick, *Legal Right and Social Democracy. Essays in Legal and Political Philosophy* (Clar-

civil/political right, it can be argued that this is the element that prevents Self as well as others from “selling out”; from degrading humanity.

Obviously, a traditional interpretation of respect could still connect respect with the possession of rationality, thereby automatically disqualifying various human stakeholders from the form of credentials-checking that otherwise relies on a principle from ethics while at the same time presupposing that the law’s rationale for rights-conferment is adequately captured. However, while it is correct that various basic or fundamental rights cannot be separated from the liberal idea of autonomy and freedom as interests, the broader notion of stakeholder beneficence may pick up other rights on behalf of the nonhuman constituency, *inter alia*, because of their equal status as sentient beings capable of suffering or on the ground of nonhuman integrity, meaning that concentric-circle arguments in stakeholder theory come to include the natural environment as deserving of (rights-) recognition and protection. If anything, shared stakes in vulnerability, interdependency and sustainability serve to substantiate consideration that draws on biodiversity, ultimately giving rise to public and global policies that negate speciesism and similar types of ideological discrimination and non-inclusion in theory and practice.

The Modern Interest Theory of Rights does not explain how and why basic needs function as co-founders of fundamental economic/social human rights. For this purpose, stakeholder theory has to resort to the informal logic of extensionality. According to this, the following holds. If X is a basic need, then X is something which the need-holder, Y, cannot be or do without, without at the same time, suffering serious harm. Furthermore, it holds that (if X is a basic need, then) X is something which Y, or anybody else for that matter, is unable to change by changing the way he thinks or feels about X.⁴⁷ It is not possible to un-need X just through adopting the belief that, eg, “X is a myth”. Paradigms include nutritious food, clean water, and unpolluted air. Other examples, which qualify as needs that are just as basic, belong to the class of what might be called developmental needs. For example, most human beings are born with the capacity to develop into rational and autonomous agents – which is what is generally taken to be part of the concept of the adult – and, consequently, children and adolescents have a need to receive the things that facilitate the process that places them within the norm, such as nurture, training and education. In order to be consistent, the narrow version of stakeholder theory has to at least accept these preconditions for rationality and autonomy in terms of needs (*as opposed to wants*) rather than allow inequality (of liberal core values) prior to open competition.

In practice, such a narrow/broad compromise may imply environmental interests to the extent that these affect the relevant developmental stakes. For example, approximately 1.2 million children in the United States are affected by lead poisoning, although many states do not even test “at-risk” stakeholders, *inter alia*, African Amer-

endon Press 1982) 154-166.

⁴⁷ David Wiggins, *Needs, Values, Truth. Essays in the Philosophy of Value* (Clarendon Press 1998) 9-10.

ican children in poor(er) neighbourhoods, in spite of the facts that (i) exposure to the toxin is preventable, and (ii) the neurological damage results in serious learning disabilities and corresponding deficits.⁴⁸ If environmental health considerations require agents to balance reality and morality in a way that includes redistributive measures, narrow stakeholder theorists withhold their informed agreement; whereas exponents of the broad alternative take the step of anchoring these directly in economic/social rights. That said, they realize that recent trends in general jurisprudence include conservative legal doctrines. One example is American Legal Process Theory (ALPT).⁴⁹ If pushed, broad stakeholder arguments will combat its ideological influence as an instance of propaganda.

From the point of view of logic, all needs contrast with wants – as well as desires and preferences – on the basis of considerations having to do with their status (cf the systematic aspect) as opposed to their origin (cf the genetic aspect). Unlike needs, wants – as well as desires and preferences – come and go in accordance with the beliefs, opinions or feelings of particular individuals. It follows that if I want X, then (i) I have to have a conception of X, and (ii) there has to be circumstances in which I would try to secure X – as a goal, as something I favour and therefore prefer (which is also why X is the object of my conscious pursuit). This entails that subjectivism applies to the relevant category. As groups are also in a position to determine what “we want”, relativism too has a pull. Even if the way of a group makes it correct to state, for example, that “An American family typically needs one car per household (but we really want three because that’s a status symbol)” the relevant social/cultural needs – just like the relative wants – do not describe irrevocable necessities. Thus, a need-oriented environmental consciousness and conscience on behalf of the Planet, its population and its health, may guide the response to the effects of bad choices, in particular an uncritical commitment to capitalist consumerism.

Strategically, the use of basic needs as demarcation criteria for wants may translate into freedom from the “welfare diseases” that describe many modern liberal and capitalist societies. They may also provide an anti-dote to self-destruction, as in “We want hybrid cars instead of conventional cars because we need to pollute less”). Objectively, if basic and less basic needs compete, the interest in fulfilment of basic needs should be promoted as a First Priority (Principle).

In the light of the above account, basic needs are co-founders of human rights in that the Harm Principle links these facts (cf reality) with fundamental norms (cf substantive morality). Because the argument is not directly from needs (from what “is”) to rights (to what “ought” to be), there is no risk of committing the naturalistic fallacy. At the same time, it is true to say that harm functions as a bridge-concept. The

⁴⁸ Vanessa Sacks and Susan Balding, “The United States Can and Should Eliminate Childhood Lead Exposure”, *Child Trends* (2 February 2018) <www.childtrends.org/publications/united-states-can-eliminate-childhood-lead-exposure>.

⁴⁹ See (n 16).

same is true of other principles that enable the human stakeholder constituency to remain in the image of the species, inter alia, the Principle of Consideration whereby equal consideration of needs and interests is prescribed, and the Fair Opportunity Principle that bans discrimination against other stakeholders on the basis of characteristics that they have either little or no control over, meaning that they do not have subjectivist or relativist free choices to un-acquire the characteristics without difficult and/or costly intervention.⁵⁰

Friedman's misconception that all needs reduce to a subclass of wants ethically calls for a reform of the narrow premise that the 'market makes no judgement'.⁵¹ To separate the free market ideology from the broad logic of value concepts obstructs the singular notion of ethics. Furthermore, to activate the full potential of the Modern Interest Theory of Rights, it can be argued that the more fundamental rights are, the more the implied needs or interests deserve protection, if necessary, by imposing self-regarding immunities (so the victim can no longer give his voluntary consent). For the same reason, the strategy necessitates a revision of the PCR (whereby it is impermissible to let capitalism trump the important rights of others *unless* these others participate in the decision), meaning that the exercise of autonomy should be constrained by the values that are at stake in rights.

On the premises of the broad theory, rights are not analytically tied to free choices and powers. More generally, it not only refutes the logical correlativity thesis but also the thesis that rights, for their existence, depend on the practical possibility of their fulfilment. The narrow stakeholder theory proceeds *as if* there is a synthesis between the two views, more precisely, *as if* the logical correlativity thesis commits theorists to economic realism. In turn, the alleged synthesis constitutes the basis for the distinction between civil/political rights and economic/social rights in terms of negative and positive rights. Realists and liberals alike either preclude economic/social rights or make these secondary *because* they are positive whereas civil/political rights are real or primary *because* they are negative. Logically, however, this is untenable. It does not make sense to argue that duties are prior to rights. If anything, rights are (good) reasons for duties as consequences. Whether it is practically possible to fulfil duties in the real world is something that depends on the circumstances, but this consideration is *post facto*. It cannot affect rights-recognition. To push the point, the logical correlativity thesis is "logical" only for realists and liberals.

Equipped with the Modern Interest Theory of Rights, broad stakeholder theorists are able to proceed in an unapologetic manner whenever they are confronted with critics who, in effect, are trying to re-start the Cold War in the area of human rights with references to (the myth of freedom *versus* welfare) interest-incommensurability. This does not mean that ideology and politics are superfluous. What it does mean,

⁵⁰ Matwijkiw and Matwijkiw, *Stakeholder Theory and Justice Issues* (n 7) 156 (for stakeholder jurisprudence principles).

⁵¹ *ibid* 150.

however, is that ideological and political discourse does not make rights come and go in accordance with preferences. Rather, these have to be tested against the law to secure norm-descriptive adequacy.

At both the national and international levels, broad stakeholder theory is better suited to the task of accounting for developments that stem from considerations having to do with ethics. Certainly, in stark contradistinction to Friedman, Freeman welcomes the “recently” legal constraints on the ability of managers to maximize the interests of stockholders at the expense of other claimants on the firm.⁵² When the national law created rights for these, in the 1960s and 1970s, it responded to distributive justice problems on behalf of vulnerable stakeholders, just as it contributed to the discontinuation of the classical management strategy of internalizing benefits and externalizing costs by making provisions for government regulation (*cf.* the Civil Rights Act (1964), the Clean Water Act (1972), and other measures). Concerning human rights, their existence does not depend on correlative duties in international law, albeit true that both capitalism and socialism may be accommodated *de jure* – under that individual state’s right to self-determination.⁵³ Instead, a notion of programmatic duties guides the accountability response for protection, thereby making it possible to continue to interpret rights as normative stimuli for decisions, policies and practices that otherwise would make no sense in circumstances where rights *per se* are deconstructed beforehand. If economic realists and (neo-)liberals were introduced to “green rights” as a consequence of global climate change, they would totally dismiss these *unless* the law already made provisions for them. The tactic of denying climate change may and may not be added but – regardless of this – the line of argument would be *against* using the law as an instrument for pro-environmental activism.⁵⁴ The point is that their *allegedly* value-neutral approach conserves the current state of affairs.

4. Conclusion: Towards a Comprehensive Justice Project

There are many things to be said about values which are neither ‘just opinion’, nor dry empirical studies of ‘what someone’s values happen to be’ or studies of ‘opinions held’. By paying attention to the logic of value concepts, theorists can develop better descriptions and yield more effective prescriptions for managers. Ultimately, the ‘stakeholder issue’ must be resolved in the arena of ‘distributive justice’. The sledding is rough, but the questions cannot be avoided.⁵⁵

⁵² Evan and Freeman (n 38) 98.

⁵³ Henkin and others (n 18) 283.

⁵⁴ Matwijkiw and Matwijkiw, *Biolaw Stakes* (n 32) 1073; John Foster, *After Sustainability: Denial, Hope, Retrieval* (Routledge 2015) 23-45 (for climate change deniers).

⁵⁵ Freeman (n 4) 248-249.

Undoubtedly, the narrow *cum* Hartian framework works for (neo-)liberal values that do not require self-regarding immunities for their protection. Those that do, namely basic and reciprocal stakes, can only be rescued by the broad framework, which makes no attempt to downplay or deny the values that the law wills. If anything, foundational principles for *hypernorms* function to fill gaps that may result from broad analysis of law in general and international law in particular.

Contemporary rule of law accusations of “state-sanctioned terrorism” would, however, be blatantly denied by liberals outside the domain of life, liberty and security as traditionally interpreted. That said, policies and strategies of systemic economic/social violence would suffice as counter-proof. Furthermore, given that injustice in terms of inequity is (impersonally) inflicted by the superstructure, the (narrow stakeholder) Principle of Individual Responsibility is inadequate. Broadly, the Principle of Corporate and/or State Responsibility also must or, *mutatis mutandis*, should be made to matter. In addition, collective enforcement strategies constitute best practices on account of their contribution to the pillars of, *per* Giuliana Ziccardi Capaldo, verticality (cf global democracy) and integrity (cf global norm-harmonization) as well as effectiveness (cf pragmatism) of value-protection. Cutting across the narrow/broad divide, important interests in civil/political and economic/social human rights are equally *real* and therefore selective tolerance for violations should not be allowed, especially not in an international community that ‘is no longer a community of states but of mankind as a whole (common humanity)’.⁵⁶ As pointed out by exponents of respectively the integrative approach and stakeholder jurisprudence, interests/stakes in the environment belong to the class of public *cum* global stakes.⁵⁷ As a stakeholder in its own right, the natural environment does not yet have a legal counterpart, but the detrimental effects on *homo sapiens* create an analogy to the building block argument in failed state theory. Hence, if the natural environment suffers, members of the human family are adversely affected. In actual fact, the post-World War II rationale for norm-recognition and -protection, as provided by the International Military Tribunal at Nuremberg (IMT), relied on both other-regarding interests/effects and humanity, thereby mixing the teleological and deontological aspects that also characterize broad stakeholder theory’s working rules.⁵⁸

Without the kind of concessions and subsequent reform that Negri suggests in an era that is optimally and, some critics would argue, unfairly challenged by a non-specialized regime (cf courts with limited or no jurisdiction), further setbacks to the basic and reciprocal stakes that form integral parts of environmental crimes can be expected. If legally subsumed under CAH in the manner Negri’s proposal entails, the current law-ethics separation can be overcome, together with the myth of value-incommensurability. The positivization of environmental crimes would

⁵⁶ Matwijkiw and Matwijkiw, *The Unapologetic Integration of Ethics* (n 16) 887, n. 7.

⁵⁷ *ibid* 901.

⁵⁸ *ibid* 888.

then copy the indirect and derivative procedure that the IMT used when it recognized CAH *in connection with* the commission of war crimes; and the Principle of Justice would be applicable by extension, although with decades of delay. Historically, critical voices concerning phenomena like (widespread and long-term and severe) environmental degradation (of the groundwater supplies, of fertile territories), transboundary pollution (of the atmosphere, the seas and the land), destruction of ecosystems, modifications of weather and climate (cf global warming) began in the 1960s and assumed the narrow/broad discourse format in the context of business management strategy, with the ecocide/war crimes constellation emerging in the 1970s and prevailing until the new millennium where it was referred to as ‘the 5th missing crime against peace’.⁵⁹ Thus, the emphasis was on the use of military means (with nuclear arms as the main threat) which prejudiced the health or survival of the population rather than the direct link between ecocide and the effects of this on real-world resources and economic factors (cf accessibility to drinking water, food scarcity and increased prices of the necessities for subsistence) as well as human health. Unless the full (legal/doctrinal) force of *jus cogens* norms in reasoning is brought to bear on environmental crimes, thereby making the distinctions between respectively peace and war time and intent and no intent irrelevant, the multi-dimensional stakeholder spectrum of values that ultimately explains why the criteria for rights have to be broadened to include, inter alia, ‘[e]arth protection and climate justice’ and ‘cultural loss’ will miss its mark.⁶⁰ Interestingly enough, the policy paper on ecocide that the Office of the Prosecutor of the ICC issued in 2016 explicitly mentions ‘the *social, economic* and environmental damage’ to signal the importance of negative effects on the category of economic/social rights, including ‘exploitation of natural resources’ and ‘land grabbing’.⁶¹

Paving the path towards norm-recognition and -protection is fraught with obstacles, as demonstrated by 2018 headlines like ‘UN climate talks deadlocked on final day’.⁶² Although the relevant conference in Katowice, Poland, also generated a more optimistic headline, namely ‘Nations finally agree to Paris climate treaty rules’, critical comments and observations were ample – ranging from failure to cut emissions in accordance with need, developing countries relegated to second-class stakeholders,

⁵⁹ Negri (n 33).

⁶⁰ *ibid.* Since the mandate of the ICC is limited to prosecution of heads of state and other instances of superior *cum* individual responsibility, the ICC does not provide the best fit with *jus cogens* standards and corresponding *obligatio erga omnes*. As argued by M. Cherif Bassiouni, these norms (doctrinally) extend beyond the current legal constraints *qua* their very status. Thus, Article 25 of the Rome Statute is in need of reform. See Anja Matwijkiw and Bronik Matwijkiw, ‘A Modern Perspective on International Criminal Law: Accountability as a *Meta-Right*’ in Leila N Sadat and Michael P Scharf (eds), *The Theory and Practice of International Criminal Law: Essays in Honor of M. Cherif Bassiouni* (Martinus Nijhoff Publishers 2008) 45.

⁶¹ Negri (n 33) (Authors’ emphasis).

⁶² Deutsche Welle, ‘UN climate talks deadlocked on final day’, *DW News* (14 December 2018) <www.dw.com/en/un-climate-talks-deadlocked-on-final-day/av-46748534>.

and an irresponsible divide between vulnerable *cum* impoverished nations and rich *cum* immoral blockers of progress.⁶³

While unhappy facts only exist for economic realists and their followers, the various messages undoubtedly come with “back to square one” implications in the sense that the *status quo* preference of capitalism appears to prevent broad measures and strategies. The environment is just a natural resource (to be exploited); a pre-capitalist “value” with which no relationship exists for the same reason. A neutrality-indifference “response” seems inescapable and, *ipso facto*, a narrow zero-sum game fate. As a non-stakeholder (on the relevant capitalist premises), the environment falls outside of ethics – with no claim to any particular kind of treatment. If the sole source of interest-stimulus – the marketplace supply-and-demand – is activated, a “good reason” *for them* to protect biodiversity, ecosystems, etc, *against competition*, emerges. In turn, this explains why ecocide denial is strictly a feature of capitalism as an ideology and why legal projects that aim to synthesize law, science and ethics in order to maximize objectivity pertaining to the needs that underpin standards are likely to be brushed aside as (unfair) accountability traps for developed countries like the United States.⁶⁴ The more the discourse about environmental crimes in terms of *jus cogens* norms and corresponding *obligatio erga omnes* is oriented towards the goal of interpreting basic rights to include yet more criminal stakes in life, health, physical integrity and security, the more protest and resistance can be expected, especially if such dynamic developments were to occur in the context of the ICC and if the implied public *cum* global interests ended the Westphalian opportunity to stand outside the global community. The *uti universi* strategies that modern exponents of globalization defend for measures to secure dignity, decency and respect on the basis of humanity force all states to comply as a matter of principle.⁶⁵ But, whereas they themselves reason that the implied decentralization of state responses owes to the very meaning of “*jus cogens*” (cf compelling law), antagonists will probably counter-argue that ‘force consists in subordinating the individual state to the (will, interests, values, etc) of the community’. Once again, therefore, politics and ideology will be at the forefront of the debate (eg, with references to the superpower status of the United States); and the *realpolitik* advantage that the developed nations currently enjoy is more likely than not going to be preserved in future policy-making decisions that strengthen exceptionalism, nationalism, and other state-centric strategies. Narrow stakeholder theory is not about “good reason” in terms of “right reason”, as defended

⁶³ ‘Nations finally agree to Paris climate treaty rules’, *SBS News* (16 December 2018) <www.sbs.com.au/news/nations-finally-agree-to-paris-climate-treaty-rules-after-all-night-deadlock>.

⁶⁴ Since the ALPT selectively negates the separation thesis, the problem of using ethics as an assessment tool of the law is introduced. See Matwijkiw and Matwijkiw, ‘The Unapologetic Integration of Ethics’ (n 16) 893–894.

⁶⁵ *ibid* 900; James Nickel and Daniel Magraw, ‘Philosophical Issues in International Environmental Law’ in Samantha Besson and John Tasioulas (eds), *The Philosophy of International Law* (2010) 463 (for ‘IEL norms... rely heavily on voluntary compliance’).

by Bassiouni.⁶⁶ It is a conservation-strategy – for power. Thus, only broad stakeholder theorists and practitioners would agree that “We have a problem” when the Rockefeller Foundation–Lancet Commission on Planetary Health states that:

The continuing degradation of natural systems threatens to reverse the health gains seen over the last century ... We have mortgaged the health of future generations to realize economic and development gains in the present.⁶⁷

In one important sense (having to do with sustainability), this goes to the very core of the narrow *versus* broad dispute. If admitted, the wheels of capitalism may stop. – And then what? The ethical considerations of broad business management *cum* stakeholder strategy are not radical. As the authors of this chapter have previously pointed out, the stakeholder issue concerning justice is not fully resolved by adding a framework that can tackle the larger community problems, such as “social justice” and defending ‘the rights of the oppressed’.⁶⁸ Furthermore, the framework may be recalled.⁶⁹ If so, stakeholder jurisprudence has to, in one sense at least, turn the tables by responding to all justice deficits, practical as well as doctrinal ones, with need-oriented ethics, as indeed recommended as a UN policy in 2010.⁷⁰

If this step is not taken, there cannot be any “win-win” outcomes in environmental health discourse and decision-making. While broad stakeholder theory avoids the anthropocentrism of its narrow counterpart (that precludes non-human stakeholders), its own account of [human] values and ethics comes with a so-called “fit” clause, meaning that considerations may be separated from idealism.⁷¹ If so, Friedman’s jus-

⁶⁶ Matwijkiw and Matwijkiw, *A Modern Perspective on International Criminal Law* (n 60) 37, 76-77.

⁶⁷ ‘Safeguarding human health in the Anthropocene epoch: report of The Rockefeller Foundation–Lancet Commission on planetary health’, *The Lancet* (16 July 2015) <www.thelancet.com/commissions/planetary-health>.

⁶⁸ Historically, ‘... the critics, intellectuals, and protestors of the 1960s and 1970s who raised awareness about environmental problems, advocated for social justice, and defended the rights of the oppressed’. See Caradonna (n 14) 89-90; see note 55 (here assuming that basic and reciprocal rights and their distribution are aspects of “social justice” and “the rights of the oppressed”).

⁶⁹ According to James Stieb, ‘... some advocates have moved a bit too quickly and without proper definition or argument. They have exceeded Freeman’s intentions which are more libertarian and free-market than is often thought’. See James A Stieb, ‘Assessing Freeman’s Stakeholder Theory’ (2009) 87 *Journal of Business Ethics* 401.

⁷⁰ *Meta-ethically*, this type of ethics would abridge positive duties to assist and negative duties not to harm. See Thomas Pogge, “Assisting” the Global Poor’ in Thomas Pogge and Keith Horton (eds), *Global Ethics: Seminal Essays* (Paragon House Publishers 2008) 531; Paul Farmer and others, *Reimagining Global Health: An Introduction* (University of California Press 2013) 245-287 (for utilitarianism, liberal constitutionalism, and the capabilities approach as normatively-substantive discourse frameworks for values and global health); Anja Matwijkiw, ‘Justice versus Revenge: The Philosophical Underpinnings of the Chicago Principles on Post-Conflict Justice’ in M Cherif Bassiouni (ed), *The Pursuit of International Criminal Justice: A World Study on Conflicts, Victimization, and Post-Conflict Justice* (Intersentia 2010) 240-241 (for need-oriented ethics recommendations).

⁷¹ Freeman (n 4) 83, 101.

tification of capitalism may remain intact: ‘It [the market organization of economic activity] gives people what they want instead of what a particular group thinks they ought to want’.⁷² Therefore, the contrast between environmental health stakes and capitalism is ethically sharp and significant, at least in one important sense. Furthermore, if freed from the (original) context of business management, broad stakeholder theory can make a complete and qualitative leap from the strategic *cum* instrumental approach (to values, interests, stakes, needs, etc) to a prescriptive project of redistribution that is guided and informed by the environmental health stakes themselves. It may still be true that the capitalism *versus* socialism choice misses “the mark”.⁷³ Be that as it may, fair laws and a philosophical guarantee of objectivity can properly achieve better outcomes in the future than any *ideology for the sake of ideology* dispute. Certainly, if pollution and other cases of environmental destruction are subsumed under Friedman’s idea of neighbourhood effects, the intervention that is required automatically has the additional and negative effect of limiting individual freedom.⁷⁴ Worse still perhaps, the disadvantage of tilting the private/public stakes against liberal capitalism is too great “now that government has become so overgrown” to justify (further) public/governmental measures.⁷⁵ If nothing can be done to recognize and protect basic and reciprocal environmental health stakes because “the basic rules” for a particular outlook are given comparatively more weight, then ethics is the only solution – for only ethics can tilt the weight-scales to benefit deserving stakeholders for their own sake.⁷⁶

⁷² Friedman (n 3) 75.

⁷³ Freeman (n 4) 8.

⁷⁴ Friedman (n 3) 30, 85.

⁷⁵ *ibid* 32, 77.

⁷⁶ *ibid* 27.

Chapter 2

A Human Rights Approach to Environmental Health

*Stefania Negri**

1. *Introduction*

International concerns over the adverse health impacts of environmental pollution, chemical exposure, climate change and loss of biodiversity have increased exponentially in the last decades in steps with available scientific evidence and growing public awareness about the global burden of disease attributable to environmental hazards.¹

Environmental risks represent a significant, but preventable, cause of death worldwide. International and European Union law have responded to this major challenge through the adoption of a large number of binding instruments protecting both the environment and public health,² the establishment of specialised organs and agencies entrusted with standard-setting and risk-assessment functions, the institution of bodies and procedures aimed at monitoring compliance with environmental obligations and public health needs.

Today, interconnections and interdependence between health, the environment and human rights are also widely recognised.³ International human rights bodies have often addressed these intersections in their General Comments and during their consideration of periodic reports. The relationship between human rights and environmental protection has increasingly become the object of a substantive body of literature and of specific studies developed by international institutions,⁴ while health

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¹ Annette Prüss-Ustün, Jennyfer Wolf, Carlos Corvalán, Robert Bos, Maria P Neira, *Preventing Disease through Healthy Environments: A Global Assessment of the Burden of Disease from Environmental Risks* (WHO 2016).

² See Stefania Negri, 'Introduction' to this volume.

³ Dinah Shelton, 'Human Rights, Health & Environmental Protection: Linkages in Law & Practice. A Background Paper for the World Health Organization', WHO Health and Human Rights Working Paper Series No 1, 2002.

⁴ See, inter alia, Council of Europe, *Manual on Human Rights and the Environment* (2nd edn, Council of Europe Publishing 2012) 8.

has bridged the two fields,⁵ focusing the attention of the international community on the environmental determinants of the right to health and the protection of the right to a safe environment.

Although 'there are other regulatory approaches to achieving environmental protection and public health that are not rights-based',⁶ environmental treaties generally do not establish complaint or petition procedures.⁷ Human rights law can instead be used as an effective tool to bring environmental health issues before international bodies granting legal standing to individuals, groups and NGOs and allowing redress for health damages caused by unsafe environmental conditions.

Against this backdrop, this chapter explores the interface between health and the environment through the human rights prism, focusing on the environmental dimension of the right to health and on the now widely recognised right to a healthy, safe and clean environment. To this end, it intends to offer a comprehensive analysis of the relevant provisions contained in human rights treaties and the obligations stemming therefrom. The review of these legal sources is completed by a critical assessment of the case law produced by regional human rights bodies and their evolutive interpretation of individual rights and corresponding State obligations in this field. The aim of this analysis is to evaluate the added value of a human rights approach to environmental health litigation, with a view to best achieving the overarching goal of public health protection from environmental harm.

2. The Right to Health and Its Environmental Dimensions

Health as a human right was first enunciated at international level in the preamble of the Constitution of the World Health Organization (WHO), which stated that '[h]ealth is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' and that '[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'.⁸ In 1948, the protection of health entered the lexicon of international human rights law, being recognised in both the Universal Declaration of Human Rights and the American Declaration on the Rights and Duties of Man. While article 25 of the Universal Declaration did not explicitly proclaim a human right to health but enunciated 'the right to a standard of living adequate for the health and well-being (...) including food, clothing, housing and medical care and necessary social services', article XI of the

⁵ Shelton (n 3) 3.

⁶ *ibid* at 4.

⁷ *ibid* at 10.

⁸ WHO Constitution, New York, 22 July 1946, in force as of 7 April 1948.

American Declaration affirmed instead that '[e]very person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care'.

Since then, the right to health has been enshrined in a number of binding human rights instruments – general treaties of either universal or regional scope and conventions devoted to the rights of specific categories of vulnerable persons (women, children, persons with disabilities and migrants) – while health (both healthcare and public health) has made its appearance in a range of legal instruments adopted in different fields of international law, including international humanitarian law,⁹ international labour law,¹⁰ international biolaw¹¹ and international environmental law.¹²

In the realm of international human rights law, universal treaties protecting the right to health include the International Covenant on Economic, Social and Cultural Rights,¹³ the Convention on the Elimination of All Forms of Discrimination against Women,¹⁴ the Convention on the Rights of the Child,¹⁵ the Convention on the Rights of Persons with Disabilities,¹⁶ and the International Convention on the Protection of Rights of All Migrant Workers and Members of their Families.¹⁷ At the regional level, the most relevant instruments are the European Social Char-

⁹ See arts 13, 15, 25-26, 29-33 of the Convention (III) Relative to the Treatment of Prisoners of War, Geneva, 12 August 1949; arts 38, 56, 76, 81, 85, 91-92 of the Convention (IV) relative to the Protection of Civilian Persons in Time of War, Geneva, 12 August 1949; art 11 of Protocol Additional to the Geneva Conventions of 12 August 1949, and relating to the Protection of Victims of International Armed Conflicts (Protocol I), Geneva, 8 June 1977; art 5, para 2 (e) of Protocol Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of Non-International Armed Conflicts (Protocol II), Geneva, 8 June 1977.

¹⁰ See the ILO conventions protecting the health of workers in the diverse working conditions, especially in the sectors at highest risk of occupational diseases and accidents, available at <www.ilo.org>. See in particular the Promotional Framework for Occupational Safety and Health Convention (ILO No 187), Geneva, 15 June 2006.

¹¹ Art 3 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164), Oviedo, 4 April 1997.

¹² See Makane Moïse Mbengue and Susanna Waltman, 'Health and International Environmental Law' in Gian Luca Burci and Brigit Toebe (eds), *Research Handbook on Global Health Law* (Edward Elgar Publishing 2018) 197; Stefania Negri, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale* (Giappichelli 2018) 177-179. For a European insight, see William Onzivu, 'European Environmental Health Law' in André den Exter (ed), *European Health Law* (Maklu 2017) 77.

¹³ Art 12 of the International Covenant on Economic, Social and Cultural Rights, New York, 16 December 1966.

¹⁴ Art 11, para 1 (f), art 12, para 1, and art 14, para 2 (b) of the Convention on the Elimination of All Forms of Discrimination against Women, New York, 18 December 1979. See also art 3 (f) of the Declaration on the Elimination of Violence against Women, New York, 20 December 1993.

¹⁵ Art 24 of the Convention on the Rights of the Child, New York, 20 November 1989.

¹⁶ Art 25 of the Convention on the Rights of Persons with Disabilities, New York, 13 December 2006.

¹⁷ Arts 28, 43, 45 of the International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families, New York, 18 December 1990.

ter,¹⁸ the Charter of Fundamental Rights of the European Union,¹⁹ the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights,²⁰ the Inter-American Convention on Protecting the Human Rights of Older Persons,²¹ the African Charter on Human and Peoples' Rights and its Protocol on the Rights of Women in Africa,²² the African Charter on the Rights and Welfare of the Child,²³ and the Arab Charter on Human Rights.²⁴

Given the significant number, the multilevel scope and the geographical coverage of these instruments, the right to health has come to be considered a 'universal right under general international law'.²⁵

However, when it comes to the environmental dimension of the right to health, it has to be noted that, even within such a complex legal framework, the interrelationship between health and the environment emerges only from a very limited number of provisions that explicitly impose on States the obligation to adopt protective measures against environmental hazards.²⁶

Article 12 of the International Covenant on Economic Social and Cultural Rights, which is the key provision guaranteeing the right to health at universal level, stipulates at paragraph 2 (b) that States Parties have to take steps to achieve the full realization of 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', including measures that are necessary for '[t]he improvement of all aspects of environmental and industrial hygiene'.²⁷ In its General Comment No. 14 on the right to the highest attainable standard of health, the Committee on Economic, Social and Cultural Rights states that the wording of article 12

¹⁸ Arts 11 and 13 of the European Social Charter (ETS No 35), Turin, 18 October 1961 as revised in Strasbourg, 3 May 1996.

¹⁹ Art 35 of the Charter of Fundamental Rights of the European Union [2000] OJ C64/1 and [2012] OJ C326/391.

²⁰ Art 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, San Salvador, 17 November 1988 (San Salvador Protocol); see also art 17 of the Social Charter of the Americas, OAS Resolution AG/RES.2699 (XLII-O/12), Cochabamba, 4 June 2012.

²¹ Art 19 of the Inter-American Convention on Protecting the Human Rights of Older Persons, Washington, 15 June 2015.

²² Art 16 of the African Charter on Human and Peoples' Rights, Nairobi, 27 June 1981; art 14 of the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, Maputo, 11 July 2003.

²³ Art 14 of the African Charter on the Rights and Welfare of the Child, Nairobi, 11 July 1990.

²⁴ Art 39 of the Arab Charter on Human Rights, Cairo, 15 September 1994, as amended on 22 May 2004; English translation available at <www.humanrights.se/wp-content/uploads/2012/01/Arab-Charter-on-Human-Rights.pdf>.

²⁵ Susan Marks and Andrew Clapham, 'Health' in *International Human Rights Lexicon* (OUP 2005) 381-391, at 384.

²⁶ See Negri (n 12) 180-182.

²⁷ Art 12, para 2 (b) ICESCR.

is not merely confined to the right to healthcare, but also extends to the underlying determinants of health, such as food, water, housing and a healthy environment.²⁸ Therefore, in interpreting the content and scope of the right to health and the corresponding obligations incumbent on States Parties pursuant to paragraph 2(b), the Committee considers that this provision includes ‘the requirement to ensure (...) the prevention and reduction of the population’s exposure to harmful substances such as radiation and harmful chemicals or other detrimental environmental conditions that directly or indirectly impact upon human health’.²⁹ The Committee also clarifies that obligations concerning the prevention, treatment and control of diseases include the preparation of programs to prevent and promote environmental safety.³⁰ Along this line of thought, the Committee identifies the relevant obligations to respect, to protect and to fulfil the right to health based on an environmentally-sensitive approach: the obligation to respect implies that ‘States should also refrain from unlawfully polluting air, water and soil, eg through industrial waste from State-owned facilities, from using or testing nuclear, biological or chemical weapons if such testing results in the release of substances harmful to human health’;³¹ the obligation to protect embraces the duty to enact and enforce laws that prevent pollution caused by the extractive or manufacturing industries;³² the obligation to fulfil extends to the adoption of appropriate measures to combat environmental health risks, including through the design of national policies aimed at reducing or eliminating air, water and soil pollution, including pollution from heavy metals (such as lead from gasoline).³³

A second major provision linking health to the environment is article 24, paragraph 2(c) of the Convention on the Rights of the Child, which requires that States Parties take appropriate measures ‘[t]o combat disease and malnutrition (...) taking into consideration the dangers and risks of environmental pollution’. In its General Comment No. 15 on the health of children, the Committee on the Rights of the Child declares that States have the obligation to take measures to manage the risks and damages that environmental pollution can cause to the health of children.³⁴ The Committee draws attention to the relevance of a clean environment for the healthy

²⁸ CESCR, General Comment No 14 (2000) on the right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights), E/C.12/2000/4, 11 August 2000, paras 4 and 11.

²⁹ *ibid* paras 11, 15.

³⁰ *ibid* para 16.

³¹ *ibid* para 34.

³² *ibid* para 51.

³³ *ibid* para 36.

³⁴ Environmental harm has especially severe effects on children under the age of 5. Of the 5.9 million deaths of children under the age of 5 in 2015, the WHO estimates that more than one quarter – ie more than 1.5 million deaths – could have been prevented through the reduction of environmental risks. Childhood exposure to pollutants and other toxic substances also contributes to disabilities, diseases and premature mortality in adulthood.

upbringing of children, stressing that they must be protected from exposure to toxic substances and waste or litter. It also affirms that States must regulate and monitor the environmental impact produced by the activities of the business sector and the effects that may adversely affect children's health. Finally, the Committee emphasises the importance of State measures to address the consequences of climate change, which is currently one of the greatest challenges for children's health.³⁵

In this respect, it has to be noted that in recent years human rights experts have begun to examine more closely the effect of environmental harm on the enjoyment of children's rights. For example, in its resolution 32/33, the Human Rights Council draws attention to the effects of climate change on the rights of children, recognising that climate change may have a serious impact on their enjoyment of the highest attainable standard of physical and mental health, access to education, adequate food, adequate housing, safe drinking water and sanitation.³⁶ The Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes describes the "silent pandemic" of disability and disease associated with childhood exposure to toxics and pollution and explains the obligations of States and the responsibilities of business enterprises to protect against such exposure.³⁷ The Special Rapporteur on the issue of human rights obligations relating to the enjoyment of a safe, clean, healthy and sustainable environment further explores the human rights obligations relating to the protection of children from environmental harm in his recent Report on the relationship between children's rights and environmental protection.³⁸ Focusing on the Convention on the Rights of the Child, the Rapporteur articulates the educational, procedural and substantive obligations of States to protect children and future generations from the adverse health impacts of environmental pollution and from exposure to toxic substances. The Report also formulates a range of recommendations, including urging States to take the children's best interest as a primary consideration with respect to all decision-making that may cause them environmental harm; to adopt and implement environmental standards that are consistent with the best available science and relevant international health and safety standards; to never take retrogressive measures; to pursue precautionary measures to protect against environmental harm, especially when there are threats of serious or irreversible damage.³⁹

Other relevant examples of human rights provisions enunciating the right to health and associating it to the environment are article 39, paragraph 2 (f) of the Arab Charter on Human Rights, which calls for the adoption of measures necessary to

³⁵ CRC, General Comment No 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art 24), CRC/C/GC/15, 1 February 2013, paras 49-50.

³⁶ HRC, Resolution 32/3, Human rights and climate change, 1 July 2016.

³⁷ UN Doc A/HRC/33/41, 2 August 2016.

³⁸ UN Doc A/HRC/37/58, 24 January 2018.

³⁹ *ibid* para 72.

fight against environmental pollution, and article 17 of the Social Charter of the Americas, which stipulates that States commit 'to strengthen their capacity to prevent, detect, and respond to chronic non-communicable diseases, current and emerging infectious diseases, and environmental health concerns'.⁴⁰

With the exception of the above-mentioned examples, none of the other conventional provisions articulating the right to health refers to environmental health. It is noticeable, however, that international human rights bodies have often interpreted these provisions extensively, declaring that they also encompass some environmental dimension of health. Some cases in point are offered by regional case law.

In the famous *Ogoniland* case, the African Commission on Human Rights interpreted article 16 of the African Charter on Human and Peoples' Rights in light of both article 12 ICESCR and article 24 of the same Charter, which enunciates the right to a healthy environment, and therefrom derived specific negative and positive obligations with regard to the protection of health. The Commission ruled that States must refrain from directly threatening the health and the environment of their citizens; they must protect them by adopting measures to prevent pollution and ecological degradation; they must fulfil these rights by adopting reasonable measures to prevent pollution and degradation, to promote conservation of the environment, and to pursue the concept of sustainable development. In this case, the systemic and extensive interpretation of article 16 led to the expansion of the scope of the right to health, putting it in direct relation to the environment. According to the Commission, in order to conform with the spirit of articles 16 and 24 of the African Charter, States must order, or at least allow, independent scientific monitoring of threatened environments; they must request and publicise environmental and social impact studies before any major industrial development; they must undertake appropriate monitoring and provide information to those communities exposed to hazardous materials and activities, giving people the concrete opportunity to be heard and to participate in decisions that affect their communities.⁴¹ In the case *Sudan Human Rights Organisation & COHRE*, the Commission acknowledged the developments occurred in international law with respect to the normative definition of the right to health – as including not only healthcare but also healthy conditions – and endorsed the recognition of the environment as a basic determinant of health. It thus found that the destruction of homes, livestock and farms as well as the poisoning of water sources, which exposed the victims to serious health risks, amounted to a violation of the right to health.⁴²

At the European level, the European Committee of Social Rights interpreted article 11 (the right to protection of health) of the European Social Charter in light of the growing importance that States and international organisations recognise to the relation-

⁴⁰ See *supra* n 20.

⁴¹ ACHPR, Communication No 155/96, *The Social and Economic Rights Action Center (SEARO) and the Center for Economic, and Social Rights (CESR) v Nigeria*, 27 October 2001, paras 52-53.

⁴² ACHPR, Communications No 279/03-296/05, 27 May 2009, *Sudan Human Rights Organisation & Centre on Housing Rights and Evictions (COHRE) v Sudan*, paras 208-212.

ship between health and the environment.⁴³ In examining State reports, the Committee has over time addressed a range of health issues related to air pollution, water management, risks deriving from asbestos.⁴⁴ In a few decisions on the merits it stressed the importance of applying the precautionary principle to avoid potentially dangerous effects on human health and concluded that article 11 also guarantees the right to a healthy environment, which is breached when the State fails to take the necessary measures to avoid preventable health risks deriving from environmental degradation.⁴⁵

3. The Right to a Healthy Environment: Moving Towards Legal Recognition of a Universal Right Vital to Protect Global Public Health

It is general opinion that the first enunciation of a human right to environment quality is to be found in Principle 1 of the Stockholm Declaration, which proclaims that '[m]an has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being'.⁴⁶ However, it is contended that, notwithstanding such bold statement, subsequent developments of human rights law in this field have somehow fallen short of expectations, given that the right to a healthy environment has been enshrined only in a few regional human rights instruments and still calls for formal legal recognition at the global level.⁴⁷

In fact, the right to a healthy environment is protected under article 24 of the African Charter on Human and Peoples' Rights and under article 18 of its Protocol on the Rights of Women in Africa. In the Americas, article 11 of the San Salvador Pro-

⁴³ In *Marangopoulos Foundation for Human Rights (MFHR) v Greece*, No 30/2005, 6 December 2006, para 194, the ECSR stated that 'the Charter is a living instrument, whose purpose is to protect rights not merely theoretically but also in fact (*International Commission of Jurists v. Portugal* (Complaint No. 1/1998), decision on the merits of 9 September 1999, §32). It therefore interprets the rights and freedoms set out in the Charter in the light of current conditions.'

⁴⁴ Conclusions XVII-2 (2005), Portugal; Conclusions XVII-2 (2005), Latvia; Conclusions 2013, Georgia.

⁴⁵ ECSR, *International Commission of Jurists v Portugal*, No 1/1998, 9 September 1999, para 32; *Marangopoulos Foundation for Human Rights* (n 43) paras 195, 202; *International Federation for Human Rights (FIDH) v Greece*, No 72/2011, 23 January 2013, paras 150-154. In these cases, the Committee identifies the following core obligations concerning the protection of a healthy environment: to prevent air pollution at local level and to contribute to the achievement of the objectives established by the United Nations Framework Convention on Climate Change; to adopt preventive and protective measures concerning water and noise pollution; to assess health risks through epidemiological monitoring of target groups; to protect the population from the consequences of nuclear accidents occurring abroad but having an impact on the country; to adopt a policy prohibiting the use, production and sale of asbestos and products that contain it.

⁴⁶ Declaration of the United Nations Conference on the Human Environment, Stockholm, 16 June 1972.

⁴⁷ Alan Boyle, 'Environment and Human Rights' in Max Planck Encyclopedia of Public International Law, April 2009.

toocol articulates an individual right to live in a healthy environment and at the same time the obligation of States to protect, preserve and improve the environment. Article 38 of the Arab Charter on Human Rights includes the right to a healthy environment among the basic components of the right to an adequate standard of living. The same approach is adopted in the ASEAN Human Rights Declaration of 2012, which states that the right to an adequate standard of living encompasses, among others, the ‘right to a safe, clean and sustainable environment’.

Also at the regional level, the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention) of 1998 refers to ‘the right of every person of present and future generations to live in an environment adequate to his or her health and well-being’. As is evident from its title, this Convention is particularly important because it articulates the three basic procedural rights related to the right to a healthy environment. Similarly, article 1 of the Regional Agreement on Access to Information, Public Participation and Justice in Environmental Matters in Latin America and the Caribbean (Escazú Agreement) of 2018 – which is the regional agreement similar to the Aarhus Convention covering Latin America and the Caribbean – aims at ‘contributing to the protection of the right of every person of present and future generations to live in a healthy environment and to sustainable development’ (article 1) and requires that ‘each Party shall guarantee the right of every person to live in a healthy environment’ (article 4).

Moving to the global level, there is no inclusion of this right in any of the conventions of general and universal scope. Only in soft law, a ‘fundamental right to live in an environment adequate to their health and well being’ was recognised to all individuals by the famous Brundtland Report of 1987⁴⁸ and later echoed in the UN General Assembly resolution 45/94 of 1990.⁴⁹

Since 2016, the UN Special Rapporteur on Human Rights and the Environment has devoted several studies to the interrelationship between the quality of the environment and human health, focusing on the health impact of climate change,⁵⁰ the importance of the conservation and sustainable use of biodiversity,⁵¹ the effects of environmental degradation on children’s health,⁵² and the adverse health impacts of air pollution.⁵³ In March 2018, he declared that the time is ripe for a global recogni-

⁴⁸ Report of the World Commission on Environment and Development: Our Common Future (Brundtland Commission), 1987, part I.

⁴⁹ UNGA resolution 45/94, Need to ensure a healthy environment for the well-being of individuals, 14 December 1990.

⁵⁰ Report of the Special Rapporteur on the issue of human rights obligations relating to the enjoyment of a safe, clean, healthy and sustainable environment, A/HRC/31/52, 1 February 2016.

⁵¹ Report of the Special Rapporteur on the issue of human rights obligations relating to the enjoyment of a safe, clean, healthy and sustainable environment, A/HRC/34/49, 19 January 2017.

⁵² Report of the Special Rapporteur on the issue of human rights obligations relating to the enjoyment of a safe, clean, healthy and sustainable environment, A/HRC/37/58, 24 January 2018.

⁵³ Report of the Special Rapporteur on the issue of human rights obligations relating to the enjoyment of a safe, clean, healthy and sustainable environment, A/HRC/40/55, 8 January 2019.

tion of the right to a safe and healthy environment and its incorporation into a new universal human rights treaty.⁵⁴ In his report of July 2018,⁵⁵ the Special Rapporteur recalled the increasing advocacy over the last decennia for a firm recognition of a right to a healthy environment, as also advanced by several scholars,⁵⁶ and recommended that the Human Rights Council consider the formal inclusion of this right in a new legal instrument of global scope – like the Global Pact for the Environment, currently being negotiated among States under UN auspices⁵⁷ – or in a new additional protocol to the International Covenant on Economic, Social and Cultural Rights. An alternative and more expeditious solution would be the adoption of a General Assembly resolution following the model of resolution 64/292 of 28 July 2010 recognising the right to safe drinking water. According to the Special Rapporteur, a formal endorsement by the UN would be completely consistent with the state of the law and with the widespread practice at both national and regional levels.⁵⁸ In his statement ahead of the World Environment Day of 5 June 2019, he has reaffirmed that '[t]he right to a healthy environment is fundamental to human well-being and is legally recognised by over 150 States at the national and regional levels. It should be globally reaffirmed to ensure the enjoyment of this right by everyone, everywhere while upholding the human rights principles of universality and non-discrimination.'⁵⁹ In the Rapporteur's opinion, there is strikingly positive evidence that the right to a healthy environment contributes to healthier people. In fact, national practice concerning enforcement of constitutional environmental rights shows that the legal recognition of the right to a healthy environment has resulted in many millions of people living in healthier ecosystems, breathing cleaner air, having gained

⁵⁴ OHCHR, UN expert calls for global recognition of the right to safe and healthy environment, <www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=22755&LangID=E> accessed February 2019.

⁵⁵ Report of the Special Rapporteur on the issue of human rights obligations relating to the enjoyment of a safe, clean, healthy and sustainable environment, A/73/188, 19 July 2018.

⁵⁶ See Dinah Shelton, 'Human Rights and the Environment: What Specific Environmental Rights Have Been Recognized?' (2006) 35 *Denver Journal of International Law and Policy* 130; Malgosia Fitzmaurice, 'A Human Right to a Clean Environment. A Reappraisal' (2017) 16 *Global Community* 219; John H Knox and Ramin Pejan (eds), *The Human Right to a Healthy Environment* (CUP 2018).

⁵⁷ Article 1 of the draft Global Pact for the Environment recognises the 'right to an ecologically sound environment' <<https://globalpactenvironment.org/en/>> accessed March 2019; see Yann Aguila and Jorge Viñuales, 'A Global Pact for the Environment: Conceptual Foundations' (2019) 28 *Review of European, Comparative & International Environmental Law* 3; John H Knox, 'The Global Pact for the Environment: At the Crossroads of Human Rights and the Environment', *ibid.*, 40.

⁵⁸ The above-mentioned regional human rights agreements and environmental treaties, all explicitly recognizing the right to a healthy environment, have been ratified by more than 130 States to date. Taking into consideration the ratification of these treaties, constitutions and national legislation, more than 150 States have already established legal recognition of the right to a healthy environment, with corresponding obligations.

⁵⁹ OHCHR, Every five seconds a premature death caused by air pollution, UN rights expert says <www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=24668&LangID=E> accessed 6 June 2019.

access to safe drinking water and having reduced their exposure to toxic substances. Therefore, formal recognition of a universal right to a healthy, clean, safe and sustainable environment at the global level would bring significant benefits, both in terms of public awareness and better understanding of the interconnection and interdependence between human rights and environmental protection, and in terms of empowerment of individuals, vulnerable groups and entire populations, including indigenous peoples and traditional communities, exposed to serious environmental risks. Moreover, incorporation in a binding human rights instrument would entail reporting requirements and control machineries that would guarantee effective implementation of the right. Ensuing State obligations to respect, protect and fulfil 'should ensure a minimum level of environmental quality for all members of society, consistent with international standards, with a particular emphasis on those populations that currently shoulder a disproportionate share of the burden of pollution and other environmental harms or that do not enjoy adequate access to essential environmental goods and services'.⁶⁰ In brief, 'the global recognition of this right would fill a glaring gap in the architecture of international human rights'⁶¹ and contribute to reducing the global burden of disease caused by exposure to environmental hazards.

4. Environmental Health Litigation and the Added Value of a Human Rights Approach

Environmental health issues have been the object of judicial proceedings before both national and international courts and tribunals, including the International Court of Justice,⁶² the International Tribunal for the Law of the Sea⁶³ and the WTO Dispute Settlement Body.⁶⁴ Contrary to inter-state disputes based on international environmental law, a rights-based approach to environmental health allows the victims of environmental hazards to bring their cases in court alleging the violation of their fundamental human rights – especially the right to health and to a healthy environ-

⁶⁰ See Report (n 55) at 15, para 45.

⁶¹ *ibid* at 18, para 53.

⁶² ICJ, *Aerial Herbicide Spraying (Ecuador v. Colombia)*, Application Instituting Proceedings, 31 March 2008 (discontinued in 2013); *Pulp Mills on the River Uruguay (Argentina v. Uruguay)*, Judgment, ICJ Reports 2010, 14; *Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua)* and *Construction of a Road in Costa Rica along the San Juan River (Nicaragua v. Costa Rica)*, Judgment, ICJ Reports 2015, 665.

⁶³ ITLOS, *Mox Plant Case (Ireland v the United Kingdom)*, Request for provisional measures and statement of case of Ireland, paras 9-12.

⁶⁴ WTO, Panel Report, *Brazil – Retreaded Tyres*, WT/DS322/R, 12 June 2007; Appellate Body Report, *Brazil – Retreaded Tyres*, WT/DS332/AB/R, 3 December 2007. See commentary of the case in this volume by Xavier Fernández Pons, 'The Dispute on Brazilian Measures Affecting Imports of Retreaded Tyres at the WTO: An Exemplary Intersection of Trade, Health and Environment', *infra* Chapter 4.

ment, but also other relevant substantive and procedural rights – and to obtain redress for personal damages.⁶⁵

Lacking significant practice by UN treaty bodies, the most relevant case-law in this field has been produced by the regional human rights institutions of Europe, America and Africa. These bodies have addressed several environmental health-related cases independently of any explicit jurisdiction to examine complaints alleging the violation of the rights to health or to a healthy environment. In fact, while both the African Commission and Court have clear jurisdiction on these matters under article 16 and 24 of the African Charter on Human and Peoples' Rights, neither the Inter-American Commission and Court nor the European Court of Human Rights have any such competence under the San Salvador Protocol and the European Convention on Human Rights.⁶⁶

Most interestingly, however, although devoid of competence to receive petitions based on articles 10 and 11 of the San Salvador Protocol,⁶⁷ the Inter-American institutions have dealt with environmental related cases on various occasions, especially in connection with human rights – including the right to health – of indigenous populations,⁶⁸ ruling that a healthy environment is part of an expansive interpretation of the right to a dignified life⁶⁹ and to personal integrity.⁷⁰

In the *La Oroya* case, the first case concerning a non-indigenous community, the Inter-American Commission considered the responsibility of Peru for the violation of human rights due to the severe pollution of the environment caused by the emissions of a metallurgical complex owned by an American company. The petition was filed in 2006 by a coalition of NGOs and alleged, among other rights, the violation of the rights to health and to a healthy environment of the inhabitants of La Oroya, arguing that the Peruvian Government was responsible for lack of control and supervision over the complex and failure to adopt measures to mitigate the health effects caused by its smelting operations. The Commission decided that the case was admissible but it held that it could only examine the complaints under the American Convention on

⁶⁵ See also ILA, Committee on Global Health Law, Sydney Conference Report 2018, Section IV, paras 47-51 (by Pedro A Villarreal).

⁶⁶ European Convention for the Protection of Human Rights and Fundamental Freedoms, Rome, 4 November 1950.

⁶⁷ Article 19, paragraph 6, of the Protocol limits the application of the system of individual petitions only to violations of articles 8 and 13 by actions attributable to a State Party.

⁶⁸ IACHR, *Yanomami v Brazil*, Case 7615, Resolution 12/85, 5 March 1985; IACtHR, *Case of Mayagna Sumo Awas Tigni Community v Nicaragua*, Series C No 79, Judgment of August 31, 2001; IACHR, *Maya Indigenous Community of the Toledo District v Belize*, Report No 40/40, 12 October 2004.

⁶⁹ IACtHR, *Case of Yakye Axa Indigenous Community v Paraguay*, Merits, Reparations and Costs, Judgment of June 17, 2005, Series C No 215, paras 163, 167; *Case of Xákmok Kásek Indigenous Community v Paraguay*, Merits, Reparations and Costs, Judgment of August 24, 2010, Series C No 214, para 187.

⁷⁰ IACtHR, *Case of Kichwa Indigenous People of Sarayaku v Ecuador*, Merits and Reparations, Judgment of June 27, 2012, Series C No 245, para 249; *Case of the Kaliña and Lokono Peoples v Suriname*, Merits, Reparations and Costs, Judgment of November 25, 2015, Series C No 309, paras 172, 222.

Human Rights,⁷¹ since the alleged violations of the San Salvador Protocol fell outside its competence. It stated that it would refer to the Protocol as reference source for interpretation of the Convention's rights.⁷² The Commission also ordered precautionary measures obliging the Peruvian State to provide medical diagnoses and treatment to 65 inhabitants of La Oroya who had suffered from health problems caused by exposure to toxic heavy metals.⁷³

More recently, in its Advisory Opinion on the Environment and Human Rights,⁷⁴ the Inter-American Court recalled its previous findings concerning the duty of States to regulate, supervise and control those activities that involve significant risks to people's health.⁷⁵ It added that there are also certain minimum obligations that States must fulfil within their general obligation to take appropriate measures to prevent human rights violations as a result of environmental damage. In order to comply with the obligation of prevention, the Court ruled that States must: regulate, supervise and monitor the activities carried out under their jurisdiction that could cause significant damage to the environment; carry out environmental impact assessments when there is a risk of significant damage to the environment; prepare contingency plans in order to establish safety measures and procedures to minimise the possibility of major environmental disasters and mitigate any significant environmental damage that could have occurred, even when this happened despite preventive actions. The Court also found that States must act in keeping with the precautionary principle to protect the right to life and to personal integrity in the event of possible serious and irreversible damage to the environment, even in the absence of scientific certainty. Lastly, the Court also addressed the issue of the extraterritorial application of the American Convention, affirming that States have the obligation to prevent causing transboundary damage and that a person can be considered within the jurisdiction of the State of origin if there is a causal connection between the incident that took place on its territory and the violation of the human rights occurred outside its territory. According to the Court, the exercise of jurisdiction arises when the State of origin exercises effective control of the activities that caused the damage and the ensuing violation of human rights abroad. This part of the Opinion is particularly interesting inasmuch as it broadens the range of possible victims of environmental harm entitled to file a petition before the Inter-American Commission.

⁷¹ American Convention on Human Rights, San José, 22 November 1969.

⁷² IACHR, *Community of La Oroya v Peru*, Case 1473.06, Report No 76/09, 5 August 2009.

⁷³ IACHR, Precautionary Measure No 271-05, 31 August 2007, as extended by Resolution 29/2016 of 3 May 2016.

⁷⁴ IACtHR, *The Environment and Human Rights (State obligations in relation to the environment in the context of the protection and guarantee of the rights to life and to personal integrity – interpretation and scope of Articles 4(1) and 5(1) of the American Convention on Human Rights)*, Advisory Opinion OC-23/17 of November 15, 2017, Series A No 23.

⁷⁵ See, inter alia, *Case of I.V. v Bolivia*, Merits, Reparations and Costs, Judgment of July 4, 2006, Serie C No 149, paras 89-90; *Case of Gonzales Lluy et al v Ecuador*, Judgment of September 1, 2015, Preliminary objections, Merits, Reparations and Costs, Series C No 298, para 178.

Another striking example of the potential of human rights bodies in environmental health litigation is offered by the European Court of Human Rights. The Strasbourg Court has contributed to the protection of environmental health despite the absence in the European Convention on Human Rights of any provision guaranteeing either the right to health or the right to a healthy environment.⁷⁶ In fact, over the last decades, the Court has decided several cases in which the quality of the applicants' surrounding environment was at issue, reasoning that an individual's health and well-being may be negatively impacted by unsafe or disruptive environmental conditions or severe environmental pollution.⁷⁷ As reported in a comprehensive and detailed survey of Strasbourg case law on environmental related cases, since the 1960s the Court has issued approximately 270 rulings,⁷⁸ over forty of which deal with toxic emissions and other health impacting consequences caused by nuclear plants and power stations,⁷⁹ gold and coal mines,⁸⁰ industrial plants⁸¹ and waste-treatment plants.⁸²

The majority of cases relating to health and the environment have been examined by the Court under article 8 (protecting the right to home, private and family life)⁸³

⁷⁶In *Hatton and Others*, the Court stated that '[t]here is no explicit right in the Convention to a clean and quiet environment, but where an individual is directly and seriously affected by noise or other pollution, an issue may arise under Article 8. See *Hatton and Others v the United Kingdom* [GC], no 36022/97, 8 July 2003, para 96.

⁷⁷In *López Ostra v Spain* the Court held that article 8 could include a right to protection from severe environmental pollution, since such a problem might 'affect individuals' well-being and prevent them from enjoying their homes in such a way as to affect their private and family life adversely, without, however, seriously endangering their health (no 16798/90, 9 December 1994, pp 54-55, para 51). In *Guerra and Others v Italy*, the Court observed that '[the] direct effect of the toxic emissions on the applicants' right to respect for their private and family life means that Article 8 is applicable' (no 14967/89, 19 February 1998, p 227, para 57). See also *Cordella and Others v Italy*, nos 54414/13 and 54264/15, 24 January 2019, paras 157-160; see also commentary by Grazia Scocca, 'ILVA: A Case of Shared Responsibilities for the Protection of the Environment and Public Health', *infra* Chapter 10.

⁷⁸See Natalia Kobylarz, 'The European Court of Human Rights: An Underrated Forum for Environmental Litigation' in Helle Tegner Anker and Birgitte Egelund Olsen (eds), *Sustainable Management of Natural Resources. Legal Instruments and Approaches* (Intersentia 2018) 99. See also ECtHR, Environment and the European Convention on Human Rights, Factsheet, March 2019 <https://echr.coe.int/Documents/FS_Environment_ENG.pdf> accessed April 2019.

⁷⁹ECtHR, *Balmer-Schafroth et al v Switzerland* [GC], no 22110/93, 26 August 1997; *Athanassoglou and Others v Switzerland* [GC], no 27644/95, 6 April 2000; *Jugheli and others v Georgia*, no 38342/05, 13 July 2017.

⁸⁰ECtHR, *Taşkın and Others v Turkey*, no 46117/99, 10 November 2004; *Öçkan and Others v Turkey*, no 46771/99, 28 March 2006; *Lemke v Turkey*, no 17381/02, 5 June 2007; *Tatar v Romania*, no 67021/01, 27 January 2009; *Genç and Demirgan v Turkey*, nos 34327/06 and 45165/06, 10 October 2017.

⁸¹ECtHR, *Guerra and Others v Italy* (n 77); *Fadeyeva v Russia*, no 55723/00, 9 June 2005; *Bacila v Romania*, no 19234/04, 30 March 2010; *Smaltini v Italy* (dec), no 43961/09, 24 March 2015; *Cordella and Others v Italy* (n 77).

⁸²ECtHR, *López Ostra v Spain* (n 77); *Moe and Others v Norway* (dec), no 30966/96, 14 December 1999; *Giacomelli and Others v Italy*, no 59909/00, 2 November 2006; *Di Sarno and Others v Italy*, no 30765/08, 10 January 2012.

⁸³See Thematic report: Health-related issues in the case-law of the European Court of Human Rights,

pursuant to the Court's "living instrument doctrine", which postulates that the Convention and its standards are not static but evolve through interpretation in the light of present-day conditions, so as to reflect social changes and emerging needs.⁸⁴ According to the Court, article 8 applies in environmental cases whether the pollution is directly caused by the State or whether the responsibility of the State arises from the failure to protect (eg, failure to adopt the necessary measures to ensure the effective protection of applicants' right to private life, including effective measures to protect the applicants from a serious environmental hazard, to reduce the levels of pollution harmful to health, etc) or failure to regulate or control private-sector activities (including failure to assess, to a satisfactory degree, the risks that the company's activity may entail). In such cases, regard must be had to the fair balance that has to be struck between the competing interests of the individual and of the community as a whole, bearing in mind that the State enjoys a certain margin of appreciation in determining the steps to be taken to ensure compliance with the Convention.⁸⁵

Although both the Strasbourg Court and the Inter-American Commission have pushed forward the boundaries of their jurisdiction to respond to the increasing environmental and public health concerns of modern societies, legal standing before them requires the existence of a direct legal interest, which means that the applicant must be the victim of a violation of one of the rights protected by the Conventions (direct victim requirement⁸⁶). This requirement entails that, despite the clear public interest underlying environmental health litigation, the direct victim requirement excludes any *actio popularis* in defence of public health.⁸⁷

Therefore, in order to bring a claim under article 8 ECHR, it is necessary that the denounced breach of the Convention directly affects the applicant's home, family or private life, and that the adverse effects on his/her physical or mental health attain a minimum degree of severity, which depends on the circumstances of the case. Nonetheless, it is remarkable that the Court has also recognised victim status to potential victims having submitted reasonable and convincing evidence of the likelihood of a violation bringing about determined and serious consequences (serious, specific and

June 2015 <https://echr.coe.int/Documents/Research_report_health.pdf> 22-26; Guide on Article 8 of the Convention – Right to respect for private and family life, 30 April 2019 <https://echr.coe.int/Documents/Guide_Art_8_ENG.pdf> paras 111-118, 407-426.

⁸⁴ ECtHR, *Tyrer v United Kingdom*, no 5856/72, 25 April 1978, para 31.

⁸⁵ *López Ostra v Spain* (n 77) para 51; *Giacomelli v Italy* (n 77) para 78.

⁸⁶ See *Kobylarz* (n 78) at 106.

⁸⁷ *ibid.* See Christian Schall, 'Public Interest Litigation Concerning Environmental Matters Before Human Rights Courts: A Promising Future Concept?' (2008) 20 *Journal of Environmental Law* 417, at 421-423; Malgosia Fitzmaurice, 'Global Importance of Human Rights for Environmental Protection' (2009) *Global Community* 73, at 76. Schall observes that while *actio popularis* is not admitted in the European and Inter-American systems, environmental litigation does involve issues of public interest whose importance and outcome go beyond the immediate interests of the parties (at 419). This is ever more true for environmental health litigation.

imminent danger requirement⁸⁸). This recognition is extremely important in cases alleging environmental hazards impacting on public health, where potential victims can act preventively and bring satisfactory arguments that a particular dangerous activity, or failure to adopt precautionary measures aimed to avoid environmental pollution or degradation, will have adverse effects on their health or well-being.

If lessons can be learnt from this regional practice, it can be argued that the advantages of bringing environmental health cases before human rights bodies include:

- a) the possibility for individuals and groups – who do not have legal standing before other international courts, tribunals and dispute settlement bodies – to file suit to protect their fundamental rights to life, personal integrity, health, private life, and to a healthy environment and to claim compensation for health damages;
- b) the possibility for NGOs to lodge a petition or file an application, stand in court as representatives of victims and their interests or act as *amici curiae*;
- c) the possibility to file collective applications in the form of class actions, as is the case with the European Court of Human Rights, where around 200 cases involving over 4.000 applicants are pending;⁸⁹
- d) the possibility for the alleged victims to be granted precautionary measures when the conditions of gravity and urgency of the situation and the irreparability of harm are met, as the case law of the Inter-American Commission of Human Rights clearly shows;⁹⁰
- e) the possibility that human rights courts order general measures of execution of their judgments whose benefits extend beyond the individual applicants to other members of the society and to future generations (eg, to develop laws or practices aimed at assessing environmental risks and providing adequate information on environmental hazards; to set up general frameworks for protection against industrial pollution, to rehabilitate polluting sites; to lower toxic emission levels through technical improvements; to improve waste management systems; to

⁸⁸ See Kobylarz (n 78) at 109.

⁸⁹ *ibid* at 104. See, inter alia, *Annamaria Di Caprio and others v Italy*, no 39742/14, communicated on 5 February 2019 (concerning the phenomenon of the “land of fires” in the Region Campania and its environmental and public health effects); *Loredana Locascia and others v Italy*, no 35648/10, lodged on 23 June 2010 (concerning a waste disposal plant in the Province of Caserta and the dangers to health caused by the operation of the plant and by the failure of the authorities to secure, clean-up and reclaim the area after the closure of the plant).

⁹⁰ Apart from the above-mentioned *La Oroya* case, the IACHR has recently granted precautionary measures in the following cases concerning environmental health: *Marcelino Díaz Sánchez and Others v Mexico*, Resolution 24/2019, Precautionary measures No 1498-18, 23 April 2019; *300 Inhabitants of Puerto Nuevo v Peru*, Precautionary measures No 199-09, 27 December 2010; *Communities of the Maya People (Sipakpense and Mam) of the Sipacapa and San Miguel Ixtahuacán Municipalities in the Department of San Marcos v Guatemala*, Precautionary measures No 260-07, 20 May 2010; *Oscar González Anchurayco and members of the Community of San Mateo de Huanchor v Peru*, 17 August 2004. See Séverine Fiorletta Leroy, ‘Can the Human Rights Bodies be Used to Produce Interim Measures to Protect Environment-Related Human Rights?’ (2006) 15 *Review of European, Comparative & International Environmental Law* 66.

- monitor compliance of polluting plants with environmental requirements, etc);⁹¹
- f) the possibility to defend environmental health cases through environmental procedural rights, namely the right to obtain information on environmental risks, the right of participation in decision-making and the right to have access to environmental justice, in line with the Aarhus Convention.⁹² In this respect, it has to be stressed that procedural rights are considered better positioned than substantive rights to obtain success in court.⁹³ As stressed by the UN Special Rapporteur on Human Rights and the Environment, the procedural elements of the right to a healthy environment, especially the right to access to justice, have opened the courthouse doors to citizens seeking to protect both their individual right to a healthy environment and society's collective interest in a healthy environment;⁹⁴
 - g) the added value of cross-fertilization between human rights bodies and their decisions, which contributes to the extensive interpretation of human rights provisions and the broadening of their scope so as to respond to actual and future environmental health concerns.

In conclusion, human rights can be used in court as effective tools to protect public health against the adverse effects of environmental degradation and severe pollution. As is well known, in recent years human rights courts have dealt with an increasing number of cases involving environmental hazards and the “greening” of well-established human rights – including the rights to life, health, food, water, housing, property and home and private life – has contributed to improvements in the health and well-being of people across the world. The potential of human rights bodies in the field of environmental health is yet fully unexpressed, but further positive developments towards the protection of collective and intergenerational rights related to the environment and human health can be achieved thanks to the dynamic and evolutive approach adopted by these bodies and through the virtuous circle created by judicial cross-fertilization.

⁹¹ See Kobylarz (n 78) 114-115.

⁹² ECtHR, *Sdružení Jihoceske Matky v the Czech Republic* (dec), no 19101/03, 10 July 2006; *Stéfanec v the Czech Republic*, no 75615/01, 18 July 2006; *Collectif national d'information et d'opposition à l'usine Melox – Collectif Stop Melox and Mox v France*, no 75218/01, 12 June 2007; *L'Erablière A.S.B.L. v Belgium*, no 49230/07, 24 February 2009; *Tatar v Romania* (n 80); *Lesoochranske zoskupenie Vlk v Slovakia* (dec), no 53246/08, 2 October 2012; *Valentina Viktorovna Ogliebina v Russia* (dec), no 28852/05, 26 November 2013; *Guseva v Bulgaria*, no 6987/07, 17 February 2015.

⁹³ See especially Malgosia Fitzmaurice, ‘Environmental Degradation’ in Daniel Moeckli, Sangeeta Shah and Sandesh Sivakumaran (eds), *International Human Rights Law* (OUP 2010) 590, at 608; Fitzmaurice (n 56) 225.

⁹⁴ See Report (n 55) para 53.



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Chapter 3

The Environmental Health Spillovers of Foreign Direct Investment in International Investment Arbitration

*Valentina Vadi**

1. *Introduction*

Environmental health is a growing concern of both industrialised and developing countries. As environmental hazards determined by processes of economic globalisation seriously threaten health, the question that arises is how to reconcile the need to promote environmental health with the need to encourage economic development. Economists have highlighted the pressures on societies to adopt a productive economic culture.¹ This chapter examines whether enhanced investment protection can hamper the host state's duty to pursue environmental health objectives. At the substantive level, investment treaties provide extensive protection to investor rights in order to encourage foreign direct investment (FDI). Therefore, a potential tension exists when a state adopts environmental regulations that interfere with foreign investments, as regulatory measures may be deemed to affect the economic value of the foreign investment. In parallel, there is a risk of host states adopting disguised protectionist or opportunistic measures. At the procedural level, investment treaties offer investors direct access to an international arbitral tribunal. Thus, foreign investors have directly challenged national measures aimed at protecting environmental health and have sought compensation for the impact of such measures on their business.

This chapter explores the areas of conflict between investment treaty governance and environmental health and shows that most investment treaties do not yet strike an appropriate balance between the different interests concerned. However, some tools have been developed for the protection of environmental health through recent investment treaty drafting and dispute settlement. This chapter proceeds as follows. Section I scrutinizes the conceptual and normative scope of environmental health. Section II briefly examines the main features of international investment law

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¹ Michael E Porter, 'Attitudes, Values, Beliefs, and the Microeconomics of Prosperity' in Lawrence E Harrison and Samuel P Huntington (eds), *Culture Matters* (Basic Books 2000) 14, at 26.

and arbitration. Section III explores and critically assesses the key areas where the protection of environmental health can clash with the promotion of FDI. Section IV analyses the tools that may help arbitrators reconcile the different interests at stake. The chapter concludes with a critical assessment of the explored legal framework and jurisprudence.

2. The Conceptual and Normative Scope of Environmental Health

The term *environmental health* has a working definition, referring to a regulatory field that bridges the gap between two regulatory sectors, that of environmental protection and that of public health. It relies on the assumption that '[h]ealth and the environment are inextricably linked' and that the protection of the environment is a condition for the full enjoyment of health.² Environmental health thus refers to the assessment, control, and prevention of those environmental factors that can potentially affect public health, including but not limited to ensuring clean air, safe food, and drinking water; managing waste and hazardous materials; and land use and clean energy planning.³ States have the right/duty to protect the environment; as most activities that cause harm to the environment are caused by the private sector, states have the right/duty to regulate the activities of private parties that may cause environmental damages and affect public health.⁴

There are two main reasons as to why the issue of environmental protection can be approached from a public health perspective. First, environmental factors are increasingly responsible for poor health in many parts of the world.⁵ Second, while this chapter does not contest the merit of environmental protection as such,⁶ it focuses on the anthropocentric dimension of environmental protection because such a perspective confers a degree of cogency and definition to environmental concerns. Conceptualizing environmental health as a component of public health determines a paradigm shift that allows the translation of environmental concerns into the lan-

² Makane M Mbengue and Susanna Waltman, 'Health and International Environmental Law' in Gian Luca Burci and Brigit Toebe (eds), *Research Handbook on Global Health Law* (Edward Elgar 2018) ch 8.

³ World Health Organization (WHO), draft definition developed at a WHO consultation in Sofia, Bulgaria, (1993) <www.health.gov/environment/DefinitionsEnvHealth/ehdef2.htm>.

⁴ Brigit Toebe, 'International Health Law: An Emerging Field of Public International Law' (2015) 55 *Indian Journal of International Law* 299, 299.

⁵ Yasmin von Schirnding, William Onzivu and Andronico O Adede, 'International Environmental Law and Global Public Health' (2002) 80 *Bulletin of the World Health Organization* 970, 970.

⁶ Christine Redgwell, 'Life, the Universe and Everything: A Critique of Anthropocentric Rights' in Alan E Boyle and Michael R Anderson (eds), *Human Rights Approaches to Environmental Protection* (Clarendon Press 1996) ch 4.

guage of the state's concerns to protect public health. Public health is, in turn, a fluid concept that reflects the concern of states to protect their populations. As one of the three constitutive elements of the state is its population (in addition to its territory and its organisation)⁷ it is clear that the preservation of its population is an essential function of the state. Without such protection, the very existence of the state would be endangered. Protecting public health is thus a primary duty of states that arises from constitutional and statutory law, as well as from the fundamental 'social contract' upon which most governments rest.⁸ At the international level, several international law instruments have recognised states' duty to protect public health and have set a number of standards clarifying the content of this duty. Consequently, the right/duty of the state to protect its population may be viewed as a non-contested concept.

Under international law, the linkage between environmental goods and health was originally, albeit implicitly, articulated by the founding document of international environmental law, the Stockholm Declaration on the Human Environment,⁹ which recognized 'the fundamental right to freedom, equality, and adequate conditions of life, in an environment of quality that permits a life of dignity and well-being.'¹⁰ In addition, the Declaration clearly spelled out the linkage between a clean environment and human health, requiring states to take steps to prevent the pollution of the environment by substances that affect human health.¹¹ While this instrument has a mere hortatory value, it has paved the way for subsequent legal instruments. For instance, the Aarhus Convention recognizes 'that adequate protection of the environment is essential to human well-being and the enjoyment of basic human rights, including the right to life itself.'¹² Other international law instruments similarly acknowledge the linkage between environmental protection and public health.¹³

⁷ See Montevideo Convention, Article 1. Montevideo Convention on the Rights and Duties of States, enacted on 26 December 1933, in force on 26 December 1934, 165 LNTS 19.

⁸ David Fidler, 'Challenges to Humanity's Health: The Contributions of International Environmental Law to National and Global Public Health' (2001) 31 Environmental Law Reporter 10048-10078.

⁹ Stockholm Declaration on the Human Environment 16 June 1972 UN Doc A/Conf 48/14/rev. 1 11 ILM 1416 (1972).

¹⁰ Stockholm Declaration, Principle 1.

¹¹ Stockholm Declaration, Principle 7.

¹² United Nations Economic Commission for Europe, Aarhus Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters, signed on June 25, 1998 and entered into force on October 30, 2001. 2161 UNTS 447, preambular para 6.

¹³ UN Committee on Economic, Social and Cultural Rights, *General Comment* n. 14, adopted on May 2000 (E/C.12/2000/4), at para 4.

3. *International Investment Law and Arbitration*

International investment law is one of the oldest and most complex areas of international law. More than 3,000 international investment agreements (IIAs) govern foreign investments and provide extensive protection to investors' rights in order to encourage FDI and foster economic development. While IIAs differ in their details, their scope and content have been standardized over the years, as negotiations have been characterized by an ongoing sharing and borrowing of concepts.¹⁴

At the substantive level, investment treaties typically define the scope and definition of FDI and provide for protection against discrimination, fair and equitable treatment, full protection and security, and assurances that the host country will honour its commitments regarding the investment. Other common provisions in investment treaties concern the repatriation of profits and prohibit currency controls less advantageous than those originally in place when the treaty was signed. Investment treaties generally guarantee compensation in the event of expropriation and clarify the level of compensation due in such cases.

Treaty provisions lack precise definition of these standards, and their language encompasses a potentially wide variety of state regulations that may interfere with investors' rights. Therefore, a potential tension exists when a state adopts regulatory measures interfering with foreign investments, as regulation may be deemed to violate substantive standards of treatment under investment treaties, and the foreign investor may demand compensation before arbitral tribunals. For instance, there is no settled approach in cases where investors allege that certain regulatory measures constitute a compensable form of expropriation. The concept of expropriation is broadly construed in investment treaties, which not only protect foreign assets from the direct taking of property, but also from indirect expropriation, ie, measures of equivalent effect.

At the procedural level, most international investment agreements provide investors direct access to an international arbitral tribunal. This is a major novelty in international law, as customary international law does not provide such a mechanism. The rationale for internationalising investor–state disputes lies in the intended depoliticisation of such disputes. The home country is no longer involved in litigating international disputes on behalf of its affected citizens; the host country is no longer subject to the political and/or military pressures of so-called gunboat diplomacy. The affected investor is no longer subject to the vagaries of diplomatic protection. Such protection entitles the home state to file a claim against the host state for wrongs committed against its own citizens. Nonetheless, it is rarely exercised, being traditionally perceived as a right—rather than a duty—of the home state.

¹⁴ See generally Valentina Vadi, *Analogies in International Investment Law and Arbitration* (CUP 2016).

Arbitral awards shape the relationship between the state and private individuals. Arbitrators determine matters such as the legality of governmental activity, the degree to which individuals should be protected from regulation, and the appropriate role of the state. The composition of the tribunal is determined by the parties, which generally choose legal scholars or professionals. Only recently have investment arbitration tribunals have allowed public interest groups to present *amicus curiae* briefs and achieved a certain level of transparency. Given the characteristics of the arbitral process, a significant issue is whether environmental health can be protected within a framework aimed primarily at protecting private interests.¹⁵ Possible reforms of the system are currently under discussion.¹⁶

4. Arbitrating Disputes with Environmental Health Elements

Investment disputes with environmental health elements are characterized by the need to balance the public interest of a state to protect and/or restore its environmental health and the legitimate interests of foreign investors to protect their investments. Several issues arise in this context. While environmental concerns have been integrated in some investment treaties, environmental clauses remain rather vague and sometimes even subordinate environmental measures to consistency with investment treaty provisions. The very fact that the balancing process occurs in the context of investor–state arbitration could lead to the procedure being deemed biased in favour of the investors. In fact, litigation before arbitral tribunals focuses on the protection of foreign direct investments and the alleged violation of relevant investment treaty provisions. Finally, environmental health disputes invariably raise competing scientific claims.¹⁷ The arbitral tribunals are called upon to adjudicate on different scientific views presented in an equally compelling manner. The question then becomes: How should adjudicators approach diverging scientific opinions?

Concerning the emerging environmental health jurisprudence, there is no such thing as a typical ‘environmental dispute’. Environmental cases operate across the board, arising in relation to investment in mineral exploitation, waste treatment, water management, nuclear energy, and numerous other sectors. Investors may claim that certain forms of environmental regulation constitute an indirect expropriation or regulatory taking and that compensation should be paid. If a direct expropriation has occurred, claims may concern the amount of compensation. Other claims may con-

¹⁵ For a similar argument, see Gus Van Harten, *Investment Treaty Arbitration and Public Law* (OUP 2008).

¹⁶ Anthea Roberts, ‘Incremental, Systemic and Paradigmatic Reform of Investor–state Arbitration’ (2018) 112 *American Journal of International Law* 410–432.

¹⁷ See eg *Dow AgroSciences LLC v Government of Canada*, Settlement Agreement, 25 May 2011.

cern the violation of fair and equitable treatment or non-discrimination provisions. Although the specific claims are hereby singled out for analysis, they are often linked together and their respective arguments may overlap.

Several investment treaty arbitrations have addressed the question of whether regulation allegedly aimed to protect environmental health may be deemed to be an indirect expropriation. As there is no single notion of expropriation in customary international law and definitions vary in the context of different investment treaties, arbitral tribunals have adopted different approaches to the issue. In this context, two main doctrines have emerged regarding how to determine whether a governmental measure constitutes an indirect expropriation: the *sole effects doctrine* and the *police powers doctrine*.¹⁸

The *sole effects doctrine* requires that, when making such a determination, reference be made only to the effect of the measure on the property allegedly expropriated. It gives more weight to the effects of the regulatory measure on the investor than to the regulatory purpose of a given measure. The underlying assumption of this doctrine is that regulatory measures are generally adopted for the public good and may impose some burdens on private property. However, if the burden imposed on certain properties overwhelmingly or almost completely deprives the properties' owners of any economic benefit, then the owners are entitled to compensation. Several cases lend support to such a doctrine.¹⁹

On the other hand, the *police powers doctrine* focuses on the purpose of the given regulatory measure. According to the police powers doctrine, good faith non-discriminatory regulation within the police powers of the state does not require compensation.²⁰ The police powers doctrine focuses on the inherent authority of a government to impose restrictions on private rights for the sake of public welfare, order, and security. The doctrine was derived from common law principles mandating the limitation of private rights when needed for the preservation of the common good. Analogous principles exist in civil law countries: *sic utere tuo ut alterum non laedas* (use what is yours in a way that does not injure others) and *salus publica suprema lex esto* (public safety is the supreme law).²¹

Under international law, there is no comprehensive and categorical definition of which regulations fall within the police power of states. The application of police

¹⁸ Ben Mostafa, 'The Sole Effects Doctrine, Police Powers and Indirect Expropriation under International Law' (2008) 12 Australian International Law Journal 267.

¹⁹ See eg *Metalclad Corporation v The United Mexican States*, Award 30 August 2000, Case No. ARB(AF)/97/1, 40 ILM 36; *Técnicas Medioambientales TECMED S.A. v the United Mexican States*, Case No. ARB(AF)/00/2, 29 May 2003, (2004) 43 ILM 133. For in depth discussion of these and other cases, see Valentina Vadi, *Public Health in International Investment Law and Arbitration* (Routledge 2012).

²⁰ See Andrew Newcombe, 'The Boundaries of Regulatory Expropriation in International Law' (2005) 20 ICSID Review FILJ 1, 2.

²¹ See Glenn H Reynolds and David B Kopel, 'The Evolving Police Power: Some Observations for a New Century' (2000) *Hastings Constitutional Law Quarterly* 511-537.

power has traditionally implied the capacity of the state to promote the public health, morals, or safety and the general well-being of the community by enacting and enforcing laws for the promotion of the general welfare and regulating private rights in the public interest. A common element of the measures is that property rights are restricted in order to prevent harm or nuisance caused by their use.²²

While some authors deem this theory to be a justification of state action that would otherwise amount to a compensable deprivation or appropriation of property,²³ others deem it as a necessary corollary of property. As Howard Mann and Konrad von Moltke note: 'Under the traditional international law concept of the exercise of police powers, when a state acted in a non-discriminatory manner to protect public goods such as its environment, the health of its people or other public welfare interests, such actions were understood to fall outside the scope of what was meant by expropriation ... Such acts were simply not covered by the concept of expropriation, and therefore were not a taking of property, thus no compensation was payable as a matter of international law'.²⁴ In fact, not every state measure with a public purpose falls within the police powers of the state. One needs to distinguish between the exercise of police powers and other regulations that may constitute indirect expropriation and therefore require compensation. The introduction of the police powers doctrine in investment treaty arbitration has been successful in a number of cases.²⁵

Neither doctrine has prevailed over the other in the investment jurisprudence, nor have scholars adopted a single stance on this issue.²⁶ The adoption of the sole effects doctrine may end up 'threatening to place prohibitive costs on rational environmental management'.²⁷ Both the Metalclad and Tecmed tribunals paid little attention to

²² Ernst Freund, *The Police Power: Public Policy and Constitutional Rights* (Callahan 1904).

²³ Newcombe (n 20) 21.

²⁴ Howard Mann and Konrad Von Moltke, *Protecting Investor Rights and the Public Good: Assessing NAFTA's Chapter 11* (2003) IISD 16 <www.iisd.org/trade/ILSDWorkshop/pdf/background_en.pdf>.

²⁵ See eg *Myers v Canada*, Partial Award, 13 November 2000, § 281; *Methanex Corporation v United States of America*, UNCITRAL, NAFTA Arbitral Tribunal, Final Award, August 3 2005, Part IV - Chapter D - Page 4 (holding that '... as a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, *inter alios*, a foreign investor or investment is not deemed expropriatory and compensable unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation.'). *Chemtura v Canada*, Award, August 2010, para 266 (holding that 'the measures challenged by the claimant constituted a valid exercise of the Respondent's police powers. The PMRA took measures within its mandate, in a non-discriminatory manner, motivated by the increasing awareness of the dangers presented by Lindane for human health and the environment. A measure adopted under such circumstances is a valid exercise of the state's police powers and, as a result, does not constitute an expropriation.')

²⁶ Catharine Titi, 'Police Powers Doctrine and International Investment Law' in Filippo Fontanelli, Andrea Gattini and Attila Tanzi (eds), *General Principles of Law and International Investment Arbitration* (Brill 2018) 323-343, 323 (noting that '[d]isagreement is endemic to the study of concepts so fluid and elusive as the state's police powers').

²⁷ Marc A Munro, 'Expropriating Expropriation Law: The Implications of the Metalclad Decision

the environmental health goals of the national measures; in both cases, the host state merely claimed that the goal of the adopted measures was public health protection, without articulating the claim.²⁸ If states more clearly voiced their claims, it would be possible for arbitral tribunals to better balance the different interests at stake.

A crucial element in investment disputes involving environmental elements is the ascertainment of non-discrimination. The key question is whether foreign investments 'are being regulated because the activity in question presents certain risks to the environment, or ... because they are foreign invest[ments].'²⁹ Nowadays it is difficult to spot openly discriminatory *language* in environmental regulations, although this has appeared in the past. For instance, Chile adopted openly discriminatory environmental regulation that imposed particular environmental requirements on foreign firms that were not required of other firms.³⁰ The discriminatory *effect* of a given regulatory measure is more difficult to assess. For instance, the Bilcon Tribunal found a breach of the national treatment standard under NAFTA Article 1102, in that a domestic Joint Review Panel evaluated an investment project using more stringent criteria than those imposed on Canadian investors in like circumstances.³¹ Moreover, the use of apparently neutral criteria may affect a particular group of people. For instance, in the *Ethyl* case, Ethyl argued that even equally formal treatment may result in less favourable treatment for a foreigner, and that the term 'no less favourable' calls for effective equality in treatment.³² As the case was settled, no ruling on these arguments was made.³³ In other cases, however, investors alleged indirect discrimination, and the host state attempted to justify its regulation on the basis of multilateral environmental agreements without success. For instance, in *Myers*, the Tribunal found inter alia that Canada had violated the national treatment provision.³⁴ Very little attention was paid to the Basel Conven-

on Canadian Expropriation Law and Environmental Land Use Regulation' (2005) 5 *Asper Review of International Business & Trade Law* 75.

²⁸ Ryan Suda, 'The Effect of Bilateral Investment Treaties on Human Rights Enforcement and Realization' in Olivier De Schutter (ed), *Transnational Corporations and Human Rights* (Hart Publishing 2006) 73-145, 140.

²⁹ See Mann and Von Moltke (n 24) 25.

³⁰ Konrad Von Moltke, *Discrimination and Non-Discrimination in Foreign Direct Investment Mining Issues* (OECD 2002) 16.

³¹ William Ralph Clayton, William Richard Clayton, Douglas Clayton, Daniel Clayton and Bilcon of Delaware Inc. v Government of Canada, UNCITRAL, Permanent Court of Arbitration (PCA) Case No. 2009-04, Award on Jurisdiction and Liability, 17 March 2015, para 696.

³² *Ethyl Corporation v Canada*, Notice of Arbitration under the Arbitration Rules of the UNCITRAL and the NAFTA, April 14, 1997, paras 15-17.

³³ Canada settled the claim, agreeing to pay Ethyl \$19.3 million and repeal the ban on MMT. For commentary see R Moloo and J Jacinto, 'Environmental and Health Regulation: Assessing Liability under Investment Treaties' (2011) 29 *Berkeley Journal of International Law* 101, 130.

³⁴ *S.D. Myers Inc v Government of Canada*, Award November 13, 2000 40 *ILM* 6, 1408-1492, para 183.

tion on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Basel Convention),³⁵ which was applicable to the dispute. Indeed, Canada argued that even if its export ban favoured domestic industry, as a signatory to the Basel Convention, the state was legitimately entitled, and in fact required, to ensure the availability of adequate in-country disposal facilities for dangerous chemical substances such as PCB. However, the arbitral panel found impermissible discrimination against the claimant since the export ban favoured Canadian companies over non-Canadian companies.

The fair and equitable treatment (FET) standard has become a key issue in disputes with environmental elements. Although the FET standard allows different interpretations, it provides a basic standard of protection that an investor may invoke, which is detached from the law of the host country. Because of its elasticity, the FET clause fills the gaps left by more specific standards in order to obtain the level of investor protection intended by the treaties.³⁶ While historically the FET standard was considered to be breached when the state's conduct was of an egregious and shocking nature,³⁷ it has been interpreted more extensively in recent cases to include the state's failure to provide 'a transparent and predictable framework' for FDI.³⁸ Under this expansive reading of the FET standard, the host state must respect specific representations made by its officials to investors, who have reasonably relied upon such representations in good faith.³⁹ Nonetheless, a mere 'scientific divergence ... cannot in and of itself serve as a basis for a finding of breach of [the FET standard]'.⁴⁰ In sum, the FET provision has come to the forefront of environmental health-related investment disputes. While corporations may see legislative changes and administrative procedures as a normal business risk, this does not exempt states from a general obligation of good faith and transparency.

Recent jurisprudential trends suggest that, on one side, the FET standard includes transparency, legitimate expectations, and good faith. For example, in *Bilcon v Canada*,⁴¹ involving the rejection of a project to develop and operate a quarry in Nova Sco-

³⁵ Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Basel Convention), March 22, 1989, 28 ILM 656 (1989).

³⁶ Martins Paparinskis, *The International Minimum Standard and Fair and Equitable Treatment* (OUP 2014); Roland Kläger, 'Fair and Equitable Treatment' in *International Investment Law* (CUP 2013); Ioana Tudor, *The Fair and Equitable Treatment Standard in the International Law of Foreign Investment* (OUP 2008).

³⁷ *Neer v United Mexican States*, Award, 4 RIAA 60 (1960).

³⁸ *Metalclad Corporation v The United Mexican States*, ICSID Case No. ARB(AF)/97/1, Award, 30 August 2000, para 99.

³⁹ *Técnicas Medioambientales Tecmed, S.A. v The United Mexican States*, ICSID Case No. ARB (AF)/00/2, Award, 29 May 2003, paras 154, 164, 166.

⁴⁰ *Chemtura Corporation v Government of Canada*, UNCITRAL/NAFTA, Award, 2 August 2010, para 154.

⁴¹ *William Ralph Clayton, William Richard Clayton, Douglas Clayton, Daniel Clayton and Bilcon of*

tia, the Tribunal found that the government's environmental assessment was in breach of the investors' legitimate expectations, which were based on domestic law and specific representations by government officials who encouraged Bilcon to pursue the project. In its assessment of legitimate expectations, the Tribunal did not consider the broader public policy concerns or weigh the investors' expectations against the objectives of sustainable development, including environmental protection.

5. *Reconciling Environmental Health with Investor Rights*

Arbitral tribunals are not courts of general jurisdiction; rather, they have to interpret and apply international investment agreements. While some international investment agreements refer to international law, others refer to domestic law as the applicable law. Article 42 of the ICSID Convention gives the parties full autonomy in regard to the selection of the law applicable to the merits of their dispute. In the absence of party agreement on applicable law, the ICSID tribunal will apply the law of the state party to the dispute and such rules of international law as may be applicable.⁴² If the applicable law is domestic law, most domestic legal systems regulate economic activities affecting environmental protection. Therefore, investors should comply with domestic environmental standards and requirements.⁴³

If the applicable law is international law, arbitral tribunals can refer to applicable multilateral environmental agreements (MEAs), customary law, or general principles of law. Many public health principles that belong to national constitutional orders have already been translated into international law. Some such norms have become rules of customary international law or general principles of international law; others have been codified in a series of multilateral environmental agreements and are binding on the states that have ratified them. Although arbitral tribunals cannot issue a finding of compliance or non-compliance with the MEA because this ultimately falls outside their mandate, they can evaluate the legitimacy and good faith character of a given regulatory measure in light of international standards, such as those elaborated in the relevant MEA.

Can the protection of environmental health give rise to an independent cause of action before investor–state arbitral tribunals? A recent attempt has been made to ‘twist’ international investment arbitration to protect environmental health by requiring a state to respect its own environmental laws that are critical to the success of the investment. A Canadian investor filed a claim against Barbados for failure to enforce its own environ-

Delaware Inc. v Government of Canada, UNCITRAL, Permanent Court of Arbitration (PCA) Case No. 2009-04, Award on Jurisdiction and Liability, 17 March 2015.

⁴² ICSID Convention, article 42.

⁴³ *Pac Rim Cayman LLC v El Salvador*, ICSID Case ARB/09/12, Award, 14 October 2016; *Emilio Agustín Maffezini v Kingdom of Spain*, ICSID Case No. ARB/97/7, Award, 13 November 2000.

mental law.⁴⁴ As the investor acquired wetlands and subsequently developed them into an ecotourism facility, he claimed that Barbados failed to prevent the discharge of raw sewage into wetlands and to investigate or prosecute polluters, thus reducing the profitability of his investment.⁴⁵ Although the arbitral tribunal ultimately rejected the claim,⁴⁶ as Viñuales points out, this case ‘illustrates a novel form of complementariness between international investment law and international environmental law.’⁴⁷

However, unless the applicable law enables such claims,⁴⁸ arbitrators cannot adjudicate on the violation of provisions of multilateral environmental agreements, as this is outside their arbitral mandate.⁴⁹ However, they *can* refer to environmental protection as embodied in the national law of the host state or in international law standards, provided that these are binding on the host state. If the applicable law was the law of the host state, and the host state was a party to a MEA, then this MEA would become relevant as part of the internal law of the host state. Furthermore, the home state of the investor could make known its views about the interpretation of both the bilateral investment treaty (BIT) and the MEA to an arbitral tribunal, either by way of an *amicus curiae* submission to the Tribunal or by agreeing with the host country to a shared interpretation of the mutual obligations under the BIT and the MEA.

Two avenues can facilitate the consideration of environmental health in international investment disputes. First, as international investment treaties are periodically

⁴⁴ Peter A. Allard *v* Government of Barbados, Notice of Dispute <www.graemehall.com/legal/papers/BIT-Complaint.pdf>.

⁴⁵ *ibid* para 16.

⁴⁶ Peter A. Allard *v* The Government of Barbados, PCA Case No. 2012-06, Award, 27 June 2016.

⁴⁷ Jorge E Viñuales, *Foreign Investment and the Environment in International Law* (CUP 2012); Pierre-Marie Dupuy and Jorge E Viñuales (eds), *Harnessing Foreign Investment to Promote Environmental Protection* (CUP 2013); Jorge E Viñuales, ‘Foreign Investment and the Environment in International Law: An Ambiguous Relationship’ (2010) 80 *British Yearbook of International Law* 7.

⁴⁸ See eg *Burlington Resources Inc. v Ecuador*, Decision on Counterclaims, ICSID Case No. ARB/08/5, 7 February 2017 (awarding damages in respect of Ecuador’s environmental counterclaims on the basis of Ecuador tort law) and *Urbaser S.A. and Consorcio de Aguas Bilbao Bizkaia, Bilbao Biskaia Ur Partzuergoa v The Argentine Republic*, Award, 8 December 2016, ICSID Case No. ARB/07/26 (accepting Argentina’s counterclaim on the basis of a broad jurisdictional clause). For a discussion of the possible use of counterclaims to achieve some balance between investors’ interests and non-economic concerns, see Eric De Brabandere, ‘Human Rights and International Investment Law’ in Markus Krajewski and Rhea Hoffmann (ed), *Research Handbook on Foreign Direct Investment* (Edward Elgar 2019) 619-645; Valentina Vadi, ‘Cultural Heritage in International Investment Law’ in Ana Filipa Vrdoljak and Francesco Francioni (eds), *Oxford Handbook on Cultural Heritage Law* (OUP forthcoming 2019); Tomoko Ishikawa, ‘Counterclaims and the Rule of Law in Investment Arbitration’ (2019) 113 *AJIL Unbound* 33-37.

⁴⁹ The principle *nec ultra petita* or *nec ultra fines mandati* requires the arbitral tribunal to limit itself to the scope of power allowed and the violation of such principle is widely recognized as a cause for the annulment of the international arbitral award. The recognition or enforcement of an award shall be refused under the New York Convention, Article V.1 (c), if the award contains decisions on matters beyond the scope of submission to arbitration. Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York Convention) adopted on 10 June 1958, in force 7 June 1959.

renegotiated, treaty drafters can expressly accommodate environmental health in the text of these treaties (ie, a ‘treaty-driven approach’). Only in recent decades, have investment treaties addressed environmental health issues and included specific provisions pertaining to health and the environment. A number of preambles of international investment agreements contain reference to the environment.⁵⁰ Others include non-preclusion clauses. For instance, the 1995 BIT between Russia and Hungary states that ‘this Agreement shall not preclude the application of either Contracting Party of measures, necessary for the maintenance of defence, national security and public order, protection of the environment, morality, and public health’.⁵¹ Other treaties provide for more articulated clauses, incorporating Article XX of GATT and its interpretative notes with regard to trade in goods and Article XIV of GATS with regard to trade in services.⁵² These exceptions include measures necessary to inter alia protect human, animal or plant life or health, conservation of living and non-living exhaustible natural resources, and public morals.⁵³ Similarly, the Energy Charter Treaty (ECT) requires states to regulate the environmental and safety aspects of the exploration and development of their energy resources.⁵⁴ In a more detailed fashion, Annex 10-C(4)(b) of the Central America Free Trade Agreement (CAFTA)⁵⁵ expressly states: ‘Except in rare circumstances, non-discriminatory regulatory actions by a party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriations.’ Similarly, ad hoc provisions of several recent US free trade agreements clarify that ‘Except in rare circumstances, non-discriminatory regulatory actions by a

⁵⁰ See eg 2018 United States–Mexico–Canada Agreement (USMCA) (not yet in force) preamble (recognizing ‘the [parties] inherent right to regulate and resolve to preserve the flexibility of the Parties to set legislative and regulatory priorities, in a manner consistent with this Agreement, and protect legitimate public welfare objectives, such as public health, safety, the environment, the conservation of living or non-living exhaustible natural resources, the integrity and stability of the financial system and public morals, in accordance with the rights and obligations provided in this Agreement’); 2012 US Model BIT preamble (expressing the parties’ ‘[d]esir[e] to achieve [a stable framework for investment maximizing effective utilization of economic resources and improving living standards] in a manner consistent with the protection of health, safety, and the environment, and the promotion of internationally recognized labor rights.’); Energy Charter Treaty (ECT), preamble (recognizing ‘the increasingly urgent need for measures to protect the environment.’); Accord entre la Confédération Suisse et la Serbie-et-Monténégro concernant la promotion et la protection réciproque des investissements, signed on 7 December 2005, in force on 20 July 2007, preamble (expressing the parties’ firm belief ‘*que ces objectifs peuvent être atteints sans abaisser les norms d’application générale relatives à la santé, à la sécurité et à l’environnement.*’)

⁵¹ 1995 BIT between Russia and Hungary, signed on 6 March 1995, in force 29 May 1996, article 2.

⁵² See eg the 2004 Canada Model Foreign Investment Promotion and Protection Agreement (FI-PA), article 10.

⁵³ 2012 US Model BIT, article 12.

⁵⁴ Energy Charter Treaty (ECT) 17 December 1994, 2080 UNTS 95, article 18(3).

⁵⁵ Dominican Republic–Central America Free Trade Agreement signed on 5 August 2004 <www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/asset_upload_file747_3918.pdf>.

Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriation.’⁵⁶

These and similar provisions seem to provide space for environmental health protection, but they present some limits. In particular, the expression ‘except in rare circumstances’ opens the door to deeming certain regulatory measures as regulatory expropriations. Moreover, introducing public health considerations as an exception to investment rules is admittedly at odds with the alleged importance of public health. Exceptions are traditionally interpreted in a restrictive way. Scholars have stressed that investment treaty clauses referring to environmental protection often include ‘purely hortatory’ language with unenforceable character.⁵⁷ While it is generally held that preambles do not contain binding obligations *per se*,⁵⁸ they can influence the interpretation of treaties, as they provide context, explain the underlying philosophy of the document, and establish a dialogue between the treaty drafters and the adjudicators. Although inserting environmental concerns in preambles or merely imposing obligations of means rather than results may amount to ‘pseudo-action’,⁵⁹ as the former is not binding and the latter merely imposes due diligence, these provisions are important steps to infusing investment treaties with environmental health considerations.

Second, international arbitral tribunals can take into account environmental health within the current framework of international investment law (ie, a ‘judicially driven approach’). Pursuant to the process of treaty interpretation, many apparent conflicts between environmental health and investor rights can be resolved or even prevented. However, other conflicts may have a genuine nature, and take the form of either inherent normative conflicts or conflicts in the application of the relevant norm.⁶⁰ Inherent normative conflicts—when a norm constitutes, in itself, breach of another norm—will rarely, if ever, appear in practice. Instead, both apparent conflicts and conflicts in the applicable law—when compliance with one norm entails non-compliance with the other—have often arisen in the context of investor–state arbitration. Indeed, it may be argued that conflicts in the application of norms arise

⁵⁶ US-Chile Free Trade Agreement, Chapter 10, Annex 10-D, Article 4 (b). The US-Chile FTA entered into force on 1 January 2004. The text of the agreement is available at <www.ustr.gov>.

⁵⁷ See Jane Kelsey, ‘International Economic Agreements and Environmental Justice’ in Klaus Bosselmann and Benjamin J Richardson (eds), *Environmental Justice and Market Mechanisms: Key Challenges for Environmental Law and Policy* (Kluwer Law International 1999) 154–168, 168.

⁵⁸ *Victor Pey Casado et Foundation “President Allende” contre République du Chili*, ICSID Case No ARB/98/2, Arbitral Award, 8 May 2008, para 348.

⁵⁹ Thomas Wälde, ‘Sustainable Development and the 1994 Energy Charter Treaty: Between Pseudo-Action and the Management of Environmental Investment Risk’ in Friedl Weiss, Erik MG Denters and Paul JIM De Wart (eds), *International Economic Law with a Human Face* (Kluwer 1998) 244.

⁶⁰ Erich Vranes, ‘The Definition of Norm Conflict in International Law and Legal Theory’ (2006) 17 *European Journal of International Law* 395, 395.

because conflict prevention and management of apparent conflicts have not been attempted or have failed.

For instance, any distinct treatment of a foreign investor based on its foreign status may be unjustifiable, except where legitimate reason for differential treatment exists. It is important for states to show that their regulations aim at achieving legitimate public goals and follow due process of law. As one arbitral tribunal held, “public interest” requires some genuine interest of the public. If mere reference to “public interest” can magically put such interest in existence and therefore satisfy this requirement, then this requirement would be rendered meaningless since the Tribunal can imagine no situation where this requirement would not have been met.”⁶¹ Nonetheless, if the adopted measures rely on international standards, adopted under the aegis of international bodies, such as the World Health Organization, they may be presumed to be legitimate.⁶²

If a case presented scientific uncertainty and a plurality of scientific opinions, adjudicators may put emphasis on the scientific method and on due process, particularly with regard to transparency and public participation.⁶³ Accordingly, adjudicators should assess whether policymakers have adopted reasonable scientific method and due process in their risk assessment. Their enquiry would focus on whether regulations have been adopted in a transparent manner and whether they are subject to domestic remedies and/or judicial review. In addition, arbitral tribunals should not undertake a *de novo* review of the evidence once before the national authorities, but rather an objective assessment of the issues at stake.⁶⁴ In this sense, such controls can be seen as a desirable constraint on the domestic political process, and investor–state arbitration may constitute a step towards good governance in international economic relations. At the same time, however, investor–state arbitration should not be abused.⁶⁵ Arbitral awards should therefore not result in a general regulatory chill on environmental matters.⁶⁶

⁶¹ *ADC Affiliate Limited and ADC & ADMC Management Limited v Republic of Hungary*, ICSID Case ARB/03/16, Award 2 October 2006, para 432.

⁶² *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, Award, 8 July 2016.

⁶³ Marcos A Orellana, ‘The Role of Science in Investment Arbitrations Concerning Public Health and the Environment’ (2006) *Yearbook of International Environmental Law* 48, 54.

⁶⁴ Valentina Vadi, *Proportionality, Reasonableness and Standards of Review in International Investment Law and Arbitration* (Edward Elgar 2018).

⁶⁵ *Philip Morris Asia Limited v The Commonwealth of Australia*, UNCITRAL, PCA Case No. 2012-12, Award on Jurisdiction and Admissibility, 17 December 2015.

⁶⁶ Jonathan Bonnitcha, Lauge N Skovgaard Poulsen, Michael Waibel, *The Political Economy of the Investment Treaty Regime* (OUP 2017) 238–244. See also *Bilcon of Delaware et al v Government of Canada*, PCA Case No. 2009-04, Dissenting Opinion of Professor Donald McRae, 10 March 2015, para 48 (arguing that ‘a significant intrusion into domestic jurisdiction ... will create a chill on the operation of environmental review panels.’) and para 49 (arguing that ‘subjugation of human environment concerns to the scientific and technical feasibility of a project is not only an intrusion into the way an environ-

In conclusion, investment treaties aim at establishing a level playing field for foreign investors and a sort of shield against their discrimination and mistreatment by the host state. At the same time, they also aim at fostering the sustainable development of the host state. Therefore, international investment agreements should not become 'a charter of rights for foreign investors, with no concomitant responsibilities or liabilities ... and no protection for public welfare in the face of environmentally or socially destabilizing foreign investment.'⁶⁷ International investment law should not be seen as a 'corporate bill of rights'⁶⁸ or a 'system of corporate rights without responsibility or liability.'⁶⁹ In all legal systems, including the international legal system, the very first goal of state activity appears to be that of securing the very existence of the state itself, by protecting public safety. Corporations are expected to respect the rights of others and to do no harm, according to the principle of *neminem laedere*, or duty of care.⁷⁰

6. Conclusions

This chapter has examined the particular intersection between environmental health and international investment law. Environmental health is a theoretical tool that highlights the linkage between the environment and public health. The regulatory competence of states to protect environmental health, which has traditionally been part of state sovereignty, has somehow been reinforced by a web of MEAs that have reaffirmed the states' duty to protect the environment. Several investment treaties acknowledge such competence through declaratory statements in their preambles, coordination clauses and exceptions.

However, conflicts may arise between investment treaty guarantees and national regulations aimed at protecting environmental health. Foreign investors, who have direct access to international arbitral tribunals, may claim that such regulations violate their rights under international investment agreements. Scholars have cautioned

mental review process is to be conducted, but also an intrusion into the environmental public policy of the state.')

⁶⁷ Howard Mann, 'The Right of States to Regulate and International Investment Law: A Comment' in UNCTAD *The Development Dimension of FDI: Policy and Rule-Making Perspectives* (UN 2003) 211, 212.

⁶⁸ Todd Weiler, 'Balancing Human Rights and Investor Protection: A New Approach for a Different Legal Order' (2004) 1 *Transnational Dispute Management* 1, 2.

⁶⁹ Mann (n 67) 215.

⁷⁰ UN Human Rights Council, *Protect, Respect and Remedy: a Framework for Business and Human Rights: Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises*, John Ruggie, 7 April 2008, A/HRC/8/5.

that investment treaty law and arbitration may risk becoming an ‘example of ... the asymmetrical scale politics of neoliberalism [where] local institutions and actors [are] being given responsibility without power, while international institutions and actors [are] gaining power without responsibility’.⁷¹

This chapter has shown the possible areas of conflict between environmental health concerns and investors’ rights and has scrutinized the legal tools that may help the reconciliation of these different values and goals within investment treaty law and arbitration. It argues that international investment law does not constitute a self-contained regime; rather, it must be interpreted and applied in light of public international law. The chapter also examined the law governing investment disputes and the interpretative tools that may help adjudicators to reconcile the different interests at stake.

⁷¹ Vivian HW Wang, ‘Investor Protection or Environmental Protection? “Green Development” Under CAFTA’ (2007) 32 *Columbia Journal of Environmental Law* 251.

Chapter 4

The Dispute on Brazilian Measures Affecting Imports of Retreaded Tyres at the WTO: An Exemplary Intersection of Trade, Health and Environment *

Xavier Fernández-Pons **

1. Introduction

Waste tyres generate serious pollution problems in many countries. Frequently, waste tyres are accumulated in large landfills, are burned releasing harmful substances or go, clandestinely, to the slopes of roads or river beds, being a factor that generates fires and other environmental and health damages. This is particularly worrisome in tropical countries, where waste tyres facilitate the proliferation of mosquitoes, favouring the spread of various diseases, such as dengue, yellow fever or malaria.¹

The Brazilian Government tried to reduce the number of waste tyres in its territory by prohibiting the importation of used and retreaded tyres. Retreaded tyres are used tyres to which a new rubber tread is added, through an industrial process, in order to lengthen their useful life. However, Brazil considered that the importation of retreaded tyres, with a short life once introduced into its territory, meant to increase the number of waste tyres in this country more quickly.

This Brazil's import ban was challenged in various instances. At the World Trade Organization (WTO), the European Communities (currently, European Union – EU) filed a claim against Brazil,² alleging that the Brazilian authorities were violating basic princi-

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¹ On the most common problems arising from the inadequate management of waste tyres, see: Aurelio Ramírez-Hernández and Jorge Conde-Acevedo, 'Tyres: Destination End' (2013) 16 *International Journal of Environmental Technology and Management* 279, 282-283.

² WTO, Dispute WT/DS332: *Brazil – Measures Affecting Imports of Retreaded Tyres* (short title: *Bra-*

ples of the multilateral trading system. Brazil tried to defend its import ban on the grounds that it was necessary to protect human life and health and the environment.

This contribution will examine this dispute, which has great relevance in the intense debate on the possible justification of trade restrictions for health and environmental reasons. So, this case has received numerous comments, published in English³ and other languages,⁴ and the assessments, as we will see later, do not always converge.

2. The Brazilian Measures at Issue and the Different Claims Against Them

The Brazilian Government has established diverse and successive regulations on the importation of used and retreaded tyres. In 1991, the Brazilian Department of Operations for Foreign Trade (Departamento de Operações de Comércio Exterior – DECEX) passed the Portaria (infralegal regulation) DECEX 8/1991,⁵ prohibiting the importation of used consumer goods, including used tyres, but without referring to retreaded tyres, which continued to be imported from other countries.

In 2000, the Brazilian Secretariat for Foreign Trade (Secretaria de Comércio Exterior – SECEX) passed the Portaria SECEX 8/2000,⁶ establishing a general import ban of both used and retreaded tyres. This import ban was destined to reduce the total number of waste tyres in Brazil and to diminish the indicated sanitary and environmental risks that they cause. These measures did not affect the import of new tyres neither the commercialization of domestic used and retreaded tyres, which contribute to lengthen the life of tyres already used in Brazil. Instead, the import of used and retreaded tyres from other countries involved the introduction into Brazil of tyres with a short life, increasing the number of waste tyres.

zil – Retreaded Tyres).

³ See, for instance: Chad Bown and Joel Trachtman, 'Brazil – Measures Affecting Imports of Retreaded Tyres: A Balancing Act' (2009) 8 *World Trade Review* 85; Kevin R Gray, 'Brazil – Measures Affecting Imports of Retreaded Tyres' (2008) 102 *American Journal of International Law* 610; Nikos Lavranos, 'The Brazilian Tyres Case: Trade Supersedes Health' (Fall 2009) 1 *Trade, Law & Development* 230; Sébastien Thomas, 'Trade and Environment under WTO Rules after the Appellate Body Report in *Brazil – Retreaded Tyres*' (2009) 4 *Journal of International Commercial Law and Technology* 42; and Joseph HH Weiler, 'Brazil – Measures Affecting Imports of Retreaded Tyres' (2009) 8 *World Trade Review* 137.

⁴ See, for example: Guillaume Areou, 'Brésil: Mesures visant l'importation de pneus rechapés' (2008) 112 *Revue Générale de Droit International Public* 192; Adriana Macena S. Savio, 'O caso dos pneus perante a OMC e o Mercosul' (2011) 9 *Universitas Relações Internacionais* 349; Hannes Schloemann, 'Asunto Brasil – Medidas que afectan a las importaciones de neumáticos recauchutados (Brasil – Neumáticos): se confirma el espacio de política en el marco del Artículo XX del GATT' (2008) 9 *Puentes ICTSD* 1.

⁵ Brazil, Portaria DECEX No 8 of 13 May 1991.

⁶ Brazil, Portaria SECEX No 8 of 25 September 2000.

These measures adopted by the Brazilian authorities were challenged in diverse instances. On the one hand, some private companies interested in the import of used and retreaded tyres into Brazil (essentially, Brazilian companies interested in importing used tyres as raw material to retread them) impugned these infralegal regulations at different Brazilian domestic lower courts, alleging that these trade restrictions violated higher rules, including the right to freedom of enterprise. Inside the complex judicial system of Brazil and before the pronouncement of the Brazilian Federal Supreme Court, numerous domestic lower courts accepted such claims and approved injunctions authorising the complainant companies to continue importing used tyres for several years.⁷

On the other hand, Uruguay presented in 2001 a claim against Brazil at the MERCOSUR dispute settlement system. From Uruguay there were some exports of retreaded tyres to Brazil and Uruguay considered that the general import ban of retreaded tyres established by the quoted Portaria SECEX 8/2000 violated the rules of this regional organization. A MERCOSUR arbitral tribunal endorsed, with an award of 9 January 2002, the Uruguay's position.⁸ This award had no direct effect on the Brazilian domestic legal order, but the Brazilian authorities modified their regulations, introducing an exemption for the import of retreaded tyres from other MERCOSUR countries. This MERCOSUR exemption was included in successive regulations, as the Portaria SECEX 14/2004.⁹

Finally, the EU presented in 2005 a claim against Brazil at the WTO dispute settlement system, alleging that the general import ban of retreaded tyres, taken together with import permits granted by numerous injunctions of domestic lower courts and the MERCOSUR exemption, were incompatible with the GATT 1994.¹⁰ The EU focused its claim on retreaded tyres, as the European companies that manufacture them were interested in maintaining their exports to Brazil, while exports of used tyres were not comparable. Brazil defended, fundamentally, that its measures were justified under the general exceptions contemplated in Article XX of GATT 1994, where there are diverse legitimate objectives (some linked to the protection of health and environment) that can justify certain trade restrictions.

⁷ See a detailed description of these claims at Brazilian domestic courts in: Marcelo D Varella, 'Dificuldades de implementação das decisões da OMC: um estudo de caso a partir do contencioso pneus' (2014) 19 *Revista Direito Getulio Vargas* – GV 53, 61 and 65.

⁸ MERCOSUR, Laudo del Tribunal Arbitral *ad hoc* del MERCOSUR constituido para entender de la controversia presentada por la República Oriental del Uruguay a la República Federativa del Brasil sobre la prohibición de importación de neumáticos remoldeados (*remolded*) procedentes de Uruguay de 9 de enero de 2002, available at <www.mercosur.int/institucional/solucion-controversias/laudos/> accessed 18 January 2019.

⁹ Brazil, Portaria SECEX No 14 of 17 November 2004.

¹⁰ WTO, Request for Consultations by the European Communities, *Brazil – Retreaded Tyres*, WT/DS332/1, 23 June 2005.

3. *Analysis of the WTO Adjudicative Bodies Reports*

Since the initial consultations between the EU and Brazil were fruitless, the WTO Dispute Settlement Body (DSB) established a Panel on 28 November 2005, whose final report circulated on 12 June 2007.¹¹ This report was challenged before the Appellate Body, whose report circulated on 3 December 2007.¹² The conclusions of both WTO adjudicative bodies are quite alike, although there are some relevant differences. Next, we will analyze the main conclusions of such reports.

3.1. *The Measures Are Inconsistent with Basic Principles of the GATT 1994*

The WTO adjudicative bodies considered that the Brazil's import ban of retreaded tyres and other complementary measures (as the fines established on importing and marketing, transportation, storage, keeping or warehousing of imported retreaded tyres) were inconsistent with Article XI:1 of GATT 1994, which establishes the principle of "General Elimination of Quantitative Restrictions".

Thus, WTO Members can impose tariffs on imported products (provided they do not exceed bound tariffs pursuant to Article II of GATT 1994) but, in general and in order to promote the liberalization of international trade, they cannot impose quantitative restrictions on imports (or exports) of products. Article XI:1 prohibits import quotas, zero quotas and other equivalent measures.

Other disputes on trade and health or environment at the WTO, as the *EC-Asbestos* case,¹³ have referred to the prohibition of the commercialization of a product that was considered intrinsically harmful, affecting both imported and domestic products. In such cases, as Pauwelyn points out,¹⁴ the measure should not be examined in the light of Article XI:1, which is intended for restrictions that specifically affect imports (or exports) and not for measures indistinctly applicable to domestic and imported products. These indistinct measures should be examined under other GATT 1994 provisions (such as the principle of "National Treatment on Internal Taxation and Regulation", in Article III) and other WTO agreements (such as the Agreement on Technical Barriers to Trade or the Agreement on the Application of Sanitary and Phytosanitary Measures).

¹¹ WTO, Panel Report, *Brazil – Retreaded Tyres*, WT/DS322/R, 12 June 2007.

¹² WTO, Appellate Body Report, *Brazil – Retreaded Tyres*, WT/DS332/AB/R, 3 December 2007.

¹³ WTO, Dispute WT/DS135: *European Communities – Measures Affecting Asbestos and Products Containing Asbestos* (short title: *EC – Asbestos*). On this dispute, see Rosa María Fernández Egea, 'El asunto amianto – Por fin una decisión saludable' (2001) 3 *Revista Electrónica de Estudios Internacionales* 1.

¹⁴ Joost Pauwelyn, 'Rien ne va plus? Distinguishing Domestic Regulation from Market Access in GATT and GATS' (2005) 4 *World Trade Review* 131.

The quoted Brazilian measures in this case are clearly subject to Article XI:1, since, as we have seen, they involve a specific import ban and the imposition of fines is only envisaged for marketing, transportation, storage and other activities with imported retreaded tyres.

3.2. The Import Ban Is Necessary to Protect Human, Animal or Plant Life or Health

The elimination of quantitative restrictions on the importation of any product is established under the quoted Article XI:1 as a general principle, but it is not an absolute principle. Thus, the GATT 1994 contemplates various exceptions that may justify certain trade restrictions. There are, particularly, the “General Exceptions” included in Article XX of GATT 1994, which can be seen as one of the main bridges that connect the rules of the multilateral trading system with other ‘societal values and interests’.¹⁵ The application of Article XX is traditionally based on a two-tier test: first, it must be determined whether the measure can provisionally be justified under one of the specific objectives listed in its paragraphs (a) to (j); next, it shall be determined if the measure satisfies the horizontal requirements of its introductory clause (commonly designated with the French word *chapeau*).¹⁶

Brazil invoked paragraph (b) of Article XX on ‘measures necessary to protect human, animal or plant life or health’. The quoted paragraph does not make an explicit reference to the environment, but Brazil argued that its import ban of retreaded tyres was necessary to protect “human life and health and the environment” against risks arising from the accumulation of waste tyres.¹⁷ The Panel admitted that paragraph (b) may cover risks to the environment, but pointed out that, according to the paragraph text, it must be a risk to “human, animal or plant life or health” rather than “the environment” generally.¹⁸ It should be noted that other environmental measures may be covered under other paragraphs of Article XX, particularly under paragraph (g) on measures “relating to the conservation of exhaustible natural resources”. The Panel also noted that Brazil’s chosen level of protection was the reduction of the risks of waste tyres accumulation “to the maximum extent possible”.¹⁹

After determining that the objectives of a measure fit within paragraph (b) of Article XX, the so-called ‘necessity test’ must be done to check whether the import ban of retreaded tyres is really a measure “necessary” to reduce the multiple health and environmental risks caused by the accumulation of waste tyres. Within the multilat-

¹⁵ Peter Van den Bossche and Denise Prévost, *Essentials of WTO Law* (CUP 2016) 83.

¹⁶ See, for example: WTO, Appellate Body Report, *US – Gasoline*, WT/DS2/AB/R, 21 April 1998, 22.

¹⁷ WTO, Panel Report, *Brazil – Retreaded Tyres*, (n 11) paras 4.9 and 7.44.

¹⁸ *ibid* para 7.46.

¹⁹ *ibid* para 7.108.

eral trading system there is a fairly abundant jurisprudence on the meaning of the term “necessary” and on how to proceed when performing the necessity test.²⁰ In any case, it is a complex operation, to be carried out case by case, weighting and balancing, on the one hand, the degree of commercial restriction of the measure, and, on the other hand, the importance of the objective pursued and the contribution of the measure to it. Finally, it is checked if there is an alternative measure less restrictive, which can equally contribute to the objective and is reasonably available for the Member. Therefore, the necessity test includes many indeterminate legal concepts, being a good example of what Hart described as the “open texture” of legal rules.²¹

Brazil argued, obviously, that the import ban complied with the necessity test. Brazil recognized that the prohibition of the importation of retreaded tyres is a drastic commercial restriction, but tried to compensate it by emphasizing, on the other side of the scale, the importance of health and environmental risks caused by the accumulation of waste tyres and the contribution of the import ban of retreaded tyres to their reduction.²²

The EU argued that this import ban could not pass the necessity test. The EU stressed, in particular, that health and environmental risks caused by the accumulation of waste tyres would not be eliminated by the prohibition of the importation of retreaded tyres and that the Brazilian authorities had not specified, quantitatively, what would be the concrete contribution of this import ban to the reduction of the total amount of waste tyres. In addition, the EU argued that there were other less trade-restrictive alternatives, such as a proper management and treatment of waste tyres, which could equally contribute to reducing waste tyres and which were reasonably available alternatives for the Brazilian authorities.²³ The EU also noted, according to the Appellate Body in *Korea—Various Measures on Beef*, that “necessity” is a high standard located considerably closer to the pole of “indispensable” than to that of “making a contribution to”.²⁴

The *Brazil—Retreaded Tyres* case posed, then, a choice between two possible visions of the necessity test: a more qualitative approach, which grants greater deference to the Members establishing trade restrictions; and a more quantitative approach, which would require to make concrete calculations of the contribution of the trade restrictions to the objectives pursued.

Finally, the WTO adjudicative bodies concluded that a qualitative argumentation of the contribution is enough. Thus, Brazil did not have to quantify the specific contribution of the import ban of retreaded tyres to the reduction of waste

²⁰ See Deborah Akoth Osiro, ‘GATT/WTO Necessity Analysis: Evolutionary Interpretation and Its Impact on the Autonomy of Domestic Regulation’ (2002) 29 *Legal Issues of Economic Integration* 123.

²¹ HLA Hart, *The Concept of Law* (Clarendon Press 1961) 123-126.

²² WTO, Panel Report, *Brazil – Retreaded Tyres* (n 11) paras 4.38-4.40.

²³ *ibid* paras 4.41-4.43.

²⁴ *ibid* para 4.42. See also WTO, Appellate Body Report, *Korea Various Measures on Beef*, WT/DS161/AB/R, para 161.

tyres and the Appellate Body stressed that it was enough that the measure was qualitatively apt to make a “material contribution” to the achievement of its objective.²⁵ In this way, Brazil did not have to make statistics or numerical projections, since the import ban, logically, could contribute materially (and not just theoretically) to the objective.

Regarding possible alternative measures suggested by the EU, the Appellate Body confirmed that a measure ‘will not be viewed as an alternative’ unless it preserves for the responding Member ‘its right to achieve its desired level of protection with respect to the objective pursued’.²⁶ The Appellate Body concluded, qualitatively and without the need for calculations, that the proper management and treatment of waste tyres would always be a technically more difficult measure for Brazil than the imposition of an import ban.²⁷ These other measures could be complementary measures, but not alternatives reasonably available for Brazil.²⁸

Although some authors have been critical of certain aspects of the Appellate Body’s conclusions about the necessity test,²⁹ other authors celebrate that the Appellate Body has recognized, with this case, a broad “policy space” or “regulatory autonomy” for Members in the defence of the need of certain trade restrictions imposed for health and environmental reasons, facilitating the overcoming of the necessity test.³⁰

3.3. The Exemptions to the Import Ban Result in Arbitrary or Unjustifiable Discriminations

After determining that the import ban was provisionally justified under paragraph (b) of Article XX of GATT 1994, the WTO adjudicative bodies had to verify whether the Brazilian measures as a whole, including the aforementioned import permits (‘exemptions’) conferred by certain domestic court injunctions and the MERCOSUR exemption, satisfied the requirements of the *chapeau* of Article XX, which requires that the measures “are not applied in a manner which would constitute a

²⁵ WTO, Appellate Body Report, *Brazil – Retreaded Tyres* (n 12) para 150.

²⁶ *ibid* para 170.

²⁷ *ibid* paras 173-175.

²⁸ See Benn McGrady, ‘Necessity Exceptions in WTO Law: Retreaded Tyres, Regulatory Purpose and Cumulative Regulatory Measures’ (2009) 12 *Journal of International Economic Law* 153, who affirms that: ‘The express recognition that some regulatory measures are complementary to one another rather than reasonably available alternatives constitutes a welcome step forward’ (at 153).

²⁹ For example: Ben McGrady, *ibid*, considers that, in certain aspects, the WTO adjudicative bodies reports in *Brazil – Retreaded Tyres* involve ‘arbitrariness in application of necessity tests’; and Lavranos (n 3) at 231, criticizes the use, by the Appellate Body, of the vague expression ‘material contribution’ and ‘the narrow application of Article XX’.

³⁰ See, for instance: Hannes Schloeman (n 4) at 1; and Sébastien Thomas (n 3) at 48.

means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade". At this point there were some relevant discrepancies between the interpretations of the Panel and the Appellate Body.

According to the Panel, neither the exemptions based on domestic court injunctions nor the MERCOSUR exemption should be considered "arbitrary" discriminations, considering that both exemptions had not been established by a capricious or random act of the Brazilian Government but as a consequence, respectively, of the decisions taken by various domestic courts and an arbitral tribunal of the MERCOSUR.³¹

The Panel considered that the exemptions based on domestic court injunctions incurred in "unjustifiable" discriminations, considering that there was no substantive basis justifying, in the light of the multilateral trading system, that some companies in Brazil could keep importing used tyres.³²

The Panel also considered that the high number of used tyres imported through domestic court injunctions, used by Brazilian retreaders, implied that Brazil was incurring, with the parallel general import ban of retreaded tyres, in a 'disguised restriction on international trade'.³³

However, the Panel found that the MERCOSUR exemption was not an "unjustifiable" discrimination. The Panel avoided a possible conflict with the previous award of the MERCOSUR arbitral tribunal and observed that imports into Brazil of retreaded tyres originating from MERCOSUR countries were very reduced. Thus, the Panel concluded that the MERCOSUR exemption, due to its scarce quantitative relevance, was a tolerable discrimination and was not a 'disguised restriction on international trade'.³⁴

In short, according to the Panel, the general import ban, as such, and the MERCOSUR exemption would be fully justified under Article XX, while the only measures incompatible with the GATT 1994 were the import permits granted by certain domestic court injunctions.

The Appellate Body disagreed, first, with the separate analysis that the Panel had made between the terms "arbitrary" or "unjustifiable" discriminations, which have traditionally been treated jointly. The Appellate Body considered that "the analysis of whether the application of a measure results in arbitrary or unjustifiable discrimination should focus on the cause or rationale given for the discrimination".³⁵ According to the Appellate Body, there is arbitrary or unjustifiable discrimination, within the meaning of the *chapeau* of Article XX, 'when a Member seeks to justify the dis-

³¹ WTO, Panel Report, *Brazil – Retreaded Tyres* (n 11) paras 7.281 and 7.294.

³² *ibid* para 7.306.

³³ *ibid* para 7.349.

³⁴ *ibid* paras 7.289 and 7.354.

³⁵ WTO, Appellate Body Report, *Brazil – Retreaded Tyres* (n 12) para 246.

crimination resulting from the application of its measure by a rationale that bears no relationship to the accomplishment of the objective that falls within the purview of one of the paragraphs of Article XX'.³⁶

The Appellate Body understood, then, that the determination of whether the exemptions result in "arbitrary or unjustifiable" discriminations should consider the legitimate objective pursued by the general import ban. Thus, if the exemptions were based on health and environmental reasons, they could be justifiable exemptions (for instance, an exemption granted to a hypothetical type of retreaded tyres with a useful life comparable to new tyres). On the other hand, if the exemptions are based on reasons unrelated to the health and environmental objectives that justify the general ban, it must be concluded that they incur in "arbitrary or unjustifiable" discriminations.

Regarding the import permits granted by domestic court injunctions, the Appellate Body concluded that, since they were not based on health or environmental grounds, they clearly resulted in "arbitrary or unjustifiable" discriminations.³⁷

Concerning the MERCOSUR exemption, the Appellate Body rejected the Panel's conclusion tolerating it due to its scarce quantitative relevance.³⁸ The Appellate Body found that the MERCOSUR exemption, despite its little amount, resulted in discriminations between countries that were not based on health or environmental reasons.

The Appellate Body rejected that the existence of the MERCOSUR, as a regional trade agreement, could justify, in this case, the exemption to imports of retreaded tyres from MERCOSUR countries. Certainly, Article XXIV of GATT 1994, on "Customs Unions and Free-trade Areas", provides for an exception to the "General Most-Favoured-Nation Treatment". Article XXIV allows giving certain advantages to the countries of a regional trade agreement (for example, the elimination of customs duties) without extending these advantages to the rest of WTO Members. But Article XI:1 of the GATT 1994 establishes, as a general principle among all WTO Members, the prohibition of quantitative restrictions on imports. If a country, such as Brazil, imposes a general ban on the importation of retreaded tyres for health and environmental reasons, it cannot justify the ban exemption to some countries simply because they have a regional trade agreement. This ban exemption cannot be delinked from the reasons that have justified the general import ban under paragraph (b) of Article XX.³⁹

In sum, the Appellate Body concludes that a general import ban would be fully justified under paragraph (b) of Article XX, but the two existing exemptions (the im-

³⁶ *ibid.*

³⁷ *ibid.*

³⁸ *ibid* para 247.

³⁹ *ibid* paras 228 and 234. On the relationship between Article XXIV and the *chapeau* of Article XX of GATT 1994, see Arwel Davies, 'Interpreting the Chapeau of GATT Article XX in Light of the "New Approach" in Brazil – Tyres' (2009) 43 *Journal of World Trade* 507.

port permits granted by domestic court injunctions and the MERCOSUR exemption) imply that the Brazilian measures result in “arbitrary or unjustifiable” discriminations, incompatible with the requirements of the *chapeau* of Article XX.

4. The Sweet Defeat of the Brazilian Government and the Implementation of the Adopted Reports

On 17 December 2007, the DSB adopted the Appellate Body report and the Panel report, as modified by the Appellate Body report. These adopted reports can be considered as a ‘sweet defeat’ for the Brazilian Government. In principle, there is a defeat because the Appellate Body considered that the measures at issue were, as a whole, incompatible with the multilateral trading system. However, this defeat is sweet because the Appellate Body confirmed that the essential core of the measure, the general import ban, was justified as a necessary measure to protect human, animal or plant life or health. Implicitly, the Appellate Body assumed that a complete import ban, without the import permits granted by certain domestic court injunctions and the MERCOSUR exemption, would be fully compatible with the multilateral trading system.

Certainly, the Appellate Body concluded that the domestic court injunctions and the MERCOSUR exemption resulted in arbitrary or unjustifiable discriminations, but it must be remembered that both exemptions were not included in the original regulations and they were established against the genuine will of the Brazilian Government.

In this way, the Brazilian Government was able to focus the implementation of the adopted reports as a return to its original will, maintaining the general import ban and trying to eliminate the domestic court injunctions and the MERCOSUR exemption. As several Brazilian scholars have pointed out, this implementation was complex in practice.⁴⁰

It is worth remembering that the WTO law and the reports of its adjudicative bodies usually have no direct effect on domestic legal systems, and this requires that each Member, within its domestic legal order, establishes the implementation measures. At the DSB meeting of 15 January 2008, Brazil said that it intended to implement the adopted reports in a manner consistent with its WTO obligations, but Brazil required a reasonable period of time for implementation.

⁴⁰ See, for instance: João Paulo Ribeiro Lima Carnevali de Oliveira and Márcio Bobik Braga, ‘Caso dos pneus: adequação da orden jurídica brasileira à jurisdição internacional’ (2017) 16 *Revista da Advocacia-Geral da União – AGU* 219; Varella, (n 7) and Marcelo Dias Varella, ‘Difficulties in Implementing DSB Reports: An Analysis Based on Brazil’s Retreaded Tires Case’ (2014) 32 *Wisconsin International Law Journal* 699.

In the framework of such implementation, there was a judicial action filed by the Brazilian Government at the Brazilian Federal Supreme Court against the domestic court injunctions that had granted import permits. The judgment, dictated on 24 June 2009,⁴¹ endorsed the position of the Brazilian Government, interpreting that trade and the freedom of enterprise must be subordinated to the protection of other fundamental rights enshrined in the Brazilian Federal Constitution of 1988. The judgment found that those domestic court injunctions violated fundamental constitutional precepts concerning the human right to health (Article 196) and the human right to 'an ecologically balanced environment, which is a common good for the people's use and is essential for a healthy life' (Article 225).⁴²

After this important judgment, Brazil's Secretary of Foreign Trade issued a new regulation, Portaria SECEX 24/2009,⁴³ which prohibits new licenses for the importation of used and retreaded tyres, irrespective of their origin. Subsequently, at the DSB meeting on 25 September 2009, Brazil reported, with satisfaction, its full compliance with the recommendations and rulings of the DSB.⁴⁴

It is interesting to note that Brazil, in order to comply with its WTO obligations, eliminated the MERCOSUR exemption, and this contravened, in principle, the quoted award of the MERCOSUR arbitral tribunal of 2002. This disparity between the decisions of the WTO and the MERCOSUR has been analyzed by some authors, as an example of the fragmentation of international law and the contradictions that may arise between different international jurisdictions.⁴⁵ In any case, the WTO Appellate Body already pointed out that, in the case raised by Uruguay before the MERCOSUR, Brazil focused its defence on essentially commercial arguments, without developing a defence based on health and environmental grounds under Article 50(d) of the Treaty of Montevideo, which has a very similar text to Article XX(b) of GATT 1994.⁴⁶ In addition, Brazil met with the other MERCOSUR countries and,

⁴¹ Brazil, Supremo Tribunal Federal, *Arguição de Descumprimento de Preceito Fundamental* (ADPF) 101, 24 June 2009.

⁴² Own translation. The original text, in Portuguese, of Article 225 of the Brazilian Federal Constitution is: 'Todos têm direito ao meio ambiente ecologicamente equilibrado, bem de uso comum do povo e essencial à sadia qualidade de vida [...]'. See, Brazil, *Constituição da República Federativa do Brasil*, available at <www2.senado.leg.br/bdsf/bitstream/handle/id/518231/CF88_Livro_EC91_2016.pdf> accessed 20 January 2019.

⁴³ Published in the Brazilian Official Gazette on 28 August 2009.

⁴⁴ WTO, Status Report Regarding Implementation of the DSB Recommendations and Rulings, *Brazil – Retreaded Tyres*, WT/DS332/19/Add.6, 15 September 2009.

⁴⁵ See, for instance: Nicolaos Lavranos and Nicolas Viellard, 'The Brazilian Tyres Case: Competing Trade and Non-Trade Interests and Competing Jurisdictions between MERCOSUR and WTO' (2008) 17 *European Energy and Environmental Law Review* 306; Yulia Ya Qin, 'Managing Conflicts between Rulings of WTO and RTA Tribunals: Reflections on the Brazil – Tyres case' (2009) Wayne State University Law School Research Paper No. 09-24.

⁴⁶ WTO, Appellate Body Report, *Brazil – Retreaded Tyres* (n 12) para 234.

with the strong support of Argentina, sought to find a negotiated solution to ensure coherence between the WTO and the MERCOSUR.⁴⁷

5. *Concluding Remarks*

The *Brazil–Retreaded Tyres* case shows that many trade restrictions for health and environmental reasons can be perfectly justified under the multilateral trading system. Although the Brazilian measures at issue were considered, as a whole, incompatible with the GATT 1994 and some authors affirm that trade superseded health,⁴⁸ the WTO adjudicative bodies found that the import ban of retreaded tyres, as such, was a measure necessary to protect human, animal or plant health and life, according to paragraph (b) of Article XX of GATT 1994. The incompatibilities with the *chapeau* of Article XX only resulted from the ban exemptions. The Appellate Body fully endorsed the restrictive aspects of the measure and only rejected its discriminatory aspects.

This case can be considered, really, as a triumph for health and environmental policies within the framework of the WTO. This case confirms that paragraph (b) of Article XX can cover trade restrictions aimed at reducing, simultaneously, multiple risks to health and the environment and that each Member can choose its level of protection.

In contrast with previous jurisprudence, the necessity test is presented in particularly open-handed terms, depending, essentially, on whether the restrictive measure makes a “material contribution” to the objectives pursued, based on qualitative criteria and without requiring quantitative data. Likewise, regarding the possible existence of alternative measures (less trade restrictive and reasonably available) the Appellate Body recognizes a great deference to the respondent Member, discarding possible measures more expensive or technically complex.

Regarding the interpretation of the *chapeau* of Article XX, the Appellate Body repeatedly stated that the determination of whether certain exemptions to a general import ban should be considered as arbitrary or unjustifiable discriminations must take, as an essential referent, the same objectives that have justified the general import ban. This was appropriate for the measures examined in *Brazil–Retreaded Tyres*, but, in other cases, an exemption to a general import ban may serve a legitimate objective not connected to the same objective pursued by the general import ban. Thus,

⁴⁷ See Fabio Morosini, ‘The MERCOSUR Trade and Environment Linkage Debate: The Disputes over Trade in Retreaded Tires’ (2010) 44 *Journal of World Trade* 1127.

⁴⁸ See Lavranos (n 3) at 230, who affirms that, in this case, ‘trade supersedes health’.

for example, in a subsequent case at the WTO, *EC – Seal Products*,⁴⁹ the general ban on the import of seal products was aimed at protecting animal welfare, while the exemption for seals captured by indigenous communities had a different legitimate objective (to protect the culture, traditions and subsistence of indigenous peoples).⁵⁰

The *Brazil–Retreaded Tyres* case is of great relevance to justify the prohibition of products that, once introduced into the territory of a country, may increase health and environmental risks, but this case does not refer to trade restrictions based on non-product-related processes and production methods (NPR PPMs), which do not leave a physical trace in the final product. Such cases refer to damages caused beyond borders and involve extraterritorial aspects. The justification of such cases under the WTO law is more difficult, although not impossible, as was seen in the *US–Shrimp* case.⁵¹

Finally, it should be emphasized that an import ban on retreaded tyres contributes to reducing the number of waste tyres and the health and environmental risks involved, but such risks do not disappear, as new tyres will also end up being waste tyres. Therefore, together with the import ban on retreaded tyres, countries should adopt other complementary policies for the proper management and treatment of waste tyres.

⁴⁹ WTO, Dispute WT/DS400-401: *EC – Measures Prohibiting the Importation and Marketing of Seal Products* (short title: *EC – Seal Products*).

⁵⁰ See Xavier Fernández-Pons, 'Bienestar animal y moral pública en la OMC: la diferencia sobre las medidas de la UE que prohíben la importación y comercialización de productos derivados de las focas' in José Juste Ruiz and Valentín Bou Franch (eds), *El desarrollo sostenible tras la Cumbre de Río + 20 – Desafíos globales y regionales* (Tirant lo Blanch 2017) 183.

⁵¹ WTO, Dispute WT/DS58: *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (short title: *US – Shrimp*). In this regard, see, for instance: Christiane R Conrad, *Processes and Production Methods (PPMs) in WTO Law – Interfacing Trade and Social Goals* (CUP 2011); Aaron Cosbey and Petros C. Mavroidis, 'Heavy Fuel: Trade and Environment in the GATT/WTO Case Law' (2014) 23 *Review of European Community and International Environmental Law* 288; Margaret Young, 'Trade Measures to Address Environmental Concerns in Faraway Places: Jurisdictional Issues' (2014) 23 *Review of European, Comparative and International Environmental Law* 302.



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Part II

Environmental Health at the Intersection of Energy, Climate Change, and Atmospheric Pollution



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Chapter 5

Protecting Human Health in a Green Energy Context: Regulatory Scenarios between International and EU Law

Francesco Buonomenna^{*}

1. *Introduction*

Over the last twenty years a great deal of emphasis has been placed on researching new sources of energy and its use as an alternative to fossil fuels. The commitment to reducing CO₂ has become a fundamental objective in order to protect the Earth's and living organisms' health. As such, environmental protection has become one of the main goals which is pursued in this vein.

Only in recent times has it been considered important that human health be placed at the centre of these goals. Thus, a double framework in the study of environmental law has been created, which encompasses both the ecosystem and a source for the development and protection of human health. In light of this, it is also possible to analyse State or European Union choices in terms of promoting renewable resources. Indeed, only recently has scientific research considered the fact that not all renewable resources have zero emissions. Therefore, there has been much debate over the use of some energy resources considered to be green and their effects on human health. A double profile has been created in order to highlight both the effects arising from the use of functional tools for renewable resources and the use of some renewable sources.

In terms of the former profile, the relationship between health and energy is compromised to its own detriment, particularly in terms of the disposal of electric batteries. The highly incentivised promotion of electric motors has brought about an increase in the use of batteries, which have a limited durability and, due to the fact that these batteries have a specific composition, they need to be disposed of using highly specialised systems.

As regards the second profile, the relationship between health and energy is compromised when referring to the use of wood biomass, especially for domestic use. In-

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deed, recent studies show that these sources have an extremely detrimental effect on human health.

This paper aims to highlight how the use of renewable resources is not entirely criticism free in terms of issues related to health and energy. Nevertheless, the importance of using renewable energy sources in order to reduce the levels of CO₂ emissions is not being brought into question, but the focus is on some critical issues which can be resolved thanks to technological developments.

2. Developments in the Environment-Energy Relationship

Sustainable development, based on the equilibrium between environment and economic growth in the green economic framework, was an important issue of the United Nations Conference on Sustainable Development of 2012 (Rio+20).¹ In this equilibrium, the Energy-Environment relationship plays a crucial role.

The evolutive phases of this relationship were several: the first one was characterised by conflicting needs, whilst at present the relationship is inter-functional.² During the industrial revolution, the energy interest consisted in technical development, necessary for the improvement of the quality of life, and represented an affirmation of state communities in the international context, without primary attention environmental protection issues. Only after industrial accidents with severe polluting impacts on the natural reserves (mainly, water and maritime resources) the awareness that such reserves are an essential heritage for the present and future generations arose. In this way, the protection of the environment became an important component of the international policy of the States, with the awareness of the possible global impact of environmental accidents that may produce adverse effects beyond national borders, albeit caused by localised events.³

¹ For a close examination of the sustainable development peculiarities with particular attention to the energy sector, see Susanna Quadri, *Energia sostenibile. Diritto internazionale, dell'Unione europea e interno* (Giappichelli 2012); Francesco Vetrò, 'Sviluppo sostenibile e problemi dell'energia' in Aristide Police and Andrea Crismani (eds), *Scritti in onore di Maria Luisa Bassi* (Editoriale Scientifica 2011). For a broad reconstruction of the green economy notion, intended as functional aim to the sustainable development promotion, see Pia Acconci, 'La green economy e la realizzazione dei diritti dell'uomo alla base dello sviluppo sostenibile' (2012) *Diritti umani e diritto internazionale* 587.

² The inter-functional character of this relationship may be found in the normative choices which are present both in art 19 of the Energy Charter Treaty (Lisbon, 17 December 1994, in force 16 April 1998) and in arts 192 and 194 of Treaty on the Functioning of the European Union (Lisbon, 13 December 2007, in force 1 December 2009). For an in-depth analysis of the normative sources also in relation to the environment/energy relationship, see Marilù Marletta, *Energia. 'Integrazione europea e cooperazione internazionale'* (Giappichelli 2010) 351 ff; Marilù Marletta, 'Il Trattato di Lisbona e gli sviluppi nel settore dell'energia' (2012) *Quaderni europei, Serie energia* 10 <www.lex.unict.it/cde/quadernieuropei/energia/interno_energia.asp> accessed January 2019.

³ The legal literature on international environmental law, borne in the last thirty years and related to

This latest aspect determined a drastic change in the legal approach to questions concerning the use of energy resources by States, in particular water, mineral and gas resources: the protection of the environment represents, in this phase, a limit to the unreserved economic development of the States. In this context, various principles of environmental law were affirmed, such as the modern concept of sustainable development, which was the object of several legal tools approved by the United Nations Conference on Environment and Development, held at Rio de Janeiro in June 1992. Since then, the need to affirm the compatibility between the economic development of States and the protection of the environment (Kyoto's Protocol, 11 December 1997, and Johannesburg Summit on Sustainable Development, 26 August–4 September 2002), strongly appears, enhancing both the technological development to favour the reduction of CO₂ emissions coming from the use of traditional fossil fuels and the use of renewable energy sources, compatible with the new environmental standards.⁴ The outcome document of the Rio+20 Conference addresses these goals in some points of paragraphs 127–128. In particular, Governments declare (paragraph 128):

we reaffirm support for the implementation of national and subnational policies and strategies, based on individual national circumstances and development aspirations, using an appropriate energy mix to meet developmental needs, including through increased use of renewable energy sources and other low-emission technologies, the more efficient use of energy, greater reliance on advanced energy technologies, including cleaner fossil fuel technologies, and the sustainable use of traditional energy resources.

the relationship environment/energy starting from the protection of natural resources, is very broad. Therefore, in the present work, only some recent general references are cited, missing out the reference to the several contributions focused on single general principles of environmental protection. See David Langlet and Said Mahmoudi, *EU Environmental Law and Policy* (OUP 2016); Michel Prieur, *Droit de l'environnement* (LGDJ 2011); Ida Caracciolo, 'Gli strumenti convenzionali internazionali in materia di protezione dell'ambiente: la protezione dell'atmosfera' in Umberto Lanza and Ida Caracciolo, *Il diritto internazionale: diritto per gli Stati e diritto per gli individui* (Giappichelli 2010); Patricia Birnie, Alan Boyle and Catherine Redgwell, *International Law and the Environment* (OUP 2009); Alessandro Fodella and Laura Pineschi, *La protezione dell'ambiente nel diritto internazionale* (Giappichelli 2009); Malgosia Fitzmaurice, *Contemporary Issues in International Environmental Law* (Edward Elgar 2009); Tullio Scovazzi, 'I principi generali del diritto internazionale dell'ambiente' in Stefano Nespore and Ada Lucia de Cesaris (eds), *Codice dell'ambiente* (Giuffrè 2009); Giovanni Cordini, Paolo Fois and Sergio Marchisio, *Diritto ambientale, Profili internazionali europei e comparati* (Giappichelli 2008); Angela Del Vecchio and Arno Junior Dal Ri (eds), *Il diritto internazionale dell'ambiente dopo il vertice di Johannesburg* (Editoriale Scientifica 2005).

⁴ In the final declaration of the Aquila Summit of July 2009 emerges a progressive care for the realization and reduction of emissions in the contest of sustainable development. In fact, in the declaration of the leaders of the major economies is reported: 'We recognize the scientific view that the increase in global average temperature above pre-industrial levels ought not to exceed 2 degrees C. In this regard and in the context of ultimate objective of the Convention and the Bali Action Plan, we will work between now and Copenhagen, with each other and under the Convention, to identify a global goal for substantially reducing global emissions by 2050.' For a systematic setting of L'Aquila G8 summit and Copenhagen Conference of the same year in the above cited prospective, see Enzo Di Giulio, 'Copenhagen: dopo la semina il raccolto' (2009) 3 *Energia* 54.

In addition, in the next paragraph it is reported that

we recognize that improving energy efficiency, increasing the share of renewable energy and cleaner and energy-efficient technologies are important for sustainable development, including in addressing climate change. We also recognize the importance of promoting incentives in favour of, and removing disincentives to, energy efficiency and the diversification of the energy mix, including promoting research and development in all countries, including developing countries.

In the new scenario, the characteristics of the energy are well emphasized: this relationship is not exclusively based on renewable sources but includes all the technological supports in order to develop energy efficiency based on the combined use of renewable energy and fossil sources. Moreover, these aspects were at the core of several specific studies, which highlighted how energy efficiency cannot be obtained only by addressing the interest to renewable energy sources, because fossil fuels are constantly used.⁵ It is contended that neither the moderate installation rate of the renewable energy plants (wind, solar, salinity gradient, biomass, etc.) nor their immediate and short period ability of producing energy in a competitive way are enough to make renewable energy sources challenging for the price of energy from fossil sources.⁶ These criticisms on all the renewable energy sources make their development impossible at a rate able to satisfy the incremental demand of energy for the first half of this century. In particular, the field of renewable energy sources is at early stages for various States, in expansion due to both the government economic support, indispensable to reduce the production costs, and the availability of the consumers to pay green energy at higher price compared to the cost of fossil fuels.⁷ Therefore, the attention will be focused on a rapid implementation of technologies related to CO₂ capture and storage, combined with a policy of environment-friendly consumptions which will favour those fossil fuels with reduced environmental impact (*e.g.* natural gas).⁸ These aspects represent a necessary

⁵ For a general setting, it should be considered that coal has met nearly half of the rise in global energy demand over the last decade, growing faster even than total renewables. Whether coal demand carries on rising strongly or changes course will depend on the strength of policy measures that favour lower-emissions energy sources, the deployment of more efficient coal-burning technologies and, especially important in the longer term, CCS. See IEA, *Will coal remain a fuel of choice?*, World Energy Outlook 2012, at 5. See also Guntis Moritis, 'CO₂ Sequestration Adds New Dimensions to Oil and Gas Production' (2003) 101 *Oil and Gas Journal* 39-44.

⁶ For a development of these scenarios, see Peter Odell, 'Uno scenario realistico sul futuro energetico' (2010) 2 *Energia* 2.

⁷ Some of these criticisms were well evidenced by IEA, in the World Energy Outlook 2012 by affirming that the rapid increase in renewable Energy is underpinned by falling technology costs, rising fossil-fuel prices and carbon pricing, but mainly by continued subsidies: from \$88 billion globally in 2011, they rise to nearly \$240 billion in 2035. Subsidy measures to support new renewable energy projects need to be adjusted over time as capacity increases and as the costs of renewable technologies fall, to avoid excessive burdens on governments and consumers.

⁸ See IEA, *Different shades of gold for natural gas*, World Energy Outlook 2012, 5.

goal to be pursued because renewable energy sources satisfy only about 30% of global energy consumptions and therefore cannot be considered the substantial solution for the reduction of CO₂ emissions.

3. Energy and Health

The goal of reducing CO₂ emissions inevitably requires using renewable energies as a supply source and as a source which is less harmful to human health. As is outlined in the Global Energy Transformation,⁹ in order to meet the emission reduction targets set out in the Paris Agreement, it is essential to increase worldwide renewable energy adoption six-fold, thus limiting the increase in global warming by 2 degrees Celsius. In order to achieve this target, the cumulative CO₂ emissions must be reduced by at least another 470 gigatons (Gt) by 2050 compared to the business-as-usual scenario of current and planned policies. This relationship is of particular interest, given that it comes at a time when both the European Union and Italy are committed more than ever to discussing the emission reduction strategies by 2050. This commitment also involves the European Commission, which must prepare a climate strategy for 2050 that is compatible with the Paris Agreement, while in Italy the National Energy Strategy aims to reduce emissions by 63% by 2050.¹⁰

The relationship between renewable energy and health represents a strong and functional relationship towards the prevention of various diseases deriving from atmospheric pollution. The scientific evidence regarding the effects of air pollution on human health has been significantly developed in recent years thanks to the wide availability of epidemiological studies that have documented a wide spectrum of acute and chronic health problems, ranging from respiratory symptoms to morbidity and even deaths due to cardiological, respiratory diseases and tumours. The substances responsible for these health problems are mainly particulate matter (PM), sulphur dioxide (SO₂), nitrogen dioxide (NO₂) and ozone (O₃).¹¹

The World Health Organization has provided a clear mapping of pollution levels in cities around the world, which is a study that highlights a clear call for action to eliminate our dependence on fossil fuels. This is the most complete mapping of city pollution levels globally available to date.¹²

The key feature worthy of attention is the air that we breathe. Indeed, the indi-

⁹ IRENA, *Global Energy Transformation: A Roadmap to 2050*, 2019.

¹⁰ See Umberto Mazzantini, 'Irena: Economia e benessere possono crescere solo se le energie rinnovabili aumentano di 6 volte' (April 2018) <www.greenreport.it> accessed January 2019.

¹¹ WHO, *Ambient (outdoor) air quality and health*, Fact sheet, 2 May 2018 <[www.who.int/en/news-room/fact-sheets/detail/ambient-\(outdoor\)-air-quality-and-health](http://www.who.int/en/news-room/fact-sheets/detail/ambient-(outdoor)-air-quality-and-health)> accessed January 2019.

¹² See at <www.who.int/gho/phe/outdoor_air_pollution/exposure/en/> accessed January 2019.

vidual States' regulatory interventions aiming at reducing CO₂ represent a positive objective, even more if the objectives that will be pursued are not left to the discretion of States but are regulated by international organisations. Within this context, the European Union has also turned its attention to the relationship between energy and health. Such attention has long been centred on air pollution levels and identifying progressive objectives aimed at implementing clean air programs for Europe. In 2019, four directives will aim at regulating air pollution incident sectors through the implementation of emission reduction measures. The European Commission addressed the issue of the relationship between energy and clean air in a 2013 study that represented the premises of current regulatory choices aimed at regulating the behaviour of States for the coming years.¹³

It emerges that Europe's air quality has improved markedly in recent decades but air pollution remains the major environmental factor linked to preventable illness and premature mortality in the EU and still has significant negative effects on much of Europe's natural environment. According to the Organisation for Economic Co-operation and Development, '[u]rban air pollution is set to become the top environmental cause of mortality worldwide by 2050, ahead of dirty water and lack of sanitation'.¹⁴ According to a study by the European Union, the ongoing substantial breaches of air quality standards can be resolved in the short to medium term by effective implementation of existing EU legislation, notably on emissions from light-duty diesels.¹⁵

Europe's ambitious long-term goal on air quality can only be achieved in steps. The reductions of the previous (2005) Strategy will be broadly delivered by 2020, through a combination of Member State and EU action. This will deliver a major reduction in the negative impacts of pollution on people's health and on the environment, but substantial problems will remain.

A strong air policy will answer citizens' aspirations for their health and wellbeing, but also has direct economic benefits. Better air also offers economic opportunities including for the EU's clean technology sectors. Major engineering firms in the EU already earn up to 40% of revenues from their environment portfolios, and this is set to increase. Improvements in productivity and reduced health-care costs fully compensate the compliance costs, and the policy is expected to deliver a net increase in employment.¹⁶

¹³ See Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions - A Clean Air Programme for Europe, COM(2013) 918 final.

¹⁴ OECD Environment Outlook 2050 <oecd.org/document/11/0,3746,en_2649_37465_4903655_5_1_1_1_37465,00.html> accessed January 2019.

¹⁵ Directorate General for Internal Policies, Implementation of the Ambient Air Quality Directive, April 2016.

¹⁶ See Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions - 'A Clean Air Programme

4. *The Limits of Renewable Energy on Health Protection*

Through our reflections, our aim is not to draw into question the positive impact that the use of renewable energy has on human health, we only wish to highlight some profiles related to the world of renewables that require reflection. Several questions have also been raised for some time in terms of the environmental impact of renewable energy and the incidence of this impact on human health. The activities linked to the use of these energies are not of zero impact and can indeed endanger human health.¹⁷

In the current debate on environmental impact, the issue surrounding the disposal of electric vehicle batteries certainly plays a significant role. The substantial encouragement to purchase electric cars and vehicles does not correspond to the sensitive issue of battery disposal. Indeed, their composition and their average life span of five years pose a well-documented danger to human health if their disposal is not carried out in its entirety. Although this topic is of great relevance in China, the problem of the disposal of electric batteries is also a serious issue for Europe and the United States.¹⁸ Serious health incidents have already occurred in China. Between 2009 and 2011 more than a hundred children in the Anhui Province were victims of lead poisoning and the cause was identified in a factory producing batteries for electric bicycles. Other similar cases were recorded in the provinces of Yunnan, Hubei and Henan. According to a 2011 report by the Chinese Battery Industry Association, more than 80% of spent batteries were disposed of by small businesses that did not have permission to do so because they were not able to meet environmental standards.¹⁹

On the topic of the impact on health, studies conducted with reference to developed countries are still very few, whereas there is a vast and well-documented availability of scientific literature concerning the negative impact that the domestic use of biomass for cooking and heating can produce in developing countries. According to these studies there is a cause-effect relationship between the emission of PM and the onset of acute respiratory infections in children, of chronic obstructive pulmonary disease in adults and the development of cataracts in women who live in developing countries. Furthermore, in these areas, the fumes emitted from the biomass combustion process in homes have been classified as 'likely cancerous' to humans by the In-

for Europe', COM (2013) 918 final.

¹⁷ Marco Frojo, 'Allarme per le batterie esauste: l'altra faccia dell'auto elettrica' (October 2017) <themeditelgraph.com> accessed January 2019.

¹⁸ Indeed, the Gaogong Industry Research sounded the alarm for the Chinese market. In fact, the disposal sites for discarded batteries are lacking in China, which, according to the research institute, will amount to 248 thousand tonnes by 2020.

¹⁹ Driven by state incentives, sales of electric cars in China have seen a staggering growth. Reported by Frojo (n 17).

ternational Agency for Research on Cancer. In Europe, estimates conducted in different countries indicate that the combustion of biomass (especially wood) has substantially contributed to increasing the concentration of PM in the air.

Future prospects are not particularly optimistic: by 2020, some estimates indicate that the burning of biomass/wood for domestic use will be the main source of emissions of thin primary particles, making up 38% of total emissions. To date, the areas which use biomass in the European Union are numerous and it is used for: domestic heating; district heating; industrial production of heat and electricity. In most cases, however, the equipment still has a low technological level, as well as poor performance in terms of efficiency in combustion and emissions.

In terms of the effects of chronic or sub-chronic PM exposure resulting from the burning of wood for domestic use, the analysis models developed in Vancouver showed positive correlations with low birth weight, infantile bronchiolitis, otitis media and hospitalization for obstructive chronic bronchopneumonia. A study conducted in Southern California, on the other hand, reported significant positive correlations between emissions related to biomass combustion and premature births but it did not show a connection with low birth weight.

For several years the critical importance of air pollution associated with burning wood in the Scandinavian and Alpine countries has been recognised, especially during the winter period. In Europe, the Directive on renewable sources²⁰ states that the objective of a 20% reduction of the overall energy consumption by 2020 has led to an increase in the use of wood/biomass to produce electricity. Between 2010 and 2020, biomass energy production increased from 57% to 110% in the European Union. Scientific research into the use of energy resources certainly plays a significant role. Indeed, only careful monitoring can guarantee the balance between energy resources and health protection.

²⁰ See at <<https://ec.europa.eu/energy/en/topics/renewable-energy/renewable-energy-directive>> accessed January 2019.

Chapter 6

Between the Potential to Reduce Global Warming and to Cause Irreversible Damage to Human Health and the Environment: The Role of International Law in Marine Geoengineering*

*Mar Campins Eritja***

1. *Introduction*

The aim of this paper is to address some issues that arise from the use of geoengineering in reducing the risks inherent in global warming and to do so in relation to its potential to cause irreversible damage to human health and the environment. It briefly describes the role of marine geoengineering in the fight against climate change, followed by an examination of the issue from the perspective of International Law. To that end, the paper introduces the current international legal framework and identifies the most significant principles in the field of protection of human health and the environment, which are potentially relevant, as well as the conventional provisions that may apply to research and deployment of marine geoengineering. Lastly, the paper concludes with a number of brief final remarks on the *status quo*.

2. *Marine Geoengineering in the Fight against Climate Change*

New technological developments serve as a catalyst for the gradual development of International Law and, at the same time, push certain fields of knowledge toward new

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frontiers of science whose industrial and commercial applications are meeting vital human needs, both individual and collective ones. In this context, the use of new geoengineering technologies to alter the global environment in order partly to offset the phenomenon of climate change poses major challenges for International Law, given our limited knowledge of their impact on human health and the environment.¹

2.1. *Marine Geoengineering: What for?*

Unsurprisingly, the international community's main response to climate change has been to adopt a series of measures to mitigate greenhouse gas (GHG) emissions. More recently, the Paris Agreement of 2015² has directed the focus toward a second type of response involving adaptation,³ which seeks to lower the vulnerability of human and natural systems to climate change. These responses, however, appear to be insufficient in the face of global warming. Fossil fuels, the main source of CO₂, remain essential for economic activity and they can only be reduced at substantial economic cost. Also, while industrialised countries account for the greater part of historical emissions, much of the current and future GHG emissions come from emerging countries that are disinclined to make swingeing cuts. At the same time, access to affordable energy in developing countries is largely based on the use of conventional sources. There is limited adaptive capacity, especially in the countries most vulnerable to the effects of climate change, and the situation is only aggravated by the diffi-

¹ Nonetheless, the issue does not appear to have attracted much attention from legal scholars. Aside from Professor Bodansky, who advocated for an international legal framework already in 1996, it is not until the publication of works by Crutzen in 2006 and Shepherd in 2009 that the academy begins to take a tentative interest in the challenges raised by geoengineering. Since then, Keohane and Horton & Reynolds have found a large number of studies in the Anglo-Saxon literature, but few of them examine the issues from the standpoint of the Social Sciences and even fewer do so from the perspective of International Law. See Daniel Bodansky, 'May We Engineer the Climate?' (1996) 33 *Climate Change* 309; Paul J Crutzen, 'Albedo Enhancement by Stratospheric Sulfur Injections: A Contribution to Resolve a Policy Dilemma?' (2006) 77 *Climatic Change* 211; John Shepherd and others, *Geoengineering the Climate: Science, Governance and Uncertainty* (Royal Society 2009); Robert O Keohane, 'The Global Politics of Climate Change: Challenge For Political Science' (2015) 48 *Political Science & Politics* 19; Joshua B Horton and Jesse L Reynolds, 'The International Politics of Geoengineering: A Review and Prospectus for International Relations' (2016) 18 *International Studies Review* 438, 441; Jesse L Reynolds, 'Geoengineering Field Research: The Favorable Setting of International Environmental Law' (2014) 5 *Washington & Lee Journal of Energy, Climate & Environment* 417, 434. However, the legal journal *Carbon & Climate Law Review* addressed the issue in two special issues in 2013 (Vols 2 and 3, 2013, *Special Issue: Climate Change Geoengineering*), as did *Climate Law* in 2015 (Vol. 5, 2015, *Special Issue: Geoengineering Law*). Legal monographies dealing with the topic from the Public International Law standpoint have already been published: Haomiao Du, *An International Legal Framework for Geoengineering: Managing Risks of an Emerging Technology* (Routledge 2018).

² Decision 1/CP.21, Doc. FCCC/CP/2015/10/Add.1.

³ IPCC, Climate Change 2014: Impacts, Adaptation and Vulnerability, www.ipcc.ch/report/ar5/wg2/ accessed 23 January 2019.

culties of reaching consensus on adequate funding among the industrialised Parties to the UN Framework Convention on Climate Change (UNFCCC).⁴

Against this backdrop, geoengineering emerges as a third type of response to climate change.⁵ Few international legal instruments offer a definition of the concept. On one hand, the 10th Conference of Parties (COP) of the UN Convention on Biological Diversity (CBD)⁶ defines geoengineering in Decision X/33, of 2010, as

any technologies that deliberately reduce solar insolation or increase carbon sequestration from the atmosphere on a large scale that may affect biodiversity (excluding carbon capture and storage from fossil fuels when it captures carbon dioxide before it is released into the atmosphere).⁷

On the other hand, the new article 5 *bis* of the 1996 Protocol to the London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (LC/LP),⁸ which was added by amendment in 2013 (not yet in force), defines geoengineering as

a deliberate intervention in the marine environment to manipulate natural processes, including to counteract anthropogenic climate change and/or its impacts, and that has the potential to result in deleterious effects, especially where those effects may be widespread, long-lasting or severe.⁹

In short, geoengineering involves the intentional large-scale manipulation of earth systems¹⁰ with the twofold aim of modifying the radiation budget and redistributing energy in the climate system through the long-term capture of GHGs in the atmosphere and a reduction in the solar radiation that gets absorbed. Geoengineering is deployed through two core technologies: first, directly removing CO₂ from the atmosphere by means of carbon capture using chemical techniques to enhance the weathering of the oceans and biological techniques for their fertilisation, or to store captured CO₂ in the oceans (carbon dioxide removal or CDR); second, limiting or

⁴ UNTS Vol. 1771, p. 107.

⁵ Reynolds, 'The International Politics of Geoengineering' (n 1), 422.

⁶ UNTS Vol. 1760, p. 79.

⁷ Doc. UNEP/CBD/COP/DEC/X/33, footnote 2. *See also* Phillip Williamson and Ralph Bodle, *Update on Climate Geoengineering in Relation to the Convention on Biological Diversity: Potential Impacts and Regulatory Framework* (2016), Secretariat of the Convention on Biological Diversity, Technical Series No. 84 <www.cbd.int/doc/publications/cbd-ts-84-en.pdf> accessed 23 January 2019.

⁸ UNTS Vol. 1046, 138.

⁹ Resolution LP.4 (8) on the amendment to the London Protocol to regulate the placement of matter for ocean fertilisation and other marine geoengineering activities, 18 October 2013, Doc. LC 35/15, Annex 4.

¹⁰ The Royal Society, *Geoengineering the Climate: Science, Governance and Uncertainty* (The Royal Society 2009) <<https://royalsociety.org/geoengineering-the-climate/>> accessed 23 January 2019.

reducing the intensity of the sun's electromagnetic waves in order to reduce the flow of energy that reaches the surface of the Earth (solar radiation management or SRM). Prominent in the first group, which is the focus of this paper, are "negative emission technologies", which involve the absorption of CO₂. This absorption occurs naturally through photosynthesis and biomass conversion, but it can also take place or be heightened artificially through ocean fertilisation (direct fertilisation through the addition of iron, nitrogen or phosphorus into the ocean, and indirect fertilisation by upwelling and downwelling of ocean water); through enhanced weathering caused by adding alkaline minerals or spreading silicate minerals in the ocean; through afforestation, reforestation and land-use management; and through biomass-related techniques such 'bioenergy with carbon capture and sequestration' (BECCS) or CO₂ "direct air capture" (DAC).¹¹ As for the second group of technologies, those are the most relevant: enhanced surface albedo, which consists in artificially increasing the reflectivity of the Earth's surfaces in order to return to the atmosphere a greater flow of solar radiation in order to induce global cooling; "marine cloud whitening" (MCW) through the increasing of cloud droplet concentrations; "stratospheric aerosol injection" (SAI) to produce a sulphate aerosol layer to reflect sunlight back into space; and space-based reflectors stationed in outer space to deflect sunlight.¹²

2.2. Marine Geoengineering: At What Cost?

Although these technologies have initially been designed to mitigate the consequences of global warming and their deployment could offset the damage caused by the planet's rising temperatures, it proves very difficult at present to predict and quantify the overall risks that they may pose to human health or the environment.¹³ The deployment of geoengineering in a marine environment will probably cause changes in the composition of the oceans and the atmosphere. Ocean fertilisation, for instance, could lead to an excessive rise in phytoplankton due to the large-scale growth of micro and macro algae, and such a rise would increase the chances of developing toxic diatoms that could result in death and disease for thousands of marine mammals and birds in the human food chain. Similarly, marine biomass can decompose in subsurface water, critically diminishing oxygen levels and negatively affecting marine organisms. Thus, some marine geoengineering technologies might impact on food production and land use and even have economic consequences upon multilateral trade.

The risks inherent in the use of these technologies have already been raised by a host of international institutions. In 2007, the LC/LP Scientific Groups noted with

¹¹ According to the classification of Du (n 3) 13.

¹² *ibid* 20.

¹³ David A Wirth, 'Engineering the Climate: Geoengineering as a Challenge to International Governance' (2013) 40 Boston College Environmental Affairs Law Review 413, 421.

concern the possible large-scale negative effects of ocean fertilisation on the marine environment and on human health.¹⁴ A year later, the LC/LP Parties took the view that ‘given the present state of knowledge, ocean fertilisation activities other than legitimate scientific research should not be allowed’.¹⁵ In that same year, the UN General Assembly (UNGA) warned that, given the current state of knowledge on ocean fertilisation, such operations were not justified.¹⁶ Two years later, the Intergovernmental Oceanographic Commission (ICO) published a study on the extent of scientific knowledge about ocean fertilisation and bemoaned the lack of experimental studies, which made it impossible to speak with certainty about the phenomenon’s impact on the water column, seabed or subsoil.¹⁷ Likewise, the Intergovernmental Panel on Climate Change (IPCC) has commented explicitly on this particular risk and has issued a warning not only about the biochemical and technical limitations of CO₂ removal, but also about the social challenges, both local and regional, that it poses.¹⁸

In addition, geoengineering carries a further risk: its limited cost may prompt some States with sufficient financial and technological capabilities to try to “solve” the problem of climate change unilaterally.¹⁹ As Victor points out, this possibility ‘turns the politics of climate protection upside down’²⁰ insofar as they are based on a collective effort to lower GHG emissions. The fact that such technologies could be deployed at relatively low cost by a single State or a group of States or even a non-State actor turns geoengineering into a problem that is fundamentally different from mitigation, which requires a costly sustained effort by the international community as a whole,²¹ even as it raises major issues of legitimacy and a serious threat of systemic instability.²² This clearly shows the need to

¹⁴ Doc. LC/SG 30/14, 25 July 2007, 10.

¹⁵ Resolution LC-LP.1(2008) on the Regulation of Ocean Fertilisation, 31 October 2008, Doc LC 30/16, Annex 6, 2.

¹⁶ Doc A/RES/62/215, 14 March 2008, para 97.

¹⁷ Doug Wallace and others, *Ocean Fertilisation: A Scientific Summary for Policy Makers* (2010) IOC/UNESCO, Doc. IOC/BRO/2010/2, 8 <<http://unesdoc.unesco.org/images/0019/001906/190674e.pdf>> accessed 23 January 2019.

¹⁸ Rajendra K Pachauri and Leo Meyer (eds), *Cambio climático 2014: Informe de síntesis. Contribución de los Grupos de trabajo I, II y III al Quinto Informe de Evaluación del Grupo Intergubernamental de Expertos sobre el Cambio Climático* (2014) IPCC at 97 and 113.

¹⁹ Daniel Bodansky, ‘The Who, What, and Wherefore of Geoengineering Governance’ (2013) 121 *Climatic Change* 539, 540 and 548; Florian Rabitz, ‘Going Rogue? Scenarios for Unilateral Geoengineering’ (2016) 84 *Futures* 98.

²⁰ David G Victor, ‘On the Regulation of Geoengineering’ (2008) 24 *Oxford Review of Economic Policy* 322, 323; David G Victor and others, ‘The Geoengineering Option: A Last Resort against Global Warming’ (2009) 88 *Foreign Affairs* 64, 72.

²¹ Thomas C Schelling, ‘The Economic Diplomacy of Geoengineering’ (1996) 33 *Climatic Change* 303, 305; Bodansky (n 19) 450 and 548.

²² Daniel Bodansky, ‘What’s in a Concept? Global Public Goods, International Law, and Legitimacy’ (2012) 23 *European Journal of International Law* 651, 659; Elizabeth F Quinby, ‘Regulating Ge-

develop international mechanisms to ensure the legitimacy of any decision to deploy geoengineering technologies and to limit the possibility of their unilateral use. Without such mechanisms, some authors have pointed to the “moral hazard” that geoengineering technologies imply since they could undermine already inadequate efforts to mitigate GHG emissions and, to a lesser extent, undercut adaptation actions, because they would cast doubt on the policies of this nature that States have adopted.²³

3. *The International Legal Framework in the Field of Geoengineering*

Today, the international legal framework applicable to research and deployment of marine geoengineering can be described as inadequate. At present, only a few limited rules of a conventional sort are identifiable. Isolated and incomplete,²⁴ they have arisen in the context of environmental legal regimes that may ultimately be affected by marine geoengineering activities.²⁵

3.1. *International Law Principles Governing Marine Geoengineering*

With regard to marine geoengineering activities some principles of International Law in particular are potentially relevant and will likely play a role in future geoengineering regulation.

On the one hand, the principle of *sic utere tuo ut alienum non laedas* requires all States to ensure that the activities carried out under their jurisdiction or control do not cause environmental damages in the territorial jurisdiction of other States or in areas outside of national jurisdiction or control. In this sense, it is widely accepted that States have a duty to prevent any significant transboundary damage; so that this is a principle that now

oengineering: Applications of GMO Trade and Ocean Dumping Regulation’ (2018) 51 *Vanderbilt Journal of Transnational Law* 211, 229.

²³ Juan Moreno-Cruz, ‘Mitigation and the Geoengineering Threat’ (2011) Georgia Tech School of Economics Working Paper WP2011-007, <<https://pdfs.semanticscholar.org/b294/0f758cdfcbcb5d3869f59e7c2fa9f5849a47.pdf>> accessed 23 January 2019; Vasiliki Manousi and Anastasios Xepapadeas, ‘Mitigation and Solar Radiation Management in Climate Change Policies’ (2013) Fondazione Eni Enrico Mattei Working Paper 41.2013 <www.econstor.eu/bitstream/10419/74822/1/NDL2013-041.pdf> accessed 23 January 2019; David G Victor, *Global Warming Gridlock: Creating More Effective Strategies for Protecting the Planet* (CUP 2011) 190; David Humphreys, ‘The Global Politics of Geoengineering’ in Peter Dauvergne (ed), *Handbook of Global Environmental Politics* (2nd ed, Edward Elgar 2012) 455, 460; Reynolds (n 1) 425.

²⁴ Tuomas Kuokkanen and Yulia Yamineva, ‘Regulating Geoengineering in International Environmental Law’ (2013) *Carbon and Climate Law Review* 161, 163.

²⁵ Doc UNEP/CBD/SBSTTA/16/INF/29, 4 ff.

forms part of the corpus of customary norms in international environmental law.²⁶ This obligation has been endorsed explicitly by some soft law instruments (Principle 21 of the Stockholm Declaration²⁷ and Principle 2 of the Rio Declaration)²⁸ as well as by the International Law Commission in its Draft Articles on International Liability for Injurious Consequences Arising out of Acts Not Prohibited by International Law (Prevention of Transboundary Harm from Hazardous Activities).²⁹ It has also been recognized by the arbitral award given in the Trail Smelter Case (1941),³⁰ as well as by the International Court of Justice (ICJ) in the judgement in the Corfu Channel Case (1949),³¹ in the Court's advisory opinion on the Legality of the threat or use of nuclear weapons (1996),³² in its judgment in the Gabčíkovo-Nagymaros Case (1997),³³ and most recently in the case of the Pulp Mills on the River Uruguay (2010)³⁴ and the case of Certain Activities Carried Out by Nicaragua in the Border Area (2015).³⁵

This commitment, however, does not entail the prohibition of any and all environmental damage or impact. Rather, it prohibits States from causing "significant" transboundary damage and it requires them to take adequate measures to control and regulate the sources of potential damage in advance. To honour this commitment States must act in accordance with the standards of due diligence and that constitutes the core of the obligation of prevention.³⁶ However, the threshold for due diligence depends to a large extent on the circumstances of each case and the subjective assessment of each State.

From the procedural point of view, the ICJ has emphasized the existence of a duty of information, notification and negotiation that derives from the requirement of due diligence. Besides that, the fulfilment of this obligation involves a particular commitment. It requires States to conduct a prior environmental assessment of activ-

²⁶ ICJ, *Legality of the Threat or Use of Nuclear Weapons*, Advisory Opinion 8 July 1996, [1996] ICJ Reports 226-267, para 29.

²⁷ Doc A/CONF.48/14/Rev.1.

²⁸ Doc A/CONF.151/26 (Vol. I).

²⁹ Doc A/56/10, Yearbook of the International Law Commission 2001, vol II, Part Two.

³⁰ Trail Smelter Case (United States, Canada), 16 April 1938 and 11 March 1941, Reports of International Arbitral Awards, Vol. III, 1905-1982, 1965.

³¹ ICJ, *The Corfu Channel Case (United Kingdom v. Albania)*, Judgment 9 April 1949, [1949] ICJ Reports 4-169, 22.

³² ICJ, *Legality of the Threat or Use of Nuclear Weapons* (n 26) para 29.

³³ ICJ, *Gabčíkovo-Nagymaros Project (Hungary/Slovakia)*, Judgment 25 September 1997, [1997] ICJ Reports 7-84, para 140.

³⁴ ICJ, *Pulp Mills on the River Uruguay (Argentina v. Uruguay)*, Judgment 20 April 2010, [2010] ICJ Reports 14-107, paras 185 and 197.

³⁵ ICJ, *Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) and Construction of a Road in Costa Rica along the San Juan River (Nicaragua v. Costa Rica)*, Judgment 16 December 2015, [2015] ICJ Reports 665-742, para 104.

³⁶ ICJ, *Pulp Mills* (n 34) para 80.

ities that might have a significant adverse effect in a transboundary context or on a shared resource. This is a commitment laid out, for example, in article 14 of the CBD³⁷ and, specifically in the case of geoengineering, in article 8.w) of the Decision X/33 of the COP of the CBD, which states clearly that

no climate-related geo-engineering activities that may affect biodiversity take place, until there is an adequate scientific basis on which to justify such activities and appropriate consideration of the associated risks for the environment and biodiversity and associated social, economic and cultural impacts.

Similarly, annex 5 of the LC/LP, which incorporates the amendment of 2013, requires that 'all impact evaluations are satisfactory completed' for the authorisation of ocean fertilisation activities, including an 'assessment of potential effects' that comprises 'a concise statement of the expected consequences of the placement activity within the area of the activity and within the area of potential impacts, including transboundary effects' and that also specifies 'the potential effects on human health, on marine ecosystem structure and dynamics including sensitivity of species, populations, communities, habitats and processes, amenities and other legitimate uses of the sea'.³⁸

The ICJ recognised in the case of the *Pulp Mills* that the above practice was an accepted one among States and affirmed that the rule establishing the need for a prior assessment of any environmental impact could be regarded at present as 'a requirement under general international law'.³⁹ As a result, where there exists a risk that a specific activity relating to the deployment of geoengineering may have a significant adverse effect in a transboundary context, the requirement to conduct an environmental impact assessment is applied even in the absence of a conventional obligation to that effect.⁴⁰ However, International Law does not define the scope and content of the assessment⁴¹ nor does it appear that it can be extended sufficiently,

³⁷ However, the Court considered that this article 'does not create an obligation to carry out an environmental impact assessment before undertaking an activity that may have significant adverse effects on biological diversity', *ibid* para 164.

³⁸ Resolution LP.4 (8), on the amendment to the London Protocol to regulate the placement of matter for ocean fertilisation and other marine geoengineering activities (n 9) Annex 5; and Resolution LC-LP.2(2010) on the 'Assessment Framework for Scientific Research Involving Ocean Fertilisation (adopted on 14 October 2010)' LC 32/15.

³⁹ ICJ, *Pulp Mills* (n 34) para 204.

⁴⁰ Cymie R Payne, 'Pulp Mills on the River Uruguay: The International Court of Justice Recognises Environmental Impact Assessment as a Duty under International Law' (2010) 14 ASIL Insights <www.asil.org/insights/volume/14/issue/9/pulp-mills-river-uruguay-international-court-justice-recognizes> accessed 23 January 2019; José Juste Ruiz; Valentín Bou Franch, 'El caso de las plantas de celulosa sobre el río Uruguay: Sentencia de la Corte Internacional de Justicia de 20 de abril 2011' (2011) 21 *Revista Electrónica de Estudios Internacionales* 1.

⁴¹ ICJ, *Pulp Mills* (n 34) para 205. About the potential elements to be assessed, see Article 1.(vii) of the 1991 Convention on Environmental Impact Assessment in a Transboundary Context, into force since October 2017, UNTS Vol 1989, 309.

insofar as the matter is of interest here, as to create a requirement for a strategic environmental assessment prior to the deployment of geoengineering technologies,⁴² especially in areas outside national jurisdiction. Indeed, when the ICJ has referred to such an assessment, it has been limited to specific projects that are carried out under the State's jurisdiction and that have a detrimental effect in the jurisdiction of another State.⁴³ In its 2015 judgment in the case of *Certain Activities Carried Out by Nicaragua in the Border Area*, the ICJ insisted on this element and required that

to fulfil its obligation to exercise due diligence in preventing significant transboundary environmental harm, a State must, before embarking on an activity having the potential adversely to affect the environment of another State, ascertain if there is a risk of significant transboundary harm, which would trigger the requirement to carry out an environmental impact assessment.⁴⁴

On the other hand, the management of this scientific uncertainty is a core challenge for International Law, especially when it involves new and emerging technologies, such as geoengineering. The guiding principle for handling uncertainty of this sort is the precautionary principle. As an instrument of International Law, the precautionary principle typically lies at the heart of the decision-making process. Its unique character stems from the lack of knowledge that results in scientific uncertainty. In the presence of any risk whose existence, scope and potential cannot be demonstrated through irrefutable scientific evidence, it is necessary to turn to the precautionary principle. Two features immediately stand out: first, the danger of the harm is identified by the likelihood that the deleterious effects will actually occur; second, the notion of uncertainty is linked to situations in which there does not exist sufficient scientific evidence that an activity is harmless within acceptable tolerance thresholds.⁴⁵

The content and scope of this principle has been the subject of a host of assessments and the debate over its legal status is still on the agenda. In the international

⁴² Article 1.(vi) of the 1991 Convention on Environmental Impact Assessment in a Transboundary Context, defines environmental impact assessment from a uniquely procedural perspective as 'a national procedure for evaluating the likely impact of a proposed activity on the environment' and it is applied especially to the 'policies, plans and programmes' (art 2(7)), without any activity relating to geoengineering or similar being set out in Appendix 1. In addition, the 2003 Protocol on Strategic Environmental Assessment, in force since July 2010, insists on the public nature of the projects that are subject to strategic assessment, which is defined in article 2(6) as 'the evaluation of the likely environmental, including health, effects, which comprises the determination of the scope of an environmental report and its preparation, the carrying-out of public participation and consultations, and the taking into account of the environmental report and the results of the public participation and consultations in a plan or programme'. Thus, article 1 refers only to the 'development of plans and programmes' that article 2.5 identifies as 'those required by legislative, regulatory or administrative provisions', UNTS Vol. 2685, 140.

⁴³ ICJ, *Pulp Mills* (n 34) para 205.

⁴⁴ ICJ, *Certain Activities* (n 35) para 104.

⁴⁵ ICJ, *Pulp Mills* (n 34), Separate Opinion of Judge Cançado Trindade, para 62.

setting, the ICJ has made several indirect appeals to the principle.⁴⁶ However, in the case of the Pulp Mills, the ICJ preferred not to describe precaution as a principle, referring to the concept instead through the circumlocution “precautionary approach” in order to find that, while it ‘may be relevant in the interpretation and application of the provisions of the Statute, it does not follow that it operates as a reversal of the burden of proof.’⁴⁷ The ICJ insisted that the damaged State must provide the conclusive evidence that the obligation of due diligence has been broken. This is a particular challenge given the difficulty of proving with conclusive scientific evidence the connection between environmental damage and geoengineering activities, even more if the damage occurs in areas outside the jurisdiction of the State. Thus, when there is a possibility of irreversible damage, the principle should point preferably to the burden of proof falling on the actors responsible for the proposed activity.⁴⁸ In this vein, Judge Cançado Trindade, in a separate opinion, noted his disappointment that the Court had not taken the opportunity to state and clarify the general principles of International Law, preferring instead ‘to guard silence on this relevant point’.⁴⁹

The determination of an acceptable level of damage, which rests on an assessment that is still conducted by States, generally concerns the seriousness of the damage, which must be significant and will depend on the legal interest under threat and the irreversibility of the damage. As Ellis has indicated, it is hard to establish global criteria for the identification of an acceptable damage threshold, because it is more appropriate to make such assessments within the framework of specific regimes, based on the likelihood of the risk happening and the seriousness of the consequences.⁵⁰ As a result, for its application in the

⁴⁶ At present, the precautionary principle has only been interpreted very tentatively under international case law. ICJ, *Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court’s Judgment of 20 December 1974 in the Nuclear Tests (New Zealand v. France) Case*, [1995] ICJ Reports 288-308, paras 5, 34 and 35; *Gabcikovo-Nagymaros* (n 33) para 113; *Pulp Mills* (n 34) para 164; *Whaling in the Antarctic (Australia v. Japan)*, Judgment 31 March 2014, [2014] ICJ Reports 226-300, para 71.

⁴⁷ ICJ, *Pulp Mills* (n 34) para 164.

⁴⁸ ICJ, *Request for an Examination* (n 46), Dissenting Opinion of Judge Weeramantry, 348. Some decisions from the International Tribunal for the Law of the Sea are also relevant: ITLOS, *Southern Bluefin Tuna Cases (New Zealand v. Japan; Australia v. Japan)*, Provisional Measures, Case No 3 & 4, Reports of Judgments, Advisory Opinions and Orders, Order 27 August 1999, 280-301; *The MOX Plant Case (Ireland v. United Kingdom)*, Provisional Measures, Case No 10, Reports of Judgments, Advisory Opinions and Orders, Order 3 December 2001, 95-112; *Case concerning Land Reclamation by Singapore in and around the Straits of Johor (Malaysia v. Singapore)*, Provisional Measures, Case No 12, Reports of Judgments, Advisory Opinions and Orders, Order 8 October 2003, 11-29; *Responsibilities and obligations of States sponsoring persons and entities with respect to activities in the Area (Request for Advisory Opinion submitted to the Seabed Disputes Chamber)*, Case No 17, Reports of Judgments, Advisory Opinions and Orders, Advisory Opinion 1 February 2011, 9-78.

⁴⁹ ICJ, *Pulp Mills* (n 34), Separate Opinion of Judge Cançado Trindade, paras 67 and 113.

⁵⁰ Jaye Ellis and Alison Fitzgerald, ‘The Precautionary Principle in International Law: Lessons from Fuller’s Internal Morality’ (2004) 49 McGill Law Journal 795; see also Elizabeth Tedsen and Gesa Homann, ‘Implementing the Precautionary Principle for Climate Engineering’ (2013) 2 Carbon & Climate Law Review 90; Jesse L Reynolds and Floor Fleurke, ‘Climate Engineering Research. A Precautionary Response to Climate Change’ (2013) 2 Carbon & Climate Law Review 101.

area of geoengineering, it is necessary, to the extent that the principle is not yet legally binding or even enforceable in its own right, that it is made operational in a given context. For example, use of the principle is explicitly set out in article 3(3) of the FCCC, in article 3(1) of the LC/LP and in Decision X/33 of the COP of the CBD, specifically in reference to the fertilisation of the oceans, biological diversity and climate change.

3.2. The Current Conventional Framework Applicable to Marine Geoengineering

Conventional International Law does contain very few specific regulation concerning to research and deployment of marine geoengineering. These activities, however, can be accommodated within the more general framework of environmental international standards.

In general terms, the UN Convention on the Law of the Sea (UNCLOS)⁵¹ establishes the legal framework that governs all activities on the oceans and seas, including the activities of marine geoengineering. However, while they do remain subject to the Convention's general provisions, scientific advances such as the ones occurring in the field of ocean fertilisation or ocean weathering were unthinkable at the time of the Convention's adoption and therefore were not dealt with explicitly. That now raises a number of important questions.

First, it will be necessary to assess the extent to which the geoengineering technologies that introduce certain substances into the marine environment to speed weathering or fertilise the ocean are covered by the Convention's notion of pollution or its ban on dumping or, to the contrary, these types of activity are permitted under a strict regime of control and supervision.⁵² In articles 1(4) and 1(5), the Convention sets out very traditional definitions of marine pollution and dumping. However, the operations related to geoengineering, particularly ocean fertilisation and weathering, would appear to be excluded under article 1(5) (b) (ii) to the extent that they involve the placement of matter for a purpose other than the mere disposal thereof.⁵³

Second, Part XII of UNCLOS may not contain specific rules on the subject, but it does lay out basic guidelines. Pursuant to articles 192 to 196 of the Convention, States have an obligation to 'protect and preserve the marine environment' (art. 192) and to take all necessary measures to 'prevent, reduce and control pollution of the marine environment from any source' (art. 194(1)), including 'the release of toxic, harmful or noxious substances, especially those which are persistent, from land-based

⁵¹ UNTS Vol. 1833, at 3; 1834, at 3 and 1835, at 3.

⁵² David Freestone and Rosemary Rayfuse, 'Ocean Iron Fertilisation and International Law' (2008) 364 *Marine Ecology Progress Series* 227, 229.

⁵³ Resolution LC-LP.1(2008) on the Regulation of Ocean Fertilisation, Report of the Thirtieth Consultative Meeting and the Third Meeting of Contracting Parties, Doc LC 30/16, Annex 6, 1.

sources, from or through the atmosphere or by dumping' (art. 194(3) (a)), as well as any pollution from 'installations and devices used in exploration or exploitation of the natural resources of the seabed and subsoil' (art. 194(3)(c)) or from 'other installations and devices operating in the marine environment' (art. 194(3)(d)). In addition, States must take

all measures necessary to prevent, reduce and control pollution of the marine environment resulting from the use of technologies under their jurisdiction or control or the intentional or accidental introduction of species, alien or new, to a particular part of the marine environment, which may cause significant and harmful changes thereto (art. 196).

When States have reasonable grounds to believe that planned activities under their jurisdiction or control may cause substantial pollution or significant and deleterious changes to the marine environment, they must to the extent possible evaluate the potential effects of said activities and communicate the results of their evaluations. In this regard, States have an obligation to act so as not to transfer 'directly or indirectly, damage or hazards from one area to another or transform one type of pollution into another' (art. 195), but also to refrain 'from unjustifiable interference with activities carried out by other States in the exercise of their rights' (art. 194(4)) and 'to protect and preserve rare or fragile ecosystems as well as the habitat of depleted, threatened or endangered species and other forms of marine life' (art. 194(5)).

Third, UNCLOS makes clear reference to 'rules and standards' of a global and regional nature in articles 210(4 and 6) and 216. Such specific rules can currently be found in the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention),⁵⁴ which bans the storage of CO₂ in the water column or in the seabed, but does permit the storage of CO₂ in geological formations beneath the seabed under a 2007 amendment into force since 2011.⁵⁵ The LC/LP is also presented as a specific rule. It has been reviewed with a view toward facilitating the use of these new technologies in the context of the fight against climate change through CO₂ mitigation. To this end, the Meeting of Contracting Parties has so far adopted several actions linked to the issue. First, Resolution LC-LP.1 (2008) allowed ocean fertilisation activities for scientific research.⁵⁶ It was followed by Resolution LC-LP.2 (2010) on assessment for scientific research involving ocean fertilisation, including an environmental assessment with risk management and monitoring.⁵⁷ Finally, the 2013 amendment (not yet into force) directly regu-

⁵⁴ UNTS Vol. 2354, p. 67.

⁵⁵ OSPAR Decision 2007/2 on the Storage of Carbon Dioxide Streams in Geological Formations, and Amendments to Annexes II and III and the Convention for the Protection of the Marine Environment of the North-East Atlantic relating to the storage of carbon dioxide streams in geological structures (OSPAR), Doc OSPAR 07/24/1-E, Annex 6, 25-29 June 2007.

⁵⁶ Resolution LC-LP.1 (2008) on the regulation of ocean fertilisation, 31 October 2008.

⁵⁷ Resolution LC-LP.2 (2010) on the assessment framework for scientific research involving ocean fertilisation, 14 October 2010.

lates ocean fertilisation and other marine geoengineering activities.⁵⁸ Specifically, it permits, upon a State's explicit authorisation, 'the placement of matter into the sea from vessels, aircraft, platforms or other man-made structures at sea for marine geoengineering activities', when this involves 'legitimate scientific research taking into account any specific placement assessment framework'. However, besides causing a clear systemic rift with well-established principles in the framework of international environmental law, the compatibility of these rules may be questionable under the LC/LP and UNCLOS, as Juste Ruiz rightly warns.⁵⁹ The greater openness to the activities of geoengineering in the ocean, in the absence of scientific certainty over their harmlessness for the marine environment, might not only subvert the strongly precautionary approach that originally characterised the LC/LP, but also prove contrary to the obligations in articles 194 (4 and 5), 195 and 196 of UNCLOS.

From the perspective of climate change, neither the FCCC nor the Kyoto Protocol (KP) of 1997⁶⁰ nor the Paris Agreement of 2015 has explicitly addressed the regulation of marine geoengineering activities, each being limited in scope to the development of guidelines relating to smaller-scale afforestation, reforestation and soil carbon improvement. First of all, the commitments set out in article 4 of the FCCC point to general mitigation activities, including the protection and improvement of sinks and reservoirs, but it does not allow deducing any prohibition or authorisation relating to the use of geoengineering to stabilise GHG emissions. In this sense, the Convention's definition of reservoirs and sinks is so broad that it can hardly exclude such processes when they do not have a natural origin, but rather an artificial one. The only limit appears to arise in article 3(3), which sets out the precautionary principle and states that 'the Parties should take precautionary measures to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects'.

Second, the KP also fails to mention any new geoengineering technologies, except insofar as it addresses, in article 3(4), how to organise more conventional activities relating to changes in land use and the modalities, rules and guidelines for adding to, or subtracting from, the assigned amounts for Parties included in Annex I. To this end, the Decisions of the Meeting of the Parties (MOP) of the KP define certain forms of land use (LULUCF),⁶¹ which are to be added to the earlier Decisions taken in the context of REDD+.⁶² In 2011, however, the Parties to the KP agreed to in-

⁵⁸ Resolution LP.4 (8) on the amendment to the London Protocol to regulate the placement of matter for ocean fertilisation and other marine geoengineering activities (n 9).

⁵⁹ José Juste Ruiz, 'Ocean Options for Climate Change Mitigation: Disposal of Greenhouse Gases at Sea under the 1996 London Protocol' (2016) MEPIELAN E-Bulletin <www.mepielan-ebulletin.gr/default.aspx?pid=18&CategoryId=4&ArticleId=236&Article=Ocean-Options-for-Climate-Change-Mitigation-Disposal-of-Greenhouse-Gases-at-Sea-under-the-1996-London-Protocol#ref#17> accessed 23 January 2019.

⁶⁰ UNTS Vol. 2303, 162.

⁶¹ Decision 2/CMP.7, Land use, land-use change and forestry, Doc FCCC/KP/CMP/2011/10/Add.1.

⁶² Decision 2/CP.13, Reducing emissions from deforestation in developing countries: approaches to stimulate action, Doc FCCC/CP/2007/6/Add.1.

clude carbon capture and sequestration as a component of BECCS within the KP's Clean Development Mechanism.⁶³

Lastly, the Paris Agreement does not prevent either the inclusion of CO₂ removal by means of geoengineering among the accepted mitigation activities; in fact, article 4(1) explicitly foresees the achievement of 'a balance between anthropogenic emissions by sources and removals by sinks of greenhouse gases in the second half of this century'. Indeed, the Agreement acknowledges the central role of anthropogenic removal by sinks to attain its objectives and includes climate policy that would permit the use of geoengineering technologies.⁶⁴ One example appears in article 3, related to the content of Nationally Determined Contributions (NDCs) of the Parties, which does not exclude the possibility that at least a portion of their contributions may come from geoengineering measures, provided that these are compatible with the specific provisions of the Agreement.

4. Some Final Remarks on the Status Quo and Future Prospects

The nearly twenty-five years since UNCLOS, CBD and UNFCCC entered into force have clearly demonstrated the adaptability of these instruments to the changing conditions of a world in constant flux, through the evolving interpretation of their rules and the adoption of complementary agreements on new or specific aspects. The international community strives to keep pace with the evolving situation, which is, in turn, a trigger or catalyst for the ongoing development of the international legal order. However, one thing is the speed at which these phenomena unfold and another is the need to identify at a more deliberate pace the international rules to regulate them, not only in relation to the characteristics of the technology as such, but also because of the setting in which the technology will be put to use. In this context, the challenges posed by the deployment of new geoengineering technologies are enormous and affect the assessment of the risk itself and the suitability of the processes designed to incorporate any associated legal, social or even ethical concerns.⁶⁵

⁶³ Decision 10/CMP.7, Modalities and procedures for carbon dioxide capture and storage in geological formations as clean development mechanism project activities, Doc FCCC/KP/CMP/2011/10/Add.2.

⁶⁴ Joshua B Horton, David H. Keith, Matthias Honegger, *Implications of the Paris Agreement for Carbon Dioxide Removal and Solar Geoengineering* (2016) Harvard Project on Climate Agreements, Belfer Center <www.belfercenter.org/sites/default/files/legacy/files/160700_horton-keith-honegger_vp2.pdf>, 3; Neil Craik and William CG Burns, *Special report: Climate Engineering under the Paris Agreement: A Legal and Policy Primer* (2016) Centre for International Governance Innovation <www.cigionline.org/publications/climate-engineering-under-paris-agreement-legal-and-policy-primer>; William CG Burns, *The Paris Agreement and Climate Geoengineering Governance* (2016) Centre for International Governance Innovation Papers No 111, <www.cigionline.org/sites/default/files/documents/CIGI%20Paper%20no.111%20WEB.pdf>.

⁶⁵ Neil Craik, 'International EIA Law and Geoengineering: Do Emerging Technologies Require Special Rules?' (2015) 5 *Climate Law* 111.

With advancements in our knowledge about the viability and the consequences of geoengineering technologies, pressure mounts for international regulation. For now, though, International Law does not offer an adequate legal framework and few of its principles find broad application in this sector – some fully consolidated, others in a still emerging state – but present important limitations, suffer from a certain lack of definition and often do not facilitate the adoption of adequate measures to control and regulate the sources of potential damage in advance. Along with this, the few international rules that are applicable to these activities are of ill-defined scope (FCCC), govern only a particular area in a contradictory manner (UNCLOS, LC/LP) or have no more than a limited legal effect (CBD Decisions). The result is a patchwork of regulations provided by multilateral agreements designed for other purposes with many holes.⁶⁶ This is indeed a serious challenge that demands a sufficiently clear legal framework to allow each State's commitments to be properly adjusted. This in turn requires this legal framework to be built not only from the perspective of international environmental law, but also considering other sectors, from human health, food security or international security to multilateral trade law.

The current debate is bounded on the one hand by the possibility of a ban on the deployment of such technologies in the form of a short and medium-term moratorium and on the other hand by the articulation of a regime to anticipate the action of States, which must necessarily be organised on a multilateral basis.⁶⁷ Even though many difficulties still stand in the way of adopting such a legal framework,⁶⁸ all sorts of challenges associated with the deployment of these technologies call for a proactive attitude from the international community.⁶⁹

The configuration of a specific regime for marine geoengineering could be shaped around one of the existing regimes: either the CBD⁷⁰ or the UN-

⁶⁶ Kuokkanen and Yamineva (n 24) 165.

⁶⁷ Daniel Bodansky, 'Governing Climate Engineering Scenarios for Analysis: Discussion Paper' (Harvard Project on Climate Agreements 2011) at 11 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1963397> accessed 23 January 2019; Gareth Davies, 'Framing the Social, Political and Environmental Risks and Benefits of Geo-Engineering: Balancing the Hard-to-Imagine Against the Hard-to-Measure' (2011) 46 *Tulsa Law Review* 261.

⁶⁸ Scott Barrett, 'Climate Treaties and "Breakthrough" Technologies' (2006) 96/2 *The American Economic Review* 22 <<http://www.jstor.org/stable/30034607>> accessed 23 January 2019; Scott Barrett, 'The Coming Global Climate: Technology Revolution' (2009) 23 *Journal of Economic Perspectives* 53.

⁶⁹ Davies (n 67); Quinby (n 22) 211; Edward A Parson and Lia N Ernst, 'International Governance of Climate Engineering' (2013) 14 *Theoretical Inquiries in Law* 307, 325; Edward A Parson, *Starting the Dialogue on Climate Change Engineering Governance: A World Commission* (Centre for International Governance Innovation, Policy Brief, Fixing Climate Governance Series, No 8, 2017) <www.cigionline.org/sites/default/files/documents/Fixing%20Climate%20Governance%20PB%20no8_0.pdf> accessed 23 January 2019.

⁷⁰ Ralph Bodle and Sebastian Oberthur and others, 'Options and Proposals for the International Governance of Geoengineering' (Ecologic Institute Berlin, Climate Change 14/2014, Report No (UBA-FB) 001886/E, 2014) 21.

FCCC,⁷¹ both frameworks being potentially suitable for the future development of an international regulation. At least, it would demand the creation of specific coordination mechanisms between the UNCLOS and its related agreements, the CBD and the UNFCCC regimes.⁷² Otherwise the incipient fragmentation of the legal framework applicable to these activities will only increase as they continue to be governed by specific rules devised under each particular conventional framework.⁷³

Whatever the approach that is adopted in the management of marine geoengineering research and deployment activities, it should contribute to the achievement of the aims of sustainable development and uphold the protection of the environment as a common concern of humankind. The effects of geoengineering are probably not uniform. Moreover, even if applied optimally to climate change, those technologies would likely result over the long run in 'winners and losers',⁷⁴ potentially exacerbating the tensions between industrialised and developing countries, given the appearance of new imbalances in ecological exchange.⁷⁵ Some regions of the planet might suffer a heating or cooling effect and experience changes in their weather conditions, increasing the frequency and/or intensity of extreme weather events. This might become a source of political, economic and social instability.⁷⁶ As a result, the deployment of geoengineering technologies also raises questions of environmental justice⁷⁷ to the extent that there are no mechanisms to allocate the more or less predictable costs of implementing such an option and the consequences for future generations remain unknown.

⁷¹ Albert C Lin, 'Geoengineering Governance' (2009) 8/3 Issues in Legal Scholarship; Jesse L Reynolds, 'The Regulation of Climate Engineering' (2011) 3 Law, Innovation and Technology 113.

⁷² Kuokkanen and Yamineva (n 24) 165; Freestone and Rayfuse (n 52) 232.

⁷³ Bodansky (n 67) 11.

⁷⁴ Bodansky (n 1) 309.

⁷⁵ J Timmons Roberts and Bradley C Parks, *A Climate of Injustice: Global Inequality, North-South Politics and Climate Policy* (The MIT Press 2007); Antoni Pigrau Solé, 'Conceptual background' in Antoni Pigrau Solé and others, *International Law and Ecological Debt: International Claims, Debates and Struggles for Environmental Justice* (2014) EJOLT Report No 11, 10, 24 <www.ejolt.org/2014/01/international-law-and-ecological-debt/> accessed 23 January 2019.

⁷⁶ Shepherd (n 1) 51; Paul Nightingale and Rose Cairns, 'The Security Implications of Geoengineering: Blame, Imposed Agreement and the Security of Critical Infrastructure' (2014) 18 Climate Geoengineering Governance Working Paper Series 13.

⁷⁷ Antonio Cardesa-Salzmänn, 'Foundations for a Systemic Change in International Law' and Jordi Jaria i Manzano, 'Governing a Global Community' in Antoni Pigrau Solé and others (n 75) 61, 88, respectively; Edith Brown Weiss, *In Fairness to Future Generations: International Law, Common Patrimony, and Intergenerational Equity* (Transnational Pub Inc. 1989); Donella H Meadows, Jorden Randers and Dennis L Meadows, *Limits to Growth: The 30-Year Update* (Earthscan 2005); Klaus Bosselmann, 'Mind the Gap: State Governance and Ecological Integrity' in Laura Westra, Janise Gray and Vasiliki Karageorgou (eds) *Ecological Systems Integrity: Governance, Law and Human Rights* (Routledge 2015), 275; Roberts and Parks (n 75) 25.

Research and deployment of geoengineering is also related to the current debate on the governance of global public goods, a concept that poses major challenges for International Law in its own right.⁷⁸ Their protection affects sovereign rights of States, their link to processes that jeopardise the conservation of spaces and resources, and the formulation of protective measures through agreements accepted by the States concerned.⁷⁹ Climate change mitigation and biodiversity are regarded as two such public goods. Thus, Resolution 43/53 of the UNGA recognised, in 1988, that 'climate change is a common concern of mankind, since climate is an essential condition which sustains life on earth'.⁸⁰ There is broad consensus on the intrinsic value of the environment and natural resources, particularly biodiversity, which is also identified with the concept of common concern of humankind in the CBD's Preamble. A growing understanding of our ecological interdependence raises questions about the adequacy of prevailing international rules and the need to establish collective mechanisms to promote their protection in the face of challenges from new technologies.

Until very recently, however, marine geoengineering related issues have not been addressed by international regulation, at least not in any thorough manner. The reasons are varied: because research on geoengineering seems overly speculative and remote, particularly given the priority of GHG mitigation in the short run; because the deployment of these technologies is regarded as categorically unacceptable when weighed against the risks they pose, or simply because the construction and management of such a regulatory regime is considered ungovernable. That said, there is increasingly a clear need to promote research on the international legal challenges raised by marine geoengineering, given that such research is an essential element to adequately inform the international community's decision-making process and to facilitate management of the challenges of global governance. As Parson bluntly puts it

whether future use of CE [Climate Engineering] options will be judged desirable or not, there is an urgent need to begin an honest debate about them, while also pursuing mitigation and adaptation with much greater vigour than has been achieved thus far. Not doing so would make already grave climate-change risks even more severe.⁸¹

⁷⁸ Bodansky (n 22) 652; José Juste Ruiz, 'La gobernanza de los *global commons* como patrimonio colectivo en el Derecho Internacional' (2018) 34 *Anuario Español de Derecho Internacional* 133, 134.

⁷⁹ Juste Ruiz (n 78) 140.

⁸⁰ Doc A/RES/43/53, Protection of global climate for present and future generations of mankind, 6 December 1988, para 1, <<http://www.un.org/es/comun/docs/?symbol=A/RES/43/53&Lang=S>> accessed 23 January 2019.

⁸¹ Edward A Parson, 'Opinion: Climate Policymakers and Assessments Must Get Serious about Climate Engineering' (2017) 114 *Proceedings of the National Academy of Sciences of the United States of America*, PNAS Early Edition 9227-9230.



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Chapter 7

The Revised EU Air Quality Policy and Public Health

Samvel Varvastian *

1. *Introduction*

The introduction of certain substances or energy into the air, deteriorating its quality, and harming human, animal and plant health, ecosystems as well as material property, known simply as air pollution,¹ is a constant process caused both by natural sources (eg volcanic activity, dust, etc) and by humans (power generation, transport, industrial processes and waste, agriculture, etc).² Some air pollutants are emitted directly into the atmosphere (primary pollutants), while others are formed in the atmosphere through reaction of precursor pollutants (secondary pollutants).³ The most notorious primary air pollutants are particulate matter (PM, including PM_{2.5} and PM₁₀), black carbon (BC), sulphur oxides (SO_x), nitrogen oxides (NO_x, including NO and NO₂), ammonia (NH₃), carbon monoxide (CO), carbon dioxide (CO₂), methane (CH₄) and non-methane volatile organic compounds (NMVOC) as well as certain toxic metals (for example, lead (Pb), mercury (Hg), etc.) and polycyclic aromatic hydrocarbons.⁴ Among the main secondary air pollutants are ground-level ozone (O₃) and NO_x.⁵

Air pollution has a multifold effect on humans and the environment. The effect on human populations is expressed, first and foremost, by the total number of premature deaths caused by air pollution – about 7 million globally⁶ and over 400,000 in the EU

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¹ See the definition of air pollution in UN Economic and Social Council Convention on Long-Range Transboundary Air Pollution (LRTAP) (adopted 13 November 1979, entered into force 16 March 1983) 1302 UNTS 217 (CLRTAP) art 1(a).

² European Environment Agency, Air Pollution Sources <www.eea.europa.eu/themes/air/air-pollution-sources> accessed 14 January 2019.

³ European Environment Agency, Air quality in Europe – 2018 report <www.eea.europa.eu/publications/air-quality-in-europe-2018> accessed 14 January 2019, 18 (hereinafter Air quality in Europe).

⁴ *ibid* 18.

⁵ *ibid*.

⁶ See WHO, Air Pollution <www.who.int/airpollution/en/> accessed 14 January 2019.

each year.⁷ This makes air pollution the number one environmental cause of death in Europe,⁸ far exceeding the number of deaths in road traffic accidents.⁹ The most common reasons for air pollution-caused premature deaths are cardiovascular diseases and lung diseases, including lung cancer.¹⁰ Air pollution also causes or contributes or, at the very least, is linked, to a wide range of health disorders and morbidity (most notably, respiratory problems), especially among vulnerable populations.¹¹ The most widespread pollutants affecting the current European air quality are PM, NO₂ and O₃.¹²

Air pollution can also endanger public health by damaging natural resources and ecosystems.¹³ Additionally, while it is true that the atmospheric concentrations of some air pollutants, namely toxic metals, is low, these pollutants do not break down in the environment, meaning that they can accumulate in plants and animals, poisoning them through long-term exposure to even small amounts of these substances.¹⁴ This process can affect human health via contamination of the food chain.¹⁵ Furthermore, some pollutants, including O₃ and CH₄ are also potent greenhouse gases (GHGs), contributing to the anthropogenically-driven climate change,¹⁶ the

⁷ Air quality in Europe (n 3) 8.

⁸ *ibid* 11.

⁹ Impact Assessment, Commission Staff Working Document, SWD (2013)531 final, 18 (hereinafter Impact Assessment).

¹⁰ Air quality in Europe, 11.

¹¹ *ibid*. See, for example, Health Effects Institute, State of Global Air 2018: A Special Report on Global Exposure to Air Pollution and its Disease Burden <www.stateofglobalair.org/sites/default/files/soga-2018-report.pdf> accessed 14 January 2019; Daniela Nuvolone, Davide Petri and Fabio Voller, 'The effects of ozone on human health' (2017) 25 Environmental Science and Pollution Research 8074; Ian J Litchfield and others, 'Is Ambient Air Pollution Associated with Onset of Sudden Infant Death Syndrome: A Case-Crossover Study in the UK' (2018) 8 BMJ Open 1; Emily Midouhas, Theodora Kokosi and Eirini Flouri, 'Outdoor and Indoor Air Quality and Cognitive Ability in Young Children' (2018) 161 Environmental Research 321; Sundeep Mishra, 'Is Smog Innocuous? Air Pollution and Cardiovascular Disease' (2017) 69 Indian Heart Journal 425; Joshua S Apte and others, 'Ambient PM2.5 Reduces Global and Regional Life Expectancy' (2018) 5 Environmental Science and Technology Letters 546.

¹² Air quality in Europe, 8.

¹³ For instance, O₃ damages vegetation, thus reducing agricultural crop yields, forest growth and biodiversity. Emission of nitrogen and sulphur into the atmosphere leads to the creation of airborne acids that eventually cause acidification of soils and waters, damaging plant and animal life in forests, lakes and rivers, as well as buildings and historical sites by corrosion. Emission of NO_x and NH₃ results in eutrophication – the excess of nutrients in rivers and lakes – posing a serious threat to aquatic biodiversity. See Air quality in Europe, 68-72.

¹⁴ Air quality in Europe, 72.

¹⁵ *ibid*.

¹⁶ IPCC, 2014: *Climate Change 2014: Synthesis Report. Contribution of Working Groups I, II and III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change* [Core Writing Team, RK Pachauri and LA Meyer (eds)]. IPCC, Geneva, Switzerland, 4. It should be observed that some other air pollutants actually have a cooling effect.

estimated health effects of which are truly devastating.¹⁷

Last, but certainly not least, the health and environmental impacts of air pollution also affect the global economy, including that of the EU.¹⁸ Given all the factors outlined above, it is unsurprising that the European citizens perceive air pollution as the second biggest environmental concern after climate change.¹⁹ In 2011–2013 the Commission carried out a comprehensive review of the available policy mechanisms and came up with a set of both short-term and long-term measures, known as the Clean Air Policy Package.²⁰ This chapter addresses the regulatory framework that emerged as a result of the newly-adopted policy and its potential to substantially reduce the impact of air pollution on public health.

2. The Long-term Air Quality Objective and the Need for Policy Review

The initial steps to address atmospheric emissions in the EU, albeit dispersed and limited to specific pollution sources, date back to the 1970s, while a more consistent regulatory approach began developing in the mid 1980s.²¹ Since then, several legal and political instruments have been adopted, including environmental action programmes, defining the overall EU environmental policy²². The 6th Environment Action Programme (6th EAP), adopted by the Council and the European Parliament in 2002, established a common EU long-term objective for air quality: to achieve, ‘levels of air quality that do not give rise to significant negative impacts on and risks to human health and the environment’, thus following the relevant WHO standards.²³ This objective was later reiterated in the new General Union

¹⁷ See, for example, Camilo Mora and others, ‘Broad Threat to Humanity from Cumulative Climate Hazards Intensified by Greenhouse Gas Emissions’ (2018) 8 *Nature Climate Change* 1062.

¹⁸ OECD (2016), *The Economic Consequences of Outdoor Air Pollution*, OECD Publishing, Paris. <<http://dx.doi.org/10.1787/9789264257474-en>> accessed 14 January 2019. According to OECD, these costs will reach about 2% of European GDP by 2060, leading to a reduction in capital accumulation and a slowdown in economic growth. See also Air Quality Report, 14.

¹⁹ European Commission, 2017, Special Eurobarometer 468: Attitudes of European citizens towards the environment <http://data.europa.eu/euodp/en/data/dataset/S2156_88_1_468_ENG> accessed 14 January 2019.

²⁰ See Samvel Varvastian, ‘Achieving the EU Air Policy Objectives in Due Time: A Reality or a Hoax?’ (2015) 24 *European Energy and Environmental Law Review* 2.

²¹ Ludwig Krämer, *EU Environmental Law* (8th edn, Sweet & Maxwell 2016) 299.

²² *ibid* 299–300.

²³ Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme [2002] OJ L242/1, art 7(1).

Environment Action Programme to 2020 (7th EAP).²⁴

Over the years, the existing EU environmental protection mechanisms related to air quality have yielded significant results. Thus, throughout 2000-2015, the EU's combined GDP grew by 32% while emissions of the main air pollutants decreased by between 10% (for NH₃) and 70% (for SO_x).²⁵ Notably, these reductions might have been the result of several contributing factors, including increased regulation and policy implementation, fuel switching and technological improvements as well as improvements to energy or process efficiencies.²⁶ However, inspiring as they are, these achievements still fall short of reaching the EU long-term air quality objective, as illustrated by the mortality attributed to air pollution and the fact that a significant percentage of European citizens continue to be exposed to unacceptably high levels of different air pollutants.²⁷

During the 2011-2013 policy review, this failure of the then-existing policy to reach the minimum impact levels, as recommended by the WHO, was identified as one of the major policy shortcomings.²⁸ The reason for that was that even in case of full compliance with the existing legislation, major health and environmental impacts of air pollution were expected to persist.²⁹ For instance, the policy estimated significant reductions in the number of premature deaths from exposure to the pollutants between 2010 and 2020, while the reductions beyond 2020 were estimated to be marginal.³⁰ In other words, it seemed obvious that the review of the policy had to include multiple factors that needed addressing, particularly, tapping the pollution from contributing sectors and addressing background pollution.³¹

3. *The Current Regulatory Framework*

The 2011-2013 policy review introduced certain novelties to the EU regulatory framework on air quality, most notably the adoption of several new legislative acts.

²⁴ Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' [2013] OJ L354/171 (7th EAP), Recitals 3 and 15.

²⁵ Clean Air Report at 18-20, European Commission, Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. The First Clean Air Outlook, COM (2018) 446 final, 1-2.

²⁶ Clean Air Report, 20.

²⁷ *ibid* 6-8.

²⁸ Varvastian (n 20) 6.

²⁹ Impact Assessment, 24.

³⁰ *ibid* 27. A similar scenario was drawn for the impact on the environment as well, both with regard to expected reduction in percentage of areas with exceeding acidification and eutrophication.

³¹ *ibid* 35.

However, the framework's architecture itself was left untouched: as prior to the policy review, it is based on three major pillars – the ambient air quality standards, the national emission reduction targets and the emissions standards for major sources of air pollution.³² The section will now address each of these regulatory pillars in more detail.

3.1. The Ambient Air Quality Directives

The first pillar, the ambient air quality standards, is established by the two legislative acts – Directive 2008/50/EC on ambient air quality and cleaner air for Europe (AAQD)³³ and Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air.³⁴

The first one is the result of substantial revision and merging of several legal instruments and covers major primary pollutants, such as SO₂, NO₂, NO_x, CO and PM as well as secondary pollutant, O₃. The scope of the AAQD is quite broad³⁵ and its primary target is to set ambient concentrations for a range of parameters to be achieved everywhere in the EU as well as define the minimum standards for assessing and managing air quality in the Member States.³⁶ This is implemented by means of introducing certain requirements for zones and agglomerations,³⁷ expressed in a range of limit values³⁸ and target values.³⁹ The Member States are responsible for as-

³² European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Europe that protects: Clean air for all, COM (2018) 330 final, 2 (hereinafter Clean air for all).

³³ Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe [2008] OJ L152/1.

³⁴ Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air [2005] OJ L23/3.

³⁵ The Directive aims at: defining and establishing objectives for ambient air quality designed to avoid, prevent or reduce harmful effects on human health and the environment as a whole; assessing the ambient air quality in Member States on the basis of common methods and criteria; obtaining information on ambient air quality in order to help combat air pollution and nuisance and to monitor long-term trends and improvements resulting from national and Community measures; ensuring that such information on ambient air quality is made available to the public; maintaining air quality where it is good and improving it in other cases; promoting increased cooperation between the Member States in reducing air pollution (AAQD, art 1).

³⁶ Impact Assessment, 15.

³⁷ Zones and agglomerations are parts of Member States' territory, established by the Member States to carry out air quality assessment and management pursuant to art 4 of the AAQD.

³⁸ A scientifically based level, with the aim of avoiding, preventing or reducing harmful effects on human health and/or the environment as a whole, to be attained within a given period and not to be exceeded once attained (art 2(5)).

³⁹ A scientifically based level, above which direct adverse effects may occur on plants or ecosystems but not on humans (art 2(9)).

sessing the ambient air quality with respect to pollutants covered by the Directive and in case these values are exceeded, the persons in concern have a right to require the authorities to draw up an action plan in order to reduce the risk and to limit its duration.⁴⁰ Nevertheless, the Directive does not specify what particular measures Member States should adopt in such cases, thus leaving Member States a certain amount of leeway in terms of implementation.⁴¹

Overall, while the AAQD provides a robust regulatory scheme,⁴² it is also prone to criticism owing to its reduced field of application and difficulties of enforcing compliance.⁴³ Furthermore, albeit covering numerous pollutants, AAQD is not a comprehensive piece of legislation as its provisions do not extend to some heavy metals with high carcinogenic properties, namely As, Cd, Hg and Ni as well as to other large group of organic pollutants known as polycyclic aromatic hydrocarbons; instead, these pollutants are regulated by Directive 2004/107/EC.⁴⁴ The reason for this is that due to the strong hazardous nature of the pollutants in question, scientific evidence has shown that there is no identifiable threshold below which these substances do not pose a risk to human health. Therefore, the Directive limits itself on providing only target values rather than binding limit values, although the latter may be introduced in the future.⁴⁵ The most difficult case proved to be mercury, which led to the absence of a target value for this especially hazardous substance and the undertaking of a separate research programme that resulted in the suspension of the setting of

⁴⁰ AAQD, art 24(1). This rule follows from the decision of the European Court of Justice (ECJ) in the case C-237/07 *Janecek v Freistaat Bayern* [2008] ECR I-6221, based on art 7(3) of the preceding Directive 96/62/EC. That case revolved around the claim of a natural person living on Munich's central ring road. The claimant was concerned about the level of PM₁₀, which exceeded the limit value fixed for this pollutant for much more than 35 times. The ECJ stated that 'natural or legal persons directly concerned by a risk that the limit values or alert thresholds may be exceeded must be in a position to require the competent authorities to draw up an action plan where such a risk exists, if necessary by bringing an action before the competent courts.' (para 39). See also Ludwig Krämer, '480.000 Dead per Year are Enough: The CJEU Opens a New Way to Better Enforce Air Quality Laws' (2018) 15 *Journal for European Environmental and Planning Law* 111; Ugo Taddei, 'A Right to Clean Air in EU Law? Using Litigation to Progress from Procedural to Substantive Environmental Rights' (2016) 18 *Environmental Law Review* 3.

⁴¹ This seems to be the case even within one Member State at the municipal level – see, for example Elena Bondarouk and Duncan Liefferink, 'Diversity in Sub-National EU Implementation: The Application of the EU Ambient Air Quality Directive in 13 Municipalities in the Netherlands' (2017) 19 *Journal of Environmental Policy & Planning* 733. See also Suzanne Kingston, Veerle Heyvaert and Aleksandra Čavoški, *European Environmental Law* (CUP 2017) 315.

⁴² For more on AAQD, see David Langlet and Said Mahmoudi, *EU Environmental Law and Policy* (OUP 2016) 212-215.

⁴³ The same, however, can be said about air quality legislation in general. See Krämer (n 21) 301-306 and Emily Barritt, 'Standing Up for British Lungs: Effective Judicial Enforcement in Environmental Law' (2015) 24 *Review of European, Comparative & International Environmental Law* 368, 372.

⁴⁴ Altogether, these two directives cover 12 key pollutants and it is deemed possible for them to merge in the future. See AAQD, Recital 4.

⁴⁵ Directive 2004/107/EC, art 8(2)(b).

a target value in respect of this substance until the research is complete.⁴⁶ Finally, one of the key shortcomings of the AAQD is that it fails to establish air quality standards recommended by the WHO.⁴⁷ Despite that, both directives were excluded from the 2011-2013 policy review, as it was assumed to be of little practical use at that point, even though it was acknowledged that the AAQD is a key policy instrument for meeting the WHO recommendations.⁴⁸

3.2. The National Emissions Ceilings Directive

During the 2011-2013 policy review, the revision of the National Emissions Ceilings Directive (NECD) was considered one of the main legislative goals to achieve the necessary long-term pollution reductions.⁴⁹ The revised NECD⁵⁰ is the second pillar of the EU regulatory framework on air quality as it sets the national emission reduction targets, aiming at limiting the total emissions from each Member State for a set of acidifying and eutrophying pollutants and O₃ precursors,⁵¹ namely SO₂, NO_x, NMVOC and NH₃ as well as PM_{2.5}.⁵² The Directive is meant to achieve the long-term EU air quality objective⁵³ and its key requirement for Member States is to limit their annual national emissions of these pollutants to amounts not greater than the emission ceilings laid down in Annex II and ensure that they are not exceeded after 2020.⁵⁴ To achieve this, Member States are required to draw up and implement na-

⁴⁶ *ibid* Recitals 9 and 10.

⁴⁷ The current AAQD standards for PM₁₀, PM_{2.5} and O₃ are as follows: 40 µg/m³ and 25 µg/m³ averaged over a calendar year limit values for PM₁₀ and PM_{2.5} respectively to be attained by 2010 (Annex XI and Annex XIV respectively) with the decrease in limit value for PM_{2.5} to 20 µg/m³ to be attained by 2020 (Annex XIV), and the long-term objective for O₃ averaged in a daily eight-hour mean within a calendar year set at 120 µg/m³ (Annex VII). The updated WHO 2005 guidelines set the concentrations for these pollutants at 20 µg/m³, 10 µg/m³ and 100 µg/m³ respectively. See: WHO Air quality guidelines for particulate matter, ozone, nitrogen dioxide and sulfur dioxide, 2005, summary of risk assessment, 9 and 14. See at <http://whqlibdoc.who.int/hq/2006/WHO_SDE_PHE_OEH_06.02_eng.pdf?ua=1> accessed 14 January 2019.

⁴⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Clean Air Programme for Europe. COM (2013) 918 final, 4.

⁴⁹ Varvastian (n 20) 8-9.

⁵⁰ Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC [2016] OJ L344/1.

⁵¹ Art 1.

⁵² Art 4(1).

⁵³ Art 1(1).

⁵⁴ Art 4.

tional programmes to meet the emission ceilings.⁵⁵

One of the major aspects of the revised NECD is that it aligns the EU reduction commitments beyond 2020 for the regulated pollutants to the requirements of the amended Gothenburg Protocol⁵⁶ and, accordingly, introduces commitments for the reduction of PM_{2.5} as well as covers black carbon, unaddressed by the previous NECD. Notably, however, the plans to introduce the reduction commitments for the pollutant not covered by the Protocol, namely CH₄, although initially proposed,⁵⁷ were eventually scrapped from the revised NECD.⁵⁸ Also, like its predecessor, the revised NECD, does not cover emissions from international maritime traffic, nor does it feature an initially proposed flexible approach allowing Member States to offset emission reductions achieved by international maritime traffic against emissions released by other sources in the same year, in order to comply with the interim emission levels determined for 2025 and the national emission reduction commitments applicable from 2030 onwards.⁵⁹

3.3. Emissions Standards for Major Sources of Pollution

The third pillar is comprised of emissions standards for major sources of pollution – transportation, energy generation and industrial emissions. The importance of controlling air pollution at source is obvious: for instance, the transport sector is the largest contributor to NO_x emissions and a significant contributor to PM emissions, fuel combustion by power plants and households for generating power and heat is the largest contributor to PM and SO₂ emissions, the industry is the largest contribu-

⁵⁵ Art 6.

⁵⁶ Recitals 5-7. The 1999 Gothenburg Protocol to Abate Acidification, Eutrophication and Ground-level Ozone is part of the LRTAP – the first international treaty to deal with air pollution on a broad regional basis. The Convention has been extended by several protocols, including the Gothenburg Protocol, that identify specific measures to be taken by parties to cut their emissions of air pollutants. Initially, the Gothenburg protocol was designed to reduce acidification, eutrophication and O₃ by setting emissions ceilings for SO₂, NO_x, NMVOC and NH₃. The 2012 amendments to the Protocol introduced tighter reduction commitments for the above-mentioned substances as well as new requirements for yet another pollutant, PM_{2.5} <www.unece.org/environmental-policy/conventions/air/guidance-documents-and-other-methodological-materials/gothenburg-protocol.html> accessed 14 January 2019.

⁵⁷ See Proposal for a Directive of the European Parliament and of the Council on the reduction of national emissions of certain atmospheric pollutants and amending Directive 2003/35/EC COM (2013) 920 final, Recitals 5 and 6, art 4(1) and Annex II.

⁵⁸ For now, the NECD limits itself on providing a brief reference to the Commission's declaration that 'there is a strong air quality case for keeping the development of methane emissions in the Member States under review in order to reduce ozone concentrations in the EU and to promote methane reductions internationally' and that it 'will consider measures for reducing those emissions, and where appropriate, submit a legislative proposal to that purpose.'

⁵⁹ Art 5(1) of the proposed NECD.

tor to NMVOC emissions, while the agricultural sector is a key source of air pollutants such as NH_3 .⁶⁰ Some of the existing standards were adopted prior to the 2011-2013 policy review.⁶¹ These include legislation covering industrial emissions,⁶² energy performance of products,⁶³ as well as passenger cars and transport fuels.⁶⁴

The policy review introduced some new tools to address the regulatory gaps, one of the most important being the Medium Combustion Plants Directive (MCPD),⁶⁵ which sets the emission limit values for SO_2 , NO_x and dust into the air as well as the monitoring of CO emissions.⁶⁶ The scope of the Directive is restricted to combustion plants with a specified thermal input and it does not cover a range of plants and other similar facilities, in which the gaseous products of combustion are used for the direct heating, drying or any other treatment of objects or materials, technical apparatuses used in the propulsion of vehicles, ships or aircraft, gas turbines and diesel engines, when used on offshore platforms, reactors used in the chemical industry, coke battery furnaces, etc.⁶⁷ The Directive envisages a Member States-based permit and registration system for the plants to operate.⁶⁸

At the same time, the requirements of the MCPD are subject to multiple exemptions and exceptions,⁶⁹ for example, in case of limited plant operating hours, weather conditions in case of plants used for heat production, plants linked to a national gas transmission system or firing solid biomass as the main fuel, etc.⁷⁰ However, there is also a possibility for Member States to apply stricter emission limit values than those set out in the Directive for individual plants within zones or parts of zones not complying with the air quality limit values laid down in the AAQD.⁷¹ Such measures

⁶⁰ Clean air for all, 4-5.

⁶¹ Most notably, vehicle emissions standards that have always been a part of the EU air quality policy. See Aleksandra Čavoški, 'The Unintended Consequences of EU Law and Policy on Air Pollution' (2017) 26 *Review of European, Comparative & International Environmental Law* 255, 259.

⁶² Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) [2010] OJ L334/17.

⁶³ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products [2009] OJ L285/10.

⁶⁴ Clean air for all, 2.

⁶⁵ Directive (EU) 2015/2193 of the European Parliament and of the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants [2015] OJ L313/1. See also Samvel Varvastian, 'Filling the Gap in the EU Air Quality Legislation: The Medium Combustion Plants Directive' (2017) 8 *IUCN Academy of Environmental Law eJournal* 131 (report).

⁶⁶ Art 1.

⁶⁷ Art 2(3).

⁶⁸ Art 5.

⁶⁹ See art 6 and Annex II.

⁷⁰ *ibid.*

⁷¹ Art 6(9).

may thus be a part of the development of air quality plans referred to in article 23 of the AAQD,⁷² taking into account the results of the information exchange between the Commission, the Member States, the industry and NGOs⁷³ and provided that applying the stricter emission limit values would effectively contribute to a noticeable improvement of air quality.⁷⁴ Finally, the MCPD also provides a list of obligations of the operators.⁷⁵ In case of non-compliance with the emission limit values, the operator is required to take the measures necessary to ensure that compliance is restored within the shortest possible time.⁷⁶ If non-compliance causes a significant degradation of local air quality, the Member States should ensure that operation of the plant shall be suspended until compliance is restored.⁷⁷

Apart from the MCPD, several other acts have been adopted following the policy review, including, for instance, legislation implementing the Ecodesign Directive and covering new solid fuel boilers and solid fuel stoves⁷⁸ as well as legislation covering new engines.⁷⁹ Furthermore, following the 2015 vehicles emissions scandal,⁸⁰ a set of real driving emissions rules was adopted to ensure that air pollution emissions stand-

⁷² Under art 23(1) of the AAQD, the Member States must establish the air quality plans when the levels of pollutants in ambient air exceed the respective values. Such plans may include measures in relation to motor-vehicle traffic, construction works, ships at berth, and the use of industrial plants or products and domestic heating (art 24(2)).

⁷³ Namely, information on the emission levels achievable with best available and emerging technologies and the related costs (art 6(10) of the MCPD).

⁷⁴ Art 6(9).

⁷⁵ Art 7.

⁷⁶ Art 7(7).

⁷⁷ Art 8(3).

⁷⁸ See Clean Air Outlook, 4.

⁷⁹ Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC [2016] OJ L252/53.

⁸⁰ In 2015, the US Environmental Protection Agency issued a notice of violation of the federal air quality legislation to German automaker Volkswagen Group. The agency's investigation led to the finding that the automaker had intentionally programmed the emissions control software to improve the results of vehicles' NOx emissions during testing, while emitting up to 40 times more in real-world driving. However, Volkswagen was not the only company that was involved in the emissions scandal, as cars produced by other giant manufacturers, including Renault, Nissan, Hyundai, Citroen, Fiat Chrysler and Volvo, were also found to be emitting substantially higher levels of pollution when tested in real driving conditions. See Damian Carrington, 'Wide range of cars emit more pollution in realistic driving tests, data shows', (2015) *The Guardian* <www.theguardian.com/environment/2015/sep/30/wide-range-of-cars-emit-more-pollution-in-real-driving-conditions-tests-show> accessed 14 January 2019. The scandal revealed an apparent oversight in the EU regulatory approach, despite the long history of vehicle emissions standards. See Yulia Yamineva and Seita Romppanen, 'Is Law Failing to Address Air Pollution? Reflections on International and EU Developments' (2017) 26 *Review of European, Comparative & International Environmental Law* 189, 197.

ards and related requirements are properly implemented.⁸¹ Finally, with regard to vehicles, it is worth mentioning that the Commission has proposed new CO₂ emission standards that is expected to have indirect, yet long-term, effects on air quality by improving fuel efficiency and GHG emissions.⁸² At the same time, some major sources of air pollution, most notably the shipping and aviation sectors, still have no EU emission limit values.⁸³

4. Revised Policy, Old Problems

Substantial reducing the impact of air pollution on public health requires, first and foremost, compliance with existing air quality standards. In other words, it is unrealistic to expect that the long-term air quality objective could be achieved without meeting the requirements set by the existing regulatory framework. Unfortunately, the problem of non-compliance is still strongly persisting.⁸⁴ The reasons behind non-compliance may vary, although the two main drivers identified during the policy review were the pollution sources themselves and the failure to manage air quality properly.⁸⁵ Hence, even though vehicles in general have delivered emission reductions across the range of regulated pollutants, diesel engines, especially in light-duty vehicles, still deliver significant NO_x emissions, and to make matters worse, many Member States continue to promote the sale and use of such vehicles compared to cleaner vehicles by means of national taxation policies.⁸⁶ The problem is further exacerbated by the increase in traffic volumes, especially in urban areas.⁸⁷ Finally, the illegal practices by some end users – and, as it was confirmed after the 2015 vehicles emissions scandal, by some of the leading automakers – that defeat the anti-pollution systems, also contribute to the problem.⁸⁸ Consequently, despite broad compliance reached for a number of key pollutants, standards for some other pollutants, namely PM₁₀, NO₂ and O₃, remain widely exceeded throughout Europe with a large part of

⁸¹ Clean air for all, 3.

⁸² *ibid.*

⁸³ Krämer (n 21) 314-315. For example, for the shipping sector, the only step made so far is the requirement for large ships using EU ports to report their verified annual emissions and other relevant information from 2018, which is not nearly enough to address the challenges posed by this vast and rapidly growing source of emissions (see <https://ec.europa.eu/clima/policies/transport/shipping_en> accessed 14 January 2019).

⁸⁴ See Clean air for all, 9-11.

⁸⁵ Impact Assessment, 21-22.

⁸⁶ *ibid.*

⁸⁷ *ibid.*

⁸⁸ *ibid.*

the EU population and environment exposed to harmful pollution levels.⁸⁹

At this point, it is also important to observe that the failure of some Member States to comply with the existing air quality standards has resulted in a series of infringement procedures against those Member States⁹⁰ and, ultimately, referral to the Court of Justice of the EU, with the latter finding these Member States to be in breach of the relevant air quality legislation.⁹¹ So far, almost all these cases have revolved around the respective Member States' failure to meet the requirements of the AAQD⁹² and their overall number has been very small, although in late 2018 several new applications were made when the Commission brought action against France, Germany, Hungary, Italy, Romania and the United Kingdom.⁹³

Returning to the new set of measures introduced after the policy review and their potential to achieve substantial progress in reducing the impact of air pollution on public health, according to the Commission, the overall reduction in negative health impacts – namely, premature mortality due to PM and O₃ – is expected to reach 54% for 2030 relative to 2005.⁹⁴ Converting this into the actual number of premature deaths from air pollution in the EU will get a result of over 200 000 deaths in 2030 and, at the existing and projected mortality rates, several million deaths in total over the next decade. Clearly, these numbers are staggering and are by no means acceptable; rather, they reflect the unacceptably low EU air quality standards, which are at the moment, and would likely be in the near future – following further regulatory action – still below the WHO standards.

All this leads into thinking that the feet-dragging regulatory approach to air pollution needs to be addressed in a multipronged way, not only by adopting the necessary standards, but also through the adoption and promotion of subsidiary measures, such as, for instance, incentivising the development and use of clean vehicles and other technologies.⁹⁵ To an extent, the policy review covered some of these measures, while even more such measures are anticipated in the future.⁹⁶ Still, while instrumental, such

⁸⁹ Clean Air Outlook, 2.

⁹⁰ For example, there are currently 30 infringement procedures open against Member States concerning the failure to comply with AAQD (Clean Air Outlook, 3).

⁹¹ See C-365/10 *Commission v Slovenia* [2011] ECR I-0040; C-479/10 *Commission v Sweden* [2011] ECR I-0070; C-34/11 *Commission v Portugal* [2012] ECJ, 15 November, 2012; C-68/11 *Commission v Italy* [2012] ECJ, 19 December, 2012; C-488/15 *Commission v Bulgaria* [2017] ECLI:EU:C:2017:267; C-336/16 *Commission v Poland* [2018] ECLI:EU:C:2018:94.

⁹² One of the very few cases concerning compliance with NECD is case C-304/15 *Commission v United Kingdom* [2016] ECLI:EU:C:2016:706, where, similarly, the Court held that the UK failed to fulfil its obligations under the Directive.

⁹³ C-635/18 *Commission v Germany* [2018]; C-636/18 *Commission v France* [2018]; C-637/18 *Commission v Hungary* [2018]; C-638/18 *Commission v Romania* [2018]; C-644/18 *Commission v Italy* [2018]; C-664/2018 *Commission v United Kingdom* [2018].

⁹⁴ Clean Air Outlook, at 4.

⁹⁵ Varvastian (n 20) 8.

⁹⁶ See, in general, Clean air for all.

measures would not substitute the primary action – that is, the adoption and enforcement of ambitious air quality standards in line with the WHO recommendations. Similarly, national courts could play an increasingly important role by taking all measures necessary to ensure that Member States' governments comply with their obligations under the existing EU air quality legislation,⁹⁷ for instance, by restricting the use of older diesel vehicles.⁹⁸ And although air quality governance can proliferate from different regulatory strategies,⁹⁹ the persisting air pollution crisis demands action that is urgent, comprehensive and effective, which necessitates, first and foremost, further tightening of air quality standards and further introduction of relevant technical standards.¹⁰⁰

5. Concluding Remarks

The 2011–2013 policy review led to positive results in terms of newly-adopted legislation, which has either filled the existing regulatory gaps (for example, the MCPD) or further tightened the existing emissions standards (namely, the revised NECD), thus bringing the EU air quality policy into compliance with international standards and closer to WHO established recommendations. At the same time, notwithstanding these benefits, the revised policy is still insufficient to achieve the long-term EU air quality objective by 2030 or even by 2050¹⁰¹ – in other words, within the reasonably foreseeable future. Of course, much more benefit could be expected following the revision of the AAQD. However, it must be kept in mind that neither the discussed policy update nor the potential revision of the AAQD in the near future could make any immediate impact. There are various reasons for that, including limited technical capabilities, global climate, weather and air quality variations, the interaction between natural and anthropogenic pollution, inefficiency of some of the adopted abatement schemes and last, but certainly not least, social and economic trends.¹⁰²

⁹⁷ Namely, by enforcing EU environmental law against public authorities, as follows from the EU Court of Justice case C-404/13 *The Queen, on the application of Client Earth v Secretary of State for the Environment, Food and Rural Affairs* [2014] ECLI:EU:C:2014:2382, para 58. See also Aine Ryall, 'Enforcing EU Environmental Law against Member States: Air Pollution, National Courts and the Rule of Law' (2015) 6 *European Journal of Risk Regulation* 305, 308.

⁹⁸ This is especially true for the courts in Germany, see 'Factbox: German cities ban older diesel cars' <www.reuters.com/article/us-germany-emissions-factbox/factbox-german-cities-ban-older-diesel-cars-idUSKCN1NK28L> accessed 14 January 2019.

⁹⁹ See Kingston, Heyvaert and Čavoški (n 41) 309.

¹⁰⁰ *ibid.*

¹⁰¹ This timescale reflects the long-term vision of the EU priority objectives for 2050 required by the 7th EAP (recital 8).

¹⁰² See 7th EAP, Recital 7, WHO air quality guidelines for Europe, 2nd edition, 2000 <www.euro.who.int/__data/assets/pdf_file/0005/74732/E71922.pdf> accessed 14 January 2019, 41.

Still, while these factors may lead the governments to mitigate or even forgo the carried out abatement measures,¹⁰³ it is clear that the protection of public health needs to be prioritized at every level – from adopting the relevant legislation to its enforcement – in order to achieve the long-term air quality objective. It is also clear that so far, this has not happened. It is high time to understand and accept that hundreds of thousands of lost lives on a yearly basis simply cannot be bargained for the alleged economic or social convenience.

¹⁰³ For example, in *Commission v Italy* the government claimed that its failure to fulfil the obligations with regard to PM₁₀ emission reduction was forced by the mentioned factors (paras 36, 40 and 41) and alleged that ‘ensuring compliance with those limit values would have involved the adoption of drastic economic and social measures and the infringement of fundamental rights and freedoms such as the free movement of goods and persons, private economic initiative and the right of citizens to public utility services’ (para 59). The Court deemed the force majeure situation possible but held that the government’s arguments were too general and vague to constitute a case of it (paras 64-65). In its recent case-law, the Court was similarly unpersuaded by the respective governments’ arguments that: a) measures leading to the immediate cessation of the emissions exceedances would ‘have significant socio-economic consequences, especially by requiring populations to use more expensive fuels, which has an impact, in particular, on their health’ and that the ‘precarious nature of Polish society is a barrier to any extensive use of renewable energy sources’ (*Commission v Poland*, para 89), and b) that ‘PM₁₀ emissions are difficult to reduce because of the sources of pollution such as domestic heating and road transport’, having in mind that ‘wood and coal are used in huge quantities for heating during the winter period because of the economic difficulties of a large part of the Bulgarian population’ (*Commission v Bulgaria*, para 64).

Chapter 8

Intergenerational Equity in Times of Climate Change Legal Action: Moving towards a Greater Protection of Human Health?

Angeliki Papantoniou *

1. *Introduction*

Intergenerational equity is a concept most prominent within the environmental protection sphere. In simple terms, it means the protection of the interests and rights of generations not yet born. The concept of intergenerational equity is part of the principle of sustainable development. This was acknowledged in the 1987 Brundtland Report 'Our Common Future', issued by the United Nations,¹ which led to the Rio Earth Summit of 1992.² The definition of sustainable development in the report was clearly linked to intergenerational equity: 'Development that meets the needs of the present, without compromising the ability of future generations to meet their own needs'.³ Thus, the protection of human health, being a vital component of sustainable development goals,⁴ clearly links with intergenerational equity.

A reference to future generations is present in a number of international environmental law treaties, such as, the 1946 International Convention for the Regulation of Whaling,⁵ the 1979 Bonn Convention on the Conservation of Migratory Species of Wild Animals⁶ and the 1992 United Nations Framework Convention on Climate Change.⁷ Moreover, it has been part of numerous soft law instruments, in-

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¹ Gro Harlem Brundtland, Report of the World Commission on Environment and Development: *Our Common Future* (1987) <www.un-documents.net/our-common-future.pdf> accessed 5 March 2019.

² United Nations Conference on Environment and Development (UNCED), Rio de Janeiro 3-14 June 1992.

³ Brundtland Report (n 1), ch 4, para 1.

⁴ UN General Assembly, 'Transforming our world: the 2030 Agenda for Sustainable Development', 21 October 2015, A/RES/70/1, Goal 3: Good Health and Well-being.

⁵ International Convention for the Regulation of Whaling, 62 Stat. 1716; 161 UNTS 72.

⁶ Bonn Convention on the Conservation of Migratory Species of Wild Animals 1979, 1651 UNTS 333.

⁷ United Nations Framework Convention on Climate Change 1992, 1771 UNTS 107.

cluding the 1992 Rio Declaration on Environment and Development, the 2002 Johannesburg Declaration on Sustainable Development⁸ and 2030 Agenda for Sustainable Development.⁹

Being an integral part of environmental law and sustainable development considerations, the rights of future generations contribute towards the protection of human health. As will be seen in this chapter, although a highly controversial topic in legal theory and practice,¹⁰ intergenerational equity is gaining increasing prominence within the area of climate change adjudication. The applicants are acting on their behalf and on behalf of future generations in the protection of their rights against climate change, including the protection of their health. The extent to which intergenerational equity can empower legal action against climate change and hence offer meaningful protection of the health of present and future generations will be examined in this chapter. First, the chapter will look at the conceptual foundations of intergenerational equity in legal theory and the references of the concept in landmark decisions of international environmental law.

2. Intergenerational Equity's Theoretical Foundations

The first scholar to conceptualise intergenerational equity was Professor Brown-Weiss. Brown-Weiss elaborated a trusts theory where each generation acts both as a trustee for the planet with duties to care for it and a beneficiary with rights to use it. According to Brown-Weiss, all of us, the 'human species', we 'hold the natural environment of our planet in common with all members of our species: past generations, the present generations and future generations'.¹¹ It follows that the concept of intergenerational equity encompasses all generations, past, present and future and it is useful to see human community 'as a partnership among all generations'.¹² Each generation acts both as a trustee for the planet with duties to care for it and a beneficiary with rights to use it.¹³

Moving on from this basic premise, Brown-Weiss lays out three basic principles of intergenerational equity. The first is the 'conservation of options', according to

⁸ Johannesburg Declaration on Sustainable Development and Plan of Implementation of the World Summit on Sustainable Development: the final text of agreements negotiated by governments at the World Summit on Sustainable Development, 26 August–4 September 2002, Johannesburg, South Africa.

⁹ 'Transforming our world' (n 4).

¹⁰ For an in-depth comprehensive account of the concept in legal theory and practice see Malgosia Fitzmaurice, *Contemporary Issues in International Environmental Law* (Edward Elgar 2009) ch 3.

¹¹ Edith Brown Weiss, 'Our Rights and Obligations to Future Generations and the Environment' (1990) 84 *American Journal of International Law* 198, 198–199.

¹² *ibid* 199.

¹³ *ibid*.

which each generation should be required to attain the conservation of 'the diversity of the natural and the cultural resource base to a level comparable to that enjoyed by the previous generation'.¹⁴ This is for not unduly restricting the available options to future generations when they will be solving their problems and will be satisfying their own values.¹⁵ The second principle is the 'conservation of quality', which requires each generation to maintain the quality of the planet so that it is inherited in no worse condition than when it was first received.¹⁶ The final principle is the 'conservation of access' which requires that each generation provides its members 'with equitable rights of access to the legacy of past generations' and the conservation of the present generations of this access for future generations.¹⁷ While the three principles put a limit to the actions of present generations in their development and usage of the planet, they do not prescribe the way that each generation should manage its resources.¹⁸

The principles rather form the basis of a set of intergenerational obligations and rights, which derive from each generations position as part of the 'intertemporal entity of human society'.¹⁹ According to Brown-Weiss the type of rights stemming from this are 'intergenerational planetary rights',²⁰ which may be regarded as group rights and which exist, 'regardless of the number or identity of individuals making up each generation'.²¹ Planetary rights are integrally connected to obligations and coexist in each generation.²²

In terms of a practical protection of intergenerational rights, Brown-Weiss suggests the establishment of a guardian for future generations in order to enforce laws for their benefit and represent them as a group.²³

The philosophical basis of Brown-Weiss' trusts theory is the theory of distributive justice of John Rawls, which sees 'justice as fairness', where 'society is interpreted as a cooperative venture for mutual advantage'.²⁴ Rawls introduced his famous 'veil of ignorance' behind which all principles of justice are chosen.²⁵ Moreover, he devel-

¹⁴ *ibid* 201-202.

¹⁵ *ibid* 202.

¹⁶ *ibid*.

¹⁷ *ibid*.

¹⁸ *ibid*.

¹⁹ *ibid*.

²⁰ *ibid*.

²¹ *ibid*.

²² *ibid*.

²³ *ibid* 205.

²⁴ John Rawls, *A Theory of Justice* (Harvard University Press 1999) 84; Edith Brown Weiss, 'In Fairness to Future Generations and Sustainable Development' (1992) 8 *American University International Law Review* 19, 21.

²⁵ Rawls (n 24).

oped the 'original position', according to which the people in the society creating the conception of justice do not know their place in society, class position or social status, the particular economic, political and cultural situation and have no information of the generation to which they belong.²⁶ The operation of Rawls' two concepts assures that everyone is treated equally. Brown-Weiss borrows from Rawls, who 'describes a condition of veiled ignorance in which every generation exists somewhere in the spectrum of time but does not know in advance where it will be located'.²⁷

Rawls formulated two principles of justice, which regulate institutions and form the basic structure of society: The first is that 'each person is to have an equal right to the most extensive basic liberty compatible with a similar liberty to others'²⁸ and the second that 'social and economic inequalities are to satisfy two conditions: first, that they are to be attached to positions and offices open to all under conditions of fair equality and opportunity and the second that they are to be of the greatest benefit of the least advantaged members of society'.²⁹ According to Brown-Weiss, future generations have a claim in inheriting the planet in no worse condition than they received it and with an access to its resources comparable to present generations.³⁰ Therefore, each generation has the obligation to leave the planet 'in a non-worse condition than it received it' and to provide future generations 'equitable access to its resources and benefits'.³¹

Brown-Weiss' theory has raised some strong objections.

Perhaps the most severe critic of Brown-Weiss is Vaughan Lowe. He characterises the theory as 'Chimera', lacking legal content and giving rise to unanswered questions: who are the beneficiaries, what are their rights of actions and finally what are the duties of the trustees?³² He concludes that the perceived rights of future generations are purely metaphorical.³³ According to Lowe, obligations and duties of trustees are not enforceable, as 'international law lacks institutions and mechanisms with the authority and ability to make rational choices of this kind'.³⁴

Professor D'Amato has also offered a strong criticism.³⁵ He criticises the future

²⁶ *ibid* 117.

²⁷ *ibid*.

²⁸ *ibid*.

²⁹ *ibid*.

³⁰ Brown Weiss (n 11).

³¹ *ibid*.

³² Vaughan Lowe, 'Sustainable Development and Unsustainable Arguments' in Alan Boyle and David Freestone (eds), *International Law and Sustainable Development: Past Achievements and Future Challenges* (OUP 1999) 27.

³³ *ibid*.

³⁴ *ibid* 28.

³⁵ Anthony D'Amato, 'Do We Owe a Duty to Future Generations to Preserve the Global Environment?' (1990) 84 *American Journal of International Law* 191.

element of the theory based on Derek Parfit's paradox theory.³⁶ He argues that if we discharge our obligations to future generations by changing the environment, such intervention would deprive of life the future generations that would have been conceived had we not changed the environment to protect the rights of future generations to begin with.³⁷ In intervening, we are destructing the given hypothetical specimen of future generations for which we initiated the intervention to begin with. According to D'Amato, Weiss' theory fails to see future generations as beyond an abstraction. He proposes that we should instead rely on a 'preverbal sense of morality' to achieve intergenerational justice, through the employment of human rationality, as developed by philosophers like Aristotle and Plato.³⁸ Finally, D'Amato criticises the theory as anthropocentric.³⁹

Furthermore, Hadjiargyrou argues that the analysis of Brown-Weiss' theory is *prima facie* entirely legal, as it implies that beneficiaries have rights by virtue of their status as beneficiaries and that trustees have obligations by virtue of their status as trustees. This premise is indeed as it is the case with the law of trusts.⁴⁰ Hadjiargyrou finds this unnecessary, as it gives rise to the contingencies of the creation of a trust.⁴¹ However, Brown-Weiss' theory itself moves beyond the legal and has a moral dimension stating that the planetary rights 'represent at first a moral protection of interests, which must be transformed into legal rights and obligations'.⁴² Moreover, Brown-Weiss's trust theory brings to mind the public trust doctrine under USA constitutional law, which provides that the state holds on trust for the people the use of and access to natural resources.⁴³ While this is a legal doctrine, it involves also moral considerations. As will be seen later on in the chapter, it has formed the basis for national climate change law jurisprudence in the United States.

The main conceptual difficulty with Brown-Weiss' theory is the application of Rawls theory in the intergenerational context. This is because Rawls social contract theory is based on the premise that existing individuals must agree upon the principles, therefore within an existing society.

³⁶ Derek Parfit, 'On Doing Best for Our Children', in Michael D Bayles (ed), *Ethics and Population* (Transaction Publishers 1976) 100.

³⁷ D'Amato (n 35) 193.

³⁸ *ibid* 197.

³⁹ D'Amato continues to find the whole concept is anthropocentric and does not take into a sufficient degree the rights of animals. D'Amato (n 35) 195.

⁴⁰ Zena Hadjiargyrou, 'A Conceptual and Practical Evaluation of Intergenerational Equity to International Environmental Law' (2016) 3-4 *International Community Law Review* 248, 253.

⁴¹ *ibid*.

⁴² Brown Weiss (n 11) 202.

⁴³ Michael O'Loughlin, 'Understanding the Public Trust Doctrine through Due Process' (2017) 58 *Boston College Law Review* 1321 <<http://lawdigitalcommons.bc.edu/bclr/vol58/iss4/7>> accessed 5 March 2019.

However, the greatest challenge is the application of intergenerational equity in international and national adjudication.

3. *Intergenerational Equity in International Case Law*

The concept of intergenerational equity has been seeded in the early days of environmental case law and developed in the jurisprudence of the International Court of Justice, in landmark decisions for international environmental law and international law in general. International case law, most notably before the International Court of Justice, indicates that future generations considerations form an important part of environmental concerns in international adjudication.

The first and far-sighted case, which can be said that advocated a concept of intergenerational equity was the *Pacific Fur Seal Arbitration*. The case concerned a dispute between the UK and the USA concerning seal hunting in the high seas territory of the Bering Sea. The case arose because the British government was contesting USA's claim to sovereignty over the Bering Sea and the fur seals found therein, outside the three miles of sea from land – the Bering Sea's high seas territory –, prescribed by international law at the time. The argument of the US was visionary in that it justified her actions on the ground of a common interest of mankind, a concept that will later on manifest and evolve into one of the most important concepts in international environmental disputes.⁴⁴ The US claimed that seals belonged or were within the jurisdiction and control of the United States, or else they are the common heritage of mankind. The US was thus acting as a trustee for protecting seals, as part of this common heritage. While future generations were not expressly mentioned, the concept of heritage denoted the protection of the interests of future generations.

The International Court of Justice (ICJ) has noted in its case law the rights of future generations, especially in relation to nuclear testing.

A paramount decision for the concept of intergenerational equity and environmental law in general is the 1995 *Nuclear Test II* case.⁴⁵ The case concerned under-

⁴⁴ The common heritage of mankind is included in the Convention on the Law of the Sea, Dec. 10, 1982, 1833 UNTS 397, entered into force as the "United Nations Convention on the Law of the Sea" on 1 November 1994.

(UNCLOS) in part XI, covering the 'Area' (seabed and ocean floor and subsoil ... beyond the limits of national jurisdiction. The concept has gained prominence within the ITLOS adjudication and especially in cases in relation to the Area. See for example, ITLOS, *Responsibilities and obligations of States with respect to activities in the Area*, Advisory Opinion, 1 February 2011, ITLOS Reports 2011, p. 10.

⁴⁵ ICJ, *Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgment of 20 December 1974 in the Nuclear Tests (New Zealand v France) Case*, Order, [1995] ICJ Reports 317; *Nuclear Tests (Australia v France)*, Judgment, [1974] ICJ Reports 457.

ground nuclear testing to be conducted by France in the South Pacific. New Zealand requested the induction of provisional measures for France to refrain from further nuclear tests before an environmental impact assessment would have been conducted and that no action be taken, which might aggravate the dispute. The case followed from the 1974 Nuclear Test I case,⁴⁶ the subject matter of which was atmospheric nuclear testing. The Court declined its jurisdiction based on the fact that the testing would be underground, as opposed to atmospheric, therefore denying the provisional measures. The Court's narrow interpretation of its jurisdiction gave rise to considerable controversy and was criticised for focusing on technicalities, as opposed to the merits of the case.⁴⁷

However, Judges Weeramantry, Koroma and Judge ad hoc Sir Geoffrey Palmer viewed the Court's role from a broader perspective, as a trustee of rights of future generations. Judge Weeramantry's strong dissenting opinion stressed out the importance of the principle of intergenerational equity: 'The case before the Court raises ... the principle of intergenerational equity – an important and rapidly developing principle of international law ... This court must regard itself as trustee to those (intergenerational rights) ... The rights of the people of New Zealand include the rights of unborn posterity. Those are rights which a nation is entitled, and indeed obliged, to protect.'⁴⁸ Judge Weeramantry went on to argue that, due to its importance, the principle of intergenerational equity has to be recognised in its own right.

In 1996 the ICJ gave an *Advisory Opinion on the Legality of the Threat or Use of Nuclear Weapons*,⁴⁹ pursuant to Article 96(1) of the UN Charter. The UN General Assembly asked the Court: 'Is the threat of use of nuclear weapons in any circumstance permitted in international law?' In that case the Court stated that 'The Court recognises that the environment ... represents ... the very health of human beings, including generations unborn.'⁵⁰ Moreover, the Court found that 'The destructive power of nuclear weapons cannot be contained in either space or time and ... the use of nuclear weapons would be a serious danger to future generations' and can cause 'genetic defects and illness in future generations'.⁵¹ Furthermore, the Court found it

⁴⁶ ICJ, *Nuclear Tests (New Zealand v France)*, Admissibility, Judgment, [1974] ICJ Reports 457.

⁴⁷ Malgosia Fitzmaurice, 'Intergenerational Equity, Ocean Governance and the United Nations', in David Joseph Attard, Malgosia Fitzmaurice, Alexandros XM Ntovas (eds), *The IMLI Treatise on Global Ocean Governance: Volume II: UN Specialized Agencies and Global Ocean Governance* (OUP 2018) 357-375, 364.

⁴⁸ ICJ, *Request for an Examination of the Situation on Accordance with Paragraph 63 of the Court's judgment of 20 December 1974 in the Nuclear tests (New Zealand v France) Case*, Order (Dissenting Opinion of Judge Weeramantry) [1995] ICJ Reports 317-62.

⁴⁹ ICJ, *Legality of the Threat or Use of Nuclear Weapons*, Advisory Opinion, [1996] ICJ Reports 226.

⁵⁰ This is a landmark judgment for environmental law because the Court found that the general obligation of states to ensure that activities within their jurisdiction respect the environment of other states beyond national control is part of customary international law, at para 29 of the Judgment.

⁵¹ ICJ, *Legality of the Threat or Use of Nuclear Weapons*, Advisory Opinion, [1996] ICJ Reports 35.

imperative to take account of the unique characteristics of nuclear weapons and ‘their ability to cause damage to generations to come’⁵².

Intergenerational equity was also referred to in *Gabcikovo-Nagymaros Project*,⁵³ a dispute between Slovakia and Hungary, concerning the construction and operation of a hydroelectric power plant on the Danube River. The Court referred to present and future generations, making a link between economic and environmental norms under the concept of sustainable development. Judge Weeramantry in his separate opinion referred to the trusteeship of earth resources,⁵⁴ much like the USA argument in the Fur Seals arbitration case above.

Although the Court has noted in its jurisprudence the rights of future generations, it has not elaborated either on their legal character or its role as a trustee of the rights of future generations. The rights of future generations are not easily defined from a legal point of view and as such are not explicitly set out in international agreements. With lack of legal substance, it would be very difficult for any Court to elaborate on the legal content of those rights. However, intergenerational equity is a principle recognised by the ICJ and although not explicitly prescribed in their content, intergenerational rights can be considered a nexus of legal and moral rights.⁵⁵

However, the landmark decisions of the ICJ clearly point out to the prominence of the concept in international law and international adjudication, especially in relation to serious and irreversible environmental threats to the survival of human kind. In this sense, they recognise the inevitability of the universal vulnerability against the natural forces.

4. Minors Oposa and Early National Case Law

The *Minors Oposa* case⁵⁶ is the most well-known case concerning intergenerational equity. A group of children, including those of the environmental activist Antonio Oposa, brought an action together with the Philippine Ecological Network Inc., a non-profit environmental organisation, to stop the depletion of the fast disappearing rain forest in their country, the Philippines. The children claimed that they were ‘entitled to the full benefit, use and enjoyment of the natural resource treasures that is

⁵² *ibid* para 36.

⁵³ ICJ, *Case Concerning the Gabčíkovo-Nagymaros Project (Hungary v Slovakia)*, Judgment, [1997] ICJ Reports 77-78.

⁵⁴ ICJ, *Case Concerning the Gabčíkovo-Nagymaros Project (Hungary v Slovakia)*, 1997 Separate Opinion of Vice President Weeramantry, <www.icj-cij.org/files/case-related/92/092-19970925-JUD-01-03-EN.pdf> accessed 5 March 2019.

⁵⁵ Fitzmaurice (n 47) 366-367.

⁵⁶ Supreme Court of Philippines, *Minors Oposa v Secretary of the Department of Environment and Natural Resources (DENR)*, 30 July 1993, 33 ILM (1994) 173 (hereinafter *Minors Oposa* or *Oposa*).

the country's virgin tropical forests'. The children claimed that they represented themselves and generations yet unborn, incorporating intergenerational equity into their action. The Court found a connection between the claim of children and that of future generations. 'Needless to say that every generation has a responsibility to the next to preserve that rhythm and harmony for the full enjoyment of a balanced and healthy ecology. ...'.⁵⁷ Moreover, the national court acknowledged the fundamental importance of the right to ecology under the Constitution for both present and future generations '... the day would not be too far when all else (rights to a balanced and healthful ecology) would be lost not only for the present generation but, but also for those to come generations which stand to inherit nothing but parched earth incapable of sustaining life.'⁵⁸

However, the case is not without difficulties, especially in relation to standing for future generations. In his separate Opinion Judge Feliciano clearly expressed his concerns on the limits of locus standi before the national court. He argued that because of 'the very broadness of the concept of "class"', this includes 'everyone living in the country whether now or in the future'. He continued that there were no clear indications of the limits of circumstances that would fall under such action and against which entities, being public or private. Finally, he observed that the issue of standing is approached very widely and loosely.⁵⁹

A similar critique was offered by Gatmayan, who argued among other things, that the decision did not affect, in practice, the government's conduct in relation to the national Timber Licencing Agreements, which continued operating after the judgment. Therefore, the judgement had no real effect for future generations.⁶⁰

Lowe also expressed a negative view in relation to *Oposa*. He stated that future generations cannot possess rights of enjoyment or exercise their duty even to mitigate logging because they do not exist. He argued that in the case 'it is not the right of a future generation, but the duty of some members of the present generation that is being enforced at the instance of other members of the present generation'. Future generations, he argues, cannot be bound by *Oposa*.⁶¹

After *Oposa* there were a number of other cases where the concept of intergenerational equity arose but not with the same result. In *M Faroque v Bangladesh and others*⁶² the petitioner relied on *Oposa* to bring an action on his behalf and that of future generations. However, his claim was rejected due to the fact that no constitutional rights inherently entailed the right to future generations.

⁵⁷ *ibid.*

⁵⁸ *ibid* 9.

⁵⁹ Fitzmaurice (n 47) 367.

⁶⁰ Dante B Gatmayatan, 'The Illusion of Intergenerational Equity: *Oposa v Factoran* as Pyrrhic Victory' (2003) 15 *Georgetown International Environmental Law Review* 459.

⁶¹ Lowe (n 32).

⁶² Supreme Court of Bangladesh, *M Faroque v Bangladesh and others*, 15 July 2001 <www.ecolex.org/details/court-decision> accessed 5 March 2019.

5. Climate Change National Litigation and Intergenerational Equity

Reference to future generations appears to be prominent in recent climate change litigation before national courts. What is significant about the cases is that they have started formulating a new movement of adjudication based partly on intergenerational equity claims.⁶³ While the subject matter of the cases is climate change, human health appears in most claims as one of the elements that require protection.

In the highly documented case of *Urgenda Foundation v the State of the Netherlands*,⁶⁴ a Dutch environmental group, the Urgenda Foundation, and nine hundred citizens brought an action against the Dutch government, based on the Dutch Constitution and the tort of nuisance under the Dutch civil code. The government was asked to increase its efforts to prevent global climate change and reduce its greenhouse gas emissions by 25% by 2020 compared to 1990 levels. In their claim the applicants stated that ‘the State wrongly exposes the international community to the risk of dangerous climate change, resulting in serious and irreversible damage to human health and the environment’.⁶⁵ In relation to intergenerational equity, the claimants were acting on the behalf of present and future generations. In support of their claim they cited, inter alia,⁶⁶ the Brundtland report, its definition of sustainable development and the United Nations Framework Convention on Climate Change.⁶⁷ The government argued that Urgenda’s claim was inadmissible because it defended the rights and interests of current or future generations in other countries also. It was not disputed between the parties that the claim of Urgenda, insofar as it is on behalf of the current generations of Dutch nationals is admissible. The court of first instance held that it did not need to decide whether Urgenda’s claim can extend to current and future generations of other countries because ‘the State’s unlawful acts towards the current and future generations of the Netherlands is sufficient’.⁶⁸ In the opinion of the court the possibility of damages to those represented by Urgenda, current and future generations of Dutch nationals ‘is so concrete that given its duty of care the state must make an adequate contribution, greater than its current contribution, to prevent hazardous

⁶³ The number of climate change cases before national courts is rapidly increasing. This section will examine some key cases for the development of the law in the area. Comprehensive databases of climate change litigation are provided by the Graham Research Institute on Climate Change and the Environment and the Sabin Center for Climate Change Law.

⁶⁴ The Hague District Court, *Urgenda Foundation v the State of the Netherlands*, 24 June 2015, HA-ZA C/09/00456689 <www.urgenda.nl/en/themas/climate-case/> accessed 5 March 2019.

⁶⁵ *ibid* para 4.1.

⁶⁶ The applicants also based their claims on Articles 2 and 8 of the European Convention on Human Rights (right to life and family life) as well as EU law.

⁶⁷ *Urgenda Foundation* (n 64), paras 2.3, 2.36, 2.38, 4.8, 4.56.

⁶⁸ *ibid* para 4.92.

climate change'.⁶⁹ Therefore, sufficient causal link was assumed to exist between Dutch greenhouse gas emissions, global climate change and the current and future effects on the Dutch living climate and so the court upheld Urgenda's claim.⁷⁰ Recently, the appeal court upheld the decision of the Hague District Court.⁷¹

The case has created a movement of national climate change claims. A notable example is *Plan B Earth and other v Secretary of State for Business, Energy and Industrial Strategy*,⁷² where the applicants referred to *Urgenda* when they claimed that the UK government was in violation of the Climate Change Act 2008 because it failed to revise its 2050 carbon emissions reduction target in light of the Paris Agreement and latest scientific development. At the time of this writing the decision is still pending at the appeal level on admissibility grounds. Another noteworthy case is *Union for Swiss Senior Women for Climate Protection v Swiss Federal Council*,⁷³ which is still pending before the Swiss courts. It concerns a senior women's association, which brought an action against the local government for failure to take adequate measures to mitigate climate change, voicing 'their concern and those of future generations'. The senior women's claim is in relation to the particular vulnerability of their health as senior citizens against the effects of climate change. Finally, following the *Urgenda* argument, in the case of *VZW Klimaatzaak v Kingdom of Belgium and Others*,⁷⁴ the non-profit organisation Klimaatzaak argued that Belgian Law should have a much stricter approach in relation to emission reductions, requesting specific emission reduction targets. At the time of this writing, the case is still pending before the Belgian courts on procedural grounds.

Moving away from the European context, in South Africa appears to be a trend of climate change litigation in relation to large scale power projects, based on the constitution. The cases link future generation considerations with international climate change law in a domestic context. *Earth Life Africa Johannesburg v Minister of Environmental Affairs and Others*,⁷⁵ concerned the South African government's considerations for reviews of plans for the Thabametsi Power Project. It is the first case where a South African court decided to order the government to take action for climate

⁶⁹ *ibid* para 4.89.

⁷⁰ *ibid* para 4.90.

⁷¹ The Hague Court of Appeal, *The State of the Netherlands v Urgenda Foundation*, 9 October 2018, HAZA C/09/456689/13-1396 <www.urgenda.nl/en/themes/climate-case/> accessed 5 March 2019.

⁷² *Plan B Earth and Others v The Secretary of State for Business, Energy and, Industrial Strategy*, Case No. CO/16/2017.

⁷³ *Union of Swiss Senior Women for Climate Protection v Swiss Federal Council, Verein KlimaSeniorinnen Schweiz v Bundesrat*, 2016.

⁷⁴ *VZW Klimaatzaak v Kingdom of Belgium and Others*, summary available at <<http://climatecasechart.com/non-us-case/vzw-klimaatzaak-v-kingdom-of-belgium-et-al/>> accessed 5 March 2019.

⁷⁵ *Earthlife Africa Johannesburg v Minister of Environmental Affairs and Others* (65662/16) [2017] ZAGPPHC 58; [2017] 2 All SA 519 (GP) (8 March 2017) <www.saflii.org/za/cases/ZAGPPHC/2017/58.html> accessed 5 March 2019.

change. The court was asked to consider whether the government had the obligation to conduct a climate change impact assessment of the project, which would be in operation until 2060. Specifically, whether climate change is a relevant consideration for environmental review under the Environmental Management Act 1998, without this being prescribed in the act. In its application Earthlife emphasized that ‘climate change will continue to impact on water resources, air quality, human health, biodiversity and marine fisheries and that South Africa has an international obligation to commit to the reduction of GHG emissions as part of a global solution to a global problem’.⁷⁶ The court, after observing that the state did not expressly contemplate climate change, held that climate is a relevant consideration, citing a number of reasons, including South Africa’s commitments under the Paris Agreement.⁷⁷ The Court referred to the constitutional right to have the environment protected ‘for the benefit of present and future generations’.⁷⁸ In the court’s view, climate change posed a substantial risk to sustainable development in South Africa, a notion which is integrally linked with the principle of intergenerational justice.⁷⁹ In this respect, the state must take reasonable measures to protect the environment for the benefit of present and future generations and therefore adequate consideration of climate change.⁸⁰ As such, the South African government is not only bound by the legislative provisions and regulations but also by the broader obligation found in the constitution and international law, to protect the environment for present and future generations.⁸¹ Based on the above, the court ruled that the government should conduct a climate change impact assessment before proceeding any further with its plan. From the above mentioned, it appears that the rights of future generations played a part as important as the rights of current generations in ordering the government to reassess the impact of power coal plant, a decision which can have a direct impact on the protection of human health.

The decision has already been part of the argument of the more recent case of *Trustees for the Time Being of GroundWork v Minister of Environmental Affairs, ACWA Power Khanyisa Thermal Power Station RF (Pty) Ltd, and Others*,⁸² where the environmental organisation ground Work filed a claim requesting the South African Court to review and set aside the government’s authorisation to develop a type of coal-fired power plant, the Khanuisa Project’, without first considering the climate change impacts of the plan.

⁷⁶ *ibid* para 54.

⁷⁷ *ibid* para 35.

⁷⁸ *ibid* para 82.

⁷⁹ *ibid*.

⁸⁰ *ibid* para 83.

⁸¹ *ibid*.

⁸² *Trustees for the Time Being of GroundWork v Minister of Environmental Affairs, ACWA Power Khanyisa Thermal Power Station RF (Pty) Ltd, and Others*, Case no. 61561/2017, Decision pending.

6. *Children, Youth and Intergenerational Equity in Climate Change National Case-Law*

Climate change has brought up a new wave of legal claims where the claimants are children and young people acting on their behalf and on behalf of future generations, some of which are very recent and, at the time of this writing, still pending. Most of the cases involve a public trust claim, echoing Brown-Weiss' trust theory of intergenerational justice. In all cases, human health is part of the argument.

In *Ali v Federation of Pakistan*,⁸³ the petitioner Rabab Ali, a seven year old girl from Karachi, filed a pro-bono petition before the country's supreme court under the Constitution of Pakistan⁸⁴ challenging the actions and inactions of Pakistan's federal government on the part of the Province of Sindh. Ali brought the legal action on her behalf and on the behalf of future generations. In the filing statement it is noted that 'the Earth is a legacy left to this youth Petitioner, other children and future generations, who live to endure the inherited Environment degraded as a result of the choices made today by her government and current generations'.⁸⁵ Ali alleged violations of fundamental rights under the constitution, including the rights to health and life, because it relates to Pakistan's atmosphere and climate.⁸⁶ Moreover, she alleged violation of rights relating to the environmental degradation as a result of burning coal for energy plants.⁸⁷ One of the questions of law raised before the court was whether the respondents have a non-discretionary, fiduciary duty under the Doctrine of Public Trust to reduce Pakistan's contribution of CO₂ levels and among other things 'restore the balance of mother Earth at large, for the benefit of current and future generations' and by choosing to develop coal as an energy source instead of renewable energy the respondents are in violation of the fundamental rights of current and future generations of Pakistan and the principle of inter-generational equity.⁸⁸ To support her claim, the petitioner stressed out the fact that the Pakistani government acknowledged the reality and consequences of climate change by launching the National Climate Change Policy in 2013.⁸⁹ Moreover, she emphasised that the impacts associated with CO₂ emissions today will be borne 'by our children and future

⁸³ *Ali v Federation of Pakistan Constitutional Petition No._/I of 2016*, judgment pending, summary of claim at <<http://climatecasechart.com/non-us-case/ali-v-federation-of-pakistan-2/>> accessed 5 March 2019.

⁸⁴ Article 184(3) of the Constitution of the Islamic Republic of Pakistan 1973, petition claim page 4.

⁸⁵ *Ali v Federation of Pakistan* petition 2016, available at <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/non-us-case-documents/2016/20160401_Constitutional-Petition-No.-___-I-of-2016_petition-1.pdf> accessed 5 March 2019, 1.

⁸⁶ *ibid.*

⁸⁷ *ibid.*

⁸⁸ *ibid.* Questions x and xxiv at 6 and 8.

⁸⁹ *ibid.* 14.

generations'.⁹⁰ The petitioner alleged violations from a number of specific acts or omissions of the government. Its particular focus though, was the approval of a plan to develop coal fields in the Thar desert region, which was expected to increase significantly greenhouse gas emissions and will result in degradation of water and air quality and displace residents of the region.⁹¹

This is not the first case before Pakistani courts in relation to climate change. In *Leghari v Federation of Pakistan*⁹² the appellate court of Pakistan ruled in favour of the claimant, Ashgar Leghari, a Pakistani farmer. He brought an action against the government challenging the 'inaction, delay and lack of seriousness' on the part of Federal government and the government of Punjab to address the challenges and meet the requirements of National Climate Change Policy of 2012 and the Framework for Implementation of Climate Change Policy (2014-2030). The petitioner submitted that climate change poses a serious threat to water, food and energy security and offended the right to life under the Constitution.⁹³ The court found that the 'delay and lethargy of the state in implementing the Framework offend the fundamental rights of the citizens'.⁹⁴ However, intergenerational equity was not mentioned in the decision. Moreover, the petitioner in *Ali* does not mention the case in her claim. Given the above, whether the supreme court of Pakistan will uphold Ali's claim remains to be seen.

Similar considerations were presented by the applicants in the *Future Generations v Ministry of the Environment and Others (Demanda Generaciones Futuras v Minambiente)*,⁹⁵ twenty-five claimants between the ages of nine and twenty-six brought an action against the Colombian government, local and central bodies and a number of corporations to enforce their rights to a healthy environment, life, health, food and water. The claimants alleged that the government's failure to ensure compliance with the agreed National Development Plan (NDP) under the Paris Agreement threatens their fundamental rights. The NDP plan is to reduce deforestation and ensure compliance with a target for zero-zero deforestation in the Colombian Amazon by year 2020. The trial court ruled against the claim because it deemed that the applicants did not provide with sufficient grounds to substantiate their claim under the particular constitutional adjudicating route they used (termed *tutela*).⁹⁶ The court of ap-

⁹⁰ *ibid* 15.

⁹¹ *ibid* 9.

⁹² *Leghari v Federation of Pakistan* [2015] W.P. No. 25501/201 <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/non-us-case-documents/2015/20150404_2015-W.P.-No.-25501201_decision-1.pdf> accessed 5 March 2019.

⁹³ *ibid* 2.

⁹⁴ *ibid* 6.

⁹⁵ *Future Generations v Ministry of the Environment and Others (Demanda Generaciones Futuras v Minambiente)*, 2018.

⁹⁶ *Future Generations* (n 95), judgment of the Court of Appeal of Bogota 5 April 2018, available

peal overruled the decision of the trial court. It recognised that the undeniable link between fundamental rights, such as life and health and the protection of the environment were linked and determined by the environment and the ecosystem.⁹⁷ Moreover, it recognised intergenerational equity as an integral part of sustainable development and future generations as the subject of rights.⁹⁸ The court ruled the government to formulate action plans to address deforestation in the Amazon. Therefore, the rights of future generations together with the rights of children and young applicants, lead to the court to order the government specific measures.

Consistent with a trend of climate change adjudication brought by children applicants, claims brought in the USA based on the public trust doctrine are becoming increasingly prominent.

The public trust approach has also been the subject matter of the highly published case of *Juliana v United States*.⁹⁹ At the time of the writing the case is pending at the appeal level.¹⁰⁰ The complaint was filed by twenty-one plaintiffs, ranging from ten to nineteen years of age. The plaintiffs asked the court to rule that the defendants must take action to reduce carbon dioxide emissions. They argued that the defendants 'knowingly endanger Plaintiffs' health and welfare by approving and promoting fossil fuel development, including exploration, extraction, production, transportation, importation, exportation, and combustion',¹⁰¹ that the 'nation's climate system' was critical to their rights to life, liberty and property and that the defendants had violated their rights by allowing fossil fuel production, consumption and combustion at dangerous levels.¹⁰² They invoked, inter alia, the rights under the public trust doctrine of the US Constitution, the rights of present and future generations 'to those essential natural resources that are of public concern to the citizens of our nation'.¹⁰³ They continued that dangerous climate system substantially impaired national public trust resources and the defendants have failed in their duty to protect the plaintiffs'

only in Spanish at <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/non-us-case-documents/2018/20180405_11001-22-03-000-2018-00319-00_decision.pdf> accessed 5 March 2019, 2.

⁹⁷ *ibid* 13.

⁹⁸ *ibid*.

⁹⁹ *Juliana v United States*, original complaint filed 12 August 2015 <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/case-documents/2015/20150812_docket-615-cv-1517_complaint-2.pdf> accessed 5 March 2019.

¹⁰⁰ On 2 November 2018, in a surprising turn, the Supreme Court ordered against the motion of the defendants to stay trial on the merits of the case. However, three days later, a temporary partial stay on the proceedings was granted in favour of the government for writ of mandamus. All legal documents are available at <<http://climatecasechart.com/case/juliana-v-united-states/>> and details of proceedings at <www.ourchildrenstrust.org/us/federal-lawsuit/> accessed 5 March 2019.

¹⁰¹ *Juliana v United States*, original complaint (n 99), para 280.

¹⁰² *ibid* para 98.

¹⁰³ *ibid* para 308.

‘fundamental constitutional rights and interests in these essential trust resources’.¹⁰⁴ The plaintiffs presented a novel argument in climate change litigation based on equality. They alleged that themselves and future generations are ‘separate suspect classes in need of extraordinary protection’, pursuant to the principles of Equal Protection under US law.¹⁰⁵ The defendants have discriminated against children and future generations ‘in exerting their sovereign authority’ over the nation’s air space and federal fossil fuel resources ‘for the economic benefit of future generations of adults’.¹⁰⁶ The plaintiffs argued that they, as children, are an ‘insular minority’ with no voting rights and hardly any political power or influence that have ‘immutable age characteristics that they cannot change’.¹⁰⁷ Similarly, future generations also do not have political power or influence, have immutable characteristics and are also an insular minority.¹⁰⁸ As a consequence, the Plaintiffs have no avenues to redress other than the court.¹⁰⁹ Therefore, ‘as Plaintiffs include citizens presently below the voting age and future generations, this Court should determine they must be treated as protected classes, and federal laws and actions that disproportionately discriminate against and endanger them must be invalidated’.¹¹⁰ The Oregon Federal Court went beyond the applicants claim to affirm for the first time, that the plaintiffs had asserted a fundamental right ‘to a climate system capable of sustaining human life’ and that the defendants’ knowledge of the consequences of their actions, and the defendants’ deliberate indifference in failing to act to prevent the harm were sufficient to state a “danger-creation” due process claim.¹¹¹

Thus, the Oregon Federal court asserted a novel right to a healthy ‘climate system’, based on the equality argument that the plaintiffs presented on their part and on behalf of future generations. It appears that the rights of future generations were acknowledged in the assertion of the right to a healthy ‘climate system’ by the Federal Court and the protection of the constitutional rights invoked by the plaintiffs. However, the Court, as in *Oposa*, did not specify the exact parameters of the rights and did no order on the specific action that the US government must take to fulfil them. Therefore, the rights of future generations, together with those of the children’s applicants, remain aspirational and the subject matter of what, appears to be judicial activism, at least for the time being.

¹⁰⁴ *ibid* para 98.

¹⁰⁵ *ibid* para 294.

¹⁰⁶ *ibid*.

¹⁰⁷ *ibid*.

¹⁰⁸ *ibid* para 295.

¹⁰⁹ *ibid*.

¹¹⁰ *ibid* para 297.

¹¹¹ *Juliana v United States*, Opinion and Order of the Oregon Federal Court of 10 November 2016 <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/case-documents/2016/20161110_docket-615-cv-1517_opinion-and-order.pdf> accessed 5 March 2019.

Perhaps not surprisingly, the decision was not subsequently followed. In *Aji P. v State of Washington*¹¹² the applicants were twelve resident applicants are twelve residents of the state of Washington under the age of 18, 'taken the burden at very young ages of trying to protect their lives and the lives of future generations ...'.¹¹³ Their claim was against the Washington state, to compel it to develop and implement an enforceable climate recovery programme. As in *Juliana* the legal basis was the constitutional and public trust obligation to protect the inalienable and fundamental common law and constitutional rights to life, liberty, property, public trust resources and healthful and pleasant environment. However, the court declined to follow *Juliana's* right to stable climate system because the decision was considered an 'outlier'. Along those lines, the court dismissed the plaintiff's claim to a 'healthful and pleasant environment' because there was no such right in the Washington State constitution.

However, *Juliana* seems to have ignited a movement of climate change cases based on the public trust doctrine and constitutional rights. In the recent application of *Reynolds v Florida*¹¹⁴ the plaintiffs are eight residents of the state of Florida, aged up to nineteen years. Echoing *Juliana*, they filed a lawsuit in Florida state court, alleging that the State of Florida, the governor of Florida and other state officials and agencies violated their fundamental rights to a stable climate system. Their claim is based on common law and the Florida constitution. According to the complaint, the defendants' 'contributions to climate change and creation and operation of a fossil fuel-based energy system have caused widespread harm to the natural resources in Florida'¹¹⁵. The case is still pending hearing.

Like in *Juliana* and *Aji P.*, the plaintiffs claimed, inter alia, that the defendants are in breach of their fiduciary duty to protect Florida's natural resources under a common law public trust doctrine, which is expressly found in the Florida constitution. The plaintiffs allege that the defendants have created and exacerbated 'unconstitutional conditions' of 'excessive human-caused atmospheric carbon dioxide' concentrations with adverse impacts.¹¹⁶ They pledge that the dangerous levels of greenhouse gas emissions have caused considerable impairment to the essential natural resources

¹¹² *Aji P. v State of Washington* Docket number 18-2-04448-1 SEA, Washington Superior Court, <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/case-documents/2018/20180814_docket-18-2-04448-1-SEA_opinion-and-order.pdf> accessed 5 March 2019.

¹¹³ *Aji P.* (n 112), complaint available at http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/case-documents/2018/20180216_docket-18-2-04448-1-SEA_complaint-1.pdf accessed 5 March 2019.

¹¹⁴ *Reynolds v Florida*, Florida Circuit Court, 37 2018 CA 000819, not decided, <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/case-documents/2018/20180416_docket-37-2018-CA-000819_complaint.pdf> accessed 5 March 2019.

¹¹⁵ *Reynolds v Florida*, complaint available at <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/case-documents/2018/20180416_docket-37-2018-CA-000819_complaint.pdf> accessed 5 March 2019, 2.

¹¹⁶ *ibid.*

on which ‘current and future generations depend in the exercise of their inherent rights’¹¹⁷. The plaintiffs request the court to order the defendants to prepare and implement an enforceable, remedial and comprehensive plan for the whole of the state of Florida.¹¹⁸ Whether the court will uphold the plaintiff’s claims remains to be seen. Following the *Aji P.* ruling, it is clear that the trusts doctrine that the plaintiffs are invoking for themselves and future generations appears to be problematic in its application.

Nonetheless, *Juliana’s* equality argument has been followed outside the US border, in the recent application of *Armando Ferrao Carvalho and Others v. The European Parliament and the Council*,¹¹⁹ the first climate case brought by individuals before the Court of Justice of the European Union (CJEU). At the time of this writing, the case is still at the application level, filed in May 2018. The applicants are ten families, including children, from Portugal, Germany, France, Italy, Romania, Kenya, Fiji, and the Swedish Sami Youth Association Sáminuorra.¹²⁰ The applicants allege that the EU’s existing target to reduce GHG emissions by 40% by 2030, as compared to 1990 levels, is insufficient to avoid dangerous climate change¹²¹ and threatens the applicants’ fundamental rights to life, health, occupation and property,¹²² demanding a target of at least 50%-60% below the level of 1990 by 2030.¹²³ The legislative instruments in question are ETS Directive on emissions from large power generation installations¹²⁴ and the Regulation on emissions from and removals by land use, land use change and forestry (LULUCF Regulation)¹²⁵ and the proposed regulation on Effort Sharing for the reduction of GHG emissions.¹²⁶ The application has two main

¹¹⁷ *ibid.*

¹¹⁸ *ibid.*

¹¹⁹ *Armando Ferrao Carvalho and others v The European Parliament and the Council*, [2018] Application for Annulment pursuant to article 263 TFEU and for non-contractual liability pursuant to articles 268 and 340 TFEU and for measures of inquiry pursuant to articles 88 and 91 of rule of procedure of the General Court <http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/non-us-case-documents/2018/20180524_Case-no.-T-18_application-1.pdf> accessed 5 March 2019.

¹²⁰ Thirty-seven applicants in total, including the Sami Youth Association, application (n 119) 1, 2.

¹²¹ Application (n 119) para 3.

¹²² *ibid* ch H.

¹²³ *ibid* para 418.

¹²⁴ Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.

¹²⁵ Regulation (EU) 2018/841 of the European Parliament and of the Council of 30 May 2018 on the inclusion of greenhouse gas emissions and removals from land use, land use change and forestry in the 2030 climate and energy framework, and amending Regulation (EU) No 525/2013 and Decision No 529/2013/EU.

¹²⁶ Proposal for a Regulation of the European Parliament and of the Council on binding annual greenhouse gas emission reductions by Member States from 2021 to 2030 for a resilient Energy Union and to meet commitments under the Paris Agreement and amending Regulation No 525/2013 of the

claims. Firstly, under Article 263 of the Treaty on the Functioning of the European Union¹²⁷ that the CJEU orders for the three instruments to be void¹²⁸ with the Court ordering some intermediate solution until new adequate targets are introduced.¹²⁹ Secondly, for an injunction under article 340 of the TFEU, which provides for the EU's non-contractual liability,¹³⁰ to set more stringent GHG emissions reductions targets through the existing framework of the ETS, ESR and LULUCF regimes, in order to bring the EU into compliance with its legal obligations. According to the applicants this target should be at least 50%-60% below the level of 1990 by 2030.¹³¹

The application makes an important link between children, intergenerational equity and the combat against climate change based on equality. According to the claim, the effects of climate change are more severe for children and future generations than for adults. The applicants are referring to the findings of UNICEF and other bodies to make that claim based on children's particular vulnerability to environmental degradation.¹³² The applicants continue that climate change will progressively worsen over time, affecting children and the 'succeeding generations with increasing severity'.¹³³ Therefore, 'a failure to abate climate change... violates equality of treatment based on age'.¹³⁴

This is a novel, visionary approach. For the first time children and future generations are explicitly considered as equal to adults in relation to the combat against climate change. In this respect, while the particularity of the vulnerability of children and future generations is acknowledged, the failure to act to protect it amounts to unequal treatment. What follows is that action must be taken by the EU institutions which must prioritize the particular needs of children and future generations as part of the whole spectrum of combating climate change. Therefore, the rights of children and future generations are considered as equal to adults. Whether the CJEU will uphold the claim remains to be seen.

What can be inferred by the cases before the national courts and the CJEU is that intergenerational equity has strengthened the position of children and young people

European Parliament and the Council on a mechanism for monitoring and reporting greenhouse gas emissions and other information relevant to climate change COM (2016) 482 final 2016/0231(COD).

¹²⁷ European Union, Treaty on the Functioning of the European Union, 13 December 2007, [2008] OJ C115/01. Article 263 which provides for the judicial review by the European Court of Justice of legislative acts of the Commission, Council and European Central Bank, with certain exceptions.

¹²⁸ Application (n 119) para 3 and para 419.

¹²⁹ *ibid* paras 417-421.

¹³⁰ Article 340 provides for injunction relief if three conditions are met: 1) There is an unlawful act by the EU institutions; 2) the unlawful act is a serious breach of the law that protects individual rights and 3) there is sufficient causal link between the breach and the damages.

¹³¹ Application (n 119) para 418.

¹³² *ibid* para 251.

¹³³ *ibid*.

¹³⁴ *ibid*.

as applicants in judicial cases, thus empowering their position in the combat climate change and environmental threats more broadly.

7. Conclusion

Few subjects in law and philosophy have generated such intense discussion as the rights of future generations. It is a subject of multidisciplinary dimensions, with legal, philosophical and ethical aspects. The rights of future generations have not yet been clearly defined and are inconclusive. However, they are gaining prominence in climate change litigation at the national and regional levels. What is clearly apparent is a nexus between climate change, the protection of human health and intergenerational equity. Therefore, no matter how ill-defined and merely aspirational, the rights of future generations will be part of the claims for a healthy climate and thus a healthier world.

Chapter 9

Damages from Electromagnetic Fields between the Right to Health and Environmental Protection: Reflections on the Italian Experience

*Vitulia Ivone**

1. Public Health Protection According to the Italian Constitution

The issue of electromagnetism – and related damage to human health – concerns a correct management of the environment and an effective role of the law. Special relevance is to be attributed to the principle of sustainable development and the precautionary principle, which can be seen as the two cornerstones of EU environmental policy.

Article 32, paragraph 1, of the Italian Constitution states that ‘The Republic protects health as a fundamental right of the individual and as a collective interest and guarantees free medical care to the indigent’.¹

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¹ Constitution of the Italian Republic, in force as of 1 January 1948, English text available at <www.senato.it/documenti/repository/istituzione/costituzione_inglese.pdf>. See Silvio Lessona, ‘La tutela della salute pubblica’, in Piero Calamandrei, Alessandro Levi (eds), *Commentario sistematico alla Costituzione italiana* (Barbèra 1950) 336; Claudio Lega, *Il diritto alla salute in un sistema di sicurezza sociale* (Roma 1952) 79; Costantino Mortati, ‘La tutela della salute nella Costituzione italiana’ (1961), I *Rivista infortuni e malattie professionali* 1, now *Raccolta di scritti*, (Giuffrè 1972) 433; Lorenza Carlassare, ‘L’art. 32 cost. e il suo significato’, in Renato Alessi (ed), *L’amministrazione sanitaria italiana, Atti del congresso celebrativo del centenario delle leggi amministrative di unificazione* (Neri Pozza 1967) 89; Mario Bessone, Enzo Roppo, ‘Diritto soggettivo alla salute, applicabilità diretta dell’art. 32 Cost. ed evoluzione della giurisprudenza’ (1974), 3 *Politica del diritto* 54; Mario Bessone, Enzo Roppo, ‘Garanzia costituzionale del diritto alla salute e orientamenti della giurisprudenza di merito’ (1975), 4 *Giurisprudenza italiana* 67; Diana Vincenzi Amato, ‘Art. 32’, in *Commentario alla Costituzione Branca* (Zanichelli 1976); Francesco Donato Busnelli, Umberto Breccia (eds), *Tutela della salute e diritto privato*, (Giuffrè 1978); Salvatore Panunzio, ‘Trattamenti sanitari obbligatori e Costituzione’ (1979) 2 *Diritto e società* 14; Massimo Luciani, ‘Il diritto costituzionale alla salute’ (1980), 2 *Diritto e società* 769; Franco Modugno, ‘Trattamenti sanitari “non obbligatori” e Costituzione (A proposito del rifiuto delle trasfusioni di sangue)’ (1982) 2 *Diritto e società* 303; Pietro Perlingieri, ‘Il diritto alla salute’ (1982) *Rivista di diritto costituzionale* 347; Barbara Pezzini, ‘Il diritto alla salute: profili costituzionali’ (1983) I *Diritto e società* 21 ss.;

The idea of pursuing a specific ‘(individual) right to health’ was an inspired intuition by the fathers of the Italian Constitution, although it was not implemented until the 1970s. In fact, in the evolution of the normative framework concerning the protection of health, the collective dimension of health – i.e. health conceived as a “collective interest” and thus as a limit to individual freedoms – has prevailed for a long time.²

Two other dimensions of health are sided with this one: the right to psychophysical integrity, which is in many cases protected – besides civil law³ – by the broader protection of personal freedom (for example, article 13 of the Italian Constitution); and the right to healthcare, which emerged at the Constitutional level with the establishment of the welfare State in the first half of the XX century, and with the ensuing constitutionalisation of social rights.

The current regulation of the right to health suffers from a complex legal framework, mainly deriving from the “multilevel” evolution of contemporary constitutionalism.

The existence of several treaties and international legal documents has allowed a wider margin of protection of the rights and interests of individuals and communities. However, at the same time, the vast plethora of existing norms makes harmonisation more difficult, also in the light of the the existence – in health law – of two above-mentioned dimensions of health as a freedom, and health as a social right.

società 21 ss.; Beniamino Caravita, ‘La disciplina costituzionale della salute’ (1984) *Diritto e società* 12; Carlo Bottari, *Principi costituzionali e assistenza sanitaria*, (Giuffrè 1991); Franco Modugno, *I “nuovi diritti” nella Giurisprudenza Costituzionale* (Giappichelli 1995); Giorgio Pelagatti, *I trattamenti sanitari obbligatori* (CISU 1995); Enzo Cheli, ‘Il fondamento storico della Costituzione italiana’, in Silvano Labriola (ed), *Cinquantenario della Repubblica italiana, Quaderni della Rassegna Parlamentare* (Giuffrè 1997); Ida Teresi, ‘La tutela della salute nelle decisioni della Corte costituzionale’ (1998), *1 Rassegna diritto civile* 11; Monica Cocconi, *Il diritto alla tutela della salute* (Cedam 1998); Carlo Bottari, ‘Il diritto alla tutela della salute’, in Paolo Ridola, Roberto Nania (eds), *I diritti costituzionali* (II, Giappichelli 2001); Donatella Morana, *La salute nella Costituzione italiana* (Giuffrè 2002), Renato Balduzzi, Giuseppe Di Gaspere, *Sanità e assistenza dopo la riforma del Titolo V* (Giuffrè 2002); Lorenzo Chieffi (ed), *Il diritto alla salute alle soglie del terzo millennio. Profili di ordine etico, giuridico ed economico* (Giappichelli 2003); Renato Balduzzi, ‘Salute (diritto alla)’, in Sabino Cassese (ed), *Dizionario di diritto pubblico* (VI, Milano 2006) 5394; Pia Acconci, *Tutela della salute e diritto internazionale* (Cedam 2011); Stefano Grassi, *Problemi di diritto costituzionale dell’ambiente* (Giuffrè 2012); Donatella Morana, *La salute come diritto costituzionale* (Giappichelli 2015); Stefania Negri, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale* (Giappichelli 2018).

² This profile is clearly visible in the Italian Constitution, which mentions health as a limitation to home freedom (in the sense that it is a ground for authorising limitations to this freedom that are not subject to the reserve of jurisdiction: art 14) and to the freedom of movement and residence (limits to this freedom may be provided by the law for reasons of “health”: art 16) and that indirectly evokes it under the form of “public safety” as a limit to freedom of assembly (for these reasons a meeting may be prohibited: art 17). This approach is also reflected in the European Convention on Human Rights and Fundamental Freedoms of 1950, which allows limitations on personal freedom (art 5, alinea e), freedom of expression (art 10, para 2), freedom of assembly and association (art 11, para 2) for public health reasons.

³ See article 5 of the Italian Civil Code of 1942 (prohibition of acts of disposal of one’s body). Civil law and administrative law (in particular the branch represented by health law) were the disciplinary fields in which the problems of legal protection of health were studied until some decades ago. In this regard, see the synthesis by Giampiero Cilione, *Diritto sanitario* (Maggioli 2003).

Neglecting the profile of health as a freedom,⁴ since it is not fully relevant to our discussion, the social dimension of health emerges as the most important, since it stresses the right of every citizen to request the intervention of the State to guarantee a treatment, to provide a service or to respond to the concerns of the collectivity.⁵

Given that the right to health is a multi-dimensional and multi-faceted “complex legal situation”, the protection of the environment has to be led back to it.

2. The Constitutional Right to a Healthy Environment

The Italian Constitution of 1948 did not mention the environment, which has instead entered the constitutional lexicon only in the wider context of the revision of the second part of Heading V, that we will discuss later.

Article 9 of the Constitution guarantees the protection of the national historical and artistic heritage. Originally, this provision conceived the landscape as a simple sum of some specific legal goods (villas, gardens of historical or artistic interest, and real estate compounds with a traditional or aesthetic value), today it expresses a wider notion. Such notion is not limited to the natural heritage, to be preserved as aspect and shape of the territory;⁶ it considers landscape as an asset in constant evolution and change.

⁴ In the rights to freedoms the individual asks the State essentially to abstain and with the abstention of the State (and of course also of third parties, individuals and groups) freedom is protected, since the right holder can freely choose how to use the space that is left free (in his favor) by the law. In this sense, see Paolo Grossi, *I diritti di libertà ad uso di lezioni* (Giappichelli 1991).

⁵ Barbara Pezzini, *La decisione sui diritti sociali. Indagine sulla struttura costituzionale dei diritti sociali* (Giuffrè 2001).

⁶ Aldo Maria Sandulli, *La tutela del paesaggio nella Costituzione* (III, Giuffrè 1967); Alessandro Predieri, *Urbanistica, tutela del paesaggio, espropriazione* (Giuffrè 1969); Giovanni Torregrossa, ‘Profili della tutela dell’ambiente’ (1980), *Rivista trimestrale di diritto e procedura civile* 1441; Salvatore Patti, ‘Ambiente’ in Natalino Irti (ed), *Dizionario di diritto privato* (Giuffrè 1981) 32; Alessandro Predieri, ‘Paesaggio’ in *Enciclopedia del diritto* (XXXI UTET 1981) 503; Lina Bigliazzi Geri, ‘Divagazioni su tutela dell’ambiente e uso della proprietà’ (1987) *Rivista critica del diritto privato* 496; Beniamino Caravita, ‘Profili costituzionali della tutela dell’ambiente in Italia’ (1989) 4 *Politica del diritto* 569; Franco Giampietro, ‘La valutazione del danno all’ambiente: i primi passi dell’art. 18, legge 349/1986’ (1989) 1 *Foro amministrativo* 2958; Francesco Saverio Marini, ‘Profili costituzionali della tutela dei beni culturali’ (1999) 3 *Nuova rassegna legale dottrina e giurisprudenza* 633; Francesco Fonderico, ‘La tutela dell’ambiente’ in Sabino Cassese (ed), *Trattato di diritto amministrativo* (V Diritto amministrativo speciale 2003) 2015; Paolo Carpentieri, ‘La nozione giuridica di paesaggio’ (2004) 3 *Rivista trimestrale di diritto pubblico* 363; Giovanni Cordini, Paolo Fois, Sergio Marchisio, *Diritto ambientale, Profili internazionali europei e comparati* (Giappichelli 2005); Ornella Porchia, ‘Le competenze dell’Unione Europea in materia ambientale’ in R Ferrara (ed), *La tutela dell’ambiente* (Giappichelli 2006) 37; Vittorio Capuzza, ‘La tutela dell’ambiente nell’ordinamento giuridico internazionale, comunitario e interno. Origini, principi, funzioni e applicazioni’ (2009) *Rivista amministrativa* 5; Paolo Dell’Anno, ‘La tutela dell’ambiente come “materia” e come valore costituzionale di solidarietà e di elevata protezione’ (2009) *Ambiente e sviluppo* 585; Cesare Salvi, ‘Libertà economiche, funzione sociale e diritti personali e sociali

Landscape protection is currently based on the criteria of integrity and entirety, which involve a reconsideration of the whole national territory in the light of its cultural and aesthetic value.

Environment law, by its nature, has to be compared with other constitutional provisions, primarily the freedom of private economic initiative. Article 41 of the Constitution, in establishing that such freedom cannot be expressed in contrast with social utility, provides counterbalances to it with other ontologically distinct articles, in order to avoid that it conflicts with the ecosystem.

On the other hand, the absence of the term “environment” in the Constitution – only introduced with the amendment of article 117 concerning the division of competences between the State and the Regions – did not prevent the expansive interpretation of some provisions already present in the Constitutional Charter to obtain a stronger protection of the good under consideration.

As said, even article 32 of the Constitution contributes to the definition of the environment as a good, given that the constitutional jurisprudence, overtaking the original meaning of protection of the individual, interpreted the provision as the right of every individual to live in a healthy environment, thus filling a gap in the law that contrasted with the relevance of this good.⁷ This evolution delivers a definition of environment as a single intangible asset, protected as a determinant of the quality of life at whose base there is the need to live in a healthy habitat which may neither

tra diritto europeo e diritti nazionali’ (2011) Europa e diritto privato 437; Francesca Sabatelli, ‘Diritti economici e solidarietà ambientale. Spunti per una funzionalizzazione delle disposizioni costituzionali sui rapporti economici a fini ambientali’ (2013) Diritto ed economia 211; Beatrice Bertarini, *Tutela della salute, principio di precauzione e mercato del medicinale. Profili di regolazione giuridica europea e nazionale* (Giappichelli 2016).

⁷ Civil Court of Cassation, Joined Chambers, 6 October 1979, no 5172, I/1 Giurisprudenza italiana 859, in which the judges of the Supreme Court specify that article 32 of the Constitution takes shape as a fundamental right of the individual protected in the primary way, in unconditional and absolute manner as a state of being of the human person. The link between article 32 and article 2 of the Constitution confers on the right to health a content of social dimension and security in a way that consists not only of a mere right to life and physical safety, but also of a genuine right to a healthy environment that not even the public administration can sacrifice or limit due to needs related to public health. This is a leading case in matter of environmental damages, in which environmental protection is established on forms of protection guaranteed by private law: it is underlined that the right to health is not relevant as much as a mere right to life and physical safety, while as a right to a healthy environment, based on articles 2 and 32 of the Constitution, which can be activated by any citizen on the basis of article 2043 of the Civil Code. Between the 1970s and the 1980s a dual approach to the configuration of the right to the environment took shape. The first is based on the judgement of Cassation Court no. 5172/1979 and construes this right as a right to a healthy environment, protected under articles 2 and 32 of the Constitution. The second is of the opposite opinion, particularly supported by the Court of Auditors (Court of Auditors, 18.9.80, no. 868, (1981) III Foro italiano 167) and considers environmental damage as a “damage to the treasury” of public nature and only protectable by the State. This latter position excludes the possibility to construe a subjective right of citizens and accepts only public entities as capable of invoking environmental protection. This way, emerges the substantial difference between collective and individual environmental damage, namely between the damage on the community in its entirety, and the damage affecting even the individual in a relevant way.

limit the freedom of action of individuals nor impinge on the development of their personality.⁸

The protection of human health extends to include the protection of the environment in which the right to health is exercised. Damage caused to the environment – for example, by pollution – spills over or can spill over into an immediate damage to the individual's psycho-physical integrity. In this case, however, contrary to the occurrence of a direct damage to health, it is much more problematic to identify the causal link between the damage to the environment and the action that produced it, and equally problematic to identify the damaged individuals and to obtain direct compensation. The protection of health against electromagnetic emissions is a recent frontier of the right to health, conceived as the right to a healthy environment.

3. The Protection of Human Health from Electromagnetic Fields: The Role of the Precautionary Principle

The issue of electromagnetism and the dangerousness of the related polluting factors evidenced a constant scientific uncertainty in respect of which the legal system intervened *ex post* and sometimes even very late after the occurrence of the event.

Recently, the demand for a better understanding of the potential risks deriving from the use of instruments emitting electromagnetic waves has become urgent. This implies the need for constant studies and for cooperation in the assessment of the risks and of the consequences on human health. Electromagnetism is on the fundamental properties of the matter:⁹ it involves electric fields, which are the forces generated by free electrical charges of the “fixed” type (for example, a ionized atom, namely an atom deprived or added of an electron) or of the “mobile” type (referring the currents, namely the fluxes of electrical charges deriving from the application of a difference of voltage at the opposites of a metal conductor) on another surrounding charge.¹⁰

⁸ Environmental law does not have autonomy, but it is referred anyway to health; in relation to this, certain scholarly reflections are relevant (Pietro Perlingieri, ‘Il diritto alla salute quale diritto della personalità’ (1982) *Rassegna diritto civile* 1020), which underlines how health is a ‘notion expressible not only from the strictly sanitary point of view, but also from the behavioural, social, and environmental one’ (at 1022); this interest is ‘indissoluble from the one of the free personal development, and it can behave in different shapes, getting different relevance and configuration, as if intended as the right to healthcare, to a healthy environment, to physical or mental integrity’ (at 1025).

⁹ Giorgio Franceschetti, Donato Riccio, Maria Rosaria Scarfi, Bartolomeo Sciannimanica, *Esposizione ai campi elettromagnetici* (Bollati Boringhieri 2000); AA.VV., *Protezione dei campi elettromagnetici non ionizzanti* (Cnr-Iroee 2001).

¹⁰ Francesco Fonderico, ‘La tutela dell’inquinamento elettromagnetico’ (2002) 2 *Giornale di diritto amministrativo* 27.

The latter generates, besides the electric field, a magnetic field defined as the action of the mobile charges on the surrounding currents. The electromagnetic field derives from the link between the electric field and the magnetic field, whose respective sources have a value that varies during time: consequently, electromagnetic waves can be defined as oscillating magnetic and electric fields. Electromagnetic waves consist of very small “packages” of energy called photons, characterized by wave length, frequency, and energy. The energy is directly proportional to the wave frequency. If we consider low frequency, we are in the domain of electromagnetic fields; instead, if we consider high frequency, we are in presence of electromagnetic radiations. These can be distinguished in “ionising” and “non-ionising”. The relevance of this distinction relates to both the physical-biological profile, and the legal discipline. The first are electromagnetic waves possessing a sufficient amount of photon energy to break the atomic bonds that keep molecules linked, creating atoms or molecule parts positively or negatively charged. The whole part of the spectrum including the electromagnetic waves having energy too low to break the atomic bonds belongs to the class of the non-ionising radiations.¹¹ During the last thirty years many studies emerged around the possibility that the exposure to magnetic fields, which have the capacity to penetrate biological tissues, results in a damage to health.

The unprecedented increase, by number and diversity, of the sources of electric and magnetic fields (EMF) used for individual, industrial, and commercial goals, generated concerns about the possible health risks connected to their use.

The issue of the legal regulation concerning the protection from electromagnetic radiations strongly recalls the thoughts of jurists on the role of the principles for the development of environmental law. Most relevant is the precautionary principle, which an attentive scholar did not hesitate to frame as a cornerstone of the environmental policy of the European Union.¹²

The precautionary principle appears in Italian law in the Framework law on electromagnetic pollution.¹³ Currently, it is explicitly included among the principles of environmental action together with the principles of prevention, of correction at source of environmental damage and the “polluter pays” principle.¹⁴ Additionally, article 301 of Legislative decree n. 152 of 2006, regulates the implementation of the

¹¹ In the visible part of the spectrum, such are ultraviolet radiation, visible light, infrared; in the invisible part, radiofrequencies and microwaves, extremely low frequency fields and static electric and magnetic fields.

¹² Guido Corso, ‘La valutazione del rischio ambientale’ in Giampaolo Rossi (ed), *Diritto dell’ambiente* (Giappichelli 2011) 168.

¹³ Franco Giampietro, ‘Precauzione e rischio socialmente accettabile: criterio interpretativo della legge n. 36/2001’ (2001) *Ambiente* 429; Fabio Merusi, ‘Dal fatto incerto alla precauzione: la legge sull’elettromog’ (2001) 1 *Foro amministrativo* 221; Francesco Fonderico, ‘Tutela dall’inquinamento elettromagnetico e amministrazione «precauzionale»’ (2004) 3-4 *Rivista italiana di diritto pubblico comparato* 907; Gian Domenico Comporti, ‘Contenuto e limiti del governo amministrativo dell’inquinamento elettromagnetico alla luce del principio di precauzione’ (2005) 2 *Rivista giuridica dell’ambiente* 215.

¹⁴ Art 3 ter, D.Lgs. no 152 of 2006.

precautionary principle, recognizing to the Ministry of Environment and Protection of the Territory and the Sea the power of intervention where a danger – even if only potential – for the health and the environment (para. 1), provided that this is a risk ‘which can be anyway identified after a prior objective scientific evaluation’ (paragraph 2).

Where a scientific uncertainty exists, in considering the use of precautionary measures, the precautionary principle connects to the principle of sustainable development under two profiles: on the one hand, it anticipates the protection threshold, rebalancing the relation between humans and nature; on the other, it legitimates measures restricting the expectations of the present generations in order to safeguard the existence and the rights of future generations¹⁵.

The precautionary approach, framed as principle of environmental action in article 3, paragraph 3, of Legislative decree n. 152 of 2006, constitutes the action parameter for both normative production and the exercise of the administrative activity.

Actually, as evidenced by the Italian jurisprudence, the precautionary principle has marked the transition from the subjection to certain science to the governance of uncertain science.¹⁶ It should not be confused with the constitutional principle of health protection, enshrined in article 32 of the Constitution, because, while the right to health assumes substantive nature, capable of producing non-derogable subjective rights, the precautionary principle conversely represents a principle of general nature, addressed to the legislator.¹⁷

¹⁵ Laura Buffoni, ‘La «dottrina» dello sviluppo sostenibile e della solidarietà intergenerazionale. Il giusto procedimento di normazione ambientale’ (2007) *Federalismi.it* 8.

¹⁶ According to the Council of State (12 January 2011, section VI, no 98), the precautionary principle postulates in advance: a) the identification of potential risks; b) a scientific evaluation, carried out in a rigorous and complete manner on the basis of all the existing data, as well as c) the lack of scientific certainty that allows reasonably to exclude the presence of identified risks. Furthermore, the precautionary principle postulates by application: the adoption of precise measures (moreover only of a temporary nature, pending the achievement of a more adequate degree of scientific knowledge) which are proportional to the level of protection sought and identified at following the examination of the consequent advantages and charges, also in terms of an economic cost/benefit analysis.

¹⁷ Mauro Tallacchini, ‘Ambiente e diritto della scienza incerta’ in S Grassi, M Cecchetti, A Andronio (eds), *Ambiente e diritto* (Olschki 1999) 59; Stefano Grassi, ‘Prime osservazioni sul principio di precauzione come norma di diritto positivo’ (2001) *Diritto gestione ambientale* 37; Carlo Maria Grillo, ‘Radiazioni elettromagnetiche (nel dubbio difendiamoci)’ (2002) *Rivista ambiente* 77; Luciano Butti, ‘Principio di precauzione, Codice dell’ambiente e giurisprudenza delle Corti comunitarie e della Corte Costituzionale’ (2006) *Rivista giuridica ambiente* 809; Ilaria Carmassi, ‘Emissioni elettromagnetiche: tutela della persona e principio di precauzione’ (2008) 7 *Danno e responsabilità* 32; Enrico Al Mureden, ‘Uso del cellulare e danni alla salute: la responsabilità del produttore tra dannosità tollerabile, principio di precauzione e nuovi obblighi informativi’ (2013) 3 *Il corriere giuridico* 18; Gerardo Villanacci, ‘L’opaco profilo del risarcimento civilistico nella complessa disciplina ambientale’ (2014) 3 *Contratto e impresa* 606; Claudio Vivani, ‘Principio di precauzione e conoscenza scientifica’ (2015) 11 *Giurisprudenza italiana* 89; Enrico Al Mureden, ‘I danni da utilizzo del cellulare tra conformità del prodotto – agli standards legislativi, principio di precauzione e auto responsabilità dell’utente’ (2017) 8-9 *Il corriere giuridico* 81.

3.1. *The Principle of Sustainable Development and the Principle of Sustainable Integration*

The existing background tension between the necessity of promoting economic development and the indispensable need for safeguarding natural resources and the environment moves its first steps at the beginning of the 1970s. Its most significant formulations have to be found at the international level, as in the 1987 Brundtland Report ('Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs') and in the 1992 Rio Declaration (principle 3: 'The right to development must be fulfilled so as to equitably meet developmental and environmental needs of present and future generations'; and principle 4: 'In order to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it').

In the EU framework, article 3 of the Treaty on the European Union includes among the Union's goals 'the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment'.

Along with the principle of a correct sustainable development, the principle of integration appears has a functional role, for which 'environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting sustainable development'.¹⁸

As it is well known, 'the high level of environmental protection and the improvement of its quality must be integrated in the policies of the Union and guaranteed in conformity to the principle sustainable development'.¹⁹

In 2015, the United Nations approved the Global Agenda for Sustainable Development and its related 17 Goals (Sustainable Development Goals - SDGs), structured in 169 targets, to be reached by 2030. This has been an historical event, because it somehow established the non-sustainability of the current model of development and, hopefully, ultimately overcame the idea that sustainability is exclusively an environmental issue. Every country is required to contribute to this change, each on the basis of its own strategy for sustainable development, and accounting the results achieved in the framework of a process which is coordinated by the United Nations. Naturally, the implementation of the Agenda calls for a strong involvement of all components of society: not only every country is called to contribute to the necessary effort to bring the world on a sustainable path, with no more distinctions between developed, developing, and emerging countries, but also private enterprises

¹⁸ Article 11 of the Treaty on the Functioning of the EU, formerly art 6 of the EU Treaty.

¹⁹ See article 37 of the Charter of Fundamental Rights of the EU (Nice, 2000) on the protection of the environment.

and the public sector, as well as the civil society and academic research centres.

In fact, the realization of the new development goals, with universal character, lies in the engagement of every State: the implementation at national level, consisting in the adoption of 'national strategies for sustainable development', is not restricted to the economic dimension of development, but is indivisibly sided next to the realization of the two other fundamental pillars – social inclusion and protection of the environment.

The relevance of the event is given by some significant factors: a clear judgement emerged on the unsustainability of the current development model, not only on the environmental dimension, but also on the economic and social ones. This implied that the idea for which sustainability is a solely environmental issue is outdated and replaced by an integrated vision of the different dimensions of development.

4. The Italian Legislation on Electromagnetic Pollution and the Problematic Knots of Environmental Law

In light of the close relation existing between health protection and the possible adverse health effects caused by electromagnetic waves, it seems appropriate to focus on the multiplicity of relevant positions. While some scientific studies suggest that exposure to electromagnetic fields generated by certain devices causes harmful effects on health (cancer, fertility reduction, memory loss, negative changes in behaviour and in the development of children), other studies contradict this hypothesis. Currently, the real entity of health risk is still unknown, but the general interest for the instruments producing electromagnetic waves is rising.

The legal regulation of the protection from electromagnetic radiations was essentially included – before 2001 – in three documents. The first is the Decree of the President of the Council of Ministers (DPCM) dated 23 April 1992 ('Maximum limits of exposition to electric and magnetic fields generated at the nominal industrial frequency (50Hz) in the households and the external environment') adopted on proposal of the Minister of the Environment and the Minister of Health on the basis of the constitutive law of the Ministry of Environment (Law no. 349 of 1986) essentially to answer the need to establish limits for the exposition of the population to electric and magnetic fields generated by power lines (implemented with the DPCM 28 September 1995). The second is the Ministerial Decree 10 September 1998, no. 381 ('Regulation providing rules to determine radiofrequency ceilings compatible with human health'), issued by the Ministry of Environment joint with the Ministry of Health and the Ministry of Communications, in accordance with Law no. 249 of 1997 instituting the Authority for Communications Guarantees, to establish limit-values of exposure of the population to electromagnetic fields related to the functioning and the exercise of fixed telecommunication and radio-tv systems operating in the frequency interval included between 100kHz and 300 GHz.

Lastly, Law 12 November 1996, no. 615 ('Implementation of Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of Member States relating to electromagnetic compatibility, as modified and integrated by Council Directive 92/31/EEC of 28 April 1992, Council Directive 93/68/EEC of 22 July 1993, and Council Directive 93/97/EEC of 29 October 1993') established the necessary requirements for the market placement of devices capable of generating electromagnetic emissions or whose functioning could have been altered by electromagnetic disturbances present in the environment.

After 2001, the Italian legislator intervened posing limits, leveraging on the precautionary principle, in the exercise of the exclusive competence in matter of 'protection of the environment and the ecosystem', pursuant to article 117, paragraph 2, *alinea s*, of the Italian Constitution.

Law 22 February 2001, no. 36 ('Framework law on the protection from exposure to electric, magnetic, and electromagnetic fields') introduced in Italian law a general and coherent regulation of the protection from electromagnetic pollution, applicable to all facilities, systems and devices for civilian, military, and police use that may cause exposure of workers and the population to electric, magnetic, and electromagnetic fields with frequencies included between 0 Hz and 300 GHz. In particular, the law applies to the power lines and radio-electric plants, including plants for mobile phones, radars and plants for broadcasting (the intentional exposure to fields generated by diagnostical devices is excluded by article 2).

The 2001 law intended to ensure the protection of the health of workers and the population at large from the effects of exposure to electric, magnetic, and electromagnetic fields; to promote scientific research for the evaluation of the long-term effects and to adopt precautionary measures for the risks connected to exposure to electromagnetic fields. Moreover, it aims to ensure environmental and landscape protection and to promote technological innovation and the recovery actions targeted to minimise the intensity and the effects of the electric, magnetic, and electromagnetic fields with the best available technologies.

The Framework law constitutes the first Italian legal text that explicitly recalls the precautionary principle (article 1, paragraph 1, *alinea b*). In effect, the protection from harmful effects of electromagnetic radiations represents one of the elective fields of the precautionary approach, which imposes to the public authority to intervene in order to avoid a potential damage to health or the environment even in absence of certain scientific information about the harmfulness of an anthropogenic activity, adopting highly discretionary measures for the political management of a risk that threatens the community.²⁰

Actually, the main critical issues of the Italian legal panorama on this topic are essentially related to two aspects: the implementation of the Framework law's imposi-

²⁰ Antonio Borzi, 'Inquinamento elettromagnetico: spunti sulla disciplina comunitaria e nazionale, tra precauzione e sostenibilità' (2012) 2 *Ambiente e sviluppo* 136.

tion of the recovery of the existing infrastructure – an issue which has been remarkably delayed as compared to the schedule planned by the law – and the information to the population about the risks connected to the facilities and the devices generating electromagnetic radiations.

Other aspects of the missed implementation of the Framework law are directly connected to the principle of information on environmental matters, in its dual sense of the need for the public administration to acquire data and information for an effective protective action, and of the obligation for the authority to communicate to the public clear, up-to-date and transparent information on the state of the environment, the factors that can affect it, and the measures taken to guarantee its protection.

In this latter respect, it is noticeable that a historic ruling (No. 500/2019) issued by the Lazio Regional Administrative Court has recently ordered that the Ministries of Environment, Health and Education, University and Research, will have to ‘adopt an information campaign aimed at the whole population’ on ‘the correct methods of use of mobile telephones (mobile and cordless phones)’, informing the general public ‘of the risks to health and the environment connected to improper use of devices.’²¹

The Regional Administrative Court has upheld the appeal of the Association for the prevention and fight against electrosmog, on the grounds that the Ministries have not complied with their duty to ‘inform the population of the short and long-term damages related to the use of mobile phones’. The Ministries have defended themselves by arguing that it has not been proven that mobile phones cause cancer and that, in any case, there is already a leaflet in the mobile phone packaging. Therefore, no information campaign was required. On the contrary, the administrative judge did not consider the information contained in the leaflet of the mobile phones to be sufficient, hence it ordered them to launch an information campaign on the correct use of these devices and on the consequences stemming from an incorrect use of mobile phones, that is to say on the serious damage to health that can be caused by exposure to electromagnetic fields.

5. Electromagnetic Fields, Mobile Phones and Risks for Health: The Role of the World Health Organization

Electromagnetic fields are present everywhere in the environment, generated by both natural sources (electricity present in the atmosphere and the magnetic field of Earth) and artificial sources as household appliances, radio, tv, mobile phones, and medical devices.

Electromagnetic fields are given by the sum of an electric field and a magnetic field: the first is given by the potential difference (or tension) that, for example,

²¹ TAR, Lazio-Roma, sez. III quater, judgment No 500 of 18 January 2019.

pushes electrons to move along a cable. When tension rises, the electrical field increases its strength. Electrical fields are measured in volt per metre (V/m).

Magnetic fields are generated by the movement of fluxes of electrons, namely with the passage of electrical current along cables of electrical devices; its intensity increases as the current increases. The strength of a magnetic field quickly decreases with the increase of the distance from the source. Magnetic fields are measured in microtesla (μT , or millionth of tesla).

Electric fields are produced independently from the fact that a device is turned off or on, while magnetic fields are produced only when the current is passing – and this usually requires that a device is turned on. Electrical lines continually emit magnetic fields because current is always passing along them. Electric fields are easily shielded or weakened by walls and other objects, while magnetic fields can pass through buildings, living beings, and the majority of materials.

It has been scientifically demonstrated that electromagnetic fields interact with biological tissues: this interaction is more powerful as closer we get to the source, and varies in relation to frequency. The main biological effect of the penetration of electromagnetic waves in the human body is warming. However, the levels to which we are normally exposed are too low to cause a significant warming. Currently, the effects on health caused by long term exposure are not known.

Epidemiological and experimental studies carried out so far have not yet shown any significant correlation between the exposure to magnetic fields and an increase in the occurrence of cancer in children and adults. By way of exception, the results of some laboratory studies showed an increase in the risk of heart Schwannoma (a type of heart tumour) after the exposure to radiofrequencies similar to the ones to which the population is exposed daily in the environment.

In this respect, the Italian law established exposure limits that are far below such values (named “threshold values”); if such limits are respected, there is no scientific evidence of health risks.

In response to the growing public health concerns related to the possible adverse effects on health deriving from the exposure to a growing number and a variety of sources of electromagnetic fields, in 1996 the World Health Organization (WHO) started a wide effort of multidisciplinary research. The International EMF project has been established to assess health and environmental effects of exposure to static and time varying electric and magnetic fields in the frequency range 0-300 GHz. It collects the knowledge and the available resources available from the main national and international agencies and scientific institutions.

In the domain of the biological effects and the medical applications of non-ionising radiation, around 25 thousand articles have been published in the last 30 years. On the basis of a recent in-depth review of the scientific literature, the WHO concluded that the actual evidence do not confirm the existence of consequences on health deriving from the exposure to electromagnetic fields of low level. However, some gaps in the knowledge of the biological effects still exist, and thus further research seems necessary.

Even if symptoms as headache, anxiety, suicide and depression, nausea, fatigue, and loss of libido have been encountered in subjects exposed to electromagnetic fields even of low level in everyday life, as of today, scientific evidence do not support a link between these symptoms and the exposure to electromagnetic fields. As it is known, some of these health problems can be caused by noise or other factors in the environment, or by the anxiety linked to the presence of new technologies.

The growth of a real concern about the possible effects on health has been moved on those long-term ones, caused by the exposure to electromagnetic fields at lower levels of the ones necessary to activate acute biological answers.

The WHO International EMF Project has been launched to provide scientifically valid and objective answers to the concerns of the public opinion about the possible risks of low level electromagnetic fields. The core of the international research is the study of possible links between cancer and electromagnetic fields, electrical lines and radiofrequencies.

The main goal of the Project is to start and coordinate the research worldwide, in order to provide an answer based on the public's concerns. This evaluation will integrate the results of studies on cellular human and animal health to allow a more complete evaluation of the risk for health. A holistic evaluation of a variety of relevant and reliable studies will provide the most reliable answer on the harmful effects on health of long-term exposure to weak electromagnetic fields, if existent.

Countries establish their national laws for the exposition to electromagnetic fields. However, the majority of these national laws is based on the guidelines established by the International Commission on the Non-Ionising Radiation Protection (ICNIRP). This non-governmental organisation, formally recognized by WHO, evaluates the scientific results in the whole world. On the basis of an in-depth literature review, ICNIRP provides guidelines that recommend specific exposition limits. These guidelines are periodically reviewed and updated, if necessary.

The latest ICNIRP guidelines are the result of a consultation process opened on 11 July 2018 and closed on 9 October of the same year.²² After the 90 days consultation period, every comment has been submitted to an attentive examination from the ICNIRP members for the finalization of the project. The concluding information are not available yet.

These guidelines are centred on the protection of the human beings exposed to radiofrequency electromagnetic fields (EMF) in the interval from 100 kHz to 300 GHz. They aim to establish the limits of exposure to electromagnetic fields, which will provide a high level of protection for every person against the notorious harmful effects on health from direct non-medical exposure to electromagnetic fields at radiofrequency in both short and long term, in a continuous and discontinuous way.

²² International Commission on Non-Ionizing Radiation Protection, ICNIRP Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic and Electromagnetic Fields (100 kHz TO 300 GHz), 11 July 2018.

In this context, “direct” refers to the effects of radiofrequency electromagnetic fields directly on tissue, instead of through an intermediate object. Due to this reason, these guidelines do not deal with the exposure linked to medical procedures (namely, patients, assistants, and doctors) out of the scope of the guidelines. Part of the scientific literature states that the guidelines are obsolete, without scientific foundation, and that they do not represent an objective evaluation of the effects known to science about this type of radiation. It has been argued that they ignore the large amount of scientific discoveries demonstrating in a clear and convincing way the adverse effects occurring due to the density of potency far below the ICNIRP guidelines²³.

In May 2011, the WHO Agency for Cancer, the International Agency for the Research on Cancer (IARC), concluded that radiofrequency radiation in the range from 30 kHz to 300 GHz is a “possible carcinogenic for humankind” (2B group): it looks like that the ICNIRP ignores this important conclusion, especially because in the last seven years the proofs based on the evidence of carcinogenicity of the radiofrequency increased in a substantial way.

6. Lessons to be Learned from a Recent Report from the US National Toxicology Program

Many laboratory and epidemiological studies have been made to evaluate the link between exposure to magnetic fields and various types of tumours (for example, forms of leukaemia, brain tumours, and breast tumours). The majority of these studies did not establish any clear connection between the two phenomena, not in the work environment nor in the domestic one. Furthermore, scientists are studying if a correlation between the occurrence of cancer and the long-term exposure to electromagnetic fields exists.

In this context, we should remember the results of recent studies conducted on laboratory animals, in which a significant relation between exposure to electromagnetic fields, radiofrequency, and the development of certain types of tumours has emerged.

Reference is to the November 2018 Report²⁴ issued by the experts of the National Toxicology Program, which describes the topic in the following way: ‘Over the years, cell phone technology has evolved from the original analog technology (1G) commercially introduced in the 1980s to digital networks that supplanted analog phones. The

²³ Michael Carlberg and Lennart Hardell, ‘Evaluation of Mobile Phone and Cordless Phone Use and Glioma Risk Using the Bradford Hill Viewpoints from 1965 on Association or Causation’ (2017) 1 Biomed Research International 22.

²⁴ NTP Technical Report, *Toxicology and Carcinogenesis Studies in HSD: Sprague Dawley Sd Rats Exposed to Whole-Body Radio Frequency Radiation at a Frequency (900 Mhz) and Modulations (GSM and CDMA) Used by Cell Phones*, National Institutes of Health Public Health Service U.S. Department of Health and Human Services, November 2018.

digital network, referred to as 2G or the 2nd generation of technology, was commercially launched in the 1990s, with 3G and 4G subsequently deployed in the intervening years. When the current studies were being designed, 2G technology was the industry standard, and 3G technologies were under development. While newer technologies have continued to evolve, it is important to note that these technologies have not completely replaced the older technologies. In fact, today's phones are very complex in that they contain several antennas, for wi-fi, GPS, 2G/3G bands, etc. Thus, the results of these studies remain relevant to current exposures, although the power levels of the exposures were much higher than typical patterns of human use'.

Research has been conducted on both female and male rats, some of which were place in locations where they were exposed to RFR waves (radio waves or radio-frequency radiation), while others were only exposed to (GSM and CDMA). The experiment led to the following results: 'Exposure to RFR caused decreased body weights of pregnant rats during gestation and lower birth weights in their offspring. However, a few weeks after birth body weights returned to normal and were similar to non-exposed rats. In general, RFR-exposed male rats lived longer than non-exposed rats. The higher survival of exposed males was attributed to a lower severity of a natural, age-related kidney disease typically observed in male rats at the end of these types of studies, which may have been related to the RFR exposure. In both studies (GSM and CDMA), exposure to RFR in male rats resulted in higher numbers of animals with tumors of the heart and brain. In the GSM study, increased numbers of animals with tumors of the adrenal gland were also observed in exposed males. In both studies, there were tumors that occurred in several organs that we were unable to clearly determine whether these resulted from exposure or were just incidental findings. For the GSM studies, these lesions included tumors of the prostate gland, pituitary gland, and pancreas in males and of the heart in females. For the CDMA studies, these equivocal lesions included tumors of the pituitary gland and liver in males and of the heart, brain, and adrenal gland of females'.

Given that the exposure of people to RFR mainly occurs through the use of mobile phones and other wireless devices, this research studied 'the effects of nearly lifetime exposures to two different types, or modulations, of RFR (GSM and CDMA) used in cellular telephone networks in the United States in male and female rats and mice to identify potential toxicity or cancer-related hazards'.

The experiment led to the following final considerations. In the first place, 'exposures increased the number of animals with tumors in the heart'. In the second place, scholars 'are uncertain whether occurrences of prostate gland, pituitary gland, and pancreatic islet tumors in male rats exposed to GSM-modulated RFR and pituitary gland and liver tumors in male rats exposed to CDMA-modulated RFR were related to RFR exposures. This was also the case with female rats, where we conclude that exposure to GSM- or CDMA-modulated RFR may have been related to tumors in the heart. For females exposed to CDMA-modulated RFR, occurrences of brain and adrenal gland tumors may have been related to exposure'.



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Chapter 10

ILVA: A Case of Shared Responsibilities for the Protection of the Environment and Public Health

Grazia Scocca *

1. *Introduction*

In 2008, specific analyses carried out on the local food chain in the city of Taranto (Italy) found significant traces of dioxin. In the same period, 1200 infected head of cattle were culled and the local authorities interdicted the grazing activities in the area. It was the beginning of an environmental and public health emergency which remains severe in the Apulia Region.

The ILVA industrial site was identified as the major responsible for the contamination of the area, principally caused by the obsolete technologies in the making process. As reported by the enquirers, the plant generated widespread pollution in the surrounding area, seriously affecting workers as well as the local population. As a matter of fact, several studies attested an excess of mortality among the ILVA workers due to cancers and other diseases, along with a relationship between the environmental contamination and the health issues emerged in the resident population.

Since 2002, several criminal procedures were opened against the company administration for such offences as ecological disaster, poisoning of food substances, omission of prevention of accidents at the workplace, degradation of public goods, emission of pollutants and atmospheric pollution. In 2012 the Office of the Prosecutor in Taranto ordered new investigations leading to further judicial proceedings – still pending – and the plant passed under State control through special commissioners. The ILVA case was also the object of judicial proceedings before the European Court of Human Rights and the Court of Justice of the European Union.

Against this background, this paper aims to critically examine the ILVA case, especially taking into account the interdependence between the right to health and the environment, and to suggest that in this case there is a shared responsibility between the Italian State and the plant, in line with the ongoing debate on business and human rights protection.

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2. *A Brief History of ILVA*

The ILVA industrial site in Taranto represents the largest iron and steel production facility in Europe,¹ owned until 2015 by the ILVA S.p.A, a transnational company managing 24 plants located in Italy and abroad and controlled by the Riva Group.

The Taranto plant covers 15 million square meters. It includes 8 mineral parks, 2 pits, 10 batteries to produce the coke with which the blast furnaces are fed, 5 blast furnaces, 2 steel plants with LD converters and 5 continuous casts, 2 hot strip mills for the belts, a hot strip mill for metal sheets, a cold rolling mill, 3 galvanising lines and 3 tube production plants. The site contains 215 industrial chimneys, of which the biggest is 210 metres high. The production concerns flat carbon steel products, welded pipes and metal sheets. It uses an integral cycle plant, which from raw materials, such as iron and coal, and it ends with steel.²

Originally born as Italsider, the plant was founded in 1960 by the Italian State with the aim of enhancing and promoting the economic development of Southern Italy, particularly enjoying the strategic position of the city of Taranto. According to the available data, the former Italsider produced 3 million tons a year of steel and then it increased the production to 11.5 million in 1975 with a number of employees equal to 43,000 in 1981.³

Because of the iron crisis in 1995, the Government decided to privatize the industrial site, which was then acquired by the Riva Group, that managed it until 2015. In 2015, after the ILVA S.p.A declared bankruptcy, the plant came once again under State control while awaiting for a new purchaser or the plant's closure. Since then, according to the extraordinary administration judiciary procedure, three government-appointed commissioners have led ILVA S.p.A. and its subsidiaries.⁴ They had the responsibility to restore financially the corporation, but firstly to carry out safety and environmental remediation works.⁵ On 5 June 2017 the Ministry of Economic Development (MiSE) signed the decree awarding ILVA to the AM Investco Italy group consisting of Arcelor Mittal Italy Holding (51%), Arcelor Mittal SA (31%), Marcegaglia

¹ Information reported on the official company website: <www.gruppoILVA.com>. All websites reported in this chapter were last accessed 31 January 2019.

² *ibid.*

³ FIDH Report, 'The Environmental Disaster and Human Rights Violations of the ILVA steel plant in Italy', 2018, 6 <www.fidh.org/IMG/pdf/industrieitaly711aweb-1.pdf>.

⁴ The extraordinary administration regime consists in a bankruptcy procedure, introduced into the Italian law by the Decree no. 247/2003. It has been created following the Parmalat case, with the specific aim to restore from bankruptcy the companies of a 'significant' size.

⁵ According to the last report presented in August 2018 in a parliamentary hearing, the three extraordinary commissioners attested that to date, € 500 M has been spent for urgent environmental investments for compliance with the requirements, € 1.8 billion in total budget, and the park coverage activities will be completed by 2021 (2020 according to Addendum). Audizione Commissari Straordinari Gruppo ILVA, Commissioni riunite 10^a -13^a Senato, 1 Agosto 2018 <www.gruppoILVA.com>.

Carbon Steel Spa (15%). The offer presented by Investco contained the forecast of an investment of 1.25 billion euros for the implementation of the Environmental Plan.⁶

Since November 2018, the regime of extraordinary administration officially ended and the plant has been incorporated into the Anchelor Mittal group.

3. *The Environmental Impact of ILVA*

ILVA was built in the heart of the urban area of the city of Taranto. Its mineral parks are located 170 meters from the residential quarters, the coke ovens batteries are at 730 meters and the fence wall 135 meters from the nearest house in the Tamburi district, which has about 18,000 inhabitants.⁷

The plant's mining parks form 20-meter-high mountains occupying a surface area of about 90 football pitches.⁸ The latter are open-air sites and in the presence of the least amount of wind, or when the material is moved, huge quantities of iron powders are dispersed into the air. Furthermore, the parks stand on the ground without any waterproof protection, thus making it easy to contaminate the groundwater below, especially when the parks are doused with water to limit the scattering of iron dust.⁹

The main consequences of this situation entail air pollution, damage to agricultural production (and hence food safety issues), landscape degradation, soil contamination, poisoning of surface water and aquifers, including the deterioration of water quality. The major pollutants released into the environment include PAH, benzopyrene, dioxins, metals and harmful powders. These have been detected in the coke ovens, the mining area, the agglomerated area and the steelworks area.¹⁰ Investigations have also reported an illicit activity of production and discharge of toxic and dangerous waste, along with scattering of toxic sludges contaminated by micro-pollutants without authorization.¹¹

As stated in a toxicological report, in 2010 ILVA emitted 4 thousand tons of powders; 11 thousand tons of nitrogen dioxide and 11,300 tons of sulfur dioxide, 338.5 kilos of IPA, 52 grams of benzo (a) pyrene, 14.9 grams of benzodioxins and PCDD/F.¹² One of the greatest concerns is represented by dioxins emissions. In 2006, Taranto produced 92% of the Italian industrial dioxins inventoried in the

⁶ Repubblica economia, *Ilva è ufficiale: passa ad Arcelor Mittal*, 5 June 2017 <www.repubblica.it/economia/2017/06/05/news/ilva_e_ufficiale_passa_ad_arcelor_mittal-167341672/>.

⁷ Beatrice Ruscio, *Legami di ferro* (Narcissus 2015) 78.

⁸ *ibid.*

⁹ See (n 3) at 12.

¹⁰ Court of Taranto, Examining Judge Office, Preventive Seizure Decree, 22nd May 2013, following appeal R.G.N.R. 938/2010.

¹¹ *ibid.*

¹² See at <www.epiprev.it/materiali/2012/Taranto/Concl-perizia-chimica.pdf>.

INES register (National Inventory Emissions and their sources) and the EPER register reported that ILVA had release in the atmosphere an amount of dioxin equal to the sum of the total emissions by England, Spain, Sweden and Austria.¹³

These heavy emissions adversely affected the food security chain: almost 2000 head of cattle were killed because they were contaminated and grazing in the proximity of the ILVA area was banned. In 2010, the scientific studies carried out by the Local Health Authority of Taranto (ASL Taranto) revealed traces of dioxins in food for human consumption, as milk and meat products (5 samples out of 6), and breast milk among women (4 times higher than legal limits).¹⁴

Dioxins contamination was also detected in mussels bred in the Mar Piccolo (69% above the allowed threshold),¹⁵ so that an ordinance banned the rearing activity and consumption of mussels in the Mar Piccolo. Similarly, free breeding was prohibited in uncultivated areas within a range of 20 kilometres from the industrial area.¹⁶

4. *The Impact of ILVA on Public Health*

The judicial decision that ordered the closure of ILVA in 2012 stated that

[i]n the 13 years of observation, 386 deaths are attributable to industrial emissions (30 per year) or 1.4% of total deaths, most of them due to cardiac causes. 237 cases of malignancy with a diagnosis of hospitalization are also attributable (18 cases per year), 247 coronary events with hospitalization (19 per year), 937 cases of hospitalization for respiratory diseases (74 per year).¹⁷

These pathologies most seriously affect people living in the neighbourhood and children. In Taranto, in fact, children who fall ill with cancer are 54% more than the whole Region.

¹³PeaceLink, Dossier 2007, Nuovo record: a Taranto il 90,3% della diossina nazionale: <www.peacelink.it/tarantosociale/a/21516.html>; see also <www.eea.europa.eu/data-and-maps/data/eper-the-european-pollutant-emission-register-4>.

¹⁴See (n 3) 17.

¹⁵PeaceLink, Quanta diossina c'è ancora nelle cozze di Taranto?, 9 November 2017 <www.peacelink.it/ecologia/a/44835.html>.

¹⁶Ordinanza A.C. n. 1989 del 22.07.2011: blocco del prelievo e della movimentazione di tutti i mitili allevati nel I seno Mar Piccolo – Taranto; Ordinanze A.C. n. 2138 del 10.08.2011 e n. 1765 del 11.06.2012: Raccolta e distruzione di tutti i mitili di taglia commerciale presenti nel I seno Mar Piccolo e conferma blocco del prelievo e della movimentazione di tutti i mitili allevati nel I seno Mar Piccolo <www.sanita.puglia.it/documenti/890301/0/Piano_straordinario_diossine_PCB_ASL_TA/17a13900-d42f-4b9a-b439-3b4093d2e90a>.

¹⁷Tribunale di Taranto GIP, Perizia Epidemiologica, 24 giugno 2011, 143 <www.osservatoriodiritti.it/wp-content/uploads/2018/09/ilva-taranto-perizia-chimico-ambientale.pdf>.

One of the most authoritative epidemiological researches, *Studio SENTIERI 2012*,¹⁸ confirmed the existence of ‘strong scientific evidence’ proving the causal relationship between the harmful effects produced by the plant and the onset of cardiovascular and respiratory diseases in the population, along with cancers and leukaemia.

The dispersion of air pollutants from the industrial site also leads to an increase in mortality in the days immediately following those in which there is a wind coming from the North-West above 7 n/s for a period of 3 consecutive hours (so-called “Wind Days”). Some studies show that there is a ‘positive and statistically significant association for cardiac and cardiovascular and respiratory mortality in the Drum area in 2-3 days after such atmospheric events’.¹⁹ Special preventive measures for Taranto in the case of windy days are recommended by the Regional Agency for Prevention and Environmental Protection (Arpa Puglia), which gives notice to the Local Health Authority (ASL) and companies subjected to AIA (Integrated Environmental Authorization) with a 48-hour notice for them to take the necessary measures. The ASL of Taranto has published several notices inviting the resident population of the neighbourhoods to take some precautionary measures (such as closing the windows and not carrying out outdoor activities) during the days when pollution levels are higher.

In December 2017, Arpa Puglia published an assessment of the health damage caused by ILVA which confirmed the previous results highlighting the critical situation for the health of the inhabitants of Taranto.

In June 2019 an updated report of the research Studio Sentieri was released, whose data confirmed the high risk of death for the resident population due to diseases associated with the specific industrial exposure.²⁰

5. “Ambiente Svenduto”, the Affair Brought before the Italian Judiciary

In July and November 2012, the Taranto’s GIP (judge for preliminary investigations) enforced a precautionary measure prohibiting the use of the “hot working

¹⁸ Istituto Superiore di Sanità, Studio Epidemiologico Nazionale dei Territori e degli Insediamenti Esposti a Rischio da Inquinamento, Studio SENTIERI (S.E.N.T.I.E.R.I. Valutazione dell’evidenza epidemiologica, 2010-2012), Studio epidemiologico nazionale dei territori e degli insediamenti esposti a rischio da inquinamento: Mortalità, incidenza oncologica e ricoveri ospedalieri (2014) 32 Epidemiologia & Prevenzione; see also Istituto Superiore di Sanità, Asl di Taranto e l’Università di Brescia, Definizione dell’esposizione a metalli con proprietà neurotossiche (As, Cd, Hg, Mn e Pb) in fluidi e tessuti di soggetti in età evolutiva (6-12 anni) residenti nelle aree di Taranto, 2016 <http://old.iss.it/binary/ilva/cont/3__127_222___Relazione_scientifica_CCM_Taranto_Finale.pdf>; S. Catino and others, Angiogenic activity in vivo of the particulate matter (PM10), Econotoxicology and Environmental Safety (June 2017) 140, 156-161.

¹⁹ See <www.arpa.puglia.it/web/guest/wind_days>.

²⁰ Studio Epidemiologico Nazionale dei Territori e degli Insediamenti Esposti a Rischio da Inquinamento, Studio SENTIERI – Quinto rapporto, Epidemiologia e Prevenzione, 2/2019, 134.

area” of the plant. The decision marked the beginning of the long and complex legal affair, which is still pending. The Public Prosecutor’s Office of Taranto ordered the arrest of a number of the Group’s management and some politicians for having deliberately produced high levels of pollution damaging the environment and the health of Taranto’s residents. As stated in the reasoning of the Court: ‘ILVA’s past and present managers have knowingly and willingly continued their polluting activity for the pursuit of profit, thereby infringing the most basic rules of public health and safety’.²¹ The judicial order estimated the cost of the clean-up at 8 billion euros.²²

In May 2017, the trial was held in the Court of Assize of Taranto. The legal proceeding counted 44 defendants including Nicola Riva, president of ILVA S.p.A., the former director of the Taranto plant, other administrative and production chiefs of the plant as well as local and regional politicians. The charges against them included, among others: fraud disaster, food poisoning, intentional omission of precautions against accidents at work, aggravated damage to public goods, spills of dangerous substances and atmospheric pollution. The Court ascertained the violation of the limits set for dust particles and pollutants, generating environmental degradation, as well as an increase in deaths and cancer pathologies. The trial is still in progress, but part of the crimes ascribed may fall within the statute of limitations.

Following this, the Government intervened through the provision of several legislative measures known as “Save ILVA”. The first one (Legislative Decree no. 207 of 2012) established that ‘the Minister of the Environment has the power to authorize the continuation of the production activity of a plant of strategic national interest for a period not exceeding 36 months even if the judicial authorities have adopted seizure orders’.²³

Following this measure, the Italian government established a progression of legislative initiatives to regulate the several issues related to the ILVA case. In particular, it appointed a special commissioner in charge of managing the specific measures envisaged by the Integrated Environmental Authorizations (Legislative Decree no. 61 of 2013).²⁴ According to Decree no. 136 of 2013, the commissioner had the discretionary power to exclude 20% of improvement interventions from the total requirements of the integrated environmental authorization to be met by 2016.²⁵

In 2015, the government acknowledged the special commissioner and his representatives the immunity from prosecution concerning the implementation of the environmental plan envisaged by the Integrated Environmental Authorization (Legisla-

²¹ Tribunal of Taranto, Office of the Preliminary Investigation Judge, Preventive Seizure Decree, 22 May 2013, following the recourse n. R.G.N.R. 938/2010.

²² *ibid.*

²³ Decree-law no 207, *Gazzetta Ufficiale serie generale*, no 282, 3 December 2012.

²⁴ Decree-law no 61, *Gazzetta Ufficiale serie generale*, no 129, 4 June 2013.

²⁵ Decree-law no 136, *Gazzetta Ufficiale serie generale*, no 289, 10 December 2013.

tive Decree no. 1 of 2015).²⁶ The following year, the immunity was extended also to future buyers or tenants and deadline for the implementation of the environmental plan was extended of 18 months (Legislative Decree no. 98 of 2016).²⁷ The Prime Minister's Decree of 29 September 2017 extended once again the deadline for the integrated environmental authorization (AIA) to 23 August 2023.²⁸

6. *ILVA and the EU Jurisdiction*

On 30 March 2011 the Court of Justice of the European Union had already condemned Italy for failing to comply with EU rules on industrial emissions authorizations for several national plants, including ILVA.²⁹

The EU Court found Italy in breach of its obligations with respect to Directive 2008/1/EC on integrated pollution prevention and control (IPPC Directive), which prescribes the obligation for industrial activities with high polluting potential to have an Integrated Environmental Authorization (AIA).³⁰ The ILVA plant did not have such an authorization. Subsequent violations were related to Directive 89/391/EC on safety and health at work (OSH) and to Directive 2004/35/EC on environmental liability, based on "polluter pays" principle, for the dangerous activities and the alleged responsibility of the manager in case of accidents.

Moreover, according to the EU Court, Member States had to release the AIAs and provide an updated census of all the plants at risk by 30 October 2007, while Italy, by Legislative Decree no. 180 of 2007, had extended the deadline for the adaptation of the existing plants to the IPPC Directive until 31 March 2008.³¹ Furthermore, Legislative Decree no. 155 of 2010 postponed the entry into force of the emission limit values to 2012 (so-called "Save ILVA" Decrees).³²

On 4 August 2011, the Italian authorities finally issued the integrated environmental authorization to ILVA, which was later updated on 26 October 2012 and on 14 March 2014.³³

²⁶ Decree-law no 1, *Gazzetta Ufficiale* serie generale, no 1, 5 January 2015.

²⁷ Decree-law no 98, *Gazzetta ufficiale* serie generale, no 182, 05 August 2016.

²⁸ Decree of the President of the Council of Ministers of 29 September 2017, *Gazzetta Ufficiale* serie generale no 229, 30 September 2017.

²⁹ CJEU, *European Commission v Italian Republic*, Case C-50/10, Judgment of the Court (Seventh Chamber) of 31 March 2011, [2011] Reports I-45.

³⁰ Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control [2008] OJ L24/8.

³¹ Decree-law no 180, *Gazzetta ufficiale* serie generale no 254, 31 October 2007.

³² Legislative decree n.155, *Gazzetta ufficiale* serie generale no 216, 15 September 2010.

³³ Ministero dell'ambiente e della tutela del territorio e del mare, rilascio di autorizzazione integrata

In 2013 the European Commission initiated an infringement procedure against Italy for failure to ensure compliance with EU requirements on industrial emissions in the ILVA plant.³⁴

In particular, the formal notice points to failure by Italy to comply with Directive 2010/75/EU on emissions and Directive 2004/35/EC on environmental liability, which endorses the “polluter pays” principle.³⁵ With regard to the aforementioned procedure, on 16 October 2014 the Commission issued a reasoned opinion pursuant to art. 258 TFEU, emphasizing that:

While recognizing that some progress has been achieved since the date the notice was issued, serves notice of infringements of the above-mentioned Directives in the following areas:

- failure to provide roofing over storage sites for minerals and powdery materials;
- failure to implement actions aimed at minimizing gas emissions from gas treatment facilities;
- failure to adopt measures to control emissions of particulate matter with water vapour at the output of the industrial chimneys and to reduce steelworks dust emissions.

The Commission furthermore notifies failure to update the integrated environmental authorisation (AIA) in 2013 and lack of measures relating to the final closure of the plant as well as provisions for the protection of the soil and groundwater.³⁶

In July 2016, a delegation from the European Commission for the Environment, Health and Food Safety visited ILVA and concluded that: ‘despite the progress made, compliance with environmental protection standards is still far away. The ultimate goal must be to reconcile the protection of the health of the civil population with the socio-economic development of the area’.³⁷

In December 2017, the European Commission completed an in-depth investigation establishing the financial support given by the Italian State to the ILVA steelworks in 2015 involved illegal State Aid. In order to ensure the respect of the anti-trust legislation, the Commission concluded that Italy had to proceed to the recovery of this undue advantage, which could be quantified as approximately 84 million euros.³⁸

ambientale per l'esercizio dello stabilimento siderurgico sito nei comuni di taranto e statte – ILVA S.p.A, Gazzetta Ufficiale serie generale no 195, 23 agosto 2011; Riesame dell'autorizzazione integrata ambientale n.DVA-DEC-2011/450 del 4/08/2011 per l'esercizio dello stabilimento siderurgico della società ILVA S.p.A. - DVA-DEC-2012-547 del 26 ottobre 2012; Ministerial Decree 53 of 3 February 2014 (Aggiornamento del decreto di AIA del 26/10/2012 in attuazione della prescrizione no 57 del PIC).

³⁴ European Commission, European Commission urges Italy to bring a steel plant in Taranto up to environmental standards, Press release, 26 September 2013 <http://europa.eu/rapid/press-release_IP-13-866_en.htm>.

³⁵ *ibid.*

³⁶ See (n 2) 29.

³⁷ Mission report following the visit of the ENVI Committee to ILVA, Taranto 13-15 July 2016 – PE587.681v01-00. See also the PETI fact finding mission to Taranto 17-19 July 2017 <www.europarl.europa.eu/cmsdata/123280/Background%20Document%20PE571.403EN.pdf>.

³⁸ European commission, State aid: Commission concludes in-depth investigation on support to Ita-

7. The ILVA Case before the European Court of Human Rights

In March 2015, the European Court of Human Rights (ECtHR) declared the inadmissibility of the application filed in the case *Smaltini v Italy* – the first claim related to ILVA brought before the Strasbourg Court – which it considered manifestly ill-founded.³⁹

The applicant, an Italian citizen residing in Taranto, complained about the violation of article 2 (right to life) of the European Convention on Human Rights (ECHR), claiming that there was a causal link between the highly polluting impact produced by the plant in Taranto and the onset of her leukaemia, diagnosed in September 2006.

In 2007, the applicant had sued ILVA before the judicial authority in Taranto, asserting the existence of a causal link between the plant's emissions and her pathology. During the proceedings, the expert consultants appointed by the domestic Court (magistrate in charge of preliminary investigations - GIP) concluded that despite the polluting emissions from the ILVA steelworks were generating health consequences, there was no evidence of any causal relationship between the pollution and the applicant's illness based on the available scientific data. Because of this reasoning, in January 2009 the Court of Taranto dismissed the case.

Invoking article 2 ECHR, the applicant complained to the Strasbourg Court about the violation of her right to life and pleaded that the national jurisdiction had not considered the causal link between the harmful emissions of the ILVA steel plant and the development of her disease. In its decision, the ECtHR pointed out that the applicant had complained not about the inertia of the domestic authorities to take legal or administrative measures to protect her right to life, but rather about the fact that they had not ascertained the existence of the causal link between the polluting emissions and the onset of the disease. This punctual clarification allowed the ECtHR to limit the examination of the complaint exclusively to the exceptions as proposed by the applicant, according to the procedural limb of the right to life.

The Court noted that, based on the expert reports examined by the domestic judicial authorities, a greater incidence of leukaemia in the Taranto area as compared to the other Italian regions had not been ascertained. The ECtHR remarked that the applicant had benefited from an adversarial procedure during which the investigations were carried out at his request, although without success. Therefore, in the light of the scientific knowledge available at the time of the facts of the case and without prejudice to the results of future scientific studies, the ECtHR concluded that the applicant had not proved that the Italian authorities had failed in their obligation to protect the right to life under the procedural limb of article 2 of the Convention. For

ly's largest steelmaker ILVA S.p.A. in A.S. and orders recovery on two measures that involved illegal State aid, Press Release, 21 December 2017, <http://europa.eu/rapid/press-release_IP-17-5401_it.htm>.

³⁹ ECtHR, *Smaltini v Italy*, no 43961/09, decision of 16 April 2015.

this reason, the Court considered the application ill-founded, and hence declared its inadmissibility.

In January 2019, the ECtHR delivered its decision on health- and environmental-related issues caused by ILVA in its judgment on the joint cases of *Cordella and others v Italy* and *Ambrogi Melle and others v Italy*.⁴⁰

The 180 applicants in these cases had requested the Court to examine the ILVA case going beyond the content of the *Smaltini* decision and asked it to unanimously condemn the Italian State for violating articles 2 (right to life), 8 (right to respect for private and family life) and 13 (right to an effective remedy) of the Convention. They claimed that the Italian authorities had not been able to protect the environment and the health of citizens living in the area surrounding the industrial site and, additionally, that domestic remedies had been ineffective. Without resorting to the procedure of the pilot sentence, advocated by the applicants, the Court condemned Italy recognizing the absolute urgency to re-establish sufficient healthy conditions in the area, and inviting the national authorities to implement as soon as possible the environmental plan.⁴¹

Contrary to the *Smaltini* case, the Court explicitly noted that the applicants alleged the inadequacy of State measures to protect the health and the environment even in presence of a considerable scientific literature attesting the existence of a causal link between environmental exposure to polluting emissions and the disease onsets.⁴²

Concerning the victim status, contested by the Italian State, the Strasbourg Court clarified that the Convention does not guarantee a generalized protection of the environment as such, although the existence of negative effects on an individual's private or family life allows to identify a violation of article 8 para. 1.⁴³ Moreover, stressing the restriction for *actio popularis*, the Court stated that 19 applicants could not be considered as victims in the case because they did not reside in any of the municipalities classified as at "high environmental risk" by the resolution of the Italian Council of Ministers of 30 November 1990.⁴⁴

The defendant also alleged that the application was inadmissible for failure to exhaust domestic remedies in the criminal, civil and constitutional fields.⁴⁵ The applicants observed that none of the proposed remedies met their needs, although considering that some of them had already sued the corporation, they could not obtain any compensation because ILVA was subjected to the extraordinary administration regime and the immunity jurisdiction for the administrators and the future new

⁴⁰ ECtHR, *Cordella and others v Italy*, nos 54414/13 and 54264/15, judgment of 24 January 2019.

⁴¹ *ibid* paras 177-182.

⁴² *ibid* paras 162-166.

⁴³ *ibid* paras 100-101.

⁴⁴ *ibid* paras 102-108.

⁴⁵ *ibid* paras 110-113.

property of the plant. The Court added that it is for the State to prove that the domestic remedies were accessible and able to offer reasonable prospects of success and that, according to generally recognized principles of international law, particular circumstances may exempt the applicant from the obligation to perform all internal remedies.⁴⁶

Focusing on the violations of article 8, in accordance with the previous case law, the Court stated that the rule does not limit itself to providing for abstention of arbitrary acts of interference by the State. It also established positive obligations, such as the adoption of a legislative system aimed at preventing damage to the environment and health and adequately regulate any activity, public or private, while maintaining a certain margin of appreciation in balancing the regulation of private interests and society as a whole.⁴⁷

With regard to the general theory of the positive obligations to protect human rights, the Court reiterated that the State has the obligation to set up a legislative and administrative framework to provide an effective deterrent against threats, adapted to the specificities of the activity and its risk level.⁴⁸ In particular, it must provide for the regulation of licensing, the establishment, the operation, the securing and control of industrial activities, as well as to impose on any person concerned by it the adoption of practical measures to ensure the protection of citizens whose lives may be exposed to dangers. The State must also adopt concrete measures to guarantee the effective protection of those whose lives could be endangered by the risks inherent in the development of industrial activities, ensuring the right to be informed and providing appropriate procedures to quickly identify the responsibilities and faults committed.⁴⁹

In the light of the foregoing considerations, the Court found that the national authorities had failed to take all necessary measures to ensure the effective protection of the applicants' right to respect for private and family life, not adequately balancing their interest not to suffer serious environmental harm affecting their well-being and the interest of society. Based on these considerations, the Court declared the violation of articles 8 and 13 of the Convention.

⁴⁶ *ibid* para 122.

⁴⁷ *ibid* paras 157-160.

⁴⁸ The Court referred to the cases: *Öneriyıldız v Turkey* [GC], no 48939/99, para 90, ECHR 2004 XII; *Boudaïeva and others v Russia*, nos 15339/02, 21166/02, 20058/02, 11673/02, 15343/02, ECHR 2008 (excerpts); *Kolyadenko and others v Russia*, nos 17423/05, 20534/05, 20678/05, 23263/05, 24283/05, 35673/05, 28 February 2012, *Brincat and others v Malta*, nos 60908/11, 62110/11, 62129/11, 62312/11, 62338/11, 24 July 2014, *Guerra and others v Italy*, 19 February 1998, paras 56-60, Reports 1998 I).

⁴⁹ Veronica Manca, 'La tutela delle vittime da reato ambientale nel sistema Cedu: il caso Ilva' (2018) *Diritto Penale Contemporaneo* 267.

8. Conclusion

The ILVA case marked a step forward in the “greening of human rights” within the fragmented jurisprudence of the European Court of Human Rights, confirming also the central role it can play in fostering the development of the right to a healthy environment at a pan-European level.

In the recent decision delivered in the *Cordella* case, the Court reiterated once again its competence in claims dealing with the environmental impact on human health, under the umbrella of the right to respect for private and family life (article 8 ECHR). The reasoning of the Court recognised that an individual’s well-being might be negatively affected by unsafe or disruptive environmental conditions, assuming a direct link between environmental issues and the right to health.⁵⁰ It clearly affirmed that environmental harm creates significant impacts on human wellbeing as to generate a human right issue.

However, the Court reaffirmed its settled jurisprudence limiting the possibility of invoking article 2 of the Convention only in a narrow range of situations, despite the fact that some applicants had contracted diseases endangering their quality of life. Indeed, a different approach was suggested by the Inter-American Court of Human Rights in its advisory opinion on the Environment and Human rights, which clearly interpreted the State obligations in the context of environmental protection as derived from the duties to respect and ensure the rights to life and personal integrity.⁵¹

In the light of the above observations and facing the current development of the healthy environment, the interpretation of the category under the article 8 of the Convention may risk limiting the content of the State obligation related to it. More specifically, as expressed in the *Cordella* case, the right to a healthy environment under article 8 requires a balancing of the different relevant interests.

Moreover, the decision offered the opportunity to go through the theory of International Human Rights and the State obligations regime. The judges noted that, while it is not for the Court to determine precisely what steps should have been taken in this case to reduce the level of pollution more effectively, it is undeniably incumbent upon it to ascertain whether the national authorities addressed the matter with due diligence and whether they had taken into consideration all competing interests. In this connection, the Court reiterated that it is for the State to justify by precise and circumstantial elements the situations in which certain individuals must bear heavy burdens in the name of the interests of society.

The ILVA case represents an emblematic case also in the light of the current movement on Business and Human rights, advocating at the international level an

⁵⁰ ECtHR, *López Ostra v Spain*, 9 December 1994, Series A no 303-C, para 51; *Guerra and others v Italy*, 19 February 1998, para 60.

⁵¹ IACtHR, Advisory Opinion OC-23/17, Environment and Human Rights, 15 November 2017, para 3.

implementation mechanism to ensure the responsibilities of companies for the respect and the effectiveness of human rights. This scenario integrates a further model of obligations attributable to the exercise of business activities, including also environmental rights. For the first time, the “Zero draft” of the international legally binding instrument on Transnational Corporations and Other Business Enterprises with respect to Human Rights may legitimate the victims’ interests to a specific form of remedy including ‘environmental remediation and ecological restoration’.⁵²

⁵² OHCHR, Legally binding instrument to regulate, in international human rights law, the activities of transnational corporations and other business enterprises, Zero Draft, 17 July 2018, art. 8.



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Part III

Environmental Health at the Intersection of Pollution of Water and Soil and Food Safety



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Chapter 11

Public Health Risks Posed by Waste Pollution and Chemical Exposure and Legal Responses in International and EU Law

*Teresa Russo**

1. Introductory Remarks on Waste Pollution and Chemical Exposure as Major Public Health Hazards

It is a fact that pollution from waste and chemicals affects the environment, human health, and sustainable development in a catastrophic way. Indeed, the release of polluting substances into the natural environment (atmosphere, water and soil) causes serious imbalances in the ecosystem, often irreversible damage, and adverse effects on the health of human beings, plants and animals. These polluting elements can be of different kinds: gas, dust, combustion residues, liquids, but also electromagnetic radiation, radioactive substances, noise and vibrations. With the exception of the very few causes of natural release, such as the emissions of sulfur and carbon dioxide caused by volcanic eruptions, anthropic activities are heavily polluting the environment. One of the main causes of pollution is certainly the increasing production of waste, plastic waste and their improper or unsound disposal. Increased waste production is mostly a negative effect of the political choice to induce economic growth by increasing consumption.

As a consequence, waste disposal has become a serious concern in all industrialized countries and one of the elements of crisis and difficult governance of the territory and in particular of large urban systems. Furthermore, with the disposal of waste and incineration an enormous quantity of pollutants is produced and released into the environment (air, soil, water, food cycle). The damage produced by many of these substances is transmissible from generation to generation and their negative effects for mankind are difficult to calculate.

With regards to chemicals, they are used to improve the quality of life and, for the most part, they are not dangerous for the environment or human health. In fact, many chemicals exist naturally in the environment and can be found in the air, water and soil. Nonetheless, some chemicals are synthetic and are used in a wide range of every day products such as medicines, computers, textiles and fuels, while others are by-products of chemical processes. The use of these chemicals has

increased dramatically due to the economic development in various sectors including industry, agriculture and transport. They can be harmful in certain quantities and should only be used if potential risks are managed appropriately. In fact, exposure to certain chemicals can cause or increase the prevalence and incidence of serious health problems including cancer, respiratory, urinary-system and cardiovascular diseases, allergies and endocrine disruption.¹ Their effects can be classified as short-term effects, such as burns and intoxication, and long-term effects, i.e. those occurring after an extended period of time (such as cancer and other effects on different organs of the body). Exposure to certain chemicals in the early ages of development, for example in the fetus, can lead to congenital anomalies and problems of physical and mental development in newborns, which may continue into adulthood. The World Health Organization has expressed great concern because unintentional poisonings are estimated to have caused hundreds of thousands of deaths in children under five years.²

In light of the above, the strict connection between the environment and health has been widely emphasized in the international literature³ and the reduction of both the quantity and the dangerousness of waste and chemicals, as well as of the flow of waste sent for disposal, are considered the necessary strategies to be implemented at both the international and the regional level.

Since it is not possible to examine all the relevant legislation here, the present paper will move from the emergence of a global concern for waste and chemicals in the framework of the United Nations Conferences on the environment and development to focus on the three “connected” multilateral environmental agreements currently in force,⁴ that is to say the Basel, Rotterdam and Stockholm Conventions. Environmental protection is the main and predominant objective and component of these Conven-

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¹ WHO Europe, UN Environment, UNECE, *Chemical Safety. The importance of preventing early-life exposure to hazardous chemicals (Fact sheet 5)*, Sixth Ministerial Conference on Environment and Health, 13-15 June 2017.

² *ibid.*

³ See recently Makane M Mbengue and Susanna Waltman, ‘Health and International Environmental Law’ in Gian Luca Burci and Brigit Toebe (eds), *Research Handbook on Global Health Law* (Edward Elgar 2018) 197.

⁴ Indeed, the reconstruction of the regulatory framework of the matter is not easy, because it includes the different phases of the waste cycle from production to disposal and transboundary movement, as well as other acts and conventions. Thus, the specific rules of the International Atomic Energy Agency on radioactive waste, the international law of the sea, the law of international trade, as well as the agreements on liability on environmental damage and the rules concerning specific regions as Antarctica should be included in the topic. For example, marine pollution and wastes are included in the famous MARPOL Convention, that is the International Convention for the Prevention of Pollution from Ships (MARPOL), which is the main international convention covering prevention of pollution of the marine environment by ships from operational or accidental causes, adopted on 2 November 1973 at IMO.

tions, but they also regulate the shipment and “commercialization” of waste, giving rise to political and economic issues of great concern for the international community. Therefore, the paper will show how the system established by the three aforementioned Conventions is a procedural regime for the protection of human health and the environment and how the EU legal system includes the implementation of these three Conventions, although adopting its own environmental policy on waste disposal and chemicals pursuant to the pronouncements of the EU Court of Justice. Finally, it argues that a regulatory framework concerning waste is characterized by the difficult tension between economic needs and environmental health protection.

2. The Global Concern for Waste and Chemical Pollution as Emerged at UN Conferences

As is well known, the issue of waste transcends national borders and has a global dimension.⁵ Such approach was only progressively adopted by the United Nations Conferences.⁶ The Declaration of the United Nations Conference on the Human Environment of 1972 (Stockholm Declaration) introduced some common principles for the preservation and enhancement of the “human environment”.⁷ According to the General Assembly Resolution 44/228 of 22 December 1989, the environmentally sound management of waste was ‘among the environmental issues of major concern in maintaining the quality of the Earth’s environment and especially in achieving environmentally sound and sustainable development in all countries’ (section I, paragraph 12, g).⁸ Similarly, the following Declaration of the United Nations Conference on Environment and Development of 1992 (Rio Declaration) proclaimed in Principle 1 that ‘human beings are at the centre of concerns for sustainable development ...’. Thus, this Declaration aimed at ‘establishing a new and equitable global partnership through the creation of new levels of cooperation among States, key sectors of societies and people’. In particular, it focused on international cooperation ‘to protect the global environmental and development system’. However, only the Agenda 21 reflected such a global approach addressing the pressing problems of to-

⁵ See David A Wirth, ‘Hazardous Substance and Activities’ in Daniel Bodansky, Jutta Brunnée and Ellen Hey (eds), *The Oxford Handbook of International Environmental Law* (OUP 2008) 394.

⁶ See Laura Pineschi, ‘L’evoluzione storica’ in Alessandro Fodella and Laura Pineschi (eds), *La protezione dell’ambiente nel diritto internazionale* (Giappichelli 2009) 9.

⁷ See especially Principle 1: ‘the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being ...’. See also Principles 6, 7, 18 and 22.

⁸ For a critical view on the definition of ‘environmentally sound management of waste’, considered merely as descriptive and generic, see Alessandro Fodella, *Il movimento transfrontaliero di rifiuti pericolosi nel diritto internazionale* (Giappichelli 2004) 251.

day,⁹ that is to say the need to minimise the production of hazardous waste and to promote their sound management for a general reduction of pollution.¹⁰

Thanks to the next United Nations Conferences on the environment, the sound management of waste became an essential component of the protection of the environment, human health and sustainable development. Then, the diversification of types of waste (toxic, hazardous, solid, radioactive waste) confirmed the need to put in place different strategies for proper waste management in terms of a general reduction of pollution.¹¹ There are, in fact, different types of waste, but all produce a negative impact on human health and the environment, if they are not managed soundly.¹² In other words, waste is a problem that cannot be eliminated, but must be managed according to specific disposal operations. These are, on the one hand, the operations directed to eliminate the toxic substances that cannot be used in the future in order to avoid that these can cause damage to the environment and human health;

⁹ It is the global action plan for sustainable development adopted at the United Nations Conference on Environment and Development of 1992, which stated in paragraph 1.6 that it was 'a dynamic programme' and a 'political commitment at the highest level on development and environment cooperation'. It began to identify the means of achieving a sound management of waste from different perspectives. Unlike the United Nations Conference of 1972, the 1992 Rio Summit focused on the role and responsibility of States for the protection of the environment, in particular on the national policies and the need for their change. Furthermore, Agenda 21 focused on some important principles enunciated in the Rio Declaration related to waste management, such as the participation of citizens to environmental issues, including information on hazardous materials and activities (principle 10), the liability and compensation for the victims of pollution (principle 13), the precautionary approach (principle 15), the environmental impact assessment (principle 17), and so on. It dealt with the changing of patterns of production and consumption because they clearly affect the production of waste (para 4.2). In particular, the Agenda aimed at the adoption of an international approach according to some basic objectives directed distinctly to all countries and developing countries (para 4.8). The main objectives were the reorientation of national policies on the topic (para 4.15) and the minimising of the generation of waste (paras 4.19, 4.24). Indeed, the Agenda recalled the issue of waste management several times in the different programme areas. This confirmed that such issue affects all the aspects of environment protection. For example, the management of solid waste requires city planning strategies and sustainable human settlement development to reduce the health risks from environmental pollution and hazards (paras E, 6.39 ff) as well as water resources (ch 18). Furthermore, the Agenda highlighted that the sound management of biotechnology can be a means of reducing waste. See Nicholas A Robinson, *Strategies towards Sustainable Development: Implementing Agenda 21* (Oceana Publications 2004).

¹⁰ In particular, in paragraph 20.6, the Agenda stated: 'Within the framework of integrated life-cycle management, the overall objective is to prevent to the extent possible, and minimize, the generation of hazardous wastes, as well as to manage those wastes in such a way that they do not cause harm to health and the environment'. On the compliance of the objectives of Agenda 21, see Marlene Jahnke, 'Implementing Agenda 21: Overview of Progress' (2008) 38 *Environmental Policy and Law* 176.

¹¹ In Chapters 19, 20, 21 and 22, the Agenda respectively identifies different types of waste: toxic chemicals, hazardous waste, solid waste and sewage and radioactive waste. This specification is a consequence of the dangers of contamination and serious damages that these kinds of waste produce. The most important aspects related to their management concern the minimization, transportation and disposal, as well as the prevention of their illegal international traffic.

¹² See Francesco Munari and Lorenzo Schiano di Pepe, *Tutela transnazionale dell'ambiente. Principi, regole, problemi* (Il Mulino 2012) 295.

on the other hand, the operations which may lead to resource, recovery, recycling reclamation, direct re-use or alternative uses.¹³

Later on, the Declaration of the World Summit on Sustainable Development of 2002 (Johannesburg Declaration) confirmed the progress towards a global consensus on mutual commitments of States that ‘assume a collective responsibility to advance and strengthen the interdependent and mutually reinforcing pillars of sustainable development – economic development, social development and environmental protection – at the local, national, regional and global levels’. In particular, the 2002 Plan of implementation adopted at the Johannesburg Summit paid much attention to the issue of waste by changing unsustainable patterns of consumption and production.¹⁴ This means that policy interventions to prevent and combat the risks posed by waste became ever more important.¹⁵ Furthermore, the outcome document “The Future We Want”, issued from the United Nations Conference on Sustainable Development of 2012 (Rio+20), annexed to General Assembly Resolution 66/288 of 11 September 2012,¹⁶ identified a number of thematic areas and cross-sectoral issues among which chemicals and waste are expressly included (paragraphs 213–223) since their sound management was considered ‘crucial for the protection of human health and the environment’.¹⁷ Finally, the 2030 Agenda for Sustainable Development, adopted

¹³ These Disposal Operations are, for example, provided in Annex IV of the Basel Convention on the control of transboundary movements of hazardous wastes and their disposal, adopted on 22nd March 1989 and entered into force on 5th May 1992.

¹⁴ It was adopted on 6 September 2002 at the United Nations World Summit of Sustainable Development held in Johannesburg, to monitor progress on the outcome of the 1992 UNCED and to renew global commitment to sustainable development. It wanted to set out new commitments and above all expedite the realization of the remaining goals. This was according to some priorities for action in areas such as poverty eradication, health, trade, education, science and technology, regional concerns, natural resources, and the institutional arrangements. The Plan was another important step toward the sound management of waste because, in the process conducted by the United Nations for the protection of the environment, it reaffirmed more precise principles and actions in this field. For a reconstruction of the historical and normative background until the Summit of Johannesburg, see Angela del Vecchio and Arno Dal Ri Júnior (eds), *Il diritto internazionale dell'ambiente dopo il vertice di Johannesburg* (Editoriale Scientifica 2005).

¹⁵ In particular, this Plan confirmed the centrality of the change of the patterns of consumption and production to achieve global sustainable development through the necessity to prevent and minimize waste, as well as to maximize reuse, recycling and use of environmentally friendly alternative materials (para 22). In this direction, the Plan identified some actions such as the development of waste management systems based on environmentally sound disposal facilities including technology to recapture the energy contained in waste, as well as the production of reusable consumer goods and biodegradable products. Furthermore, the Plan renewed the commitment of Agenda 21 on the sound management of chemicals and hazardous waste “using transparent science-based risk assessment procedures and science-based risk management procedures”, according to the precautionary approach of principle 15 of the Rio Declaration.

¹⁶ It emphasised the close connection between economic, social and environmental aspects in order to achieve sustainable development in all its dimensions and ‘at the highest possible level’. See Fabiano De Andrade Correa, ‘The Rio+20 Conference and International Law: Towards a Multi-Layered Multi-lateralism?’ (2012) 50 *Archiv des Völkerrechts* 500.

¹⁷ The issue of waste was also included in other parts of the document (see Tseming Yang, ‘The UN Rio+20 Conference on Sustainable Development – What Happened?’, available at <www.asil.org/

by General Assembly Resolution 70/1 of 25 September 2015, aims at achieving under SDG 12 (Ensure sustainable consumption and production patterns), inter alia, the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment by 2020; the substantial reduction of waste generation through prevention, reduction, recycling and reuse by 2030; and finally aims to encourage companies, especially large and transnational companies, to adopt sustainable practices and to integrate sustainability information into their reporting cycle.

Therefore, on the one hand, the UN Conferences allowed the progressive emergence of a global issue concerning the proper management of waste and chemicals for the protection of the environment and human health. On the other hand, they stimulated the emergence of an international legal framework regulating waste and chemicals disposal thanks to the promotion of principles considered the modern international environmental law and relevant to the development of treaties, customary law, and non-binding norms in the field.¹⁸ The efforts of the United Nations are, however, complementary to the efforts that the States and private actors must put in place and of which civil society has taken charge through, for example, the Global Action Plan for the Environment developed by a group of international environmental lawyers on the basis of the Resolution 72/277 of the General Assembly of 10 May 2018. This has led to the creation of a legal framework, which would aim to address the challenges posed by environmental degradation in the context of sustainable development to preserve the future generations.¹⁹

3. *The Regulatory Regime Set Out by the Basel, Rotterdam and Stockholm Conventions*

The regulatory regime set out by the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal,²⁰ the Rotterdam Convention

insights120905.cfm>). For example, with specific reference to the use of green economy that has a lower negative environmental impact and increases resource efficiency and reduces waste (para 60). In fact, the application of the 3Rs (reduce, reuse and recycle) represents the formula for the sustainable management of waste with specific reference to the cities and human settlements (para 135). Thus, a balance between the urban development and environmental protection that results in the expression of “sustainable cities” has been considered necessary.

¹⁸ See Philippe Sands, Jacqueline Peel, Adriana Fabra, Ruth Mackenzie (eds), *Principles of International Environmental Law* (4th edn, CUP 2018) 21.

¹⁹ See Yann Aguila, Jorge E Viñuales, ‘A Global Pact for Environment: Conceptual foundations’ (2019) Review of European, Comparative & International Environmental Law, who consider that: ‘the term Pact connotes a general value stance taken by the international community’.

²⁰ The Basel Convention was adopted on 22 March 1989 and entered into force on 5 May 1992.

on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade²¹ and the Stockholm Convention on Persistent Organic Pollutants (POPs)²² represents a multilateral response of binding international agreements concerning different types of waste and chemicals that are considered particularly dangerous. These agreements introduced a common procedural regime connecting the rules on the protection of human health and the environment to the rules on the trade, movement and the management of waste and chemicals. The oldest one, that is to say the Basel Convention, is the most inclusive global treaty dealing with hazardous waste materials during their lifecycles, from production and transport to final use and disposal. In fact, already in 1989 it aimed at reducing the hazardous waste generation and the promotion of their environmentally sound management, as well as at the restriction of transboundary movements of hazardous waste to the minimum consistent with the environmentally sound and efficient management of such waste and to be conducted in a manner which protects human health and the environment against the adverse effects which may result from such movement (article 4).

Thus, the Basel Convention introduced a regulatory system applying to cases where transboundary movements are permissible.²³ In fact, where transboundary movement is not, in principle, prohibited, it may take place only: if it represents an environmentally sound solution; if the principles of environmentally sound management and non-discrimination are observed; and if it is carried out in accordance with the Convention's regulatory system. Therefore, the Basel Convention was based on the concept of prior informed consent, which requires that, before an export may take place, the authorities of the State of export notify the authorities of the prospective States of import and transit, providing them with detailed information on the intended movement. The movement may only proceed if and when all States concerned have given their written consent (articles 6 and 7). Furthermore, hazardous wastes may not be exported to a State not party to the Basel Convention (article 4.5), or to a party having banned the import of hazardous wastes (article 4, lett. e). Parties may, however, enter into bilateral or multilateral agreements on hazardous waste management with other parties or with non-parties, provided that such agreements are "no less environmentally sound" than the Basel Convention (article 11).

Similarly, the Rotterdam Convention endorsed international efforts to protect human health and the environment by regulating the exports and imports of certain hazardous chemicals and pesticides on the basis of a similar Prior informed Consent

²¹ The Rotterdam Convention was adopted on 10 September 1998 and entered into force on 24 February 2004.

²² The Stockholm Convention was adopted on 22 May 2001 and entered into force on 17 May 2004.

²³ See Juliette Voinov Kohler, 'The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal 1989' in Malgosia Fitzmaurice, Attila Tanzi, Angeliki Papantoniou (eds), *Multilateral Environmental Treaties, Elgar Encyclopedia of Environmental Law* (V edn, Edward Elgar 2017) 331.

(PIC) procedure,²⁴ enunciated by the General Assembly in 1982 and introduced by UNEP and FAO in 1989. This Convention introduced, in fact, legal obligations for the implementation of such procedure with the aims 'to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use ...' (article 1).²⁵

In the same vein, the Stockholm Convention is a global treaty that focussed on the protection of human health and the environment from highly dangerous, long-lasting chemicals by restricting and ultimately eliminating their production, use, trade, release and storage. Based on the precautionary approach, it aimed to protect human health and the environment from persistent organic pollutants (POPs) that remain intact in the environment for long periods.²⁶ In particular, this Convention distinguishes between substances the production of which should be prohibited or eliminated at national level (Annex A), substances subject to less stringent restrictions (Annex B) and substances that can be formed and released unintentionally because of chemical processes and combustion (Annex C). It also distinguishes between substances whose import/export is forbidden and substances that can be exported or imported except for the purpose of environmentally sound waste management. More specifically, the Stockholm Convention, along with the Rotterdam Convention, was adopted in the framework of the United Nations after the 1992 Rio Summit and the commitments of the abovementioned Agenda 21 and Johannesburg Implementation Plan,²⁷ which put in evidence the issue of 'compliance with laws, regulations and standards that were adopted'.²⁸ The goal was to complete a synergistic process on the

²⁴ See, among others, Paula Barrios, 'The Rotterdam Convention on Hazardous Chemicals: A Meaningful Step Toward Environmental Protection?' (2004) 16 *The Georgetown International Environmental Law Review* 679; Ted L McDorman, 'The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade: Some Legal Notes' (2004) 13 *Review of European Community & International Environmental Law* 187.

²⁵ See Tarcisio Hardman Reis, 'Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade 1998, in Fitzmaurice, Tanzi, Papantoniou (n 22) 343.

²⁶ On this Convention, see Marco Antonio Olsen, *Analysis of the Stockholm Convention on Persistent Organic Pollutants* (Oceana Publications 2003).

²⁷ In this context, the Plan reaffirmed how this commitment required the ratification and implementation of international instruments, including the Rotterdam Convention and the Stockholm Convention and a strategic approach coordinated with other actors (para 23), as well as partnerships to promote activities aimed at enhancing environmentally sound management of chemicals and hazardous waste. It confirmed also some means for this purpose, such as the implementation of the globally harmonised system for the classification and labelling of chemicals and the development of coherent and integrated information on chemicals through national registers. In addition, the Plan reaffirmed the efforts to prevent international illegal trafficking of hazardous chemicals and waste and to prevent damage resulting from their transboundary movement, according to the Basel Convention.

²⁸ Paragraph 8.15 of Agenda 21 already described that: 'The enactment and enforcement of laws and regulations (at the regional, national, state/provincial or local/municipal level) are also essential for the

specific topic of hazardous waste, although at a considerable distance of time from the Basel Convention.

In sum, the three Conventions embody a regulatory regime on waste and chemicals adopted by States at a global level that aims to put in place coordination and synergy among environmental institutions, policies and legal instruments in order to mitigate the fragmentation of international environmental law.²⁹ This synergetic process culminated in the Simultaneous Extraordinary Meetings of the Conferences of the Parties to the Basel, Rotterdam and Stockholm Conventions (ExCOPs), which took place in Bali from 22nd to 24th February 2010 with a view to guaranteeing their implementation in a more coordinated way. Thus, since 2012 the three Conventions benefit from a common management and Secretariat that expand the mechanisms of environmental governance.³⁰ Nevertheless, this regime is not exhaustive³¹ and provides for the adoption of continuous updates that take into account new emergencies. In this direction, from 29 April to 10 May 2019, the conferences of the Parties to the Basel, Rotterdam and Stockholm Conventions (COPs) met in Geneva. The theme of this Triple COP was “Clean Planet, Healthy People: Sound Management of Chemicals and Waste” and one of the main concern was the adoption of decisions aimed to minimise plastic wastes, marine plastic litter and micro-plastics and better control their transboundary movement. In this direction, Governments amended the Basel Convention to make the international trade in plastic and hazardous waste more transparent, traceable and less impacting on developing nations.

implementation of most international agreements in the field of environment and development, as illustrated by the frequent treaty obligation to report on legislative measures. The survey of existing agreements undertaken in the context of conference preparations has indicated problems of compliance in this respect, and the need for improved national implementation and, where appropriate, related technical assistance. In developing their national priorities, countries should take account of their international obligations’. See William Bradnee Chambers, *Interlinkages and Effectiveness of Multilateral Environmental Agreements* (United Nations University Press 2008).

²⁹ See Gerhard Loibl, ‘International Environmental Regulations: is a Comprehensive Body of Law Emerging or Is Fragmentation Going to Stay?’ in Isabelle Buffard, James Crawford, Alain Pellet, Stephan Wittich (eds), *International Law between Universalism and Fragmentation: Festschrift in Honour of Gerhard Hafner* (Martinus Nijhoff Publishers 2008) 783.

³⁰ In fact, the Strategic Approach to International Chemicals Management (SAICM) is another initiative of international cooperation to protect human health and the environment that was endorsed in the Johannesburg Summit of 2002. It consists of three documents: the Dubai Declaration on International Chemicals Management, the Overarching Policy Strategy and the Global Action Plan. It was adopted during the International Conference on Chemicals Management in Dubai in 2006 with the aim of providing a policy framework.

³¹ Together with the Basel, Rotterdam and Stockholm Conventions, the Minamata Convention on Mercury of 2013 forms a comprehensive global regime for the sound management of chemicals and hazardous wastes. It is, in fact, a global treaty to protect human health and the environment from the adverse effects of mercury. See Laurent Vassallo, ‘L’adoption de la convention de Minamata, ou la longue marche vers un instrument international juridiquement contraignant sur le mercure’ (2013) 38 *Revue juridique de l’environnement* 237.

4. *The EU Legal Framework Regulating Waste Disposal and Chemicals*

The connection between commercial and economic interests concerning waste disposal and environmental protection is clear also in EU law, where the adoption by the European Union of the three Conventions gave rise to a judicial debate concerning the identification of the correct legal basis and the respect of the principle of sincere cooperation.³² As is well known, there was no trace of any reference to a Community environmental policy within the founding treaties of the European Communities. The need for cooperation in this area became a reality after the 1972 Stockholm Conference, when at the Paris Summit the Heads of state or government defined new fields of Community action concerning also the environment.³³ Thus, articles 100 and 235 of the EEC Treaty initially constituted the legal basis for the adoption of acts in this field. Some examples were the Council Directive (EEC) 75/442 of 15 July 1975 on waste³⁴ and Council Directive (EEC) 78/319 of 20 March 1978 on toxic and dangerous waste,³⁵ which considered the protection of human health and the environment the essential objective of all provisions relating to waste disposal.³⁶ However, a new title specifically dedicated to environmental protection and consisting of articles 130 R, 130 S and 130 T was introduced with the Single European Act (then articles 174-176 ECT and now articles 191-193 TFEU). Within this new framework, a system of lists and catalogues of waste and hazardous waste was introduced.³⁷ In 2000, the Commission adopted a replacement decision,³⁸ which established a single classification system for wastes, including a distinction between hazardous and non-hazardous wastes. Then, the Amsterdam Treaty (article 6 ECT) established that environmental protection should have had a cross-cutting value in the context of Community policies and specifically stated that: 'environmental protection requirements must be integrated into the definition and implementation

³² See Nicolas de Sadeleer, *EU Environmental Law and the Internal Market* (OUP 2014) 126.

³³ See Ian Bailey, *New Environmental Policy Instruments in the European Union: Politics, Economics, and the Implementation of the Packaging Waste Directive* (Routledge 2003).

³⁴ [1975] OJ L194/75.

³⁵ [1978] OJ L84/78.

³⁶ See Nicolas de Sadeleer, Jacques Sambon, 'The Concept of Hazardous Waste in European Community Law' (1997) *European Environmental Law Review* 9.

³⁷ The first European Waste Catalogue (EWC) and hazardous waste list were published as two separate documents: Commission Decision (EC) 94/3 establishing a list of wastes pursuant to Article 1(a) of Council Directive (EC) 75/442 on waste [1994] OJ L 5/94, and Council Decision (EC) 94/904 establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive (EEC) 91/689 on hazardous waste [1994] OJ L356/94.

³⁸ Commission Decision (EC) 2000/532 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste [2000] OJ L226/3 and subsequent amendments.

of the Union's policies and activities, in particular with a view to promoting sustainable development'. The following Treaties confirmed this aim (now article 11 TFEU).³⁹

With specific reference to the environmental pollution from waste, the main framing effort came with the adoption of Directive (EC) 2008/98,⁴⁰ better known as Waste Framework Directive, which provided for a general framework of waste management requirements and set the basic waste management definitions for the EU. The Waste Framework Directive laid down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving efficiency.⁴¹ This Directive was also supplemented by other acts concerning specific waste, such as the Directive on waste electrical and electronic equipment (WEEE Directive).⁴² With regard to chemicals that are essential for economy and daily life, the Regulation (EC) 1907/2006 introduced a system for the Registration, Evaluation, Authorisation and Restriction (REACH Regulation), also establishing a European Chemicals Agency.⁴³ This Regulation, pursuant to the abovementioned Johannesburg Implementation Plan, established that the European Union aims to achieve that, by 2020, chemicals are produced and used in ways that lead to minimise the significant adverse effects on human health and the environment. It introduced a new system aimed at encouraging and in certain cases ensuring that substances of high concern were eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. Additionally, this Regulation was based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions,

³⁹ See Hans Hermann Bernard Vedder, 'The Treaty of Lisbon and European Environmental Law and Policy' (2010) 22 *Journal of Environmental Law* 285.

⁴⁰ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives [2008] OJ L312/08, such as Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste [2006] OJ L114/06, recently amended by Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 [2018] OJ L150/109.

⁴¹ This was adopted according to article 175.1 TEC.

⁴² Directive (EU) 2012/19 of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) [2012] OJ L197/12. See also Directive (EU) 2018/849 of the European Parliament and of the Council of 30 May 2018 amending Directives 2000/66/EC on batteries and accumulators, and 2012/19/EU on waste electrical and electronic equipment [2018] OJ L150/193.

⁴³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC [2007] OJ L136/3, amended several times.

human health and the environment are not adversely affected.⁴⁴ Together with the REACH Regulation, the so-called CLP Regulation from the acronym of Classification, Labeling and Packaging of substances and mixtures⁴⁵ completed the revision of the European legislation on chemicals.

4.1. ... and Implementing the Three Global Conventions

In this regulatory context, the European Union had also introduced a legislation concerning the export and import of certain dangerous chemicals,⁴⁶ that was replaced when the EU adopted the Rotterdam Convention according to the Regulation (EC) 304/2003.⁴⁷ The particular characteristics of the Convention brought the Commission to seek the annulment of this Regulation in so far as it was based on article 175(1) EC and not on article 133 EC.⁴⁸ In the Commission's reasoning, the commercial need aimed at avoiding any distortion of intra-Community trade was prevalent. On the contrary, the Court annulled the contested Regulation because it considered that both its purposes and terms contained commercial and environmental components, which were so indissociably linked that recourse to both article 133 EC and article 175(1) EC was required. In particular, the Court pointed out how the primary objective of the Regulation was to implement the Convention that specifically included two components regulating trade and protecting human health and the environment. This was evident from the provisions of the Regulation that highlighted the purporting to operate in parallel with the Convention. Nevertheless, the Court underlined how the Community legislature displayed a clear intention to 'go further than the provisions of the Convention in certain respects'.⁴⁹ In conclusion, a

⁴⁴ For a deeper analysis of the Regulation, see Stephen Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing 2015).

⁴⁵ Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [2008] OJ L353/1 and subsequent amendments.

⁴⁶ Council Regulation (EEC) 2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals [1992] OJ L251/13.

⁴⁷ Regulation (EC) 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals [2003] OJ L63/1. See David Langlet, 'Prior Informed Consent for Hazardous Chemicals Trade – Implementation in EC Law' (2003) 12 *European Environmental Law Review* 292.

⁴⁸ The Commission used article 133 TEC in the Proposal for a Council regulation concerning the export and import of dangerous chemicals (OJ 2002 C 126 E, p. 291). After the Parliament had been consulted on an optional basis pursuant to article 133 TEC, the Council of the European Union unanimously decided not to accept that proposal and to replace article 133 EC by article 175(1) EC. It was the sole legal basis of the contested regulation, then adopted jointly by the Parliament and the Council under the procedure of article 251 TEC.

⁴⁹ Case C-178/03 *Commission v European Parliament and Council* [2006] ECR I-00107.

new Regulation (EC) 689/2008⁵⁰ was adopted that was then recast into Regulation (EU) 649/2012.⁵¹

A similar objection was raised with reference to the Regulation (EC) 1013/2006⁵² on shipments of waste as the Commission asked the Court to annul this Regulation in so far as it was based solely on article 175(1) EC and not on articles 175(1) and 133 EC. This Regulation was adopted to replace and update the provisions of Council Regulation (EEC) 259/93 on the supervision and control of shipments of waste and, inter alia, to implement the obligations under the Basel Convention. However, in this case the Court dismissed the action because the preamble to the contested Regulation confirmed the environmental purpose and it did not make any reference to the pursuit of objectives falling within the common commercial policy. The Court observed from the content of the Regulation that the principal instrument established by it is the prior written notification and consent procedure, aimed at ensuring that shipments of waste were carried out in a manner which respects the need to protect the environment. Therefore, the Court concluded that the contested Regulation could be described as a typical instrument of environmental policy because, both by its objective and content, resulted that it is aimed primarily at protecting human health and the environment against the potentially adverse effects of cross-border shipments of waste.⁵³

With reference to the Stockholm Convention, the issue of particular interest was the respect of the principle of sincere cooperation in the light of the distribution of competences between Member States and the Union in environmental matters (now article 4.2, lett. e, TFEU). As is well known, the Community had already adopted instruments covering matters governed by the Stockholm Convention, including Regulation (EC) 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants (the so-called POPs regulation).⁵⁴ The Stockholm Convention was instead approved on behalf of the European Community by Council Decision (EC) 2006/507 of 14 October 2004.⁵⁵ This Convention establishes an institutional and procedural framework containing a body of specific rules for the adoption of amendments, including the listing of new substances in Annexes A, B or C. In this case, the European Commission considered that the Kingdom of Sweden had failed to fulfil its obligations

⁵⁰ [2008] OJ L204/1.

⁵¹ [2012] OJ L201/60.

⁵² Regulation (EC) 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste [2006] OJ L190/1 and subsequent amendments.

⁵³ Case C-411/06 *Commission v European Parliament and Council*, [2009] ECR I-07585.

⁵⁴ [2004] OJ L229/5 and subsequent amendments. This Regulation amended Council Directive (EEC) 79/117 of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances OJ L 33/36.

⁵⁵ [2006] OJ L209/1.

under articles 10 TEC and 300(1) TEC by unilaterally proposing that a certain substance (perfluorooctane sulfonate, PFOS), was added to Annex A to the Stockholm Convention.⁵⁶ In particular, the Commission pointed out that unilateral proposal, which dissociates the Member State in question from a concerted common strategy within the Council, would have had the consequence of splitting the international representation of the Community and compromising the unity achieved both during the first Conference of the Parties to that Convention.⁵⁷ Such unilateral action would have resulted in an amendment to the POPs regulation, depriving the Commission of its right of initiative in an area to a large extent covered by Community competence and depriving the Council of the opportunity of deciding on the submission of a proposal for the listing of that substance pursuant to article 300(1) EC.⁵⁸ In conclusion, the ruling placed particular emphasis on the obligations arising from the principle of sincere cooperation in the context of external relations. The Court in fact concluded that the Commission's complaint, alleging breach of article 10 EC, was well founded.⁵⁹ This principle includes a duty of the Member States to facilitate or at least not hinder the achievement of the objectives set by the Treaties even in areas where there is no originally exclusive competence.⁶⁰

Therefore, the implementation of these three Conventions had to cope with the tools previously adopted on the same subjects by the European Union. It also had to deal with the interpretation of the Court of Justice on the concept of waste intended 'widely in order to limit its inherent risks and pollution'.⁶¹ Moreover, their imple-

⁵⁶ Case C-246/07 *European Commission v Kingdom of Sweden* [2010] ECR I-03317: 'The unilateral action on the part of the Kingdom of Sweden thus resulted in splitting the international representation of the Community as regards the listing of PFOS under the Stockholm Convention, which is contrary to the obligation of unity in international representation of the Community which arises out of the duty of cooperation in good faith in Article 10 EC', paras 55 and 104.

⁵⁷ On the contrary, Member States considered that they are entitled to adopt national rules more stringent than the POPs regulation on the ground that the Regulation constituted only minimum Community rules with the consequence that according to article 176 EC they are entitled to submit proposals for amendments to the Annexes to the Stockholm Convention and to adopt national rules for the protection of the environment.

⁵⁸ According to the Commission, the purpose of the Kingdom of Sweden's proposal was to establish a new international legal rule, which would have the direct effect of affecting Community law since it would give rise to an obligation to amend the POPs regulation.

⁵⁹ Conversely, the Court concluded that the complaint alleging breach of article 300(1) TEC was not well founded.

⁶⁰ See Marise Cremona, 'Case C-246/07 *Commission v. Sweden* (PFOS), judgment of the Court of Justice (Grand Chamber) of 20 April 2010' (2011) 48 *Common Market Law Review* 1639.

⁶¹ See, among many others, Case C-9/00 *Palin Granit Oy and Vehmässalon kansanterveystyön kuntayhtymän hallitus* [2002] ECR I-03533, para. 36. For a reconstruction of the definition, see Jurgita Malinauskaite, Hussam Jouhara, Nik Spencer, 'Waste Prevention and Technologies in the Context of the EU Waste Framework Directive: Lost in Translation?' (2017) 26 *European Energy and Environmental Law Review* 66.

mentation had to deal with the discretion of the Member States through the adoption of their own national disciplines.⁶²

5. Conclusions: Is There Any Balance Between Public Health and Environmental Protection and Economic Needs?

In light of the foregoing, it can be argued that a difficult balance between economic needs and environmental and health protection emerges when it comes to waste- and chemical-related issues. First, a global approach to dealing with waste has developed only slowly and recently. This global approach has been mainly directed to waste reduction and management, trying to influence the industrial production and disposal processes regulated by States. Therefore, the concept of sustainable development ended up to include the waste component more because of the contrast between the industrialized countries that need to dispose of hazardous waste and developing countries that claim their right to economic development.⁶³ In fact, waste management is not only a question of ecology and environmental protection, but also a political issue and above all an economic issue as the transboundary movement of waste is a business of vast proportions.⁶⁴

The use of multilateral environmental agreements, and in particular of the three Conventions of Basel, Rotterdam and Stockholm, has highlighted how special regimes and models of political governance have developed under the international environmental law⁶⁵ and how these Conventions have been completed with institutional framework mechanisms whose task is to consider compliance in general and, especially, cases of alleged non-compliance by State Parties.⁶⁶ Nevertheless, the regulation of hazardous waste and chemicals does not have a unitary framework in international law.⁶⁷ There is no general definition always valid and there are no general

⁶² Case C-389/00 *Commission of the European Communities v Federal Republic of Germany* [2003] ECR I-02001.

⁶³ Lisa Widawsky, 'In My Backyard: How Enabling Hazardous Waste Trade to Developing Nations Can Improve the Basel Convention's Ability to Achieve Environmental Justice' (2008) 38 *Environmental Law* 577.

⁶⁴ See Mirina Grosz, *Sustainable waste trade under WTO law: chances and risks of the legal frameworks' regulation of transboundary movements of wastes* (Brill Nijhoff 2011).

⁶⁵ See Bharat H. Desai, *International Environmental Governance: Towards UNEPO* (Brill Nijhoff 2014).

⁶⁶ See Tullio Treves and others (eds), *Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements* (T.M.C. Asser Press 2009).

⁶⁷ See Bharat H. Desai, *Multilateral Environmental Agreements. Legal Status of the Secretariats*, (Cambridge University Press 2010); Sandrine Maljean-Dubois and Lavanya Rajamani (eds), *La mise en œuvre du droit international de l'environnement. Implementation of International Environmental Law* (Martinus Nijhoff 2011) 251.

provisions applicable to all hazardous waste and chemicals. The same definition of waste is widely discussed and otherwise understood on a case by case basis. Furthermore, technological development leads to constantly reviewing pollutants. Therefore, the protection of human health and the environment have ended up being instrumental to the political and economic needs of the States.

Indeed, major public health challenges posed by waste and chemicals have been addressed by international law, but the legal responses have not always been adequate as they are subject to the will of States. As discussed above, international environmental law has played a fundamental role in protecting public health, combining the dual objective of protecting the environment and human health. Nevertheless, health effects from waste pollution and chemical exposure are dramatic. The UN environment agency warns in the UN Environment's sixth Global Environment Outlook of 2019, which was produced by 250 scientists and experts from more than 70 countries, that humanity is 'at a crossroads' as damage to the planet poses growing risk to public health. There could be millions of premature deaths by the middle of this century, with pollutants in freshwater systems becoming a major cause of death by 2050.⁶⁸ Therefore, political choices are now urgent.

At the regional level and, in particular, from the EU legal perspective, the European Union has put in place a coordination effort in the implementation of the three Conventions that have become an integral part of EU law, binding on both EU institutions and Member States, but according to its own competences and the autonomy of its environmental policy on waste.⁶⁹ Furthermore, the EU adopted a wide range of legal and political instruments, such as the new strategy that aims to strengthen the transformation of waste into economic resources and thus to their regeneration for the purposes of a circular economy. In this direction, the goal is to combine the protection of the environment and human health and economic growth in a more balanced way, or at least to promote an economy instrumental to the protection of the environment and human health.

Thanks to the new environmental policy instruments, the European Commission, in fact, established revised targets for reduction of waste and for an ambitious and credible long-term path for waste management and recycling based on a Circular Economy Package (CEP).⁷⁰ According to the European Commission, the CEP

⁶⁸ UN Environment, Global Environment Outlook 6, 4 March 2019, available at <www.unenvironment.org/resources/global-environment-outlook-6>.

⁶⁹ See the EU declarations attached to the Rotterdam and Stockholm Convention in the part in which they stated that: "The European Community is responsible for the performance of those obligations resulting from the Convention which are covered by Community law in force. The exercise of Community competence is, by its nature, subject to continuous development". See Martin Hedemann-Robinson, 'EU Enforcement of International Environmental Agreements: The Role of the European Commission' in Ludwig Krämer (ed), *Enforcement of Environmental Law* (Edward Elgar 2016) 466.

⁷⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Plastics in a Circular Economy, COM/2018/028 final and the latest Report from the Commission to the Euro-

should help 'European businesses and consumers to make the transition to a stronger and more circular economy where resources are used in a more sustainable way'.⁷¹ In a circular economy, in fact, resources are used for as long and as productively as possible, and at the end of their useful life they are recovered and regenerated. Nevertheless, as the same Commission pointed out, the adoption of additional acts⁷² and a revised legislative framework on waste⁷³ are necessary since the EU's rules on end-of-waste are not fully harmonized, making it uncertain how waste becomes a new material and product. Consequently, many recovered materials are traded and used in the absence of established end-of-waste criteria and therefore under unclear legal circumstances and without transparency.

All this means that the challenges for environmental health are rapidly increasing, thus requiring that international and EU environmental law further develop in step with the pressing need for intervention.

pean Parliament, the Council, the European Economic Committee and the Committee of the Region on the implementation of the Circular Economy Action Plan, COM(2019) 190 final, Brussels 4.3.2019.

⁷¹ See <http://europa.eu/rapid/press-release_IP-15-6203_en.htm>.

⁷² See, for example, the proposal for a Directive on the reduction of the impact of certain plastic products on the environment, COM (2018) 340 final.

⁷³ See the amendments of the previous directives and regulations published in OJ L150, 14 June 2018.



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Chapter 12

Water Quality and the Impact on Human Health and the Environment: The Current International and EU Regulatory Framework

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‘Water is not a commercial product like any other but, rather, a heritage which must be protected, defended and treated as such.’¹

1. *Introduction*

The importance of water resources in international and European Union (EU) law derives from the fact that nearly 900 million people do not have access to safe drinking water and over 2.6 billion to basic sanitation. Astonishingly, water - and sanitation- related diseases lead to the death of around 1.5 million infants and the loss of 443 million school days annually.²

At the international level, the UN General Assembly Resolution 64/292 recognizes ‘the right to safe and clean drinking water and sanitation as a human right that is essential for the full enjoyment of life and all human rights’.³ Consequently, stopping the unsustainable exploitation of water resources and halving the proportion of people who are unable to reach or to afford safe drinking water are some of the main challenges in the protection and promotion of sustainable development that UN

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¹ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (WFD) [2000] OJ L327/1, preamble.

² United Nations Millennium Declaration, A/55/L.2, Section III and IV. On water resources in international law, see Anna Oriolo and Anna Vigorito (eds), *L’EAU* – *Questions juridiques et économiques concernant la gestion, l’utilisation et la protection des “ressources hydriques”: perspectives comparées et internationales* (Aracne 2012).

³ The Human Right to Water and Sanitation, A/RES/64/292, 28 July 2010, preamble. See Malgosia Fitzmaurice, ‘The Human Right to Water’ (2006-2007) 18 *Fordham Environmental Law Review* 537.

Member States agreed to reach also at the 3rd International Conference on Sustainable Development (Rio +20) in 2012.

In the outcome document of the Rio+20 Summit, titled “The Future We Want”, heads of State, Government and high level representatives reasserted their ‘commitments regarding the human right to safe drinking water and sanitation, to be progressively realised for [their] populations with full respect for national sovereignty’.⁴ These assurances were reaffirmed in 2015 when the heads of State committed to Sustainable Development Goal 6 and reaching its associated target by 2030 regarding ‘achieving universal and equitable access to safe and affordable drinking water for all’.⁵

At the European level, and in accordance with the Charter of Fundamental Rights of the European Union, the right to life and human dignity subsumes access to safe drinking water and sanitation, and an adequate standard of living.⁶

The Parliamentary Assembly of the Council of Europe specified ‘that access to water must be recognised as a fundamental human right because it is essential to life on earth and is a resource that must be shared by humankind’.⁷ The EU has also reiterated that ‘all States bear human rights obligations regarding access to safe drinking water, which must be available, physically accessible, affordable and acceptable’.⁸

Therefore, water safety and quality are fundamental in promoting the human right to health, yet, in the pan-European region, access to water and sanitation remains a challenge, with specific groups of the population in all countries facing real barriers.⁹

In particular, the microbiological quality of water is essential to preventing infectious and parasitic diseases, such as cholera, typhoid, dysentery, hepatitis, giardiasis, guinea worm, and schistosomiasis. Hence, adequate water management and sanitation policies play a significant role in preventing waterborne diseases (WBDs).

The aim of this article is to assess the efficiency of the current international and EU regulatory framework concerning water quality, health promotion, and disease prevention.

⁴ A/RES/66/288 - The Future We Want, 11 September 2012, para 121. See Anna Oriolo and Anna Vigorito, ‘Le droit à l’eau en tant que droit de l’homme au niveau international et européen. Sa mise en oeuvre “en harmonie avec la nature” dans “L’avenir que nous voulons”’ in Malgosia Fitzmaurice, Sandrine Maljean-Dubois and Stefania Negri (eds), *Environmental Protection and Sustainable Development from Rio to Rio+20 and Beyond* (Brill-Nijhoff 2014) 197-222.

⁵ United Nations General Assembly Resolution of 25 September 2015 “Transforming our world: The 2030 Agenda for Sustainable Development”. This Agenda was adopted in September 2015 and includes a set of 17 Sustainable Development Goals, which are broken down into 169 specific targets and 232 monitoring indicators.

⁶ Charter of Fundamental Rights of the European Union [2012] OJ C326/391.

⁷ Resolution No. 1693/2009 of the Parliamentary Assembly of the Council of Europe.

⁸ Declaration by the High Representative, Catherine Ashton, on behalf of the EU to commemorate World Water Day (Doc 7810/10), 22 March 2010.

⁹ The 2010 Parma Declaration on Environment and Health provides as key environment and health challenges, for example, the health risks posed to children as vulnerable groups by poor environmental, working, and living conditions (especially the lack of water and sanitation) (see WHO EUR/55934/5.1 Rev. 2 11 March 2010, art 3).

To this end, starting from the World Health Organization's (WHO) guiding role in promoting universal, affordable, and sustainable access to water, sanitation, and hygiene (WASH), the paper critically analyses the regional legal instruments adopted to reduce the level of waterborne disease transmission and achieve the Sustainable Development Goals, including the 1999 WHO-United Nations Economic Commission for Europe (UNECE) Protocol on Water and Health, and the 2018 EU Commission proposal for modernizing the 20-year old Drinking Water Directive.¹⁰

2.1. The New UN “International Decade (2018-2028) for Action - Water for Sustainable Development”: Toward Hydro-Diplomacy

Historically, the United Nations has focused on water as a critical resource for sustainable development and the eradication of poverty and hunger, emphasizing that water, energy, food security, and nutrition are linked, and that water is indispensable for human development, health and wellbeing, as well as a vital element for achieving the Sustainable Development Goals (SDGs) and other relevant targets in the social, environmental, and economic fields.¹¹

A more recent milestone to accelerate efforts toward meeting the water-related challenges is the 2016 UN General Assembly Resolution “International Decade (2018–2028) for Action - Water for Sustainable Development” that began in March 2018.¹² The Resolution reaffirms the sustainable development goals and targets related to water resources, including those contained in the 2030 Agenda for Sustainable Development, and determined to achieve SDG 6 ensuring the availability and sustainable management of water and sanitation for all, as well as other associated targets. In particular, safe water, sanitation, and hygiene are essential to meeting targets 6.1 and 6.2 of SDG 6, namely, universal and equitable access to safe water for all, access to adequate and equitable sanitation and hygiene for all, ending open defecation, and paying specific attention to the needs of women, girls, and those in vulnerable situations. SDG 6 is also important to prevent conflicts and sustain peace, as water shortages, aggravated by climate change or other water-related disasters, can lead to fierce clashes between people, communities, and nations.

With regard to the implementation of the 2018-2028 Decade, the President of the UN General Assembly stressed the need to invest in “hydro-diplomacy” and wa-

¹⁰ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption [1998] OJ L330/32.

¹¹ See, for example, The United Nations Water Conference (1977), the International Drinking Water Supply and Sanitation Decade (1981-1990), the International Conference on Water and the Environment (1992), and the Earth Summit (1992).

¹² A/C.2/71/L.12/Rev.1, 25 November 2016. The decade would commence on World Water Day, 22 March 2018, and end on World Water Day, 22 March 2028.

ter-related mediation. More precisely, SDG 6 should be achieved through the adoption of a conflict-prevention approach. In the President's words, '[w]hen basins and streams run dry, tensions flare – between communities, and across borders. We need to study the good examples we have seen of shared water management – and replicate them in other settings'.¹³

Furthermore, WASH-related SDGs include Target 1.4 on improving access to basic services, and SDG Target 4 on building and upgrading adequate WASH services in schools. Additionally, WASH is also critical to 'ensuring healthy lives and promote wellbeing for all at all ages' as recalled in SDG 3 and especially in the related targets 3.1 to reduce maternal mortality, 3.2 to end preventable deaths of newborns and children, 3.3 to end epidemics of major diseases, including waterborne diseases, and 3.9 to reduce the number of deaths and illnesses from hazardous chemicals, air, water, and soil pollution and contamination.

In accordance with the 2018-2028 Decade Resolution, these objectives should be pursued, *inter alia*, by improving knowledge generation and dissemination, facilitating access to such knowledge and exchanging good practices, generating new information relevant to the water-related SDGs, pursuing advocacy, networking, and promoting the partnerships and actions of different actors to implement the these goals and targets in coordination with existing initiatives, strengthening communication actions at various levels for the implementation of the goals.¹⁴

2.2. Improving Health through WASH: The WHO's Longstanding Role

Hygiene and sanitation are recognized in the WHO's Constitution,¹⁵ and for decades WASH issues have been a constant in the Organization's initiatives and strategies.

The WHO does not directly implement WASH infrastructure projects, but as a technical agency has played an enduring and relevant role in creating and promoting

¹³ Statement by H.E. Mr. Miroslav Lajčák, President of the 72nd session of the UN General Assembly, at towards implementation of the International Decade Of Action "Water for sustainable development", 2018-2028.

¹⁴ The Resolution also stresses the importance of the participation and full involvement of all relevant stakeholders, including women, children, young people, older persons, persons with disabilities, indigenous peoples, and local communities, in the implementation of the Decade at all levels, and invites the Secretary-General, with the support of UN-Water, to take appropriate steps, within existing resources, to plan and organize the activities of the Decade at the global, regional, and national levels, taking into account the outcomes of the International Decade for Action, "Water for Life", 2005-2015, and the work of the high-level political forum on sustainable development, and other relevant United Nations structures, as well as the High-Level Panel on Water.

¹⁵ See WHO Constitution, art 2. The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States and entered into force on 7 April 1948.

international guidelines and standards, providing technical advice on water quality management, sanitation, and wastewater.

In response to the 2030 Agenda for Sustainable Development and the related SDGs, the WHO developed a strategic plan for WASH aiming to ‘substantially improve health through the safe management of water, sanitation and hygiene services in all settings’.¹⁶ The WHO’s new 2018-2025 water, sanitation, and hygiene strategy reinforces its traditional role as an authoritative and leading source of reference for policymaking, increasing effectiveness through the introduction of transformational approaches and tackling new domains such as WASH in healthcare facilities.

In brief, the following eight principles inspire the WHO’s WASH strategy: 1) focus on areas with the greatest public health benefits; 2) boost health sector capabilities, including positive outbreak response systems; 3) promote the SDGs and relative targets relating to health, climate change, nutrition, and human rights principles; 4) exploit leading quality science through gathering, reviewing, and using the findings on WASH health effects, developing norms and good practices; 5) foster gradual improvement in supporting countries to establish national WASH standards and goals that are achievable; 6) exploit regional policy frameworks that promote WASH, and specify national targets; 7) promote sustainable change by strengthening those institutions and systems assigned to implement, oversee, and regulate WASH service delivery; 8) engage and positively influence partnerships to ensure the WASH sector health issues are addressed, particularly in healthcare facilities.

In addition, the new guidelines set out four main sanitation recommendations: a) ensure communities have access to toilets that safely contain waste; b) local health risk assessments to protect individuals and communities from exposure to waste from unsafe toilets, leakages, or poor treatment; c) integration with local government planning and service providers to avoid the costs of retrofitting sanitation and ensure sustainability; d) greater investments and coordination in sanitation planning.

The WHO also acts as global monitor of the UN Millennium Development Goal 6; more precisely, since 1990, together with the United Nations Children’s Fund (UNICEF), implementing the Joint Monitoring Programme (JMP) for Water Supply, Sanitation, and Hygiene. The aims of the JMP are to examine managed drinking water services in the context of the Agenda for Sustainable Development and track progress on global water and sanitation challenges through: monitoring trends; helping develop monitoring capabilities in developing countries; creating and coordinating questionnaires, measures, and definitions to ensure the comparability of data over time and across nations; updating policymakers on global water supply and the status of the sanitation sector through relevant publications. In ad-

¹⁶WHO water, sanitation and hygiene strategy 2018-2025 (2018), available at <www.who.int/water_sanitation_health/publications/wash-strategy-2018-2025/en/> accessed January 2019.

dition, JMP makes recourse to a technical advisory group of leading water supply, sanitation, and hygiene experts, as well as institutions involved in data collection and sector monitoring.¹⁷

The JMP also provides a normative interpretation of each of the terms used in target 6.1 by 2030: achieve universal (ie, related to all exposures and settings, including households, schools, health facilities, workplaces, and public spaces) and equitable (ie, progressive reduction and elimination of inequalities between population subgroups) access (sufficient water to meet domestic needs reliably available close to home) to safe (free from pathogens and elevated levels of toxic substances at all times) and affordable (without barriers to access or preventing meeting other basic human needs) drinking water (ie, water for drinking, cooking, food preparation, and personal hygiene) for all (men, women, children of all ages, and those with disabilities).

While all these elements are currently not routinely measurable in all countries, the JMP's approach to global monitoring aims to reflect the normative interpretation to the fullest extent.¹⁸

2.3. From Non-Binding Guidelines to Legal Obligations for International WBDs Management: The WHO-UNECE Protocol on Water and Health

Although establishing an effective WBDs surveillance system is important to reducing and controlling water-related diseases, the current recommended guideline limits are not mandatory and should be set by national authorities using a risk-benefit approach, taking into consideration the local environmental, social, economic, and cultural conditions. Thus, most supranational instruments concerning the management of waterborne outbreaks are not compulsory.

The first international agreement setting numerous legal obligations in the area of water supply and sanitation is the Protocol on Water and Health to the 1992 Convention on the Protection and Use of Transboundary Watercourses and International Lakes (Water Convention).

The main aim of the 1999 WHO-UNECE Protocol is to protect human health and wellbeing, promote the integration of sustainable water management policies,

¹⁷The WHO/UNICEF JMP for Water Supply, Sanitation and Hygiene has published its first report of the SDG period, Progress on drinking water, sanitation and hygiene: 2017 update and SDG baselines. The report introduces and defines the new indicators of safely managed drinking water and sanitation services <<https://apps.who.int/iris/bitstream/handle/10665/258617/9789241512893-eng.pdf>> accessed January 2019.

¹⁸WHO/UNICEF, Safely Managed Drinking Water - Thematic Report on Drinking Water 2017 <https://data.unicef.org/wp-content/uploads/2017/03/safely-managed-drinking-water-JMP-2017-1.pdf> accessed January 2019.

and report, prevent, and reduce water-related diseases in the UNECE region.¹⁹ This region covers Europe and all succession States of the former Soviet Union in Eastern Europe, the Caucasus, and Central Asia.²⁰

To support the protection of human health and wellbeing (both individual and collective) at the national, transboundary, and international level under the sustainable development framework, the Protocol requires Parties to take all appropriate measures 'to prevent, control and reduce water-related disease within a framework of integrated water-management systems aimed at sustainable use of water resources, ambient water quality which does not endanger human health, and protection of water ecosystems'.²¹

Under Article 4, the Parties shall, in particular, ensure: (a) untainted drinking water devoid of micro-organisms, parasites, and substances that due to their quantity or accumulation may endanger human health, safeguarding drinking water sources and resources, establishing, improving, and maintaining collective systems, and the treatment of water; (b) hygiene standards that adequately protect human health and the environment through the collective systems;²² (c) protecting sources of drinking water and their related water ecosystems from pollution deriving from agriculture, industry, and the emission of substances deemed harmful to human health and water ecosystems; (d) appropriate safeguards against water-related diseases when used for recreational ends, aquaculture, shellfish production or harvesting, waste water used for irrigation, and sewage sludge in agriculture or aquaculture; (e) effectively monitoring and counteracting situations that may lead to the manifestation of water-related diseases and their risks.

With a view to achieving adequate access to drinking water and sanitation for all, the Protocol stipulates two core provisions: target setting and surveillance.

First, it requires Parties to establish and publish national and/or local targets (and target dates) for the standard and levels of performance that need to be achieved or maintained for a high degree of protection against water-related disease. These targets shall cover, inter alia, (a) the provision of drinking water with regard to the WHO

¹⁹ For the purposes of the Protocol, "water-related diseases" include death, disability, illness or disorders (or any significant adverse effects on human health) caused directly or indirectly by the condition, or changes in the quantity or quality, of any waters (see WHO-UNECE Protocol, art 2).

²⁰ The Protocol was adopted in 1999 at the Third Ministerial Conference on Environment and Health in London and entered into force in 2005, becoming legally binding for the ratifying countries. To date, 26 countries have ratified it, covering about 60% of the population of the WHO European Region.

²¹ WHO-UNECE Protocol, art 4.

²² Under art 2 (9) of the WHO-UNECE Protocol: "Collective system" means: (a) A system for the supply of drinking water to a number of households or undertakings; and/or (b) A system for the provision of sanitation which serves a number of households or undertakings and, where appropriate, also provides for the collection, transport, treatment and disposal or reuse of industrial waste water, whether provided by a body in the public sector, an undertaking in the private sector or by a partnership between the two sectors'.

Guidelines for drinking-water quality; (b) the reduction of water-related diseases; (c) effective systems to manage, develop, protect, and use water resources, adopting the established good practices to control pollution from all types of sources.

In addition to the measures to promote equitable access to water and sanitation, Article 5 of the Protocol also specifically commits its Parties to giving due account to the environmental principles as fundamental components of the human right to water. These include the polluter-pays principle, the precautionary approach, and access to information and public participation in decision-making concerning water and health.

More specifically, action to prevent, control, or reduce water-related disease shall not be postponed on the grounds that scientific research has not fully proven a causal link between the factor at which such action is aimed on the one hand, and the potential contribution of that factor to the prevalence of water-related diseases and/or transboundary effects on the other hand; the costs of pollution prevention, control, and reduction shall be borne by the polluter; finally, the public shall have the opportunity to express its concerns, and public authorities shall take due account of such concerns through appropriate access to judicial and administrative reviews of the relevant decisions.

As for the surveillance mechanisms, Article 8 of the Protocol mandates that Parties establish, maintain, or improve comprehensive national and/or local control and early-warning systems to prevent and respond to water-related disease, which will: (i) detect actual or significant threats of water-related disease outbreaks or incidents, including from water-pollution incidents or extreme climactic events; (ii) duly notify the relevant public authorities about such outbreaks, incidents, or threats; (iii) in the event of any impending threat, ensure all members of the public who may be affected have all the information that could assist in preventing or lessening harm; (iv) provide the pertinent public authorities, and when relevant to the public, guidance on preventive and remedial actions.²³

Additionally, national contingency and outbreak response plans shall be adopted to ensure the efficiency of the response system under the Protocol.²⁴

To review and facilitate adherence to the Protocol, a Compliance Committee composed of nine independent members was established in 2007²⁵ to examine compliance issues (lodged by State Parties or members of the public), make recommendations or take measures as and when appropriate, provide advice and assistance, request developing a plan to achieve compliance or submit intermittent progress reports on compliance efforts.

²³ Protocol, art 8 (1).

²⁴ Protocol, art 8 (2).

²⁵ Report of the First Meeting of the Parties to the Protocol on Water and Health of the Convention on the Protection and Use of Transboundary Watercourses and International Lakes (Geneva, 17-19 January 2007), ECE/MP.WH/2/Add.3 EUR/06/5069385/1/Add.3, 3 July 2007.

3. The EU (Drinking) Water Policy

3.1. Protection and Sustainable Use of Water in European Countries

Safeguarding water resources, fresh and salt water ecosystems, and the water we drink and bathe in is one of the cornerstones of environmental protection in Europe. The implications are far-reaching, and concrete measures are needed at the EU level to ensure effective protection.

The main legislative instrument for the protection and sustainable use of water in EU countries is the Water Framework Directive (WFD) adopted under Article 175(1) of the Treaty establishing the European Community (EC) (now Article 192 of the Treaty on the Functioning of the European Union (TFEU)).²⁶

The WFD establishes the common principles and an overall framework for action in relation to water protection, as well as coordinating, integrating and, over the longer term, developing the overall principles and structures for the protection and sustainable use of water in the European Union.²⁷

The purpose of this Directive is to establish an agenda for the protection of inland surface waters, transitional waters, coastal waters, and groundwater that: '(a) prevents further deterioration and protects and enhances the status of aquatic ecosystems and, with regard to their water needs, terrestrial ecosystems and wetlands directly depending on the aquatic ecosystems; (b) promotes sustainable water use based on a long-term protection of available water resources; (c) aims at enhanced protection and improvement of the aquatic environment, inter alia, through specific measures for the progressive reduction of discharges, emissions, and losses of priority substances and the cessation or phasing-out of discharges, emissions and losses of the priority hazardous substances; (d) ensures the progressive reduction of pollution of groundwater and prevents its further pollution; and (e) contributes to mitigating the effects of floods and droughts'.²⁸

To this end, the WFD contributes to providing a sufficient supply of good quality surface water and groundwater as needed for sustainable, balanced, and equitable water use, significantly reducing pollution of groundwater, protecting territorial and marine waters, compliance with the relevant international agreements, including those that aim to prevent and eliminate pollution of the marine environment, cease or phase out discharges, emissions, and losses of priority hazardous substances with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances.²⁹

²⁶ WFD (n 1), preamble.

²⁷ *ibid* preamble.

²⁸ *ibid* art 1.

²⁹ See, for example, the Convention on the Protection of the Marine Environment of the Baltic Sea

Common principles are needed to coordinate Member States' efforts to protect the quantity and quality of EU waters, foster sustainable water use, control cross-border water problems, protect the aquatic and terrestrial ecosystems and the wetlands that rely on them, defend and develop the potential uses of EU waters.³⁰

'Good water quality will contribute to securing the drinking water supply for the population'.³¹ As protecting drinking water resources is an indispensable part of the plans and measures under the WFD, consistency of EU legislation in this domain with the established EU legislation in the field of water is paramount.

The 30-year long history of the European Union's drinking water policy ensures that water intended for human consumption can be ingested safely in the long term, representing a high level of health protection.³²

The issue of drinking water (and bottled water in particular) involves legislation from different domains and regulated by various acts, including inter alia, Directive 2003/40/EC establishing the constituents of natural mineral waters that may present a risk to public health,³³ Directive 2001/83/EC introducing the concept of medicated waters,³⁴ and most importantly, Council Directive 98/83/CE on the quality of water intended for human consumption (Drinking Water Directive (DWD)).³⁵

Area, signed in Helsinki on 9 April 1992 and approved by Council Decision 94/157/EC, the Convention for the Protection of the Marine Environment of the North-East Atlantic, signed in Paris on 22 September 1992 and approved by Council Decision 98/249/EC, and the Convention for the Protection of the Mediterranean Sea Against Pollution, signed in Barcelona on 16 February 1976 and approved by Council Decision 77/585/EEC, and its Protocol for the Protection of the Mediterranean Sea Against Pollution from Land-Based Sources, signed in Athens on 17 May 1980 and approved by Council Decision 83/101/EEC.

³⁰ WFD (n 1), preamble.

³¹ *ibid.*

³² Ensure that drinking water quality is controlled through standards based on the latest scientific evidence; secure efficient and effective monitoring, assessment and enforcement of drinking water quality; provide consumers with adequate, timely and appropriately information; contribute to the broader EU water and health policy.

³³ Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits, and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters [2003] OJ L126/34.

³⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67. Particularly with regard to the rules on labelling, Directive 2009/54 of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (Recast) ([2009] OJ L164/45) contains additions to and derogations from the general rules contained in the legislation on the labelling of foodstuffs (see Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of Member States relating to the labelling, presentation, and advertising of foodstuffs [2000] OJ L109/29). See recital 8 in the preamble to Directive 2009/54.

³⁵ Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption [1980] OJ L229/11, which was repealed and replaced by Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption [1998] OJ L330/32, as amended.

DWD is designed specifically to protect people from the adverse effects of drinking contaminated water by ensuring that it is wholesome and clean.³⁶ In general, this Directive has been relatively well implemented by Member States, but the approach to monitoring quality at the point of consumption uses parameters determined over 20 years ago. As such, it calls for an examination of whether the Directive effectively deals with current and future needs and guarantees that EU inhabitants and visitors will be able to avail themselves of high-quality drinking water in the near and distant future.

3.2. A New Proactive Approach to Ensuring Drinking-Water Safety in Europe: The WHO Guidelines

As the WHO has highlighted, despite the DWD's high compliance with essential water quality parameters, outbreaks of infectious waterborne diseases remain pervasive in the EU.³⁷ This is largely attributable to the fact that compliance monitoring does not consider the restricted amount of water with highly variable pathogens sampled, and the results generally provided when exposure has already taken place. Such outbreaks cause a serious health burden and may undermine the confidence of EU citizens in the safety of their water supply.

Therefore, compliance monitoring of faecal indicator bacteria would seem to provide insufficient safeguards to public health, and additional requirements are needed to protect EU citizens from exposure to enteric pathogens via drinking-water, particularly viruses and protozoan parasites, as well as opportunistic pathogens that thrive in drinking-water systems, particularly *Legionella*.³⁸

In a proactive approach, and to address the shortcomings resulting from overemphasizing microbiological compliance monitoring, the WHO issued a framework for safe drinking-water, providing a conceptual basis to manage public health risks from water supplies. The Water Safety Plan (WSP) is a core pillar of this framework and provides the most effective means of consistently ensuring the safety of a drinking-water supply through a 'comprehensive risk assessment and risk management approach that encompasses all steps in water supply from catchment to consumer'.³⁹ For each supply, the WSP advocates the development of a supply-specific profile of

³⁶ *ibid* art 1 (2).

³⁷ WHO, Drinking Water Parameter Cooperation Project Support to the revision of Annex I Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption (Drinking Water Directive) Recommendations Bonn, 11 September 2017, available at <http://ec.europa.eu/environment/water/water-drink/pdf/20171215_EC_project_report_final_corrected.pdf> accessed January 2019.

³⁸ *ibid* ix.

³⁹ *ibid*.

chemical and microbiological hazards of local concern, including the events and routes by which such hazards can enter the supply system. These profiles form the basis for the effective management, operation, and monitoring of water supplies.

The WHO recommended a number of steps aimed at further improving the level of health protection of European citizens by means of amending the Directive.⁴⁰ In particular, the main objective of the recommended amendments in their entirety is applying a “risk-based lens” in accordance with the WHO framework for safe drinking-water, and specifically the core requirements of the WSP approach. In brief, the WHO recommended periodic catchment appraisals and investigative monitoring of source water quality as part of the hazard analysis and risk assessment by introducing generic and specific requirements for operational monitoring; refining the requirements for assessing and effectively controlling potential health risks from enteric pathogens in drinking-water, specifically viral and protozoal pathogens; specific requirements for the prevention and control of *Legionella* proliferation in warm drinking-water installations in priority buildings; and regulating a list of selected parameters among the many for which WHO guideline values exist.

3.3. The EU Commission Proposal for Modernizing the 20-Year Old European Drinking Water Directive

In line with the latest WHO recommendations, on 1 February 2018 the European Commission adopted a proposal for an amended drinking water directive to improve the quality of drinking water and provide greater access and information to citizens.⁴¹

The proposal directly follows up on the European citizens’ “Right2Water” initiative submitted to the Commission in December 2013, which urged in particular that ‘EU institutions and Member States be obliged to ensure that all inhabitants enjoy the right to water and sanitation’, and that ‘the EU increases its efforts to achieve universal access to water and sanitation’. In its response, the Commission invited Member States to do everything they can to ensure everyone has access to a minimum water supply.⁴²

In this perspective, the proposal contributes to meeting the Agenda 2030 targets, in particular, the aforementioned Sustainable Development Goal 6 and the associated objective of achieving universal and equitable access to safe and affordable drinking water for all.⁴³

⁴⁰ *ibid* x ff.

⁴¹ Proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast), COM/2017/0753 final - 2017/0332, 1.2.2018 (hereinafter Proposal).

⁴² COM (2014)177 final.

⁴³ *Supra*, footnotes 5 and 21 and corresponding text.

As for the legal basis, subsidiarity and proportionality, first (as well as recasting the Directive) the proposal is based on Article 192(1) of the TFEU (former Article 130 of EC Treaty). Further, since the EU shares competence with Member States in terms of regulating the environment and health in the water sector, the proposal establishes general rules at the EU level, within the remit of the EU's powers and in full respect of subsidiarity but safeguards the Member States' ability to take decisions and actions to ensure compliance with access to safe drinking water.

Finally, in accordance with the principle of proportionality, the most suitable and cost-effective measures that could be taken at the EU level when revising the Directive included: '(a) reviewing and updating the list of parameters in the Directive in line with newest scientific findings whilst introducing the risk-based approach for large and small water suppliers; (b) improving rules on transparency and access to up-to-date information for consumers; (c) improving and simplifying reporting; (d) removing obstacles that prevent the free trade in materials in contact with drinking water; (e) improving access to safe drinking water'.⁴⁴

In terms of the scope of the proposal, it adheres to the general principle that considers water as "food" under Regulation (EC) No 178/2002 of the European Parliament and the Council laying down the general principles and requirements of food law.⁴⁵ It therefore proposed that provisions related to 'water put into bottles and containers and intended for sale' be removed from the scope of Directive 98/83/EC, as any bottled drinking water would fall under the scope of Regulation (EC) No. 178/2002 after the point of compliance.

Concerning specific categories of bottled water, natural mineral waters are exempt from the scope of this Directive in accordance with Directive 2009/54/EC of the European Parliament and the Council.⁴⁶ However, in accordance with the third subparagraph of Article 9(4) of Directive 2009/54/EC, spring waters should comply with the provisions of this Directive, and therefore remain within its scope.

As for the proposal's compliance with the WHO recommendations, the Commission has adopted the majority of the suggested parameters and parametric values, but on a few parameters has put forward a different approach. Specifically, the WHO recommended including chlorate (ClO₃) and chlorite (ClO₂) as new parameters, and set a value of 0.7 mg/l for both, adopting parametric values for two individual perfluorinated substances: perfluorooctanesulfonic acid (PFOS) with a value of 0.4 µg/l and perfluorooctanoic acid (PFOA) with a value of 4 µg/l. Second, the WHO recommended that five parameters be removed from the DWD: benzene, cyanide, 1,2-dichloroethane, mercury, and polycyclic aromatic hydrocarbons (PAHs). Third,

⁴⁴ Proposal (n 41), Section 2.

⁴⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety [2002] OJ L31/1).

⁴⁶ Directive 2009/54/EC (n 34).

the WHO suggested raising the parametric values for antimony (from 5 to 20 $\mu\text{g/l}$), boron (from 1 to 2.4 mg/l) and selenium (from 10 to 40 $\mu\text{g/l}$).

Most of these changes are not considered necessary by the Commission, as the risk-based approach introduced by Commission Directive (EU) 2015/1787⁴⁷ allows water suppliers to remove a parameter from the list to be monitored under certain conditions, and treatment techniques to meet those parametric values are already in place.

Despite the absence of specific WHO guidelines concerning endocrine disrupting compounds, the Commission considered including these under the Directive based on the precautionary principle, which is supported by stakeholders, as this would also help protect human health. As for chromium and lead, although the WHO guidelines maintain the current parametric value of 10 $\mu\text{g/l}$ for lead and 50 $\mu\text{g/l}$ for chromium total, the Commission proposed lowering the value after entry into force of the Directive.

Taking into account the WHO's latest scientific knowledge and recommendations, the addition of new and emerging substances (including legionella and chlora) to the criteria determining water safety ensure the preservation of high quality drinking water in the long run. According to estimates, such measures would reduce the potential health risks associated with drinking water from 4% to below 1%.⁴⁸ In this perspective, the revised European legislation on drinking water will guarantee access to essential and good quality services, one of the principles of the European Pillar of Social Rights unanimously endorsed by Heads of State or Government at the Gothenburg Summit.⁴⁹

Further, seeking to empower consumers and enable a comparison with bottled water, the new rules foresee a better management of drinking water by water suppliers through the use of digital information technologies and providing clearer information on water consumption, cost structure, and price per liter. This would contribute to achieving the other environmental goals and SDGs, including the reduction of plastic waste, and limiting the EU's carbon footprint.⁵⁰

Finally, the Commission's proposal modernizes the DWD and increases coherence with the WFC, for example, by introducing the risk-based approach from abstraction to tap and improving communications between Member States' authorities and water suppliers to ensure the full governance cycle for water. With a more uniform European water policy, this approach would ensure the same level of protection of human health from adverse effects of any contamination across the whole EU.

⁴⁷ Commission Directive (EU) 2015/1787 of 6 October 2015 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption [2015] OJ L260/6.

⁴⁸ Commission Staff Working Document Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast), Brussels, 1 February 2018, SWD (2017) 449 final.

⁴⁹ EU Social Summit for Fair Jobs and Growth, Gothenburg, 17 November 2017.

⁵⁰ See especially SDGs 12 and 13.

4. Conclusions: Globalizing the (Pan-)European Approach toward a Harmonized International Water and Health Regulation

The critical analysis of the current international and EU regulatory framework on water quality and the impact on the environment emphasizes that access to safe sanitation for everyone, everywhere, is fundamental to guaranteeing human health, expressed in the WHO's Constitution as 'a state of complete physical, mental, and social wellbeing, and not merely the absence of disease or infirmity'.⁵¹

Safe, sustainable, and well-managed water systems are also required to achieve the SDGs.

For decades, the WHO has promoted links between hygiene and health, endorsing safe sanitation systems and practices, offering guidance to encourage international, national, and local sanitation policies and actions that protect public health and the environment. Despite the non-binding nature of the WHO guidelines on the prevention and management of waterborne outbreaks, they confirm the Organization's key role in assisting countries to improve policy, governance, and monitoring the WASH-related SDGs and health. The WHO is also pivotally positioned in providing normative guidance at the national and regional level on safe water, adequate sanitation, and proper hygiene issues.

The WHO-UNECE Protocol on water and health, and the more recent recommendations to modernize the 20-year old EU DWD, are clear examples of the WHO's pivotal tasks.

In our view, the international water and health regulation could be much more harmonized, exporting the existing binding regional instruments worldwide. The 2003 amendments opening the 1992 Water Convention to non-UNECE member States constituted a first step in this direction.⁵²

Of course, as the most attentive commentators have pointed out, the universal opening of the Water Conventions to all UN Member States could give rise to confusion, or worse, conflicting obligations with respect to the 1997 Convention on the Law of the Non-Navigational Uses of International Watercourses covering the same subject matter. Nevertheless, we share the view that, while the 1997 Watercourses Convention addresses the "economic" aspect of the use and development of freshwater resources, the former treaty is more exhaustive and rigorous in the "environmental" and "human" dimensions, as confirmed by the adoption

⁵¹ WHO Constitution (n 15), preamble.

⁵² Meeting of the Parties to the Convention on the Protection and Use of Transboundary Watercourses and International Lakes Sixth session Rome, 28–30 November 2012, Decision VI/3 Accession by non-United Nations Economic Commission for Europe countries, ECE/MP.WAT/37/Add.2, 19 September 2013 at 12 ff. See Attila Tanzi, *The Economic Commission for Europe Water Convention and the United Nations Watercourses Convention. An analysis of their harmonized contribution to international water law*, Water Series No. 6, 2015.

and entry into force of the Protocol on Water and Health.⁵³

In this perspective, despite the threat of fragmentation of contemporary international law, future opening and accession to the Water Convention Protocols on more specific issues (such as water and health) could strengthen cooperation and partnerships promoting environmental and human health at the global level.⁵⁴

⁵³ Tanzi (n 52).

⁵⁴ As Wolfgang Friedmann stated, 'we should view universal and regional developments together, as part of a continuing process of the internationalisation of law', in *The Changing Structure of International Law* (Stevens & Sons 1964) xiii, 152.

Chapter 13

From Sea to Plate: Pollution of the Marine Environment and Food Safety in International and EU Law

*Gabriela A. Oanta**

1. *Introduction*

Marine areas are a very valuable source of dietary protein for a large part of the global population. Eating fish is widely known to have numerous human health benefits. According to the Food and Agriculture Organization of the United Nations (FAO), in 2013, fish provided about 3.2 billion people with almost 20 per cent of their average per capita intake of animal protein, and about 5.1 billion people with around 10 per cent.¹ The populations of some small developing island states rely on fish for around 40 per cent of their protein intake.²

About 90 per cent of the Earth's habitat is located in marine areas, which face pressure from climate change, the various forms of anthropogenic pollution, and fishing, in some cases conducted by illegal means. Whilst there is no doubt that the seas and oceans could continue to exist without humans, it would be impossible for humans to exist on Earth without the benefits provided by the marine environment.³

Today, much of the marine environment is polluted. Under the United Nations

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¹ In 2013, global per capita fish consumption was 19.8 kg. Data from: *FAO Yearbook 2016* (FAO 2018) xxi.

² 'Seafood and Human Health', European Marine Board and Centre for Environment, Fisheries and Aquaculture Science (2014).

³ Rosemary Rayfuse, 'Preface' in Rosemary Rayfuse (ed), *Research Handbook on International Marine Environmental Law* (Edward Elgar 2015) xiii.

Convention on the Law of the Sea (LOSC),⁴ ‘pollution of the marine environment’ refers to the introduction by man, directly or indirectly, of substances or energy into the marine environment that ‘results in or is likely to result in such deleterious effects as harm to living resources and marine life, hazards to human health, hindrance to marine activities, including fishing and other legitimate uses of the sea, impairment of quality for use of sea water and reduction of amenities’.⁵ There is increasing data on the various types of marine pollution that could have negative consequences for human food health through the fishery products entering the food chain at any given time. In this context, *from the sea to plate* principle takes on particular importance and should be taken into account to ensure real human food safety.

This gives rise to two questions. First, to what extent can food resources from the sea that enter the human food chain cause health problems as a result of their contact with hazardous substances intentionally or accidentally introduced by humans into the marine environment? And, second, what measures could be jointly taken by states, individually or collectively, within the framework of institutionalized international systems to prevent and ultimately reduce all forms of marine pollution?⁶

This paper will focus on food safety, i.e. the quality standards to be met by fish and fishery products intended for human consumption.⁷ Therefore, it will not address food security in the sense of all people’s right to food. Nor will it examine food security from the perspective of the development cooperation carried out by States and international organizations or humanitarian aid for people from third countries who are victims of natural or man-made disasters or the structural crises suffered by some States.

In light of these considerations, the present paper will focus on those international organizations – both universal and regional – whose actions are most important for the protection of the marine environment and are directly related to the issue of hu-

⁴United Nations Convention on the Law of the Sea (Montego Bay, 10 December 1982, in force since 16 November 1994; at present, there are 168 Parties, namely 167 States and the European Union) 1833 *UNTS* 396.

⁵Art 1(1)(4) LOSC.

⁶For example, the Resolution adopted by the UN General Assembly on 6 July 2017 ‘Our ocean, our future: call for action’ (A/RES/71/312) calls upon ‘all stakeholders to conserve and sustainably use the oceans, seas and marine resources for sustainable development by taking, inter alia, the following actions on an urgent basis, including by building on existing institutions and partnerships: [...] (g) Accelerate actions to prevent and significantly reduce *marine pollution of all kinds*, particularly from land-based activities, including marine debris, plastics and microplastics, nutrient pollution, untreated wastewater, solid waste discharges, hazardous substances, pollution from ships and abandoned, lost or otherwise discarded fishing gear, as well as to address, as appropriate, the adverse impacts of other human-related activities on the ocean and on marine life, such as ship strikes, underwater noise and invasive alien species’ (italics are the author’s). See: A/RES/71/312, para 13.g).

⁷For an overview of this aspect of food safety, see Gaëlle Bossis, *La sécurité sanitaire des aliments en droit international et communautaire. Rapports croisés et perspectives d’harmonisation* (Bruylant 2005); Gabriela A Oanta, *La Política de seguridad alimentaria en la Unión Europea* (Tirant lo Blanch 2007).

man food safety. To this end, the remainder of the paper will be divided into two main parts. The *first part* will analyse the legal framework created and implemented to date by various universal international organizations, such as the United Nations (UN), the International Maritime Organization (IMO), and the World Health Organization (WHO) and FAO, through the Joint FAO/WHO Food Standards Programme, the *Codex Alimentarius* (2). The *second part* will focus on the actions taken with regard to these issues by the European Union (EU), the world's largest fish market (3).

2. The International Law Response to Pollution of the Marine Environment and Its Potential Consequences for Human Food Safety

2.1. The Work of the United Nations

Protection of the marine environment is one of the more recent concerns of international law and is regarded as one of the achievements of the transformations effected in international law of the sea over the last half-century or so.⁸ The need to protect the marine environment was scarcely mentioned in the working sessions for the first United Nations Conference on the Law of the Sea (1958).⁹ Although the United Nations Convention on the High Seas (1958) did finally introduce the obligation for States to prevent marine pollution due to the discharge of oil from ships, amongst other things, it did not define the term 'pollution'.¹⁰ The United Nations Convention on the Territorial Sea and the Contiguous Zone (1958) provides for the rights of coastal states to legislate matters related to transport and navigation in their territorial sea.¹¹ The alarming acidification of the oceans¹² and the presence in the seas of

⁸ Patricia Birnie, Alan Boyle and Catherine Redgwell, *International Law & the Environment* (3rd edn, OUP 2009) 382 ff.

⁹ For an analysis of the work conducted in the framework of this international conference, see Yoshifumi Tanaka, *The International Law of the Sea* (CUP 2015) 21-24.

¹⁰ 450 UNTS 11 (Geneva, 1959, in force since 30 September 1962). Art 24 provides: 'Every State shall draw up regulations to prevent pollution of the seas by the discharge of oil from ships or pipelines or resulting from the exploitation and exploration of the seabed and its subsoil, taking account of existing treaty provisions on the subject.'

¹¹ 516 UNTS 205 (Geneva, 1958, in force since 10 September 1964). Thus, art 17 of this Convention provides: "Foreign ships exercising the right of innocent passage shall comply with the laws and regulations enacted by the coastal State in conformity with these articles and other rules of international law and, in particular, with such laws and regulations relating to transport and navigation". For a more detailed examination of these issues, see Douglas Brubaker, *Marine Pollution and International Law: Principles and Practice* (Belhaven Press 1993) 119-120.

¹² Resolution adopted by the General Assembly on 5 December 2017 'Oceans and the law of the sea' A/RES/72/73, 4 January 2018, para 194. It is estimated that the acidity of ocean surface waters has

plastics,¹³ pollutants and toxins, especially as a result of land-based human activities,¹⁴ underscore the need to find solutions, including legal ones, to a problem with serious and complex implications for human food safety.

The adoption by the UN, in 1982, of the LOSC marked a before and after in the regulation of marine environmental protection. Part XII of the Convention is dedicated to this issue. Consisting of 45 articles, this Part of the LOSC begins by establishing the obligation for each state to protect and preserve the marine environment (Article 192). It is a key customary¹⁵ provision in this matter, violation of which entails the international responsibility of the state in breach. The other articles of this Part of the LOSC are much weaker, as they impose very flexible standards.¹⁶ In addition, the LOSC lists all the measures that states should take, individually or jointly, to prevent, reduce and control pollution of the marine environment (Article 194) and establishes the duty for states not to transfer damage or hazards or transform one type of pollution into another (Article 195). Article 197 LOSC establishes the obligation to cooperate on the protection of the marine environment 'directly or through competent international organizations'.¹⁷ As the following section will show, IMO is one such subject of international law through which States can and do cooperate on this matter.

Other provisions of the LOSC focus on the issue of the adoption of laws, rules and standards by flag states, coastal states and port states to prevent, reduce and control the various forms of marine pollution.¹⁸ According to the treaty, there are six

increased approximately 30% since the beginning of the industrial era. In this regard, see the contribution of Working Group I to the Report of the Intergovernmental Panel on Climate Change regarding the physical science basis of climate change, published in 2013.

¹³ Manuel Hinojo Rojas, 'Los plásticos y el derecho internacional del mar' in Jaime Cabeza Pereiro and Belén Fernández Docampo (coords), *Estrategia Blue Growth y Derecho del Mar* (Bomarzo 2018); Nate Seltenrich, 'New Link in the Food Chain? Marine Plastic Pollution and Seafood Safety', (2015) 123(2) *Environmental Health Perspectives* 34; Madeleine Smith, David C Love, Chelsea M Rochman and Roni A Neff, 'Microplastics in Seafood and the Implications for Human Health', (2018) 5 *Current Environmental Health Reports* 375.

¹⁴ A/RES/72/73, para 221. See also United Nations Environment Programme (UNEP) document UNEP(DEPI)/GPA/IGR.3/6, Annex.

¹⁵ In this regard, see 'Law of the Sea: Protection and preservation of the marine environment. Report of the Secretary-General', A/44/461, 18 September 1989, 29.

¹⁶ See Nathalie Klein, *Dispute Settlement in the UN Convention on the Law of the Sea* (CUP 2005) 152. Regarding the existence of soft law rules in the sphere of international law of the sea, see Teresa Fajardo del Castillo, 'Soft Law and the Law of the Sea: Its Presence in the UNCLOS' in José Manuel Sobrino Heredia (ed), *The Contribution of the United Nations Convention on the Law of the Sea to Good Governance of the Oceans and Seas* (Scientifica 2014) 65.

¹⁷ This regional cooperation has been carried out especially through the regional sea programmes funded and coordinated by UNEP and the broad marine ecosystem mechanisms, many of which have been funded by the Global Environment Facility (GEF).

¹⁸ See, amongst others, James Harrison, *Saving the Oceans through Law. The International Legal Framework for the Protection of the Marine Environment* (OUP 2017) 17-165; Moira L McConnell and Edgar Gold, 'The Modern Law of the Sea: Framework for the Protection and Preservation of the Marine Environment' (1991) 23 *Case Western Reserve Journal of International Law* 83; Nathalie Ros, 'La

types of marine pollution, namely: pollution caused by human land-based activities; pollution from installations and devices used in the exploration or exploitation of natural resources of the seabed and subsoil and that are under national sovereignty and jurisdiction; pollution from activities carried out in the Area, i.e. the seabed and ocean floor beyond the limits of national jurisdiction; pollution from dumping; pollution from vessels; and pollution caused by the release of toxic, harmful or noxious substances from or through the atmosphere.¹⁹ Each of these types of pollution poses a clear threat to marine environmental health and, furthermore, can negatively impact human food safety, which could be affected by the seas' and oceans' health status at any given time.²⁰

2.2. *IMO's Work to Prevent Pollution of the Marine Environment and Its Potential Impact on Peoples' Food Health*

IMO was established on 6 March 1948 as a specialized agency of the UN in the field of shipping.²¹ The LOSC explicitly refers to it only once (in Article 2(2) of Annex VIII concerning the list of experts for special arbitration). However, it implicitly refers to it numerous times, insofar as it is the competent international organization to develop the international rules and standards for shipping.²²

gouvernance des mers et des océans, entre mythes et réalités juridique' (2017) *Journal du Droit International* 757, 768-771.

¹⁹ For a detailed analysis of the types of marine environmental pollution, see Robin Rolf Churchill and Alan Vaughan Lowe, *The Law of the Sea* (3rd edn, Manchester University Press 1999) 328-399; Daud Hassan and Md Saiful Karim (eds), *International Marine Environmental Law and Policy* (Routledge 2019) especially 69-86; Véronique Labrot, 'Marine Pollution: Introduction to International Law on Pollution Caused by Ships' in André Monaco and Patrick Prouzet (eds), *Governance of Seas and Oceans* (John Wiley & Sons 2015) 77; Laura Movilla Pateiro, 'Las actividades mineras en los fondos marinos y oceánicos y la protección del medio marino' in Jaime Cabeza Pereiro and Belén Fernández Docampo (coords), *Estrategia Blue Growth y Derecho del Mar* (Bomarzo 2018).

²⁰ Regarding the important and close connection between the marine environment and food safety, see, amongst others Stefania Negri, 'Healthy Oceans for Healthy Lives: The Contribution of the World Health Organization to Global Ocean Governance' in David J. Attard (ed), *The IMLI Treatise on Global Ocean Governance: Volume II: UN Specialised Agencies and Global Ocean Governance* (OUP 2018) 262-263.

²¹ Convention on the International Maritime Organization (signed on 6 March 1948, entered into force on 17 March 1958). *UNTS* vol. 289, p. 3 and vol. 1520, p. 297. At present, 174 States ratified it, which represents 97.34% of the world tonnage (<www.imo.org/en/About/Conventions/StatusOfConventions/Documents/StatusOfTreaties.pdf>). For a more detailed overview of IMO, see, amongst others, Aldo Chircop, 'The International Maritime Organization' in Donald R Rothwell and others (eds), *The Oxford Handbook of the Law of the Sea* (OUP 2015) 416; James Harrison, *Making the Law of the Sea: A Study in the Development of International Law* (CUP 2011) 154; Gaetano Librando, 'The International Maritime Organization and the Law of the Sea' in David Joseph Attard, Malgosia Fitzmaurice and Norman A Martínez Gutiérrez (eds), *The IMLI Manual on International Maritime Law. Volume I: Law of the Sea* (OUP 2014) 577.

²² In the author's view, this would include the following LOSC provisions: art 21, paras 2 and 4; art

One advantage of IMO is that the international rules and standards included in the treaties it has promoted are widely accepted by states. Over its seventy years of existence, IMO has adopted a large number of legal texts dealing exclusively with the prevention of marine pollution, such as: the International Convention Relating to Intervention on the High Seas in Cases of Oil Pollution Casualties (INTERVENTION, 1969), the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (LC 1972), the Protocol Relating to Intervention on the High Seas in Cases of Pollution by Substances other than Oil (INTERVENTION PROT 1973), the International Convention on Oil Pollution Preparedness, Response and Co-operation (OPRC 1990), the International Convention on the Control of Harmful Anti-fouling Systems on Ships (AFS 2001), etc.²³

The three most important conventions promoted by IMO, ratified to date by a significant number of states,²⁴ are: the International Convention for the Prevention of Pollution from Ships (MARPOL), adopted in 1973, as modified by the Protocol of 1978 relating thereto, known as MARPOL 73/78; the International Convention for the Safety of Life at Sea (SOLAS), adopted in 1974; and the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers (STCW Convention), adopted in 1978. For the purposes of the present paper, MARPOL 73/78 is the most interesting of these legal texts, as it specifically deals with the prevention of all forms of intentional marine pollution from vessels, except for dumping. This treaty, which is also the most important environmental treaty adopted by IMO,²⁵ has twenty articles, two Protocols and six Annexes. However, Annexes III-VI are not currently mandatory for all the parties that have ratified the Convention, but not the Annexes themselves. In contrast, Annexes I and II entered into force on 2 October 1983 and have been ratified, to date, by 153 states, accounting for 98.52 per cent of world shipping tonnage in 2014.²⁶

With regard to human food safety, which could be affected by the health status of the fish and fishery products entering the food chain at any time, paragraph 1.11

22(3); art 23; art 39(2); art 41(4); art 53(9); art 54; art 60; art 80; art 94, paras 3, 4 and 5; art 210, paras 4 and 6; art 211, paras 6.a) and c) and 7; art 216.1; art 217, paras 1, 2 and 3; art 218, paras 1 and 3; art 219; art 220, paras 1, 2 and 3; art 226(1). For a detailed exploration, see 'Implications of the United Nations Convention on the Law of the Sea for the International Maritime Organization: Study by the Secretariat of the International Maritime Organization', IMO, LEG/MISC.7, 19 January 2012, 8-10. See also Librando (n 21) 580-582.

²³ For a more detailed look at the legal framework created by IMO in relation to the prevention of marine pollution, see: 'Implications of the United Nations Convention' (n 22) 49-51. See also Librando (n 21) 590-605; José Juste Ruiz, 'El accidente del Prestige y el Derecho internacional: de la prevención fallida a la reparación insuficiente' (2013) LV(1) *Revista Española de Derecho Internacional* 27-28.

²⁴ See at <www.imo.org/About/Conventions/StatusOfConventions/Documents/SummaryofStatusofConventions>.

²⁵ Edgar Gold, *Gard Handbook on Protection of the Marine Environment* (3rd edn, Gard SA 2006); James Harrison, *Making the Law of the Sea* (CUP 2011) 159.

²⁶ See at <www.imo.org/About/Conventions/StatusOfConventions/Documents/SummaryofStatusofConventions>.

of Annex I MARPOL 73/78 has particularly important connotations. In accordance with this provision, a special area can be created in a given sea, in light of its oceanographical and ecological conditions and the traffic registered in its waters, requiring the adoption of special mandatory methods for the prevention of sea pollution by oil.²⁷ Under these provisions, for example, the discharge into the water of the oil from ships is prohibited, a ship seeking to pass through such an area's waters must have the necessary facilities to store the waste from the oil used during navigation, etc.²⁸

Finally, about five years ago, IMO unveiled a new shipping-related concept. Right after the Rio+20 Conference, the IMO Secretary General began to develop the concept of a sustainable maritime transportation system, which could have undeniable implications for human food health.²⁹ The system would include a wide range of existing activities at the regional, subregional and national levels, which would pursue various objectives, such as: promoting a safety culture and environmental stewardship, minimizing the environmental impact of shipping and the activities of maritime industries, having port facilities to keep the operational efficiency of ships at the highest level, coordinating the interests of ocean protection and good ocean governance, etc.³⁰ Each and every one of these human activities clearly has direct consequences for the health status of the fish and fishery species that might enter the human food chain at any given time.

2.3. The Role of the Codex Alimentarius Commission as an Expression of Cooperation between WHO and FAO in the Field of Food Safety

WHO has been carrying out extensive and outstanding work in the fields of health and international health for many years. For several decades, it has had a monopoly on the development, adoption and implementation of a wide range of standards in these sectors. As economic, political and social relations have evolved, so have the or-

²⁷ For an overview of the issue of special areas, see Markus J Kachel, *Particularly Sensitive Sea Areas: The IMO's Role in Protecting Vulnerable Marine Areas* (Springer 2008) 37-134; Jean Claude Sainlos, 'The International Maritime Organization and the Protection of the Marine Environment' in Davor Vidas and Peter Johan Schei (eds), *The World Ocean in Globalisation: Climate Change, Sustainable Fisheries, Biodiversity, Shipping, Regional Issues* (Martinus Nijhoff Publishers 2011) 331-334; Tullio Scovazzi, 'Marine Protected Areas and Navigation' in Marta García Pérez and Javier Sanz Larruga (coords), *Seguridad Marítima y Medio Ambiente* (Netbiblo 2006) 80.

²⁸ 'Simplified overview of the discharge provisions of the revised MARPOL Annex V which entered into force on 1 January 2013', IMO.

²⁹ 'World Maritime Day. A Concept of a Sustainable Maritime Transportation System', IMO, 2013.

³⁰ *ibid* 11-32.

ganization's competencies and tasks. Today, WHO is leader in the adoption of international public health standards, many of which are closely related to food safety.

Since its Resolution of May 2000, the World Health Assembly has stressed the need to work towards 'integrating food safety as one of WHO's essential functions, with the goal of developing sustainable, integrated food safety systems for the reduction of health risk along the entire food chain, from the primary producer to the consumer'.³¹ The promotion of food safety is thus one of WHO's essential functions. Accordingly, it has undertaken to act as the international broker and coordinator of food safety initiatives.³² To this end, the organization has to cooperate with other actors and subjects of international law. In the author's view, FAO is the international intergovernmental organization with which WHO has cooperated the most in the matter of food safety standards. Improving food quality and safety is one of the core goals of FAO's activities, and the organization plays an important role in the development, adoption and implementation of international food safety standards.³³

The cooperation between WHO and FAO in this area is based on the Agreement the two organizations signed in 1948,³⁴ under which they can cooperate with and consult each other in regard to matters of common interest 'with a view to facilitating the effective attainment of the objectives set forth in their respective Constitutions'.³⁵ In the author's view, the creation, in 1962, of the Joint FAO/WHO Food Standards Programme – the *Codex Alimentarius* initiative – is the most important outcome so far of the cooperation between WHO and FAO in the field of food safety, including the quality of seafood products in the human food chain.³⁶

The creation of this Programme coincided with an increase in the importance given to internationally accepted food standards, such as consumer protection measures. At the same time, FAO was becoming aware of the growing importance of closely cooperating with WHO, which was establishing itself as the foremost inter-

³¹ Resolution of the World Health Assembly on Food Safety, WHA53.15, Geneva, 15-20 May 2000, paras 2.1 and 2.11. See also Negri (n 20) 268-281.

³² WHO, 'WHO global strategy for food safety: safer food for better health', Geneva, 2002, 15.

³³ Art I.1 and 2.a-b) of the Constitution of FAO.

³⁴ Off. Rec. Wld Hlth Org, 13, 96, 323.

³⁵ *ibid* art I.

³⁶ The *Codex Alimentarius* should not be confused with the *Codex Alimentarius Europaeus* or the *Codex Alimentarius Austriacus*. The *Codex Alimentarius Europaeus* was a regional food code, drawn up in 1958, which brought together a number of European states for the primary goal of increasing food regulation quality. Today, the *Codex Alimentarius Europaeus* is used as a reference for establishing identification rules for certain foods; in fact, the current *Codex Alimentarius* took its name from it. In contrast, the *Codex Alimentarius Austriacus*, which was applicable in the Austro-Hungarian Empire in the early 20th century, was a compilation of rules and descriptions encompassing a wide range of foods. See: 'Understanding the Codex Alimentarius', IGO 9768, FAO/OMS, 1999, 6. At present, the *Codex Alimentarius* Commission has 189 members (188 States and the European Union, which became a member in November 2003; see Council Decision 2003/822/EC of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission [2003] OJ L 309/14.

locutor for matters related to health and the development of food standards. The creation of the joint programme gave rise to a novel situation on the international scene: two international organizations were creating a new international legal order in order to pursue their objectives. The joint programme's goals include, amongst other things, protecting consumers' health, including food safety, and ensuring fair practices in the food trade at the national and international levels.

Over its more than fifty years of existence, the *Codex Alimentarius* has proved to be one of the most important international players in the field of food safety governance. It regularly and decisively helps to achieve viable food safety in the international arena, whilst also promoting the inclusion of food product concerns on the international political agenda to ensure that food is safe and healthy.³⁷

The international agency's standards are not binding *per se*; they are simply voluntary soft law provisions.³⁸ Members can choose whether or not to transpose them into their domestic law, and the *Codex Alimentarius* consists merely of recommendations with regard to food safety.³⁹ Furthermore, these standards have no legal force and there are no sanctions for the *Codex Alimentarius* members that fail to comply. In this context, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures is particularly important. This Agreement considers national food standards conforming to the standards established by the *Codex Alimentarius* to be legal measures, i.e. valid from a legal point of view, whilst measures establishing a higher level of protection at the national level than that established by international standards must be justified as necessary.⁴⁰

Of the standards adopted by the *Codex Alimentarius* specifically in relation to fish and fishery products that could enter the human food chain, attention should be

³⁷ For a detailed overview of the activities of the *Codex Alimentarius*, see Nathalie Ferraud-Ciandet, 'La Commission du Codex Alimentarius' in (2009) 136 *Journal du droit international* 1181; Alexia Herwig, 'Health Risks, Experts and Decision Making within the SPS Agreement and the Codex Alimentarius' in Monika Ambrus and others (eds), *The Role of 'Experts' in International and European Decision-making Processes: Advisors, Decision Makers or Irrelevant Actors?* (CUP 2014) 211-215; Laura Huici Sancho, "'Nuevos" alimentos y alimentos "funcionales" en el sistema del Codex Alimentarius' in Xavier Pons Rafols (ed), *Alimentación y Derecho internacional: Normas, instituciones y procesos* (Marcial Pons 2013); Ryan O'Rourke, *European Food Law* (2nd ed., Palladian Law Publishing Ltd 2001) 192-193.

³⁸ Mariëlle D Masson-Matthee, 'The Codex Alimentarius Commission and its food safety measures in the light of their new status' in Michelle Everson and Ellen Vos (eds), *Uncertain Risks Regulated* (Routledge 2009); Naomi Roht-Arriaza, 'Shifting the Point of Regulation: The International Organization for Standardization and Global Lawmaking on Trade and the Environment' (1995) 22 *Ecology Law Quarterly* 481.

³⁹ The exception is the decision-making powers in relation to its internal work, such as its decisions regarding the development of food standards and the distribution of certain tasks to its subsidiary bodies.

⁴⁰ Art 3(2) of the SPS Measures Agreement. Art 2(4) of the WTO Agreement on Technical Barriers to Trade. For a detailed examination of these issues, see Chris Downes, *The Impact of WTO SPS Law on EU Food Regulations* (Springer 2014).

called to the Code of Practice for Fish and Fishery Products, adopted in 2003,⁴¹ and several provisions on food additives whose use is considered acceptable in fish and fishery products (including molluscs, crustaceans and echinoderms) intended for human consumption.⁴² In this regard, this body has adopted specific detailed provisions concerning both fresh fish and various processed fishery products.⁴³

3. The Legal Response of the European Union to Pollution of the Marine Environment and Its Potential Consequences for Human Food Safety

The environmental status of the sea basins that rim the coasts of the EU Member States and its potential impact on the food health of European consumers are key concerns for various EU policies, including, quite especially, the Common Fisheries Policy (CFP). This is only natural as fishery and aquaculture products are a very important part of the European diet. In 2015, the average EU citizen consumed 25.1 kg of fish or seafood per year. In some EU Member States (e.g. Portugal, Spain and France), the average is much higher, whilst others (e.g. Romania, Bulgaria and Hungary) lie at the other end of the spectrum.⁴⁴ The EU is also one of the most prominent players in the international fishery sector. It is the world's largest importer of fishery products and the fourth largest producer, accounting for 3.07 per cent of such products, behind only China, Indonesia and India.⁴⁵ In light of this situation, it is clearly possible for animal diseases to be introduced into or propagated in the EU, which could have major economic consequences for certain fishery sectors, as well as significant implications for human food safety.

EU law seeks to offer a response to the potential negative impact of pollution of the European marine environment, which can have multiple consequences for the health of existing fish stocks in marine areas under the sovereignty or jurisdiction of EU Member States and, ultimately, the health of European consumers through fishery products entering the human food chain at any given time. In this regard, the

⁴¹ CAC/RCP 52-2003.

⁴² Including, for example, aquatic vertebrates (fish and aquatic mammals (e.g. whales)), aquatic invertebrates (e.g. jellyfish), molluscs (e.g. clams, snails), crustaceans (e.g. shrimp, crabs, lobsters) and echinoderms (e.g. sea urchins, sea cucumbers). See at <www.fao.org/gsfonline/foods/details.html?id=146&lang=es&print=true>.

⁴³ For example, fish products may be treated with coatings, such as glazes or spice rubs, prior to marketing to the consumer, in which case they are known as 'glazed frozen fish fillets'.

⁴⁴ For more information, see 'Facts and figures on the common fisheries policy: Basic statistical data' (18 edn, European Union 2018).

⁴⁵ *ibid.*

CFP has been endowed with an extensive set of specific regulations regarding: first, the processing and marketing of fish products through the establishment of the Common Organization of the Markets (CMO) in fishery and aquaculture products; second, control and enforcement of processing and marketing standards for fish and fishery products; and, third, the EU's international economic relations with third countries of great interest to the EU Member States from the perspective of the processing and marketing of fish and fishery products. All of these issues are clearly very important for the food safety of European citizens.⁴⁶ They are also quite complex. Since the 2013 reform of the CFP, Regulation 1379/2013 has been the most important legal text concerning the CMO in the fishery product sector.⁴⁷ The Preamble notes that fishery products in the human food chain in the EU should comply with applicable rules on food safety and hygiene,⁴⁸ whilst also stressing the importance for European consumers of having access to the necessary information to ensure their food health through the proper labelling of such products.⁴⁹ The information to be included on the labelling of fishery products placed on the market should include, amongst other things: the commercial designation of the species and its scientific name, the production method, the area where the product was caught, the category of fishing gear used in the capture of fisheries, whether the product has been defrosted, and, where appropriate, the date of minimum durability.⁵⁰ Additionally, under Article 36 of the Regulation, the European Commission has worked to implement an eco-label scheme for fishery products. In 2016, it submitted a Report to the European Parliament and the Council on the real options for implementing an eco-label scheme for fishery products.⁵¹ Adequate labelling would also comply with the re-

⁴⁶ For a detailed examination of these aspects of the CFP, see Robin Churchill and Daniel Owen, *The EC Common Fisheries Policy* (OUP 2010); Ernesto Penas Lado, *The Common Fisheries Policy: The Quest for Sustainability* (Wiley Blackwell 2016).

⁴⁷ Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000 [2013] OJ L354/1.

⁴⁸ *ibid* recital 20.

⁴⁹ *ibid* recitals 6, 22 and 23. For a study of the problem of labelling fishery products in the EU, see Fernando González Laxe, Isabel Novo Corti and Federico Martín Palmero, 'El etiquetado de los productos pesqueros: un análisis de sus ventajas y de las controversias en su aplicación' in Jorge Pueyo Losa and Julio Jorge Urbina (dirs), *La reforma de la gobernanza pesquera internacional europea* (Thomson Reuters-Aranzadi 2017); Petruta-Elena Ispas, 'La Política de la Unión Europea relativa al etiquetado de los productos pesqueros' in José Manuel Sobrino Heredia (dir), *La toma de decisiones en el ámbito marítimo: su repercusión en la cooperación internacional y en la situación de las gentes del mar* (Bommarzo 2016) 189. For an analysis of this issue from a general point of view, see Paolo Borghi, 'El nuevo marco normativo europeo relativo al etiquetado y la información al consumidor' in Luis González Vaqué (coord), *Lecciones de Derecho Alimentario 2015-2016* (Thomson Reuters-Aranzadi 2015).

⁵⁰ *ibid* art 35(1).

⁵¹ Commission, 'Report on options for an EU eco-label scheme for fishery and aquaculture products' COM (2016) 263 final.

quirement established in this field under the Framework Regulation on Food Safety – Regulation (EC) No 178/2002⁵² – with a view to facilitating the traceability of all fishery products in the food chain.

Another important aspect of this regulatory framework is Directive 2004/41/EC of the European Parliament and of the Council repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption.⁵³

The implementation of the standards concerning the processing and marketing of fishery products requires subjecting all products for which these common standards have been adopted to the pertinent control in order to guarantee, amongst other things, homogeneous quality throughout the EU's territory of such products as well as the food protection of European consumers.⁵⁴ This control can be carried out at any stage of the process from when the fish are caught at sea to their entry in the human food chain through their placement on the market. This idea formed the basis for the adoption of Council Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the CFP.⁵⁵

The food quality of fishery products in the human food chain will surely decline if the seas where the fish sold on the EU market are caught are polluted. As the degree of domestic supply of the EU's fish-processing industry is declining and, thus, the industry's dependence on imports from third countries or catches by the Union's ships in waters not under the sovereignty or jurisdiction of its Member States is rising, the establishment and development of appropriate economic relations with these countries becomes increasingly important, as does the EU's own commitment to fighting the pollution of marine areas.

To this end, European lawmakers have equipped the system for protecting the food health of European citizens in the case of fishery products imported from third countries with various measures that Member States can use, such as the possibility of suspending customs duties when dealing with fish for human consumption. This system has been further reinforced by the EU's system for combating illegal, unreported and unregulated fishing, which, since 2008, has been another aspect of the

⁵² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1. See especially art 18(4) of this Regulation.

⁵³ [2004] OJ L157/33.

⁵⁴ For an analysis of the issue of the enforcement and control of the rules adopted in the context of the CFP, see José Manuel Sobrino Heredia, 'La aplicación de las normas de la Política Pesquera Común en los Estados descentralizados: referencia al caso español' in *Conferencia 'Aspectos jurídicos de la aplicación de las normas de la Política Pesquera Común'*. Bruselas, 20 de junio de 2005 (Oficina de Publicaciones Oficiales de las Comunidades Europeas 2005) 20.

⁵⁵ [2009] OJ L343/1, art 1. For a detailed overview of this Regulation, see Adela Rey Aneiros, 'Compleja reforma integral del sistema de control de la política pesquera común' (2011) 23 *Revista General de Derecho Europeo*.

legal, economic and social framework that the EU has devised to guarantee a high level of protection of the food interests of European consumers.

Finally, aware of the risks posed to European consumers' food health by the state of fishery products in the human food chain as a result of the potential pollution of their living environment before the fish are caught, and similarly aware of the negative impact that the presence of plastics in the seas and oceans can have on fishery stocks subsequently entering the European food chain, on 28 May 2018, the EU published a Proposal for a Directive on the reduction of the impact of certain plastic products on the environment.⁵⁶

The amount of plastic litter in oceans and seas is growing, affecting human health and causing widespread concern in civil society. Of the plastics present in the marine environment, single-use plastics⁵⁷ and fishing gear containing plastic may be the ones of greatest concern. In order to prevent and reduce the impact of certain plastic products, especially on the aquatic environment and human health, the objective of the Proposal for a Directive is, first, for the Member States to adopt a series of measures aimed at substantially reducing the use of such products in the EU and, second, to establish certain prohibitions concerning the placing on the EU's market of single-use plastic products.⁵⁸

4. Final Considerations

The essential work undertaken by the various international organizations and agencies discussed in this paper – including the UN, IMO, and WHO and FAO via the *Codex Alimentarius* – regarding pollution of the marine environment and its potential repercussions for human food safety has highlighted the need to guarantee human food safety. In the author's view, this is the result of the logical evolution of the concerns of a more developed part of international society that, having achieved food sufficiency, has turned its attention to issues that previously went unnoticed, such as the quality of the food in the human food chain.

⁵⁶ European Commission, 'Proposal for a Directive of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment' COM (2018) 340 final.

⁵⁷ Including food containers (e.g. boxes with or without a cover, the containers used for fast food, plates, and packets and wrappers containing food) and cups for beverages. See COM (2018) 340 final (n 56) Annex Part A. On a discussion about the presence of plastics in the seas and oceans and the legal response within the international law of the sea, see Manuel Hinojo Rojas, 'Los plásticos y el Derecho internacional del mar' in Jaime Cabeza Pereiro and Belén Fernández Docampo (coord), *Estrategia Blue Growth y Derecho del Mar* (Bommarzo 2018).

⁵⁸ Such as: cotton bud sticks, except for swabs intended and used for medical purposes, plates, cutlery, straws, beverage stirrers, etc. COM (2018) 340 final (n 56) Annex Part B. See also Parts C-G of the Annex of this Communication.

These international organizations and agencies have made significant contributions in recent decades, due not only to the scope of the standards they have adopted, but also to the principles that have gradually emerged from this legal construction and which today figure prominently in the field of food safety. This is the case of the principle of traceability, which is the corollary of the principle known in the seafaring world as 'from the sea to place'. All of this has occurred in the context of a changing world in which, due to the trade flows of food products sourced from the sea, the pollution of the seas and oceans can pose a real threat to human food safety.

At the regional level, specifically, that of the EU, in the author's view, the Union already has the necessary legal framework to adopt all measures deemed appropriate to prepare to defend itself against food risks posed by fishery products from polluted marine areas that do not comply with the food safety requirements established by the EU itself. It now falls to the various actors in the European food chain to use these legal tools that the Union has offered them. However, much remains to be done before the state of pollution of the seas and oceans ceases to pose a risk to the food safety of European consumers.

Chapter 14

The Contribution of International Organizations to Food Security and Safety through a Healthy Environment

*Pia Acconci**

1. *Introductory Remarks*

Scientific evidence has proven the negative impact of environmental degradation on public health, food security and safety.

Air and marine pollution, ozone layer depletion, acid rain, global warming, climate change, soil degradation and loss of biodiversity are environmental problems with a negative impact on health protection and, directly or indirectly, on food safety and/or security. As will be seen, environmental degradation has altered the four main elements of food security. Environmental degradation has also altered the quality of agricultural and food products.

As a result, tackling inter-connected key issues, that reflect the negative impact of environmental degradation on public health, food security and safety, has become a matter of some urgency. Inequity, poverty and emigration are examples of these issues. All these aspects are adversarial social determinants of the protection of health at the international level, as they increase the requests and the costs for healthcare services and bring about a common burden. In particular, these adversarial social determinants have a negative impact on the control of certain infectious diseases, such as HIV/AIDS as they may affect the effectiveness of anti-retroviral treatments, and/or on the control of certain non-communicable diseases, like diabetes, cardiovascular diseases, obesity and dental health.¹

The need of managing collectively such issues is shown by their specific relevance in the political agenda of several States and international organizations, such as those belonging to the UN system, and by growing social media attention. Active international organizations within the United Nations (UN) system have been the Food and

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¹ For an overview, see Annette Prüss-Ustün and others, *Preventing Disease through Healthy Environments* (WHO 2016); Matthew Saunders and others, *Key Policies for Addressing the Social Determinants of Health and Health Inequities*, (WHO Europe 2017).

Agriculture Organization (FAO), the World Health Organization (WHO),² the World Food Program (WFP), the International Fund of Agricultural Development (IFAD), the UN Environment Program (UNEP), the UN Development Program (UNDP), the World Meteorological Organization (WMO) and the World Bank.

These UN international organizations, the World Organization for Animal Health (OIE) and the World Trade Organization (WTO), as well as the European Union (EU), have focused on possible responses to the recurrent problems.

Specifically, all these international organizations have adopted a comprehensive approach to deal with the different causes at the root of such problems, by promoting the negotiation of international conventions on specific topics, as well as by organizing conferences and by publishing a great number of reports, declarations and special programs.

This paper will look at the main features of all the various activities carried out by international organizations with the aim of understanding how international organizations carry out cooperation and coordination activities for the purpose of ensuring food security and safety through a healthy environment. A few concluding remarks will be made in relation to the prevalence of soft regulatory instruments to this end.

2. The Activities of International Organizations for Food Safety through a Healthy Environment

As to the relationship among the safeguard of the environment, health protection and food safety, there has been a great deal of common ground among international organizations that the usage of synthetic fertilizers and other chemical components – typical of the *post*-Second World War ‘Green Revolution’ concerning the agriculture sector –,³ as well as the overuse of antibiotics, as growth promoters, in livestock and agriculture⁴ have contributed to environmental degradation. In principle, international organizations also agree that such a degradation has altered the quality of agricultural and food products.

As to relevant international binding rules, international conventions have been

² In light of art 2 (i) of its 1948 Constitution, the WHO has dealt with several environmentally related matters with a detrimental impact on public health. Under this article, the WHO is competent ‘to promote, in co-operation with other specialized agencies where necessary, the improvement of nutrition, housing, sanitation, recreation, economic or working conditions and other aspects of environmental hygiene’.

³ See FAO, *Climate Change and Food Security: A Framework Document* (FAO 2008) especially 20 ff.

⁴ See, in particular, the Global Action Plan on Antimicrobial Resistance adopted by the WHO in collaboration with the FAO and the OIE in 2015, as an implementing tool of the ‘One Health’ approach (available on <www.who.int/antimicrobial-resistance/global-action-plan/en/>). Cf Stefania Negri, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale* (Giappichelli 2018) especially 176-177.

concluded on the Control of Transboundary Movements of Hazardous Wastes and their Disposal,⁵ on Persistent Organic Pollutants,⁶ on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,⁷ but, until now, there has not been a specific convention dealing with the environment, health protection and food safety all together. As a rule, international conventions tend to include provisions on individual problems.

International organizations operating within the UN system, particularly the World Health Organization and the Food and Agriculture Organization, the World Trade Organization, the World Organization for Animal Health, the European Union and several States have achieved the result of connecting the safeguard of the environment, health protection and food safety as common interests through the adoption of voluntary rules and the realization of multi-purpose activities.

The goals of detection, control and prevention of foodborne diseases through food safety have been a priority within the most interested UN organizations and agencies.

The World Health Organization and the Food and Agriculture Organization have contributed to the adoption of specific international standards on food safety through the establishment of an ad hoc Commission, the Codex Alimentarius Commission.⁸

This Commission has been successful in negotiating and adopting international standards on specific matters related to food safety. As to recent standards on contaminants, the Codex Alimentarius Commission has adopted a revised text of Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice⁹ and a Code of Practice for the Prevention and Reduction of Mycotoxins in Spices¹⁰ in 2017. This practice has facilitated the adoption of recommendations and international standards on animal health and plant protection by the World Organization for Animal Health¹¹ and by the Secretary of the International Plant Protection Convention (IPPC).¹² Over the last decade, this Secretary has expressed a specific interest

⁵ The 1989 Basel Convention.

⁶ The 2001 Stockholm Convention. This was revised in 2009.

⁷ The 1998 Rotterdam Convention. This was revised in 2015. Art 3 of the Rotterdam Convention excludes, among others, '[c]hemicals used as food additives' and 'food' from its field of application.

⁸ The establishment of a Codex Alimentarius Commission was decided at the 11th FAO Conference as a joint FAO/WHO Food Standards Programme in 1962. For more information, see the website of the Commission <www.fao.org/fao-who-codexalimentarius/about-codex/history/en/>.

⁹ See CAC/RCP 77-2017; and CL 2017/25-CF, draft code, proposed in February 2017.

¹⁰ See CAC/RCP 78-2017. See also, among others, the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs, adopted in 2008 (CAC/RCP 65-2008).

¹¹ In 2003 the Office International des Epizooties – established in 1924 – became the World Organization for Animal Health for the same chief purpose of 'improv[ing] animal health worldwide'. For further information, see the OIE website <www.oie.int/about-us/>.

¹² The International Plant Protection Convention was concluded in 1951 for the main objective of

in international actions aimed both at the safeguard of plant health and the protection of the environment. These actions have encouraged a trend towards a reversal of the traditional pesticide-based approach to pest mitigation.¹³

In addition, the World Health Organization has succeeded in preparing, discussing with heterogeneous actors – whether public or private –, and adopting special agenda, plans of action and strategies within its extensive work on tackling non-communicable diseases. As to the prevention of foodborne diseases, the World Health Organization has established and implemented a specific programme, called Five Keys to Safer Food Programme, to assist Member States for the promotion of ‘safe food handling behaviors and educate all food handlers, including consumers, with tools easy to adopt and adapt’.¹⁴ This Programme acknowledges the existence of a direct connection between food safety, public health and the safeguard of the environment. The use of safe water, particularly in aquaculture, and the washing and peeling of raw materials are considered basic aspects of the Five Keys to Safer Food Programme.

In order to render food commodities and products of developing and least-developed Member States safer and thus more exportable/traded, the World Health Organization, the Food and Agriculture Organization, the World Organization for Animal Health and the World Bank established the Standards and Trade Development Facility (STDF) in 2001, within the framework of the World Trade Organization. This Facility aims at supporting such States to meet international standards on food safety and thus promoting market access for their food products and commodities.¹⁵

In connection with relevant international actions in the field of food safety as a goal connected with the protection of the environment and of public health, a few remarks must also be made as to the actions of the European Union because the European Union has become a regulatory protagonist in this field, since the beginning of this Millennium.¹⁶

‘prevent[ing] and [...] control[ling] the introduction and spread of pests of plants and plant products’. The Convention aims at promoting ‘international cooperation, harmonization and technical exchange’ among its Contracting States. For more general information, see its website <www.ippc.int/en/>.

¹³ As to recent relevant recommendations and standards adopted within the IPPC context, see, for instance, the 2017 Recommendation on *Replacement or reduction of the use of methyl bromide as a phytosanitary measure* (CPM-3/2008) jointly prepared by the Secretariats of the Montreal Protocol on Substances that Deplete the Ozone Layer and the International Plant Protection Convention.

¹⁴ According to the WHO, almost all the WHO Member States, that is over one hundred and thirty States, have supported this Programme. The WHO has also developed specific Five Keys to Safer Food Programmes for informed choices by ‘rural people who grow fruits, vegetables and fish for their own use or for sale on local markets’. For further information, see <www.who.int/foodsafety/publications/consumer/en/5keys_en.pdf?ua=1>.

¹⁵ For further information, see <www.standardsfacility.org/vision-and-goal>.

¹⁶ As to the main trends on food safety in the EU food law, cf Pia Acconci, *Tutela della salute e diritto internazionale* (Cedam 2011) especially 206-238; Irene Scholten-Verheije, *Roadmap to EU Food Law* (Eleven International Publishing 2012); Vessela Hristova, ‘Food Safety: The Resilient Resistance of the EU’ in Gerda Falkner and Patrick Müller (eds), *EU Policies in a Global Perspective: Shaping or Taking International Regimes* (Routledge 2014) 58.

The European Union has adopted an integrated approach to food safety that aims to involve all the key actors and is based on risk assessment and risk management measures, that is on the analysis of risks associated with the food chain. This analysis includes risk communication activities.

The European Union has focused on food safety, the protection of consumers and of the welfare of animals.

The most important regulatory outcome of its actions is Regulation 178/2002.¹⁷ This lays down the general principles and requirements of food law, establishes the European Food Safety Authority (EFSA) and lays down procedures in matters of food safety.

The European Food Safety Authority works on monitoring, analysis and risk assessment. It is an independent scientific advisory body. Its recommendations provide for risk reduction measures and reduction programs by specifying, for example, targets for the reduction of pathogenic microorganisms in foodstuffs. The Authority also supervises on the progress made in meeting the reduction targets. In addition, the Authority aims at the harmonization of monitoring activities related to pathogenic microorganisms in animals, food and water.¹⁸

The European Union also established the European Centre for Disease Prevention and Control (ECDC) by Regulation (EC) No. 851/2004. The ECDC is another independent scientific advisory body with no regulatory powers.

The EU Hygiene Regulations are another important regulatory outcome of the action of the European Union in the field of food safety.¹⁹ These Regulations provide for hygiene requirements for food producers and operators, as well as rules for official controls of fresh meat, fruit, milk and eggs.

Such Regulations include regulatory measures for minimizing the prevalence of food-borne infection diseases throughout the food chain. Salmonella has, for instance, been a priority.²⁰

In this connection, the EU Member States have been and are still crucial to supply staff and financial means to ensure the implementation of necessary controlling measures.

¹⁷ See Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying down Procedures in Matters of Food Safety [2002] OJ L31/1.

¹⁸ For further information on the EFSA and references to the EFSA special programmes, see its website <www.efsa.europa.eu>

¹⁹ See Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs [2004] OJ L139/1; Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 Laying down Specific Hygiene Rules for Food of Animal Origin [2004] OJ L139/55; and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 Laying down Specific Rules for the Organization of Official Controls on Products of Animal Origin Intended for Human Consumption [2004] OJ L139/206.

²⁰ See the 2003 Enhanced Salmonella control programmes in poultry in all Member States. Specifically, Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the Control of Salmonella and other Specified Food-borne Zoonotic Agents [2003] OJ L325/1.

The EU approach has influenced the reactions of States other than its Member States as to the goals of detection, control and prevention of foodborne diseases through food safety, even of important players like the United States²¹ and China,²² as we can infer from their recent food safety laws.

3. *The Activities of International Organizations for Food Security through a Healthy Environment*

A number of States and the United Nations have also succeeded in negotiating and adopting a few relevant international conventions on specific matters of the relationship among the safeguard of the environment, health protection and food security.

The 1994 UN Convention to Combat Desertification²³ is an important example. Its preamble recognizes the negative connection among desertification, drought and, among others, food security.²⁴ Article 10, related to National Action Programmes, provides that Contracting States could adopt specific regulatory and policy measures for the ‘establishment and/or strengthening, as appropriate, of food security systems, including storage and marketing facilities, particularly in rural areas’.²⁵ Article 4 adds that national action programmes could ‘promot[e] alternative livelihoods and improv[e] national economic environments with a view to strengthening programmes aimed at the eradication of poverty and at ensuring food security’. This provision underlines the positive connection between poverty eradication and food security.²⁶

²¹ See the 2011 US Food Safety Modernization Act (FSMA) which highlights the importance of preventing foodborne diseases. For further information, see <www.fda.gov/food/guidanceregulation/fsma/>.

²² See the 2009 Food Safety Law of the People’s Republic of China which has been revised in 2015. This Law focuses on the importance of risk analysis, food standards and control of food production and management. Cf, among others, Francis G Snyder, *Food Safety Law in China* (Brill-Nijhoff 2016); Jérôme Lepeintre and Juanjuan Sun (eds), *Building Food Safety Governance in China* (Luxembourg Publications Office of the EU 2018) <https://eeas.europa.eu/sites/eeas/files/building_food_safety_governance_in_china_0.pdf>.

²³ The full name of the Convention is the Convention to Combat Desertification in Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (UNCCD). For general information on this Convention, see <www.unccd.int/>.

²⁴ The relevant part of the preamble of the UNCCD Convention runs as follows: ‘[m]indful that desertification and drought affect sustainable development through their interrelationships with important social problems such as poverty, poor health and nutrition, lack of food security, and those arising from migration, displacement of persons and demographic dynamics’.

²⁵ See art 10, para 3, letter (c).

²⁶ A similar provision is included in art 2, letter (d) of the implementing programme for Asia 1994, Annex II, of the UN Convention to Combat Desertification and Drought. This reads as follows: ‘[i]n carrying out their obligations under the Convention, the Parties shall, as appropriate, take into consideration the following particular conditions which apply in varying degrees to the affected country Parties

The Preamble of the 2010 Cartagena Protocol recognizes ‘the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change’.²⁷

The 2015 Paris Agreement on Climate Change Mitigation is another important example.

This Agreement acknowledges the adversarial connection between climate change and food security, as the 1992 UN Framework Convention on Climate Change (UNFCCC) and the 1992 UN Convention on Biological Biodiversity already did.²⁸ Its preamble recognizes that food production should not be threatened by climate change.²⁹ For the attainment of its general purposes of strengthening ‘the global response to the threat of climate change, in the context of sustainable development and efforts to eradicate poverty’, its Art. 2, (b), specifies that the Agreement, among others, aims at ‘[i]ncreasing the ability to adapt to the adverse impacts of climate change and foster climate resilience and low greenhouse gas emissions development, in a manner that does not threaten food production’.³⁰

However, most of the relevant international rules are voluntary.

Typically, non-binding rules are included in final acts, plan of actions, agenda and/or declarations adopted at the end of international conferences organized within the United Nations system or recommendations and/or concept notes adopted by special bodies established by an international organization, that are usually affiliated to the United Nations.

All these voluntary regulatory instruments assume a multilevel conceptualization of

of the region [...] (d) the significant impact of conditions in the world economy and social problems such as poverty, poor health and nutrition, lack of food security, migration, displaced persons and demographic dynamics’.

²⁷ The preamble of the Nagoya Protocol also recognizes ‘the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard’. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity is a supplementary agreement to the 1992 Convention on Biological Diversity. The Nagoya Protocol was adopted in 2010.

²⁸ Art 2 related to the “objective” of the Convention reads as follows: ‘[t]he ultimate objective of this Convention and any related legal instruments that the Conference of the Parties may adopt is to achieve, in accordance with the relevant provisions of the Convention, stabilization of greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system. Such a level should be achieved within a time frame sufficient to allow ecosystems to adapt naturally to climate change, to ensure that food production is not threatened and to enable economic development to proceed in a sustainable manner’.

²⁹ See the preamble where it is asserted that ‘[r]ecognizing the fundamental priority of safeguarding food security and ending hunger, and the particular vulnerabilities of food production systems to the adverse impacts of climate change ...’.

³⁰ See art 2 of the Paris Agreement.

food security, as the relevant reference point. The Food and Agriculture Organization has many times underlined that food security exists when ‘all people, at all times, have physical, social, and economic access to sufficient safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life’. In line with the Plan of Action adopted at the 1996 World Food Summit in Rome,³¹ the Food and Agriculture Organization has promoted this conceptualization, by specifying that environmental degradation has altered the four main elements of food security, that is food availability in terms of quality and quantity; food access in terms of high prices of food products, high production costs and low incomes for small-scale farmers, especially in low-income States; food utilization in terms of calorie intake capacity because of growing food-borne, both infectious and chronic, diseases, and hunger; and instability as to the effective implementation of food policy actions. In other words, the multilevel conceptualization of food security presupposes the enhancement of livelihood conditions, in terms of ‘food access, availability, food use and stability’,³² by taking into account both economic, social and political aspects. This conceptualization inspired the 2000 Millennium Development Goals and has been at the root of the ‘Goal 2’ of the 2015 Sustainable Development Goals.³³ The end of poverty and the reduction of hunger have been considered as chief objectives in both instruments. Specifically, in accordance with the 2030 Agenda for Sustainable Development, the achievement of ‘Goal 2’ would mean to ‘[e]nd hunger, achieve food security and improved nutrition and promote sustainable agriculture’.³⁴

³¹ See World Food Summit, *Plan of Action*, 1996, para 1.

³² FAO has clarified that ‘[f]ood availability [means] the availability of sufficient quantities of food of appropriate quality, supplied through domestic production or imports (including food aid). Food access [means] access by individuals to adequate resources (entitlements) for acquiring appropriate foods for a nutritious diet. Entitlements are defined as the set of all commodity bundles over which a person can establish command given the legal, political, economic and social arrangements of the community in which they live (including traditional rights such as access to common resources). Utilization [means] utilization of food through adequate diet, clean water, sanitation and health care to reach a state of nutritional well-being where all physiological needs are met. This brings out the importance of non-food inputs in food security. Stability [means] to be food secure, a population, household or individual must have access to adequate food at all times. They should not risk losing access to food as a consequence of sudden shocks (e.g. an economic or climatic crisis) or cyclical events (e.g. seasonal food insecurity). The concept of stability can therefore refer to both the availability and access dimensions of food security’. See, FAO, *Food Security*, Policy Brief, June 2006, Issue 2.

³³ The Sustainable Development Goals should be achieved by 2030. They reflect many of the targets of the 2000 ‘Millennium Development Goals’. For an overview, see Sakiko Fukuda-Parr, ‘Sustainable Development Goals’ in Thomas G Weiss and Sam Daws (eds), *The Oxford Handbook of the United Nations* (OUP 2018) 766.

³⁴ According to para 2 of the Plan of Action adopted at the 1996 World Food Summit, ‘[p]overty eradication is essential to improve access to food’. The General Assembly of the United Nations has reaffirmed the same goal in its Resolution Transforming Our World: the 2030 Agenda for Sustainable Development (A/RES/70/1, 21 October 2015). Para 24 of this Resolution runs as follows: ‘[w]e are also determined to end hunger and to achieve food security as a matter of priority and to end all forms of malnutrition’.

The multilevel conceptualization of food security has also been based on a human-rights approach, in accordance with Article 11 of the 1948 Universal Declaration of Human Rights adopted by the UN General Assembly and the 1966 UN Covenant of Economic, Social and Cultural Rights.³⁵

The ad hoc General Comment No. 12 on the Right to Food – adopted by the UN Committee of the Covenant on Economic, Social and Cultural Rights³⁶ – has underlined the connection between, on the one hand, the access to safe food and drinkable water and, on the other, the protection of human health, the safeguard of animal welfare and plant protection. However, the General Comment has not referred to the relationship among the safeguard of the environment, health protection, food safety and security as a whole. In effect, at the time of its publication, in 1999, international organizations and their Member States did not focus on interconnected economic, political and social issues, as they are trying to do at present.

The UN Secretary General has contributed to the human-rights approach to food security by appointing UN Special Rapporteurs on the Right to Food. These have promoted the resort to a qualitative approach to agriculture and food production through ‘environmental sound’ methods and technologies.³⁷ The UN General Assembly has been promoting this kind of approach within the 2030 Agenda for Sustainable Development.³⁸ As a matter of fact, this approach was already at the root of the special implementing programme for Africa of the 1994 UN Convention to Combat Desertification and Drought directed, among others, to the sustainability of land management.³⁹

³⁵ Cf, among others, Stefania Negri, ‘Food Safety and Global Health: An International Law Perspective’ (Fall 2009) III Global Health Governance 1 <www.ghgj.org>; Anna Bulman and others, ‘Tying the Knot: An Interdisciplinary Approach to Understanding the Human Right to Adequate Nutrition’ (2018) 57 Columbia Journal of Transnational Law 62.

³⁶ See E/C.12/1999/5, 2 May 1999.

³⁷ See, in particular, the Final Report of the Special Rapporteur on the Right to Food, Olivier De Schutter, ‘The Transformative Potential of the Right to Food’, A/HRC/25/57, 24 January 2014, paras 29-31 on the importance of a “new paradigm” based on ‘strong support [by States] to small-scale food producers, based on the provision of public goods for training, storage and connection to markets, and on the dissemination of agroecological modes of production’ (para 30). In this connection, see also the Report of the Special Rapporteur on the Right to Food, Hilal Elver, ‘The Impact of Climate Change on the Right to Food’, A/HRC/70/287, 5 August 2015, especially paras 73-81, in relation to “agroecology” as the “alternative to industrial agriculture”; and the Report of the Special Rapporteur on the Right to Food, ‘The Effects of Pesticides on the Right to Food’, A/HRC/34/48, 24 January 2017, especially paras 90-95, in relation to “agroecology” as the “alternative to extensive use of pesticides.” Non-chemical alternatives should be used. Para 92 of this Report clarifies that “[a]groecology, considered by many as the foundation of sustainable agriculture, replaces chemicals with biology”.

³⁸ See, among others, UN General Assembly, Agriculture Development, Food Security and Nutrition, A/RES/72/238, 22 December 2017; and UN General Assembly, Impact of Rapid Technological Change on the Achievement of the Sustainable Development Goals, A/RES/72/242, 22 December 2017.

³⁹ Art 8, para 3, letter (a), of Annex I to the Convention includes measures ‘promoting the use of drought resistant crops and the application of integrated dry-land farming systems for food security

Important acts have also been adopted within the United Nations for the purpose of integrating the sustainable management of forests, aquaculture and fishery production into the internationally relevant concept of food security, in order to effectively tackle malnutrition and food insecurity in developing States. These acts are binding⁴⁰ and non-binding.⁴¹

One may expect that the broad conceptualization of food security and its connection with food safety could have an impact on the international actions aimed at providing food assistance, particularly in situations of emergency.⁴² If so, international organizations of the UN system and economic advanced States would purchase local food products and, in case these products would not be available, regional food products within food aid programmes in favour of developing and least developed States. By supporting local small producers and manufacturers, these purchases would facilitate the promotion of local sustainable development through inclusive growth.

At any rate, food commodities and products made by developing and least-developed States could be included in food aid transactions carried out within the framework of international assistance programmes, as long as they were 'safe'. This is one of the basic principles of international food assistance provided in the Food Assistance Convention that was concluded within the UN framework in 2012.⁴³

purposes', among possible 'measures to improve the economic environment with a view to eradicating poverty'. Art 4, letter (c), of the implementing programme for Latin America and the Caribbean, Annex III, is also relevant. This states that '[i]n the light of their respective situations, the affected country Parties of the region may take account, inter alia, of the following thematic issues in developing their national strategies for action to combat desertification and/or mitigate the effects of drought, pursuant to article 5 of the Convention: [...] (c) achieving food security and sustainable development and management of agricultural, livestock-rearing, forestry and multipurpose activities'.

⁴⁰ See, in particular, the 2009 Agreement on Port State measures to prevent, deter, and eliminate illegal, unreported and unregulated fishing concluded within the FAO.

⁴¹ See, among others, the 2016 Rome Declaration: Ten Steps to Responsible Inland Fisheries by the FAO Committee on Fisheries (COFI/2016/Inf.14) and the Information Paper named Executive Summary of the Agenda 2030, Sustainable Development Goals and Fisheries and Aquaculture by the same Committee (COFI/2016/Inf.20). See also the 2018 UN Declaration on the Rights of Peasants and Other People Working in Rural Areas (Resolution No. A/C.3/73/L.30 adopted by the Third Committee on Social, Humanitarian and Cultural matters of the UN General Assembly). Seven UN States, for instance Australia, the United Kingdom and the United States, were against the adoption of this Declaration, whereas forty-nine UN States, including Italy, abstained.

⁴² For further remarks, see Pia Acconci, 'Food Security within the Framework of International Assistance for Development: Working towards Rural Sustainability for the Realization of the Right to Food' in Malgosia Fitzmaurice, Sandrine Maljean-Dubois and Stefania Negri (eds), *The Challenges of Environmental Protection and Sustainable Development from Rio to Rio+20 and Beyond/Les défis de la protection de l'environnement et du développement durable de Rio à Rio+20 et après* (Brill 2014) 177.

⁴³ See letter (c) (iii) of Art. 2 on 'Principles of Food Assistance' of the Convention that refers to the provision of 'food assistance that meets applicable safety and quality standards, and that respects cultural and local dietary habits and the nutritional needs of the beneficiaries' as one of the "principles on the provision of food assistance". See also Art. 4, para 3, of the same Convention according to which "[e]ligible products" means products for human consumption that comply with relevant national poli-

Therefore, food safety, that today characterizes the international trade of food products, would extend to food transactions brought about by international assistance programmes.⁴⁴ However, the Convention does not specify what standards must be used to assess food safety. In this connection, the activity of the above-mentioned WTO Standards and Trade Development Facility appears essential.

4. International Organizations as Coordinators and Facilitators, particularly of Multi-stakeholder and Multi-sectoral Partnerships and Platforms

Health promotion and equitable, that is affordable, access to healthy food products have become relevant aspects under both the food security and food safety perspectives.

At the international level, there have been relevant achievements not only from a regulatory point of view, but also from an operational one because most international organizations, particularly those of the UN system, have resorted to an integrated approach to food safety and security with the aim of involving all the key actors, both public and private.

The analysis of the regulatory achievements shows that one appropriate response could be the production of food in a way which preserves the environment, particularly by reducing the amount of hazardous chemicals and greenhouse gas emissions which contribute to pollution and global warming. Another could be the promotion of qualitative investments in agriculture, both public and private, to lead agricultural productivity and food production systems towards sustainability in terms of soil fertility, resilience, adaptation, biodiversity preservation and water use efficiency.

This kind of response requires an appropriate regulatory and policy framework and presupposes the availability of appropriate financial and technical resources. The latter has been the main reason why the active participation in international actions for financial and technical assistance of the private sector has become common through the resort to an operational approach.

Resilient agricultural practices and sustainable food production systems are a kind of response that rely on the involvement, as active players, of food corporate manufacturers that have expressed their concern, on the one hand, by taking a corporate

cies and legislation of the country of operation, including, as appropriate, applicable international food safety and quality standards as well as products that contribute to meeting food needs and protecting livelihoods in emergency and early recovery situations'. Australia, Austria, Canada, Denmark, the European Union, Finland, Japan, Luxembourg, Russia, Slovenia, Spain, Sweden, Switzerland, United States are Contracting Parties of the Convention.

⁴⁴ Cf Kira Villa, Cynthia Mathys, 'Quality and Safety of Food Assistance' in Christopher B Barret, Andrea Binder and Julia Steets (eds), *Uniting on Food Assistance* (Routledge 2012), especially 111-116.

social responsibility perspective through the adoption of special codes of conduct and principles of good practices and, on the other, by supporting the establishment of international public-private multi-stakeholder and multi-sectoral partnerships and platforms, as well as financial and technical mechanisms. There have been relevant achievements this regard.

The FAO Committee on World Food Security (CFS) is one important example of an international multi-stakeholder platform for food security and nutrition for all. This Committee has succeeded in adopting a number of voluntary acts⁴⁵ that aim at promoting a broad conceptualization of sustainability, at coordinating actions by heterogeneous actors, at supporting States, particularly developing ones, and affected peoples to “build resilience”, to prepare adaptation and mitigation plans, as well as innovative strategies related to extreme climate change events, and to promote the growth of farmer markets and programs that increase access to locally and/or traditionally produced foods.⁴⁶

In addition, a relevant number of transnational food companies have individually adopted standards, best practices and codes of conduct to show their attention to the safeguard of social interests. The approach of these companies has fostered the achievement of health protection through food safety.

The European Union has also been a protagonist in this connection, especially by integrating food safety concerns within the agricultural sector and food chain, as well as by revising its regulatory framework on renewable energy and biofuels from crops, in order to mitigate the possible economic competition between food production and biofuel production, more specifically between food security and energy security.⁴⁷ The EU revised regulatory framework on renewable energy and biofuel production promotes the voluntary adoption by investors and host States of a coherent integrated approach based on economic, environmental and social considerations.⁴⁸

⁴⁵ The main acts adopted by the Committee on World Food Security are: the 2017 Global Strategic Framework for Food Security and Nutrition, the 2015 Framework for Action for Food Security and Nutrition in Protracted Crisis, the 2014 Principles for Responsible Investment in Agriculture and Food Systems, the 2012 Voluntary Guidelines on the responsible governance of tenure of land, fisheries and forests in the context of national food security, the 2004 Voluntary Guidelines to support the progressive realization of the right to adequate food in the context of national food security. These are all available on the website of the Committee <www.fao.org/cfs/home/products/en>.

⁴⁶ Initiatives that aim to increase awareness of and access to fresh, local produce such as schoolyard gardens, community-based agriculture, and farm- to-school or farm-to-cafeteria programs’ are relevant examples (Karen Rideout, ‘Food Security and Environmental Health’ (2014) 57(4) *Environment Health Review* 83).

⁴⁷ See Directive 2015/1513/EU of the European Parliament and of the Council, 9 September 2015 amending the Directive 98/70/EC concerning the quality of petrol and diesel fuels and amending the Directive 2009/28/EC on the promotion of the use of energy from renewable sources [2015] OJ L239/1, and Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 concerning the promotion of the use of energy from renewable sources and amending and subsequently repealing the Directives 2001/77/EC and 2003/30/EC [2009] OJ L140/16.

⁴⁸ For an overview of the EU regulatory and policy approach to biofuel production through private

5. Conclusion

The relevant international actions aimed at ensuring food security and safety through a healthy environment and the actors involved therein are heterogeneous, in terms of interests, competences and approaches. There have been binding and non-binding regulatory responses at an international and EU level. These responses have been based on common principles, such as sustainability, free trade and investment. Food safety tends to be seen as the production and sale of qualitative food, whereas food security as the access to nutritious and affordable food products. The prevention of food-borne diseases, through food safety and security, has become one of the chief objectives of international regulatory and operational actions aimed at the satisfaction of basic social needs.

Because of the heterogeneity of the actors, on the one hand, diversification characterizes the international regulatory and policy frameworks and, on the other, soft regulatory instruments have become predominant for integrating healthy environment, food security and safety and ensuring that food production is not “threatened” by environmental degradation.

International regulatory and policy diversification can be inferred from the great number of lines of action and rules, whether binding or not, on specific aspects of the connection among the environment, public health, food security and food safety. Regulatory and policy diversification, arising from the significant number of institutions, might be a detrimental phenomenon because it may affect the effective satisfaction of the social interests at stake. To some extent, regulatory diversification and informalism have affected the resort to a human rights-based approach to food safety and security, aimed at effectively implementing the right to food. The *ad hoc* General Comment on the Right to Food by the UN Committee of the Covenant on Economic, Social and Cultural Rights and the Reports by the UN Special Rapporteurs on the Right to Food have not been enough to this end, given their voluntary nature.

A few recent reports published within the United Nations have shown that rates of food insecurity have increased and continue to increase, so having a negative impact on health protection,⁴⁹ and a “dramatic” change in the lifestyle, diet habits included, of ordinary people in every State, whether economic advanced or least economic advanced, is highly recommended, in order to tackle the negative implications of climate change for the economic stability of States and for the welfare of current and future generations, as well as for animal welfare and plant protection.⁵⁰

investment, see Pia Acconci, ‘Biofuel Production through Sustainable Investment from the Standpoint of the European Union’ (2017) 100 *Rivista di diritto internazionale* 1040.

⁴⁹ See, among others, FAO, *The State of Food and Agriculture. Leveraging Food Systems for Inclusive Rural Transformation*, 2017.

⁵⁰ See the Report adopted by the Intergovernmental Panel on Climate Change (IPCC) on 8 October 2018. According to this Report, the target of ‘climate action towards 1.5°C can be a significant step

Heterogeneous rules, policy actions and technical assistance for prevention, like programs and trust funds, show that international organizations have made and continue to make relevant efforts not only to pursue sustainable development as a macroeconomic and political goal of international relations, within a systemic and collective approach, but also to support appropriate implementing strategies at the State level, particularly by developing States.⁵¹ In this regard, one might wonder if the fact that most of the relevant international rules on the connection among the safeguard of the environment, health protection and food security are voluntary might be due to the fact that food security is perceived above all as a matter of concern for developing States, in particular least developed States, as far as livelihood conditions for vulnerable people in big cities and rural areas are concerned. At any rate, this cannot be the only possible reason why an important industrialized State, like the United States, has chosen not to be a protagonist of the collective actions against environmental degradation due to fertilizers, waste and/or climate variability. The United States has not ratified the Basel, the Stockholm and the Rotterdam Conventions yet and announced its withdrawal from the Paris Agreement on 1 June 2017.⁵²

In addition, the effectivity of regulatory actions, whether binding or not, taken by international organizations has been, and is undermined, by the shortage of specific remedies under international law, in case of noncompliance by their Member States. When we talk about non-binding rules, judicial enforcement is not an option. Compliance by States through appropriate implementation within their domestic law systems of the international applicable rules, whether these are binding or voluntary, still appears as the possible best available remedy. In effect, a few practitioners have

towards achieving the SDGs'. In light of scientific data, the IPCC recommends States and private parties to take immediate appropriate measures to react to the "danger" of global warming. The Report, among others, points out the 'poverty, equality and equity implications of a 1.5°C Warmer World' (ch 5, at 10-12). The IPCC was established by the UN Environment Programme (UNEP) and by the World Meteorological Organization (WMO) 'in 1988 to provide the world with a clear scientific view on the current state of knowledge in climate change and its potential environmental and socio-economic impacts'. For further information on the IPCC, see its website <<http://ipcc.ch/organization/organization.shtml>>.

⁵¹ For instance, para 5 of the UN General Assembly, Agriculture Development, Food Security and Nutrition, A/RES/72/238, 22 December 2017 '*[r]eiterates* the importance of developing countries determining their own food security strategies, that improving food security and nutrition is a global challenge and a national policy responsibility and that any plans for addressing this challenge in the context of eradicating poverty must be nationally articulated, designed, owned, led and built in consultation, as an inclusive process, with all key stakeholders at the national level, as appropriate, and urges Member States, especially those affected, to make food security and nutrition a high priority and to reflect this in their national programmes and budgets'. Para 6 '*[c]alls upon* the international community to continue its support for the implementation of the Comprehensive African Agriculture Development Programme and its results framework, which is an integral component of the Programme that provides guidance on planning and implementing investment programmes'.

⁵² In accordance with Art. 28 of the Paris Agreement, the US withdrawal will be effective only four years after such an Agreement came into effect in the United States, that is 4 November 2020.

highlighted the importance of domestic proceedings in this regard.⁵³

On the other hand, the proliferation of soft regulatory instruments has contributed to the effectivity of the principles of international cooperation and integration by mainstreaming the safeguard of non-economic interests, like the environment and public health, into international regulatory and policy frameworks directed to the promotion and protection of economic interests, such as trade and investment.⁵⁴

Overall, international and EU regulatory responses have been directed to establishing satisfactory policy frameworks and good manufacturing practices. International organizations have acted as coordinators and facilitators of activities of a different kind, either public or private. Such activities have been scientific, operational and regulatory. From this standpoint, international organizations may be seen as technical and scientific advisory “authorities”.

The influence of the Food and Agriculture Organization and World Health Organization, as the most engaged UN international organizations in this connection, and the prevalence of soft regulatory instruments have brought about an innovative approach to the agriculture sector and food production by other international organizations and agencies, as well as by a number of enterprises.

However, international organizations do not act beyond their conferred powers, as their activities tend to be consent-based, contractual and aimed to establish horizontal coordination within the sovereignty of their Member States.

⁵³ See Munich Re, *Liability for Climate Change?* München, 2010 (available on <www.munichre.com/site/touchpublications/get/documents_E753942211/mr/assetpool.shared/Documents/5_Touch/_Publications/302-05493_en.pdf>).

⁵⁴ See, in particular, the new approach of a few economic advanced States, such as Canada, and of the European Union and its Member States, with the aim of injecting the safeguard of a number of non-economic interest within the drafting of international investment rules.



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Chapter 15

Environmental Impact Assessment: Environmental Health and Food Safety

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1. Introduction: The Environmental Impact Assessment Technique in the European Union and the Need to Treat It to Preserve Environmental Health

One of the main purposes that democratic States have included in their public agendas is to comply with the environmental commitments acquired by the Member States, both in the international sphere and in the context of the European Union. These commitments are the result of the progressive political and social awareness regarding the need to take effective measures, mainly preventive, for the protection of the environment in its entirety, as it is always the way to allow the survival of our planet, its animal and plant species, and human beings. The evolution of the environmental regulation has been dizzy and intrusive into other areas of public action that, initially, are not within environmental policy. However, the transversal nature of the environment causes that this variable must be taken into account in the rest of public policies, as the health policy or the food safety.

We could ask ourselves what are the purposes of environmental law and organise them in the following three: the preservation of the environment, the guarantee of a sustainable use of natural resources, and their conservation in the conditions that allow a better quality of life for human beings.¹ Since the second half of the 20th century, the concern of the States for the preservation of the environment and of the natural resources, have grown to such an extent that an overwhelming amount of regulation, both general and specific, have been generated, integrating this Corpus

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¹ This way, among others, Blanca Lozano Cutanda in 'Derecho Ambiental: Algunas reflexiones desde el Derecho Administrativo' (Environmental Law: Some Thoughts from Administrative Law) (2016) 200 *Revista de Administración Pública* 409, 411 ff, defines the current environmental law as the regulatory system aimed at the preservation of the human environment through the pollution control and the guarantee of a sustainable use of the natural resources and of the biosphere systems that serve as a support for life. At the same time, highlights that, despite the considerable advances of the environment protecting regulation, its application faces up to important "economic-political obstacles".

Iuris and whose effective application is requested by the civil society, specially through the environmental NGOs that are in charge to carry out the appropriate requests and claims. Globally, the international law offers an itinerary marked by important events such as the 1972 Stockholm Conference, the 1987 Brundtland Report and the new concept of sustainable development, the 1992 Rio Declaration, the 1997 Kyoto Protocol, the 1998 Aarhus Convention or the 2002 Johannesburg Summit;² also, the 2015 Paris Agreement or the United Nations Sustainable Development Summit, held in the same year, of the “2030 Agenda and the Sustainable Development Goals”³ are of particular interest. It is worth to highlight, regarding the 2030 Agenda, the environmental implications of all the goals that suggests, some of them affecting the environment in a direct way, like the 6th goal, which refers to the need to ensure the availability and sustainable management of water and sanitation for all; and the 12th goal, referred to the need to ensure sustainable consumption and production patterns.⁴

Within the European Union framework, the commitments acquired in the international field are integrated in the European policy on environmental protection, whose competence finds its legal grounds in article 4.2.e) of the Treaty on the Functioning of the European Union (TFEU), setting up as a shared competence between the European Union and the Member States, although, in practice, national competencies are much more conditioned by the environmental policies of the EU. The legal basis of these competencies is found in articles 11 and 191-193 of the TFEU, which legitimate the European Union to legislate in all fields related with the environmental policy, with the limit of the subsidiarity principle and of the unanimity of the Counsel in some aspects.⁵

In order to achieve these goals, the legislation acts well with a preventive nature, through the design of tools and instruments applied to certain activities and projects

² See Blanca Lozano Cutanda, ‘Eclósión y crisis del Derecho Ambiental’ (2007) 174 Revista de Administración Pública 375.

³ A general reference to the most important international milestones can be seen in Leonardo Sánchez-Mesa, ‘Aspectos básicos del Derecho Ambiental: objeto, caracterización y principios. Regulación constitucional y organización administrativa del medio ambiente’ in M Asunción Torres López and Estanislao Arana García, *Derecho Ambiental* (Tecnos 2017) 45; see Alejandro Lago Candeira, ‘Compromisos internacionales ambientales’ in Fernando López Ramón (coord), *Observatorio de Políticas Ambientales 2016*, 25.

⁴ See Agenda 2030, the 17 sustainable development goals, available at <www.un.org/sustainabledevelopment/>; a more in-depth examination in Lago Candeira (n 3) 58 ff, who indicates the goals that have direct environmental implications, which are, along with the ones mentioned in the text, the following: goal 7 (ensure access to affordable, reliable, sustainable and modern energy for all); goal 11 (make cities and human settlements inclusive, safe, resilient, and sustainable); goal 13 (take urgent action to combat climate change); goal 14 (conserve and sustainably use the oceans, seas and marine resources for sustainable development); and goal 15 (protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss).

⁵ This way, regarding fiscal affairs, the planning of the territory, the use of the land, the quantitative management of water resources, the selection of energy sources or the structure of the energy supply.

that are potentially harmful to the environment, and whose purpose is to avoid those damages or minimise their effects. Among these techniques is the environmental impact assessment or the strategic assessments. Other rules regulate the contamination process, demanding certain quality standards that are considered reasonable; this legal framework is completed with the appropriate sanction regime, in case of failure to comply with the regulations, and with the application of one of the most significant measures, that is, the obligation to restore the damaged environment.⁶ Along with this, since the legislation is focused on risk activities, the principle of precaution is the instrument to manage the risk when there is scientific uncertainty on a potential risk for the environment or for the human health; this way, when in doubt, even after the objective scientific assessment, the withdrawal of the product from the market or from distribution can be imposed.⁷ Although this principle has its origin mainly in the environmental protection field, it has spread to other areas, like health protection or food safety, being its purpose not only the environmental protection but the public health as well.⁸

Without a doubt, one of the most effective legal tools to analyse the risk of potentially harmful activities for the environment and, therefore, harmful for human health, is the environmental impact assessment, along with the assessment of the impact on health.

The evolution of the European Union Law in terms of environment has been overwhelming, and in the last years, the concept of environmental health has gained importance and an appropriate treatment. In this sense, the need to adapt the European policies of environmental prevention to the principles of public intervention of potentially harmful activities for the environment, has been established, as currently

⁶ See Dionisio Fernández De Gatta, 'Derecho Ambiental: aspectos generales sobre la protección jurídica del medio ambiente' (2004) 12 Revista electrónica E-Derecho Administrativo. On the obligation to restore the environment see Jesús Conde Antequera, *Deber jurídico de restauración ambiental* (Comares 2004).

⁷ These are risks generated from the application of technological advances, basically long-term risks, which makes it more difficult to verify if there will be a damage in the future, and what will be its extent. See Manuel Rebollo Puig and Manuel Izquierdo Carrasco, 'El principio de precaución y la defensa de los consumidores' (2003) 265-266 Documentación Administrativa 187. Applied to the protection of the environment, it has been addressed, among others, by José Esteve Pardo, 'La intervención administrativa en situaciones de incertidumbre científica. El principio de precaución en materia ambiental' in José Esteve Pardo (coord), *Derecho del Medio Ambiente y Administración Local* (Fundación Democracia y Gobierno Local 2006) 201. And by the same author, 'La operatividad del principio de precaución en materia ambiental', (2004) 26 Manuales de Formación Continuada 191. In this same number, the article of Carlos M Romeo Casabona, 'Salud humana, biotecnología y principio de precaución', 215. More recently, Carla Amado Gomes, 'Precaución y protección del ambiente: de la incertidumbre a la condicionalidad' (2017) 38 Revista Aranzadi de Derecho Ambiental 247.

⁸ This is how it is stated by César Cierco Seira, 'El principio de precaución: reflexiones sobre su contenido y alcance en los Derechos comunitario y español' (2004) 163 Revista de Administración Pública 73, where it is also referred the impact that this principle has in other areas, as medicine, psychology, sociology, bioethics, economy, philosophy or political sciences; fields where the advance of the science leads to uncertainty regarding the risks that it generates.

the reconsideration of the control institutions and prevention tools is urgent, taking into account the variables that must be included in the most used technique for the environmental protection, which is the environmental impact assessment. This is where the environmental health and its protection through the environmental impact technique become important. The objective is to find out the new possibilities of the environmental assessment as an instrument to face the risks to human health generated from certain activities, suggesting a regulatory need to integrate the public health aspects in the environmental impact assessment procedures within the health programmes. To incorporate the health impact assessment in the environmental impact assessments.

This way, the technique of environmental impact assessment turns its focus from the exclusive environmental protection of natural resources, to the prevention or decrease of the risks that a certain activity poses to human health. In connection with the environmental impact assessment, the health impact assessment is also carried out, precisely because the environmental protection techniques tends to preserve the environment so the living conditions of people are not only acceptable, but of the best quality possible.

This environment-health relation leads to the concept of environmental health or environmental healthcare, whose protection originates from the conviction that health protection does not exclusively depends on the organisations in charge of the health policy through the healthcare services; but goes beyond, as people health depends from a series of factors that are external to the healthcare field, as living habits, biological factors or the very environmental risks or factors. Therefore, the analysis of environmental risks and their impact in human health are necessary to properly protect the health of people.

2. Environmental Health and Its Protection through the Environmental Impact Assessment Technique in EU Law

In the context of the European Union, the incorporation of health in the environmental assessment instruments is mandatory, as derived from Directive 2001/42/EC of the European Parliament and of the Council of 27th June, on the assessment of the effects of certain plans and programmes on the environment; and from Directive 2014/52/EU of the European Parliament and of the Council of 16th April, on the assessment of the effects of certain public and private projects on the environment.⁹ In the environmental impact assessments, it is required to inform of any significant effect, both direct or indirect, as well as to describe the risks for human health.

The environmental impact assessment is shaped as an important instrument to in-

⁹ [2001] OJ L197/30 and [2014] OJ L124/1, respectively.

tegrate environmental considerations in the preparation and adoption of some plans and programmes that may have significant repercussions on the environment in the Member States. Although the main objective is to reach a high level of protection of the environment and to integrate environmental aspects in the preparation and adoption of plans and programmes, that objective is aimed to achieve a sustainable development. That is why it is required to assess the significant effects and risks for human health, originated from the application of those plans and programmes, in the environmental report.

One of the main grounds for the environmental health protection is to integrate the health variable in the environmental policies.¹⁰ Several programmes for the protection of health have been adopted in the European Union, although they did not include the environmental variable directly, which is, undoubtedly, determinant for human health. This way, in the EU Health Strategy 2014-2020, to promote health, prevent disease and foster healthy lifestyles through 'health in all policies', was already considered as one of its four specific goals.¹¹

So that, besides the natural environment, there are other environmental conditions that must be taken into account, which derive directly from human actions and not only affect the environment, but also affect health, leading to a series of problems with political, social and legal implications as a result of factors like noise, pollution, electromagnetic waves, climate change or even activities like the production of expired food, its consumption or food waste. This way, the assessment of the effects of expired food production regarding food safety, the assessment of the environmental impact of activities that generate expired food, the waste treatment regarding the waste of food, and also, the food advertising addressed to minors in connection with the risk of obesity, are considered important.

Therefore, the legal analysis of the environmental assessment procedures gains importance, as they are linked with the management of the environmental risks and those in connection with human health, with the purpose of determine how decisions are taken regarding the risks.

There are many activities that affect the environment, and the European Union has established both general and specific regulations with the intent to protect the

¹⁰ See, among others, Almudena García Nieto, 'Propuesta técnica para incorporar la salud en los procedimientos de evaluación del impacto ambiental de políticas, planes, programas, proyectos y actividades' (2015) 15 *Revista de Salud Ambiental* 59. Reference is made to the health priorities and the paths to make the integration of the health variable feasible, in the process of environmental assessment of public and private plans, programmes and projects.

¹¹ The third health programme of the EU 2014-2020 has its legal grounds in the Regulation (EU) No 282/2014. The other three goals are: To protect EU citizens from serious cross-border health threats; to contribute to innovative, efficient and sustainable health systems; and to facilitate access to high quality, safe healthcare for EU citizens. See Regulation 282/2014/EU for the third Health Programme ([2014] OJ L/86), available at <http://ec.europa.eu/health/programme/policy/index_en.htm>. The first Health Programme of the EU was designed for 2003-2007, and the second Health Programme comprised the EU Health Strategy 2008-2013 of the European Commission.

environment, demanding previous actions and controls. This way, the air pollution, the biological and chemical contamination of food and water, the genetically modified food, the so-called persistent toxic substances in the environment, the noise and the electromagnetic waves or the climate change, which results in certain effects on health; all of them have a special impact on human health.¹²

In this sense, the incorporation of the health variable in the impact assessments is vital, in order to determine the risks that a certain activity, subject to environmental impact techniques, may generate for the health of the population.

Although, along with the environmental impact assessment technique, that prioritise the protection of the environment, even when the significant risks for health analysis is required, in many cases, when the primary purpose is the protection of health, it is necessary to carry out the so-called health impact assessment in certain plans, programmes or activities that are not linked to healthcare sectors, and which could be made in parallel with the environmental impact assessment.

3. Environmental Health and Health Impact Assessment

The health impact assessment is defined by the WHO as a combination of procedures, methods and instruments that allow to judge the possible effects of a policy, programme or project on the health of a population, as well as the distribution of the potential effects inside it. This assessment is related to the person's physical, chemical and biological external factors.¹³

In the context of the European Union, the European Commission published a guide with the steps to be taken in detail to carry out a health impact assessment.¹⁴ According to the guide, first, the impact that the activity, plan or programme may have on public health must be assessed, in order to determine if there is a need to carry out a health impact assessment. If it is considered appropriate to carry out a health

¹² See F García López, 'Efectos del deterioro ambiental sobre la salud' (2007) 5 *Panorama Social* 143, in which an analysis of the environmental factors that affect human health is carried out, stating the need to coordinate the protection techniques through the principle of precaution, given the legal uncertainty, in many cases, of the extent of the risks for health.

¹³ Website of the World Health Organisation, <www.who.int/phe/en/>. WHO European Centre for Health Policy. Health impact assessment. Main concepts and suggested approach. Gothenburg Consensus Paper. Copenhagen: WHO Regional Office for Europe; 1999. See María Sandín-Vázquez and Antonio Sarriá-Santamera, 'Evaluación de impacto en salud: valorando la efectividad de las políticas en la salud de las poblaciones' (2008) 3 *Revista de Salud Pública* 261; Amaia Bacigalupe and others, 'La evaluación de impacto sobre la salud: una herramienta para incorporar la salud en las intervenciones no sanitarias' (2009) 23 *Gazeta Sanitaria* 62.

¹⁴ See Debbie Abrahams and others, 'EPHIA-European Policy Health Impact Assessment: A Guide', International Health Impact Assessment Consortium. Liverpool: IMPACT, University of Liverpool, 2004.

impact assessment, its extent must be defined, that is, depending on the potential risks, the assessment must be well planned and its intensity has to be established. From here, the plan, programme or policy subject to the assessment must be analysed through a specialised advisory group, establishing or negotiating recommendations after that analysis; and present the measures that must be adopted to improve the policy, plan or programme, after the advice, identification, analysis and impacts' prioritisation process. Those measures are intended to avoid or minimise the potential risks for health. Finally, it is important to value if the adoption of those measures have had the expected results, in order to calculate the efficacy and efficiency of the health impact assessment. That is to say, if the advice and the recommendations given have affected the decision-making process and have reflected in the avoidance of impacts for human health that were detected in the first phase.

The health impact assessment is important because it allows to know better the possible consequences for health of certain programmes, activities or policies that are outside the healthcare sector. It is a method whose specific purpose is to preserve human health. Although, one of the biggest problems of its application is precisely the absence of agreement regarding the methodology to be followed, and the greater or lesser extent of the precision in terms of legal requirement to start-up a certain policy, plan or programme, specially when it has a public nature. Moreover, in our opinion, when it comes to health risks or potential impacts on the health of the population, the application of the principle of precaution is of critical importance; whose concept, which comes from its application to the environmental damages, can be perfectly transferred to the specific field of health. So that, when a serious or irreversible danger arises, the absence of information or scientific certainty, must not be used as a reason to defer the adoption of effective measures, depending on the costs, to avoid the degradation of health of the population.¹⁵ Besides, in today's society, where the risks come from the progress, technical advances and new technologies, whose application may produce unexpected results, precisely because of the scientific uncertainty regarding their perception, the perception of the risk is vital. In this sense, the law, the legal rules, are the ones that determine the concept of risk perception, and how, when, and where will be perceived, ultimately affecting the decision-making process.¹⁶ In any case, it must be coordinated by the set of general principles of law, and among them, the principle of proportionality gains special relevance.

¹⁵ On the principle of precaution, among many others, see the studies by José Esteve Pardo on the matter, and among them: 'La intervención administrativa en situaciones de incertidumbre científica. El principio de precaución en materia ambiental' in José Esteve Pardo (dir), *Derecho del Medio Ambiente y Administración Local* (Fundación Democracia y Gobierno Local 2006) 201; *Técnica, Riesgo y Derecho. Tratamiento del riesgo tecnológico en el Derecho Ambiental* (Ariel 1999); 'Ciencia y Derecho ante los riesgos para la salud. Evaluación, decisión y gestión' (2003) 255-256 Documentación Administrativa 137.

¹⁶ In this sense, see Juan Antonio Carrillo Donaire, 'Derecho, técnica y riesgo: el principio de precaución en el ámbito medioambiental' (2016) 281 Revista de fomento social 251. Also, Blanca Soro Mateo, 'Construyendo el principio de precaución' (2017) 49-50 Revista Aragonesa de Administración Pública 87.

The health impact assessment is a convenient instrument and, in many cases, needed when it comes to start-up public or private policies, plans or programmes outside the healthcare sector. The protection of the human health, considered from the disease prevention perspective, is a vital public goal, and depends on the environment where life is developed, and therefore all public policies are involved. The purpose is to prevent the negative impacts that products, elements, environmental processes, physical, chemical and biological agents may have on human health; the risks derived from the environmental factor of physic, chemical or biological nature.

4. Environmental Health and Food Safety

Food safety is one of the essential policies in all States, through which health inspections and prevention of health risks derived from food products, as well as the improvement of their nutritional qualities, are addressed.

In the European Union context, the White Paper on Food Safety established the regulatory guidelines of food safety in the Member States, based on rigorous rules that will serve to protect and promote consumers' health, and although the health protection is always a priority, the food production and consumption has economic, social and environmental repercussions that must be taken into account during the food policy development. Specially, the condition and quality of the environment can affect the different links of the food chain, so the environmental policy has an important function when it comes to guarantee healthy food.¹⁷ Besides, among its principles, the risk analysis is considered the base of the food safety policy, with its three components: establishment of the risk, management of the risk and communication process, considering the application of the principle of precaution when there is scientific uncertainty.

The basic body of law on food legislation in the European Union consists of the Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; and other regulations that complements it in terms of hygiene and official control, establishing the basic regulation that is applicable to all phases of the food chain and, in particular, of animal origin, in this matter.¹⁸

¹⁷ White Paper on Food Safety, presented by the European Commission, COM (1999) 719 final, 12 January 2000.

¹⁸ This way, the Regulation (EC) No 852/2004 on the hygiene of foodstuffs; the Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, the Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption; the Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs; or the Regulation (EC)

There are some problems that affect the health of the population regarding the food safety policy:

1. Food contamination, that affects or may affect, in varying degrees, the quality of the food and generate diseases, in addition to the problems that affect the water consumption. Whether if it is chemical or microbiological contamination. The risks that can be associated to genetically modified food. Also, the persistent toxic substances, that are substances external to the organism that persist for a long time in the environment, accumulate in the biological tissues and produce harmful effects on health.¹⁹ There is a regulatory body in the European Union between Regulations and Recommendations that establishes measures regarding the presence of contaminants in the food.²⁰

The environmental impact assessment technique and the analysis of the impacts on health are essential. Alongside this, an appropriate information, well detailed, of the components of every food specially addressed to the consumer.²¹

2. The current obesity problem and child obesity. A problem that worries the States also in the international scope. Obesity is a disease and efficient prevention measures must be adopted, which, in addition, will reduce the healthcare cost. Among these measures, it may be efficient the use of the health impact assessment for certain activities, as the food advertising addressed to minors. In addition to the appropriate information on the composition of food and the presence of contaminants within the legal limits.

3. The food waste and expired food treatment. This is one of the problems that requires an immediate answer in the European Union and that demands the adoption of measures for the reduction of food waste generation, at the same time that allow a proper treatment of the food donation and of the expired food consumption, differentiating the terms of best-before date and expiry date.

The food waste generation is produced along the entire food chain, from the production, through the transformation, and until the sale and consumption. In the Eu-

No 1069/2009 laying down health rules as regards animal by-products.

¹⁹ See García López (n 12) 145 ff.

²⁰ The Community provisions of general nature on food contaminants are the Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs and the Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food. Along with these Regulations, other specific ones have been issued on specific contaminants and the tolerable limits for their presence in food (this way, regarding the presence of acrylamide in food; on the sampling, analysis and control of dioxins and PCB levels; polycyclic aromatic hydrocarbons; heavy metals and other environmental and industrial contaminants; mycotoxins and plant toxic substances; or nitrates).

²¹ It is applicable Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

ropean Union context does not exist an unique legal concept for food waste or food residue. In this sense, the definition used by the Food and Agriculture Organization of the United Nations is taken, according to which the food loss is defined as ‘the decrease in quantity or quality of food’ and the part of food loss called “food waste” refers to discarding or alternative (non-food) use of food that is safe and nutritious for human consumption along the entire food supply chain, from primary production to end household consumer level.²² The reduction of the food waste and the need to establish a hierarchy that prevails the use instead of the waste, is one of the key purposes of the Committee on World Food Security; and is also one of the goals of sustainable development, through which a real food safety can be achieved.

It is also one of the missions of the European Union to treat a problem that has gained a significant political, social and economic relevance, along with the environmental repercussions that entails. The European Commission has focused on this matter and has integrated the prevention of food waste in the pack of the circular economy of the Commission to stimulate the transition of Europa towards a circular economy;²³ the waste legislation of the European Union of 30 May 2018, requires the Member States to adopt measures in order to reduce food waste in every phase of the food supply chain, to monitor the food waste levels, and to inform on the progress accomplished. The quality of the environment and the protection of the human health, goals of the sustainable development, depend on an adequate management of the waste.²⁴ It should also be mentioned that, in 2016, the European Court of Auditors drawn up a Special report on ‘Combating Food Waste: an opportunity for the EU to improve the resource-efficiency of the food supply chain’.²⁵

In the context of this article, it is worth highlighting that this combat against food waste involves different policies of the European Union, even when food waste is not their goal.²⁶ However, it is necessary the integration of all of them when it comes to adopt efficient measures towards the prevention of waste or to facilitate the donation of food, as it is mentioned in the report. In this sense, the environmental or health

²² See at <www.fao.org/platform-food-loss-waste/food-waste/definition/en/>. Food waste is recognized as a distinct part of food loss because the drivers that generate it and the solutions to it are different from those of food losses (FAO 2014).

²³ The value of the products, materials and resources must be kept in the economy for as long as possible, reducing the waste generation to its maximum. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions ‘Closing the loop – An EU action plan for the Circular Economy’, COM (2015) 614 final, 2 December 2015.

²⁴ Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018, amending Directive 2008/98/EC on waste (Text with EEA relevance).

²⁵ Available at <www.eca.europa.eu/Lists/ECADocuments/SR16_34/SR_FOOD_WASTE_EN.pdf>. See Luis González Vaqué, ‘El desperdicio de alimentos en la Unión Europea: ¿Un problema sin solución? (2017) 22 Revista CESCO de Derecho del Consumo 132.

²⁶ This is the case of the political fields regarding agriculture, fishing, food safety, environment, social affairs and taxation.

impact assessment techniques for policies, plans or programmes regarding the treatment of food waste (discards) gain importance, insofar as being susceptible of generating harmful impacts in the environment and on human health (by contamination during the food chain process); or regarding the alternative use of food (non-food). The prevention and reduction of food waste is a big challenge for the Member States; and it's a goal according to the 2030 Agenda for Sustainable Development, adopted by the General Assembly of the United Nations on the 25th September 2015. The Member States must adopt the measures needed to achieve a food waste reduction of 50 %, at European Union scale, in 2030.

On the other hand, in a study carried out by the European Commission in 2018, it is estimated that a 10% of the 88 million tons of food waste generated each year in the European Union, is linked to the expiry date.²⁷ Therefore, another question that must be faced, in order to improve the quality of the environment and of the human health, is the marking of the food date. Some essential questions, like the selection of the marking of the date, the adjustment of the expiry date, information on the product labelling regarding its shelf-life and storage instructions, legibility and date marking design, etc. must be solved. In this study, it is noted that the food waste can be avoided with the adoption of homogeneous measures regarding the labelling conditions of the product, the clear and easy to understand information for the consumer, and the appropriate marking of the date.

4. Finally, regarding the above, it is interesting to stand out as well the relation that may exist between the excess of food generation, turned into waste, from the climate change perspective. The greenhouse gases generation as a consequence of an excess of production, along with that of the subsequent treatment of its waste, leads to the failure to comply with all the goals of the European legislation intended to satisfy the goals of the Horizon 2020.

²⁷ European Commission, Directorate-General for Health and Food Safety, 'Market study on date marking and other information provided on food labels and food waste prevention', written by ICF in association with Anthesis, Brook Lyndhurst, and WRAP, January 2018.



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Chapter 16

Mercury Pollution and Its Impact on Human Health: The Minamata Case

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1. Mercury Pollution and Its Impact on Human Health

Mercury is a basic chemical element belonging to the group of metals. It is considered by the World Health Organization (WHO) as one of the top ten chemicals, or groups of chemicals, of major public health concern.¹

Human exposure to mercury is a result of both natural phenomena and human activities. In fact, this metal is a naturally occurring element present in air, water and soil, which can be released into the environment from volcanic activity or weathering of rocks. Once released in inorganic form, mercury is transformed by bacteria into its organic form, namely methylmercury, a highly toxic derivative that can penetrate the food chain and expose humans and animals to serious toxicological risks.²

Anthropogenic activities are the major cause of mercury releases, especially coal-fired power stations, residential coal burning for heating and cooking, industrial processes, waste incinerators, as well as mining and extractive activities of gold and silver (due to the ability of mercury to amalgamate with most metals). Mercury is widely used in many industrial processes, including the production of fluorescent lamps, thermometers,³ sphygmomanometers, barometers,⁴ batteries, switches, electrodes and some chemical catalysts. It has also been used in medicine as a component of dental amalgam and as an antiseptic (mercury-chromium) and has in general contributed to the evolution of medical diagnostics. Currently, the most important sources of anthropogenic emissions of mercury are metallurgical and chemical activities.

Despite the fact that mercury has had a significant role in technological development and is still widely employed in productive and industrial activities, nowadays its

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¹ WHO, Mercury and health, Fact sheet, 31 March 2017 <www.who.int/en/news-room/fact-sheets/detail/mercury-and-health> accessed 10 January 2019.

² *ibid.*

³ It is mainly used in thermometers because it is a metal with a high rate of thermal expansion.

⁴ Its high density allows it to be effectively used in the manufacture of these products.

use is “unsustainable” from the perspective of both the health of ecosystems and human health. In fact, due to its high toxic potential, mercury is considered a global threat to human and environmental health.

Mercury exposure can produce multiple harmful effects on human health. Factors that determine the occurrence and severity of such effects include: the type of mercury concerned (elemental, inorganic and organic); the dose; the age or developmental stage of the person exposed; the duration of exposure; the route of exposure (inhalation, ingestion or dermal contact). At low exposure, developmental delays or neurological and muscular damage may occur; at high exposure, the consequences become even more serious and can involve brain damage culminating in death. In general, the major problems arising from exposure to mercury include damage to the kidneys, lungs, liver, tremors, mood changes, loss of sight or hearing, up to the onset of serious neurological disorders, such as the Hunter-Russel syndrome⁵ or the well-known Minamata syndrome.⁶

The main source of human exposure is represented by food. In fact, once mercury is introduced into the environment, it is able to penetrate and accumulate in the various stages of the food chain, especially in the aquatic chain, since methylmercury bioaccumulates (bioaccumulation occurs when an organism contains higher concentrations of the substance than do the surroundings) in fish and shellfish. The increase in mercury concentration in fish has created a general alarm, especially regarding the exposure of specific categories of vulnerable people who are more sensitive to the effects of mercury, such as pregnant women and children. In this regard, it is interesting to note that in 2001 the U.S. Food & Drug Administration, due to an exponential increase in cases of contamination of fish with mercury and methylmercury, urged pregnant women and children to consume only certain types of fish, such as anchovies, mackerel, mullet or freshwater fish, limiting the consumption of large predators such as swordfish or tuna, in which an enormous presence of this toxic metal was found.⁷

Concerns about the toxicity of mercury are equally shared by the major international organizations directly involved in the food safety sector, namely the Food and Agriculture Organization (FAO), operating within the United Nations, and the European Food Safety Authority (EFSA), a specialized agency instituted by the European Union (EU). FAO has dealt with, and continues to deal with, the presence of mercury and methylmercury in food within the Codex Alimentarius Commission,⁸

⁵ The Hunter-Russel syndrome develops due to a huge concentration of methylmercury in the human body. It is a disease that affects the whole body causing paresthesias, ataxia, tremors, mental disorders, hearing problems. See ‘Methylmercury poisoning’ in *Medical Encyclopedia* <<https://medlineplus.gov/ency/article/001651.htm>> accessed 15 January 2019.

⁶ Mercury and health (n 1).

⁷ Food & Drug Administration, ‘Eating Fish: What Pregnant Women and Parents Should Know’, <<https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm393070.htm>> accessed 10 January 2019.

⁸ The Codex Alimentarius Commission is an intergovernmental commission set up in 1963 jointly

an organ created jointly with the WHO. The Codex Alimentarius Commission, taking into account the benefits of fish consumption and also the fact that mercury can concentrate more in fish that live longer, has established the highest tolerable levels of mercury and methylmercury in food,⁹ also urging States to carry out information and consumer awareness campaigns. Similarly, at the regional level, the Panel on Contaminants in the Food Chain (CONTAM), set up by EFSA at the request of the European Commission, has established the maximum values of “tolerability” of this metal in food.¹⁰ The EU has consequently adopted several regulations that set maximum limits for mercury in food, especially in fish products.¹¹

2. The Minamata Disease

In the early twentieth century the Chisso Corporation began producing chemical fertilizers in the Japanese town of Minamata, located on the West coast of the island of Kyushu, the southernmost island of the Japanese archipelago. The inhabitants of Minamata mainly ate fish and molluscs caught in the city bay and in the Shiranui Sea. In 1932 the plant started producing acetaldehyde,¹² using mercury sulfate as a catalyst in the production process. A derivative of this cycle was methylmercury, which flowed into the Minamata Bay through the wastewater of the plant.

In the Fifties it was observed that the cats in the city of Minamata performed erratic

by FAO and WHO. It is an integral part of the Joint FAO/WHO Food Standards Program and has the duty to protect public health through the development of fair practices in food trade and the control of food safety. The Codex Alimentarius Commission has elaborated, during its sessions, a Codex Alimentarius, that is a set of standards, guidelines, practices regarding food safety, including food additives and contaminants, such as mercury.

⁹For mercury and methylmercury the Codex Alimentarius Commission has established a Codex guideline level (GL). The maximum level of mercury was quantified at 0.001 mg/kg in natural waters and 0.1 mg/kg in salty foods. Instead, the maximum level of methylmercury is different according to the types of fish considered. The maximum level in tuna, for example, is 1.2 mg/kg. For further information see Codex Alimentarius, General Standard for Contaminants and Toxins in Food and Feed <www.fao.org/news/story/en/item/1024512/icode/> accessed 15 January 2019.

¹⁰EFSA Panel on Contaminants in the Food Chain (CONTAM), Scientific Opinion on the risk for public health related to the presence of mercury and methylmercury in food, 10 April 2018. Based on this scientific opinion, the Panel proposed to establish 0.004 mg/kg of body weight and 0.0013 mg/kg body weight for the “tolerable” values of mercury and methylmercury in the food chain.

¹¹See Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs [2001] OJ L 77/1; Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs [2006] OJ L 364/5.

¹²Acetaldehyde is a toxic substance, implicated in the alcohol flush reaction and in certain physical sequelae of alcohol consumption: see World Health Organization, ‘Lexicon of alcohol and drug terms’ (WHO 1994).

movements, including twitching, spasms and convulsions, that led them to death.¹³ This unknown disease was called “dancing cats disease”. Very soon similar symptoms appeared also in the human population, in which the disease caused the loss of sensitivity and numbness of hands and feet; inability to grasp small objects; loss of hearing and visual ability; lack of balance; inability to coordinate movements and move; difficulty in articulating words.¹⁴ Furthermore, many children showed signs of the disease from the very first months and often could not survive over two years of age.

The spread of the phenomenon was considered the outbreak of an unknown epidemic affecting the central nervous system, which at the time was associated with brain diseases, syphilis, and alcoholism.¹⁵ A Committee for Countermeasures Against Strange Diseases in Minamata City was immediately established in collaboration with the local medical association. The Committee was entrusted with the task of carrying out epidemiological studies and more in-depth medical research. Members of the University of Kumamoto and of the Health Science Research Team established by the Ministry of Health and Welfare (MHW, currently Ministry of Health, Labour and Welfare, MHLW) actively participated in the activities of the Committee. In order to understand what had triggered this disease, the Committee started from considering the diet of the inhabitants of Minamata. Hence, the main object of the analysis of the research team were the fish and the waters of the Bay. In 1956, the Committee came to the conclusion that the cause of the disease was due to a heavy metal poisoning linked to food.¹⁶

As a precautionary measure, it was initially adopted a regime of total prohibition of fishing by the Minamata City Fisheries Cooperative and by the Government of the Prefecture of Kumamoto. This ban was considered unlawful by the MHLW due to insufficient evidence supporting the argument that the cause of the disease was related to fish and molluscs. The results of the research later allowed to prove that there were large quantities of mercury in fish and shellfish as well as in the waters of the Bay. The presence of mercury increased close to the discharges of Chisso Corporation, which was immediately considered the major source of environmental contamination, and hence the cause of the disease.

Despite this evidence, Chisso did not admit its responsibilities nor followed the directives of the Ministry of International Trade (MITI¹⁷), which required the installation of an effluent treatment system that would allow mercury to be disposed of

¹³ Douglas Allchin, ‘The Poisoning of Minamata’ (2000) University of Minnesota <<http://shipseducation.net/ethics/minamata.htm>> accessed 15 January 2019.

¹⁴ Katuyuki Murata and Mineshi Sakamoto, ‘Minamata Disease’ (2011) Encyclopedia of Environmental Health 774.

¹⁵ Allchin (n 13).

¹⁶ Ministry of the Environment, Government of Japan, *Minamata Disease. The History and the Measures* (2002).

¹⁷ Minister of International Trading & Industry.

from the waters of the Bay.¹⁸ This also happened because the company was supported by the local government – and probably also by the national government – which initially tried to defend the “reputation” of a company that had largely contributed to the economic prosperity of the city of Minamata. However, the lack of disclosure of relevant information by the local authorities and the denial of responsibilities by the chemical industry could not continue any longer as also people living along the Minamata River – where Chisso had moved its wastewater systems in an attempt to avert the increase of protests by groups of sick citizens who demanded compensation for the damage suffered – began to fall ill.

It was only in 1968 – thirty years after Chisso had begun to discharge methylmercury-contaminated wastewater into the Bay – that the MHV and the Agency for Technology and Science finally recognized that the Minamata disease was caused by ‘a compound of methylmercury produced by acetaldehyde and acetic acid production plants’ at Chisso Corporation.¹⁹ The same source of pollution was similarly recognized as the cause of the disease that had developed in Niigata, on the Agano river basin, due to the spillage of methylmercury-contaminated water by the chemical industry Showa Denko.²⁰ Following these assessments it was possible to certify the persons who had been affected, and the damages that the disease had caused to them could be recognized. In this regard, the company acknowledged that affected persons who were certified under the Relief Act were entitled to a compensation (“consolation payment”) which ranged from sixteen to eighteen yen depending on the severity of the case, the payment of medical expenses and a lifetime annuity.

3. The Minamata Convention on Mercury

Since 2003, when mercury was acknowledged as a global pollutant by the Governing Council of the United Nations Environment Programme (UNEP), a process has been underway under the auspices of UNEP to forward global cooperation to reduce the impacts of mercury pollution. In February 2009 negotiations on a global legally binding instrument on mercury were launched. The European Commission and many EU Member States were leading advocates for the Convention and active participants in the negotiations.

The Intergovernmental Negotiating Committee²¹ met for the first time in Stock-

¹⁸ Ministry of the Environment, Japan, *Lessons from Minamata Disease and Mercury Management in Japan* (2011).

¹⁹ *ibid.*

²⁰ Hence the name “Minamata-Niigata disease”.

²¹ Prior to the beginning of the negotiation process, two meetings of the Open Working Group were held in 2007 to examine the global mercury issue. In 2009, the Board of Directors of UNEP

holm in 2010. During the first session of the Committee's work, the participants were able to see concretely the seriousness of the phenomenon through a test performed on the hair of forty diplomats coming from as many countries in the world. This test proved that each of them had "with him" a dose of mercury higher than the threshold of tolerance provided by the National Council of Research of the United States of America.²² The results of this test gave a further boost to the negotiation and strengthened the awareness of the need for concerted action regulating the use of mercury.

The Convention preparatory work lasted about three years, during which the Committee discussed the structure and content of a possible binding legal instrument²³ and negotiated the draft of the Convention,²⁴ paying special attention to the situation of developing countries.²⁵ During the last meeting of the Committee, held in Geneva in 2013, it emerged, more than at any other meeting, that the would-be convention should have pursued the dual purpose of protecting human health and the environment,²⁶ considering first of all the dangerousness of the presence of mercury in medical devices²⁷ and in the food chain.

The draft convention was approved by the Intergovernmental Negotiating Committee in Geneva, on 19 January 2013,²⁸ and adopted on 10 October 2013 at a Diplomatic Conference held in Kumamoto, Japan.

issued Decision 25/5 with which it established the Intergovernmental Committee and started negotiations.

²² Rebecca Kessler, 'The Minamata Convention on Mercury: A First Step toward Protecting Future Generations' (2013) 121 *Environmental Health Perspectives* A304. The US National Research Council set this threshold value in 1,000 µg/kg. The levels of mercury highlighted in the hair of the participants were higher, reaching around 1,182 µg/kg for those from the poorest countries and around 669 µg/kg for those from the richest countries.

²³ UNEP, 'Report of the intergovernmental negotiating committee to prepare a global legally binding instrument on mercury on the work of its second session', Doc UNEP(DTIE)/Hg/INC.2/20, 28 February 2011.

²⁴ UNEP, 'Report of the intergovernmental negotiating committee to prepare a global legally binding instrument on mercury on the work of its third session', Doc UNEP(DTIE)/Hg/INC.3/8, 31 October 2011.

²⁵ UNEP, 'Report of the intergovernmental negotiating committee to prepare a global legally binding instrument on mercury on the work of its fourth session', Doc UNEP(DTIE)/Hg/INC.4/8, 15 August 2012.

²⁶ UNEP, 'Report of the intergovernmental negotiating committee to prepare a global legally binding instrument on mercury on the work of its fifth session', Doc UNEP(DTIE)/Hg/INC.5/7, 14 March 2013. According to some of the representatives of the States participating in the meeting, Minamata's disastrous experience was a warning to guarantee future generations greater control of mercury emissions. For this reason they wanted health protection to play a central role in the document.

²⁷ Some representatives of the participating States also urged the WHO to phase out mercury from the health sector, in accordance with the precautionary principle.

²⁸ UNEP, 'Report of the intergovernmental negotiating committee to prepare a global legally binding instrument on mercury on the work of its fifth session', Doc UNEP(DTIE)/Hg/INC.5/7, 14 March 2013.

Nowadays, the Minamata Convention on Mercury, which currently counts 102 Parties,²⁹ is the only global treaty aimed to protect human health and the environment from the adverse effects of mercury.

The Preamble to the Convention acknowledges the lessons learned from the Minamata syndrome and its effects on health and the environment, recalling the final document of the United Nations Conference on Sustainable Development.³⁰ It also recalls the principle of “common but differentiated responsibilities” enshrined in the Rio de Janeiro Declaration and underlines the efforts made by the WHO for the protection of human health in relation to mercury. It is interesting to note that the Preamble (nor the text of the agreement) does not mention the precautionary principle. In fact, some delegations had requested the inclusion of a specific provision on this principle, also in support of the aforementioned principle of common but differentiated responsibilities, but no one considered it necessary to explicitly refer to it since precaution had to underlie the whole convention, being mercury a “global concern”.³¹ This gap marks the difference with the Stockholm Convention on persistent organic pollutants (POPs),³² in which the precautionary principle is mentioned several times, starting from the Preamble where it is stated ‘that precaution underlies the concerns of all the Parties and is embedded within this Convention’.

The Convention regulates the procurement, production and trade of mercury or products containing mercury. It imposes on States Parties the obligation to take an active part in the process of progressive elimination of mercury. In fact, it is required that each Party adopts the most appropriate measures in order to reduce, until progressively and definitively eliminating, the use of mercury in the majority of productive and industrial processes.³³

As stated in Article 1, the purpose of the Minamata Convention is the protection of both human health and the environment from emissions and anthropogenic releases of mercury and mercury compounds. This twofold objective is present

²⁹ See at <www.mercuryconvention.org> accessed 31 January 2019.

³⁰ Outcome document of the United Nations Conference on Sustainable Development, ‘The Future We want’, para 221: ‘We welcome the ongoing negotiating process on a global legally binding instrument on mercury to address the risks to human health and the environment, and call for a successful outcome to the negotiations’.

³¹ Henrik Hallgrim Eriksen and Franz Xaver Perrez, ‘The Minamata Convention: A Comprehensive Response to a Global Problem’ (2014) 23 *Review of European Community & International Environmental Law* 195.

³² Convention on Persistent Organic Pollutants, done in Stockholm on 22 May 2001, in force as of 17 May 2004.

³³ In particular, reference is made to articles 3, 4, 5, 7 of the Convention governing respectively: mercury supply sources and trade; mercury-added products; manufacturing processes in which mercury or mercury compounds are used; artisanal and small-scale gold mining. In each of these provisions a distinction is made between the activities started prior to the approval of the Convention and those possibly subsequent to it, leaving the possibility of continuing to execute only for a specific period and in accordance with the purposes and methods provided for by the Convention.

throughout the whole treaty, given that also the provisions regulating aspects concerning environmental protection indirectly protect public health.

The link between environmental protection and health protection can be found in the provisions concerning atmospheric emissions of mercury and mercury compounds (article 8) and their releases into the soil and water (article 9). This is a crucial aspect of the whole text since the control of emissions has also a certain political and economic significance, given that the majority of mercury emissions derives from the activities carried out by coal-fired power plants. For these reasons, there have been many clashes between the most industrialized countries (supported by the African group and those countries that pay more attention to environmental protection) advocating the need for strict control of emissions and releases, and China and India, currently the world's largest mercury emitters, supporting instead a voluntary reduction approach.³⁴ From this clash derived articles 8 and 9 by way of compromise. In both cases, in fact, the Minamata Convention provides that, once the existing sources that emit or release mercury into the atmosphere, in the soil and in the water have been identified, States must take the necessary measures of control, also through the predisposition a national plan defining the measures to be taken and the purposes of the control itself. With regard to the new sources of emissions, however, each Party is required to use the best available techniques and best environmental practices. Even in this case, however, the compromise emerging from the different positions between industrialized and developing countries clearly emerges. Unlike the measures to be prepared for the control of the already existing emission and release sources – for which a more rigorous and less flexible plan could probably have been foreseen – in this case perhaps a greater flexibility to the economic and productive context of each Party to the Convention seems necessary.

Remarking the double objective of protecting the environment and health, article 16 of the Convention refers to the measures aimed at the protection of human health. In this provision, unlike those previously mentioned, the Convention employs a less detailed language, encouraging the Parties to promote and elaborate strategies aimed at implementing health care. Article 16 refers to “specific” but at the same time wide categories of subjects, thus demonstrating its centrality and importance within the Convention.³⁵ The provision urges the Parties to develop strategies and programs aimed at protecting at-risk populations (letter a)); then it encourages them to implement education programs for those who, because of their profession, are exposed to mercury and mercury compounds (letters b) and d)); and finally, it urges the Parties to ‘promote adequate health care services for prevention, treat-

³⁴ Henrik Selin, ‘Global Environmental Law and Treaty-Making on Hazardous Substances: The Minamata Convention and Mercury Abatement’ (2014) 14 *Global Environmental Politics* 1.

³⁵ The provision of an article that specifically dealt with aspects related to health protection was strongly requested by the representatives of the countries participating in the Convention’s preparatory works, so much so that it was required as an essential condition for the purposes of the negotiations: see Hallgrim Eriksen and Xaver Perrez (n 31).

ment and care for populations affected by the exposure to mercury or mercury compounds' (letter c)). This suggests that the best approach to implementing the Convention will necessarily have to be multi-sectoral.

In this respect, the cooperation between the WHO and the national Ministers of Health, as explained in the second paragraph of Article 16, is fundamental. Health Ministers have played a leading role in the progressive elimination of mercury thermometers by 2020 and mercury-based dental amalgam. They have also been involved in the development of public health strategies in national action plans to reduce the health impact of mercury in small-scale and artisanal gold mining (article 7) and in the evaluation of contaminated sites for health risks (article 12).³⁶

As for the WHO, during its sixty-seventh session, the World Health Assembly issued a Resolution in which it encouraged States to adopt national measures to sign, ratify and participate in efforts to implement the Minamata Convention. It also urged them to address the health aspects of exposure to mercury and mercury compounds and to promote adequate health services for prevention, treatment and assistance to populations affected by exposure to mercury. Moreover, the WHO aptly highlighted the interrelation between the environment and public health in the context of the implementation of the Minamata Convention. This is the reason why it invited States to ensure close cooperation between the Ministers of Health and the Environment, other Ministries responsible for implementing the health aspects of the Mercury Convention, and other international bodies and International Organizations, in particular UNEP, in order to fully support the implementation of the relevant health aspects of the Convention.³⁷

The Convention is completed by a series of standard provisions, which have found easy agreement among the States. These provisions relate to the exchange of scientific and strategic information between the Parties; the methods of communication and education of the public; cooperation on monitoring and developing research on mercury and mercury compounds;³⁸ the establishment of the Conference of the Parties with its institutional functions.³⁹

³⁶ WHO, 'Public health impacts of exposure to mercury and mercury compounds: the role of WHO and ministries of public health in the implementation of the Minamata Convention on Mercury. Report by the Secretariat', Doc. EB134/23, 2013.

³⁷ WHO, Sixty- seventh World Health Assembly, Resolution WHA67.11, Public health impacts of exposure to mercury and mercury compounds: the role of WHO and ministries of public health in the implementation of the Minamata Convention.

³⁸ Minamata Convention on Mercury, arts 17-19.

³⁹ Minamata Convention on Mercury, art 20. The Conference of the Parties is a body instituted by several international treaties. Autonomous from a financial and organizational point of view, it gathers all the Parties on an ordinary or extraordinary basis with the task, among others, to keep the implementation of the Convention under constant control and cooperate with international organizations and other intergovernmental and non-governmental bodies.

4. *European Measures against Mercury Pollution and Implementation of the Minamata Convention*

As it clearly emerges from the Preamble to the Minamata Convention, the concerns generated by the release of mercury into the environment are serious and global. Action at European level is particularly important in light of the fact that within Europe the use and emissions of mercury have historically been high.

For this reason, in 2005, the European Community (EC), acting in the framework and under the umbrella of UNEP's work, developed an ad hoc strategy – the Community Strategy in relation to Mercury – based on six objectives and accompanied by specific actions aimed at reducing the quantity and exposure to mercury within the EU.⁴⁰

Later on, the EC issued its Regulation 1102/2008 on the prohibition of export and the safe storage of metallic mercury.⁴¹ In order to reduce the global offer of mercury,⁴² the essential point of the Regulation was represented by the export ban on metallic residual mercury from industrial activities, which were considered as waste. This prohibition, however, generated considerable quantities of mercury within the EC, and for this reason the second obligation imposed by the Regulation was the obligation to store mercury through methods suitable for not impacting with environmental safety and human health.

In 2014, the EU started the procedure to join the Minamata Convention, which ended in May 2017 with the adoption of Council Decision 2017/939.⁴³ As a result, the EU started an action aimed at adapting its legislation to the Convention, although, according to a study conducted by the European Commission, conformity with the Minamata Convention required a limited number of adjustments to the EU *acquis* rather than significant reform or extension of controls. This was due to the fact that the EU already had a well-developed strategy and legislative framework to prevent and control the risks posed by mercury. Moreover, the overall goals of the Minamata Convention were in line with the EU Mercury Strategy

⁴⁰ Communication from the Commission to the Council and the European Parliament. Strategy Concerning Mercury of 28 January 2005, COM(2005)20 final. The objectives of the Strategy were: reducing mercury emissions; reducing the entry into circulation of mercury in society by cutting supply and demand; resolving the long-term fate of mercury surpluses and societal reservoirs (in products still in use or in storage); protecting against mercury exposure; improving understanding of the mercury problem and its solutions; supporting and promoting international action on mercury.

⁴¹ Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury [2008] OJ L304/75.

⁴² *ibid* Recital 5.

⁴³ Council Decision (EU) 2017/939 of 11 May 2017 on the conclusion on behalf of the European Union of the Minamata Convention on Mercury [2017] OJ L142/4.

and several of its provisions were similar to existing EU legislation on mercury.⁴⁴

Implementation of the Convention at EU level was carried out with the adoption of Regulation 2017/852 on mercury,⁴⁵ repealing Regulation 1102/2008. The new Regulation, aimed at ‘ensur[ing] a high level of protection of human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds’, establishes the conditions relating to the use, storage and disposal of waste mercury and manufactured products containing mercury, regulating individual activities that can generate emissions or releases of mercury and mercury compounds.⁴⁶ The Regulation imposes restrictions and prohibitions on the use of mercury, including a ban on exports,⁴⁷ except in the case of research or laboratory activities, and a ban on imports, except for the importation of mercury itself.⁴⁸ For products containing mercury, import and export are equally prohibited, except for products used for civil protection or for research and laboratory purposes.⁴⁹ Furthermore, the use of mercury for gold mining and processing or for the composition of dental amalgam is definitely prohibited.

With a view to protecting human health and the environment from anthropogenic mercury releases, not only does the Regulation put a brake on the use of “on-going” mercury, but it is also aimed – in compliance with the principle of prevention – also to any new products containing mercury and any new manufacturing processes that require its use. Therefore, as of 1 January 2018, new products cannot be manufactured with the addition of mercury, nor can mercury be used in manufacturing processes, unless such products and processes are authorized.⁵⁰

In line with the Minamata Convention, the temporary storage of mercury and waste products containing mercury must take place in an “ecologically correct manner”, an open expression that can be understood in the sense that these activities must be consistent with the relevant international and European norms, and that they must be carried out through modalities such as not to aggravate the risk and the possibility of exposure to mercury releases.⁵¹

⁴⁴ European Commission, ‘Study on EU Implementation of the Minamata Convention on Mercury. Final report’, 30 March 2015.

⁴⁵ Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 [2017] OJ L137/1.

⁴⁶ *ibid* art 1.

⁴⁷ *ibid* art 3 para 1.

⁴⁸ *ibid* art 4. The import of mercury for disposal purposes can be allowed only if the exporting country does not have the necessary capacity to properly dispose of the substance or the compound containing mercury.

⁴⁹ *ibid* art 5.

⁵⁰ The authorization can be granted following the demonstration of the absence of mercury-free manufacturing alternatives and of the detailed explanation of the methods of manufacture, use and disposal of waste.

⁵¹ *ibid* ch IV.

Finally, the Regulation requires Member States to introduce sanctions within their legal systems to ensure the implementation of its provisions. As established practice, the Regulation confers on Member States the freedom to choose the most appropriate type of sanction (criminal, civil or administrative), requiring, however, that they be effective, proportionate and dissuasive. It will therefore be the responsibility of each State to provide for the preparation of a sanctioning framework such as to discourage violations of the Regulations.

5. Concluding Remarks

The adoption of the Minamata Convention represented a decisive step forward in global efforts to prevent and control the dangers and public health risks caused by exposure to mercury and its organic compounds, such as methylmercury. Nowadays, it is acknowledged that problems stemming from exposure to this toxic metal must be addressed from both the environmental and health perspectives. Moreover, considering that the release of mercury in its organic forms can penetrate the food chain and bioaccumulate, especially in fish products, the work carried out by WHO, FAO and EFSA in the field of standard setting for food safety is of the utmost importance.

This way of looking at the problem is in line with the “One Health” approach, which recognizes that human health is interconnected with animal and environment health, and therefore is based on a multisectoral and multidisciplinary approach aimed to address and respond to potential health risks arising from environmental contamination.⁵²

This multisectoral approach, in turn, imports that the Minamata Convention is not isolated in the international conventional system, but it should be applied in synergy with other mutually supportive multilateral agreements in the field of environmental protection and trade.⁵³ Key among these treaties are the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal⁵⁴ and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,⁵⁵ both mentioned in the Preamble to the Minamata Convention. In particular, the Basel Convention is referred to in articles 10 and 11 – which concern the interim

⁵² See, among others, Stefania Negri, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale* (Giappichelli 2018) 176 ff.

⁵³ See Preamble to the Minamata Convention.

⁵⁴ Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, done in Basel on 22 March 1989, in force as of 5 May 1992.

⁵⁵ Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, done in Rotterdam on 10 September 1998, in force as of 24 February 2004.

storage of mercury other than mercury waste and the management of mercury wastes – and require that these activities be carried out in harmony with the relevant Basel guidelines.

In conclusion, it can be stated that the Minamata Convention and the EU Regulation 2017/852 contribute, together with the Basel and Rotterdam Conventions and the corresponding EU implementing legislation, to the creation of an integrated regime for the protection of human health from the risks caused by exposure to mercury and its derivatives, establishing a series of important prohibitions and controls that contribute to achieving the objectives of global protection of public health from environmental risks.



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Chapter 17

EU's Re-approval of Glyphosate: The Role of Science and the Competence of Member States

*Daniela Corona**

1. *Introduction*

Renewing the authorisation of glyphosate by European Commission (EC) in 2017 has been a highly controversial issue in the European Union (EU). The findings of the International Agency for Research on Cancer (IARC) published in March 2015 as regards the carcinogenic potential effect of glyphosate strongly impacted on the process of renewal and pushed the EC to ask the European Food and Safety Authority (EFSA) to review its former scientific risk assessment. Also the Committee for Risk Assessment of the European Chemicals Agency (ECHA) participated in the procedure, in the attempt to add some clarity. Furthermore, the conflicting views of the Member States (MSs) made the whole authorisation process particularly complex.

After having briefly analyzed the various steps of the EU authorisation procedure of plant protection products (PPPs), the chapter examines the specific case of the renewal authorisation procedure of glyphosate and highlights two particular aspects of such procedure, namely the role that the science has played in it and the responsibility of the MSs in the regulatory framework governing the authorisation and the use of pesticides in the EU.

2. *The EU Authorisation Procedure of Plant Protection Products*

PPPs (more commonly called 'pesticides') are substances used to protect crops and plants against pests or diseases. In the EU PPPs are regulated by Regulation (EC) No 1107/2009¹ (hereafter the Regulation) and Regulation (EC) No 396/2005.² While

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the latter deals with the setting, modification and controls of maximum residue levels of pesticides in or on food and feed of plant and animal origin, the former lays down both the rules for the approval of active substances which PPPs contain or consist of, and the rules for the authorisations of PPPs in commercial form and for their placing on the market. It is important to clarify from the outset that, according to the Regulation, the competence to give, renew or withdraw the authorisation of the active substances lies within the EC. If an active substance is authorised, such authorisation is valid throughout the EU and the active substance is added to a list contained in Regulation 540/2011³ and managed by the EC. In contrast, MSs have the competence to authorise the placing on the market of pesticides (ie, the commercial products) in line with Regulation (EU) 546/2011,⁴ laying down uniform principles for evaluation and authorisation of PPPs. If an active substance is not authorised at EU level, MSs cannot in principle approve the marketing of pesticides containing such active substance.⁵ By way of derogation, according to article 53 of the Regulation, in special circumstances a MS may authorise for a period not exceeding 120 days the placing on the market of PPPs where such a measure appears necessary because of a danger which cannot be contained otherwise.⁶ Where an active substance is authorised at EU level, MS may still refuse authorisation of the PPP containing such active substance in its territory in case of concerns relating to human or animal health or the environment.⁷ The latter scenario is made clear in article 1, paragraph 4, which is dedicated to the precautionary principle:

The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L309/1.

² Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC [2005] OJ L70/1.

³ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances [2011] OJ L153/1.

⁴ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products [2011] OJ L155/127.

⁵ Art 28, para 1 of the Regulation.

⁶ In such case, the MS concerned shall inform the other MSs and the EC of the measure taken; the latter may ask EFSA for an opinion.

⁷ Art 36, para 3, second indent, *ibid*.

The approval criteria for active substances are laid down in article 4 of the Regulation. The assessment starts with the analysis of the so called “cut-off criteria”: an active substance cannot be approved if it classified, in accordance with Regulation (EC) 1272/2008,⁸ as carcinogen category 1A or 1B, unless the exposure of humans to that active substance is negligible;⁹ or where such active substance is considered to be a persistent pollutant.¹⁰ This provision is extremely important as it introduces the “hazard-approach” in the EU regulatory framework for PPPs: if an active substance meets the criteria of these particularly dangerous categories, it will be cut-off from the EU market on the basis of the health or environment hazard it poses, without a risk assessment that considers the actual levels of exposure.

The approval procedure for an active substance, as well as the renewal of the authorisation – as in the case of the glyphosate –, is made up of several steps and provides for the participation of different actors. As regards the procedure for the renewal of the active substance, it starts with the submission of an application and of a supplementary dossier to the rapporteur MS (RMS) by the producer of the active substance, in accordance with articles 4 and 9 of Regulation (EU) 1141/2010.¹¹ The RMS prepares a report (the ‘renewal assessment report’) assessing whether the active substance can be expected to continue to meet the requirements for inclusion in the above-mentioned list.¹² Such report is sent to EFSA and is circulated to all MSs and to the applicant; it is also made available to the public via the EFSA website.

In this respect, it is important to highlight that article 16, paragraph 2, of the Regulation provides for the possibility for the manufacturer of the active substance to request the confidential treatment of information submitted the disclosure of which might undermine his commercial interests.¹³ In such a case, these documents are excluded from those made public by EFSA.

According to article 16, paragraph 2, of Regulation (EU) 1141/2010 ‘The Commission may consult the Authority (ie, EFSA) asking it for a conclusion on the entire risk assessment or on the specific points thereof. Such consultation may include a request to organize a consultation of experts ...’. Thus, contrary to the first approval

⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [2008] OJ L353/1.

⁹ Annex II, points 3.6.2 to 3.6.4 of the Regulation.

¹⁰ Annex II, point 3.7, *ibid*.

¹¹ Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances [2010] OJ L322/10.

¹² See n 3.

¹³ The public access to information under the PPPs Regulation is governed by art 63; such rules also applies to the application for the first authorisation (art 7 para 3), to the summary dossier submitted by the applicant (art 10) and to the application for the authorisation for placing PPPs on the market sent to MSs (art 33 para 4).

procedure where the consultation of EFSA is mandatory,¹⁴ in the renewal process of the authorisation of active substances, EFSA is involved only if the EC so requires.

Based on the renewal assessment report by the RMS, the possible comments from other MSs and, where applicable, the conclusion of EFSA, the EC prepares a review report and a draft regulation where it may propose the renewal of the authorisation of the active substance with, where appropriate, conditions and restrictions.¹⁵

The draft regulation is then sent to the Standing Committee on Plants, Animals, Food and Feed (hereafter, the '*standing committee*', which is made up of representatives from relevant ministries of all EU MSs) that, according to article 5 of Regulation (EU) No 182/2011¹⁶ (the so-called "Comitology regulation"), delivers its opinion by means of qualified majority voting. If it fails to find a qualified majority in favour or against the draft regulation by the EC ('no opinion' outcome), the latter may either submit an amended version of that act to the same committee within two months of the vote, or submit the draft implementing act within one month of the vote to the Appeal committee (made up of EU MSs' representatives but at a higher level of representation) for further deliberation. If the Appeal committee cannot find a qualified majority in favour or against either, the EC may adopt its draft implementing act. It is important to highlight, in this regard, that in accordance with article 13, paragraph 2, of the Regulation, the regulation renewing the approval of an active substance shall be adopted not only on the basis of the above-mentioned review report by the EC, but also taking into consideration '... other factors legitimate to the matter under consideration and the precautionary principle ...'.

The renewal of the authorisation is given for a maximum of 15 years;¹⁷ however, the EC may decide to review the approval/renewal of an active substance at any time, where new scientific and technical knowledge call into question the approval criteria set in article 4 of the Regulation.¹⁸

In case the procedure for renewing the approval of an active substance is not closed before the expiration of the initial authorisation, an extension of the approval period can be adopted thorough the same Comitology procedure seen above.¹⁹

Finally, as mentioned before, once the renewal of an active substance has been granted, MSs must decide on the renewal of the authorisation of the PPPs containing it within 12 months.²⁰

¹⁴ Art 12 of the Regulation.

¹⁵ *ibid* art 6.

¹⁶ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [2011] OJ L55/13.

¹⁷ *ibid* art 14.

¹⁸ *ibid* art 21.

¹⁹ Art 17 of the Regulation.

²⁰ *ibid* art 43 para 5.

3. The Renewal of the Authorisation of Glyphosate

Glyphosate is an active substance used in many PPPs to combat weeds that compete with cultivated crops or present problems for other reasons. To date, glyphosate-based compounds are the most frequently used herbicide in the world.²¹

In the EU glyphosate was first authorised in 2002.²² In 2010 a request for renewing its approval was submitted to Germany, which acted as RMS; at the same time, in order to give the applicant more time to prepare his application and to enable the EC to evaluate and decide upon it, the approval was extended until 31 December 2015.²³ In December 2013, the RMS prepared a renewal assessment report in which it found, inter alia, that glyphosate was not carcinogenic.²⁴ The report was then submitted to EFSA and forwarded to all MSs for comments; the supplementary summary dossier was made available to the public by EFSA.

In March 2015, IARC published a report in which it concluded that glyphosate is 'probably carcinogenic to humans', thus falling within the 'Group 2A'.²⁵ Predictably, these findings had a huge impact on the public opinion and generated several initiatives aiming at stopping the use of all compounds containing glyphosate. The IARC report was of great importance also for the on-going process of renewal of the active substance at the EU level; in fact, even though the classification schemes used by IARC are not the same of those provided in by Regulation (EC) 1272/2008,²⁶ the criteria used by IARC for Group 2A are considered comparable to those for Category 1B in the EU regulation above.²⁷ As we have seen before, the immediate consequence for

²¹ Charles M Benbrook, 'Trends in glyphosate herbicide use in the United States and globally' in Henner Hollert et al. (eds), *Environmental Sciences Europe, Bridging Science and Regulation at the Regional and European Level* (Springer open 2016).

²² Commission Directive 2001/99/EC Commission Directive 2001/99/EC of 20 November 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances [2001] OJ L304/14.

²³ Commission Directive 2010/77/EU of 10 November 2010 amending Council Directive 91/414/EEC as regards the expiry dates for inclusion in Annex I of certain active substances [2010] OJ L293/48.

²⁴ The report was prepared by the German Federal Institute for Risk Assessment (BfR). See <www.bfr.bund.de/en/the_bfr_has_finalised_its_draft_report_for_the_re_evaluation_of_glyphosate-188632.html> accessed 30 January 2019.

²⁵ IARC, Monographs Volume 112, *Evaluation of five organophosphate insecticides and herbicides*. The detailed assessment was published in 2017 <<https://monographs.iarc.fr/wp-content/uploads/2018/07/mono112.pdf>> at 398, accessed 30 January 2019.

²⁶ See n 8.

²⁷ For a detailed analysis of the comparison of the carcinogenicity assessments of pesticides conducted by EFSA and IARC, see José V Tarazona and others, 'Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC' (2017) 91 Archives of Toxicology 2723.

an active substance being classified under EU carcinogen Category 1A or 1B is its immediate withdrawal from the list of approved active substances in the EU and, also, the cut-off of the chemical compounds containing it from the market by MSs.

Thus, the EC mandated the EFSA to consider the findings by IARC and to include them in its conclusion. Waiting for the EFSA opinion to be finalized, in October 2015 the EC extended again the approval of glyphosate until 30 June 2016.²⁸

On 30 October 2015, EFSA communicated to the EC its conclusion on the risk assessment of glyphosate.²⁹ It found that 'glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008'. Thus, according to EFSA opinion, glyphosate met the approval criteria provided for in article 4 of the Regulation. However, in a separate statement, EFSA highlighted some concerns on the carcinogenicity and endocrine disrupting potential of POE-tallowamine, a co-formulant often used in compounds containing glyphosate.³⁰

On the basis of the EFSA opinion, in February and then in May 2016 the EC submitted to the standing committee two draft implementing acts in which it proposed to renew the approval of glyphosate for 15 years in the first draft, and for 9 years in the second. Since both proposals did not have the support of a qualified majority of MSs in the comitology committee, eventually the drafts were withdrawn.³¹

In the meanwhile, in March 2016, the RMS requested an opinion to the Committee for Risk assessment of the ECHA on the harmonized classification as regards the carcinogenicity of glyphosate. ECHA adopted its opinion in March 2017, in which it concluded by consensus that there was no evidence to link glyphosate to cancer in humans and that no hazard classification for carcinogenicity was justified for glyphosate.³² Before the ECHA opinion, in April 2016, the European Parliament (EP) adopted a resolution by which it asked the EC to further strengthen the conditions for the renewal of glyphosate and to limit such renewal to 7 years.³³ Also, in May 2016, a Joint Meeting on Pesticide Residues (JMPR) held by the Food and Ag-

²⁸ Commission Implementing Regulation (EU) 2015/1885 of 20 October 2015 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazone, cyhalofop butyl, diquat, esfenvalerate, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), glyphosate, iprovalicarb, isoproturon, lambda-cyhalothrin, metalaxyl-M, metsulfuron methyl, picolinafen, prosulfuron, pymetrozine, pyraflufen-ethyl, thiabendazole, thifensulfuron-methyl and triasulfuron [2015] OJ L276/48.

²⁹ 'Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate' (2015) 13 EFSA Journal 4302.

³⁰ 'Request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine' (2015) 13 EFSA Journal 4303.

³¹ See the preparatory documents SANTE 10026/2016 Rev. 1-2, available from the Comitology register: <<http://ec.europa.eu/transparency/regcomitology/index.cfm>> accessed 30 January 2019.

³² The report from ECHA is available at <<https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa>> accessed 30 January 2019.

³³ Renewal of the approval of the active substance glyphosate, adopted on 13 April 2016, 2016/2624(RSP), P8TA(2016)0119.

riculture Organization (FAO) and the World Health Organization (WHO) concluded that 'glyphosate is unlikely to be genotoxic ...' and 'is unlikely to pose a carcinogenic risk to humans from exposure through diet'.³⁴

In June 2016, following a 'no opinion' outcome in both the standing and the Appeal committees,³⁵ the EC extended the approval of glyphosate for the third time, until 31 December 2017.³⁶ Later, in August 2016, the EC also adopted a regulation providing certain restriction to the use of glyphosate and, also, the obligation for MSs to prohibit the use of glyphosate-base pesticides containing the co-formulant POE-tallowamine.³⁷

In March 2017, at the same time as ECHA adopted its opinion, in the context of a lawsuits filed in the United States by plaintiffs who claimed to have developed non-Hodgkin's lymphoma as a consequence of exposure to glyphosate, the U.S. court unsealed internal documents by Monsanto, the owner and producer of Roundup, a product whose active substance is glyphosate.³⁸ The so-called "Monsanto papers" case stepped on the EU procedure for renewing the approval of glyphosate, as the released documents raised serious doubts on the credibility of some studies which were among the evidence used by the RMS, EFSA and ECHA for their evaluation of the safety of glyphosate.

Despite the growing concerns of the public opinion over glyphosate, in May 2017, on the basis of EFSA and ECHA opinions, the EC proposed to renew the approval of glyphosate for 10 years;³⁹ the vote in the standing committee was postponed due the impossibility to reach a qualified majority against or in favour to the EC proposal. While the EC was attempting to find a way out of the *impasse*, in October the EP adopted a second resolution in which it asked the EC to further restrict the approval criteria of glyphosate and, finally, to phase it out by December 2022.⁴⁰

On 9 November 2017 a new proposal of the EC failed again to gain the support of a qualified majority of MSs in the standing committee.⁴¹ However, quite surpris-

³⁴ Joint FAO/WHO meeting on pesticide residues, Geneva, 9-13 May 2016, Summary Report Issued on 16 January 2016.

³⁵ See the preparatory document SANTE/10829 Rev.0- 1 (see n 29).

³⁶ Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate [2016] OJ L173/52.

³⁷ Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate [2016] OJ L208/1.

³⁸ For a detailed analysis of the 'Monsanto papers' see <<https://usrtk.org/monsanto-papers/state-court/#jccp>> accessed 30 January 2019.

³⁹ See the preparatory document SANTE/10441/2017 Rev.1.

⁴⁰ Reviewing the approval of the active substance glyphosate, adopted on 24 October 2017, 2017/2904(RSP), P8TA(2017)0395.

⁴¹ The results of committee voting were as follows: 14 MSs voted in favour, 9 voted against and 5 abstained.

ingly, on 27 November the Appeal committee supported the draft⁴² and the EC was able to formally adopt the Implementing Regulation (EU) 2017/2324 which has renewed the authorisation of glyphosate for 5 years.⁴³ Also, the latter regulation has provided specific restrictions and conditions MSs have to take into account when considering applications for the renewal of glyphosate-based products in line with article 43, paragraph 5, of the Regulation.⁴⁴ In the recitals of the regulation the EC specified that it based its decision to renew the authorisation for only 5 years (and not 15 years as foreseen in the EU legislation) on *other legitimate factors* and on the views of the EP. In fact, it recognised that additional information on glyphosate is being published at an exceptionally high rate compared to other active substances and that there are possibilities of rapid future developments in science and technology which may impact the safety assessment of the substance.

Finally, as a corollary to the adoption of the renewal regulation, the EC published a communication⁴⁵ in response to the European Citizens' Initiative "Stop-Glyphosate" submitted to it in October 2017.⁴⁶ In the document, the EC stressed that the scientific evidence – as assessed by EFSA and ECHA – did not support the conclusion that glyphosate has the potential to cause cancer and that MSs finally endorsed the EC draft. Thus, according to the EC, there were neither scientific nor legal grounds to ban the use of glyphosate.

4. Concluding Remarks

After having briefly analyzed the procedure for the renewal of the authorisation of glyphosate, it is now possible to make some general remarks on two major elements

⁴² The results of the Appeal committee voting were as follows: 18 MSs voted in favour (representing 65.71% of the EU population, just above the 65% threshold needed under the qualified majority rule); 9 voted against (Belgium, Greece, France, Croatia, Italy, Cyprus, Luxembourg, Malta, and Austria) and 1 abstained (Portugal).

⁴³ Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 [2017] OJ L333/10.

⁴⁴ In particular: protection of groundwater; protection of terrestrial animals and non-target plants; certain elements that MS must ensure during assessment and decision making for authorisation (eg use in public areas should be minimised); the ban of POE-tallowamine was put in place in 2016.

⁴⁵ Communication from the Commission on the European Citizens' Initiative "Ban Glyphosate and protect people and the environment from toxic pesticides", Strasbourg, 12 December 2017, C(2017) 8414 final.

⁴⁶ To read the content of the proposal and look at the progress of the initiative, see the dedicated webpage on the official register: <<http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002/en?lg=en>> accessed 1 February 2019.

that characterized such procedure, namely the role that science has played in it, and the responsibility of the MSs in the regulatory framework governing the authorisation and the use of pesticides in the EU.

The scientific opinions of both EFSA and ECHA have had a pivotal role in the renewal of the authorisation of glyphosate. As we have seen above, amid conflicting national positions in both the standing and the Appeal committees, the EC based its draft implementing decision on the opinion of the two scientific bodies according to which glyphosate is unlikely to be carcinogenic. The scientific assessment performed by EFSA, however, has not stopped public opinion's great concerns about the carcinogenicity of glyphosate. The following question, indeed, has remained open: how is it possible that IARC has reached an opposite conclusion?⁴⁷

The answer mainly lies in the rules for selecting evidence: IARC takes into consideration "*only reports that have been published or accepted for publication in the openly available scientific literature*"⁴⁸, including reports and database publicly available from government and agencies. On the contrary, EFSA and ECHA rely on a broader range of evidence, including unpublished studies and test laboratories funded or carried out in-house by manufacturers, as specified in the Regulation.⁴⁹

This raises a number of problems related to the transparency in scientific assessment and decision-making at EU level, as the most sensitive data and materials on which EFSA bases its risk assessment are not subject to public scrutiny according to the confidentiality rules provided in the Regulation.⁵⁰ Those rules, indeed, operate by way of exception from the general principle of public access to information and documents⁵¹ and, as such, have often given rise to issues before the Court of Justice of the EU.⁵² The EC recognized that there is at least a *perceived* problem related to

⁴⁷ Emanuela Bozzini, *Pesticide Policy and Politics in the European Union* (Palgrave Macmillan 2017) 87; András Székács, Béla Darvas, 'Re-registration Challenges of Glyphosate in the European Union' (2018) 6 *Frontiers in Environmental Science* 78.

⁴⁸ IARC, *Preamble of the IARC Monographs on the Identification of Carcinogenic Hazards to Humans* (2019) 9.

⁴⁹ Art 8 of the Regulation; see also art 10 of Regulation 1141/2010; see n 10.

⁵⁰ See n 13.

⁵¹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L145/43; Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies [2006] OJ L264/13.

⁵² As for the public access to documents related to the renewal of the authorisation of glyphosate, see Case T- 545/11 *Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission* EU:T:2013:523 (GC, 8 October 2013); the case has been appealed before the European Court of Justice, Case C-673/13P EU:C:2016:213 (ECJ, 23 November 2016), and finally referred back to the General Court, Case T-545/11 RENV EU:T:2018:817 (GC, 21 November 2018). See also, Case T-329/17 *Heidi Hautala and Others v European Food Safety Authority* EU:T:2019:142 (GC, 7 March 2019); Case T-716/14 *Antony C. Tweedale v European Food Safety Authority* EU:T:2019:141 (GC, 7 March 2019).

the transparency of the risk analysis process; thus, following its response to the citizens initiative aiming at banning glyphosate, in April 2018 it put forward a legislative proposal addressing the issues of the transparency and reliability of the risk analysis performed by EFSA.⁵³ The procedure for the adoption of this regulation is still ongoing; if adopted, among alia, it would clarify the scope of application of the confidentiality rules provided in by the Regulation and would enhance the reliability of the studies submitted by industry in the context of authorisation procedures. The latter objective would be achieved, in particular, by creating a Union register of all studies commissioned by operators to obtain an authorisation under EU food law. According to the EC proposal, such register would be managed by EFSA, which will be able to cross-check the information on the studies performed, so diminishing its reliance on only industry studies. Moreover, the proposal provides that, in exceptional circumstances, the EC may request EFSA to commission scientific studies with the objective of verifying the evidence used in the risk assessment process. The rationale for such provision clearly lies in the specific case of the renewal of the authorisation of glyphosate, which, as we have seen, has been characterized by a public's increasing distrust in the impartiality of the scientific studies at the basis of EFSA opinion.

The "glyphosate saga" has also shed some light on the role of the MSs in the regulatory framework governing the authorisation of active substances and the use of pesticides in the EU. As we have seen, MSs fully participated to the exchange of information between EFSA, the RMS and the EC in the renewal procedure. Moreover, according to the Regulation they had the responsibility to confirm or stop the adoption of the EC draft decision authorising such renewal. The various "no opinion" outcomes that have characterized the different rounds of voting in the comitology procedure, have highlighted the fragility of such procedure; indeed, MSs have often proved to be deeply divided over politically sensitive issues of direct impact on citizens and businesses, like in the case of glyphosate.⁵⁴ In order to prevent similar situation occurring, in February 2017 the EC put forward a legislative proposal amending the current Comitology regulation.⁵⁵ As specified in the explanatory memorandum

⁵³ Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods], Brussels 11 April 2018, COM(2018)179 final.

⁵⁴ The 'no opinion' outcome is used to happen in the comitology procedures for the authorisation of GMOs; see the Annual Reports on the working of comitology committees available here <<http://ec.europa.eu/transparency/regcomitology/index.cfm>> accessed 11 February 2019.

⁵⁵ See n 15. Proposal for a Regulation of the European Parliament and the Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, Strasbourg, 14 February 2017, COM (2017)85 final.

of the proposal, the initiative follows up on a statement by the President of the Commission in his State of the Union in September 2016 when he said: 'It is not right that when EU countries cannot decide among themselves whether or not to ban the use of glyphosate in herbicides, the Commission is forced by Parliament and Council to take a decision. So we will change those rules – because that it not democracy'.⁵⁶ The proposal aims at improving the functioning of the comitology procedure at the level of the Appeal committee by reducing the risk of 'no opinion' outcomes. In particular, the proposed amendments provide for the possibility of holding a further meeting of the Appeal committee at ministerial level whenever no opinion is delivered; it also foresees that in case of no opinion outcome in the Appeal committee, the EC may ask the Council to indicate its views and orientation on the wider implications of the absence of opinion; lastly, the proposal aims at increasing the transparency of the voting procedure within the Appeal committee, by making the votes of the MSs' representatives public.

While it is still uncertain *if* the legislative proposal will be finally adopted by the co-legislators and *if* it could eventually achieve all stated objectives, it is undoubtable that an increased level of transparency also in the comitology procedures could help gain a better understanding of the MSs' responsibility in the EU regulatory framework for PPPs. It is worth reminding, indeed, that MSs have the last word in the procedure for renewing the authorisation of active substances; only if they fail to take a decision in the Appeal committee, the EC is obliged to adopt an act that, as article 13 of the PPPs Regulation provides, is based on EFSA opinion and '*on other factors legitimate to the matter under consideration and the precautionary principle*'. In the case of glyphosate, in light of the 'no opinion' outcome in the Appeal committee, EC rightly based its decision on the positive scientific assessment of EFSA and, taking into consideration possible future developments, it reduced the duration of the renewal to only 5 years. It is quite hard to imagine a scenario where (as some authors suggested)⁵⁷ the EC simply ignores the scientific opinion of EFSA and bases its decision to deny the renewal of glyphosate only on the precautionary principle; indeed, such decision would be of political nature and, as such, it should be taken by MSs' representatives sitting in the comitology committees.

Moreover, a clearer understanding of the role of MSs in the decision-making for active substances could push them to take full responsibility in granting national authorisations for the marketing and use of pesticides. In fact, MSs only have the competence to authorise or not the final products; in particular, according to article 1, paragraph 4, of the Regulation, MSs are asked to rely on the precautionary principle in case of scientific uncertainty as to the risks with regard to human or animal health

⁵⁶ European Commission, *State of the Union 2016: Towards a better Europe – a Europe that protects, empowers and defends* (2016).

⁵⁷ Giulia Claudia Leonelli, 'The glyphosate saga and the fading democratic legitimacy of European Union risk regulation' (2018) 25(5) *Maastricht Journal of European and Comparative Law* 582.

and the environment posed by PPPs to be authorised in their territory. Thus, following the adoption of Regulation (EU) 2017/2324 that has renewed the authorisation of glyphosate, MSs has been asked to keep monitoring if the pesticides containing such active substance are safe or not. In accordance with the latter Regulation, some MSs have adopted stricter rules for the use of glyphosate-based herbicides, but none of them have totally banned the marketing and the use of *all* glyphosate-containing products⁵⁸. In France, for example, the sale and use of Roundup 360 (an herbicide containing glyphosate) has been banned in January 2019 as a consequence of a court ruling stating that French regulators had committed an error of assessment in the light of precautionary principle when they had authorised the marketing and use of this herbicide.⁵⁹

More in general, the audit performed by the EC in 2017 on the systems put in place by MSs for the authorisation of PPPs has highlighted significant deficiencies on two important steps of the procedure:⁶⁰ namely the re-evaluation of PPPs already on the market, according to article 43, paragraph 5, of the Regulation;⁶¹ and the possibility to grant emergency authorisations without a full evaluation being performed, pursuant to article 53 of the Regulation.⁶²

A full and effective implementation of the Regulation by MSs, together with a more transparent decision-making would be a concrete response to the concerns expressed by EU citizens on the “glyphosate saga”.

⁵⁸ Italy has restricted the conditions for the use of glyphosate-containing compounds since 2016; other MSs as Netherlands, Germany, Belgium have followed.

⁵⁹ Jugement n°1704067 Comité de recherche et d'information indépendantes dur le génie génétique, Tribunal Administratif de Lyon, 6ème chambre, 15 janvier 2019.

⁶⁰ European Commission, *Overview Report – Authorisation of Plant Protection Products* (2017).

⁶¹ See n 20.

⁶² See n 6.

Part IV

New Challenges in Environmental Health: Pathogen Sharing, Biodiversity and Antimicrobial Resistance



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Chapter 18

Biodiversity, Pathogen Sharing and International Law

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1. Introduction

The sharing of pathogens is fundamental to global health and has the capacity to contribute, inter alia, to enhancing disease surveillance activities necessary for global health security, building and bolstering diagnostic capacity, assisting in risk assessment, as well as the development of vaccines and treatments such as antivirals.¹ In order for an effective infectious disease response to be realised, however, pathogen sharing on its own is not enough. Instead, ‘fair and equitable access to diagnostics, vaccines and treatments’² is also required.

Sharing of pathogens occurs in a number of ways; ‘ad hoc, bilaterally, as the need arises, or through existing networks of institutions and researchers.’³ The World Health Organisation (WHO) is often involved in pathogen sharing, performing a coordination or support role.⁴ The Global Polio Laboratory Network (GPLN), co-ordinated by the WHO, is an example of an existing network through which collaborating laboratories share samples of poliomyelitis virus.⁵ The GPLN complements the work of the Global Polio Eradication Initiative (GPEI) launched in 1988, which

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¹ WHO, ‘Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications – Study by the Secretariat’ available at <www.who.int/un-collaboration/partners/Nagoya_Full_Study_English.pdf> 6.

² *ibid.*

³ *ibid.* 5.

⁴ *ibid.* 19-20.

⁵ *ibid.* 6.

aims to ‘complete the eradication and containment of all wild, vaccine-related and Sabin polioviruses.’⁶ The global incidence of polio has decreased by 99.9% since the inception of the GPEI programme.⁷ The public health context is similar in respect of influenza, for which ‘monitoring the evolution and spread of viruses, and responding to outbreaks, is a continuous process, requiring constant access to samples of circulating influenza viruses.’⁸ Accordingly, thousands of samples are shared each year among collaborating laboratories of the Global Influenza Surveillance and Response System (GISRS), allowing for timely risk assessment as well as the development of measures of risk management such as vaccines.⁹

While the sharing of pathogens is clearly important to global health, it is not an area without controversy. Recently, particular concern has arisen in respect of the sharing of influenza viruses with human pandemic potential and of their benefits, including vaccines.¹⁰ This prompted the World Health Assembly to adopt in 2011 resolution WHA64.5 establishing the Pandemic Influenza Preparedness (PIP) Framework. The aim of this Framework is to promote the ‘objective of a fair, transparent, equitable, efficient, and effective system for, on an equal footing: (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits, such as diagnostics and antivirals.’¹¹ Accordingly, under the PIP Framework, the sharing of influenza viruses of human pandemic potential is balanced with access to vaccines and the sharing of other benefits.

Shortly before the passing of resolution WHA64.5, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (hereinafter the Protocol) was adopted as a supplementary protocol to the UN Convention on Biological Diversity (CBD).¹² The Protocol expands upon the existing provisions of the CBD on access and benefit-sharing (ABS) with its objective being to promote the ‘fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.’¹³ While the Nagoya Protocol is silent on whether genetic resources within its scope include those with pathogenic potential, pathogens are considered by at least some commentators to fall within the scope of the

⁶ Polio Global Eradication Initiative ‘Our Mission’ <<http://polioeradication.org/who-we-are/our-mission/>> accessed 15 January 2019.

⁷ *ibid.*

⁸ WHO (n 1) 5.

⁹ *ibid.*

¹⁰ See discussion in section two, below.

¹¹ World Health Organization (WHO), Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, WHA64.5, 24 May 2011, <http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf> (hereinafter PIP Framework).

¹² Convention on Biological Diversity (CBD) 1992, 1760 UNTS 79.

¹³ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization 2014, CBD Decision X/1 (2010) (hereinafter Nagoya Protocol), art 1.

Protocol.¹⁴ However, the particularities of pathogens are recognized within the Protocol, as Parties are required to 'pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health.'¹⁵

The WHO PIP Framework is an ABS instrument that aims to put the sharing of influenza viruses of human pandemic potential on a par with access to benefits such as vaccines. Negotiated at broadly the same time, the 'negotiation dynamics' between the Nagoya Protocol and the PIP were 'highly interlinked.'¹⁶ Despite these dynamics, however, a recent study by the WHO noted the existence, inter alia, of concerns that implementation of the Protocol could result in complexity, high transaction costs and potentially limit pathogen sharing.¹⁷ While the WHO study noted that the Protocol and the PIP were potentially complementary, it found a lack of legal clarity in respect of the relationship of the PIP Framework's ABS provisions with that of the Protocol, with a consequent potential impact upon public health.¹⁸

Against the above background, this chapter focuses on the relationship between the PIP Framework and the Protocol to illustrate the legal issues arising from the interaction of different ABS systems. The chapter will also focus on concerns about fragmentation of international law, as well as the defensive approach adopted by States to prevent the establishment of normative hierarchy, particularly in the area of pathogen sharing. While there has been some discussion in the literature about the relationship between the Nagoya Protocol and the PIP Framework, much of this has sought to determine which instrument should apply in a particular situation. Our approach in this chapter is different: we seek to emphasise the potential of the principle of mutual supportiveness in international law as a tool to facilitate fruitful interactions between overlapping regimes. The legal and conceptual space, as well as the practical need, for such mutual supportiveness to guide interaction(s) between the two regimes at issue stems from the fact that the Nagoya Protocol, to borrow from the work of Cass Sunstein, is constructed as an 'incompletely theorised agreement' which offers opportunities for learning and experimentation with other regimes. On to this conceptual foundation, we construct a framework for analysis of the PIP Framework and Nagoya Protocol focused on 1) opportunities for mutual learning and 2) experimentation across different international regimes and instruments.

In section two, we will delve further into the legal issues surrounding the relationship between the PIP Framework and the Nagoya Protocol with a view to discerning at a more granular level the legal issues arising from the interaction of these different ABS systems. In section three, we seek to position the current debate regarding the

¹⁴ See discussion in Marie Wilke, 'A Healthy Look at the Nagoya Protocol - Implications for Global Health Governance' in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective* (Martinus Nijhoff 2013) 132.

¹⁵ Nagoya Protocol, art 8(b). See also preambular para 17.

¹⁶ Wilke (n 14) 125.

¹⁷ WHO (n 1) 7.

¹⁸ See generally *ibid* 18.

interaction of different ABS systems as one ultimately engaging the more fundamental question of how to facilitate effective interactions between regimes with overlapping scope. In this section, we draw from a range of literature, including from the realm of political science, as well as from the principle of mutual supportiveness in international law. In section four, we identify specific opportunities for mutual learning and experimentation under the Protocol and the PIP Framework, drawing on the concept of the incompletely theorised agreement to elucidate how uncertainties in the interaction between regimes may in fact produce positive externalities for ABS regimes that both allow for – but also require – further development for their effective operationalization. In section five, we conclude by reflecting on the opportunities for mutual learning across these two regimes premised on a proactive approach to experimentation in international law, rather than an exclusively defensive focus aimed at preventing normative hierarchy by clarifying the applicability of different regimes.

While our focus is on the relationship between the Protocol and the PIP Framework, our findings are nevertheless relevant for devising ways to manage constructively the interplay between the Nagoya Protocol with other pathogen-sharing schemes beyond influenza with pandemic human potential. As we confront a widening array of new and emerging infectious diseases whose control requires international collaboration such as MERS-CoV, Zika and new strains of influenza with pandemic potential, the world requires maximizing opportunities for collaboratively learning how to best address these global issues.¹⁹

2. Section Two – Legal Background

In this section, we begin by elucidating upon the legal background to the development of both the Nagoya Protocol and the PIP Framework. In so doing, we seek to articulate the flexibilities envisaged in the implementation of the Nagoya Protocol, highlighting its multi-level structure and the opportunities provided for experimentation by its non-hierarchical construction. Such flexibility could, however, be seen as detrimental to legal certainty, a concern which finds expression in recent discussions within the WHO on the (potential) implications for public health of the ABS system established by the Protocol. We then go on to provide some necessary additional background to the legal structure and underpinning dynamics of the PIP Framework. In the last strand of this section, we turn our attention to key aspects of the international debate on the interactions between the Protocol and the PIP Framework.

¹⁹ See generally WHO Executive Board, 140th Session, Report of the 2016 PIP Framework Review Group EB140/16 (2016) Annex 1, 14 <http://apps.who.int/gb/ebwha/pdf_files/EB140/EB140_16-en.pdf>.

2.1. *The Nagoya Protocol*

The Nagoya Protocol is a significant expansion on the existing provisions of the CBD on access and benefit-sharing²⁰ in respect of genetic resources and traditional knowledge associated with such resources.²¹ It aims to put into effect the 3rd objective of the CBD²² by detailing how to operationalise the provisions of CBD Article 15 with the aim of further supporting the effective implementation of the ABS provisions of the Convention.²³ CBD Article 15 established in general terms that sovereignty over natural resources extended to a right to regulate access to genetic resources: it stipulated that such access should be on mutually agreed terms (MAT) and with prior informed consent (PIC) (unless otherwise specified by the country concerned), implying a bilateral ABS system between providers and users of genetic resources. These provisions are expanded upon in the Protocol and importantly, they are coupled by specific, innovative obligations to support compliance with the domestic legislation of the Party providing genetic resources, and contractual obligations reflected in MAT. The Protocol sets down in Article 6, for example, baseline procedural requirements for PIC, as well as minimum specifications for MAT.²⁴ In the same vein, Article 5 of the Protocol gives further flesh to the meaning of fair and equitable benefit-sharing, clarifying that such benefits may be both monetary as well as non-monetary with States directed under Article 5 (5) to introduce ‘legislative, administrative or policy measures, as appropriate’ to ensure the sharing of benefits upon MAT.

Article 5 of the Protocol is illustrative of the particular reliance placed on national legislation to operationalise the Protocol’s “primary mandates”,²⁵ with Young, for example, articulating how the Protocol does not actually *create* an ABS regime, but rather calls for its creation through myriad paths of “implementation” and “regime

²⁰ Indeed, art 1 of the CBD sets out that it is aimed, among other things, at the achievement of, ‘the fair and equitable sharing of benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.’ See also art 8 (j) and art 15 CBD.

²¹ See Elisa Morgera, Matthias Buck and Elsa Tsoumani, ‘Introduction’ in Morgera, Buck and Tsoumani (n 14) 1-17.

²² Nagoya Protocol, 2nd preambular recital, which reiterates the relevant wording of CBD, art 1.

²³ Nagoya Protocol, 4th and 12th preambular recital.

²⁴ See discussion in Elisa Morgera, Elsa Tsoumani and Matthias Buck, *Unravelling the Nagoya Protocol: A Commentary on Access and Benefit-sharing to the Convention on Biological Diversity* (Brill 2014) 139-169.

²⁵ Tomme Rosanne Young, ‘An International Cooperation Perspective on the Implementation of the Nagoya Protocol’ in Morgera, Buck and Tsoumani (n 14) 451, 462. That is not to say that there are not, to use the terminology of Young, ‘international ABS implementation tools’ with, for example, the ABS clearing house provided for in art. 14 Nagoya Protocol one such international tool; at 469.

development”.²⁶ In this regard, Young has opined that the creation of a functional ABS regime under the Protocol calls for coordination across different levels and functional areas of law.²⁷ This extends to a requirement for coordination across different legal orders and among different actors involved in ABS.²⁸ In this sense, the Protocol’s approach to governance is *multi-level* rather than hierarchical, with possibilities existing for flexibility and learning through implementation domestically and internationally.²⁹ Such flexibility arguably provides room for *experimentation* with a number of provisions, such as that on model contract clauses,³⁰ allowing a range of actors to contribute to building legal understandings as to their operation as well as to their implementation. However, an acknowledged ‘by-product’ of flexibility is the challenge(s) this can pose to Parties involved in the Protocol’s implementation.³¹ We can discern, at least in part, the challenges regarding the flexibility in the Protocol’s operation in respect of the relationship between the Nagoya Protocol and the PIP Framework. The 2016 Review of the PIP Framework noted, for example, that significant overlap existed with respect to the operation of the PIP Framework and the Protocol. The PIP Framework Review further noted that there was uncertainty as to whether both instruments would potentially apply to sharing of influenza virus of human pandemic potential.³² This could result in duplication and potentially slow down virus sharing, with a consequent impact upon pandemic preparedness and response.³³ We turn to these challenges in due course but before doing so, we delineate in more detail the legal structure and defining features of the PIP Framework.

2.2. *The Pandemic Influenza Preparedness Framework*

The origins of the PIP Framework are traceable to the avian influenza (H5N1) outbreak in 2006, with a growing fear that the virus could successfully transmit among humans and start a highly lethal pandemic.³⁴ Indonesia had shared human samples with the network of WHO-coordinated laboratories for risk assessment and risk management purposes³⁵ but in 2007 refused to continue doing so upon discov-

²⁶ *ibid* 457.

²⁷ *ibid* 462-463

²⁸ See Morgera, Buck and Tsioumani, ‘Introduction’ (n 21) 10.

²⁹ *ibid*.

³⁰ Nagoya Protocol, art 19.

³¹ See Morgera, Buck and Tsioumani, ‘Introduction’ (n 21) 11.

³² WHO (n 19) 96.

³³ *ibid*.

³⁴ See generally Wilke (n 14) 124.

³⁵ See generally David Fidler, ‘Influenza Virus Samples, International Law, and Global Health Diplomacy’ (2008) 14 *Emerging Infectious Diseases* 88.

ering that an Australian pharmaceutical firm had developed a vaccine from one of the shared samples.³⁶ Indonesia also based its refusal to share samples upon the principle of sovereignty over genetic resources enshrined in the CBD; in essence, 'it had never consented to the sharing of samples with private companies or to the commercial application of the samples ... now limiting Indonesia's access to said vaccines ... in violation of the principle of sovereignty over genetic resources.'³⁷ The WHO subsequently confirmed that H5N1 samples shared through its Global Influenza Surveillance Network (GISN, later renamed GISRS) were modified and patents applied for in respect of genetic sequences of these modified samples without Indonesia's consent.³⁸ This led to a situation which, in the words of Fidler, meant that '(d)eveloping countries provided information and virus samples to the WHO-operated system; pharmaceutical companies in industrialized countries then obtained free access to such samples, exploited them, and patented the resulting products, which the developing countries could not afford.'³⁹

Following the controversy, the World Health Assembly in 2007 passed Resolution WHA60.28 which urged Member States, 'to continue to support, strengthen and improve the WHO Global Influenza Surveillance Network and its procedures through the timely sharing of viruses or specimens with WHO Collaborating Centres, as a foundation of public health, to ensure critical risk assessment and response, and to aim to ensure and promote transparent, fair and equitable sharing of benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies.'⁴⁰ The WHO Director General was further mandated, 'to identify and propose, in close consultation with Member States, frameworks and mechanisms that aim to ensure fair and equitable sharing of benefits, in support of public health, among all Member States, taking strongly into consideration the specific needs of developing countries.'⁴¹ Four years of arduous negotiations resulted in the adoption in 2011 of World Health Assembly resolution WHA64.5 and the creation of the PIP Framework. As a World Health Assembly Resolution, it is not an international agreement in the 'traditional' international law sense⁴² though it clearly has legal effects.

As articulated in the introduction to this piece, the aim of the Framework is to ensure the sharing of biological material (BM) of influenza viruses with human pandemic potential (IVPP) on an 'equal footing' with access to the benefits arising from

³⁶ *ibid.*

³⁷ Wilke (n 14) 124.

³⁸ Fidler (n 35) 88.

³⁹ *ibid.*

⁴⁰ WHA60.28, 1(1).

⁴¹ *ibid.* 2(1).

⁴² On the legal effects of WHA Resolutions, see Gian Luca Burci and Claude-Henry Vignes, *World Health Organization* (Kluwer Law International 2004).

such sharing. Only IVPP falls within the PIP Framework system to the exclusion of seasonal influenza viruses though there have been discussions on whether to expand PIP Framework's scope accordingly.⁴³ Under the PIP Framework, Member States should share IVPP BM through the GISRS.⁴⁴ GISRS functions under WHO terms of reference with transfers of PIP BM between GISRS collaborating institutions conducted through standard material transfer agreements (SMTA1).⁴⁵ BM of IVPP transferred to recipients outside the system are again regulated by standard material transfer agreements negotiated and concluded by the WHO (SMTA2). Each SMTA, once executed, constitutes a binding contract. The PIP Framework also introduced an Influenza Virus Tracking Mechanism (IVTM) as a confidence-building measure, to track transfers of BM within the system.

Transfers taking place under SMTA1 do not attract benefit-sharing obligations, nor can recipients apply for intellectual property rights over materials exchanged under the SMTA1.⁴⁶ There is no such exclusion for intellectual property rights in respect of recipients of PIP BM under SMTA2. However, recipients under an SMTA2 must engage in benefit-sharing activities according to a range of options annexed to the Agreement and to be agreed upon case-by-case. This can include a commitment to provide vaccines and antivirals during an outbreak of pandemic influenza.⁴⁷ Benefits are not shared on a bilateral basis between provider and recipient, but rather multilaterally through WHO with particular regard to the needs of developing countries. As a contract, the terms of SMTA2, including agreed benefit-sharing arrangements, are binding upon the relevant parties. Accordingly, while the PIP Framework is itself a soft law instrument, its central innovation from a global health perspective⁴⁸ is its reliance upon *private* law contractual instruments (SMTAs) to facilitate a central goal of global *public* health goal in the guise of pandemic preparedness and response. The goal of global health security is ultimately enshrined in the International Health Regulations, IHR (2005).⁴⁹ Not only do SMTAs assist in enrolling the private sec-

⁴³ For a note of discussion to bring seasonal influenza under the PIP see WHO (n 19), 3.2.1. Samples of seasonal influenza are shared through the GISRS, which predates (as GISN) the formation of the PIP Framework. GISRS is coordinated by the Global Influenza Programme (GIP) although there is now close collaboration with the Secretariat of the PIP Framework; see generally Alan J Hay and John W McAuley, 'The WHO Global Influenza Surveillance and Response System (GISRS)-A Future Perspective' (2018) 12 *Influenza and Other Respiratory Viruses* 551.

⁴⁴ PIP Framework, 5.1.1; 'Member States, through their National Influenza Centres and Other authorized laboratories, should in a rapid, systematic and timely manner provide PIP biological materials from all cases of H5N1 and other influenza viruses with human pandemic potential, as feasible, to the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory of the originating Member State's choice.'

⁴⁵ PIP Framework, Annex 1.

⁴⁶ *ibid.*

⁴⁷ *ibid* Annex 2.

⁴⁸ Lawrence Gostin, *Global Health Law* (Harvard University Press 2014) 376.

⁴⁹ World Health Assembly, Revision of the International Health Regulations, WHA58.3, 23 May 2005 (hereinafter IHR (2005)).

tor into a normative commitment to global health preparedness and response,⁵⁰ but they are also an important element in achieving the equity envisaged during the negotiations of the PIP Framework.⁵¹

An additional and indeed innovative form of benefit-sharing established under the PIP Framework is the ‘partnership contribution.’⁵² This is unique in the international ABS landscape and consists of financial contributions from vaccine, diagnostic and pharmaceutical manufacturers who use GISRS. The partnership contribution funds pandemic preparedness and response. The sum due is equivalent to 50% of the running costs of the GISRS which at present is approximately \$28 million.⁵³ As articulated by Gostin, international instruments in the sphere of global health seldom address private actors, so the approach of the PIP Framework is a ‘governance innovation’⁵⁴ that has contributed significantly to bolstering preparedness.⁵⁵

2.3. The Relationship between the PIP Framework and the Nagoya Protocol

In terms of the relationship between the PIP Framework and the Protocol,⁵⁶ while a number of proposals were made during the negotiation of the PIP Framework and Health Assembly resolution WHA64.5 which, if accepted, would have put the Framework either outside the scope of the Nagoya Protocol or have recognised it as hierarchically ‘superior’, these were not adopted and hence do not find expression within the final text of the Framework.⁵⁷ However, the regimes are linked both textually and normatively. Public health is, for example, accorded particular recognition in the preamble to the Protocol which directs Parties to be, ‘[m]indful of the International Health Regulations (2005) of the World Health Organisation and the importance of ensuring access to human pathogens for public health preparedness and response purposes.’ As discussed further below, there are further references to health in the Protocol, specifically, ‘present or imminent emergencies that threaten or dam-

⁵⁰ On the enrolment of the private sector into the normative underpinnings of the IHR, see Gearóid Ó Cuinn and Stephanie Switzer, ‘Ebola and the Airplane – Securing Mobility through Regime Interactions and Legal Adaptation’ (2019) 32 *Leiden Journal of International Law* 71.

⁵¹ Gostin (n 48).

⁵² PIP Framework, 6.14.3.

⁵³ See at <www.healthpolicy-watch.org/who-report-shows-global-progress-on-influenza-preparedness-response/>.

⁵⁴ Gostin (n 48).

⁵⁵ See generally <www.healthpolicy-watch.org/who-report-shows-global-progress-on-influenza-preparedness-response/>.

⁵⁶ See discussion in Wilke (n 14) 141.

⁵⁷ See *ibid* 143.

age human, animal or plant health' within the text of Article 8 (b) though the meaning of such an emergency is not defined. Conversely, the PIP Framework recognizes as one of its principles 'the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks'.⁵⁸

As noted above, in 2016 the WHO Secretariat undertook a study on the implications of implementation of the Nagoya Protocol for public health.⁵⁹ While noting positive aspects of the Protocol from its capacity to promote 'greater trust and more equitable sharing of benefits', the study nevertheless found that there was a lack of clarity in respect to the application of the Nagoya Protocol to the sharing of influenza samples – both seasonal and pandemic.⁶⁰ The study also noted concerns that, depending upon the national legislation adopted by States to implement the Protocol, the procedures for bilateral PIC and MAT could prove overwhelming to the GISRS system that shares thousands of samples annually.⁶¹ A 2016 PIP Framework Review Group made similar findings, articulating that while the PIP Framework was the result of international negotiations aimed at balancing access with benefit-sharing, the Protocol could pose a threat to the PIP Framework. This, in the view of the Review Group, was due to the fact that, 'the implementation of the Nagoya Protocol may introduce uncertainty in relation to the sharing of influenza viruses, since numerous bilateral transactions could be required to be negotiated, which could delay the access to viruses.'⁶²

As a 'path' to deal with such uncertainty, the WHO 2016 study proposed three ways forward. The first would be to recognize the PIP Framework as a 'specialized international access and benefit-sharing instrument' within the meaning of Nagoya Protocol Article 4 (4). Under this provision, where such an instrument 'is consistent with and does not run counter to the objectives of the CBD and the Nagoya Protocol, the Nagoya Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resources covered by and for the purpose of the specialized instrument.'⁶³ In essence, recognition of the PIP Framework as a specialised international ABS instrument would exclude the applicability of the provisions of the Protocol to IVPP BM shared under the PIP Framework system. The 2016 WHO study also recommended that flexibilities in national implementing legislation such as those provided for under Article 8 (b) be availed of. Finally, the study suggested that use could be made of the space provided in Article 19 of the Protocol to develop standard templates for PIC and MAT in respect of pathogen sharing. The study suggested that this could be accompanied by codes of conduct for access to pathogens and benefit-sharing, as provided for in Article 20 of the Protocol.

⁵⁸ PIP Framework, 1 (11).

⁵⁹ WHO (n 1).

⁶⁰ *ibid* 18.

⁶¹ *ibid*.

⁶² WHO (n 19) finding 71.

⁶³ WHO (n 1) 24.

In 2016, the second meeting of the Conference of the Parties serving as the Meeting of the Parties (COP/MOP 2) to the Nagoya Protocol discussed the WHO study with some expressing concern over the initiative taken outside of the Protocol to clarify its relationship with the PIP Framework. As a result, Parties requested the CBD Secretariat to liaise with WHO, share information on implementation of Article 8(b) of the Protocol, and carry out a study on the criteria and process to identify a specialised international ABS instrument within the meaning of Article 4(4) of the Protocol.⁶⁴ In 2018, COP/MOP 3 considered possible criteria for identifying specialized international ABS instruments and requested more time to take a decision.⁶⁵ Arguably, what these decisions reveal is a concern among States regarding the creation of hierarchy in international law and a propensity to address unclear relationships among different international instruments in a defensive way by avoiding the creation of hierarchies and focusing on concerns about which fora and/or which conditions determine priority among regimes. Some developing countries in particular were concerned about missing opportunities to promote fair and equitable benefit-sharing in the context of implementation of the Nagoya Protocol, due to developments happening in other fora, where they may be in a weaker negotiating position.

What is usually not considered in these intergovernmental discussions, however, is the opportunity for different regimes to share learning and support experimentation that can be mutually beneficial in their respective development and implementation. This is particularly important in the context of international regimes where the key concept, in this case, benefit-sharing, gives rise to unsettled questions about the achievement of its objectives, notably fairness and equity, as well as effectiveness.

An additional element of complexity in the implementation of each regime, as well as in their relationship, consists in the unexpectedly rapid development of biotechnology, in particular the increasing ability of laboratories to completely sequence the genomic structure of living organisms and turn them into digital files that can be stored and accessed via databanks. Such a technology is referred to as 'Genetic Sequence Data' (GSD) by WHO and 'Digital Sequence Information' (DSI) in the environmental context: it enables laboratories to reconstruct a pathogen using a digital file as a source. This development creates challenges both for the implementation of each individual regime, as well as for their interactions, since both the PIP Framework and the CBD/Nagoya Protocol are explicitly premised on access to biological materials rather than information. Increasing reliance by research institutions and pharmaceutical companies on GSD/DSI to produce vaccines and other medical technologies risks side-lining, both legally and politically, the bargain achieved by the instruments under consideration. Both WHO and the Meeting of the Parties to the Nagoya Protocol are currently discussing the implications of GSD/DSI, in the former case with a view to expanding the

⁶⁴ CBD/NP/MOP/DEC/2/5 (16 December 2016). See generally Earth Negotiations Bulletin, 'Summary of the UN Biodiversity Conference – 2-17 December 2016' (20 December 2016) <<http://enb.iisd.org/download/pdf/enb09678e.pdf>>, 27-28.

⁶⁵ CBD/NP/MOP/DEC/3/14 (30 November 2018).

PIP Framework's scope to GSD and in the latter to consider whether information can be plausibly subsumed within the scope of the Protocol.⁶⁶ While this development is of the highest importance for the future of ABS and pathogen-sharing, the current transitional phase and uncertainty over both legal nature as well as practical consequence have led us in this chapter to focus on the sharing of biological materials *stricto sensu*.

3. *Section Three*

In this section, we present the current debate regarding the interaction of different ABS systems as one ultimately engaging the more fundamental question of how to facilitate effective interactions between regimes with overlapping scope.⁶⁷ We do so by exploring the complementary perspectives of regime interaction from international relations and the principle of mutual supportiveness from general international law.

As articulated above, the Nagoya Protocol establishes the framework for building an ABS regime but it does not build the regime as such.⁶⁸ Further regime development through multi-level implementation is required and more broadly, the structural foundation of the Protocol mandates coordination across different spheres, levels and actors within the Nagoya legal space.⁶⁹ In the words of Young, 'completion and implementation of any sub-component of a regime, without the rest of the overall regime may not, in itself, achieve any ABS objective.' Rather, what is required is consideration of how these different elements 'will interact (to) avoid gaps, overlaps, loopholes and other obstacles to effectiveness.'⁷⁰

Building the Nagoya Protocol regime clearly *also* implies consideration of how it will interact with other (related) regimes in practice, with active efforts required to navigate overlaps and governance gaps. Consideration of the interaction between the Protocol and the PIP Framework is only one part of the overall jigsaw. Conceptualised in this way, we begin to see the overlap and interaction between the Protocol and the PIP Framework not only as a legal issue, but rather as one requiring *management* of the inevitable – and indeed ongoing – regime interactions within the broader ABS space.⁷¹ These interactions could amount to a 'regime complex' – a network of

⁶⁶ WHO, 'Approaches to Seasonal Influenza and Genetic Sequence Data Under the PIP Framework' (December 2018) <www.who.int/influenza/pip/WHO70108b_Analysis.pdf>.

⁶⁷ Please note section three and four both draw heavily on the work of Elisa Morgera, Stephanie Switzer and Elsa Tsioumani, 'Study into Criteria to Identify a Specialized International Access and Benefit-Sharing Instrument, and a Possible Process for Its Recognition' (2018) (CBD/SBI/2/INF/17).

⁶⁸ Young (n 25) 456.

⁶⁹ See discussion in section two, above.

⁷⁰ Young (n 25) 457.

⁷¹ From the IR domain, one of the more commonly used definitions of a regime is 'a set of implicit or explicit principles, norms, rules, and decision-making procedures around which actors' expectations

‘partially overlapping and non-hierarchical institutions governing a particular issue-area,’⁷² ‘exhibiting overlapping membership, and generat[ing] substantive, normative or operative interactions recognized as potentially problematic, whether or not they are managed effectively.’⁷³ Clearly, the governance of ABS may be conceptualised as a complex consisting of the Protocol, the CBD and approximately a dozen international institutions and processes including, inter alia, the WHO, as well as the Food and Agricultural Organization of the UN (FAO) with its International Treaty on Plant Genetic Resources for Food and Agriculture.⁷⁴ The CBD and the Protocol are undoubtedly at the centre of this institutional complex,⁷⁵ but within the ABS institutional complex are various sub-complexes that each have different dynamics and approaches to interaction.⁷⁶

Navigating these ABS sub-complexes, and indeed, working out proactive tools to manage the interactions between them, is a key task within the ABS institutional complex. *Managing* interactions among these sub-complexes requires an approach that is by necessity *legal*, but also goes beyond the law. This is because interaction *both originates from and is shaped by* political decisions.⁷⁷ This is a point echoed in the International Law Commission’s report on fragmentation, which noted that while international law offers the structure for coordination and cooperation, either between States or between regimes and institutions, it does not contain clear-cut rules through which a global society’s problem would be resolved, so ‘[d]eveloping these is a political task.’⁷⁸ Hence, when dealing with overlapping regimes, thinking upon how to use law to promote cooperation while at the same time recognising the inherently political aspect of this task is vital. Our approach echoes that of recent literature on overlapping regimes that has sought to draw attention to the ways in which certain legal processes have, ‘created a space for pluralism, and contestation, and for the politicization of international law and of the jurisgenerative processes.’⁷⁹

converge in a given area of international relations’: Stephen D Krasner, ‘Structural Causes and Regime Consequences’ (1982) 36 *International Organization* 185, 186.

⁷² Kal Raustiala and David G Victor, ‘The Regime Complex for Plant Genetic Resources’ (2004) 58 *International Organization* 277, 279.

⁷³ Amandine Orsini, Jean-Frédéric Morin and Oran Young, ‘Regime Complexes: A Buzz, a Boom or a Boost for Global Governance?’ (2013) 19 *Global Governance* 27, 29.

⁷⁴ Sebastian Oberthür and Justyna Pozarowska, ‘Managing Institutional Complexity and Fragmentation: The Nagoya Protocol and the Global Governance of Genetic Resources’ (2013) 13 *Global Environmental Politics* 100, 106.

⁷⁵ *ibid.*

⁷⁶ Indeed, Oberthür and Pozarowska identify ‘three such sub-complexes that display separate logics of interaction, different types of division of labor and varying dynamics’, *ibid.*

⁷⁷ *ibid.* 102.

⁷⁸ International Law Commission, *Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law*, UN Doc A/CN.4/L.682, 2006 (thereafter ILC study) para 488.

⁷⁹ Anne Peters, ‘The Refinement of International Law: From Fragmentation to Regime Interaction and Politicization’ (2017) 15 *International Journal of Constitutional Law* 671, 672.

Interplay management is 'the *conscious* efforts by relevant actors or groups to address and improve institutional interaction and its effects, usually in pursuit of collective objectives as enshrined in the institutions in question.'⁸⁰ Interplay management can take a number of different forms. It can relate to 'processes of learning' between institutions and regimes.⁸¹ Interplay management may be *normative* in that the norms of one institution either support or contradict those of another.⁸² It can also be *utilitarian* in that interplay may 'alter the costs and benefits of options available in another institution.'⁸³ Furthermore, interplay management may be *regulatory* with regard to prohibiting or permitting certain behaviour across regimes, as well as *enabling* it, in that it aims to create knowledge and understanding and enhance capacities to achieve shared governance goals.⁸⁴

The tools used by institutions to facilitate regime interplay management range from high-level coordination between institutions via the creation of a new institution for managing interaction, to 'lower' forms of interplay management such as information sharing.⁸⁵ Softer tools such as the latter may help foster mutual relationships between regimes by helping to facilitate institutional cooperation,⁸⁶ focusing upon processes and procedures designed to bring about learning and deliberation by multiple stakeholders.⁸⁷ Even when the capacity of information exchange and enhanced communication to bring about effective interplay between overlapping international regimes may not be obvious, policy diffusion across regimes, by building upon and cross-referencing norms from other regimes, may bring potential benefits.⁸⁸

⁸⁰ Oberthür and Pozarowska (n 74) 103 (emphasis added). Indeed, '[a]s the international legal system becomes more and more complex, the need for interplay management increases'; see Mark Axelrod, 'Savings Clauses and the "Chilling Effect" - Regime Interplay as Constraints on International Governance' in Sebastian Oberthür and Olav Schram Stokke (eds), *Managing Institutional Complexity: Regime Interplay and Global Environmental Change* (MIT Press 2011) 87, 89.

⁸¹ Olav Schram Stokke, 'The Interplay of International Regimes: Putting Effectiveness Theory to Work' (2001) FNI Report 14/2001 <www.fni.no/getfile.php/132044/Filer/Publikasjoner/FNI-R1401.pdf> 10.

⁸² *ibid.*

⁸³ Sebastian Oberthür and Thomas Gehring, 'Institutional Interaction - Ten Years of Scholarly Development' in Oberthür and Stokke (n 80) 36.

⁸⁴ Sebastian Oberthür, 'Interplay Management: Enhancing Environmental Policy Integration Among International Institutions' (2009) 9 *International Environmental Agreements: Politics, Law and Economics* 371, 377.

⁸⁵ *ibid.* 375-377. See also Stokke (n 81) 12. See also discussion in Morgera, Switzer and Tsioumani (n 67) from which this discussion draws.

⁸⁶ See for example Harro van Asselt, 'Managing the Fragmentation of International Environmental Law: Forests at the Intersection of the Climate and Biodiversity Regimes,' (2012) 44 *New York University Journal of International Law and Politics* 1205, 1258.

⁸⁷ Margaret A Young, 'Fragmentation or Interaction: the WTO, Fisheries Subsidies, and International Law' (2009) 8 *World Trade Review* 477, 479. Though see Oberthür (n 84) 382.

⁸⁸ See generally Young, *ibid.* On the synergistic potential of cross-referencing to promote synergistic regime interactions, see generally Ó Cuinn and Switzer (n 50). See also Morgera, Switzer and Tsioumani (n 67).

The literature on regime interactions discussed above is instructive for a number of reasons. First, it provides empirical support for the contention that overlaps between regimes may promote synergies, depending upon how such overlaps are managed.⁸⁹ Furthermore, the literature also points to the potential of softer tools⁹⁰ to promote synergistic and mutually supportive outcomes.⁹¹

These insights provide a significant complement to legal approaches: general international law privileges a pragmatic solution to harmonizing what may appear as a fragmented legal landscape, through the adoption of new rules or the coordination of existing ones, while relying on legal interpretation to help structure the debate in order to foster *increased cooperation*.⁹² Foremost among the rule of international legal interpretation is mutual supportiveness, which builds upon the idea of international law as a 'system' comprised of disparate international rules that should be understood and applied as supporting each other.⁹³ Mutual supportiveness calls on States to avoid or resolve tensions between competing international regimes both through interpretation, as well as through law-making. In essence, the principle of mutual supportiveness calls upon States to pursue the negotiation in good faith of instruments that help to clarify the relationship between competing regimes, particularly when efforts to interpret such conflict away have been to no avail.⁹⁴ Mutual supportiveness is therefore a broader concept than the general rules of treaty interpretation, because it also addresses law-making and is not limited to treaties, but applies also to other international '*instruments*' (such as decisions taken under a treaty or otherwise inter-governmentally approved).⁹⁵ These decisions may represent 'different ways of dealing' with a common issue under different international regimes, but can still 'lead to mutually supportive outcomes,'⁹⁶ thereby pav-

⁸⁹ See generally Oberthür (n 84) 376.

⁹⁰ van Asselt (n 86) 1258. See also Oberthür (n 84). See further Young (n 87).

⁹¹ Oberthür (n 84) 383.

⁹² Erik Franckx, 'The Protection of Biodiversity and Fisheries Management: Issues Raised by the Relationship between CITES and LOSC' in David Freestone, Richard Barnes and David Ong (eds), *The Law of the Sea: Progress and Prospects* (OUP 2006) 210 231-232 (albeit focused on *lex posterior* rather than *lex specialis*).

⁹³ Riccardo Pavoni, 'Mutual Supportiveness as a Principle of Interpretation and Law-Making: A Watershed for the "WTO-and-Competing-Regimes" Debate?' (2010) 21 *European Journal of International Law* 649, 650.

⁹⁴ *ibid* 661-669.

⁹⁵ The term "instrument", which, for example, is used in art 4(4) of the Protocol is not a term of art in international law, but it can be argued that such a term can cover both binding and non-binding instruments of an intergovernmental nature. We are grateful to Prof. Robin Churchill for pointing this out; see discussion in Morgera, Switzer and Tsoumani (n 67).

⁹⁶ Harro van Asselt, Francesco Sindico and Michael Mehling, 'Global Climate Change and the Fragmentation of International Law', (2008) 30 *Law and Policy* 423, 430.

ing the way for ‘fruitful interactions’ between the two regimes.⁹⁷

As we discuss in the next section, the legal structure of the Protocol provides space for particular forms of interplay management, with a focus on experimentation and mutual learning with other regimes. Accordingly, we aim to throw light on the use of law and legal techniques to promote cooperation, while recognising that interplay management is not simply a legal process but one that has a political dimension.

4. *Section Four – Translations*

In this section, we examine the opportunities for mutual learning and experimentation in respect of both the Protocol and the PIP Framework. We draw on the concept of the incompletely theorised agreement to elucidate how uncertainties in the interaction between regimes may in fact produce positive externalities in the sense of leaving space for proactive cross-regime conversations and mutual learning.

Approaches to managing regime interplay based upon mutual learning and experimentation are explicitly foreseen within the text of the Protocol. Article 4 (3) of the Protocol, for example, encourages ‘due regard ... to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided they are supportive of and do not run counter to the objectives of the Convention and this Protocol.’ The reference to ‘useful’ arguably conveys an understanding that such a process can provide opportunities for fruitful exchanges and mutual learning. Furthermore, the text of Article 4 (3) directs the Parties to implement the Protocol, ‘in a mutually supportive manner with other international instruments relevant to this Protocol.’ Accordingly, the text of the Protocol provides an explicit recognition that its ongoing operation – the building of the regime, to paraphrase Young⁹⁸ – is not based on ideas such as hierarchy but rather on the promotion of mutual supportiveness.

Another way in which mutual supportiveness between the PIP Framework and the Protocol could manifest in practical terms is through Article 4 (4) of the Protocol. This provision of the Protocol underlines that Nagoya functions as a residual regime for ABS,⁹⁹ and does not apply in the case of application of a specialized ABS instrument as long as Parties ensure *not only* that specialized ABS agreements do not

⁹⁷ Margaret A Young, ‘Climate Change and Regime Interaction’, (2011) 5 Carbon and Climate Law Review 147, 147.

⁹⁸ See generally Young (n 25).

⁹⁹ The first sentence of art 4(4) indicates that: ‘This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention.’ The phrasing of the second sentence in art 4(4) indicates that the Nagoya Protocol does not subsume other ABS agreements, but rather functions as a *residual* regime operating in the absence of specialized ABS instruments that meet certain conditions. See discussion in Morgera, Switzer and Tsioumani (n 67).

undermine the CBD and Protocol objectives, but *also*, that they contribute to their realization.¹⁰⁰ Attention should also be given to thinking upon how *ongoing* interactions such as information exchange, learning and deliberation might be fostered and promoted so as to prevent the *legal* recognition of an ABS instrument as a specialized international instrument under Article 4 (4) from leading to a political disconnection between the instrument in question and the Nagoya Protocol.¹⁰¹ This point is supported by the text of Article 4 (3), which while mainly addressing ongoing work in other fora, would also be helpful after the recognition of an instrument as a specialized international ABS instrument pursuant to Article 4 (4).¹⁰²

Mutual supportiveness may also involve an element of experimentation at a number of levels; in essence, a process of determining 'best practices' across different scales to determine a solution best suited to achieving synergistic outcomes. This is the case of the Protocol provisions on model contractual clauses and on codes of conduct. Moreover, the provision under Article 10 of the Protocol for a global multilateral benefit-sharing mechanism for transboundary situations or where it is not possible to obtain PIC provides further potential for experimentation.¹⁰³ In addition, and as elucidated upon above, 'space' for experimentation and mutual learning can be found under Nagoya Protocol Article 8 (b). A health emergency can certainly be a 'public health emergency of international concern' as determined by the WHO Director General using powers under the IHR (2005).¹⁰⁴ The broad formulation of Article 8 (b), however, does not exclude other international organizations working on pathogens, such as the International Plant Protection Convention¹⁰⁵ and accordingly foresees space for experimentation and mutual learning between countries with respect to cross-regime implementation at the domestic level.

The importance of experimentation can be motivated by the characterization of the Nagoya Protocol as an incompletely theorised agreement – that is, an agreement on which Parties could agree on 'a highly abstract theory' about benefit-sharing, but not necessarily on 'what it entails in particular cases.'¹⁰⁶ While incompletely theo-

¹⁰⁰ Art 4(2) provides that Parties must ensure that these agreements, 'are supportive of and do not run counter to the objectives of the Convention and of the Protocol.' Indeed, Nagoya Protocol, art 4(2) explicitly points the negative and positive side – 'supportive of and do not run counter to the objectives of the Convention and [the] Protocol'. See Riccardo Pavoni, 'The Nagoya Protocol and WTO Law' in Morgera, Buck and Tsioumani (n 14) 185, 207.

¹⁰¹ See discussion in Morgera, Switzer and Tsioumani (n 67).

¹⁰² See discussion in *ibid* and above at section 2.3.

¹⁰³ See further <www.cbd.int/doc/meetings/abs/abs-a10em-2016-01/official/abs-a10em-2016-01-02-en.pdf>.

¹⁰⁴ Wilke (n 14) 130.

¹⁰⁵ International Plant Protection Convention (Rome, 6 December 1951, in force 3 April 1952) 2367 UNTS 223.

¹⁰⁶ Cass R Sunstein, 'Incompletely Theorized Agreements' (2005) 108 Harvard Law Review 1733, 1739. See also Cass R Sunstein, 'Incompletely Theorized Agreements in Constitutional Law', John M Olin Law and Economics Working Paper No. 322 (2 D Series).

rised agreements may represent a limited extent of consensus on a certain legal concept, they are not in themselves flawed. Such agreements may have societal benefits; we do not need to agree on everything to agree on something.¹⁰⁷ Article 4 (4) of the Protocol can be considered incompletely theorised because it encapsulates agreement on the ‘mid-level’ principle that certain ABS instruments can be specialized international instruments, but not agreement on how the principle plays out in particular circumstances – whether, for example, the PIP Framework is a specialized ABS instrument.¹⁰⁸ While the result of this may seem to be detrimental in that it produces uncertainty, it has arguably allowed space for processes of mutual learning between States, the WHO, the CBD, as well as the actors involved in this distinct space of ABS governance: for instance, on lessons learnt in the use of private contracts for the realization of fairness and equity,¹⁰⁹ or different methods to ensure the financial viability of international benefit-sharing mechanisms (such as the partnership contribution in the PIP Framework discussed above).¹¹⁰ Indeed, the signing in 2015 of a memorandum of understanding between the CBD and the WHO¹¹¹ and ongoing cooperation on a range of issues linked to the relationship between biodiversity and human health point to a recognition of the importance of inter-regime learning.

Ever since the conclusion of the aforementioned MOU, the formal channel of communication between the two Secretariats has allowed for a regular exchange of information about developments, respective positions and needs, as well as areas of uncertainty. These, in turn, are taken into account in policy and normative developments. For example, the WHO Secretariat has been advocating for the recognition of the PIP Framework as a Specialized International Instrument under Article 4(4) of the Protocol and representing that position at subsequent meetings of the COP/MOP.¹¹² While the identification of criteria for the application of Article 4 (4) is still a work in progress as of January 2019, the Nagoya Protocol COP/MOP decided to include a standing item in the agenda of its subsequent sessions on cooperation with other international organizations ‘to take stock of developments in relevant international forums, including any information on specialized international access and benefit-sharing instruments recognized by another intergovernmental body

¹⁰⁷ See generally *ibid.*

¹⁰⁸ For more on the different levels at which such agreements may be said to exist, see generally *ibid.*

¹⁰⁹ Elisa Morgera and Lorna Gillies, ‘Realizing the Objectives of Public International Environmental Law through Private Contracts: The Need for a Dialogue with Private International Law Scholars?’ in Duncan French, Verónica Ruiz Abou-Nigm and Kasey McCall Smith (eds), *Public and Private International Law: Strengthening Connections* (Hart 2018) 175–198.

¹¹⁰ Elisa Morgera, Study on Experiences Gained with the Development and Implementation of the Nagoya Protocol and Other Multilateral Mechanisms and the Potential Relevance of Ongoing Work Undertaken by Other Processes, Including Case Studies (2016) UN Doc UNEP/CBD/ABS/A10/EM/2016/1/2.

¹¹¹ See <www.cbd.int/doc/agreements/agmt-who-2015-07-23-mou-en.pdf>.

¹¹² WHO (n 66) 27.

and/or by a Party or group of Parties, with a view to enhancing mutual supportiveness between the Protocol and specialized international access and benefit-sharing instruments'.¹¹³ Similarly, WHO has impressed on the CBD Secretariat specific practical problems arising for the prompt sharing of seasonal influenza viruses from national implementation measures of the Nagoya Protocol.¹¹⁴

5. Section Five – Concluding Reflections

Amidst dominating concerns about fragmentation and potential hierarchies between the Nagoya Protocol and the WHO PIP Framework, this chapter calls attention to the need and opportunities for mutual learning across these two regimes premised both on the international law principle of mutual supportiveness and international relations studies on regime interactions. The chapter underscores how mutual learning can support a proactive approach to experimentation in international law that better suits the incompletely theorised nature of benefit-sharing under the Nagoya Protocol. This is particularly important where the key concept of benefit-sharing gives rise to unsettled questions about the achievement of its objectives as well as effectiveness. While the incompletely theorised nature of the Protocol may seem to be productive of uncertainty, our analysis has demonstrated it may also allow space for experimentation and processes of mutual learning to be engaged in between the WHO, the CBD, as well as the actors involved in this aspect of ABS governance. We therefore wish to emphasise the potential benefits of softer tools to help foster relationships between the relevant regimes by facilitating institutional cooperation and promoting learning and deliberation by multiple stakeholders.¹¹⁵ While our focus has been on the relationship between the Protocol and the PIP Framework, our findings are also relevant for thinking through and devising ways to manage the interplay between the Nagoya Protocol with other pathogen-sharing schemes beyond influenza with pandemic human potential, as well as other existing and emerging international instruments of relevance to ABS.

¹¹³ *ibid.*

¹¹⁴ *ibid* 29.

¹¹⁵ See also Young (n 87).



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Chapter 19

EU Biodiversity Law and Its Health Impacts

Riccardo Pavoni and Dario Piselli***

1. Introduction

The notion that anthropogenic environmental change represents an existential threat to the enjoyment of the human rights to life and health is by no means a new one, having played a central role in the emergence of the modern environmental movement as well as in the intergovernmental process that led to the first United Nations Conference on the Human Environment in 1972.¹ Ever since the 1960s, however, the scientific understanding of the complex interactions that exist between environmental degradation and human health and well-being has grown dramatically, as highlighted by the diffusion of concepts ranging from planetary health² to ecosystem services.³ In international law and policy, this trend has resulted in the intensification of multilateral debates around issues such as the environmental determinants of ill health, the socio-ecological dynamics of infectious disease emergence, and the direct and indirect health benefits arising from the fight against environmental threats including air, water and soil pollution, waste management, exposure to toxic chemicals, and climate and land use change.⁴

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¹ For example, the UN General Assembly Resolution 2398(XXIII), adopted in 1968 to convene the Stockholm Conference, expressed its concerns about the impact of the ‘continuing and accelerating impairment of the quality of the human environment’ on the physical, mental and social well-being of humans, and the consequential effects on their dignity and enjoyment of basic human rights. See UN-GA Res 2398(XXIII) (3 December 1968).

² Sarah Whitmee and others, ‘Safeguarding Human Health in the Anthropocene Epoch: Report of the Rockefeller Foundation – Lancet Commission on Planetary Health’ (2015) 386 *Lancet* 1973.

³ Millennium Ecosystem Assessment, *Ecosystems and Human Well-Being: Biodiversity Synthesis* (World Resources Institute 2005); and Millennium Ecosystem Assessment, *Ecosystems and Human Well-Being: Health Synthesis* (World Health Organization 2005).

⁴ This trend is highlighted by, inter alia, the growing calls for the international recognition of a human right to a healthy environment, as well as by the ongoing diffusion of initiatives and governance mechanisms seeking to improve the coordination between the respective mandates of international organizations such as the UN Environment Programme (UN Environment) and the World Health Or-

Among these threats, the accelerating loss of biological diversity at the level of genes, species and ecosystems⁵ has recently been identified as one of the leading concerns of the international community. On the one hand, it is now well-established that genetic and species diversity underpin ecosystem functioning and resilience (e.g. microorganisms driving decomposition and nutrient cycling; primary producers directly contributing to the availability of food and fibres; higher levels of diversity increasing the stability of ecosystem functions over time). On the other hand, species themselves may embody different types of ecosystem services (e.g. the service provided by pollinators in ensuring the security of food crops, the importance of certain large vertebrates for tourism, the role of umbrella or keystone species in an ecosystem) and even become 'goods' in their own right.⁶ In turn, human health depends on these material and non-material benefits provided by biodiversity and ecosystems, ranging from food, water and clean air to cultural, spiritual and recreational services, and including the positive physical and mental health impacts associated with access to, and presence of, urban green spaces.⁷

According to a growing body of literature, the loss of biodiversity can thus negatively affect human health in multiple ways. Some of these impacts are direct, as a result of, *inter alia*, reduced availability of wild living resources used for food and medicinal purposes, increased vulnerability of agro-ecosystems that rely on monocropping or uniform crop varieties, poorer diets, and reduced diversity in the human microbiota. Many others, by contrast, are mediated by biodiversity's role in the provision of regulating, supporting or cultural ecosystem services, for example higher infectious disease risk coming from land use change and shifting patterns of disease, higher prevalence of mental health disorders, and higher exposure to noise, air, water and soil pollution.⁸

ganization (WHO). For the 2018 report of the Special Rapporteur on Human Rights and the Environment, calling for the UN Human Rights Council to support the recognition of a human right to a healthy environment, see 'Report of the Special Rapporteur on the Issue of Human Rights Obligations Relating to the Enjoyment of a Safe, Clean, Healthy and Sustainable Environment' (24 January 2018) A/HRC/37/39. For an example of inter-organizational collaboration on environment and health, see the website of the WHO/UN Environment 'Health and Environment Linkages Initiative' (HELI), <www.who.int/heli/en/> accessed 15 March 2019.

⁵ See for example World Wide Fund for Nature, *Living Planet 2018: Aiming Higher* (WWF 2018); and IPBES, *Global Assessment Report on Biodiversity and Ecosystem Services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services* (edited by Eduardo S Brondizio and others, IPBES Secretariat 2019).

⁶ See for example Georgina M Mace, Ken Norris and Alastair H Fitter, 'Biodiversity and Ecosystem Services: a Multi-Layered Relationship' (2012) 27(1) *Trends in Ecology and Evolution* 19, 21-3; and Bradley J Cardinale and others, 'Biodiversity Loss and Its Impacts on Humanity' (2012) 486 *Nature* 59.

⁷ Secretariat of the Convention on Biological Diversity and WHO, *Connecting Global Priorities: Biodiversity and Human Health, a State of Knowledge Review* (Secretariat of the Convention on Biological Diversity and WHO 2015) 6; Millennium Ecosystem Assessment, *Ecosystems and Human Well-Being: Biodiversity Synthesis* (World Resources Institute 2005) 5-6.

⁸ Millennium Ecosystem Assessment, *Ecosystems and Human Well-Being: Health Synthesis* (World

Recognizing the importance of promoting more integrated approaches to the interconnected challenges of biodiversity and human health, the World Health Organization (WHO) and the Secretariat of the Convention on Biological Diversity (CBD) have announced a joint work programme in 2012. Since then, the World Health Assembly and the Conference of the Parties to the CBD have regularly called upon countries and regional organizations to mainstream health and biodiversity linkages in their policies and strategies, including through ‘nature-based solutions’ such as protected areas (PAs) and integration of green spaces in urban environments.⁹

In line with this international agenda, the establishment of synergies between biodiversity and health has also become a major challenge to the coherence and sustainability of European Union law, which routinely uses health concerns as an argument for improving environmental quality but has arguably retained a fragmented, sectoral policy response to biodiversity loss and its impacts on human health.¹⁰ At the political level, the 2013 adoption of the 7th General Union Environment Action Programme (EAP) significantly innovated on its predecessor, which had considered ‘nature and biodiversity’ and ‘environment and health’ as two largely separate areas of intervention.¹¹ In the new EAP, not only do European institutions reaffirm the protection of the Union’s citizens from ‘environment-related pressures and risks to health and well-being’ as one of the thematic priorities of the EU action on the environment; they also stress how this priority should be regarded as indivisible from the simultaneous objective of protecting, conserving and enhancing the Union’s natural capital, with the goal of promoting win-win strategies.¹² At the same time, however, the extent to which these two priorities are integrated in practice remains unclear, with the EAP itself referring to glaring data and knowledge gaps and pointing to the need for improved integration and policy coherence.¹³

In this chapter, we specifically focus on one dimension of the aforementioned debate, namely the current state of the EU internal policies on biodiversity, their im-

Health Organization 2005) 3-5; European Environment Agency and Joint Research Centre, ‘Environment and Human Health’ (EEA Report no.5/2013, Report EUR 25933 EN, European Environment Agency, 2013) <www.eea.europa.eu/publications/environment-and-human-health> accessed 10 March 2019, 69-70.

⁹ See for example WHO, ‘Human Health and Biodiversity. Report by the Director-General’ (29 March 2018) A71/11; CBD (Decision of the COP) ‘Biodiversity and Human Health’ (14 December 2016) CBD/COP/DEC/XIII/6; and CBD (Decision of the COP) ‘Biodiversity and Human Health’ (30 November 2018) CBD/COP/DEC/14/4.

¹⁰ European Environment Agency and Joint Research Centre (n 8) 81.

¹¹ In particular, the latter mostly referred to action on individual substances and/or issues, including chemicals, urban areas, pesticides, water resources, air quality, noise pollution, and scientific research. See Decision 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 Laying Down the Sixth Community Environment Action Programme [2002] OJ L242/1, 10.

¹² Decision 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 ‘Living Well, Within the Limits of Our Planet’ [2013] OJ L354/171, 178.

¹³ *ibid* 191, 195-196.

pact on human health and well-being, and the progressive incorporation of biodiversity and health linkages in the definition, implementation and interpretation of legal rules in this field. In doing so, we devote particular attention to the Birds and Habitats Directives,¹⁴ which are often described as the cornerstones of the Union's policy on biodiversity, as well as to Regulation 1143/2014 on invasive alien species (IAS Regulation).¹⁵ Accordingly, we leave aside instruments such as the Water Framework Directive and the Marine Strategy Framework Directive, which were conceived as cross-cutting from the outset and thus already in principle seek to bring biodiversity and health together by promoting ecosystem-based approaches to the conservation and sustainable use of EU waters and aquatic environments.¹⁶

The chapter proceeds as follows. In section 2, we discuss the broad legal framework within which the interplay between biodiversity and health should be understood at the EU level. In section 3, we analyse the emergence of health considerations as key dimensions in the implementation and enforcement of EU biodiversity law, with an emphasis on the Birds and Habitats Directives but referring also to the health-related aspects of the IAS Regulation. In section 4, we analyse the linkages between health and biodiversity in the interpretation and application of the precautionary principle, which constitutes a key foundation of all Union policies on the environment. Finally, in section 5, we conclude by noting that while EU biodiversity laws and policies remain vital tools for the protection and promotion of human health, the Birds and Habitats Directive still suffer from an incomplete mainstreaming of biodiversity and health linkages.

2. Biodiversity and Health in the Context of EU Law and Policy

As the status of biodiversity in the territory of the EU continues to deteriorate,¹⁷ a growing body of evidence points to the significant health benefits that existing EU biodiversity policies can offer to the Union's citizens, from the positive impacts of

¹⁴ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the Conservation of Wild Birds ('Birds Directive') [2009] OJ L207/7; and Council Directive 92/43/EEC of 21 May 1992 on the Conservation of Natural Habitats and of Wild Fauna and Flora ('Habitats Directive') [1992] OJ L206/7.

¹⁵ Regulation (EU) 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the Prevention and Management of the Introduction and Spread of Invasive Alien Species ('IAS Regulation') [2014] OJ L317/35.

¹⁶ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 Establishing a Framework for Community Action in the Field of Water Policy [2000] OJ L327/1; and Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 Establishing a Framework for Community Action in the Field of Marine Environmental Policy [2008] OJ L164/19.

¹⁷ European Environment Agency, 'The European Environment. State and Outlook 2015. Synthesis Report' (European Environment Agency 2015) 51-81.

the Natura 2000 network of PAs created by the Habitats Directive to investments in other green infrastructure,¹⁸ and including the potential contribution of the 2014 IAS Regulation to preventing the introduction and spread of human pathogens.¹⁹

From the perspective of EU primary law, however, no clear-cut individual human right to a healthy environment is explicitly envisaged in the Charter of Fundamental Rights of the EU, although high levels of both human health and environmental protection are separately considered as *principles* to be ensured and integrated within the Union policies and activities.²⁰ In the absence of clear indications of an explicit link between the environment and health in the Charter, it is article 168(1) and article 191(1) of the Treaty on the Functioning of the European Union (TFEU)²¹ that provide the broader framework through which the relationship between human health and the conservation and sustainable use of biodiversity should be understood in a European context.

Article 191(1) establishes the protection of human health as one of the objectives of the Union's policy on the environment, alongside the preservation, protection and improvement of the quality of the environment, the prudent and rational utilization of natural resources, and the promotion of measures at the international level to deal with regional or worldwide environmental problems.

The inclusion of human health in this provision essentially recognizes the connection that exists between the health and well-being of EU citizens and the state of their life-support systems, including biodiversity. In doing so, the provision also underscores that EU action to protect health should be regarded as an essential part of its environmental policy (again, including on biodiversity), whenever the former is subjected to environment-related pressures and risks. In turn, as stated by the CJEU in the *Pfizer Animal Health* case²² and confirmed by article 11 TFEU,²³ this action must be based on the precautionary principle and integrated into the definition and implementation of other Union policies.

In parallel with article 191(1), article 168(1) also requires a high level of human health protection to be ensured in the definition and implementation of all Union policies and activities. Moreover, it mandates EU action to be 'directed towards im-

¹⁸ Patrick ten Brink and others, 'The Health and Social Benefits of Nature and Biodiversity Protection' (Report for the European Commission, ENV.B.3/ETU/2014/0039, Institute for European Environmental Policy 2017).

¹⁹ Marianne Kettunen and others, 'Technical Support to EU Strategy on Invasive Species (IAS) - Assessment of the Impacts of IAS in Europe and the EU (Final Module Report for the European Commission, Institute for European Environmental Policy 2009) 18-29.

²⁰ Charter of Fundamental Rights of the European Union [2000] OJ C326/3891, arts 35 and 37. Environmental protection is clearly framed in art 37 of the Charter as a principle, rather than a human right *stricto sensu*. On the difference between principles and rights, see art 52(5) of the Charter.

²¹ Consolidated Version of the Treaty on the Functioning of the European Union ('TFEU') [2012] OJ C326/49.

²² Case T-13/99 *Pfizer Animal Health* [2002] ECR 2002 II-03305, para 114.

²³ See for example Nicolas de Sadeleer, *EU Environmental Law and the Internal Market* (OUP 2014) 29.

proving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health', thus including pathogens and other ecosystem-mediated determinants of ill-health. Whilst a joint consideration of the two provisions could suggest a broadly synergistic approach to human health and biodiversity protection under the EU Treaties, situations in which the practical realization of these two objectives might involve significant trade-offs are not to be excluded, a point reinforced by the fact that the four objectives under article 191(1) are not listed in any particular order of priority.²⁴ As will be discussed below, this conundrum is often directly resolved in EU secondary law through the provision of explicit derogations to biodiversity-related obligations that operate whenever these come into conflict with the interests of human health and public safety.

Since the publication of the EU Biodiversity Strategy to 2020,²⁵ the interplay created by articles 168(1) and 191(1) has been enriched and compounded by a growing mixture of hard and soft law instruments, including the already-mentioned 7th EAP, the Action Plan for Nature, People and the Economy,²⁶ and the European Commission communication on 'Green Infrastructure – Enhancing Europe's Natural Capital'.²⁷ Taken together, this wide array of documents aims to define and expand on the aspirational goals that are expected to guide EU law- and policy-making in the area of the environment, and specifically biodiversity, including the current targets of halting the loss of biodiversity in the EU by 2020 and restoring at least 15 percent of the EU's degraded ecosystems.²⁸ Although not all of the documents explicitly refer to human health, they nonetheless provide some clarification on the extent to which European institutions increasingly consider the need to halt biodiversity loss and ecosystem degradation in the light of their 'essential contribution to human well-being and economic prosperity',²⁹ rather than just for their intrinsic value. Besides the 7th EAP's call for increased synergies to be developed between health and biodiversity in areas such as ecosystem restoration, air and water quality, and green infrastructure,³⁰ the Commission communication on green infrastructure specifically identifies these interventions³¹ as an investment priority, owing to their capacity to deliver health benefits and

²⁴ It has been noted, with specific reference to EU biodiversity law, that setting conservation and restoration objectives for protected habitats 'may in fact require decision to be made on conflicts between various objectives'. See de Sadeleer, *ibid* 35; and Case C-241/08 *Commission v France* [2010] ECR I-1697, Opinion of AG Kokott, para 71.

²⁵ European Commission, 'Our Life Insurance, Our Natural Capital: an EU Biodiversity Strategy to 2020' COM (2011) 244 final, 3 May 2011.

²⁶ European Commission, 'An Action Plan for Nature, People and the Economy' COM (2017) 198 final, 27 April 2017.

²⁷ European Commission, 'Green Infrastructure – Enhancing Europe's Natural Capital' COM (2013) 249 final, 6 May 2013.

²⁸ European Commission (n 25) 2, 5.

²⁹ *ibid* 2.

³⁰ Decision 1386/2013/EU (n 12) 187-188.

³¹ Green infrastructure is defined by the communication as a 'strategically planned network of natu-

limit the spread of vector-borne diseases.³² Moreover, whilst the 2016 review of the Birds and Habitats Directives mainly focused on their effectiveness in ensuring the protection and sustainable use of species, it also acknowledged the growing awareness of human health and social inclusion benefits arising from their implementation.³³

Despite these statements of principle, however, the overall impression is that the role of EU biodiversity policy (as a component of the Union's wider environmental policy) in respecting, protecting and promoting human health remains more neatly articulated in EU treaties than in policy strategies and political declarations. Indeed, owing to their highly heterogeneous scope and objectives, the latter tend to retain a traditional focus on the specific substances and processes that directly threaten health, rather than on biodiversity's underlying importance for ecosystem functioning. As a consequence, biodiversity and health are often treated in these documents as the mutual beneficiaries of win-win interventions (e.g. on air pollution, chemicals, water quality), and protection of biodiversity *per se* is not necessarily framed in terms of its contribution to human health. This is exemplified by, *inter alia*, the Commission's communication on a 'European Action for Sustainability'³⁴ and its subsequent reflection paper on 'Towards a Sustainable Europe by 2030',³⁵ both of which completely omit a discussion of biodiversity and health linkages despite the relevance of the topic in the context of the implementation of the United Nations 2030 Agenda for Sustainable Development.³⁶

3. *EU Biodiversity Law and Its Health Impacts*

3.1. *The Birds and Habitats Directives: What Role in Protecting Human Health?*

At the level of secondary legislation, it has already been noted that the Birds and Habitats Directives essentially represent the two centrepieces of EU biodiversity law. Notwithstanding the significant time that has passed since their initial adoption, and the

ral and semi-natural areas with other environmental features designed and managed to deliver a wide range of ecosystem services.' Green infrastructure 'incorporates green spaces (or blue if aquatic ecosystems are concerned) and other physical features in terrestrial (including coastal) and marine areas', including rural and urban settings. See European Commission (n 27) 3.

³² *ibid* 3-4.

³³ Commission Staff Working Document, 'Fitness Check of the EU Nature Legislation (Birds and Habitats Directives)' SWD(2016) 472 final, 16 December 2016, 51.

³⁴ European Commission, 'Next Steps for a Sustainable European Future. European Action for Sustainability' COM (2016) 739 final (22 November 2016).

³⁵ European Commission, 'Towards a Sustainable Europe by 2030' COM (2019) 22 final (30 January 2019).

³⁶ UNGA Res 70/1 (21 October 2015) UN Doc A/RES/70/1.

multiple changes introduced over the years, both instruments continue to provide the main legislative framework for the conservation and sustainable use of wild animals, plants and habitat types in the territory of the Union, a relevance confirmed by their 2016 ‘fitness check’.³⁷ At the core of the two Directives lie the development of a body of norms that: (i) requires Member States to prohibit and/or regulate a wide range of harmful activities that can negatively impact on the conservation of threatened species of wild fauna and flora, as well as all species of wild birds occurring in the territory of the EU;³⁸ (ii) establishes a coherent ecological network of PAs named Natura 2000³⁹ and creates a procedure for the inclusion in the network of natural habitat types ‘of community interest’,⁴⁰ special areas of conservation (SACs) designated for the protection of species ‘of community interest’,⁴¹ and special protection areas (SPAs) designated for the conservation of wild species of birds that are endangered, vulnerable to specific changes in their habitat, considered rare or in need of particular attention because of the nature of their habitat;⁴² (iii) mandates the management and restoration of habitats that are important for wild flora and fauna beyond the Natura 2000 network, including through the creation of PAs, sustainable management of these habitats, and creation and re-establishment of biotopes;⁴³ and (iv) provides for improved research on, and monitoring of, habitats and species, as well as reporting on their condition, as well as on education and other awareness-raising activities.⁴⁴

Due to their very nature and origin, neither of the two Directives directly mentions human health as a rationale for its provisions.⁴⁵ At the same time, both instru-

³⁷ Commission Staff Working Document (n 33).

³⁸ Habitats Directive (n 14) arts 12-16; and Birds Directive (n 14) arts 5-9.

³⁹ Habitats Directive, *ibid* art 3. See European Commission, ‘Natura 2000’ (*European Commission*, last updated 23 January 2019) <http://ec.europa.eu/environment/nature/natura2000/index_en.htm> accessed 17 March 2019.

⁴⁰ Natural habitat types of community interest are defined in the Habitats Directive (art 1(c)) as those habitat types occurring within the territory of the EU that are in danger of disappearance in their natural range, have a small natural range, or present outstanding examples of typical characteristics of one or more of the five biogeographical regions: Alpine, Atlantic, Continental, Macaronesian and Mediterranean. They are listed, or may potentially be listed, in Annex I of the Directive. The rules applying to these habitats are laid down in arts 3-11 of the Directive.

⁴¹ Species of community interest are defined (art 1(g) of the Habitats Directive) as those, occurring within the territory of the EU, that are endangered, vulnerable, rare or endemic and requiring particular attention by reason of the specific nature of their habitat and/or the potential impacts of their exploitation on their habitat and/or conservation status. They are listed, or may potentially be listed, in Annex II and/or Annex IV or V of the Directive. The rules applying to the SACs are laid down in arts 3-11 of the Directive.

⁴² These species are listed in Annex I of the Bird Directive. The related habitat conservation measures are listed in art 4 of the Directive, whilst the inclusion of SPAs in the Natura 2000 network is provided for in the 7th recital of the Habitats Directive.

⁴³ Habitats Directive (n 14) art 9; Birds Directive (n 14) art 3.

⁴⁴ Habitats Directive, *ibid*, arts 17-18 and 22; and Birds Directive, *ibid*, art 10.

⁴⁵ More specifically, both the Habitats and Birds Directives affirm the need to take conservation measures at the EU level in the light of the fact that wild birds and other threatened species and habitats

ments broadly reaffirm in their recitals the links between the conservation and sustainable use of biodiversity and the attainment of the Union's essential objectives in terms of ensuring the health and well-being of its citizens. In particular, the 1st recital of the Habitats Directive explicitly refers to the conservation of natural habitats and of wild flora and fauna as an 'essential objective of general interest' pursued by the EU in accordance with article 191(1) of the TFEU. Similarly, the Directives also underline how their conservation aims are necessary to improve *living conditions*⁴⁶ and contribute to sustainable development.⁴⁷

Within this general framework, the operative provisions that appear most significant from a health perspective are arguably those relating to the creation of a coherent Natura 2000 network and the sustainable management of other habitats, biotopes and features of the landscape of major importance to wild fauna and flora, in line with existing evidence showcasing the positive contribution of PAs to human health and well-being.⁴⁸ In this respect, however, the process of mainstreaming human health considerations in the Habitats Directive and subsequent soft law instruments is still fundamentally incomplete. On the one hand, the Commission has often tried to raise the profile of human health and other socio-economic benefits provided by the network of PAs, for example by: (i) creating a specific category of the Natura 2000 Award;⁴⁹ (ii) committing to include guidance on human health in its efforts to help Member States better reflect the socio-economic benefits of investing in biodiversity as part of their financial planning for Natura 2000;⁵⁰ and (iii) recommending Member States, in its Guidelines on Climate Change and Natura 2000, to consider the negative health consequences of climate change's impacts on biodiversity in the context of their climate mitigation and adaptation measures.⁵¹

On the other hand, and perhaps most importantly, article 6(3) of the Habitats Directive does not include an explicit requirement to assess potentially negative impacts on human health arising from the adoption of plans or projects, not direct-

constitute part of the Union's natural heritage, and threats to them are often transboundary in nature. Habitats Directive, *ibid*, 4th recital, and Birds Directive, *ibid*, 4th recital.

⁴⁶ Birds Directive, *ibid*, 5th recital (emphasis added).

⁴⁷ Habitats Directive (n 14) 3rd recital; and Birds Directive, *ibid*.

⁴⁸ See for example World Wide Fund for Nature and Equilibrium Research, 'Vital Signs: The Contribution of Protected Areas to Human Health' (WWF 2010); European Environment Agency, 'Protected areas in Europe—an overview' (EEA Report 5/2012, EEA 2012) 25; and European Commission, 'The Economic Benefits of the Natura 2000 Network' (European Commission 2013) 40-2.

⁴⁹ European Commission, 'Award Categories' (*European Commission*, last updated 21 June 2016) <http://ec.europa.eu/environment/nature/natura2000/awards/the-award/categories/index_en.htm> accessed 20 March 2019.

⁵⁰ Commission Staff Working Document, 'Factsheets Providing Details of Actions in the Action Plan for Nature, People and the Economy' SWD (2017) 139 final (27 April 2017).

⁵¹ European Commission, 'Guidelines on Climate Change and Natura 2000' (European Union 2013) <<http://ec.europa.eu/environment/nature/climatechange/pdf/Guidance%20document.pdf>> accessed 20 March 2019, 95.

ly connected to the conservation or management of a Natura 2000 site, that are likely to have significant effect on the site.⁵² The provision in question, which requires any such plan or project to undergo an ‘appropriate assessment’, states that such an assessment should only be made in the light of the site’s ‘conservation objectives’, which essentially refer to the species and/or habitats for which the site itself was designated. In doing so, article 6(3) thus envisions a type of assessment that is different from those provided for by the Environmental Impact Assessment (EIA) and Strategic Environmental Assessment (SEA) Directives, both of which include human health among the aspects to be considered by the competent authorities.⁵³ Although in practice the appropriate assessment under article 6(3) of the Habitats Directive is often conducted alongside, or as part of, an EIA or SEA,⁵⁴ this is not always the case, owing to the different definitions of the activities requiring assessment.⁵⁵ In similar situations, the protection afforded to human health by the Habitats Directive is indirect and only potentially subsumed within the overall evaluation of whether the plan or project undergoing assessment will adversely affect the ‘integrity of the site’, i.e., the ‘coherent sum of the site’s ecological structure, function and ecological processes’ which sustains the habitats and/or species that justified its Natura 2000 designation.⁵⁶

In recent years, the CJEU has quite often been called to review the appropriateness of assessments conducted under article 6(3), demonstrating the continued rele-

⁵² By virtue of article 7, article 6(3) of the Habitats Directive also applies to SPAs designated under the Birds Directive.

⁵³ Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment [2011] OJ L26/1, as amended by Directive 2014/52/EU, art 3; and Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment [2001] OJ L197/30, Annex I.

⁵⁴ This is especially true after the 2014 revision of the EIA directive, which mandates the use of a joint and/or coordinated procedure whenever a project shall be subjected to both an EIA and an ‘appropriate assessment’ under the Habitats or Birds Directives. See Directive 2011/92/EU, *ibid*, art 2(3).

⁵⁵ See for example Joined Cases C-293/17 and C-294/17 *Coöperatie Mobilisation for the Environment and Vereniging Leefmilieu v College van gedeputeerde staten van Limburg and College van gedeputeerde staten van Gelderland* [2018] ECLI:EU:C:2018:882, paras 59-73. Moreover, it should be noted that the issue of the relationship between the SEA and/or EIA Directives and the Habitats Directive has recently been raised also with respect to another type of activities, that is, site management plans or any other project or measure under article 6(1) of the latter instrument, which are excluded by article 6(3) from the requirement of an appropriate assessment, see Case C-321/18 *Terre wallonne* [2019] ECLI:EU:C:2019:56, Opinion of AG Kokott, paras 37-57.

⁵⁶ European Commission, ‘Managing Natura 2000 Sites. The Provisions of Article 6 of the “Habitats” Directive 92/43/EEC. Commission Notice’ C(2018) 7621 final, 48-9. The CJEU has repeatedly stated that ‘a plan or project not directly connected with or necessary to the management of a site will adversely affect the integrity of that site if it is liable to prevent the lasting preservation of the constitutive characteristics of the site that are connected to the presence of a priority natural habitat whose conservation was the objective justifying the designation of the site [...]’. See for example Case C-258/11, *Sweetman and Others* [2013] ECLI:EU:C:2013:220, para 48.

vance of the Habitats Directive for the protection of European biodiversity. Through the use of its strict criteria of ecological integrity, the Court has particularly been able to find Member States in breach of their conservation obligations in a number of proceedings, most recently in *Coöperatie Mobilisation for the Environment and Vereniging Leefmilieu* and *Commission v Poland*.⁵⁷ It should be noted that in these cases the issue of the positive contribution of Natura 2000 sites to human health was not raised. However, it is clear that an integrated evaluation of health impacts arising from plans or projects requiring an appropriate assessment could enrich and support the findings of competent authorities, particularly insofar as such plans or projects were susceptible of having, according to the precautionary principle, direct or indirect effects on human health on top (or as a result) of their consequences for the conservation objectives of the site concerned.

As will be discussed in the following section, the approach taken by the Habitats and Birds Directive unfortunately fails to leverage this potential synergy. On the contrary, by virtue of their use of health as a potential reason for derogating to conservation obligations, the Directives largely pin biodiversity and health against each other on the balance of interests that authorities and courts are required to assess whenever reviewing the impact of human activities on Natura 2000 sites.

3.2. *Health as a Potential Ground for Derogations in the Habitats and Birds Directives*

The argument that the protection of health may restrain the protection of species and/or PAs under EU biodiversity laws arises from the absence of priority between the various environmental and human health objectives envisaged by article 191(1) TFEU. In secondary law, EU institutions are thus free to specify a hierarchy between these objectives, and the same can be done by the CJEU whenever it is called upon to decide on potential conflicts.⁵⁸

In the Habitats and Birds Directives, the strategy pursued by the Union's law-makers has been precisely that of giving a certain degree of flexibility to EU Member States in derogating from the conservation-oriented provisions included in the two instruments. First, in the Birds Directive, 'public health and safety' appear in article 9 as one of the reasons allowing Member States to derogate, when there is no satisfactory alternative, to the provisions of articles 5 to 8 concerning the prohibition and/or regulation of activities that could potentially harm the populations of wild birds. Secondly, the same ground for derogation, together with 'other imperative reasons of overriding public interest', is also set forth by article 16 of the Habitats Directive

⁵⁷ Joined Cases C-293/17 and C-294/17 (n 55); and Case C-441/17 *Commission v Poland* [2018] ECLI:EU:C:2018:255.

⁵⁸ See for example de Sadeleer (n 23) 34-35.

concerning the system of protection (article 12 to 15) set up for the animal and plant species listed in its Annexes. Thirdly, under article 6(4) of the Habitats Directive, the presence of ‘imperative reasons of overriding public interest, including those of a social or economic nature’ (such as, implicitly, health) can justify a decision to carry out a plan or project likely to have significant effects on a Natura 2000 site despite the negative result of the appropriate assessment conducted according to article 6(3) and in the absence of alternative solutions. Fourthly, when the site in question hosts what the Directive defines as priority natural habitat types and/or priority species, human health is considered (explicitly) in article 6(4) as one of the only considerations which may again be raised to undertake a plan or project under the same circumstances contemplated by article 6(3).

The derogatory force of health and safety considerations vis-à-vis the conservation of biodiversity is hardly surprising, given their nature of fundamental values for EU citizens as well as human health’s role as an objective of the Union’s environmental policy. Notably, however, the possibility to rely on human health in order to deviate from EU biodiversity conservation law is not without limits, as it rests on the presence of specific conditions set by the Directives. In the case of article 9 of the Birds Directive, these conditions are (i) the absence of another satisfactory solution;⁵⁹ and (ii) the need to provide a series of clear and specific information about the derogations adopted.⁶⁰ For its part, article 16 of the Habitats Directive confirms the same requirements and adds the condition that the derogation must not be ‘detrimental to the maintenance of the populations of the species concerned at a favourable conservation status in their natural range’.⁶¹ Finally, Article 6(4) only allows a plan or project that has been negatively assessed to go ahead if: (i) there are no alternative solutions; (ii) the Member State takes all the compensatory measures that are necessary to ensure the overall coherence of Natura 2000; and (iii) the Member State informs the Commission of the compensatory measures adopted.

The CJEU has often been called upon to evaluate the correct application of this legal framework, especially vis-à-vis the invocation of human health and public safety as derogations under article 6(4) of the Habitats Directive. Frequently, indeed, Member States have invoked human health and public safety as a justification for plans or projects approved pursuant to article 6(3). In these cases, a problem is represented by the absence of a clear definition of both ‘human health’ and ‘public safety’ in the Directive, something which has made the task of defining the limits of an ‘imperative reason of overriding public interest’ relating to health more challenging. In one decision, the CJEU held that the supply of drinking water, but not irrigation, could qualify as a consideration relating to human health or public safety (and thus operate even when priority natural habitat types and/or priority species are affect-

⁵⁹ Birds Directive (n 14) art 9(1).

⁶⁰ *ibid* art 9(2)(a)-(e).

⁶¹ Habitats Directive (n 14) art 16(1).

ed).⁶² In another, the Court stated that, in principle, the construction of a platform to facilitate the movement of disabled persons could also be subsumed under the definition of ‘human health’, even though it argued that such a justification should be of such importance that it can be weighed up against the other concerned interests.⁶³

More recently, in the *Commission v Poland* case relating to the logging and forest management activities conducted in the Natura 2000 site of *Puszcza Białowieska*, the CJEU was asked to evaluate the Polish government claim that the felling and removal of dying trees was necessary to, inter alia, avoid a public danger to the safety of persons along transport and tourist routes and reduce the risk of forest fires. In the proceedings for interim measures requested by the Commission, the Court exceptionally authorized Poland to continue active forest management operations where they were necessary and proportionate to ensure, ‘directly and immediately’, the public safety of persons (e.g. only in the immediate vicinity of transport routes or other significant infrastructure), and only ‘on condition that other, less radical, measures were impossible for objective reasons’ (e.g. signposting or temporary access bans).⁶⁴ In its final judgment the Court reaffirmed that a derogation on grounds of human health and public safety must be interpreted strictly, and can only be raised if a plan or project has been previously found, through an appropriate assessment, to be likely to cause significant effects on the Natura 2000 site.⁶⁵

In sum, the Habitats Directive, in line with its objective to promote the preservation of biodiversity, ‘taking account of [...] social [...] requirements’,⁶⁶ considers human health as a priority interest which may, in case of conflicts, impose limits on the achievement of the other objectives of the Union’s environmental policy. At the same time, the Directive also makes the possibility of imposing such limits contingent upon respect for a series of specific requirements that the Court has interpreted strictly, in order to ensure that biodiversity and health could always be weighed up and harmonized, whenever possible, through the choice of alternative solutions.

3.3. *The Invasive Alien Species Regulation: Leveraging Health and Biodiversity Synergies*

Invasive alien species, that is, living organisms introduced outside of their natural range and whose presence in a new ecosystem can pose significant threats to native

⁶² Case C-43/10 *Nomarchiaki Afodioikisi Aitolokarnanias and Others* [2012] ECLI:EU:C:2012:560, para 128.

⁶³ Case C-504/14 *Commission v Greece* [2016] ECLI:EU:C:2016:847, para 77.

⁶⁴ Case C-441/17 R *Commission v Poland* [2017] ECLI:EU:C:2017:877, Order of the Court, paras 81-82.

⁶⁵ *Commission v Poland* (n 57) paras 189-190.

⁶⁶ Habitats Directive (n 14) 3rd recital.

wildlife and biodiversity, have since long been identified as a leading cause of biodiversity loss worldwide. The cost of these so-called ‘biological invasions’ has been estimated to amount to over 12 billion per year in Europe alone,⁶⁷ and the fight against their introduction and spread has quickly emerged as a new pillar of EU nature conservation legislation. In particular, the notion that invasive alien species can also have significant effects on human health through (and together with) their harmful impacts on biodiversity and ecosystem services has now become well-established in EU biodiversity law and policy.⁶⁸ This is evident, *inter alia*, from the EU Biodiversity Strategy, which in 2011 set a specific target requiring that by 2020, ‘invasive alien species are identified, priority species controlled or eradicated, and pathways managed to prevent new invasive species from disrupting European biodiversity’.⁶⁹

In line with one of the actions recommended by the strategy, the Invasive Alien Species (IAS) Regulation was adopted in 2014 to establish a dedicated legal framework to fight the introduction and spread of invasive alien species in the territory of the Union.⁷⁰ The Regulation, which is meant to support the achievement of the objectives of other EU biodiversity policies, including the Habitats, Birds, Water Framework and Marine Strategy Framework Directives,⁷¹ considers human health as an important aspect of its goal to ‘prevent, minimise and mitigate the adverse impact on biodiversity of the introduction and spread within the Union, both intentional and unintentional, of invasive alien species’.⁷² In particular, one of the recitals highlights that the threat posed by IAS takes different forms, affecting health both directly (e.g. by acting as disease vectors or causing allergies) and indirectly (through their impacts on native species and ecosystem structure and functioning, which can in turn have negative effects on the provision of all categories of ecosystem services).⁷³

Whilst targeting ‘every species, subspecies or lower taxon of animals, plants, fungi or microorganisms’,⁷⁴ the IAS Regulation only applies to live specimens introduced outside of their natural range either intentionally or unintentionally, excluding, *inter alia*, other categories that could in principle threaten human health but are regulated under other areas of EU law (e.g. genetically modified organisms, pests of plants or of plant products, microorganisms used in plant protection products, pathogens that

⁶⁷ European Environment Agency, ‘The Impacts of Invasive Alien Species in Europe (EEA 2012) 7.

⁶⁸ See for example European Commission, ‘Halting the Loss of Biodiversity by 2010 - and Beyond’ COM(2006)216; and European Commission, ‘Towards an EU Strategy on Invasive Species’ COM (2008)789 final.

⁶⁹ European Commission (n 25) 6-7.

⁷⁰ *ibid* 15.

⁷¹ IAS Regulation (n 15) 6th recital.

⁷² *ibid* art 1.

⁷³ *ibid* 3rd recital. See also Kettunen (n 19).

⁷⁴ *ibid* art 3.

cause animal disease) or not regulated at all (e.g. species changing their natural range due to changing ecological conditions).⁷⁵ Throughout its provisions, the Regulation mainly uses human health as an aggravating factor on top of IAS' impacts on biodiversity and ecosystem services. For example, the inclusion of non-native species in the so-called List of Invasive Species of Union Concern, which represents the core of the instrument and triggers a set of prevention, surveillance, rapid eradication, and management measures,⁷⁶ can only be undertaken by the Commission if, *inter alia*, these species 'are, based on available scientific evidence, likely to have a significant adverse impact on biodiversity or the related ecosystem services, and may also have an adverse impact on human health or the economy (emphasis added)'.⁷⁷

As also made clear in other parts of the IAS Regulation,⁷⁸ the presence of potentially negative impacts on human health is not therefore a sufficient condition for a species to be added to the List and for the related measures to become applicable. In general, according to the Regulation, it is sufficient that the species in question is likely to threaten biodiversity and ecosystem services, which may (or may not) include health-related benefits. It should be noted that this is not entirely surprising, considering that several non-native species that can pose a danger to humans, but not necessarily to biodiversity, may be covered under other pieces of EU legislation. In any event, the Commission Delegated Regulation 2018/968, which supplements the IAS Regulation for what concerns the risk assessment procedure that precedes the inclusion of a species in the List,⁷⁹ clarifies the types of adverse human health and safety impacts that Member States are required to consider when proposing a new listing to the Commission. The Delegated Regulation, in particular, refers to (i) illnesses, allergies or other affections to humans that may derive directly or indirectly from a species; and (ii) damages provoked directly or indirectly by a species with consequences for the safety of people, property or infrastructure.⁸⁰

One additional aspect of the IAS Regulation that is relevant in this context is its careful consideration of human health in the context of the adoption of measures of prevention, rapid eradication and/or invasive species management. First, article 8, in requiring Member States to establish a permit system to allow for derogations to the Regulation's obligations for purposes of research or ex-situ conservation, provides for the extension of such system to the production and medicinal use of products derived from IAS included

⁷⁵ *ibid* art 2.

⁷⁶ *ibid* arts 7-13, 14-16, 17-18 and 19-20.

⁷⁷ *ibid* art 4(3)(c).

⁷⁸ For example, *ibid* art 19(1) on management measures.

⁷⁹ *ibid* art 5.

⁸⁰ Commission Delegated Regulation (EU) 2018/968 of 30 April 2018 Supplementing Regulation (EU) No 1143/2014 of the European Parliament and of the Council with regard to risk assessments in relation to invasive alien species [2018] OJ L174/5, Annex.

in the List, when this is ‘unavoidable to advance human health’.⁸¹ Secondly, articles 17 and 18 aim to ensure that the methods used to apply eradication measures are not only effective, but also that they pay due regard for human health and the environment. From this perspective, a Member State is given the possibility, on the basis of *robust scientific evidence*, not to apply such measures ‘if the available eradication methods have serious adverse impacts on human health, the environment or other species’.⁸² Finally, the requirement to ‘have due regard to human health and the environment’ is also set forth in article 19 as it relates to management measures for IAS that are already widely spread in the territory of the EU. In this case, however, there is no clause allowing a Member State to refuse to take any measure on the grounds that available methods have serious impacts on human health, presumably because inaction in this situation would inevitably lead to a comparable, if not more serious, danger for public health.

Owing to the relatively recent adoption of the IAS Regulation, the CJEU has not yet been called upon to interpret its provisions. At the same time, due to the increasingly favorable conditions created by global environmental change for the establishment and spread of IAS,⁸³ researchers have started devoting considerable attention to the classification of eradication and management measures that comply with the requirements set in the Regulation, including with respect to the impacts of such measures on human health.⁸⁴

4. *The Precautionary Principle and the Linkage between Health and Biodiversity*

One of the most tangible ways in which EU environmental laws, including in the area of biodiversity, have impacted human health is arguably represented by the progressive expansion of the scope of application of the precautionary principle, and more specifically its transformation from a sectoral principle to what the General Court has defined a general principle of EU law.⁸⁵ It is beyond the aims of this section to give an

⁸¹ IAS Regulation (n 15) art 8(1). Notably, the same article, in paras 2 and 3, lays down a long list of strict conditions that must simultaneously be respected in order to allow for the issuance (and continued possession) of a permit.

⁸² *ibid* art 18(1)(c).

⁸³ See for example Millennium Ecosystem Assessment, *Ecosystems and Human Well-Being: Synthesis* (Island Press 2005) 14-5; and Hanno Seebens and others, ‘Global trade will accelerate plant invasions in emerging economies under climate change’ (2015) 21 *Global Change Biology* 4128.

⁸⁴ Doreen Schmiedel and others, ‘Evaluation System for Management Measures of Invasive Alien Species’ (2016) 25 *Biodiversity Conservation* 357.

⁸⁵ See for example Case T-74/00 *Artegodan v Commission* [2006] ECLI:EU:T:2006:286, para 183; and, more recently, Case T-817/14 *Zoofachhandel Züpke and Others v Commission* [2016] ECLI:EU:T:2016:157, para 51.

extensive account of the academic debate that continues to surround the content and implications of the precautionary principle, including the very possibility of considering it a general principle in the first place.⁸⁶ Nevertheless, it is important to note that, ever since its proclamation in article 174(2) of the EC Treaty⁸⁷ in the context of the Union's environmental policy, this principle has progressively been understood as also applying to the area of public health,⁸⁸ and more broadly to all situations in which there are indications of potential risks to human, animal and plant health but scientific uncertainty subsists about the actual existence and extent of such risks.⁸⁹

Inter alia, this expansion of the precautionary principle into the fields of health and consumer protection is supported by the health and environmental integration clauses in articles 9 and 11 TFEU, coupled with the objectives and requirements enshrined in articles 168(1), 169(1) and (2), and 191(1) and (2) TFEU.⁹⁰ Moreover, in practical terms, the prominence of the principle can also be justified by the growing interconnectedness and complexity of socio-ecological systems, a trend which in turn has led to an 'accumulation of risks' situated at the interface between global environmental change and human well-being.⁹¹ Over time, the pervasiveness of the principle and its influence on EU secondary legislation have therefore contributed to blurring the lines of what were previously considered as the traditional boundaries between different areas of EU law, enlarging the scope of the EU environmental competence as well as the role of the CJEU in its interpretation.⁹² As a result, it is now widely accepted that the precautionary principle may not only be used to review the legality of EU acts and to interpret EU laws through the preliminary reference procedure, but it may also be applied to the review of Member States' conduct whenever they are acting within the scope of EU law, for example by implementing a EU directive that recognises the principle or by seeking to restrict one of the four fundamental market freedoms on grounds of environmental, health or safety concerns.⁹³

⁸⁶ See for example Nicolas de Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law' (2006) 12(2) *European Law Journal* 139, 142-143; and Eloise Scotford, *Environmental Principles and the Evolution of Environmental Law* (OUP 2017) 61-62.

⁸⁷ Now article 191(2) of the TFEU.

⁸⁸ Scotford (n 86) 128-129.

⁸⁹ See European Commission, 'Communication on the Precautionary Principle' COM(2000)1 (2 February 2000) 8-9. See also Council of the European Union, 'Conclusions of the Presidency, European Council Meeting – Nice, 7-10 December 2000' <www.europarl.europa.eu/summits/nice2_en.htm> accessed 20 March 2019, Annex III.

⁹⁰ Case T-817/14 (n 85) para 51.

⁹¹ See Ulrich Beck, 'Global Risk Society', *The Wiley-Blackwell Encyclopedia of Globalization* (online edition, 2012) <<https://onlinelibrary.wiley.com/doi/abs/10.1002/9780470670590.wbeog242>> accessed 20 March 2019.

⁹² Scotford (n 86) 129.

⁹³ See de Sadeleer (n 86) 143-144; Scotford, *ibid*, 122-126 and 187-188; Paul Craig, *EU Adminis-*

Two considerations relating to the principle seem appropriate for the purposes of this chapter. First, as mentioned above, the transposition of the precautionary principle into the area of human health and safety originated not from EU biodiversity law itself, but rather from the broader corpus of environmental principles and rules that have been progressively enshrined in the EU Treaties and secondary law. At the same time, however, it is still possible to identify a distinct role played by EU legislation and case law relating to biodiversity in clarifying and advancing the principle in situations characterized by potential impacts on health. With respect to legal acts, the IAS Regulation has for example endorsed an inclusive approach to health and biodiversity in the assessment of the risks resulting from the introduction and spread of invasive alien species in the territory of the Union.⁹⁴ In addition, even though the relevant jurisprudence of the CJEU has been mostly concerned with discrete aspects of EU nature conservation legislation, such as the question of the relationship between the precautionary principle and the appropriate assessment under article 6(3) of the Habitats Directive,⁹⁵ there have been a few instances in which the Court has referred to the principle in the context of cases that presented wider health implications.⁹⁶

Moreover, and from an opposite standpoint, the above-mentioned spill-over of the precautionary principle into human health has not led to its uniform application and interpretation across the respective spheres of EU law. On the contrary, the ver-

trative Law (3rd edn, OUP 2012) ch 21; Joanne Scott, 'The Precautionary Principle Before the European Courts' in Richard Macrory (ed), *Principles of European Environmental Law* (Europa Law Publishing 2004) 54-55.

⁹⁴ According to this approach, not only are Member States required to consider the risk of adverse health and safety impacts when carrying out the risk assessment procedure under article 5 of the Regulation, as they are also given the possibility of using human health as an aggravating factor when adopting emergency measures on the basis of the precautionary principle, as emerging from a combined reading of articles 4(3)(c) and article 10(1).

⁹⁵ From this perspective, it is interesting to note that the CJEU has acknowledged the relevance of the principle for two different stages of the appropriate assessment procedure. In its essence, according to the Court in its *Waddenzee* decision, article 6(3) would not only require the precautionary principle to inform the authorization of a plan or project at the end of the assessment, but also the very decision of undertaking an assessment in the first place. See Case C-127/02 *Waddenvereniging and Vogelbeschermingsvereniging* [2004] ECR I-7405, paras 44 and 58. For further examples, see *Sweetman and others* (n 56) paras 44-8, *Commission v Poland* (n 57) paras 110-119; and Case C-2/10 *Azienda Agro-Zootecnica Franchini and Eolica di Altamura* [2011] ECR I-06561, paras 106-115.

⁹⁶ For example, the decision of the Court in *Commission v France* referred to the precautionary principle in the context of an action brought against that Member State's alleged failure to fulfil its obligations under Directive 91/271/EC on urban waste water treatment. In addressing the risk of eutrophication coming from discharges of urban waste water, the Directive was primarily aimed at protecting biodiversity, but the Court also emphasized the danger posed to health by the proliferation of phytoplankton species that had been found to produce toxins liable of accumulating in shellfish used for human consumption. More recently, in her opinion in *Craeynest and Others*, AG Kokott discussed the applicability of the strict standard of review used by the Court in the context of article 6(3) of the Habitats Directive to the assessment of legality of the siting of sampling points used to assess air quality under Directive 2008/50/EC. See Case C-280/02 *Commission v France* [2004] ECR I-08573, paras 34-36; and Case C-732/17 *Craeynest and Others* [2019] ECLI:EU:C:2019:168, Opinion of AG Kokott, paras 57-61.

sion of the precautionary principle endorsed in the areas of human health, food safety and consumer protection has largely taken on a life of its own, owing to the specific nature of the hazards to be considered, the different type of scientific evidence to be assessed, and the higher risk of legitimising restrictions to the free movement of goods.⁹⁷ On the one hand, this has resulted in a generally stricter approach taken by the Court when reviewing product bans and restrictions enacted on the basis of the precautionary principle, as compared to its interpretation of wider questions of environmental law and policy.⁹⁸ On the other, it has also led EU secondary legislation to establish more rigorous requirements for risk assessment in the field of health and safety, including with respect to issues that are likely to carry wide-ranging implications for the protection of biodiversity, such as pesticides or GMOs.⁹⁹

5. Conclusion

This chapter has discussed a few aspects of EU biodiversity law through the lens of their impacts on human health. Whilst the complex interaction between biodiversity and health objectives of the Union's policy on the environment might not have been immediately evident at the time of the adoption of key nature conservation instruments such as the Birds and Habitats Directives, the growing awareness about the contribution of biodiversity and ecosystems to human health and well-being has now placed greater responsibility on EU institutions to further integrate health-related aspects in their relevant internal policies. This attention is evident in the inclusive approach to biodiversity and health linkages in the provisions of the IAS regulation as well as in the incessant promotion of synergies in a number of Union's strategies, from the incorporation of green infrastructure in EU funding mechanisms¹⁰⁰ to the emphasis on so-called nature-based solutions in the EU Research and Innovation policy agenda.¹⁰¹

⁹⁷ Kenisha Garnett and David J Parsons, 'Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law' (2017) 37(3) *Risk Analysis* 502, 513.

⁹⁸ Garnett and Parsons, *ibid*, 511-513; de Sadeleer (n 86) 140, 172; and Craig (n 93) 655-656.

⁹⁹ Garnett and Parsons, *ibid*, 509-511; and de Sadeleer, *ibid*, 151, 172. A recent example can be found in Directive (EU) 2018/350, which amended Directive 2001/18/EC on the deliberate release into the environment of GMOs. The Directive, whose legal basis rests on article 114 of the TFEU relating to the internal market rather than on Title XX on environmental policy, was adopted with a view to strengthening the risk assessment of these organisms, particularly as it relates to their long-term environmental effects.

¹⁰⁰ Trinomics, 'Supporting the Implementation of Green Infrastructure' (Final Report for the European Commission, ENV.B.2/SER/2014/0012, European Union 2015) <http://ec.europa.eu/environment/nature/ecosystems/docs/green_infrastructures/GI%20Final%20Report.pdf> accessed 25 March 2019.

¹⁰¹ European Commission, 'Towards an EU Research and Innovation Policy Agenda for Nature-Based Solutions and Re-Naturing Cities' (Final Report of the Horizon 2020 Expert Group, European Union 2015).

At the same time, if one excludes some limited attempts by the Commission to mainstream socio-economic benefits in the management of the Natura 2000 network, the critical role of the Birds and Habitats Directives in protecting and supporting the health of EU citizens remains essentially a side-effect of these instruments' conservationist ethos. Provisions such as article 6(3) of the Habitats Directive leave little scope for competent authorities and courts to use potential impacts on human health as an additional argument for limiting harmful activities in Natura 2000 sites or at least striking a more proactive balance between conservation and sustainable use. By contrast, public health and safety are mainly framed in these Directives as a source of derogations, offering Member States a powerful justification for restricting the scope of their own obligations to establish the necessary conservation measures. This is not to say that the EU legal framework governing biodiversity is necessarily unfit for the purpose: as several studies demonstrate, the Natura 2000 network has indeed been able to mitigate the rate of loss of certain categories of ecosystems while protecting the multiple material and non-material benefits they provide.¹⁰² It is clear, however, that as the Birds and Habitats Directives continue to suffer from poor implementation and compliance¹⁰³ resulting in ongoing deterioration of biodiversity in the Union, a more effective integration of human health and well-being within their provisions (for example, through the concept of ecosystem services) could significantly strengthen these instruments' contribution to the overall achievement of the EU Biodiversity Strategy.

¹⁰²Text to n 49; see also Carlos Romão, 'The Added Value of the Habitats Directive. Is Biodiversity Better Protected Since the Directive Entered Into Force?' in Charles-Hubert Born and others (eds), *The Habitats Directive in its EU Environmental Law Context* (Routledge Research in EU Law Series, Routledge 2015).

¹⁰³Commission Staff Working Document (n 34) 5-8.

Chapter 20

Regulating Antimicrobials in Livestock Animals: Experiences from Ten Countries

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1. Introduction

The rapidly increasing rate of antimicrobial resistance (AMR) is an urgent and universal public health concern. AMR occurs when bacteria, viruses, parasites or fungi evolve to become resistant to the antimicrobial medicines that we have long depended upon to contain them. The more antimicrobials are used and abused, the faster microbes develop resistance to them, making antimicrobial medicines increasingly less effective over time. According to one estimate, 700,000 people already die each year from drug-resistant infections, a number that is projected to increase to 10 million annual deaths by 2050.¹ From a regulatory standpoint, AMR's intersectoral nature poses a particular challenge, as an integrated management approach is needed across human medicine, agricultural production and the environment. This integrated approach, commonly referred to as "One Health",² is essential to address the complexities at the heart of the problem.

AMR is a global issue because resistant-microbes have the capacity to easily cross borders, both between countries and between species. And yet while some countries have begun the process of taking action, many lag behind. Adding to the complexity, the adopted regulatory approaches vary greatly, as does their degree of success.

Policymakers are thus faced with an enormous task, one where they must take into account the diverse set of challenges and actors and attempt to coordinate regula-

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¹ Jim O'Neill, 'Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations' (*Review on Antimicrobial Resistance, UK Government* 2014) <https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf>.

² World Organisation for Animal Health, 'The "One Health" Concept: the OIE approach' (Bulletin, 2013) <http://www.oie.int/fileadmin/Home/eng/Publications_%26_Documentation/docs/pdf/bulletin/Bull_2013-1-ENG.pdf>.

tion across several different areas simultaneously. Furthermore, given the interconnected web of factors driving AMR, the implications of any regulatory change can be difficult to predict. For example, a highly successful regulation in a specific country can prove to be ineffective in another. Regulations must therefore be context-specific and adapted accordingly.

This chapter describes a research study that used an integrated and interdisciplinary lens to examine regulatory approaches adopted by ten countries to manage the use of antimicrobials in animal health, and more specifically, in farmed animals. The main aim is to highlight key interdependencies by examining regulations governing three main entry points of antimicrobials into the agricultural process: 1) veterinary medicine; 2) agricultural production; and 3) trade in animal products. Regulations on veterinary medicine determine the availability of antimicrobials to farmers through marketing and distribution requirements. Regulations on agricultural production of farmed animals address the permitted and prohibited uses of antimicrobials. And finally, regulations governing domestic and international trade in animal products for human consumption provide a better understanding of the broader considerations that are often decisive of public policy.

This is a first attempt at conceptualizing ways in which existing regulations can help address AMR. This is done in two ways. First, regulatory approaches are identified to analyse policies governing veterinary medicine, agricultural production, and trade. Second, emerging key interdependencies are discussed to highlight potential ways in which the effectiveness of regulations can be improved. Figure 1 provides a visual representation of this approach.

Overall, this analysis of existing policies illustrates key highlights of regulatory approaches from ten jurisdictions,³ in order of appearance: France, Denmark, Australia, Canada, United States, Japan, Russia, Brazil, China and India.

1.1. *France*

In France, veterinary drugs are subject to strict restrictions even before market entry. Their approval process takes a number of factors into account, namely quality, efficacy, and safety for all stakeholders involved: the user, the consumer, the environment, and the animal. Following market entry, a follow-up is conducted by the French Agency for Veterinary Medicinal Products to ensure continued approval.⁴ Product

³ Data collected were taken from primary and secondary sources, peer-reviewed scientific texts, grey literature, press releases, as well as interviews with experts and state representatives published in the news media. The ten countries represent a purposive sample and were chosen on the basis of their share of the world livestock import and export markets, their overall representativeness of the different possible regulatory approaches, and geographic diversity.

⁴ Hélène Chardon and Hubert Brugère, 'Usage des antibiotiques en élevage et filières viandes' (*Interbev*, 2014) <www.interbev.fr/fiche/usage-des-antibiotiques-en-elevage-et-filieres-viandes/>.

sales are also regulated: the procurement of drugs, either in a pharmacy or directly from a veterinarian, requires a prescription. A prescription is also required to procure animal feed containing antimicrobials.⁵

As a member of the European Union, France is subject to the 2006 general ban on the use of antimicrobial agents as growth promoters in farmed animals.⁶ Preventative use is still permitted, with the exception of certain critical antimicrobial substances, as decreed by French legislation introduced on 1 April 2016.⁷ In addition to this decree, France has implemented additional initiatives beyond those already implemented throughout the European Union. Notably, the country has developed the *Plan ÉcoAntibio*, which achieved its objective⁸ of reducing the use of antimicrobials in veterinary medicine by 25% in five years (2012–2017).⁹ A second version of *Plan ÉcoAntibio* is currently in effect.¹⁰ Despite its success, this regulatory framework has been criticized by professionals, in part due to its complexity. This criticism highlights the importance of engaging with professionals throughout the process and ensuring regular communication about the legislative steps being taken, for purposes of transparency and clarity.¹¹

In addition, France has made recommendations to raise awareness among veterinary professionals and to educate the wider public. Nevertheless, additional work is needed on monitoring strategies. Quantitative indicators of the level of exposure to antimicrobials must take into account the type of species and the production method at play. Such quantitative measures must also line up with other European frameworks in order to facilitate state-to-state comparison. An additional suggested regulatory method has been to push for the allocation of financial incentives to veterinarians, as is common practice in the field of human health.¹²

In the context of trade, import conditions for France have been established by the European Commission.¹³ Under Directive 96/23/EC (last amendment: Directive 2013/20/

⁵ *ibid.*

⁶ Dina Fine Maron, Tyler JS Smith and Keeve E Nachman, 'Restrictions on Antimicrobial Use in Food Animal Production: An International Regulatory and Economic Survey' (16 October 2013) 9:48 *Globalization and Health* <<http://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-9-48>>.

⁷ Ministère de l'agriculture français, 'Décret no 2016-317' (*Interbev* 2016) <www.interbev.fr/fiche/decret-du-16-mars-2016-relatif-a-la-prescription-et-a-la-delivrance-des-medicaments-utilises-en-medecine-veterinaire-contenant-une-ou-plusieurs-substances-antibiotiques-dimportance-critique/>.

⁸ Pascale Briand, Catherine Dupuy and Lionel Parle, 'Le plan Écoantibio 2012-2016' (April 2017) *La lettre du CGAAER* <<http://agriculture.gouv.fr/le-plan-ecoantibio-2012-2016>>.

⁹ Chardon and Brugère (n 4).

¹⁰ Briand, Dupuy and Parle (n 8).

¹¹ République française, Ministère de l'agriculture, de l'agroalimentaire et de la forêt 'Rapport n° 16041: le plan Écoantibio 2012-2016, Recommandations pour le plan suivant' (2016) 6 <www.lafranceagricole.fr/tr/Publie/FA/pi/Infographies/Web/2017-04-12/cgaer_16041_2017_rapport.pdf>.

¹² Briand, Dupuy and Parle (n 8).

¹³ Commission européenne, 'Conditions d'importation de la viande fraîche et des produits à la base de viande dans l'UE' (*European Commission Trade* 2012) <http://trade.ec.europa.eu/doclib/docs/2012/july/tradoc_149824.pdf>.

EU), the presence of certain substances is banned in meat and meat products.¹⁴

Recognizing AMR's complexity, France has adopted laws and regulations that act on multiple levels. For example, in 2014, the French National Assembly adopted the *Loi d'avenir pour l'agriculture, l'alimentation et le forêt* ("the Law for the Future of Agriculture, Food, and Forests"). The law was expected to "align the strong economic force of this sector with a shift towards environmental and social performance"¹⁵ and aims to build and sustain a better economic, environmental, and social performance for farms. As a second example, France also adopted the European Regulation N° 1760/2000¹⁶ and the Regulation for Implementation (EU) N°1337/2013¹⁷ to reassure consumers about the quality of their meat products. In effect since 1 September 2010 and 1 April 2015 respectively, these regulations make it mandatory to label all meat products sold in France with the country in which the animal was raised and slaughtered.¹⁸ In an effort to offer trade protections to French producers, reciprocity between the EU imposed measures on products of its member countries and the French measures imposed on imported products has been suggested.¹⁹ More recently, on 30 May 2018, a bill was introduced to help balance trade relations in the agricultural sector.²⁰

1.2. Denmark

The regulations pertaining to veterinary medicine in Denmark are similar to France, where a prescription from a veterinarian is required to purchase antimicrobials.²¹ But Denmark's approach demonstrates that this measure's effectiveness can be further

¹⁴ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC [1996] OJ L125/10.

¹⁵ République française, 'Adoption de la loi d'avenir pour l'agriculture' (*Les services de l'État en Savoie*, 22 July 2015) <www.savoie.gouv.fr/Politiques-publiques/Agriculture-foret-developpement-rural/Une-agriculture-en-mouvement/Adoption-de-la-loi-d-avenir-pour-l-agriculture>.

¹⁶ Direction générale de la concurrence, de la consommation et de la répression de fraudes, 'Traçabilité de la viande bovine' (*Le portail de l'Économie et des Finances*, January 1 2009) <www.economie.gouv.fr/dgccrf/Securite/Produits-alimentaires/Tracabilite-de-la-viande-bovine>.

¹⁷ Commission Implementing Regulation (EU) No 1337/2013 of 13 December 2013 laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry [2013] OJ L335/19.

¹⁸ Caroline Evrat Georgel, 'Étiquetage de l'origine des viandes : le règlement publié' (*Idele* 23 January 2014) <<http://idele.fr/presse/publication/idelesolr/recommends/etiquetage-de-lorigine-des-viandes-le-reglement-publie.html>>.

¹⁹ Briand, Dupuy and Parle (n 8).

²⁰ Ministère de l'agriculture et de l'alimentation, '#EGalim : l'Assemblée nationale vote le projet de loi en 1^{re} lecture' (30 May 2018) <<https://agriculture.gouv.fr/egalim-lassemblee-nationale-vote-le-projet-de-loi-en-1re-lecture>>.

²¹ Maron, Smith and Nachman (n 6).

enhanced by limiting veterinarians' profits. Since 1995, the country has instated a cap²² on profits that veterinarians can make through the sale of antimicrobials and veterinary drugs and can only provide these drugs directly to farmers when specific conditions are met.²³ This has greatly reduced the use of antimicrobials in the Danish system, where, for example, from 1994 to 1995, the use of tetracyclines dropped from 37 to 9 tons.²⁴

In 2009, Danish pig farmers voluntarily agreed to stop using a specific type of antimicrobial, the consumption of which dropped from 21.9kg in 2010 (just before the measure was adopted) to between 0.17 and 0.54kg in 2011.²⁵ In 2015, the rate of antimicrobial use in the pork industry had fallen approximately 4% from the previous year, despite a 3% increase in production and a 17% increase in exports.²⁶ Denmark thus demonstrates that voluntary measures – in the shadow of a robust regulatory regime – can lead to some measure of success. And yet, despite this general decline, the use of colistin, another antimicrobial, increased significantly between 2009 and 2015.²⁷

Denmark prohibits the regular use of antimicrobials for preventative means.²⁸ This distinguishes its regulatory framework from several other countries where preventative use is accepted for animal health purposes and is permitted. Although theoretically there should be a clear distinction between antimicrobial use for disease prevention as compared to growth promotion, in practice many farmers are known to use antimicrobials for growth promotion under the guise of disease prevention – which is why Denmark has banned both practices.

Denmark has been making considerable efforts to reduce AMR rates in agricultural production since the 1990s. But despite the country's efforts, it is impossible to prevent resistant microbes from entering the country through travel and trade. Data

²² *ibid.*

²³ Ministry of Environment & Food of Denmark, 'Distribution & Use of Veterinary Drugs in Denmark' (2015) <www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Veterinary_medicine/Pages/default.aspx>.

²⁴ Australian Commission on Safety and Quality in Health Care, 'Australian One Health Antimicrobial Resistance Colloquium Background Paper' (July 2013) 13-14 <www.safetyandquality.gov.au/wp-content/uploads/2013/07/Briefing-paper-for-One-Health-AMR-Colloquium-participants-Final-Jul-2013.pdf>.

²⁵ Yvonne Agersø and Frank M Aarestrup, 'Voluntary ban on cephalosporin use in Danish pig production has effectively reduced extended-spectrum cephalosporinase-producing *Escherichia coli* in slaughter pigs' (2012) 68 *Journal of Antimicrobial Chemotherapy* 569 <<https://academic.oup.com/jac/article-lookup/doi/10.1093/jac/dks427>>.

²⁶ Birgitte Borck Høg and others, 'DANMAP 2015 - Use of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Bacteria from Food Animals, Food and Humans in Denmark' (November 2016) 34 <http://orbit.dtu.dk/files/140535625/DANMAP_2016_LOW_241017.pdf>.

²⁷ *ibid.*

²⁸ Carol Coglian, Herman Goossens and Christina Greko, 'Restricting Antimicrobial Use in Food Animals: Lessons from Europe' (2011) 6 *Microbe* 274 <http://emerald.tufts.edu/med/apua/about_us/publications_19_846139138.pdf>.

demonstrate that resistance continues to rise for certain pathogens, due to imports and transport-related infections.²⁹

Denmark is also among the largest exporters of pork in the world, exporting more than 90% of its pork. More than 70% of its pork goes to the European market. However, it is important to note that the Danish market benefits from protective measures that are absent in other competing markets.³⁰ For example, the European Union imposes tariffs on products from non-member states, preventing others from competing in the European market despite their lower production costs.³¹ Other considerations such as food safety standards and the prohibition of ractopamine also limit access to the European market for many non-member states³². While these measures create trade barriers for some countries, they also protect the Danish market and ensure its competitiveness globally. Denmark thus maintains its leading position in global markets, despite implementing sustainable production methods that require substantial investment.

1.3. *Australia*

Australia does not produce antimicrobials,³³ and yet, the country's antimicrobial approval process is among the most conservative in the world.³⁴ The majority of veterinary antimicrobials appear in Appendix 4 of the *Poisons Standard*;³⁵ acquisition of such products thus necessitates a veterinarian prescription in almost all cases.³⁶ In addition, a variety of control measures ensure that veterinary drugs are used in accordance to the Australian government's regulations. For example, labelling restricts the use of antimicrobial agents in certain circumstances.

Nevertheless, the country still faces challenges when it comes to the off-label use of antimicrobials. These challenges stem from Australia's division of legislative power

²⁹ Steven J. Hoffman and Trygve Ottersen, 'Addressing Antibiotic Resistance Requires Robust International Accountability Mechanisms' (2015) 43 *Journal of Law, Medicine & Ethics* 38 <www.ncbi.nlm.nih.gov/pubmed/26243244>.

³⁰ Danish Agriculture & Food Council, 'Danish Pig Meat Industry' (22 August 2018), <<http://agricultureandfood.dk/danish-agriculture-and-food/danish-pig-meat-industry>>

³¹ British Meat Processors Association, 'Pig Meat' <<http://britishmeatindustry.org/industry/imports-exports/pigmeat/>>.

³² *ibid.*

³³ Timothy M Dyke, 'Regulation of Veterinary Antibiotics in Australia' (2003) 27 *Communicable Diseases Intelligence* <www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-2003-cdi27suppl-htm-cdi27supc.htm>.

³⁴ Australian One Health Antimicrobial Resistance Colloquium Background Paper (n 24) 9.

³⁵ *ibid.*

³⁶ Hellen Gelband and others, 'State of the World's Antibiotics' (2015) CDDEP Global Antibiotic Resistance Partnership <https://cddep.org/wp-content/uploads/2017/06/swa_edits_9.16.pdf>.

between the federal government and the states and territories, which makes it difficult for the country to seamlessly adopt regulations, particularly because the use of antimicrobials falls under the jurisdiction of the states and territories.³⁷ Harmonization efforts with regards to AMR began in 2013 and are ongoing.³⁸

Australia lacks overall regulations regarding the use of growth promoters in agricultural production.³⁹ Only a few specific antimicrobials are prohibited for growth promotion (eg fluoroquinolones).⁴⁰

For the purposes of trade, Australian producers wishing to export their products to the European market – which prohibits growth promoters – must be certified by Australia's European Union Cattle Accreditation Scheme.⁴¹ This Australian accreditation process guarantees the traceability of animal products in the country and ensures that European standards are upheld so that these products can be sold to European markets.⁴²

Australia boasts surveillance and monitoring programs for production and for veterinary practices and, yet, only data on the sale of antimicrobials is collected, as opposed to other indicators that capture usage more specifically.⁴³ Although Australian AMR rates are some of the lowest globally, a report published in 2014 notes that the country could certainly benefit from improving its monitoring systems, particularly to ensure the quality of Australian products for both domestic and foreign markets.⁴⁴

1.4. *Canada*

For the past few years, the Canadian federal government has been working with the pharmaceutical industry to amend regulations that govern the use of antimicrobial agents in animals. For example, labelling of medicated feeds, particularly for “antimicrobials that are critically important for human medicine”, should no longer display

³⁷ Australian One Health Antimicrobial Resistance Colloquium Background Paper (n 24) 9.

³⁸ *ibid.*

³⁹ Maron, Smith and Nachman (n 6).

⁴⁰ Gelband and others (n 36).

⁴¹ Queensland Government, ‘Overseas markets and the National HGP Control System’ (28 June 2016) <www.business.qld.gov.au/industries/farms-fishing-forestry/agriculture/livestock/cattle/hormonal-growth-promotants/overseas-market>.

⁴² Australian Government, ‘European Union Cattle Accreditation Scheme EUCAS’ (3 January 2018) <www.agriculture.gov.au/export/controlled-goods/meat/elmer-3/eucas>.

⁴³ Australian One Health Antimicrobial Resistance Colloquium Background Paper (n 24) 9.

⁴⁴ Ramon Z Shaban and others, ‘Surveillance and Reporting of Antimicrobial Resistance and Antibiotic Usage in Animals and Agriculture in Australia’ (27 October 2014) 152 <https://research-repository.griffith.edu.au/bitstream/handle/10072/65151/98828_1.pdf?sequence=1>.

claims of growth promotion.⁴⁵ However, the simple act of ceasing to sell these drugs as growth promoters is unlikely to make a significant difference, particularly if the same antimicrobial agent is sold for an alternative purpose, ie, illness prevention.⁴⁶

New federal regulations require purchasers to present a prescription from a veterinarian to procure medicated feed. But given the Canadian system of federalism, requirements for veterinarians vary from province to province.⁴⁷

In 2014, approximately 82% of antimicrobial agents of critical importance to human medicine were administered to animals in Canada.⁴⁸ Canada does not prohibit the use of growth promoters and allows administration of antimicrobial agents in the food and water of farm animals.^{49, 50}

Given the importance of trade and foreign markets, the country has nevertheless adopted voluntary measures with regards to livestock, where certain substances are banned during production. In 2013, producers in the province of Alberta agreed to discontinue the use of ractopamine (a growth promoter banned in 160 countries) in pork production. Since Canada boasts higher rates of meat exports than imports, this ban led to the decisive adoption of voluntary measures.⁵¹ That same year, the Canadian government launched a Ractopamine-Free Pork Certification Program, which oversees various stages of the certification and marketing process.⁵²

1.5. *United States of America*

The US Food and Drug Administration (FDA) performs mandatory checks before a drug is approved for marketing.⁵³ The FDA has issued guidance on the labelling of veterinary products. One guidance document calls for modifying existing labels in

⁴⁵ Health Canada, 'Health Canada proposes new measures to address antimicrobial resistance' (*Canada Newswire* 17 April 2015) <<http://news.gc.ca/web/article-en.do?nid=965249>>.

⁴⁶ Kelly Crowe, 'Health Canada's quiet move to end use of antibiotics to fatten up animals' (9 July 2014) *CBC News* <www.cbc.ca/news/health/health-canada-s-quiet-move-to-end-use-of-antibiotics-to-fatten-up-animals-1.2700972>.

⁴⁷ Maron, Smith and Nachman (n 6).

⁴⁸ Government of Canada, 'Système canadien de surveillance de la résistance aux antimicrobiens – Rapport de 2016' (September 2016) <www.canada.ca/content/dam/phac-aspc/documents/services/publications/drugs-health-products/antibiotic-resistance-antibiotique/antibiotic-resistance-antibiotique-2016-fra.pdf>.

⁴⁹ Maron, Smith and Nachman (n 6).

⁵⁰ *ibid.*

⁵¹ Alberta Pork, 'Canadian Ractopamine-Free Pork Certification Program' <www.albertapork.com/Programs/CanadianRactopamine-FreeCertificationProgram.aspx>.

⁵² Association de nutrition animale du Canada, 'Lancement du Programme canadien de certification des porcs exempts de ractopamine' (5 June 2013) <www.anacan.org/fr/actualit-s-et-v-nements/actualit-s/lancement-du-programme-canadien-de-certification-des-porcs>.

⁵³ Animal Health Institute, 'Animal Antibiotics' <www.ahi.org/issues-advocacy/animal-antibiotics/>.

order to remove language suggesting the drugs will promote growth or have productivity benefits. This aligns with the growing opinion globally that the use of growth promoters should be discouraged. Yet elsewhere, the FDA refers to the preventative benefits of these drugs,⁵⁴ avoiding the term “growth promoter”, but speaking largely positively to the use of antimicrobials during production.

The most important FDA guidance is a recommendation on veterinary supervision, with the Veterinary Feed Directive⁵⁵ guiding the measure. This voluntary measure requests the authorization of a veterinarian prior to using antimicrobials critically important for human use in animal feed.⁵⁶ Although animal feed permeated with these antimicrobials is discouraged from being sold over the counter, general use of antimicrobials is still permitted.

According to the Veterinary Feed Directive, antimicrobial agents should not be used in agricultural production if they are important to human medicine.⁵⁷ Under the FDA’s Guidance Document 152, a number of antimicrobials such as penicillins, tetracyclines, macrolides, and streptogramins are considered to be important to human use; their labelling is therefore not supposed to point to growth promotion benefits.⁵⁸ The Veterinary Feed Directive has been criticized for its voluntary approach as well as the absence of compliance mechanisms and parameters to measure success.⁵⁹

In terms of trade, the requirements for exports are more rigorous than imports. This distinction can be partially explained by the different regulatory regimes in the US and its trade partners. Nevertheless, the US has still managed to negotiate special trade agreements with countries that would otherwise prohibit their products. For example, following the 2006 European ban on growth promoters, the United States lost a large portion of the market. In 2009, the United States and the European Union signed a memorandum of understanding that would allow “high quality” American beef to be imported into Europe under tariff quotas exempt from custom duties. This agreement expired on August 2, 2015.⁶⁰ An annual quota limiting the amount of “high quality” meat products that can be exported into the European Union is

⁵⁴ *ibid.*

⁵⁵ Animal Health Institute, ‘FDA Guidance 209, 213 and VFD Educational Material’ <www.ahi.org/issues-advocacy/animal-antibiotics/fda-guidance-209-educational-material/>.

⁵⁶ US Department of Health & Human Services, ‘Veterinary Feed Directive for Animal Producers’ (22 December 2016) <www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemAFSS/ucm534246.htm>.

⁵⁷ *ibid.*

⁵⁸ Food and Drug Administration, ‘Guidance for Industry #213’ (December 2013) <www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>.

⁵⁹ Federal Register, Veterinary Feed Directive, Comment 43 (June 3 2015) <www.federalregister.gov/documents/2015/06/03/2015-13393/veterinary-feed-directive>.

⁶⁰ Carol Guthrie, ‘U.S. Trade Representative Froman, Secretary of Agriculture Vilsack Announce Continued EU Market Access for American Producers of High-Quality Beef’ (1 August 2013) <www.usda.gov/wps/portal/usda/usdahome?contentid=2013/08/0152.xml&contentidonly=true>.

now in place, where eligible countries, such as the United States and Australia, compete to maximize their share within the total quota.⁶¹

1.6. *Russia*

Over the past several years, Russia has amended its legislative framework for monitoring, approval, registration, and distribution of veterinary drugs.⁶² For example, Act 241-FZ, which regulates the distribution of medical products, was modified in 2015 to include an additional clause on the registration of veterinary drugs.⁶³ While these changes provide clearer guidelines on certain administrative aspects such as product registration, there has been no attempt made for stricter non-administrative enforcement. For instance, no veterinary prescription is required to procure antimicrobials for farmed animals.⁶⁴

The sharp rise in Russia's use of antimicrobials in agriculture is closely associated with the country's main objective of improving production performance.^{65, 66} Antimicrobials for the purpose of growth promotion can be used in unlimited quantity in Russia, as long as residues are not discovered in the final product.⁶⁷ Producers therefore tend to rely on antimicrobials in-feed as a precautionary measure against infection rather than attempt to improve sanitation and environmental conditions.⁶⁸ Russia's trading partners have criticized the country on its minimal sanitary regulations.⁶⁹

⁶¹United States Department of Agriculture, 'Foreign Agricultural Service' (2011) <https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Comparison%20of%20EU%20Tariff%20Rate%20Quotas%20for%20High%20Quality%20Bovine%20Meat_Brussels%20USEU_EU-28_5-31-2018.pdf>.

⁶²Alexander Panin, 'Implementation of the Russian Pharmacovigilance regulation', State Veterinary and Phytosanitary Surveillance Agency of the Russian Federation <www.google.ca/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwjFk-m48rPMAhUlnMKHb14AgQQFggyMAI&url=http%3A%2F%2Fvichsec.org%2Foutreach-forum%2Findex.php%3Foption%3Dcom_attachments%26view%3Dattachments%26task%3Dattachment%26id%3D941&usg=AFQjCNHBP1hpC03cXuHjJmPTyLUo4-oUg>.

⁶³Vsevolod Tyupa, 'Russian Law on Circulation of Medicines – Significant amendments to come into force on 1 July 2015' (15 December 2014) <www.lexology.com/library/detail.aspx?g=710ebbe9-cca5-40eb-ba8b-e429d53b6c8f>.

⁶⁴Hilde Kruse, 'Consumption of antimicrobials in food animals outside EU/EEA' (5 February 2014) <www.ema.europa.eu/docs/en_GB/document_library/Presentation/2014/03/WC500162571.pdf>.

⁶⁵Claas Kirchelle, 'Pharming Animals: A Global History of Antibiotics in Food Production (1935–2017)' (2018) *Palgrave Communications* 4 <www.nature.com/articles/s41599-018-0152-2>.

⁶⁶Vladislav Voronnikov, 'In-feed Antibiotics Still Used in Russian Poultry' (5 December 2016) *Poultry World* <www.poultryworld.net/Health/Articles/2016/12/In-feed-antibiotics-still-used-in-Russian-poultry-66471E/>.

⁶⁷ *ibid.*

⁶⁸ *ibid.*

⁶⁹FAO, 'Russian Federation: Meat Sector Review' (2014) <www.fao.org/3/a-i3533e.pdf>.

Nevertheless, some signs point to progress and awareness: Russia contributed \$3.3 million towards FAO-led work on food safety and AMR.⁷⁰ Russia is an excellent illustration of the significant effect that political dynamics can have on trade and global markets. In 2014, Russia prohibited the import of European pork, citing concerns about the African swine fever. Later that same year, Russia imposed an embargo on a number of pork and beef products from Australia, Canada, the United States, and the European Union. This was in response to the economic sanctions that the country faced due to its dispute with Ukraine. More recently, in 2017, Russia increased the scope of the embargo, banning additional animal products.⁷¹ Since the introduction of these bans, the European Union has redirected its substantial pork exports to Asian markets. Brazil has benefitted from this particular dynamic, replacing the European Union as the largest importer of pork to Russia.⁷²

The European Union lodged a complaint to the World Trade Organization (WTO) alleging that the first 2014 Russian ban did not comply with the Agreement on the Application of Sanitary and Phytosanitary Measures. The WTO concluded that Russia's ban was indeed non-compliant; Russia has since accepted WTO's recommendations.⁷³ Although the ban has now been lifted, subsequent embargoes have limited Russia-EU trade in animal products.⁷⁴

More specifically, the Russian agricultural market has been affected by these political tensions. In March 2016, Russia's Federal Service for Veterinary and Phytosanitary Surveillance (*Rosselkhoz nadzor*) announced that the Meat Council of the Eurasian Economic Union (EEU) predicted a wave of bankruptcies in the poultry and red meat processing sector.⁷⁵ Some argue that positive trends in the Russian industry are still possible if important producers and sellers of animal products voluntarily create policies requiring the prudent use of antimicrobials.⁷⁶

⁷⁰ FAO, 'Russia Backs FAO Work to Tackle Antimicrobial Resistance with \$3.3 Million' (3 April 2017) <www.fao.org/news/story/en/item/878313/icode/>.

⁷¹ National Hog Farmer, 'Russia Expands Import Embargo: What Does It Mean for Pork Trade?' (6 November 2017) <www.nationalhogfarmer.com/marketing/russia-expands-import-embargo-what-does-it-mean-pork-trade>.

⁷² *ibid.*

⁷³ OMC, 'Fédération de Russie — Mesures visant l'importation de porcs vivants, de viande de porc et d'autres produits du porc en provenance de l'Union européenne' (21 March 2017) <www.wto.org/french/tratop_f/dispu_f/cases_f/ds475_f.htm>.

⁷⁴ National Hog Farmer, 'Russia expands import embargo: What does it mean for pork trade?' (06 November 2017) <www.nationalhogfarmer.com/marketing/russia-expands-import-embargo-what-does-it-mean-pork-trade>.

⁷⁵ Rosselkhoz nadzor, 'Russian Meat Industry Braced for Bankruptcy' (11 March 2016) <www.fsvps.ru/fsvps/press/305870.html?_language=en>.

⁷⁶ Vorothnikov (n 66).

1.7. Japan

In Japan, a veterinary prescription is required to acquire antimicrobials for farmed animals.⁷⁷ Antimicrobials can however still be used for off-label purposes with a veterinarian's approval.⁷⁸ Overall, the approval process for antimicrobials is rigorous; strict requirements also apply for product labelling.

In the context of agricultural production, the use of antimicrobials for growth promotion is permitted.⁷⁹ Specific antimicrobials that appear on an exhaustive list can also be used as food additives.⁸⁰

Trade regulation is particularly important in Japan, as more than 60% of the food that the country consumes arrives from foreign markets.⁸¹ In addition, Japan's distribution of roles is unique, in that Japanese importers, rather than the government, are responsible for ensuring that banned veterinary drugs have not been used in the production process of products entering the country and that Japanese legislative restrictions for residues and food additives are respected.⁸² Food safety controls are particularly stringent.⁸³

1.8. Brazil

Antimicrobials comprise approximately 40% of the drugs consumed⁸⁴ within a thriving Brazilian pharmaceutical industry.⁸⁵ Similar to several other countries, a prescription from a veterinarian is required to purchase antimicrobials.⁸⁶ However, different

⁷⁷ Maron, Smith and Nachman (n 6).

⁷⁸ Angelo A Valois and others, 'Geographical Differences in Market Availability, Regulation and Use of Veterinary Antimicrobial Products' in Luca Guardabassi, Lars Bogø Jensen and Hilde Kruse (eds), *Guide to Antimicrobial Use in Animals* (Blackwell Publishing 2008) 59, 73.

⁷⁹ Maron, Smith and Nachman (n 6).

⁸⁰ Kristi O Smedley, 'Comparison of Regulatory Management of Authorized Ingredients, Approval Processes, and Risk-Assessment Procedures for Feed Ingredients' (July 2013) <www.ifif.org/uploadImage/2013/7/19/272ee931adc6dacaadd762c71f8110a31374224070.pdf>.

⁸¹ Edward I Broughton and Damian G Walker, 'Policies and Practices for Aquaculture Food Safety in China' (2010) 35 *Food Policy* 471.

⁸² *ibid.*

⁸³ *ibid.*

⁸⁴ Yared Santa-Ana-Tellez, 'Impact of Over-the-Counter Restrictions on Antibiotic Consumption in Brazil and Mexico' (2013) *PLOS one* <<http://journals.plos.org/plosone/article/asset?id=10.1371%2Fjournal.pone.0075550.PDF>>.

⁸⁵ IMS Health, 'Pharmerging Markets. Picking a pathway to success' (2013) <www.imshealth.com/files/web/Global/Services/Services%20TL/IMS_Pharmerging_WP.pdf>.

⁸⁶ Global Legal Monitor, 'Brazil: Antibiotics to Be Sold with Prescription Only' (5 November 2010) Library of Congress <www.loc.gov/law/foreign-news/article/brazil-antibiotics-to-be-sold-with-prescription-only/>.

regulations apply to farmed animals and domestic animals.⁸⁷

The use of antimicrobials for therapeutic and preventative purposes as well as for growth promotion is permitted.⁸⁸ In addition, medicated food containing antimicrobials is expected to continue to rise, contributing to Brazil's significant market for food additives.⁸⁹

International harmonization is a significant priority for Brazil due to the country's export-heavy market. Since 1998, Brazil has been using a hazard analysis and critical control point system (HACCP). HACCP establishes protocols that the country must comply with in order to export its meat products to its trading partners.⁹⁰ For example, meatpacking plants monitor the use of antimicrobials for beef exports aimed at the European market.⁹¹ However, a recent scandal illustrates that this type of measure is not always foolproof. In 2017, some of the country's leading meat producers were subject to corruption allegations that pointed to companies having bribed inspectors to certify rotten meat.⁹² This immediately led to consequences in trade. For instance, China stopped importing Brazilian meat, and the European Union also imposed a partial ban on Brazilian meat products.⁹³

Brazil is also a member country of Mercosur, an economic and political alliance comprised of several Latin American countries. In 2000, Mercosur adopted legislation establishing limits on daily doses of antimicrobials that can be administered to animals, as well as residues of veterinary drugs that can be found in meat products⁹⁴. One of the objectives of this legislation was to harmonize antimicrobial-related regulations in order to eliminate the challenges that stem from differing country-specific approaches⁹⁵.

⁸⁷ Maron, Smith and Nachman (n 6).

⁸⁸ Ministério da Agricultura, Pecuária e Abastecimento, 'Produtos Veterinários' (2014) <www.agricultura.gov.br/animal/produtos-veterinarios>.

⁸⁹ PRNewswire, 'Brazil Animal Feed Additives Market is Expected to Reach USD 1,941.6 Million in 2018: Transparency Market Research' (1 October 2012) PR Newswire <www.prnewswire.com/news-releases/brazil-animal-feed-additives-market-is-expected-to-reach-usd-19416-million-in-2018-transparency-market-research-172059941.html>.

⁹⁰ Patrick Bruha, 'HACCP in Brazil' (20 November 2014) The Brazil Business <<http://thebrazilbusiness.com/article/haccp-in-brazil>>.

⁹¹ Danillo Domingues Millen and others, 'Current Outlook and Future Perspectives of Beef Production in Brazil' (2011) 1 *Animal Frontiers* 46 <www.animalsciencepublications.org/publications/af/abstracts/1/2/anfront_1_2_008>.

⁹² Aljazeera, 'Brazil's rotten meat scandal prompts major import bans' (20 March 2017) <www.aljazeera.com/news/2017/03/brazil-rotten-meat-scandal-prompts-major-import-bans-170320185259468.html>.

⁹³ *ibid.*

⁹⁴ Néstor Falcón and others, 'El problema de la resistencia a antibióticos en salud pública' (2009) 1 *Una Salud. Revista Sapuvet de Salud Pública* 75 <<http://revistas.lasalle.edu.co/index.php/us/article/viewFile/235/176>>.

⁹⁵ *Reglamento Técnico Mercosur Metodologías Analíticas, Ingesta Diaria Admisible y Límites Máximos de Residuos Para Medicamentos Veterinarios en Alimentos de Origen Animal* <http://www.inmetro.gov.br/barreirastecnicas/PDF/GMC_RES_2000-054.pdf>.

1.9. *China*

At this time, a prescription from a veterinarian is not needed to obtain antimicrobials,⁹⁶ but this is likely to change. On 26 August 2016, the Chinese government published its AMR national action plan, where objectives for 2020 include improving monitoring and adopting prescription requirements.⁹⁷ China is also undergoing other regulatory reforms to address broader concerns, including food safety.⁹⁸

Antimicrobials are permitted to be used in agricultural production as growth factors as well as for preventative and therapeutic purposes; the country has not adopted specific usage regulations in farmed animals.⁹⁹ Nevertheless, some exceptions do exist; for example, nitroimidazoles have been banned since 2002.¹⁰⁰ The use of antimicrobial agents as food additives is also regulated.¹⁰¹

In terms of trade, the administrative system that regulates Chinese imports is very complex.¹⁰² Regulations on food products vary depending on their intended markets; exports must comply with stricter food safety regulations than Chinese products intended for the domestic market.¹⁰³

1.10. *India*

In India, the procurement of antimicrobials does not require a veterinary prescription,¹⁰⁴ except for those listed in the second amendment of the Drugs and Cosmetics Rules of 2006.¹⁰⁵ However, policies regulating veterinarians have practical limita-

⁹⁶ Maron, Smith and Nachman (n 6).

⁹⁷ Kathleen McLaughlin, 'China tackles antimicrobial resistance' (31 août 2016) <www.sciencemag.org/news/2016/08/china-tackles-antimicrobial-resistance>.

⁹⁸ Broughton and Walker (n 81) 477.

⁹⁹ Maron, Smith and Nachman (n 6).

¹⁰⁰ USDA Foreign Agriculture Service 'China – People's Republic of: List of Veterinary Drugs Banned for Use for Food Animals' (2011) 4 <http://gain.fas.usda.gov/Recent%20GAIN%20Publications/List%20of%20Veterinary%20Drugs%20Banned%20for%20Use%20for%20Food%20Animals_Beijing_China%20-%20Peoples%20Republic%20of_3-11-2011.pdf>.

¹⁰¹ Switzerland Global Enterprise, 'China: Export Feed and Feed Additives into China' (2015) <www.s-ge.com/de/filefield-private/files/215269/field_blog_public_files/80271>.

¹⁰² John Balzano, 'Lingering Food Safety Regulatory Issues for China in 2016' (10 January 2016), Forbes <www.forbes.com/sites/johnbalzano/2016/01/10/lingering-food-safety-regulatory-issues-for-china-in-2016/#195accd35f5a>.

¹⁰³ Broughton and Walker (n 81) 476.

¹⁰⁴ United States Department of Agriculture, 'Livestock and Poultry: World Markets and Trade' (April 2016) <https://timedotcom.files.wordpress.com/2015/04/livestock_poultry.pdf>.

¹⁰⁵ Centre for Science and Environment, 'Regulatory Landscape in India' (2014) 2 <www.cseindia.org/userfiles/factsheets/factsheet%204.pdf>.

tions due to critical infrastructure gaps, namely India's lack of veterinarians.¹⁰⁶ It is therefore unlikely that this method will achieve the same level of success in restricting access that other countries requiring veterinary prescriptions have had.

In the agricultural sector, state-level governments in India regulate the use of antimicrobials,¹⁰⁷ which are used for therapeutic purposes, to prevent illnesses, and to promote the growth of farmed animals. Often, large quantities are added to livestock feed.¹⁰⁸ This is particularly concerning due to the high rates of bacterial diseases¹⁰⁹ and AMR¹¹⁰ present in the country. Still, regulatory measures need to acknowledge the essential role that antimicrobials serve in limiting morbidity and mortality rates in India.¹¹¹

In 2007, the Bureau of Indian Standards (BIS) recommended that the systemic use of antimicrobials in poultry feed be stopped, but this was presented as a voluntary measure and not officially enforced.¹¹² Similarly, in 2014, the Drug Controller General of India issued a directive to state governments to encourage veterinarians to prescribe antimicrobials appropriately and to discontinue the use of growth promoters and antimicrobials in livestock feed.¹¹³ Again, no strict enforcement mechanisms exist to monitor implementation,¹¹⁴ particularly because implementation for such measures in India needs to occur at the state-level.¹¹⁵ Even so, in April 2017, India's federal government finalized its AMR national action plan¹¹⁶ and issued a press release in which it recognized the importance of coordinating efforts between different stakeholders.¹¹⁷

¹⁰⁶ *ibid.*

¹⁰⁷ Thomas P Van Boeckel, 'Global Trends in Antimicrobial Use in Food Animals' (2015) 112:18 *Proceedings of the National Academy of Sciences* 5649, 5652.

¹⁰⁸ Molly Miller-Petrie, 'India's strides against AMR: local solutions, global implications' (27 April 2017) *The Center for Disease Dynamics, Economics & Policy* <www.cddep.org/blog/posts/india%E2%80%99s_strides_against_amr_local_solutions_global_implications#sthash.Y90idbTs.dpbs>.

¹⁰⁹ Ramanan Laxminarayan and Ranjit Roy Chaudhury, 'Antibiotic Resistance in India: Drivers and Opportunities for Action' (2016) 13 *PLoS Med* <<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001974>>.

¹¹⁰ CDDEP, 'Antibiotic Resistance', <<http://resistancemap.cddep.org/resmap/resistance>>.

¹¹¹ Laxminarayan and Chaudhury (n 109).

¹¹² Centre for Science and Environment, 'Regulatory Landscape in India' (2014) 1 <www.cseindia.org/userfiles/factsheets/factsheet%204.pdf>.

¹¹³ Government of India, 'Antimicrobial resistance is a serious threat to global public health that requires action across all government sectors' (19 April 2017) *Press Information Bureau* <<http://pib.nic.in/newsite/PrintRelease.aspx?relid=161160>>.

¹¹⁴ *Regulatory Landscape in India* (n 112) 2.

¹¹⁵ Menaka Rao, 'India has a massive antibiotic resistance problem, and it's up to the states to solve it' (27 September 2016) <<https://scroll.in/pulse/817377/india-has-a-massive-antibiotic-resistance-problem-and-its-up-to-the-states-to-solve-it>>.

¹¹⁶ *Regulatory Landscape in India* (n 112).

¹¹⁷ Rao (n 115).

2. Discussion

The use of antimicrobial agents is part of a complex regulatory framework in which activities of various stakeholders are governed. As of now, the largest importers and exporters have not coordinated their approaches to veterinary medicine, agricultural production, and trade.

This study of regulatory approaches across 10 jurisdictions makes it possible to identify a number of key interdependencies; these may be helpful in identifying the main barriers to regulation, incentives that are decisive for policymakers and industries, and measures that can improve the effectiveness of existing regulatory mechanisms.

2.1. Veterinary Medicine

Current veterinary medicine regulations confront AMR at its source by targeting product access, either through marketing measures (eg, labelling requirements) or limitations on purchases (eg, veterinary prescription requirements). However, success with this form of regulation is largely dependent on the availability of veterinarians. A country facing a shortage of veterinarians would need to first address this infrastructure gap before it could fully benefit from veterinary regulations that have proved successful elsewhere.

2.1.1. Regulating Sales

Regulatory changes in this sphere indicate that the task of confronting AMR is increasingly becoming the responsibility of veterinarians as opposed to farmers alone.¹¹⁸ This raises concerns about the appropriate management of antimicrobials due to the profession's connections to the pharmaceutical industry and the perceived conflict of interest that arises from their ability to make money based on the quantity of drugs they prescribe, sell and distribute.¹¹⁹ Nevertheless, any disadvantages that surface from this transfer of responsibility from farmers to veterinarians may be mitigated through the adoption of transparency measures. The availability of alternative options to antimicrobials may also address the profession's concerns by reducing antimicrobial consumption without compromising the health of animals.¹²⁰ It is here

¹¹⁸ Government of India, Ministry of Agriculture, 'Notification' (2001), Gazette of India Extraordinary, Part II sc3(ii) <<http://dahd.nic.in/sites/default/files/livestockimport.doc013.doc>>.

¹¹⁹ Regulatory Landscape in India (n 112).

¹²⁰ Jim Fairles, 'The Veterinarian's Role in Antimicrobial Stewardship' (2013) 54:3 Canadian Veterinary Journal 207 <www.ncbi.nlm.nih.gov/pmc/articles/PMC3573624/>.

that veterinary medicine faces a significant challenge, that of balancing the health of animals while preserving the efficacy of antimicrobials and their own livelihoods.¹²¹

2.1.2. Capping Veterinarians' Profits

Danish regulations suggest that solely requiring a veterinarian prescription does not necessarily lower antimicrobial consumption significantly. A combination of this measure alongside a cap for veterinary profits is perhaps a more effective option. Otherwise, the potential for profit can create an incentive that may undermine the effectiveness of the regulatory system.

2.1.3. Creating Financial Incentives for Judicious Use

Studies have demonstrated that there is a link between a drug's cost and its prescription frequency; this can also apply in veterinary medicine.¹²² An increase in antimicrobial prices would encourage farmers to consider alternatives.¹²³ However, additional research is needed to further understand the motivations of veterinarians and farmers in their choice to prescribe and use antimicrobials respectively.¹²⁴

2.1.4. Establishing Rigorous Monitoring Systems

Monitoring is essential¹²⁵ to guide policy changes and identify interventions,¹²⁶ but a comprehensive collection of data is necessary for an effective analysis. For example, Australia and the United States only collect information on the volume of antimicrobial drug sales; key information, such as the administrator of the drugs and the type

¹²¹ Jean Gauvin, 'The CVMA and Prudent Use of Antimicrobials' (2014) 55:9 Canadian Veterinary Journal 809 <www.ncbi.nlm.nih.gov/pmc/articles/PMC4137919/>.

¹²² College of Veterinarians of Ontario, 'Use of Antibiotics in Food-Producing Animals: Facilitated Discussions with Ontario Veterinarians Involved with Food-Producing Animal Practice' (2015) <<https://cvo.org/CVO/media/College-of-Veterinarians-of-Ontario/Resources%20and%20Publications/Reports/GF2DiscussionSummary.pdf>>.

¹²³ Jean Gauvin, 'The CVMA and Prudent Use of Antimicrobials' (2014) 55:9 Canadian Veterinary Journal 809 <<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137919/>>.

¹²⁴ Australian One Health Antimicrobial Resistance Colloquium Background Paper (n 24).

¹²⁵ Jim O'Neill, 'Antimicrobial in Agriculture and the Environment: Reducing Unnecessary Use and Waste' (2015) <<http://amr-review.org/sites/default/files/Antimicrobials%20in%20agriculture%20and%20the%20environment%20-%20Reducing%20unnecessary%20use%20and%20waste.pdf>>.

¹²⁶ *ibid.*

of animals receiving the treatment, is lacking.¹²⁷ A more rigorous monitoring system would lead to a better understanding of the AMR context in a given jurisdiction; this would then enable targeted policy and regulation development towards activities and actors that are best placed to act.

2.2. *Agricultural Production*

Regulations that ban the use of certain antimicrobials in agricultural production have a direct effect on the quality of products being consumed. However, less-developed markets frequently use antimicrobials to meet production goals, particularly with the stated goal of promoting animal health and food safety.¹²⁸ Many industry leaders and policymakers perceive the short-term benefits associated with antimicrobial use to outweigh the effects of rigorous regulations¹²⁹. A possible solution in this context would be to improve hygiene practices; this can greatly reduce the use and subsequent consumption of antimicrobials.¹³⁰ Regulatory reforms promoting animal health, food safety and production practices could therefore be a promising and sustainable alternative.¹³¹

2.2.1. *General Bans*

A general ban on an entire category of antimicrobial products or uses (eg, medicated feed or growth promoters) can possibly lead to prompt and significant impacts. However, a lack of clear criteria distinguishing each category may result in ineffective measures. For example, when a general ban on growth promoters is established, it may be challenging for regulators to draw the line between the use of antimicrobials for growth promotion as opposed to illness prevention. Among the jurisdictions that limit or ban the use of growth promoters, a couple of countries have asserted a position against using antimicrobials for preventative purposes. Only a selected number

¹²⁷ Sharon Levy, 'Reduced Antibiotic Use in Livestock: How Denmark Tackled Resistance' (2014) 122:6 *Environmental Health Perspectives* <<http://ehp.niehs.nih.gov/122-a160/>>.

¹²⁸ Ramanan Laxminarayan, Thomas Van Boeckel and Aude, 'The Economic Costs of Withdrawing Antimicrobial Growth Promoters from the Livestock Sector' (2015) OECD iLibrary 5 <www.oecd-ilibrary.org/docserver/download/5js64kst5wv1.pdf?expires=1462842342&id=id&taccname=guest&checksum=1D60E7B51DA74E1AAB9FE98FD3009FFA>.

¹²⁹ Honda Keiichiro, Tsunehiro Otsuki and John S Wilson, 'Food Safety Standards and International Trade: The Impact on Developing Countries' Export Performance' in Abdelhakim Hammoudi and others (eds), *Food Safety, Market Organization, Trade and Development* (Springer 2015) 151.

¹³⁰ Aude Teillant, 'How much would it cost to ban antibiotic growth promoters in the livestock sector?' (3 March 2015) The Center for Disease Dynamics, Economics & Policy <www.cddep.org/blog/posts/how_much_would_it_cost_ban_antibiotic_growth_promoters_livestock_sector#sthash.qAP2VAXn.dpbs>.

¹³¹ *ibid.*

of countries like Denmark have acted upon the possibility of misuse. Clearer definitions to distinguish the many uses of antimicrobials may thus improve regulatory frameworks.

2.2.2. Specific Bans

Banning specific substances, one antimicrobial at a time, has some advantages. For instance, it may be more feasible to collect empirical evidence on harmful effects of one targeted antimicrobial rather than attempt to do the same for an entire category. However, the lack of precise and universally accepted antimicrobial measures in the scientific literature remains a large barrier to regulation. For example, while the use of antimicrobials in farmed animals is said to present risks for human health, evidence on specific consequences are still uncertain.¹³² Stakeholders with priorities other than public health can use the lack of robust scientific data to their advantage and persuade policymakers to delay the adoption of regulatory measures.

2.2.3. Control Systems and Penalties

Denmark's regulatory measures point to a system that closely supervises veterinary practices and the purchase of antimicrobial agents. Their regulatory framework seems to be successful, although recent trends point to a rise in antimicrobial consumption. As a result, in 2010, a new system consisting of "yellow cards" and "red cards" were adopted, where farmers are responsible for antimicrobial use during production, and are penalized should their use of antimicrobials exceed a set threshold.^{133, 134} However, this method is not without weakness; any producer who is not officially registered in the system can easily evade these controls. Monitoring mechanisms are essential for such regulations to be effective.

In addition, a European study suggests that there is a stronger correlation between corruption and AMR, than between antimicrobial use and the resulting resistance.¹³⁵ This further illustrates the need for a seamless regulatory system where monitoring mechanisms ensure that requirements are respected.

¹³² Timothy F Landers and others, 'A Review of Antibiotic Use in Food Animals: Perspective, Policy, and Potential' (2012) 127 Public Health Reports 4 <www.ncbi.nlm.nih.gov/pmc/articles/PMC3234384/pdf/phr12700004.pdf>.

¹³³ Ministry of Environment and Food of Denmark, 'The Yellow Card Initiative on Antibiotics' (2015) <www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Pages/The-Yellow-Card-Initiative-on-Antibiotics.aspx>.

¹³⁴ Maron, Smith and Nachman (n 6).

¹³⁵ Peter Collignon, 'Antibiotic Resistance: Are We All Doomed?' (2015) 45:11 Internal Medicine Journal 1109 <<http://onlinelibrary.wiley.com/enhanced/doi/10.1111/imj.12902/>>.

2.3. *Trade of Agricultural Products*

2.3.1. *Coordinating Regulations to Increase Market Competitiveness*

Markets that have limited antimicrobial regulations will increasingly face challenges to be competitive in the global market, particularly with the increasing demand for better or certified quality products. Bans on growth promoters are also increasingly becoming widespread. Given that policy changes occur incrementally and gradually, markets that lack a strategy for action may quickly find themselves falling behind other markets. As a result, antimicrobial regulation can be framed as a forward-looking opportunity to maintain or increase market competitiveness.

2.3.2. *Creating Separate Standards for the Domestic Market*

Bans in large import markets do not necessarily encourage exporting countries to adopt similar practices throughout their jurisdiction and may run up against WTO obligations. Rather, “dual-speed” markets are appearing, where regulations on products for domestic consumption are less restrictive than those intended for foreign markets.

2.3.3. *Industry-led Momentum*

The United States is one of few developed countries that has not introduced ambitious regulations restricting the consumption of antimicrobials for non-therapeutic purposes. Although the United States Congress has been slow to act, major restaurant chains have voluntarily chosen to change their practices and offer their customers meat produced without growth promoters.¹³⁶ Some major meat producers have also decided to stop using antimicrobials that are critically important for human use, growth promotion and preventative measures. These efforts follow the Danish agricultural industry, where industry practices were voluntarily modified before that country’s legislature took action and introduced antimicrobial bans.

Thus, industry can play an important role to simplify the legislator’s task by disseminating important lessons expected to emerge from the implementation of these new practices. As illustrated by the European Union, it is possible for producers to be incentivized to take further action against antimicrobial misuse if important buyers require products that respect safety and health standards.

¹³⁶ *ibid.*

3. Conclusion

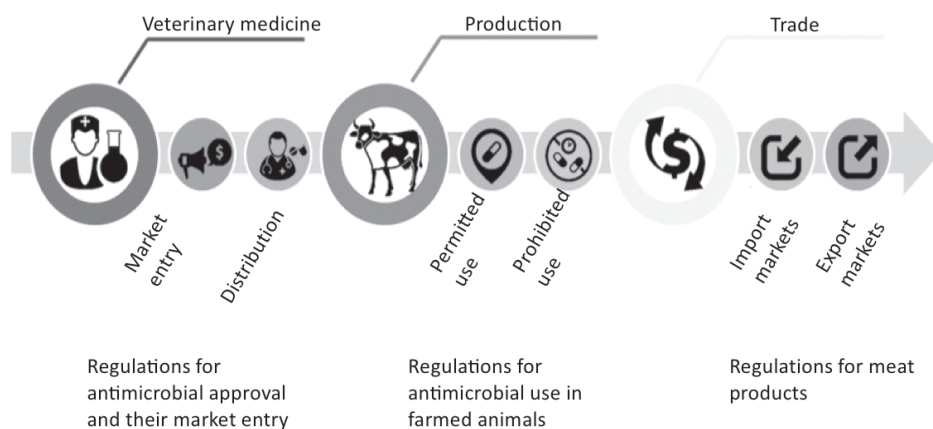
Regulating antimicrobials in livestock animals requires collective action by numerous stakeholders.¹³⁷ While it is imperative that governments take action, they cannot resolve this problem on their own; the participation of numerous stakeholders, including professional groups, private sector, and civil society, across sectors, is required.¹³⁸

Policymakers are thus confronted with significant challenges when proposing appropriate and effective regulatory mechanisms. Measures appropriate to context, available resources, existing infrastructure and stakeholder interests must be identified, implemented and evaluated to be maximally effective. In addition, international trade, a political imperative, must be addressed to ensure it does not overshadow other considerations.

As this comparative study of ten countries shows in great detail, antimicrobials can be regulated at three critical entry points, namely veterinary medicine, agricultural production, and trade. The success of any regulations will depend greatly on authentic participation of a number of stakeholders.

Further detailed, comparative, and systematic studies of technical requirements established by the different regulatory systems discussed would further deepen this legal and policy dialogue. As data becomes available, it will be important to measure the success rate of the approaches discussed to draw conclusions beyond what was possible in this study.

Figure 1. – Points of entry for antimicrobials in the agricultural process



¹³⁷ WHO, Tackling antimicrobial resistance (AMR) together. Working paper 1.0: Multisectoral coordination. Geneva, 2018 (WHO/HWSI/AMR/2018.2) <www.who.int/antimicrobial-resistance/publications/Tackling-AMR-multisectoral-coordination-june2018.pdf>.

¹³⁸ *ibid.*

The pictograms in Figure 1 belong to the *Noun Project* (thenounproject.com), with licenced content under *Creave Commons*. The authors, in order of appearance from left to right, are Alex Auda Samora, Gregor Črešnar, Joseph Wilson, James Keuning, lastspark, GRACE Communicaons Foundation and Mother Jones, Artur Shageyev, doorfortyfour and doorfortyfour.

Part V

**Environmental Health
in Case of Disasters and Conflicts**



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Chapter 21

Natural Disasters, Environment and Health: The Role Played by International Law and European Union Law in this Field

María Isabel Torres Cazorla^{*}

1. *Natural Disasters, Environment and Health: International Organizations at the Crossroads*

This chapter explores the connection between three elements: natural disasters, environment and health, together with the action of International Organizations. Special attention will be paid to a specialized agency of the United Nations system (the World Health Organization-WHO) and a regional actor (the European Union-EU), as primary examples. The definition of ‘natural disaster’ used on this research, taking into account that this is not a legal concept, will be the following:

*A natural disaster is an act of nature of such magnitude as to create a catastrophic situation in which the day-to-day patterns of life are suddenly disrupted and people are plunged into helplessness and suffering, and, as a result, need food, clothing, shelter, medical and nursing care and other necessities of life, and protection against unfavourable environmental factors and conditions.*¹

Although the expression ‘disaster’ is commonly admitted by the international community as a whole, this is an open concept, usually linked with the idea of an event with catastrophic consequences. The relevance of this category of situations was taken into account by the UN International Law Commission, studying the topic ‘Protection of Persons in the event of Disasters’.² On this paper, attention will be paid to the triangle ‘disasters, environment and health’ and the role played by Inter-

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¹ This definition comes from the Mohammad Assar, *Guide to Sanitation in Natural Disasters* (WHO 1971). This is reproduced on the website of the WHO, at <www.who.int/environmental_health_emergencies/natural_events/en/>, emphasis added. All websites, unless otherwise indicated, were last accessed on 30 January 2019.

² See all the information about the ILC work and the adoption of draft articles, with commentaries in 2016, at <http://legal.un.org/ilc/guide/6_3.shtml>.

national Organizations – in particular the WHO³ and the EU – in light of these events. The need to protect persons affected by natural disasters (cyclones, hurricanes, floods, forest fires, earthquakes, *tsunamis* ...) ⁴ and the preservation of health conditions in extreme situations are main goals for international actors and States for some time now.⁵ The linkage among Disaster Risk Reduction strategies and international cooperation is a challenge.⁶ In the same way, the notion of human security is a complementary item.⁷

1.1. *The Work of the WHO in This Field*

It is without doubt that the work of the WHO must be the primary source to understand the connection between disasters, environment and health. By focusing our attention on the so called ‘humanitarian health action’⁸ there is a preliminary distinction adopted by this International Organization into three categories of ‘emergencies’ (Grade 1, 2 and 3).⁹ The minimal, moderate or substantial public health consequences that requires a minimal, moderate or substantial WCO and/or WHO response, permit to qualify an emergency into one of these categories; Grade 1 emergencies are the least serious. On the contrary, Grade 3 emergencies are the most serious events.

The list of examples provided by the WHO website is not exhaustive and it is changed from time to time, but it is a useful instrument to analyse the common aspects of the action provided by this International Organization in order to solve problems related to health, after a disaster. Our attention will be focused exclusively on some natural disasters over recent years, studying the action promoted by the WHO on this context.

³ See Ben Wisner and John Adams (eds), *Environmental Health in Emergencies and Disasters: A Practical Guide*, (WHO 2002); Andrew J Michael and others, *Climate Change and Human Health: Risks and Responses* (WHO 2003). In the same way, see the most recent work of Emily Ying Yang Chan, *Public Health Humanitarian Responses to Natural Disasters* (Routledge 2017).

⁴ This reaction must be understood together with the idea of prevention; see Mohane Munasinghe and Caroline Clarke, *Disaster Prevention for Sustainable Development: Economic and Policy Issues* (ESD 1995).

⁵ See Obijiofor Aginam, ‘Health and Human Security in Emergencies’ <<https://unu.edu/publications/articles/health-and-human-security-in-emergencies.html>>.

⁶ See Nicola Banwell and others, ‘Towards Improved Linkage of Disaster Risk Reduction and Climate Change Adaptation in Health: A Review’ (2018) 15 *International Journal of Environmental Research and Public Health* 793.

⁷ See Lincoln C Chen and Aafje Rietveld, ‘Human Security during Complex Humanitarian Emergencies: Rapid Assessment and Institutional Capabilities’ in Taylor Owen (ed), *Human Security* (Sage Publications 2013) 45.

⁸ See <www.who.int/hac/en/>.

⁹ See <www.who.int/emergencies/crises/en/>.

1.1.1. Grade 1 Emergencies

A clear example of this category was the Sulawesi earthquake and *tsunami* (Indonesia, September 2018).¹⁰ The last report published on the WHO website (dated 26 October 2018) provides useful information about the response given by the international community and the consequences of this natural disaster for health: 616.684 affected; 222.986 displaced population; 4.612 severely injured; 2.105 fatalities and 45 health facilities affected.¹¹ The WHO, together with different organizations (a list of them is reproduced on the last page of the aforementioned report) provided technical guidelines for emergency treatment of drinking water, water quality testing, health cluster response against the expansion of HIV, malaria, diarrhoea, or acute respiratory infection diseases, between others. Water is one of the main aspects to be considered on emergency situations and the need to provide water sanitation kits to the affected population is a key point.¹²

Unfortunately, this is a vulnerable area.¹³ At the end of December 2018, Indonesia suffered another disaster, with unpredictable consequences: a *tsunami* at Sunda Strait,¹⁴ caused by the eruption of the volcano Arak Krakatau.¹⁵ This situation shows the need of a new *tsunami* early warning system on this region. The complexity of these emergencies is an aspect to be taken into account: a mixture of conditions that may produce a major disaster (a tragic mixture of earthquakes, volcanos and tsunamis).¹⁶

¹⁰ See <www.searo.who.int/mediacentre/emergencies/sulawesi-earthquake/en/>.

¹¹ See WHO, Responding to Earthquake and Tsunami hit Central Sulawesi Province (situation report #10) <www.searo.who.int/indonesia/areas/emergencies/earthquake/en/>.

¹² See Ben Wisner and John Adams, *Emerging Issues in Water and Infectious Disease*, 2002 <www.who.int/water_sanitation_health/emergencies/emergencies2002/en/>.

¹³ Vulnerability seems to be a common pattern of these emergency situations: geographical conditions, poverty and instability produce a lethal combination with dramatic effects. A practical example of this may be the case of Haiti. See María Isabel Torres Cazorla, 'La "nueva" amenaza del cólera en Haití tras el paso del huracán Matthew: ¿hay respuesta desde el contexto onusiano?' (2016) 2 *Ius et Scientia. Revista Electrónica de Derecho y Ciencia* 122 <<http://institucional.us.es/iusetscientia/index.php/ies/article/view/60/35>>; and 'A New Paradigm for the United Nations Security Council: the Relationship between Security and Health' in María Isabel Torres Cazorla and José Manuel Sánchez Patrón (coords), *International Biolaw: Human Rights, Public Health and Environment* (Tirant lo Blanch 2018) 118.

¹⁴ See the information available at <www.searo.who.int/indonesia/en> and at <www.bnpb.go.id/en/berita>.

¹⁵ See <www.theguardian.com/world/2018/dec/24/sunda-strait-tsunami-volcano-indonesia>.

¹⁶ In this paper our attention will be focused on natural disasters. Sometimes, a combination of natural and man-made disaster produces a joint impact with devastating effects; an example of this was the case of the accident of the nuclear plant in Fukushima (Japan) in 2011. See Dirk Jurgen Hanschel, 'Prevention, Preparedness and Assistance Concerning Nuclear Accidents- Effective International Legal Framework or Patchwork?' (2012) 55 *German Yearbook of International Law* 217.

1.1.2. *Grade 2 Emergencies*

Moderate public health consequences, together with a response of the same level are the main aspects of this category, following the examples provided by the WHO website. The cases of the hurricane Irma and Maria in the Caribbean¹⁷ show the need to coordinate efforts to solve health problems and infrastructure destruction. Dominica was the most affected island (90% of the island infrastructures were destroyed). The role of the PAHO (Pan American Health Organization),¹⁸ as a regional office of the WHO, must be enhanced. Dealing with health, the most relevant activities were the following:

Regional Response Teams assisting with health damage and needs assessment, restoring health care delivery capacity and access to health services in the most affected areas, increasing epidemiological surveillance to support early detection and management of disease outbreaks, ensuring access to safe water, emergency sanitation measures and vector control, and lastly supporting efficient coordination of humanitarian assistance and management of information.¹⁹

1.1.3. *Grade 3 Emergencies*

The list provided by the WHO website of this category of emergencies does not include – at least right now – cases directly connected with environment. It is referred to complex situations where the mixture of political instability, poverty and diseases provoke the emergency situation. The expansion of Ebola and malaria in the Democratic Republic of Congo is a clear example.²⁰

Undoubtedly, the work of the WHO regional offices has no limits. It is true that Asian, American and African continents seem to be the most fragile areas of the world where environmental conditions produce or help to provoke disasters that may considerably affect to public health. Although this is a reality, the European continent is not, unfortunately, free of this type of events.²¹ Due to this

¹⁷ Hurricanes of Category 5 impacted several Caribbean islands (September 2017). See <www.paho.org/disasters/index.php?option=com_content&view=article&id=3613:hurricane-irma-and-maria-in-the-caribbean-2&Itemid=904&lang=en>.

¹⁸ The work of PAHO is not new, paying attention to the prevention, preparedness and response in the case of emergencies. A useful analysis is the book *Natural Disaster Mitigation in Drinking Water and Sewerage Systems. Guidelines for Vulnerability Analysis* (PAHO 1998) <www1.paho.org/English/PED/nd-water_mit.pdf?ua=1>.

¹⁹ See the information provided <www.paho.org/disasters/index.php?option=com_content&view=article&id=3613:hurricane-irma-and-maria-in-the-caribbean-2&Itemid=904&lang=en>.

²⁰ See <www.who.int/emergencies/crises/cod/en/> and <www.who.int/ebola/situation-reports/drc-2018/en/>, related to the recent outbreak of these diseases and the way to control them.

²¹ See <www.euro.who.int/en/health-topics/emergencies>. An illustrative instrument is the Journal *Public Health Panorama*, providing information about this geographical area and environmental health problems. See Bettina Menne, Vladimir Kendrovski and James Creswick, 'Protecting Health from Cli-

fact, the next section will analyse the recent work of the European Union in this field.

1.2. *The European Union Civil Protection Mechanism: An Effective Way?*

Although the EU has focused its attention on disasters for decades²², a decisive instrument to be taken into account is the Decision 1313/2013/EU of the European Parliament and of the Council, of 17 December 2013, on a Union Civil Protection Mechanism²³. Following art. 1.1 of this Decision, this Mechanism: ‘... shall aim to strengthen the cooperation between the Union and the Member States and to facilitate coordination in the field of civil protection in order to improve the effectiveness of systems for preventing, preparing for and responding to natural and man-made disasters’.

The Mechanism tries to be a useful tool; prevention, preparedness and response (to natural and man-made disasters) are key points of this regulation,²⁴ applied to 34 States.²⁵ The relationship between humanitarian aid and civil protection must be en-

mate Change: A Seven-Country Approach’ <www.euro.who.int/en/publications/public-health-panorama/journal-issues/volume-1,-issue-1,-june-2015/protecting-health-from-climate-change-a-seven-country-approach> 11-24. At 12 it is stated that ‘the seven-country initiative covered four different geographical and climatic zones: arid and semi-arid water-stressed areas (Kazakhstan and Uzbekistan); high mountainous areas (Kyrgyzstan and Tajikistan); Mediterranean countries (Albania and the former Yugoslav Republic of Macedonia); and a subArctic region in the northern Russian Federation (Arkhangelsk Oblast and Nenets Autonomous Okrug)’. See Ute Enderlein and others, ‘The International Health Regulations (2005) Monitoring and Evaluation Framework and Its Implementation in the WHO European Region’ (2018) 4 Public Health Panorama 134. The need to coordinate efforts in the field of natural disasters and health is a challenge in the European sphere, too; an example of this was the conference held in Brussels on 2015 ‘Natural Disasters and “One-Health”. Are We Prepared?’; additional information at <www.ifaw.org/european-union/news/%E2%80%98natural-disasters-and-one-health-%E2%80%93-are-we-prepared%E2%80%99-conference>.

²² See María Isabel Torres Cazorla, ‘¿Lecciones aprendidas? El papel de la Unión Europea en materia de prevención y coordinación en caso de catástrofe’ in Daniel García San José, José Manuel Sánchez Patrón, and María Isabel Torres Cazorla (coords), *Bioderecho, seguridad y medioambiente/Biolaw, Security and Environment* (Tirant lo Blanch 2015) 151.

²³ [2013] OJ L347/924.

²⁴ A complete analysis of this Decision and its legal implications may be seen at Andrés Bautista Hernáez, ‘Recientes avances en la regulación de la Unión Europea en materia de catástrofes: el Mecanismo de Protección Civil de la Unión’ in García San José, Sánchez Patrón, and Torres Cazorla (n 22) 174; and (by the same author), ‘La relación entre la Unión Europea y sus Estados miembros en la respuesta a las catástrofes: el papel de España en el mecanismo europeo de protección civil’, in Joaquín Alcaide Fernández and Eulalia W Petit De Gabriel (coords), *España y la Unión Europea en el orden internacional: XXVI Jornadas ordinarias de la Asociación Española de Profesores de Derecho Internacional*, Universidad de Sevilla, 15 y 16 de octubre de 2015 (Tirant lo Blanch 2017) 1187.

²⁵ See the information available at <http://ec.europa.eu/echo/what/civil-protection/mechanism_en>. The Mechanism is applicable to the EU Members, together with Iceland, Norway, Serbia, the Former Yugoslav Republic of Macedonia, Montenegro and Turkey.

hanced to understand the action of the EU on this field; a relevant fact to be mentioned is that ‘since 2001, the EU Mechanism has responded to over 300 requests for assistance *inside and outside* the EU’.²⁶

Some examples of the activation of the EU Mechanism in complex emergencies are the Ebola outbreak in West Africa (2014) and in the Democratic Republic of the Congo (2018),²⁷ the earthquake in Nepal (2015),²⁸ the forest fires in the Mediterranean region (2006-2017)²⁹ or the floods in Central Europe and the Balkans.³⁰ EU action may include different means (money, instruments and tools) together with cooperation among International Organizations, civil protection resources and military forces,³¹ NGOs, etc.

2. Environment, Security and Health: The Need to Coordinate Efforts in the International, Regional and National Spheres

The 20th century has dramatically changed the conception of security, passing through an idea linked to the State and military forces to a renewed version of this, focused on human beings.³² National Security Acts and Strategies follow the same way, including emergencies and situations related to climate change and pandemics

²⁶ Emphasis added. See <http://ec.europa.eu/echo/what/civil-protection/mechanism_en>.

²⁷ See <http://wa_ebola_en.pdf>.

²⁸ See <http://ec.europa.eu/echo/where/asia-and-pacific/nepal_en>.

²⁹ See Commission Staff Working Document, Overview of Natural and Man-made Disaster Risks the European Union may face, Brussels, 23 May 2017, SWD (2017) 176 final, that includes at p. 28 a mapping of forest fires in Europe, and explains 49 EU Civil Protection Mechanism activations from 2006 to 2016 (in Greece, Portugal, Italy, France, Montenegro, Cyprus, Bulgaria, Sweden, Slovenia, Spain, Norway and the former Yugoslav Republic of Macedonia).

³⁰ *ibid*; at p. 20 the document includes a mapping of flood events in Europe (with 21 EU Civil Protection Mechanism activations during the period 2006-2016, 212 floods, 966 people killed and 4 million people affected).

³¹ The participation of military forces in the field of emergencies and disasters has been increased in the former years. On this specific topic, see Andrés Bautista Hernández, ‘La participación de las Fuerzas Armadas en situaciones de catástrofe en el ámbito de la Unión Europea’ in Elena del Mar García Rico and María Isabel Torres Cazorla (dirs), *Hacia una identidad europea en materia de seguridad y defensa: ¿Realidad o Utopía?* (Tirant lo Blanch 2019) 287-317. The need of a holistic approach is studied by Nick Spence, ‘Civil-Military Cooperation in Complex Emergencies: More than a Field Application’ (2002) 9 *International Peacekeeping* 165.

³² The evolution of this conception, including international global efforts (of the UNDP, the UN Secretary-General, the General Assembly or the Security Council of the UN), together with international organizations such as the WHO has been studied by international lawyers as a relevant topic. A complete analysis of this aspect may be found in Stefania Negri, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale* (Giappichelli 2018) 135-173.

into a 'global conception of security'.³³ Emergencies and disasters³⁴ are considered as a challenge by the Spanish National Security Strategy 2017, together with epidemic and pandemics³⁵ and the effects stemming from climate change.³⁶

The first aspect (emergencies and disasters), following the aforementioned Spanish National Security Strategy, includes different lines of action connected with the international (universal and regional) context, such as:³⁷

- Establishing management and communication protocols at the national and international levels, in coordination with the EU and other international organizations.
- Promote international coordination and cooperation in the area of civil protection, with a special focus on the EU Civil Protection Mechanism³⁸ and the UN International Strategy for Disaster Reduction,³⁹ and at the bilateral level,⁴⁰ with third countries.

The second dimension (security vis-à-vis pandemics and epidemics) deals with this main objective:⁴¹

Adopt plans to prepare for and respond to health risks, both generic and specific, in accordance with the *principle of coordination* between the General State Administration, the administrations of the Autonomous Communities, and international organizations, such as the *World Health Organization*, or, within the *EU*, the European Centre for Disease Prevention and Control.⁴²

³³ See, as an example of this tendency, the Spanish National Security Strategy 2017, English version available at <www.dsn.gob.es/sites/dsn/files/2017_Spanish_National_Security_Strategy_0.pdf> (hereinafter Spanish National Security Strategy 2017). Following this strategy, similar to the standards of other countries, security have different dimensions such as geopolitical, economic, social, technological and environmental dimensions (ibid 33-35).

³⁴ ibid 72-74.

³⁵ ibid 74-75.

³⁶ ibid 75-77.

³⁷ ibid 113.

³⁸ See <http://ec.europa.eu/echo/what/civil-protection/mechanism_en>.

³⁹ See <www.unisdr.org/>.

⁴⁰ See, for example, the Agreement on Cooperation on Disaster Preparedness and Prevention, and Mutual Assistance in the Event of Disasters, Russian Federation - Spain, of 14 June 2000, UNTS vol. 2153, No 37586, from the list of 165 bilateral agreements on this field included in Doc A/CN.4/590/Add.2, 6-14 (Protection of persons in the event of disasters. Memorandum by the Secretariat, Addendum). A complete list of bilateral cooperation agreements on emergencies and disasters may be seen at Andrés Bautista Hernández, *Las catástrofes en el ámbito del Derecho Internacional y su régimen jurídico*, Tesis doctoral, Universidad de Málaga (Spain) and Université Paris Nanterre (France), 2018, 719-736.

⁴¹ See Spanish National Security Strategy 2017, 114.

⁴² All the information about this agency of the EU is available at <<https://ecdc.europa.eu/en/home>> accessed 30 January 2019.

The list of risks related to the coordination of the national and international levels is quite long, but, in particular, attention will be paid to the following aspects: ‘Adapt the network of hospitals for treatment of confirmed cases of Ebola, to respond to any high-risk infectious disease’; ‘expand and maintain the systems for monitoring and controlling the entry of exotic and indigenous vectors, and extend the National Plan for Preparation and Response to Vectorborne Diseases, to include all vectors of interest’; ‘develop and improve, through collaboration between the ministries involved, the protocols for preventing entry into the country of animals or goods that may contain dangerous pathogens, and for ensuring appropriate assistance for people who have entered the country with high-risk infectious diseases’; ‘strengthen the response capabilities of external health response teams as regards health incidents at the borders’; and ‘adopt protocols for management and communication of food crises, in coordination with the EU and other key international organizations’.⁴³

International coordination is a challenge, and it is focused on ‘exchange information and insight into management and treatment of new diseases’, together with development of ‘the Spanish Technical Emergency Assistance and Response Teams, and *promote their participation in international missions*’.⁴⁴

The third relevant aspect to be considered in the Spanish National Security Strategy is the ‘preservation of the environment’. One of the main objectives will be ‘strengthen compliance, within the framework of the EU, with the commitments adopted to preserve the environment and biodiversity, prevent water insecurity, and combat climate change, intensifying international cooperation’.⁴⁵

The connection between environment – together with climate change implications⁴⁶ – health and security, with emergencies and disasters as a backdrop, reflects the interrelationship of all these factors at the national and international levels. The Spanish legislation has been used as an example of the connection among all the surrounding areas that will be analysed separately in the next paragraphs.

3. *The Answer to Be Given to “Complex Emergencies”: A Very Long Way to Go*

First of all, a useful definition of ‘complex emergency’ was given by the International Law Commission: ‘Complex emergency’ has been defined as ‘a humanitarian crisis in

⁴³ *ibid* 115.

⁴⁴ *ibid*.

⁴⁵ *ibid* 117.

⁴⁶ The relationship among climate change and disasters have been studied by Andrés Bautista Hernández, ‘Climate Change and Disasters: the 2015 Paris Agreement legal standards applicable to disaster prevention’ in Torres Cazorla and Sánchez Patrón (n 13) 187.

a country, region or society where there is a total or considerable breakdown of authority resulting from internal or external conflict and which requires an international response that goes beyond the mandate or capacity of any single agency and/or the ongoing United Nations programme' (Working paper on the definition of complex emergency, Inter-Agency Standing Committee, December 1994 (on file with the Codification Division)).⁴⁷ The examples mentioned in the first section may be considered as included on this category and they will be taken into account to analyse the answers provided by International Law as a whole to solve these emergencies. Special attention will be provided to the expansion of pandemics, water sanitation and health conditions, water security and the relationship of these circumstances with security, environment and health. Due to the great number of implied actors – International Organizations, NGOs, civil protection and military capacities, etc –, cooperation among them and evaluation of the challenges and measures adopted on every case⁴⁸ are key questions to be observed. It is true that prevention, preparedness and response seems to be three aspects to be taken into account to address the main challenges of disasters and emergencies, together with traditional fields of International Law.⁴⁹

The treatment of this kind of topics by the International Health Regulations (2005)⁵⁰ and some other international instruments (for example, the texts adopted in Hyogo – 2005 – or Sendai – in 2015) is something relevant. On the first point, the International Health Regulations of the WHO defines a 'public health emergency of international concern' as *an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response*' (art. 1.1). This concept, together with the definition of 'public health risk' as *'a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger'* (art. 1.1). The international impact of that event –or its eventual consequences in the international context–, together with a coordinated international re-

⁴⁷ See Doc A/CN.4/590, at 13, para 9, footnote 30.

⁴⁸ See different perspectives about "complex emergencies", merely as examples, in the following contributions: John Kirby and others, 'A Survey of Evaluation Experiences in Complex Emergencies' (2001) 5 The International Journal of Human Rights 114, 127; Barry Munslow, 'Complex Emergencies and Development' in Vendana Desai and Robert B Potter (eds), *The Companion to Development Studies* (Arnold 2002) 444; Andrew S Natsios, 'NGOs and the UN System in Complex Humanitarian Emergencies: Conflict or Cooperation?' in Paul F Diehl (ed), *The Politics of Global Governance: International Organizations in an Interdependent World* (Lynne Rienner Publishers 2005) 381.

⁴⁹ See Tilman Rodenhäuser and Gilles Giacca, 'The International Humanitarian Law Framework for Humanitarian Relief During Armed Conflicts and Complex Emergencies' in Susan C Breau and Katja LH Samuel (eds), *Research Handbook on Disasters and International Law* (Edward Elgar 2016) 132; in the same book, see Tim Stephens, 'Disasters, International Environmental Law and the Anthropocene', at 153.

⁵⁰ See <www.who.int/ihr/publications/9789241580496/en/>.

sponse seems to be the main aspects of the aforementioned definitions. Despite not explicitly mentioning natural disasters, it may be inferred that this kind of situations are linked directly with them.

A Strategy must be adopted in the international sphere, renewing the global commitment on this field; it is a challenge, and the Hyogo Declaration, adopted under the auspices of the World Conference on Disaster Reduction (Kobe, Hyogo, Japan, 18-22 January 2005)⁵¹ was focused on some facts: 'human societies have to live with the risk of hazards posed by nature'; 'prevention, preparedness, and emergency response, as well as recovery and rehabilitation'; 'it is vital to give high priority to disaster risk reduction in national policy, consistent with their capacities and the resources available to them' together with 'strengthened national efforts and enhanced bilateral, regional and international cooperation, including through technical and financial assistance'.

The Sendai Framework for Disaster Risk Reduction (2015-2030)⁵² is an essential document, focused on the near future; in this sense, environment and, strictly speaking, climate change conceived as 'one of the drivers of disaster risk, while respecting the mandate of the United Nations Framework Convention on Climate Change, represents an opportunity to reduce disaster risk in a meaningful and coherent manner throughout the interrelated intergovernmental processes'.⁵³

One of the main goals of the Sendai Framework is described on par. 17, which reads as follows:

Prevent new and reduce existing disaster risk through the implementation of integrated and inclusive economic, structural, legal, social, *health*, cultural, educational, *environmental*, technological, political and institutional measures that prevent and reduce hazard exposure and *vulnerability to disaster*, increase *preparedness for response and recovery*, and thus strengthen *resilience*'.⁵⁴

The connection between disasters, health and environment is not without doubt, as the wording of paragraph 17 makes clear. Some Guiding Principles⁵⁵ put together, as challenges of this Framework, the aforementioned ideas, such as principle c): 'Managing the risk of disasters is aimed at protecting persons and their property, *health*, livelihoods and productive assets, as well as cultural and *environmental assets*, while promoting and protecting all human rights, including *the right to development*' (emphasis added).

Cooperation need to be enhanced; local, national, regional and international

⁵¹ See <www.unisdr.org/2005/wcdr/intergover/official-doc/L-docs/Hyogo-declaration-english.pdf>.

⁵² See <www.unisdr.org/files/43291_sendaiframeworkfordren.pdf>.

⁵³ *ibid* para 1 of the Sendai Framework.

⁵⁴ *ibid* para 17 of the Sendai Framework (emphasis added).

⁵⁵ *ibid* at 13-14 of the Sendai Framework, available at <www.unisdr.org/files/43291_sendaiframeworkfordren.pdf>.

spheres and actors have to be concerned from a realistic perspective in order to get some positive results. From this perspective,

the entities of the United Nations system, including the funds and programmes and the *specialized agencies*, through the United Nations Plan of Action on Disaster Risk Reduction for Resilience, United Nations Development Assistance Frameworks and country programmes, to promote the optimum use of resources and to support developing countries, at their request, in the implementation of the present Framework, *in coordination with other relevant frameworks, such as the International Health Regulations (2005)*, including through the development and the strengthening of capacities and clear and focused programmes that support the priorities of States in a balanced, well-coordinated and sustainable manner, within their respective mandates.⁵⁶

These instruments are some recent steps focused on the subjects considered (that is to say, natural disasters, environment and health and their interrelationship) in order to accomplish with the Sustainable Development Goals.⁵⁷ Although these goals are today still unreachable, something must be done. The First Global Report on Environmental Rule of Law (published on January 2019)⁵⁸ alerts about some facts: there seems to be a contradiction between the existence of environmental rules in the international community and the compliance with these rules to develop the right to a healthy environment. On this particular point, the work of the former Special Rapporteur of the UN Human Rights Council (John Knox) must be enhanced. His last report ‘on the issue of human rights obligations relating to the enjoyment of a safe, clean, healthy and sustainable environment’⁵⁹ deserves attention. This document contains some references to the potential vulnerability of certain groups (women and girls, children, persons living in poverty, older persons, persons with disabilities, etc).⁶⁰ Dealing with natural disasters, special attention must be paid to the situation of persons with disabilities, such as paragraph (e): ‘The vulnerability of persons with disabilities to natural disasters and extreme weather is often exacerbated by barriers to receiving emergency information in an accessible format and to accessing means of transport, shelter and relief’⁶¹.

⁵⁶ *ibid* para 48, sub-para (b), at 25 (emphasis added).

⁵⁷ See <www.un.org/sustainabledevelopment/sustainable-development-goals/>. On this particular point, see Paloma Durán y Lalaguna and others (eds), *International Society and Sustainable Development Goals* (Thomson Reuters Aranzadi 2016).

⁵⁸ See this text, available at <https://wedocs.unep.org/bitstream/handle/20.500.11822/27279/Environmental_rule_of_law.pdf?sequence=1&isAllowed=y>.

⁵⁹ See Doc A/73/188, 19 July 2018, available at <<https://daccess-ods.un.org/TMP/7964861.9890213.html>>. John Knox finished his mandate in 2018; a new Special Rapporteur (David R. Boyd) was appointed in August 2018. See <www.ohchr.org/EN/Issues/Environment/SREnvironment/Pages/SREnvironmentIndex.aspx>.

⁶⁰ See Doc A/73/188, p. 19.

⁶¹ *ibid* 19, subpara (e).

And this is not the only reference made to natural disasters and vulnerable groups; by the same way of reasoning, the Special Rapporteur asserts:

‘(g) Natural disasters and other types of environmental harm often cause internal displacement and transboundary migration, which can exacerbate vulnerabilities and lead to additional human rights violations and abuses (see A/66/285 and A/67/299). These vulnerabilities often overlap, such as in the case of women and children from minority groups who live in poverty, compounding the risks of environmental harm and the concomitant violation of their human rights’.⁶²

This connection between environment, natural disasters and human rights, together with health must be enhanced. Although the so-called ‘UN Charter of Human Rights’ does not contain a direct reference to ‘the right to a healthy environment’, this right may be inferred from these conventional instruments. The work of international human rights courts – e.g. the European Court of Human Rights⁶³ and its interpretation of art. 8 of the European Convention of Human Rights – is emblematic on this point. Human rights such as they were set up at the 20th century, must be interpreted taking into account ‘ecological’ considerations. The triangle ‘human rights + environmental protection + prevention of natural disasters’ is something to be considered by international law as a whole. A polyhedral concept⁶⁴ that is going to be developed at the universal, regional and local sphere, to preserve our planet and the humanity. Together with the aforementioned ideas, humanitarian assistance in the event of disasters is another aspect to be considered. Unfortunately, there is no unanimity about the existence or not of a customary human right to the humanitarian assistance in the event of natural disasters.⁶⁵

⁶² *ibid* 19, subpara (g).

⁶³ See José Manuel Sánchez Patrón, ‘Las actividades peligrosas para el medio ambiente y la salud humana en la jurisprudencia del Tribunal Europeo de Derechos Humanos’ in José Manuel Sánchez Patrón (coord), *Bioderecho Internacional y Europeo: Desafíos actuales* (Tirant lo Blanch 2014) 131.

⁶⁴ This adjective of ‘polyhedral’ may be used on different situations; on this point, see María Isabel Torres Cazorla ‘Environmental Security: An Initial View from the Perspective of International Law’ in Elena del Mar García Rico and María Isabel Torres Cazorla (coords), *International Security in the 21st Century: New Perspectives* (Plaza y Valdés 2011) 145-146.

⁶⁵ See Doc A/CN.4/590, 172, para 257; and María Isabel Torres Cazorla, ‘Las emergencias y catástrofes como riesgo para la seguridad: una visión desde la perspectiva del Derecho Internacional Público a la luz de la Estrategia de Seguridad Nacional de mayo de 2013’ (May-August 2014) 92 *Icade, Revista Cuatrimestral de las Facultades de Derecho y Ciencias Económicas y Empresariales* 77, 99. In the same way, see José Manuel Sánchez Patrón, ‘Paz positiva, seguridad humana y medio ambiente: del ‘deber de respetar’ a la ‘obligación de proteger’ in Carmelo Faleh Pérez and Carlos Villán Durán (dirs), *El derecho humano a la paz y a la (in)seguridad humana. Contribuciones atlánticas* (AEDIDH 2017) 99.

4. *Tentative Conclusions*

International Organizations have paid attention to natural disasters and, in particular, their prevention, preparedness and response. The WHO is one example of this: the connection between complex emergencies, some of them directly related with natural disasters, such as can be seen on the webpage of this specialized agency of the United Nations, is something without doubt. Together with this fact, the relationship between environment – or natural disasters due to environmental facts – health and poverty – in many cases – are some aspects to be considered. The need to coordinate efforts to solve the problems provoked as a consequence of natural disasters, is a challenge of the international community. The word ‘cooperation’ acquires a new dimension on this field; the local, national, regional and international perspectives, together with all the actors directly and indirectly involved are relevant. Thinking globally, acting locally, are expressions that contribute to understand how to react in these cases.

The evolution of human rights – as a whole – was not traditionally connected with the adoption of an environmental perspective. Climate change,⁶⁶ together with a consensus about the degradation of our planet may be considered revolutionary factors to change the world dimension about natural disasters and the way to react, adopting a human rights perspective. All these ideas must be considered to understand this kind of phenomena. Ideas such as prevention, preparedness and response should be taken into account by States, International Organizations – universal and regional –, civil protection services, NGOs and all the actors involved in the event of disasters and emergencies. Technology⁶⁷ provides useful instruments that, used in a coordinate way, may assure a successful answer to some challenges described on this paper.

It is true that international instruments – treaties, decisions, regulations, customary rules, soft law, etc – do not provide practical answers to every situation. A mixture between common sense, together with some guidelines or principles constitute the departure point of the international community on this topic. It is a long way to run, but the first obstacle has been overcome. International Organizations – and the WHO is one of the main actors to be considered – must play a major role in the field of disasters. There is no turning back.

⁶⁶ See Daniel García San José, ‘Seguridad medioambiental y principio de necesidad en Bioderecho Internacional’ in García San José, Sánchez Patrón and Torres Cazorla (n 22) 132; and Bautista-Hernández (n 46).

⁶⁷ It is true that new technologies may be used on different contexts; see Elena del Mar García Rico, ‘Altas tecnologías, conflictos armados y seguridad humana’ (2016) 18 *Araucaria, Revista Iberoamericana de Filosofía, Política y Humanidades* 265.



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Chapter 22

The Environmental and Health Impacts of Chemical Spraying: Can Law Protect Victims? The Case of Agent Orange

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1. Introduction

What are the legal instruments allowing victims of chemical spraying to claim justice for the tort they have suffered? What may they sue for? Is it possible, besides the physical torts, to sue for the environmental destruction related to the wide scale use of these chemicals? In this chapter, we suggest elements of answers to these questions by analysing the case of Agent orange (AO) spraying during the Vietnam war. Indeed, the United States (US) Army used various types of herbicides to deprive the Vietnamese National Liberation Front (NLF) militias of forest cover and crops during 10 years (1961-1971), as part of mission *Ranch Hand*. The *Rainbow Herbicides* were manufactured at the request of the US government, by different companies, including Monsanto, Dow Chemical or Shamrock. Among these herbicides AO, named due to the orange band marking its containers, was massively sprayed in order to destroy the triple canopy jungle in South Vietnam. To comply with military demands, companies sped up AO production, thus disrespecting production norms. Such negligence led to AO dioxin-TCDD contamination. Jeanne Stellman estimates that 221kg of TCDD has been spilled over the Vietnamese territory, while 80g in potable water supply would be enough to eradicate an 8 million inhabitants' city.¹ Shortly after the beginning of AO sprayings, doctors in Vietnam started to identify the surge of rare diseases and birth defects among their patients.² Dioxin-TCDD is a

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¹ Jeanne Mager Stellman and others, 'A Geographic Information System for Characterizing Exposure to Agent Orange and Other Herbicides in Vietnam.' (2003) 111 *Environmental Health Perspectives* 321; Jeanne Mager Stellman and others, 'The Extent and Patterns of Usage of Agent Orange and Other Herbicides in Vietnam' (2003) 422 *Nature* 681.

² Fred A Wilcox, *Scorched Earth: Legacies of Chemical Warfare in Vietnam* (A Seven Stories Press 1st ed, Seven Stories Press 2011).

known carcinogen and teratogen. As such, it causes rare forms of cancers, stillbirths, birth defects (both physical and mental) and orphan diseases related to genome mutation,³ which the US government has repeatedly denied throughout the years.

After the war, several legal cases emerged to claim compensation for the endured damages, either introduced by US veterans exposed to AO, or by Vietnamese citizens and their sick children. Based on the case of AO, we will attempt to understand what victims of chemical products may file a lawsuit for. In a second part, we will oversee the reasons why asking for (war-related) chemical products' environmental and health damages is difficult.

Table 1 below shows the different trials filed against AO manufacturers throughout the decades. Besides, we also consider two consultative legal opinions. Tribunals of opinion have played an important role, but have obvious limitations due to their nature. To this day, transitional justice has not formally occurred between Vietnam and the United States, since no court has been recognized by either party of the war. The rulings that interest us here abide by existing laws and hence are useful tools for future trials, even though they are non-binding. Besides, they have their own restrictions. As tribunals of opinion, their aim is also to raise political awareness over a perceived injustice. Their interpretation of law calls for another interpretation of existing instruments (International peoples' tribunal of conscience in support of the Vietnamese victims of Agent orange, later on IPTC) or for the creation of new laws (the Monsanto Tribunal). The IPTC was settled by the International association of democratic lawyers and aimed to define the reparation victims could claim, both toward the US government and the companies, thus ignoring the issues of immunity. A proceed of the ruling was nonetheless symbolically sent to the White House⁴ The Monsanto Tribunal, held in 2016 by international jurists and civil society organisations stated Monsanto could be sued for ecocide for its deeds in Vietnam, if only ecocide was written as a crime of international law.⁵ Finally, their highly symbolic and partisan charge may discredit further attempts to obtain justice through regular courts.

³ Eva Kramárová and others, 'Exposure to Agent Orange and Occurrence of Soft-Tissue Sarcomas or Non-Hodgkin Lymphomas: An Ongoing Study in Vietnam.' (1998) 106 *Environmental Health Perspectives* 671.

⁴ André Bouny, *Agent orange: apocalypse Viêt Nam* (Éditions Demi-Lune 2010).

⁵ *Summary of the advisory opinion of the International Monsanto Tribunal* 6 (International Monsanto Tribunal).

Date	Parties	Motives	Status
Trials			
1978-1985	<i>Paul Reutershan v. Monsanto et al. Then, Agent Orange Victims International (AOVI) v Monsanto et al.</i> 15'000 plaintiffs from the United States, Australia and New Zealand	Mass tort action	Jurisdiction: New York Eastern District Court Judge: Jack B. Weinstein Ruling: Out of court settlement, \$180 M of granted by Monsanto <i>et al.</i> (goodwill based) No ruling, hence no precedent ⁶
1986-2013	<i>Korean Association for Victims of Agent Orange (KAOVA) v Korean branches of Monsanto et al.</i>	Mass tort class action	Jurisdiction: Korean Supreme Court Ruling: Recognition of chloracne as caused by AO exposure. Condemnation of Korean branches of Monsanto and other companies. Compensation to 39 Korean Vietnam War Veterans for diseases suffered following exposure to herbicides, \$41M in compensation.
2004-2008	<i>Vietnamese Association for Victims of Agent Orange/Dioxin (VAVA) v Dow et al.</i>	Violations of international law and war crime (war crime, crime against humanity, genocide) Negligent and international tort under the common law for products' liability Civil conspiracy, public nuisance and unjust enrichment, causing personal injuries, wrongful death and birth defects	Jurisdiction: New York Eastern District Court (Alien Tort Claim Act) Judge: Jack B. Weinstein, US Court of Appeals for the Second Circuit, Supreme Court Ruling: Rejected. The jury of the Supreme Court considered Monsanto produced a defoliant, which aim was to harm the forest cover, and not human beings ⁷ .
2015-	<i>Trần Tô Nga and daughters v Monsanto et al.</i>	Motive: Health damages caused by tort committed in the manufacturing and	Jurisdiction: Evry High Court (France) Status: Ongoing

⁶ Peter Sills, *Toxic War: The Story of Agent Orange* (Vanderbilt University Press 2014).

⁷ Jack B Weinstein, Memorandum, order and judgement 2005, 233.

	Subsequently the “Every trial” or “Every lawsuit”	provision of the defoliant AO to the US Armed Forces ⁸	
Consultative legal opinions			
2009	<i>International Association of Democratic Lawyers</i> <i>27 victims of AO (Vietnamese, American, Korean) v. Monsanto et al.</i> Subsequently the “IPTC case”	War crimes Crimes against humanity Violation of the right to life	Body: The International peoples’ tribunal of conscience in support of the Vietnamese victims of AO AO is a poisonous weapon. Thus, the US violated the laws of war and committed war crimes in Vietnam. The manufacturing companies are complicit of war crimes. The American government is guilty of crime against humanity for it did not discriminate civilians from combatants, inflicted unnecessary sufferings over several generations, thus violating the Geneva Conventions and its 1977 Protocol. Violation of the right to life. ⁹
2016	Legal opinion Is Monsanto guilty of complicity of war crime? Could the past action of Monsanto be considered as ecocide? Subsequently the “Monsanto tribunal”	Complicity of war crimes Ecocide	The dais deems that there is not enough proof to rule Monsanto as a complicit of war crime for the production of AO. Moreover, Monsanto, as a legal person, cannot be held liable for war crimes (Rome Statute), for which the court called in favour of extending the liability to legal persons. If ecocide was considered a crime under international law, Monsanto would be guilty of such a crime ¹⁰ .

⁸ Sandra Orus and Dounia Belua, Ordonnance 2015 [14/04980].

⁹ Bouny (n 4); *Judgement of the International peoples’ tribunal of conscience in support of the Vietnamese victims of Agent orange* 32 (International peoples’ tribunal of conscience in support of the Vietnamese victims of Agent orange).

¹⁰ *Summary of the advisory opinion of the International Monsanto Tribunal* (n 5).

2. Claims

By crossing over the different trials, we can identify three main types of claims made by plaintiffs. We analyse them one by one in this part.

2.1. Sanitary Impacts Constitutive of Crime Against Humanity and War Crime

2.1.1. Physical and Health Impacts During and After the Conflict

Among the claims of the various trials, inflicted physical and health impacts have been the most important ones. In the *KAOVA v Monsanto et al.* lawsuit (the only litigation that led to a compensation), it was the motive retained by the Korean Supreme Court, asking for veterans who were exposed to AO to be compensated for their chloracne outbreaks (the Seoul District court first accepted 11 diseases, but the decision was overturned).¹¹ Immediate health impacts such as headaches, fatigue, severe skin rashes, were declared in the *VAVA v Dow et al.* case¹² as well as the ongoing *Evry* litigation¹³ with no compensation however.

In the *KAOVA v Monsanto et al.* trial, chloracne was perceived by the court as a direct result of dioxin-TCDD exposition as demonstrated by several scientific studies.¹⁴ Scientifically-evidenced harm of chemical products is likely to be accounted for, although this success is to be nuanced: a positive relation between chloracne and AO has been recognized by courts only after the results of dioxin trials. Moreover, this link is not necessarily straightforward:¹⁵ after more than 30 years of trials, only a minority of plaintiffs could convincingly attest of one precise affliction in front of a lawcourt and be compensated. Meanwhile, the harm done by dioxin exposure may appear years after exposure, thus complicating the provision of evidence regarding physical harm.

For instance, in the *AOVI v Monsanto et al.* case, Paul Reutershan, the first person to file a complaint against Monsanto, did so by linking his rare form of cancer to AO exposure, claiming compensation for health damages appearing after the war. The class action that ensued, as a mass tort claim, was based on a wide array of health impacts, ranging from personal injury to cancers. The wives and children of servicemen

¹¹ Justine Guichard, 'The Conflictual Legacy of South Korea's Participation in the Vietnam War Veterans' Struggles for Victimhood Recognition and Denial' (2016).

¹² Constantin P Kokkoris, Preliminary statement 2004, 48.

¹³ Orus and Belua Ordonnance (n 8).

¹⁴ Sills (n 6).

¹⁵ Guichard (n 11).

were also mentioned, for miscarriages, birth defects or still births. None of the accusations were retained, for the trial was settled out of court. Judge Weinstein concluded there was not enough proof to link AO/dioxin exposure to health ailments in servicemen and their children.¹⁶ Up until now, activists in the US are still accused of pointing out “old age and life style diseases” as dioxin-related.¹⁷ The same judge ruled the 2004 *VAVA v Dow et al.* case, where post-conflict, post-exposition afflictions were underlined by Vietnamese victims. Providing testimonies and proofs on skin diseases and extreme fatigue, they also provided accounts of rare forms of diseases (mostly cancers), asking companies producing AO to be held accountable for these diseases.¹⁸ Scientific proofs brought to Weinstein led the judge to rule out the evidences brought by Vietnamese victims for lack of statistical evidence, especially years after the war.¹⁹

Afflictions related to the long-term toxicity of some chemical products are difficult to sue against, as the causal links are difficult to prove. In the *Evry* lawsuit, the plaintiff mentioned a list of health issues she deems related to her exposure to chemicals.²⁰ These issues either appeared shortly afterward, affected her daughters, or broke out decades after her exposure (from chloracne to rare forms of anaemia).²¹ The burden of proof to attest the link between AO and diseases is both financially and scientifically heavy, because of the lack of complete knowledge on AO and on its historical use.

While official jurisdictions were careful in the consideration of health impacts occurring after the war, opinion tribunals, such as the Monsanto Tribunal or the IPTC, considered the damages suffered by victims during and after the war as violations of international law as a matter of principle but without leading to effective condemnations.

Another important trend observed is that health impacts have been coupled with international humanitarian law as AO was used during an international conflict.

2.1.2. *Crime Against Humanity and War Crimes*

According to the proceeds of the Nuremberg trial and the 1998 Rome Statute, the conscious, systematic, inhumane and widespread attacks against civilians for in war

¹⁶ Sills (n 6).

¹⁷ Interview with Paul Cox, ‘US Veteran, Member of Vietnam Veterans for Peace’ (Berkeley, United States of America, 30 July 2017).

¹⁸ Kokkoris Preliminary statement (n 12).

¹⁹ Jack B Weinstein Memorandum, order and judgement (n 7).

²⁰ Orus and Belua Ordonnance (n 8).

²¹ Arnaud Vaulerin, ‘Tran To Nga, une vie empoisonnée’ *Libération.fr* (24 October 2018) <www.liberation.fr/planete/2018/10/24/tran-to-nga-une-vie-empoisonnee_1687642> accessed 13 January 2019.

constitute crimes against humanity. In several trials, the use of AO was considered as such by the plaintiffs. For those of 2004 *VAVA v. Dow et al.*, sprayings caused at least physical and mental harm that could be considered as torture and wilful atrocities against civilians, recalling the Nuremberg rulings and the 1907 Hague Conventions.²² This was however rejected altogether by the dais. Crime against humanity was tackled by IPTC, which judges ruled spraying herbicides as an inhumane treatment of civilians according to the Nuremberg Principles, considering the pain, anguish and suffering they have caused and will cause “over generations”.²³ Chemical warfare for the indiscriminate, superfluous suffering it inflicted, was hence recognized by the jury as a crime against humanity. However, no effective court has yet recognized this wider interpretation of laws.

Furthermore, according to the Rome Statute, using poisonous weapons, asphyxiating gases and analogue products, as well as not distinguishing civilians from combatants, is constitutive of war crimes. Victims of chemical attacks may hence sue with these legal tools, if the defendant is also a party to the Statute. In the case of AO victims, only the Geneva conventions and the Hague Treaties of 1907, domestic laws (Vietnamese and Americans) as well as international customary laws could be relevant.

Through the various trials, one of the most disputed elements was to attest that AO is a chemical weapon and not a simple licit herbicide as affirmed by defendants. In the 2004 *VAVA v Dow et al.* case, plaintiffs attempted to prove that the US government was guilty of war crimes, and the companies responsible of complicity to these crimes, by proving that AO could be considered as a weapon forbidden by the Geneva conventions, the Hague conventions and customary law. According to Price, chemical weapons, by their nature and effect, would already be forbidden.²⁴ Besides the unnecessary suffering, poisonous gases and liquids do not allow distinction between military and civil targets as provided by the Geneva Conventions, even though the areas sprayed were marked as strictly controlled by NFL militia. First, the insurrectional character of the Vietnam war meant that guerrillas hid in densely populated civil areas. It was hence impossible to distinguish combatants from civilians, nor was it possible to distinguish their crops. Second, because of droplet drifts, herbicides particles unavoidably fell on civilian areas.²⁵ Third, because the ongoing pollution, in times of peace, mostly affects civilians.

War crimes accusation appeared in *Dow et al.* trial in 2004^{26, 27} but were never recognized. Beside this case, plaintiffs did not point at war crimes. In the 1978-1985

²² Kokkoris Preliminary statement (n 12).

²³ 1976 *Judgement of the International peoples' tribunal of conscience in support of the Vietnamese victims of Agent orange* (n 9).

²⁴ Richard Price, 'Reversing the Gun Sights: Transnational Civil Society Targets Land Mines' (1998) 52 *International Organization* 613.

²⁵ Sills (n 6).

²⁶ Weinstein Memorandum, order and judgement (n 7).

²⁷ Kokkoris Preliminary statement (n 12).

class action, many US veterans did not want to sue their state (some of whom out of patriotism), nor to condemn it for war crimes. They mostly needed to cover the health fees engendered by their service.²⁸ In the case of *VAVA*, the demography of plaintiffs (Vietnamese people, including former NLF militants), as well as the support network behind them (Vietnamese government, Vietnamese NGOs, Vietnamese Friendship associations), explains the content of the accusations. Later on, the qualification of AO as an illegal, chemical weapon was adopted by the IPTC (Judgement of the IPTC in support of the Vietnamese victims of AO 2009) as well as by the Monsanto Tribunal²⁹. Again, the aim of these tribunals explains the strengths of their rulings compared to official courts, but their reasoning could be used in other trials against perpetrators of chemical attacks.

2.2. *Environmental Destruction*

Before sanitary damages were linked to AO sprayings by doctors, activists and plaintiffs, the extensive environmental destruction stirred indignation from the public. A 1969 report from a study conducted by two US scientists already pointed out irreversible environmental damages on Vietnamese ecosystems.³⁰ These are the only damages officially recognised by the US and cooperative clearing operations are currently undertaken by the US and Vietnamese governments. A first site has been cleared (the Da Nang airbase), and two others are currently in progress (Bien Hoa and Phu Cat airbases). Still, many civilians living around contaminated areas are at risk of water and food borne contamination, and the defoliation has had disastrous consequences on the biodiversity.

During the sprayings, up to 10% of the current Vietnamese territory had been affected by herbicide pollution. Currently, there are several “AO hotspots”, where the concentration of dioxin is high because of herbicide drums’ storage.³¹ The defoliated areas included triple canopy jungles and mangroves, which are essential to protect from coastline erosion. Therefore, herbicides sprayings could be qualified as environmental destruction. While operation *Ranch Hand* undoubtedly shaped the way states currently deal with environmental protection during wars, it happened at a time no laws existed to prevent irremediable ecosystem damages. The 1977 Additional Protocol to the Geneva Conventions limits the permitted damages to the environment during interna-

²⁸ Sills (n 6).

²⁹ *Summary of the advisory opinion of the International Monsanto Tribunal* (n 5).

³⁰ David Zierler, *The Invention of Ecocide: Agent Orange, Vietnam, and the Scientists Who Changed the Way We Think about the Environment* (University of Georgia Press 2011).

³¹ James T Durant and others, ‘Public Health Assessment of Dioxin-Contaminated Fish at Former US Airbase, Bien Hoa, Vietnam’ (2015) 25 *International Journal of Environmental Health Research* 254; Thomas Boivin and others, ‘Agent Orange/Dioxin Contamination in the Environment and Food Chain at Key Hotspots in Vietnam: Da Nang, Bien Hoa and Phu Cat’ 5.

tional conflicts. The 2002 Rome Statute of the International Criminal Court (ICC) considers attacks that intentionally inflict disproportionate, widespread and long-term damages to the environment as war crimes. In addition, Galston, who coined the term “ecocide”, did so by attesting the destruction in Vietnam.³² A few years later, and as a response to the use of AO during the Vietnam war, the United Nations (UN) pushed forward and adopted the Convention on the Prohibition of Military or any other hostile use of environmental modification techniques, known as the ENMOD convention. For Vietnamese victims of AO, these treaties were adopted too late, since the sprayings stopped five to six years before. These laws cannot be summoned retroactively in trials, but can be for other cases later on (for instance, against the use of depleted uranium around the city of Fallujah or the use of defoliants by the Israeli Defence force on the Gaza strip), if states involved are parties to the treaties.

Moreover, not much more is provided by written international law in terms of the use of herbicides. The 1969 UN General Assembly (UNGA) banned the use of herbicides and riot control agents in times of war through resolution 2603. This instrument has however not reached consensus, due to abstentions (36) and the negative vote of 3 UNGA member states. It was precisely discussed and voted during the Vietnam War and hence labelled “partisan” by the US administration.³³ Dean Kokkoris, the lawyer of the Vietnamese victims of AO in the 2004-2008 lawsuit called upon resolution 2603, but it was ruled non-binding, heavily polarized due to the Cold War context and not applicable to private actors.³⁴

Looking at tribunals of opinion, the Monsanto tribunal jury stated that if ecocide could be considered as a crime, Monsanto would be guilty of committing it. Nothing now prevents victims to sue for pollution or ecocide to establish a precedent. Nevertheless, in the state of existing law, ecocide is still not a crime one may sue for.

2.3. State and Corporate Responsibility

When the *AOVI v Monsanto et al.* case started, Paul Reutershan aimed at suing the US government. However, Washington D.C made use of its state immunity and could, as such, only be sued by a court it recognized capable of doing so. Companies could not benefit from this immunity and corporate responsibility could be called upon.

In the 2004 *VAVA v Dow et al.* trial, the plaintiffs demanded that the complicity of companies, their negligence and unjust enrichment be compensated. Based upon the extensive damages declared by the victims in the various trials, the claims for immediate damages were retained.

³² Zierler (n 30).

³³ Sills (n 6); Zierler (n 30).

³⁴ Weinstein Memorandum, order and judgement (n 7).

If plaintiffs could prove that the perpetrators knew about the toxicity of the chemical products, then the US could be ruled guilty of a breach of international law (the Geneva conventions), and the companies could then be held accountable for providing toxic products to their clients. However, this point has never been recognized by any effective court, although lawyers of victims such as Peter Sills affirm there was no way chemical manufacturers were oblivious of the consequences of dioxin exposure. This line of argumentation has been repeated in all trials up until now. It is however difficult to find tangible cases and similarities, due to the different legislations under which AO trials were ruled. Also, only the *KAOVA v Monsanto et al.* case led to compensation for damages, based upon studies conducted in the US.³⁵

Overall, barriers exist to the recognition of these different claims. We look at these barriers in the next part.

3. Social and Legal Obstacles

3.1. Agent Orange, “Just” an Herbicide

First, AO is not considered as a chemical weapon but as an herbicide. This has been a recurrent argument to dismiss claims for compensation by victims of sprayings. AO has indeed been presented as an herbicide from the beginning of the Vietnam war³⁶ and has been reiterated as such by the American jurisdiction,³⁷ being therefore considered licit. Although one is dealing with the particular case of AO, technicalities of weapons’ systems have often been used to doge accusations of weapons’ ban violation. AO, white phosphorus, depleted uranium ammunitions used during the 2nd Gulf War happen to be accidentally chemical. As stated by Richard Price, the issue with weapon-specific jurisdiction is the escape clauses it creates. According to him, a strict interpretation of the founding texts of international humanitarian law would provide protection against indiscriminate attacks causing superfluous and unnecessary suffering caused by some weapons. In case specific weapons are banned, it is a matter of time before military innovation makes a convention obsolete.³⁸

While not leading to a formal judicial verdict, the different trials led to the construction of arguments disqualifying AO as a chemical weapon, for its purpose was to harm plants, not human beings. Moreover, chemical companies and the US government have defended their actions by stating their ignorance about the toxicity of the herbicide. Although the lawyers of the plaintiffs insist that manufacturers were aware

³⁵ Guichard (n 11).

³⁶ Zierler (n 30).

³⁷ Weinstein Memorandum, order and judgement (n 7).

³⁸ Price (n 24).

of the hazards, the proofs are insufficient to establish their knowledge of hazards and their intention to harm human beings.³⁹

AO is a specific case but resembles depleted uranium, as it affected human beings while mainly targeting the environment or infrastructures. The full range of consequences over people's health unfolds years after, thus making the link between diseases and their primary cause difficult to prove, and hence to rule. Other types of chemical products, those with immediate and more visible effects, will not face the same difficulties undergone by those suing for AO related afflictions. Looking at different cases in which long-term poisoning was recognized (such as asbestos), a fair share of activism was necessary⁴⁰ to have long term health ailments recognized. Civil society support is positive for victims (provision of a support network, legal counseling as well as increased transnational visibility of the trial) but it can discredit attempts to obtain justice by apparently tainting lawsuits with partisanship.

3.2. *State Immunity and Applicability of Laws*

In any case, because the use of chemical weapons is a war crime, only states and individuals may be sued for it, not companies. The former may benefit from *de facto* or *de jure* immunities, which has made suing the US for their use of chemical weapons impossible up to now. While state apparatus takes the decision to conduct wars and to utilize contested weapons, it is difficult to sue them due to their sovereign immunity.

In the case of AO, the US government invoked its sovereign immunity. According to this clause, it may only stand in a lawsuit if it consented to⁴¹. This has prevented the plaintiffs to sue the government, and hence led them to sue the manufacturing companies. Moreover, by the time of the sprayings, the US had not yet ratified the Geneva Gas Conventions (they only did in 1972)⁴² and the 1993 Chemical Weapons Convention did not exist at this time. While AO sprayings contributed to the adoption of ENMOD or of the UNGA 2603 resolution, these instruments were available too late or did not gain unanimous support to be accounted as customary laws by US courts.⁴³

Since the US neither recognizes the International Court of Justice, nor the ICC, the only way victims could sue for their plight was by doing so in the US (*AOVI v Monsanto et al.*), or by using extra-territorial competences of national courts. This

³⁹ Sills (n 6).

⁴⁰ Emmanuel Henry, *Amiante, un scandale improbable: sociologie d'un problème public* (Presses universitaires de Rennes 2007).

⁴¹ Richard A Roth, 'The Essence of the Agent Orange Litigation: The Government Contract Defense' (1983) 12 Hofstra Law Review 983.

⁴² Zierler (n 30).

⁴³ Weinstein Memorandum, order and judgement (n 7).

was the case of the *VAVA v Dow*: the plaintiffs used the Alien Tort Claim Act, which allows foreigners to sue an American physical or moral person if they committed infraction against them.⁴⁴ In the *Every* trial, Tran To Nga, a French national, invoked the competence of French magistrates to settle international law related cases if a French citizen is involved in the dispute.⁴⁵ In the case of *KAOVA v Monsanto et al.*, the Korean veterans sued the Korean wings of the multinationals under Korean law, because they struggled doing so on the American territory.⁴⁶

Immunities put a limit on *what* plaintiffs may sue for. Since private companies may not be sued for war crimes (only having legal personhood) according to the Rome Statute, this limits the range of laws applicable. In all the cases detailed in Table 1, it was not possible to sue and condemn private individuals for war crime or crime against humanity,⁴⁷ although they could be charged as accomplices.

3.3. *Proofs as Burdens*

In order to be able to sue manufacturers, plaintiffs in AO litigations need to bring proof backing their claims. With time passing by, attesting that a victim has been sprayed, and thereafter suffered diseases is financially costly, if not impossible due to the social situation of victims. It is difficult to prove that the US government intended to harm people by spraying herbicides. Several maps provided by the US government are available but proving exposure has been tricky, considering the drifts during the spraying (up to 100 km away) and the mobility of soldiers in and out of spraying areas.⁴⁸ Adding to this, accounting for the link between parental exposure and birth defects is subject to an ongoing controversy. All in all, the burden of proof on victims is heavy. In the *Every* trial for instance, the evidence requested included documents attesting the plaintiff's presence in sprayed areas, proving the non-combatant status of the plaintiff, as well as certifying health afflictions (some of which occurred as she was an inmate in South-Vietnamese jails and were solved ever since). The provision of these documents was requested by the defendants and has lengthened the judicial procedure, even though the jury ruled some of the demands unreasonable.⁴⁹

⁴⁴ Felix Klickermann, 'Legal Liability for Agent Orange-Related Illnesses: A Reassessment of the 2005 VAVA Case and Prospects for New Litigation' (2016) 32 *Medicine, Conflict and Survival* 138.

⁴⁵ France Inter, 'Tran To Nga, le parcours d'une combattante', *D'ici, d'ailleurs* (10 December 2016) <<https://www.franceinter.fr/emissions/d-ici-d-ailleurs/d-ici-d-ailleurs-10-decembre-2016>> accessed 13 January 2019.

⁴⁶ Guichard (n 11).

⁴⁷ *Summary of the advisory opinion of the International Monsanto Tribunal* (n 5).

⁴⁸ Sills (n 6).

⁴⁹ Interview with Tổ Nga Trần, 'Plaintiff of Nga Tran v. Monsanto et al., former Vietnamese war correspondant' (Ho-Chi-Minh-City, Vietnam, 4 July 2016).

Moreover, the financial cost to obtain a certificate linking health ailments and exposure is costly. At \$1000 per sample of blood and fat tissues, many victims do not have the capacity to pay for these screenings, nor to remunerate lawyers and translators. Most lawsuits listed were made possible through heavy civil society involvement (Vietnam Agent Orange Responsibility and Relief took care of the plaintiffs while they were in the US), including fundraising (Tran To Nga used fundraising platforms to pay for translation fees) and voluntary works by lawyers.

The AO case is particular, owing to its span of action and blurred notion of intention. The intention to harm is more obvious in the use of other types of weapons (white phosphorus obviously causes burns, for instance). Again, its consequences bear similarities with uranium exposure out of nuclear tests⁵⁰ or depleted uranium ammunitions.⁵¹ While suffering crippling health conditions, neither French military staff working on test sites nor American soldiers serving in Iraq managed to gain recognition of the link between their condition and their exposure to hazardous substances.

Moreover, these difficulties could only be faced if victims survived from the war and war-related afflictions. AO does not harm instantly in a tangible way. After the Vietnam war, survivors of AO sprayings found themselves sick, or repetitively gave birth to ill children, thus contributing to their pauperization and isolation.⁵² Among them, a minority of victims could find the social resources to sue companies, and many died during the legal procedure, for instance during the *VAVA v Dow et al.* lawsuit⁵³ and the *KAOVA v. Monsanto* case in Korea (out of which only 39 veterans were compensated).⁵⁴ The burden of proof therefore weights on mostly marginalized victims, who cannot bring all evidence pieces to their own trials.

3.4. “*I will never be able to marry*”, or the Social Costs of Victimhood

The social burden has often been underlined either by victims or researchers working on AO. “I will never be able to marry” was the complaint of a teenage girl, with several sick siblings. Their parents had served during the war in heavily sprayed areas and were beneficiaries of Vietnamese state support programs.⁵⁵ This expresses the social cost of victimhood, which deters witnesses and victims from speaking about their plights.

⁵⁰ Bruno Barrillot, *Les irradiés de la république: les victimes des essais nucléaires français prennent la parole* (Grip 2003).

⁵¹ Rob Nixon, *Slow Violence and the Environmentalism of the Poor* (Harvard University Press 2011).

⁵² Michio Umegaki, Lynn Thiesmeyer and Atsushi Watabe (eds), *Human Insecurity in East Asia* (United Nations University Press 2009).

⁵³ Wilcox (n 2).

⁵⁴ Guichard (n 11).

⁵⁵ Interview with Public Health Official, Covered Identity (Hanoi, Vietnam, 26 April 2018).

Affecting gonads, dioxin exposure causes birth defects and congenital health ailments. In traditional societies such as rural Vietnam, marriage and childbirth are important milestones. Because of their exposure to herbicides during the war or afterward, while living and/or working in polluted areas, some parents gave birth to sick children. In order to save the marital prospects for their healthy family members, and to avoid the social stigma of having heavily handicapped children, some chose not to declare their afflictions, while knowing it may be related to dioxin exposure. Suing, in this case, would mean accepting and embodying one's status of victim, bringing suspicions on one's children and grand-children to bear healthy offspring. Moreover, some believe being affected by heavy health ailments or giving birth to sick children is due to their karma. Wishing to avoid social exclusion, some do not accept or request social benefits they would be entitled to,⁵⁶ let alone suing to gain justice on the international level.

3.5. Politicization of the Agent Orange Trials

Last but not least AO, as a remnant of war issue, is politically charged both in Vietnam and in the US, which complicates attempts of victims to claim justice without being instrumentalized by either party to the Vietnam war. As a war-remnant issue, dioxin pollution has been the subject of difficult negotiations between the US and Vietnam and is still one of the most crucial points on the bilateral agenda. As a Cold War issue, it bears an important partisan dimension up to now, and is conditioned by US-Vietnam relations. Since the normalization and reestablishment of diplomatic ties between Washington and Hanoi, and while much progress had been done on the issue, dioxin pollution remains a sensitive issue.

The different trials have had a toll on the political exchanges between the two countries. Currently, the question of AO sanitary liability is not welcomed in an agenda packed with defence agreements deemed crucial by both partners, besides the different trade agreements linking them together. As a result, AO has become a heavily controlled issue in Vietnam, and Hanoi keeps a tight surveillance on research centres and hospitals alike. While VAVA is an NGO catering for victims, it remains intimately linked to the Vietnamese government, thus restricting Vietnamese victims' ability to sue. The only lawsuit involving Vietnamese citizens was made possible by the creation of VAVA, which leadership is composed by former Vietnamese high officials. For the Vietnamese victims, there is hence no other way to claim justice than going through their government, which is supportive toward them on the national scale, but does not have the leverage to do so on the international level. Trials such as this of Evry are hence encouraged, but not too eagerly, by the Vietnamese government. The access to courts by Vietnamese victims is hence compromised by the political agenda on defence and trade.

⁵⁶ Interview with Public Health Official II, Covered identity (Hanoi, Vietnam, 24 June 2018).

4. *Conclusion*

This chapter has analysed the different claims and results of all litigations related to the use of Agent orange, an herbicide, during the Vietnamese war. Claims have included issues of sanitary impacts, environmental degradation, and state and corporate responsibility. Overall, very few of these claims have been recognised as valid: AO has been considered as an herbicide, not a chemical weapon, states have benefited from immunity, the practical costs of scientific evidence impeded plaintiffs to fully inform their cases, social costs have been high and the AO issue is full of broader political tensions. For these reasons, AO victims have struggled to effectively file lawsuits to claim for justice.

The AO case enables us to draw some more general observations with regard to the possibility that victims of chemical products can have to make their voice heard in case of environmental and health impacts. Recent cases such as the glyphosate case could benefit from a parallel with AO. For instance, French civil society actors supporting the Evry trial have claimed taking example on AO as a “dystopian case” to push for a ban on endocrine disruptors.⁵⁷ First, tribunals of opinions, and this is also part of their role, are more favourable for new claims to be heard. They could be considered as first steps towards stronger litigations. Second, the costs of litigation should be considered and plaintiffs could be helped overcoming these costs. In particular, social repercussions are a new type of costs identified by our study that would be highly relevant when environmental and health issues impact marginalised populations. Third, the political dimension of environmental and health litigations should not be underestimated. Ideally litigations should be preserved from political struggles or at least these struggles be made clearer.

⁵⁷ Interview with Jean-Louis Roumegas, ‘Former French MP, Green Party’ (Montpellier, France, 27 February 2018).



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Chapter 23

Chronicle of a Death Foretold: The Long-Term Health Impacts on the Victims of Widespread Lead Poisoning at UN-Run Camps in Kosovo

Agostina Latino *

1. Introduction

The case under consideration in the present brief notes relates both to the legal consequences of the relocation, decided by the United Nations Interim Administration Mission in Kosovo (UNMIK),¹ of individuals of Roma, Ashkali and Egyptian ethnicity (RAE)² in camps for Internally displaced persons (IDPs) and to the health impact provoked by that relocation. IDPs camps for RAE were set up in the Northern area of Mitrovicë/Mitrovica,³ a town divided by the river Ibar in two

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¹ For an overview on the mission, see, among others, Richard Caplan, 'United Nations Interim Administration Mission in Kosovo' in Joachim A Koops and others (eds), *The Oxford Handbook of United Nations Peacekeeping Operations* (OUP 2015), 617; Erika De Wet, 'Lip-service to the Rule of Law in the Administration of Kosovo: The Limited Accountability of UNMIK for Human Rights Violations' in Clemens A Feinäugle (ed), *The Rule of Law and Its Application to the United Nations* (Hart Publishing-Nomos Verlagsgesellschaft 2016) 171.

² Within the international community, the acronym RAE is widely used to collect in one the Roma, Ashkali and Egyptian minority communities in Kosovo. The issue of distinguishing the specific ethnic identity of these communities, which share cultural traits and history of marginalization in society, is complex and debated. In short, just like different ethnic lines divide Kosovo in general, at a lower level RAE community is characterized by different lines. Romans in the strict sense are essentially Orthodox Christians and their language is mostly Serbian or Romani, while Ashkali and Egyptians are predominantly Muslim and speak mostly Albanian: see European Roma Rights Centre, 'Abandoned Minority. Roma Rights History in Kosovo', December 2011, 18 <www.errc.org/cms/upload/file/abandoned-minority-roma-rights-history-in-kosovo-dec-2011.pdf>. Especially on the health approach of these ethnicity, see Aliu Jete, *Access to Antenatal Health Services Among Roma, Ashkali, and Egyptian (RAE) Women in Kosovo* (2015), Thesis, Rochester Institute of Technology <<http://scholarworks.rit.edu/theses>>. All internet sites, unless otherwise indicated, were last accessed on 15 February 2019.

³ Verena Knaus, 'The Mitrovica Dilemma' (2005) 80 Chicago-Kent Law Review 71 <<https://scholarship.kentlaw.iit.edu/clawreview/vol80/iss1/5>>.

parts, one Serbian, the other Albanian. This area is close to Trepca, an industrial giant for the processing of lead, 320 km south of the Serbian capital of Belgrade.⁴ Ground of the unwise decision by the United Nations to set up refugee camps in an area of overt environmental risk dates back to 21 June 1999, when the Roma district Mahala, seat of the largest Roma community in Kosovo, with approximately 1000 dwellings housing 8000 people, was looted and burned by some members of the Albanian ethnic armed group, the Kosovo Liberation Army. Since September 1999, UNMIK has re-settled around 600/700 RAE individuals, about the half of which under the age of 14, in two camps – Zhikoc/Žitkovac and Cesminluke/Česmin Lug – to cope with the urgent need for provisionally relocating the refugees in an area where they could be rescued from the violence of the Albanians who considered the RAE allies of the Serbs.

Although at the beginning the fields were meant to be operational only for a short time, to the limited scope to face the coming winter,⁵ three additional fields were set up later in the same area: Leposaviq/Leposavić at the end of 1999, Kablare/Kablar in 2001 and Osterode in 2006.

The present analysis shall be based on the Opinion made on 26 February 2016⁶ by the Human Rights Advisory Panel in Kosovo,⁷ in the affair *N. M. and Others v.*

⁴ For a comment on the UN Kosovo Lead Contaminated Roma Refugee Camps Case [The 2006 Case Brought by the European Roma Rights Centre Against the UNMIK on Behalf of 184 Residents Living in U.N. Refugee Camps (Near Contaminated Abandoned Lead Smelters and Mines in Northern Kosovo) and the European Court of Human Rights' Decision Declining Review of the Case Based on the Court's Alleged Lack of Jurisdiction Over the Case] and the answer to the question: 'Are the ICC Elements Present for the ICC Crimes of Genocide by Causing Serious Mental or Bodily Harm (Rome Statute Article 6(b)), and the Crimes Against Humanity of Apartheid (Rome Statute Article 7(1)(j)) and Persecution (Rome Statute Article 7(1)(h))?', see Sonja C Grover, *The European Court of Human Rights as a Pathway to Impunity for International Crimes* (Springer-Verlag 2010) 129 ff.

⁵ On September 1999, the Special Representative of the Secretary General (SRSG), Dr. Bernard Kouchner, gave formal assurances that displaced persons would have to stay in camps between 45 and 90 days pending the negotiation of a lasting solution: see Society for Threatened Peoples, The Kosovo Medical Emergency Group, *Dossier of Evidence Supporting the Call to Take Decisive Action to Implement Immediately an Emergency Evacuation and the Highest Level of Medical Treatment for all Roma, Ashkali and Kosovan-Egyptian Families in the Displaced Persons Camps of North Kosovo*, 9 <www.gfbv.de/uploads/download/download/Dossier%20of%20Evidence.pdf>.

⁶ *N.M. and Others v UNMIK*, Case No 26/08, Opinion of the Human Rights Advisory Panel, 26 February 2016 <www.unmikonline.org/hrap/Eng/Cases%20Eng/26-08%20NM%20etal%20Opinion%20FINAL%2026feb16.pdf>.

⁷ The Panel, established pursuant to UNMIK Regulation No. 2006/12, was the only human rights mechanism dealing specifically with human rights violations allegedly committed by or attributable to a United Nations field mission. It started its activities in November 2007, receiving and reviewing since then over 500 complaints. At the end of its work, it subsequently issued a Final Report in July 2016 (*The Human Rights Advisory Panel History and Legacy in Kosovo, 2007-2016. Final Report*, 30 June 2016 <www.unmikonline.org>). The Panel was composed of three Panel Members who met in Prishtinë/Priština each month in order to render determinations on complaints against UNMIK. The Presiding Member was responsible for the work of the Panel, while the permanent Secretariat in Prishtinë/Priština provided it with legal and administrative support. Any person who believed that UNMIK

UNMIK, an opinion issued almost eight years after 138 complainants, all Roma victims of lead poisoning, had filed a claim in July 2008.⁸

First of all, we will expose the factual and legal elements which led the Advisory Panel to recommend to UNMIK, in addition to official apologies, to compensate for material and moral damages suffered by the applicants. Secondly, we will face with the decision of the Secretary General of the United Nations, who announced, in May 2017,⁹ the creation of a Trust Fund 'as an exceptional measure' (*sic*), aimed at financing assistance projects on account of the RAE communities, especially for health services, economic development and infrastructure. Finally, we will consider the latest disappointing developments in the affair.

2. A Chronology of the Facts and a Critical Consideration Thereof

It is well-known that, on 10 June 1999, the UN Security Council adopted Resolution 1244 (1999).¹⁰ By decision under Chapter VII of the UN Charter, this Resolution established in the territory of Kosovo the deployment of international security (Kosovo Force-KFOR) and civil presences (UNMIK) and invested the UN with full legislative and executive powers for the interim administration of Kosovo. In particular, KFOR was entrusted with the task of establishing 'a secure environment in which refugees and displaced persons can return home in safety'¹¹ and temporarily ensuring 'public safety and order until the international civil presence [could] take over responsibility for this task'.¹² UNMIK was created with the task to 'promote and pro-

was responsible for a violation of his or her human rights could file a complaint to the Panel in order to obtain a decision on the alleged violation. The group of experts then examined the admissibility of the complaint according to the applicable legislation and made a decision to that effect. In case of acceptance, the Panel issued an opinion on UNMIK's responsibility for the violation of one of the human rights instruments in force in Kosovo, making any recommendations to the Special Representative of the Secretary-General (SRSG), which, in turn, ought to publicly declare how it would follow these recommendations.

⁸ On the case, see the contribution, included quoted bibliography, of Giovanni Cellamare, 'Danni alla salute da operazioni di peace-keeping delle Nazioni Unite: profili di responsabilità e di immunità dell'Organizzazione' in Laura Pineschi (ed), *La tutela della salute nel diritto internazionale ed europeo tra interessi globali e interessi particolari* (Editoriale Scientifica 2017) 421.

⁹ See the 'Statement attributable to the Spokesman for the Secretary-General on the Human Rights Advisory Panel's recommendations on Kosovo', 26 May 2017 <www.un.org/sg/en/content/sg/statement/2017-05-26/statement-attributable-spokesman-secretary-general-human-rights>.

¹⁰ Resolution 1244 (1999), adopted by the Security Council on 10 June 1999 at its 4011th meeting <www.un.org/Docs/scres/1999/sc99.htm>.

¹¹ *ibid* para 9, c).

¹² *ibid* para 9, d).

tect human rights'¹³ in Kosovo in accordance with internationally recognised human rights standards, and was based on four main pillars under the ultimate authority of the Special Representative of the Secretary General-SRSG, each pillar assigned to the competence of a different international organisation (the United Nations, for civil administration; the United Nations High Commissioner for Refugees-UNHCR for humanitarian assistance, ceased in June 2000; the Organisation for Security and Co-operation in Europe-OSCE for institution building; and the European Union, for reconstruction and economic development).

As already mentioned, following the looting of the Roma Mahala district, which took place in front of the French contingent of KFOR,¹⁴ some IDPs camps were set up for those RAEs who could not escape to other countries: Zhikoc/Žitkovac (operational from 1999 to 2006) Cesminluke/Česmin Lug (operational from 1999 to 2010), Leposaviq/Leposavić (operational from 1999 to 2013), Kablare/Kablar (operational from 2001 to 2006)¹⁵ and Osterode (operational from 2006 to 2012).

With the exception of Leposaviq/Leposavić, all the other camps were established very close to the Trepca mining and smelting complex (the largest producer of zinc and lead in the former Yugoslavia), which included, in the Mitrovicë/Mitrovica area, located near to the camps, also a factory lead smelter and three big tailing dams for storing the waste of mining. The camp of Leposaviq/Leposavić was set up about 25 kilometres north of Mitrovicë/Mitrovica.

Scientific studies carried out since the 1970s, already pointed out that this mining and smelting complex is the cause of environmental pollution and lead contamination of the surrounding areas. It is worth emphasising that severe lead exposure may give rise in adults to increased blood pressure and decreased functions of the kidneys and central nervous system. In children, high level of exposure may cause convulsions, coma and even death; even lower levels of exposure are associated with decreased intelligence, growth and hearing. In addition to the problems of lead contamination, the field conditions were extremely precarious from a health and hygiene point of view due to the frequent lack of running water, electricity, heating, adequate health care or access to food.¹⁶

¹³ *ibid* para 11, j).

¹⁴ See European Roma Rights Centre, 'Abandoned Minority. Roma Rights History in Kosovo', December 2011, 18 <www.errc.org/cms/upload/file/abandoned-minority-roma-rights-history-in-kosovo-dec-2011.pdf>.

¹⁵ Between March and April 2006, some IDPs (about 600 from Zhikoc/Žitkovac and Kablare/Kablar camps), moved to Osterode abandoning their camps which were closed and demolished by UNMIK. A smaller group from Cesminluke/Česmin Lug also move to Osterode, but the camp of Cesminluke/Česmin (only 150 metres away from Osterode), was not dismantled, since about 140 of its residents refused to relocate, thinking that Osterode was as contaminated as Cesminluke/Česmin Lug (see UNMIK Press Release, 'SRSG welcomes start of lead-toxicity treatment for IDPs at Osterode camp', UNMIK/PR/1577, 1 September 2006, at <<https://unmik.unmissions.org/1577-srsg-welcomes-start-lead-toxicity-treatment-idps-camp-osterode>>).

¹⁶ *N.M. and Others v UNMIK*, Opinion (n 6) para 45.

In August 2000, following an environmental audit which qualified Smelter Trepca an 'unacceptable source of air pollution', tests were carried out on KFOR and UNMIK personnel. These tests revealed a worrisome too high Blood Lead Level (BLL), so that the SRSG at the time, Bernard Kouchner, ordered the closure of the plant as a health emergency measure.¹⁷ In other words, KFOR contingents implemented measures (among which the removal from the area) to protect their personnel, but not RAE IDPs.

In November 2000, UNMIK commissioned to two scientists, Sandra Moreno and Andrej Andrejew, a report (*First Phase of Public Health Project on Lead Pollution in Mitrovica Region*) which, although not made public, formed the basis for the report Human Rights Watch (HRW), which stressed, on the one hand, that the lead contamination in the vegetation and the soil samples of Mitrovicë/Mitrovica exceeded the acceptable standards by 176 and 122 times respectively, and, on the other, the worrying rate of BLL in RAE IDPs.¹⁸ Despite the particular gravity of the findings, UNMIK neither took into account the recommendations set out in the Report, nor informed the Security Council, nor did it inform the RAE IDPs of the high level of lead concentration in the camps.

However, in the following years, numerous international organisations (first of all WHO¹⁹ together with United Nations Children's Fund, UNICEF),²⁰ human rights

¹⁷ UNMIK Press Release, 'UNMIK Assumes Responsibility for Operations at Zvečan Smelter', UNMIK/PR/312, 14 August 2000 <unmik.unmissions.org/312-unmik-assumes-responsibility-operations-zvecan-smelter>: 'The people of Mitrovica are at risk because of this smelter', said SRSG Bernard Kouchner. 'As a doctor, as well as chief administrator of Kosovo, I would be derelict if I let this threat to the health of children and pregnant women continue for one more day. Recent tests indicate that current levels of lead exposure are approaching the most extreme in decades. Levels of atmospheric lead measured last month [in July 1999] were around 200 times the World Health Organization's acceptable standards. (...) French tests of atmospheric lead taken in June-July (2000) showed average levels of 250 micrograms per cubic meter, two-thirds higher than acceptable limits for workers' exposure in France'. A report on the so-called *Volcano Operation*, with which the plant was closed, can be read at <www.bulgaria-italia.com/notizie-est/articled09c.asp>.

¹⁸ See Human Rights Watch, 'Poisoned by Lead, a Health and Human Rights Crisis in Mitrovica's Roma Camps', 2009, 23 <www.hrw.org/report/2009/06/23/kosovo-poisoned-lead/health-and-human-rights-crisis-mitrovica-roma-camps>.

¹⁹ World Health Organisation (WHO), office in Pristina issued a 'Preliminary Report on Blood Levels in northern Mitrovica and Zvečan' (July 2004) and a second report on 'Capillary Blood Lead Confirmation and Critical Lead-related Health Situation of the Roma Camps Children' (October 2004). In these two Reports, it emerged that almost a third of the children examined had unacceptable levels of lead in their blood, and in 12 cases the levels were exceptionally high. The WHO stated that '...the Roma case is urgent. Children's lives and development potentials are at risk'. IDP camps were declared uninhabitable by the WHO on the ground that the lead concentration in the soil at the Zhikoc/Zitkovac camp was 100.5 times higher than the recommended levels, while the lead in the soil at the Cesminluke/Cesmin Lug camp was 359.5 times what was considered safe for human health. Because of these conditions, the WHO recommended urgent responses including, 'the immediate closure of the IDP camps and the removal of dust and soil in the immediate surroundings of the Zhikoc/Zitkovac smelter and tailing dam; investigation of possible smelting activities in the camps and their cessation; ensuring access to clean water as a preventative measure in the camps; the immediate removal from the

NGOs (especially Human Rights Watch and Amnesty International),²¹ local human rights institutions (primarily the Ombudsperson Institution in Kosovo)²² and UN and European human rights monitoring mechanisms (among which the UN treaty bodies and Special Rapporteurs,²³ and the Council of Europe Human Rights Commissioner),²⁴ had the possibility to visit and monitor RAE camps since 2005 and defined the situation as the most serious humanitarian and environmental health problem in Europe.

Actions which were carried out by the UNMIK in order to find a solution for such an untenable situation were basically of two kinds. First, the start of a co-funded project for the reconstruction of the Mahala district.²⁵ Secondly, the reconversion of the Osterode barracks, previously used by KFOR, to host, on a voluntary basis, part of the RAE IDPs of the Zhikoc/Žitkovac and Kablare/Kablar camps (which were consequently closed) and a small number of individuals from Cesminluke/Česmin Lug.²⁶

camps, until the confirmation of the results, of pregnant women and children aged up to six years old' (*N.M. and Others v UNMIK*, Case No 26/08, para 73).

²⁰ From January 2005, WHO together with UNICEF, and the United States Centre for Disease Control and Prevention (CDC), started a Blood Lead Surveillance Programme consisting in periodic rounds of blood testing in order to monitor the BLLs of children living in the camps. See CDC, 'Recommendations for Preventing Lead Poisoning among the Internally Displaced Roma Population in Kosovo from the Centers for Disease Control and Prevention' (October 2007) and 'Evaluation and Recommendations for Preventing Lead Poisoning among the Internally Displaced Roma Population in Kosovo from the Centers for Disease Control and Prevention' (January 2011).

²¹ Amnesty International, *The UN in Kosovo: A legacy of impunity*, 2006. The report is available at <www.amnesty.org/download/Documents/76000/eur700152006en.pdf>.

²² Ombudsperson Institution in Kosovo, 'Fifth Annual Report to the Special Representative of the Secretary-General of the United Nations', 11 July 2005, 35, where the Ombudsperson described the living conditions in the camps of Zhikoc/Žitkovac, Kablare/Kablar and Cesminluke/Česmin Lug as 'appalling ... marked by poverty, malnutrition and a lack of the most basic hygiene and health services', therefore calling on the authorities to evacuate the camps immediately as a separate measure from any plans of reconstruction of the Roma Mahala.

²³ In October 2005, the UN Special Rapporteur on the rights of IDPs expressed his shock to see that the RAE IDPs had been settled on "highly contaminated land" and appealed to the international community to immediately evacuate the camps: see 'A comprehensive review of the situation in Kosovo', Report of the Special Envoy of the Secretary-General, Kai Eide, UN Document S/2005/635, 7 October 2005.

²⁴ 'Report of the Council of Europe Commissioner for Human Rights' Special Mission to Kosovo (23-27 March 2009)', CommDH(2009)23, Strasbourg, 2 July 2009, para 146.

²⁵ See *N.M. and Others v UNMIK*, Opinion (n 6) para 55: 'In mid-2005, UNMIK established the Mitrovicë/Mitrovica Action Team, a task-force comprising members from UNHCR, UNICEF, WHO and the OSCE, to coordinate efforts aimed at decreasing lead exposure of the IDPs, while organising their evacuation from the contaminated camps. After difficult negotiations, on 18 April 2005, the "Return to Roma Mahala Agreement" was signed between UNMIK, the OSCE, UNHCR and the Municipality of Mitrovicë/Mitrovica to allow and support the return of the IDPs who originated from the former Mahala to new homes to be built with donors' contributions in the area of the Mahala. No RAE representative agreed to sign the agreement'.

²⁶ Although, as already mentioned in footnote 15, the camp of Osterode was only about 150 metres away from that of Cesminluke/Česmin Lug, the WHO held that the camp was "safer" because of the

In the Osterode camp, a small health facility was set up, with a doctor and two nurses, with the task to carry out regular tests and provide children with high BLL chelation treatment, a therapy aimed at removing lead from blood, which requires, during convalescence, the transfer of patients into a lead-free environment, since, conversely, in a contaminated environment, their bodies would absorb even greater amounts of this lethal metal, with consequent greater health risks. Therefore, until October 2007, the therapy was provided on emergency grounds, on the basis of the promise that all RAE IDPs would be transferred within six months: which, as already mentioned, did not occur at all, given that the Osterode camp was closed only in December 2012.

After the unilateral declaration of independence of Kosovo, in May 2008 the responsibility for the management of the Osterode and Cesminluka/Česmin Lug camps shifted from UNMIK to the Kosovo Ministry of Communities and Returns of the Provisional Institutions for Self-Government.

3. Analysis of the Opinion of the Human Rights Advisory Panel in Kosovo on the N. M. and Others v. UNMIK Affair

On the basis of these facts, on 4 July 2008, 138 members of the RAE community in Kosovo submitted a request to the Human Rights Advisory Panel (the Panel),²⁷ claiming that UNMIK violated their human rights by placing them in camps known to be highly contaminated, without informing them about the health risks or the required medical treatment, as well as by failing to relocate them to a safe place.²⁸

cement flooring, the absence of lead painted doors – as were found in other camps – and general better hygienic conditions, in particular due to the presence of running water. See ‘SRSG welcomes start of lead-toxicity treatment for IDPs in Camp Osterode’, UNMIK/PR/1577, 1 September 2006 (<<https://unmik.unmissions.org/1577-srsg-welcomes-start-lead-toxicity-treatment-idps-camp-osterode>>).

²⁷ Although, on 5 June 2009, the appeal was declared partially admissible, the Panel subsequently refrained from examining the matter, affirming its momentary incompetence in application of the Administrative Direction No 2009/1 Implementing UNMIK Regulation No 2006/12 on the Establishment of the Human Rights Advisory Panel. In fact, since the regulation provided for a cut-off date expiring on 31 March 2010, the Panel could not proceed with the examination of the requests submitted or likely to be submitted to the third-party claim commission procedure. However, the Panel suggested that, if the applicants had not been able to activate such a claim commission procedure, ‘such a result would offend basic notions of justice’, and, after the procedure had ended, the Panel itself invited the applicants to claim again for reopening the process, which happened on 10 November 2010. See *N.M. and Others v. UNMIK*, Decision, 31 March 2010 <www.unmikonline.org/hrap/Eng/Cases%20Eng/DC_No_26-08-2.pdf>. On the evolution of these procedural questions, see *N.M. and Others v UNMIK*, Opinion (n 6) Proceedings before the Panel: paras 1-36.

²⁸ At the time of the submission to the Panel, about half of the 138 complainants were children; 75 were women and girls, and since at least 13 of them delivered babies in the camps, they filed the request also on behalf of their children. All applicants claimed to have suffered lead poisoning and health problems, on

The Panel rejected the argument, held by the Secretary General, according to which ‘UNMIK cannot be held accountable for a situation that existed for decades prior to its establishment [and that, vice versa] UNMIK had done everything within its power to end’.²⁹ In fact, the Panel observed that, ‘based on the documents made available to it, UNMIK also knew, or should have known, that the main source of exposure to lead was the proximity of the camps’.³⁰ In other words, UNMIK, could not but know the situation of the camps and the risks existing for those who had been transferred there; therefore it should have foreseen appropriate measures instead remaining inactive. Given the full awareness of the contamination problem, though admitting the initial “urgent need” to offer a place in order to rescue the said minorities from the looting of the Mahala, the first timid attempts by UNMIK – which proved however to be counterproductive –, to find a solution to the problem of the environmental health risk in the camps by transferring people to nearby sites, took place after five years of exposure to the poisoning. Furthermore, it does not seem that the transfer of RAEs to the notoriously contaminated fields respected the cumulative requirements indicated by the Secretary-General himself. In particular, in order to be legitimate, the measure shall be linked to the objectives and the content of the mandate, in the light of the specific situation; it shall be based on an assessment not of mere convenience or opportunity; it shall be determined by the absence of other options; there must be proportionality between what is strictly necessary for the achievement of the objectives and the damage caused by the pursuit thereof.³¹

the one hand, because of the soil contamination in the camps due to their proximity to the Trepča smelter and mining complex, and on the other hand, because of their very poor hygiene and living conditions. Four complainants stated that their family members died in the camps as a result of lead poisoning: see ‘Eighth Annual Report of the Human Rights Advisory Panel 2015/2016’ <www.europarl.europa.eu/meetdocs/2014_2019/documents/dsee/dv/09_hr_advisory/09_hr_advisoryen.pdf> paras 68-69.

²⁹ *N.M. and Others v UNMIK*, Opinion (n 6) para 151.

³⁰ *ibid* para 210.

³¹ It is true that ‘consensual peacekeeping operations are conducted for the benefit of the country in whose territory they are deployed, and that having expressly or implicitly agreed to the deployment of a peacekeeping operation in its territory, the host country must be deemed to bear the risk of the operation and assume, in part at least, liability for damage arising from such an operation’ (‘Report of the Secretary-General to the General Assembly’, 21 May 1997, Doc A/51/903, para 12). But it is also true that operational necessity works ‘as an exemption from liability, or a legitimization of an act that would otherwise be considered unlawful [so that] the liability of the Organization for property loss and damage caused by United Nations forces in the ordinary operation of the force is subject to the exception of “operational necessity”, that is, where damage results from necessary actions taken by a peacekeeping force in the course of carrying out its operations in pursuance of its mandates’. The difficult determination of ‘what would constitute “operational necessity” in any given situation ... must remain within the discretionary power of the force commander, who must attempt to strike a balance between the operational necessity of the force and the respect for private property. Therefore, in this determination, ‘the following must be taken into account: (a) There must be a good-faith conviction on the part of the force commander that an “operational necessity” exists; (b) The operational need that prompted the action must be strictly necessary and not a matter of mere convenience or expediency. It must also leave little or no time for the commander to pursue another, less destructive option; (c) The act must be executed in pursuance of an operational plan and not the result of a rash individual action; (d) The damage

From the foregoing, it can be said that the measures adopted by UNMIK were not the most appropriate for the prevention and treatment of health damage arising from environmental pollution in contaminated sites. This omission and highly negligent behaviour appear even more serious if one considers that the UNMIK broad mandate of direct territorial administration expressly included the protection of human and minority rights.³² The mandate, therefore, (based and) centred on the protection of human rights, directed – *rectius*: should have directed – the activity of the Administration in the wake of the respect and promotion of individual rights which, since they constitute the ultimate goal of each peacekeeping mission, in the opinion of the present writer, define the operational scope thereof.³³ The right to health stands out in the group of individual rights, as it is guaranteed by the well-known acts referred to in the mandate of the Mission and by the relevant internal rules as well.³⁴ In the opinion of the present writer, therefore, in particular the position of Patricia O'Brien, Under Secretary-General for Legal Affairs, according to which 'while having *no legal obligation* to do so, UNMIK has taken substantial steps to improve the condition of the IDP population',³⁵ seems completely untenable, both be-

caused should be proportional to what is strictly necessary in order to achieve the operational goal' ('Report of the Secretary-General to the General Assembly', 20 September 1996, Doc. A/51/389).

³² Under UNMIK Regulation No 1999/1 on 25 July 1999, in exercising its functions UNMIK had the obligation to respect internationally recognised human rights standards. The details of this commitment can be read in UNMIK Regulation No 1999/24 of 12 December 1999, where UNMIK undertook specific obligations under the following human rights instruments: the Universal Declaration of Human Rights, the European Convention on Human Rights and Protocols thereto, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination Against Women, the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, the Convention on the Rights of the Child (see <www.unmikonline.org/regulations/1999/re1999_24.htm>).

³³ It seems to us that this clearly emerges from several UN documents variously referred to in the *Memorandums of Understanding* between the United Nations and the contingent-providing States in United Nations Peacekeeping Operation: see 'Principles and Guidelines' (so called "Capstone Doctrine"), 2008 (<https://peacekeeping.un.org/sites/default/files/peacekeeping/en/capstone_eng.pdf>), as well the Report 'Human Rights Due Diligence Policy on United Nations Support to Non-United Nations Security Forces', (Doc A/67/775-S/2013/110, 5 March 2013 <<https://undocs.org/A/67/775>>), the guideline 'United Nations Police in Peacekeeping Operations and Special Political Missions' (1 February 2014, Review 1 February 2017 <<https://police.un.org/sites/default/files/sgf-policy-police-2014.pdf>>). In general, on peacekeeping policy and guidance materials see <<https://peacekeeping.un.org/en/policy-and-guidance>>.

³⁴ On the right to health see, among others, Stefania Negri, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale* (Giappichelli 2018); Pia Acconci, *Tutela della salute e diritto internazionale* (Cedam 2011).

³⁵ Letter of Patricia O'Brien, Under Secretary-General for Legal Affairs, 25 July 2011 <www.sivola.net/download/UN%20Rejection.pdf> (emphasis added). In the Letter, the admissibility of the claims is rejected under Section 29 of the General Convention or General Assembly Resolution A/RES/52/247, on the ground of two arguments. Firstly, the requests «involved alleged widespread health and environmental risks arising in the context of the precarious security situation in Kosovo». Secondly, the claims have no private law character, so that their examination would 'amount to a review of the performance of UNMIK's mandate as the interim administration in Kosovo'. As already men-

cause precise legal obligations were assigned to UNMIK, as it emerges from the Mission's mandate, and because the measures taken in order to improve the conditions of the RAE IDPs were late, insufficient and – sometimes – counterproductive.³⁶ It is also unacceptable that the SRSG's allegation that the health crises in the camps was due to the "unhealthy" life-style of the RAE IDPs, an allegation expressly tainted by racial prejudice, and certainly not objective and reasonable justification, contradicted by scientific evidence.³⁷

The Advisory Panel has therefore stressed that UNMIK has violated numerous international guarantees of RAE IDPs such as the right to life,³⁸ prohibition of torture and inhuman or degrading treatment,³⁹ right to respect for private and family life,⁴⁰ children's rights with specific regard to health,⁴¹ prohibition of discrimination

tioned in footnote 27, the refusal to submit the claims to a United Nations Third Party Claims Process allowed to resume the procedure before the Human Rights Advisory Panel.

³⁶ In line with such a recalcitrant position, it shall be stressed that 'no documentation has been submitted by UNMIK to the Panel, notwithstanding the special knowledge that UNMIK had or should have had about the health situation in the camps and despite the Panel's repeated requests to submit especially those documents referred to or relied upon by the SRSG and considered that it could justly draw "strong inference" from the available documentation in this case': in 'Eighth Annual Report of the Human Rights Advisory Panel' (n 28) para 70.

³⁷ *N.M. and Others v UNMIK*, Opinion (n 6) para 302.

³⁸ The Panel, in fact, stated that 'the record showed that the heavy exposure to contamination, coupled with poor living conditions in the camps had been such as to pose a real and immediate threat to the complainants' life and physical integrity'. See *Final Report* (n 7) para 53.

³⁹ As regards to the prohibition of torture and inhuman or degrading treatment «the Panel did not exclude UNMIK's responsibility towards the complainants, especially when considering that the situation complained of had lasted for more than ten years»: see *Final Report* (n 7) para 55. In the opinion of the Panel, 'the marginalisation of the Roma and the traumatic experiences which led to their IDP status in Kosovo made the complainants especially vulnerable to inhuman and degrading treatment and UNMIK was responsible for their well-being': *N.M. and Others v UNMIK*, Opinion (n 6) para 244.

⁴⁰ The lack of access to relevant information affected also the reproductive rights of many women in the camps, in particular those pregnant women who, as a consequence of lead poisoning, reportedly incurred self-abortion or miscarriage. Further, UNMIK affirmed to have given priority to other political, security or economic issues, as a justification of its failure to take proper actions in order to prevent the complainants from the environmental hazards they were exposed to. With regard to the relocation of the complainants to a safe area, the Panel acknowledged UNMIK's efforts to accommodate them, but considered that no sufficient evidence was given to prove that a safer relocation was impeded by pressing difficulties making it a disproportionate burden. Therefore, 'the Panel considered that UNMIK did not succeed in striking a fair balance between the interests of the community and the complainants' enjoyment of their rights to respect for private and family life': *N.M. and Others v UNMIK*, Opinion (n 6) para 259.

⁴¹ The Panel found that the actions taken by UNMIK in order to fulfil its obligation under the International Convention on the Rights of the Child (CRC) were insufficient and inadequate. UNMIK's response to the situation should have been directed by the overriding interest of the lives and health of children; nor UNMIK did explain how the best interest of the children in the camps was pursued, assessed or determined in the decision and implementation of the measures to face with the situation in the camps. Consequently, the Panel stated that 'through its actions and omissions, UNMIK was responsible for compromising irreversibly the life, health and development potential of children who were born and grew up in the camps': *N.M. and Others v UNMIK*, Opinion (n 6) paras

against members of minority communities, prohibition of violence and discrimination against women.⁴²

In particular, as regards the violation of the right to health, on the one hand, the Panel stated that UNMIK, through systematic blood testing, should have monitored the lead contamination in the camps; and on the other hand, it held that UNMIK carried out appropriate therapy only for a too short time, if compared with the fact that UNMIK was fully aware of the high health risks provoked by lead poisoning in particular to pregnant women and children.

In the light of these considerations, the Panel called upon UNMIK to give a public apology, both to the complainants and their families and through media, for failing to comply with applicable human rights standards while responding to the adverse health condition caused by lead contamination in the IDP camps and for the consequent harms suffered by the complainants. In addition, the Panel invited UNMIK to award adequate compensation for pecuniary and non-pecuniary damage according to the finding of the violations of the human rights provisions listed in the Opinion.⁴³

4. Concluding Remarks on the UN Failure to Implement the Recommendations of the Human Rights Advisory Panel, Notwithstanding the Latest Discomforting Developments

Responding to the Opinion of the Panel, on 22 April 2016, the Special Representative to Secretary-General issued a statement expressing his 'regret regarding the adverse health conditions suffered by the complainants and their families at the IDP camps', but neither gave his apologies, nor did even mention the question of providing financial compensation.⁴⁴ As a matter of fact, despite a number of decisions of a

340 ff. and quoting from para 347.

⁴² The Panel held that conditions which in lead contamination camps favoured self-abortion by female IDPs in order to avoid delivery of babies affected by abnormalities, amounted to a form of gender-based violence: *Final Report* (n 7) para 51.

⁴³ A further recommendation by the Panel was that 'UNMIK take appropriate steps to ensure that UN bodies working with refugees and IDPs promote and ensure respect for international human rights standards and that the findings and recommendations of the Panel in this case are shared with such bodies, as a guarantee of non-repetition'; and, in addition, both that 'UNMIK take appropriate steps towards UN bodies to ensure effective distribution of information relevant to the health and well-being of people under their authority and control', and that 'UNMIK urge UN bodies and relevant authorities in Kosovo to protect and promote the human rights of Roma people, especially women and children': see *N.M. and Others v UNMIK*, Opinion (n 6) para 349 letters d, g, and f, respectively.

⁴⁴ See 'SRSG's Decision in the complaint of N.M. and Others (no. 26/08)', 28 April 2016 <www.unmikonline.org/hrap/Eng/Cases%20Eng/SRSGs%20Decision%2026-08.pdf>.

different sign on cases where the responsibility of UN peacekeeping forces was at stake,⁴⁵ in May 2017, ‘in view of the unique circumstances in Kosovo’, the Secretary-General has decided, ‘as an exceptional measure’, to establish a voluntary contribution Trust Fund, whose resources will be allocated to financial assistance projects from ‘which [...] more broadly the Roma, Ashkali and Egyptian communities’ will benefit, thus not intending specifically the victims of lead poisoning.⁴⁶ Essentially, the United Nations, far from complying with the Panel’s recommendations, have ruled out the question of assuming the harm suffered by RAE IDPs, and not only did not offer adequate reparation to the victims and their families through individual compensation, but did not even give their public apologies.

On 11 July 2018, UN Special Rapporteur on toxics addressed an open letter to the Secretary General ‘asking for updates regarding the operation and funding of the Trust Fund established in July 2017 and charged with implementing community-based assistance projects in several municipalities of Kosovo’, recalling the need to individually compensate the victims of lead poisoning; but on 5 October 2018, replying to this letter, the Under-Secretary-General for Peacekeeping Operations affirmed that, ‘despite targeted outreach and resource mobilization campaigns by a UN Task Force encouraging contributions to the Trust Fund, “no contribution has yet been received from the international community in response to these appeals”’.⁴⁷

In November 2018, a Resolution of the European Parliament also called on the UN ‘to swiftly deliver the necessary support to the victims of lead poisoning in some refugee camps set up in Kosovo’.⁴⁸

Later, on 31 January 2019, fifty-five members of the European Parliament wrote a letter to UN Secretary General Antonio Guterres, inviting him to ‘take long overdue steps to ensure that the victims of widespread lead poisoning at UN-run camps in Kosovo receive individual compensation, adequate health care and educational

⁴⁵ In compliance with another Opinion of the Human Rights Advisory Panel, UNMIK awarded compensation to the families of two men killed and others wounded by peacekeepers during a protest in 2007: see the case *Kadri Balaj, Shaban Xheladini, Zenel Zeneli and Mustafë Nerjovaj v UNMIK* (No 04/07), 27 February 2015 <www.unmikonline.org/hrap/Eng/Cases%20Eng/04_07%20Balaj%20Opinion%20FINAL%20rev2mar15.pdf>.

⁴⁶ ‘Statement attributable to Stéphane Dujarric, Spokesman for the Secretary-General on the Human Rights Advisory Panel’s recommendations on Kosovo, 26 May 2017’ <www.un.org/sg/en/content/sg/statement/2017-05-26/statement-attributable-spokesman-secretary-general-human-rights>.

⁴⁷ Baskut Tuncak, Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes, 23 November 2018, OL OTH 69/2018 <www.ohchr.org/Documents/Issues/ToxicWastes/Communications/OL_OTH_23.11.2018_69.2018.pdf>. The situation does not seem to have changed yet: see Filip Rudic, ‘UN Fund for Kosovo Poisoning Victims Receives No Contributions’, 1 February 2019, *BalkanInsight* <<https://balkaninsight.com/2019/02/01/un-fund-for-kosovo-poisoning-victims-receives-no-contributions-02-01-2019/>>.

⁴⁸ European Parliament resolution of 29 November 2018 on the 2018 Commission Report on Kosovo (2018/2149(INI)), para 43 <www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2018-0479+0+DOC+XML+V0//EN&language=GA>.

support'. In this Letter, it is affirmed that the UN's response to the situation had been "inadequate", and the Organisation is harshly reproached of 'falling short of offering individual compensation and specifically targeting those affected by lead poisoning [so that] it is essential that the UN (...ensure) full, effective and transparent remedy, including individual compensation for victims, pursuant to established human rights standards'.⁴⁹

In conclusion, although in 2016 the UN Human Rights Advisory Panel clearly stated that UNMIK violated the victims' rights to life and health, and invited the Organisation to take adequate compensation, until now there is but a deafening silence by the Organization regarding the willingness to comply with these recommendations and assuming direct responsibility for what happened. This raises in the present writer an alarming question: if the yearning for justice and truth, which is the real test of the effectiveness of the fundamental rights of the individual in front of the exercise of a public, organised power, succumbs and is silenced by the Organization which *par excellence* should protect and exalt it, how can – in a credible and authoritative way – the United Nations ask the international community, in general, and their members, in particular, to respect it?

⁴⁹ The Letter can be read at <<https://feministinitiative.eu/assets/uploads/2019/01/letter-to-mr-un-secretary-general.pdf>>. See also Katharina Rall, 'EU Legislators Urge UN to Compensate Kosovo Lead Poisoning Victims', 1 February 2019, Human Rights Watch <www.hrw.org/news/2019/02/01/eu-legislators-urge-un-compensate-kosovo-lead-poisoning-victims>.