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The Future of Environmental Law:  
International and European Perspectives

**WORKING GROUP ON ENVIRONMENTAL LAW  
COLLECTED REPORTS 2004 - 2005**



**EUROPEAN UNIVERSITY INSTITUTE**

Department of Law

**EUROPEAN UNIVERSITY INSTITUTE  
DEPARTMENT OF LAW**

*The Future of Environmental Law: International and European Perspectives*

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## **ABSTRACT**

The materials collected in this Working Paper are the result of intensive and interactive discussions that took place in the Working Group on Environmental Law of the European University Institute during the 2004-2005 academic year. The contributions consider recent developments in environmental law and offer an international or European perspective on the future in the areas of: sustainable development, the reform of the United Nations, climate change, biodiversity and biotechnology, environmental justice and environmental liability.

## **KEYWORDS**

Environmental law, sustainable development, United Nations, climate change, biotechnology, environmental justice, environmental liability, precautionary principle, Aarhus Convention



## Introduction

The Working Group on Environmental Law (WGEL) was established in spring 2004 by a group of researchers at the European University Institute (EUI), whose Ph.D. research focuses on different aspects of international, European or comparative environmental law.

The WGEL objectives are:

- providing updates on the developments of environmental law at the national, European and international level;
- information sharing on research sources, publication opportunities, and conferences/events concerning environmental law; and
- keeping environmental law on the agenda of the European University Institute.

Three meetings were convened from March to June 2004, when the Working Group mainly exchanged information on web links, bibliography, contacts, and discussed some case law. Since autumn 2004, WGEL started meeting regularly with presentations given by participants and visiting professors, and debates on substantive issues of environmental law. The discussions were often enriched by the presence of guest professors from the EUI and Italian universities, as well as EUI visiting fellows. The Working Group has proved to be a highly useful and interactive forum for researchers to present their thesis, as well as exchange ideas and address emerging issues. The working languages of the Working Group are English, Italian, and French. WGEL is particularly grateful to EUI Prof. Francesco Francioni for his continuous personal contribution to the discussions of the Working Group.

The Working Paper hereinafter is thus a synthetic collection of some of the presentations that took place among the WGEL between the months of November 2004 and June 2005.

## WGEL members

### *EUI Researchers*

- Hélène Boussard, *Human Genome and the Relation between Ethics and Law*
- Patrycja Dabrowska, *New Governance and Regulation of GMOs in the EU*
- Sofia de Abreu Ferreira, *Aarhus Convention and EU Law*
- Hanne Birgitte Jensen, *From Economic to Sustainable Development*
- Elisa Morgera, *Corporate Accountability and International Environmental Law*
- Emanuela Orlando, *Environmental Liability Instruments, EU Law and the International Perspective*
- Patricia Quillacq, *Comparative Study on the Principle of Public Participation in Environmental Planning*
- Aphrodite Smagadi, *Natural Plant Genetic Resources and Benefit-Sharing*
- Virginie Barral, *Sustainable Development and International Law*
- Chien-Huei Wu, *Judicial Review of Legal Measures concerning External Trade*

### *EUI Professors*

- Francesco Francioni, Professor of International Law and Human Rights
- Pierre-Marie Dupuy, Professor of International Law
- Fabrizio Cafaggi, Professor of Comparative Law
- Christian Joerges, Professor of Economic Law

### *Visiting professors and other guest speakers*

- Prof. Massimiliano Montini, Università di Siena, Italy
- Prof. Riccardo Pavoni, Università di Siena, Italy
- Dott. Federico Lenzerini, Università di Siena, Italy
- Prof. Han Somsen, University of Amsterdam, Netherlands
- Kati Kulovesi, visiting researcher, London School of Economics, UK

- Bettina Lange, Jean Monnet Fellow
- Francesca De Vittor, EUI Jean Monnet Fellow

### **Meetings and Agenda of the Working Group on Environmental Law**

#### **30/11/2004**

- Main characteristics of the 2004 EU Directive on Environmental Liability, Emanuela Orlando
- Latest Developments on Plant Genetic Resources, Elisa Morgera
- Recent Case Law of the Court of First Instance about the Precautionary Principle (Pfizer and Artogodan cases), Patricia Quillacq

#### **27/01/2005**

- Overview of Environmental Law in Italy, Prof. Massimiliano Montini
- Climate Change Regime: Recent Developments and National Legislation Issues, Prof. Massimiliano Montini
- Mauritius International Meeting: SIDS +10, Elisa Morgera

#### **24/02/2005**

- The Environment in the Report of the UN High-Level Panel of Experts on Threats, Challenges and Change, Elisa Morgera

#### **23/03/2005**

- Biodiversity and Biotechnology, Aphrodite Smagadi and Prof. Riccardo Pavoni

#### **21/04/2005**

- UNFCCC COP-10, Kati Kulovesi
- From Economic to Sustainable Development, Hanne Birgitte Jensen

#### **19/05/2005**

- UN Reforms: Elisa Morgera, Prof. P.-M. Dupuy, Prof. F. Francioni, Prof. Riccardo Pavoni and Federico Lenzerini
- The Working Group on Environment and Human Rights at the Council of Europe, Patricia Quillacq

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Many sincere thanks are also due to those that participated in the collective review of the papers submitted: H  l  ne Boussard, Patrycja Dabrowska, Sofia de Abreu Ferreira, Chien-Huei Wu, Francesca De Vittor, Hanne Birgitte Jensen, Kati Kulovesi, Federico Lenzerini, Massimiliano Montini, Elisa Morgera, Emanuela Orlando, Riccardo Pavoni, Patricia Quillaq, and Aphrodite Smagadi.

The Working Group on Environmental Law is extremely grateful to Prof. Francesco Francioni and Pierre-Marie Dupuy for their support and involvement in the Working Group and in the publication of its Working Paper, and to Mario Mendez for his language supervision.

The contributions contained in this Working Group are updated to 1 September 2005.

For more information on the activities of the EUI Working Group on Environmental Law and for accessing its online documents, including periodic Environmental Law Newsletters, please visit <http://www.iue.it/LAW/WorkingGroupOnEnvironmentalLaw.shtml>.

### List of acronyms

<b>AB</b>	Appellate Body
<b>BPOA</b>	Barbados Plan of Action
<b>BSP</b>	Biosafety Protocol
<b>CBD</b>	Convention on Biological Diversity
<b>CFI</b>	Court of First Instance
<b>CHM</b>	Common Heritage of Mankind
<b>CMD</b>	Clean Development Mechanism
<b>COP</b>	Conference of the Parties
<b>EC</b>	European Community
<b>ECCP</b>	European Climate Change Programme
<b>ECHR</b>	European Convention on Human Rights
<b>ECJ</b>	European Court of Justice
<b>ECtHR</b>	European Court of Human Rights
<b>ELD</b>	Environmental Liability Directive
<b>ETS</b>	Emissions Trading Scheme
<b>EU</b>	European Union
<b>EUI</b>	European University Institute
<b>FAO</b>	Food and Agriculture Organization
<b>GA</b>	General Assembly
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>UNDHR</b>	United Nations Declaration on Human Rights
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>GEF</b>	Global Environment Facility
<b>GHG</b>	Greenhouse Gases
<b>GMOs</b>	Genetically Modified Organisms
<b>HGR</b>	Human Genetic Resources
<b>ILA</b>	International Law Association
<b>IMO</b>	International Maritime Organization
<b>IMPTEL</b>	Implementation and Enforcement of Environmental Law
<b>ISDL</b>	International Sustainable Development Law
<b>IU</b>	International Undertaking
<b>JI</b>	Joint Implementation
<b>KP</b>	Kyoto Protocol
<b>LDCs</b>	Least Developed Countries
<b>LMOs</b>	Living Modified Organisms
<b>MA</b>	Millennium Ecosystem Assessment
<b>MDGs</b>	Millennium Development Goals
<b>MEAs</b>	Multilateral Environmental Agreements
<b>MET</b>	Ministry for Environment and Territory, Italy
<b>MOP</b>	Meeting of the Parties
<b>NGOs</b>	Non-Governmental Organizations
<b>NPGR</b>	Natural Plant Genetic Resources
<b>NRP</b>	National Plan for the Reduction of Greenhouse Gases
<b>ODA</b>	Official Development Assistance
<b>OECD</b>	Organization for Economic Cooperation and Development
<b>PP</b>	Precautionary Principle
<b>SIDS</b>	Small Island Developing States
<b>SPS</b>	Sanitary and Phytosanitary Measures
<b>TBT</b>	Technical Barriers to Trade
<b>TRIPs</b>	Trade-Related Aspects of Intellectual Property Rights
<b>UDBHR</b>	Universal Declaration on Bioethics and Human Rights

<b>UDHGHR</b>	Universal Declaration on the Human Genome and Human Rights
<b>UN</b>	United Nations
<b>UNCED</b>	United Nations Conference on Environment and Development
<b>UNCLOS</b>	United Nations Convention on the Law of the Sea
<b>UNDP</b>	United Nations Development Programme
<b>UNEO</b>	United Nations Environment Organization
<b>UNEP</b>	United Nations Environment Programme
<b>UNESCO</b>	United Nations Educational, Scientific and Cultural Organization
<b>UNFCCC</b>	United Nations Framework Convention on Climate Change
<b>WCED</b>	World Commission on Environment and Development
<b>WEO</b>	World Environment Organization
<b>WGEL</b>	Working Group on Environmental Law
<b>WIPO</b>	World Intellectual Property Organization
<b>WSSD</b>	World Summit on Sustainable Development
<b>WTO</b>	World Trade Organization

## Preface

Prof. Francesco Francioni<sup>1</sup>

The materials collected in this Working Paper are the result of intensive and interactive discussions that took place in the Working Group on Environmental Law (WGEL) during the 2004-2005 academic year. It was a pleasure and a learning experience for me to be associated with the WGEL and with the enthusiastic and dedicated team of researchers that animated it. It is a privilege now to provide a brief introduction to the seven chapters in which the material has been organized.

In the first chapter, H.B. Jensen examines the impact of the principle of sustainable development on the processes of law formation, and argues in favour of a new conceptualization of law as a regulatory phenomenon, whose sources and constitutive elements are to be found not in a formal and hierarchical idea of authority but rather in the continuous interaction between society, on the one hand, and science and technology, on the other.

E Morgera provides two interesting and timely contributions to the Working Paper. The first is a lucid analysis of the 2005 Mauritius International Meeting on Small Island Developing States, in the aftermath of the tsunami disaster, and on a number of timely environmental issues including climate change, hazardous waste and transport of radioactive material. The second concerns the outcome (and shortcomings) of the 2005 World Summit on the reform of the United Nations Charter, focusing on the initiatives, and missed opportunities, relating to the improvement of the system of global environmental governance.

On the same issue of the UN Charter reform, F. Lenzerini illustrates in detail the different options examined in the preliminary study carried out at the EUI on the establishment of a United Nations Environmental Organization to reinforce the system of global environmental governance. He explains the reason why a new specialized organization, under the umbrella of the UN, would be preferable to a) a minimalist solution based on the enhancement of UNEP, and b) the creation of an independent World Environmental Organization on the model of the WTO.

On the contentious issue of climate change, K. Kulovesi reports from the 2005 Buenos Aires meeting of the Conference of the Parties to the UN Framework Convention and from the following governmental experts seminar held in Bonn in May 2005. She tries to delineate a road map for future progress at a time when the Kyoto Protocol is entering into force but at the same time is under strain because of the increasing demand of energy and because of the continuing reluctance by the single most important emitter of greenhouse gases.

On the same subject, M. Montini provides a useful update on the progress made in the implementation of the Kyoto Protocol in the European Union and in Italy, through the “burden sharing” mechanism introduced by the EC Council Decision of June 1998.

A. Smagadi and H. Boussard address, in a joint contribution, the complex issues of access to and benefit-sharing from biogenetic resources. With regard to plant genetic material, A. Smagadi convincingly points out the risk of unmanageable multiple claims to exclusive control over genetic resources (the “tragedy of anti-commons”) and argues in favour of a flexible international regime that may leave ample margin of discretion to accommodate different local circumstances through bilateral or regional agreements. H. Boussard, on her part, examines the complex interface of law and ethics in the regulation of human genetic resources, and argues in favour of a public law model of regulation based on the fundamental principle of human genetic resources as heritage of humankind, rather than on a private law model of property rights and commodification of the building blocks of human life.

R. Pavoni’s paper attempts to bring unity and coherence in the fragmented legal regime of biotechnology, by identifying four general principles around which consolidation of the different regulatory approaches is deemed possible and desirable. These principles are the common concern of humankind, benefit-sharing, precaution, and mutual supportiveness. Even though the normative content of such principles remains vague and their legal force still debated, the author articulates a convincing argument in favour of their standard-setting role in international

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<sup>11</sup> Professor of International Law and Human Rights, European University Institute, Florence, Italy.

law and, possibly, in the future process of elaboration and adoption of a comprehensive treaty on the regulation of biotechnology.

In their substantial contribution on the principle of precaution, P. Dabrowska and P. Quillacq analyse with painstaking detail a set of important cases decided by the European Court of Justice and the Court of First Instance, reaching the conclusion that the EU jurisprudence provides a significant contribution to the clarification of the legal parameters of the precautionary approach. At the same time, the authors demonstrate that the standard of review adopted by the European Court remain more deferential to Community's institutions than the one adopted by the Court of First Instance. Besides, the analysis demonstrates that the judicial review of the justification of member States' measures under the precautionary principle is conducted with considerable self-restraint by the European Court of justice, thus leaving a wide margin of uncertainty on the meaning of what is the "most reliable scientific evidence" invoked to justify trade restrictive measures.

In the chapter devoted to the Aarhus Convention, the first part, written by P. Quillacq, examines the extent to which participation and access to justice under this treaty have become a component of substantive human rights under the European Convention on Human Rights, especially Articles 2, 6, 8 and 10. The second part of the chapter, written by S. de Abreu Ferreira, addresses the very timely topic of public participation in the decisions concerning the use of genetically modified organisms (GMOs) and traces the origin and development of the 2005 amendment to the Aarhus Convention, which now requires as a matter of legal obligation participation by the public in the process of authorization for the deliberate release of GMOs.

Finally, in the last chapter, E. Orlando discusses the 2004 EU Directive on liability for environmental harm, which she correctly construes as a *sui generis* regulatory instrument of administrative environmental governance, rather than a classical instrument of harmonization of laws in the area of civil liability. The contribution provides also a pragmatic assessment of foreseeable obstacles in its practical implementation, especially after the enlargement of the EU to 25 member States.

As a whole, this Working Paper provides a valuable, up-to-date analytical contribution to a broad range of critical issues in the area of environmental governance. It deserves praise and appreciation for the professional standards and dedication shown by all members of the Working Group both in the oral proceedings and in the preparation of these written reports.

## **Sustainable Development**

## Sustainable Development: Paradigm Shift or just Another Field of Law?

Hanne Birgitte Jensen\*

This contribution demonstrates how an awareness of the implications of pollution and degradation of natural resources over a period of 30-40 years has resulted in the establishment of a wholly new sector of environmental protection and how, by the end of the century, that awareness began an evolution toward an articulation of the need for a global development process of a different quality, a process termed sustainable development that encompasses environmental, social and economic aspects. The legal discipline has responded to the challenges by developing tools and mechanisms for environmental protection and management and legal principles for sustainable development. In what follows, I present the emergent field of international sustainable development law in some detail, as it is a novel phenomenon. Within this context, I introduce my current EUI research on the idea of enlarging the concept of law from within the perspective of sustainable development as a jurisprudential response to the challenges of global change towards sustainable development.

### 1. From environmental protection to sustainable development

In 1987, when the World Commission on Environment and Development (WCED) published its report *Our Common Future*,<sup>2</sup> the environment had evolved from a stage of mere conceptualization to a well-established sector internationally as well as in the national context.<sup>3</sup> *Our Common Future*, aka the Brundtland report, launched the idea of sustainable development characterizing it as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs." In 1992, at the Earth Summit<sup>4</sup> (UNCED) in Rio, the idea of sustainable development was firmly established as a global policy concept. Rooted in the recognition of the scientifically based reality of ecological interdependence and its global implications, the sustainable development policy prescribed integration as the main strategy for reconciliation of the perceived dichotomies between environmental protection and economic development. Despite this strategy, from the beginning the concept was regarded as conflicting and ambiguous, and the debate concerning meaning was, by my interpretation, only settled by the Johannesburg Summit<sup>5</sup> in 2002. The Summit clarified the question authoritatively, however, only indirectly, by pulling economic, social and environmental issues together in a hugely participatory process under the heading of the "World Summit on Sustainable Development" (WSSD). Indeed, I suggest that the Summit expressed a core content of the policy, and it provided the basis for articulating the boundaries of a policy embodying a distinct whole, i.e., the global development process with identifiable features and a rationality of its own, distinct from the aggregate of the individual social, economic and environmental components. This is a process that is premised on the awareness of interdependence and on the necessity of upholding the biosphere, satisfaction of the needs of present and future generations, and universal participation. This interpretation is, however, novel and as such not explicitly supported by the institutionalized discourse emanating from, for example, the UN, which in practice addresses sustainable development as a matter of "managing and protecting our common environment" and not as a matter related to the quality of the overall

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\* Researcher, European University Institute, Florence, Italy.

<sup>2</sup> The report of the World Commission on Environment and Development (WCED), *Our Common Future* (Oxford University Press, 1987).

<sup>3</sup> The debate concerning environmental problems relating to the global economic development process began in the late 1960s and the United Nations Conference on the Human Environment<sup>3</sup> (UNCHE) in 1972 marked the beginning of international cooperation within the field of the environment. Report of the United Nations Conference on the Human Environment, Stockholm, 5-16 June 1972, (UN Doc. A/CONF.48/14/Rev. 1, 1973).

<sup>4</sup> Report of the United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992, (UN Doc. A/CONF.151/26/Rev.1, 12 August 1992).

<sup>5</sup> Report of the World Summit on Sustainable Development, Johannesburg, 26 August - 4 September 2002, (UN Doc. A/CONF.199/20, 4 September 2002).

development process. Sustainable development is perceived as "a key element of the overarching framework of United Nations activities"<sup>6</sup> i.e. as an element and an activity and not as *the* framework.

## 2. The legal field

In what follows, I show that this evolving nature of the concept, moving from protection of the environment to the challenge of implementing sustainable development, reverberates within the field of law.

### 2.1 International environmental law

The Stockholm Conference was hailed as the birthplace of international environmental law.<sup>7</sup> Today environmental law and international environmental law are vast and distinct fields.<sup>8</sup> From the outset, the integral relationship between sustainable development and the environment is reflected in the legal field. For example, the Brundtland report includes an Appendix entitled *Legal Principles for Environmental Protection and Sustainable Development*. Furthermore, in 1992, the world agreed in Rio on the *Declaration on Environment and Development*.<sup>9</sup> Principle 4 of the Declaration specifies that, if we are to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it. Consequently, in the legal field as elsewhere, there has been a tendency to conflate sustainable development with the integration of environmental protection into the economic development process. However, a differentiation seems to have taken place. In 2002, the *Declaration of Principles of International Law Relating to Sustainable Development*<sup>10</sup> was presented at the Johannesburg Summit together with a summary of the work of the International Law Association's (ILA) Committee on Legal Aspects of Sustainable Development. Hence, based on the following account of developments in the legal field after 2002, I argue that perhaps we will come to see the Johannesburg Summit as marking the birth of international sustainable development law as a distinct field of law with identifiable features and a rationality of its own.

### 2.2 International sustainable development law (ISDL)

Since 2002 several books have been published and a peer reviewed law journal launched on the topic of international sustainable development law (ISDL).<sup>11</sup>

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<sup>6</sup> For more information see, e.g., the contribution by E. Morgera 'Towards the 2005 World Summit: UN Reforms and the Protection of the Environment' in this Working Paper.

<sup>7</sup> L.B. Sohn, 'The Stockholm Declaration on the Human Environment', 14:3 *Harvard International Law Journal* (1973), 423-515.

<sup>8</sup> See e.g., P. Sands, *Principles of International Environmental Law* (2nd ed., Cambridge University Press, 2003).

<sup>9</sup> P. Sand, 'International Environmental Law After Rio', 4 *European Journal of International Law* (1993), 377-89.

<sup>10</sup> A new Committee was formed May 2003. The objective of the Committee is to study the legal status and legal implementation of sustainable development. For this purpose the Committee's mandate includes: - assessment of the legal status of principles and rules of international law in the field of sustainable development, with particular reference to the ILA New Delhi Principles (now also published as UN Doc. A/57/329), as well as assessment of the practice of States and international organizations in this field; - the study of developing States in a changing global order, particularly the impact of globalization on the sustainable development opportunities of developing countries; - in the light of the principle of integration and interrelationship, a re-examination of certain topics of the international law of development, including analysis of (i) the position of the least developed countries in international law, (ii) the right to development and (iii) the obligation to co-operate on matters of social, economic and environmental concern. <<http://www.ila-hq.org>>.

<sup>11</sup> M-C. Cordonier Segger and A. Khalfan, *Sustainable Development Law: Principles, Practices and Prospects* (Oxford University Press, 2004). M-C. Cordonier Segger and C. G. Weeramantry, *Sustainable Justice: Reconciling Economic, Social and Environmental Law* (Martinus Nijhoff, 2005). The McGill International Journal of Sustainable Development Law and Policy was launched in 2005. <<http://www.law.mcgill.ca/jsdlp/>>



In the following, I introduce ISDL based on *Weaving the Rules for Our Common Future*.<sup>12</sup> The book consists of five parts. Part I provides the introduction. Part II surveys the origins of the concept of sustainable development, identifies its legal aspects, and provides for the formation of a body of international law related to sustainable development. Part III examines the principles of international law related to sustainable development and suggests that legal instruments in this field can be analyzed according to a typology of degrees of integration between international, social, economic and environmental law as follows:

We believe that a conceptual 'continuum' can be designed, based on the degree to which international regimes integrate economic, social and environmental law. Four degrees of integration must be identified. These range from regimes that envisage international economics social and environmental law as separate, independent fields to regimes that fully integrate these areas of law and form the corpus of international sustainable development law. The degree of integration along this continuum can be described as follows: a) *Separate spheres*; b) *Parallel yet interdependent*; c) *Regimes in the process of integration*; d) *Highly integrated new regime*.

Part IV provides practical case studies of legal instruments at these various degrees of integration. Part V establishes a research agenda in six areas at the intersection of international social, economic and environmental law, and identifies several themes which cross-cut these substantive agendas. This final section also examines prospects for a new approach to international *sustainable development governance* in the context of *Agenda 21* and the outcomes of the WSSD.

According to Case Study II concerning compliance-building in ISDL, integration of the economic, social and environmental objectives is evident not only in rules and principles of ISDL regimes, but also in their implementation, monitoring and enforcement. This integrated approach to compliance is considered a distinctive feature of ISDL, and a key to its effectiveness. The Case Study tracks the genesis, operation, and distinctive features of the ISDL approach to compliance through analysis of several highly integrated treaty-based regimes, namely:

- *The Convention to Combat Desertification in Countries Experiencing Serious Drought and/or Desertification, particularly in Africa*
- *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity*
- *The Montreal Protocol, including the non-compliance procedures and the provisions governing the multilateral fund*

The Study emphasizes two creative tensions. The first is between national sovereignty and the protection of the common interest. According to the Study, an ISDL approach would attempt to resolve the tension by suggesting that States should fully and freely delegate national sovereignty to international, independent, expert institutions, where necessary, to advance the protection of common interest. The second tension, dispersal versus centralization of compliance-coordination, is a manifestation of the first, and apparent in the ISDL approach to compliance in particular. Specifically, the Study concludes that ISDL should address this tension through a prescription for governance at the most appropriate level. The Case Study concludes by stating that the creative

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<sup>12</sup> Downloaded from <[www.cisd.org](http://www.cisd.org)>. Accessed April 2003. "Weaving the Rules for Our Common Future: Principles, Practices and Prospects for International Sustainable Development Law." The text of the publication was first released for consultation, in draft form, at a meeting on Sustainable Justice 2002: Implementing International Sustainable Development Law, Montreal, Canada, June 13-15 2002, organized in partnership with the United Nations Environment Programme and the World Bank Legal Vice-Presidency. Published in 2004, see *supra* note 10.

CISDL <[www.cisd.org](http://www.cisd.org)>: The Centre for International Sustainable Development Law (CISDL) has been established to promote sustainable societies and the protection of ecosystems by advancing the understanding, development and implementation of international sustainable development law.

force of the fundamental tensions that animate ISDL is demonstrated by the four key trends in ISDL approaches to compliance, namely:

- From "balanced governance" to self-governance.
- From treaty-monitoring bodies to compliance-coordinating bodies.
- From individualized relief to systematic relief.
- From reaction to pro-action: shifting the paradigm from correction of action to prevention of harm.

Concerning the theoretical basis of highly integrated ISDL regimes, the Case Study refers to the orientation of the interactional theory of international law as holding great promise for ongoing ISDL research in the field of compliance. Moreover, the philosophical framework promoted by CISDL for developing the ISDL is seemingly based on traditional values.<sup>13</sup> Hence, the development of ISDL has not yet resulted in the articulation of specific theoretical implications.

### **3. The jurisprudential field: From economic to sustainable development: unfolding the concept of law**

Brunne and Toope have suggested that law might be evaluated by the influence it exerts rather than by formal tests of validity rooted in normative hierarchies.<sup>14</sup> They suggest that we should stop looking for the structural distinctions that identify law, and examine instead the processes that constitute a normative continuum bridging from predictable patterns of practice to legally required behaviour. This approach recognizes that there is not a radical discontinuity between law and non-law, and that the process of building legal normativity requires many of the same building blocks as other forms of social normativity. This argument accords with the research explained below, which is the outcome of my PhD thesis to be defended in spring 2006.

My thesis attempts to demonstrate the plausibility of the claim that the policy of sustainable development represents a wider epistemic shift; and that, through a re-description of the concept of law, we can integrate the new knowledge into global institutions, and thus, enable us to act socially and politically from a grander perspective than the individual or the nation State alone and allow for integration of greater diversity within a common framework.

The basic premise of my argument is that the emergence of the sustainable development policy was driven by the science-supported awareness of interdependence. This awareness is also reinforced by a conceptualization of the world as a singular and interdependent entity brought about by the first photos of the earth taken from space in the 1950s. My analysis and interpretation of the sustainable development policy process attempts to show that an important insight arising from the policy is that practice reports back to the academic quarters the message that the philosophy and theory of change underlying the present economic development paradigm no longer fully corresponds to our collective knowledge.

The theory of change underlying the sustainable development policy represents then a wider epistemic shift, recognizable in the world at large. It is a distinct shift from the model of economic development, which builds on the idea of separation and functional specialization, to a model of sustainable development, which builds on interdependence and integration.

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13 "Developing the Underlying values for a Sustainable Globalisation - Liberty, Equality and Fraternity Revisited" Academic Workshop, Oxford University. Hon. Charles Gonthier, former Judge of the Supreme Court of Canada and Wainwright Senior Research Fellow of the McGill University Faculty of Law, gathers international relations and law scholars to consider the values to provide foundations for a more sustainable globalisation. Participants will discuss recent developments at the intersection of international economic, environmental and human rights law. Debate will focus on one of the most potent and under-explored values of western political and legal philosophy: fraternity, the underlying sense of solidarity or membership that makes up a society, and its implications for international law and policy in a changing world. With discussants Richard Tarasofsky, Royal Institute of International Affairs (London), Bradnee Chambers, United Nations University (Tokyo), and Duncan French, International Law Association Committee on International Law on Sustainable Development, the academic dialogue seeks to develop a deeper understanding of the character and meaning of these values in a rapidly changing, increasingly inter-dependent global society.

<sup>14</sup> J. Brunnee and S. J. Toope, 'International Law and Constructivism: Elements of an Inter-actional Theory of International Law', 39:19 *Columbia Journal of Transnational Law* (2000), 19.

Effectuating the shift from a principle of separation to that of interdependence requires paradigmatic conceptual changes, i.e. theory-building, because the nature of interdependence is dynamic, while the nature of separation is mechanical. Therefore, to act on the epistemological insights arising from sustainable development confronts academia with not only concrete technical and institutional/legal issues but also with complex conceptual theoretical questions relating, for example, to the nature of knowledge and language, and the relationship between these questions and law and society.

Philosophically, the policy of sustainable development is thus concerned with fostering a new understanding of the human condition in a global age. Through it we can understand reality as contingent and the self as existing within the unified field of a biosphere too complex to be directed and controlled by humans. To express this relationship it is necessary to construe an analytical interface between the physical and the social worlds. I suggest that the interface between individual understanding of interdependence can be expressed as following a rule-based theory of cognition, and the basic interface between individual cognition and societal communication and action can be construed and made operational by enlarging the concept of law and articulating cognition as a third order framework for communication and action. This model is of general relevance as an analytical framework and as such it can be seen as a theoretical contribution distinct from but integral to the policy and practice of sustainable development.

In short, I believe the policy of sustainable development has been the impetus for two distinct ongoing developments. First, the policy is evolving into a new field of law; second, it epitomizes a wider epistemic shift, which has been perceived as a crisis of truth.

... What they [the articles included in the chapter] do seem to share - and what places them in this chapter - is a sense that the conventional ways of thinking and talking about law are no longer adequate to describe law as it is practiced and law as it lived. And they arrive at this point not because law has become divorced, in their view, from mainstream epistemologies, but rather because these epistemologies are no longer adequate to convey a sense of the world. The crisis of justice, in short, is concurrent with the crisis of truth.<sup>15</sup>

That crisis of truth may become more particularly described as a crisis of representation. It is essentially (and hence superficially and far too generally), a three-fold crisis, generated by radical challenges to the traditional conceptions, first, of reality; second, of the language we use to describe that reality; and third, of the subject who perceives and describes that reality, that is, the self. In the postmodern world these categories largely dissolve: the demise of the objective, of the real, is accompanied by the destruction of the subjective.<sup>16</sup>

I argue that the policy practice further provides us with the means to respond to the situation and to articulate a new paradigm of knowledge. To make the paradigm operational in a global polity, I suggest that the conceptual machinery of the legal discipline is required because this exercise cannot be undertaken by the descriptive and quantitative disciplines, which, in a very fundamental way, cannot transcend their own rules for production of valid knowledge. I do not claim that my analysis is in any way complete but only that the perspective it offers deserves further investigation.

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<sup>15</sup> Cf. S. Benhabib, 'Epistemologies of Postmodernism: A Rejoinder to Jean-Francois Lyotard', in L.J. Nicholson, *Feminism/Postmodernism* (Routledge, 1990), 107, at 124 ("Questions of truth ...are questions of justice as well.").

<sup>16</sup> R. Hayman, 'Postmodernism', in R. Hayman and N. Levit, *Jurisprudence - Contemporary Readings, Problems, and Narrative* (West Publishing Co., 1994), 505, at 509.

## **Sustainable Development and Small Island Developing States: The Mauritius International Meeting**

Elisa Morgera\*

This contribution summarizes, and comments on, the main outcome of the 2005 Mauritius International Meeting on the Sustainable Development of Small Island Developing States (SIDS), namely the Mauritius Strategy. Starting with some introductory remarks on SIDS' special circumstances and on the results of the first UN Conference on SIDS in 1994, this contribution sets the scene of the Mauritius Meeting and sketches the negotiating position of Small Island Developing States. The central section provides an overview of the Mauritius Strategy, focusing in particular on three sections of the document: climate change, waste, and trade. The final section highlights the follow-up process to the Mauritius Meeting and links this process with the 2005 World Summit.

### **From 1994 to 2004**

SIDS<sup>17</sup> are a country grouping within the UN System, including countries with a territory comprising one island (Barbados and Jamaica, for example), and archipelagos (Maldives and Micronesia), or partly islands or low-lying coastal areas (such as Suriname, Belize and Guyana). Albeit heterogeneous in composition, SIDS share common features and face common challenges to their sustainable development: limited land territory, specific environmental and economic vulnerability, and a great exposure to natural disasters. Their special circumstances were initially recognized at the Rio Conference on Environment and Development in 1992, in Chapter 17 of Agenda 21. Later on, a UN International Conference on the Sustainable Development of SIDS was held in Barbados in 1994. The outcome of the conference was a Plan of Action (Barbados Plan of Action, BPOA), in which the international community committed itself to recognize the special status of SIDS and their need for international support in specific priority areas: climate change, biodiversity, marine resources, tourism and waste management, among others.

Ten years later, sustainable development in SIDS has been achieved only to a limited extent. Notwithstanding the fact that some SIDS have reached quite a high level of economic development, mainly thanks to the tourism industry (as in the case of Caribbean SIDS, whose majority counts on an elevated gross domestic product and ranks high in the Human Development Index of the United Nations Development Programme), their environmental and economic vulnerability has stayed the same. On the one hand, the impact of climate change and marine pollution and the difficulties of environmentally sound waste management continue to pose serious threats to the sustainable development of SIDS. On the other hand, the increasing frequency and magnitude of natural disasters hitting SIDS (such as the 2004 hurricane season in the Caribbean, and the tsunami in South East Asia) completely undermine their social and economic progress. A significant example is that of the Maldives, which, after graduating in December 2004 from the status of least developed countries (LDCs) by the UN General Assembly, were just a few days later among the countries most severely hit by the tsunami. In addition, the BPOA has not succeeded in eliciting the international technical and financial support that had been agreed in Barbados in 1994. Since then, new problems have emerged that now threaten the sustainable development of SIDS: the erosion of SIDS' preferential commercial treatment due to international trade liberalization, and the spread of HIV/AIDS. It should be also noted that the term SIDS lacks a definition within the UN System, and different UN agencies and programmes have developed their own, often different, lists of SIDS.

### **Mauritius International Meeting**

From the 10<sup>th</sup> to the 14<sup>th</sup> January 2005, SIDS sustainable development was the focus of an international meeting held in Mauritius for the ten-year review of the BPOA.<sup>18</sup> During the formal and informal negotiations of the preceding meetings and the International Meeting, SIDS aimed at obtaining not only a renewed and strengthened commitment from the donors' community to support SIDS' sustainable development in the priority areas already identified at the Barbados meeting ten years earlier (particularly climate change), but also the recognition of a

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<sup>17</sup> <[www.sidsnet.org](http://www.sidsnet.org)>.

<sup>18</sup> See <<http://www.un.org/smallislands2005/>> and <<http://www.sidsmauritius2005.mu/>>.

fully-fledged special status for SIDS and special and differential treatment within the World Trade Organization (WTO).

Negotiations were very intense, heightened by the recent tsunami disaster in the South-East Asian SIDS. Notwithstanding the significant controversy between SIDS and donor countries on climate change and international trade, the meeting approved the Mauritius Strategy,<sup>19</sup> which reaffirms the importance and urgency of SIDS' environmental, social and economic challenges, and aims at redirecting international cooperation in this regard.

### **The Mauritius Strategy**

The Mauritius Strategy focused on the following themes: climate change, marine resources, freshwater, land resources, biodiversity, LDCs promotion, international trade, and implementation of the Strategy. The innovative aspect of the Strategy, as opposed to the BPOA, is the effort in balancing the support of the international community with the action needed by SIDS themselves, in order to ensure the respect of national priorities and national poverty reduction strategies. The resulting novel formula often reads: "action is required by small island developing States, with the necessary support of the international community."

This contribution will focus upon the most controversial topics in the negotiations: climate change, waste and radioactive materials, and trade. In the section devoted to climate change (paras. 16-20), the desired outcome for SIDS and many other States was that of a strong call for the ratification and implementation of the Kyoto Protocol, emphasizing the danger for the very existence of SIDS deriving from climate change and sea-level rise. The opposition from the US and a negotiation *impasse* similar to that experienced at the 2004 December Conference of the Parties to the UN Framework Convention on Climate Change (UNFCCC) justified fears that compromise was out of reach in Mauritius on such a vital section of the Strategy. After overnight discussions, delegates succeeded in agreeing that "the long-term impact of climate change *may* threaten the very existence of *some* SIDS"<sup>20</sup> and, in reaffirming their commitment to the ultimate objective of the UNFCCC, "the international community should promote increased energy efficiency and development and use of renewable energy as a matter of priority, as well as advanced and cleaner fossil fuel technologies."<sup>21</sup> The call for the ratification of the Kyoto Protocol is only included in the Mauritius Declaration,<sup>22</sup> drafted by Mauritius as the host country and briefly submitted to the attention of the other delegations during the last phases of the meeting.

In the section of the Strategy on waste management (paras. 22-25), negotiations focused on a few proposals by SIDS concerning liability for transport of dangerous waste, World War II sunken shipwrecks, and the transport of radioactive materials. The Mauritius Strategy calls for further action by SIDS, with the necessary support of the international community, to strengthen the control of the transboundary movement of hazardous wastes especially through the enhancement of activities under the Basel Convention on the Transboundary Movement of Hazardous Waste, but failed to make express reference to the principles of prior informed consent, liability and compensation.<sup>23</sup> The paragraph on sunken vessels was significantly watered down, due to the opposition of Japan that owns most sunken vessels in the Pacific, and does not mention issues of liability. The compromise text, although highlighting the "concern with the environmental implications of potential oil leaks from sunken state vessels to SIDS' marine and coastal ecosystems", regrettably only encourages bilateral consultation, on a case-by-case basis, between SIDS and relevant vessel owners.<sup>24</sup> On the positive side, SIDS was victorious with regard to the transport of radioactive substances, the Strategy recognising that the "cessation of transport of radioactive materials through SIDS regions is an ultimate desired goal of SIDS and some other countries", as well as the need for "further development and strengthening, within the appropriate fora, of *international regulatory regimes* to enhance safety, disclosure, liability, security and compensation in relation to such

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<sup>19</sup> Mauritius Strategy for the Further Implementation of the Programme of Action for the Sustainable Development of Small Island Developing States (A/CONF.207/11, 14 January 2005), Annex II.

<sup>20</sup> *Ib.*, para. 16.

<sup>21</sup> *Ib.*, para. 18 (c).

<sup>22</sup> Mauritius Declaration (A/CONF.207/11, 14 January 2005), Annex I.

<sup>23</sup> Mauritius Strategy, para. 23 (b).

<sup>24</sup> *Ib.*, para. 24.

transport.”<sup>25</sup> The compromise language on “international regulatory regimes” aims at accommodating SIDS’ call for a fully-fledged international regime on liability and the more cautious approach of some countries of the European Union that supported only “regulations” on this matter.

Finally, in the section on international trade (paras. 66-69), donor countries opposed the possibility of special and differential treatment for SIDS, but rather agreed to support SIDS’ efforts in integrating into the world’s economy and in effectively representing their positions within the WTO.<sup>26</sup>

### **Concluding remarks**

The Mauritius Strategy, as an internationally agreed political document, embodies a series of commitments that donor countries carefully negotiated in order to coordinate their efforts to support the sustainable development of SIDS. The significance of the Strategy also lies in its impact on the UN System. First of all, the section on implementation calls upon the UN Secretary General to prioritize the Mauritius political commitments and the areas for action therein identified. Secondly, a series of follow-up actions have been laid out during the closing session of the Mauritius International Meeting, among which the inclusion of the Strategy in the work programmes of the UN Environmental Programme (UNEP) and UN Development Programme (UNDP), as well as in the process aimed at the achievement of the Millennium Development Goals (MDGs).

The revitalization and updating of the BPOA has been, to a large extent, achieved on paper in Mauritius. The actual impact of the Strategy on international cooperation remains to be seen. In this regard, the 2005 UN World Summit seems to bode well. The agreed Outcome Document refers to the special circumstances of SIDS with reference to climate change,<sup>27</sup> financial flows<sup>28</sup> and transport of radioactive materials,<sup>29</sup> and also reaffirms the commitment to take “urgent and concrete” action to address those needs and vulnerabilities through the full and effective implementation of the Mauritius Strategy through the mobilization of domestic and international resources, the promotion of international trade as an engine for development and increased international financial and technical cooperation.<sup>30</sup>

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<sup>25</sup> *Ib.*, para. 25 (emphasis added).

<sup>26</sup> *Ib.*, para. 67.

<sup>27</sup> 2005 World Summit Outcome (A/60/1, 15 September 2005), para. 55(d).

<sup>28</sup> *Ib.*, para. 25(e).

<sup>29</sup> *Ib.*, para. 56(o).

<sup>30</sup> *Ib.*, para. 66.



## **UN Reforms**



## **The Reform of Environmental Governance in the United Nations: the French Proposal**

Federico Lenzerini\*

### **Background**

In preparation of the 2005 UN World Summit on the reform of the UN Charter, a number of studies<sup>31</sup> were commissioned or independently developed on the specific issue on how to improve global environmental governance as well as its equity (through the enhancement of the participation of developing countries in the operation of global development policies) and legitimacy (through the creation of an institutional framework within the context of the UN System).<sup>32</sup> One of such studies was requested by the French Ministry of Foreign Affairs in November 2004 from Professors Pierre-Marie Dupuy and Francesco Francioni of the EUI. The present author had the privilege of participating in the elaboration and drafting of such study together with a team of researchers that included also Massimiliano Montini, Elisa Morgera, Riccardo Pavoni and Francesca De Vittor.

The study was developed on the basis of the terms of reference indicated by the French Ministry of Foreign Affairs.<sup>33</sup> According to such terms, the study was to concentrate on three main aspects of the reform of environmental governance: 1) the modalities of creating an institutionalized UN environmental agency replacing UNEP; 2) the modalities of transforming UNEP into a UN specialized institution, as well as the consequences arising from such operation, including budgetary implications; 3) the problems deriving from the statutory characterization of the new environmental agency and from its competences, with particular attention to its coordination with other UN-related bodies holding competences in the environmental field.

### **The study on the Reform of Environmental Governance**

#### **a) The preferred option: a U.N. Environmental Organization**

The study, entitled “Options and Modalities for the Improvement of International Environmental Governance through the Establishment of a U.N. Environmental Organization”,<sup>34</sup> analyzes in depth the three main options, which would be practicable *in abstracto* for the purpose of reforming environmental governance at the global level. The establishment of a new specialized agency of the United Nations, with specific and almost exclusive competences in the environmental field (UNEO), is identified by the study as the preferred option among the feasible ones, due to the positive balance resulting between the foreseeable advantages and disadvantages arising from the possible establishment of UNEO. In particular, this agency would have the advantage of being based on a strong institutional status (certainly stronger than UNEP), which would facilitate its role as the “environmental authority” at the global level, and it would also have a broader potential for wide membership than the other possible options. Also, the “global” nature of UNEO could ensure the coherency of international action in the environmental field, as well as stronger and more systematic cooperation with other agencies or programmes dealing with matters strictly linked to the environment (such as the UN Development Programme (UNDP), the UN Food and Agriculture Organization (FAO), the International Maritime Organization (IMO), etc.). In such a way, a more efficient use of the available resources would be ensured, avoiding resources being wasted in identical programmes carried out by different bodies without coordination, resulting in the useless duplication of identical activities. Furthermore, the establishment of UNEO would be particularly beneficial to developing

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<sup>31</sup> Some of these studies are available at <[http://www.diplomatie.gouv.fr/fr/actions-france\\_830/onu-organisations-internationales\\_1032/institutions-specialisees-onu\\_3187/onue-environnement\\_4347/etudes-academiques\\_4351/introduction\\_10879.html](http://www.diplomatie.gouv.fr/fr/actions-france_830/onu-organisations-internationales_1032/institutions-specialisees-onu_3187/onue-environnement_4347/etudes-academiques_4351/introduction_10879.html)> and at <[http://www.iddri.org/iddri/telecharge/gie/wp/iddri\\_IEG-architecture.pdf?var\\_recherche=ONUE](http://www.iddri.org/iddri/telecharge/gie/wp/iddri_IEG-architecture.pdf?var_recherche=ONUE)>

<sup>32</sup> See “Options institutionnelles pour un renforcement de la gouvernance internationale de l’environnement”, papier de discussion français Groupe de travail ONUE, document on file with the author.

<sup>33</sup> See “Termes de référence concernant les aspects juridiques liés à la création d’une organisation des Nations Unies pour l’environnement”, document on file with the author.

<sup>34</sup> The study is available at <[http://www.diplomatie.gouv.fr/fr/IMG/pdf/Etudes\\_iddri\\_juridique\\_EN.pdf](http://www.diplomatie.gouv.fr/fr/IMG/pdf/Etudes_iddri_juridique_EN.pdf)>

countries, on account of its institutional dimension, which would ensure adequate attention to the interests of such countries and assistance to respond to their needs. Another positive aspect of UNEO would be represented by its high visibility vis-à-vis international civil society. This could lead, through the development of appropriate initiatives, to the concrete involvement of local institutions (such as local NGOs and/or competent national institutions) and even private operators in the realization and management of environmental governance, similarly to what has been done by UNESCO in the context of the implementation of the 1972 World Heritage Convention.

According to the study, UNEO should be based on an institutionalized apparatus not dissimilar to the one characterizing other existing UN specialized agencies. Its main bodies would be: a General Assembly, having the competence of determining the policies and the priorities of work of the organization; a General Bureau (as the executive body of the organization); a Director General (having several competences, including the task of coordinating, reviewing and assessing environmental programmes within the UN system and the responsibility for the conduct of the general operations of UNEO); a Secretariat and some regional offices. The role of the regional offices would be of special importance, since one of the essential conditions to ensure truly efficient actions by UNEO would be its strong decentralization. In this sense, UNEO should be shaped as a sort of “umbrella” organization, in the context of which the decentralization of competences would be essential for ensuring adequate articulation of the complex of actions carried out by the international community for the protection of the environment, with special attention to the needs of developing countries. This outcome should be achieved through the coordination of common environmental policies and the harmonization of global environmental action, through providing, *inter alia*, efficient decentralized coordination of existing MEAs. Such decentralization could be realized by the regional offices, which could be the result of the strengthening of UNEP existing Regional Offices (located in Bangkok, Bahrain, Geneva, Mexico City, Nairobi and New York). These offices could be provided with competences, delegated by the General Bureau, concerning the implementation of the strategies decided by the General Assembly, taking into account the specific needs and priorities of the area where the office concerned is located.

With a view to adequately fulfilling its competences, UNEO should have its own budget, composed of both obligatory and voluntary contributions from member States. Obligatory contributions, in particular, would be essential for granting a secure funding system and indispensable for ensuring the concrete effectiveness of the work of the organization.

Finally, another component for ensuring the correct functioning of UNEO would consist in the setting up of an institutionalized system for dispute avoidance and resolution. The study conceives a four-stage system, which could be included in the structure of UNEO as a whole or separately. A first stage is conceived as a scheme of response action, having the purpose of preventing responsibility or liability claims by countries affected by a possible violation of a provision related to the UNEO system; this stage would be characterized by the adoption and implementation by the State concerned of emergency plans and measures necessary to control, minimize or remove the adverse effects of the potential breach. A second stage should be based on the activity of the UNEO competent offices, consisting in monitoring and reporting suspected cases of non-compliance with international environmental obligation, in view of favouring a friendly solution of the controversy arising from such non-compliance. The third stage should be envisaged, in accordance with Article 33 of the UN Charter, as a system of conciliation and mediation available to member States under the direction of the UNEO Director General, assisted by the Legal Service. The fourth stage would finally consist in the institution of judicial proceedings before an international body that could be the International Court of Justice (ICJ), the Special Environmental Chamber of the ICJ or an arbitral tribunal. In the event that member States fail to exercise their right of choosing one of the available dispute settlement options, the controversy should be automatically referred to the ICJ; this solution would provide a satisfactory compromise between the need to have a compulsory jurisdictional system and the necessity to allow a certain degree of flexibility in leaving States free to select their favourite means of dispute resolution for environmental disputes.

#### **b) Enhanced UNEP**

The second possible option for reforming environmental governance at the global level could consist in the reinforcement of the existing UNEP, through the creation of an enhanced programme that would not change the basic structure of UNEP but, at the same time, would provide it with more efficiency. In particular, this “new” programme (defined as “Enhanced UNEP” or EUNEP) should be improved through a sensible expansion of UNEP existing powers and competences (especially with regard to technology support and capacity building), as well as through the reinforcement of its present administrative structure and funding system. This reinforcement

should be realized both at the “central” and peripheral levels, by strengthening also the functions and powers of regional offices.

Although this second option would present some advantages, particularly that of not having its action eased off by the burdensome bureaucratic machine, which would inevitably characterize the option of the UN specialized agency (UNEO), it would also present serious weaknesses. In particular, the choice of EUNEP could not solve the main “physiological” problem characterizing UNEP, *i.e.* the lack of coordination of the activities carried out under the aegis of such a programme with those performed by other existing environmental programmes, agencies and organizations. In addition, the very fact of not being based on a strong organizational machine would also present its negative aspects, in particular the fact that, due to its weak institutional status, EUNEP (differently from UNEO) could not play the role of the global “environmental authority” that might lead to the effective rationalization of environmental action at the international level (which probably represents the most important objective pursued through the reform of environmental governance). Furthermore, the problem of the scarce visibility of UNEP would not be solved by simply enhancing its powers and functions. Last but not least, the establishment of EUNEP would probably not address the issue of the proliferation of Conferences of Parties and Secretariats established by MEAs, and would thus not ensure their coordination.

### **c) World Environment Organization**

The third option explored by the study is based on the establishment of a WTO-like organization with the purpose of granting the coordination of existing legal systems and frameworks for environmental protection, under the aegis of a single entity with autonomous administrative structure and a compulsory dispute settlement regime. The World Environment Organization (WEO) should constitute a pole of attraction for all environmental policies carried out at the international level, and should gather them in a single, organic global system aimed at coordinating and rationalizing the overall action for the protection of the environment.

This solution would present the positive aspect of instituting a “global environmental system” which, being based on a “take-all-or-leave-all” approach, would create the conditions for the acceptance by member States of all the rules set up by the environmental treaties administered by WEO, thus ensuring a rational international action for the protection of the environment. Nevertheless, this advantage would probably be neutralized by the fact that a system based on such a drastic approach would probably dissuade many States from adhering to it, especially in light of the fact that environmental protection is not associated with the strong political and economic interests which are connected to international trade. It is, thus, quite improbable that the institution of a WEO would be characterized by the success that has been reserved to the WTO. This perception is reinforced by the practice usually followed by most States in the environmental field, which are used to tackling only a limited number of objectives among those pursued at the supranational level: a global system of environmental protection, where you must “take all”, could thus be unacceptable to most of them. Furthermore, the efficiency of a WEO would also be impaired by the same kind of problems, which at present characterize the WTO, particularly that it is commonly perceived as not favourable to developing countries and partially disconnected (and sometimes even at odds) with the general system of international law. This latter problem would even be more serious with regard to a WTO-like environmental organization, on account of the well-defined environmental competences held by the United Nations, from which a WEO would be disconnected, thus leading to a lack of coordination of the environmental activities carried out at the international level. The balance between advantages and disadvantages, which would most likely arise from the possible establishment of a WEO, is thus clearly negative.

### **Conclusion**

The French proposal for the reform of environmental governance at the global level has been endorsed by the other member States of the European Union.<sup>35</sup> The fact that this initiative has become a EU proposal is extremely welcome progress, which will surely increase the chances of success of the proposal before the United Nations. This would constitute a very important achievement towards the setting up of truly efficient global action for preserving the health and integrity of our globe, to the benefit of present and future generations.

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See [http://www.diplomatie.gouv.fr/fr/actions-france\\_830/onu-organisations-internationales\\_1032/institutions-specialisees-onu\\_3187/onue-environnement\\_4347/](http://www.diplomatie.gouv.fr/fr/actions-france_830/onu-organisations-internationales_1032/institutions-specialisees-onu_3187/onue-environnement_4347/)

## The 2005 World Summit: UN Reforms and the Protection of the Environment

Elisa Morgera\*

2005 represented a landmark year for the United Nations (UN), as a process to review progress in the implementation of the Millennium Declarations (initially labelled “Millennium Review” process) turned into the most far-reaching attempt to reform the UN in the lead up to the largest gathering of Heads of States and Governments in history, the 14-16 September 2005 World Summit in New York. Within the WGEL, we discussed in three sessions the consequences for the global protection of the environment of the process and the proposed reforms, focusing in particular on: the report of the UN High-Level Panel of Experts on Threats, Challenges and Change (24/02/2005); UN System Reforms (19/05/2005); and the Summit Outcome Document (3/11/2005). This contribution combines and complements these presentations, integrating remarks on the environmental significance of the outcome of the 2000 Millennium Summit and the pre-2005 World Summit process and reports.

### From the UN Millennium Summit to the Millennium Development Goals

At the UN Millennium Summit in September 2000, 191 States adopted the Millennium Declaration as a plan to support global development objectives for the new century, and reaffirmed their commitment to work toward a peaceful and secure world, in which sustainable development and poverty eradication would have the highest priority.<sup>36</sup> The Declaration outlined peace, security and development concerns, in areas including the environment, human rights and governance. The Declaration also formulated measures for evaluating performance through a set of interrelated commitments, goals and targets on: fundamental values and principles; peace, security and disarmament; development and poverty eradication; the protection of the environment; human rights, democracy and good governance; the needs of the most vulnerable; the special needs of Africa; and strengthening the UN.

Following the 2000 Summit, consultations were held among international agencies, including the World Bank, the International Monetary Fund, the Organization for Economic Cooperation and Development (OECD), and the specialized agencies of the United Nations to develop a set of interconnected and mutually reinforcing development goals, targets and benchmarks based on the Declaration time-bound commitments. These were consolidated into a global agenda known as the Millennium Development Goals or “MDGs.” The MDGs took over from the International Development Goals agreed to by the OECD and the Paris Club in the 1990s, and were meant to be targets for the alignment of donor official development assistance (ODA) priorities. Eight MDGs set out time-bound goals to achieve quantifiable results to: eradicate extreme poverty and hunger; achieve universal primary education; promote gender equality and empower women; reduce child mortality; improve maternal health; combat HIV/AIDS, malaria and other diseases; ensure environmental sustainability; and develop a global partnership for development. In 2001, the General Assembly recognized the MDGs as part of the roadmap for implementing the Millennium Declaration, as set out in the Secretary General’s September 2001 report “Roadmap to the Implementation of the Millennium Declaration.”

First of all, it should be noted that not all States immediately endorsed the MDGs, as they were not intergovernmentally negotiated and adopted. Nonetheless, they have become globally accepted benchmarks of broader progress, embraced by most donors, developing countries, civil society and major development institutions alike. A major example is that of the European Union that has completely restructured its development aid policy so as to be in line with the MDGs.

From an environmental perspective, attention has initially focused on MDG-7 (specifically on environmental sustainability) and its targets: integrate the principles of sustainable development into country policies and programmes and reverse the loss of environmental resources; by 2015, reduce by half the proportion of people without access to safe drinking water and basic sanitation; and by 2020 achieve significant improvement in the lives of at least 100 million slum dwellers. Regrettably, MDG-7 is perhaps the least quantifiable goal, with few measurable indicators on which progress can be effectively measured (particularly Target 9). In his August 2004 report on the implementation of the Millennium Declaration, the UN Secretary General emphasized that

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<sup>36</sup> <<http://www.un.org/millennium/declaration/ares552e.pdf>>.

progress on MDG-7 targets has been mixed and that even regions, such as parts of Asia, that have made significant progress towards achieving other MDG targets tend to have a poorer record on environmental issues. In this regard, the Secretary General stresses the need for MDG action on access to drinking water, loss of tropical forest cover, energy use, and per capita carbon dioxide emissions.`

At the WSSD and in several MEA processes, States have recognized the importance of jointly addressing environment and poverty reduction issues under the MDGs, and have started consideration of strategies for mainstreaming MDG-7 across all other Millennium Development Goals.

### **The Millennium Ecosystem Assessment and “ecosystem services”**

In the lead up to the 2005 World Summit, the UN Secretary General, in his 2000 report “We the Peoples: The Role of the United Nations in the 21<sup>st</sup> Century”, called for the establishment of a scientific process to assess the consequences of ecosystem change for human well-being and to establish the scientific basis for actions needed to enhance the conservation and sustainable use of ecosystems and their contributions to human well-being.

Governments subsequently supported the idea, through decisions taken by four international conventions (the Convention on Biological Diversity (CBD), Convention to Combat Desertification, the Ramsar Convention on Wetlands, and the Convention on Migratory Species). As a consequence, the Millennium Ecosystem Assessment (MA) was initiated in 2001, under the auspices of the United Nations, with the secretariat coordinated by the United Nations Environment Programme (UNEP), and it was governed by a multi-stakeholder board that included representatives of international institutions, governments, business, NGOs and indigenous peoples.

The MA report<sup>37</sup> was published in March 2005, concluding that approximately 60% of the ecosystem services that support life on Earth are being degraded or used unsustainably and warning that the harmful consequences of this degradation could grow significantly worse in the next 50 years. It underlined that any progress achieved in addressing the goals of poverty and hunger eradication, improved health, and environmental protection is unlikely to be sustained, if most of the ecosystem services on which humanity relies continue to be degraded. In a nutshell, the MA report provided the first global scientific evidence of the urgency of addressing the issue of environmental sustainability and, at the same time, the inextricable link between environmental sustainability and any other development objective, particularly poverty eradication.

The use of term “ecosystem services” was a major breakthrough in this regard. Ecosystem services are described as the benefits people obtain from ecosystems, such as: food, water, timber, and fiber; regulating services that affect climate, floods, disease, wastes, and water quality; cultural services that provide recreational, aesthetic, and spiritual benefits; and supporting services such as soil formation, photosynthesis, and nutrient cycling. Accordingly, an “ecosystem services”-approach emerged among UN agencies to cooperate in responding to the findings of the MA report and mainstream environment into development processes, looking at economic strategies to mitigate the degradation of ecosystem services, to guide the allocation and use of resources as well as provide economic incentives for environmentally sustainable behaviours. Examples of such economic incentives include the establishment of carbon sequestration offsets, tradable development rights, tradable quota systems, eco-labelling, environment certification, and bio-prospecting.

### **From the High-Level Panel on Threats, Challenges and Change to the Secretary General’s Report “In Larger Freedom”**

In 2003, the Secretary General created a High-Level Panel on Threats, Challenges and Change to assess current threats to: international peace and security; to evaluate how our existing policies and institutions have performed in addressing those threats; and to make recommendations for strengthening the United Nations so that it can provide collective security for all in the twenty-first century. The Panel produced its report (“A more Secure World: Our Shared Responsibility”)<sup>38</sup> in December 2004, emphasizing that, if the world is to succeed in better protecting the security of citizens, it is essential that due attention and resources be devoted to achieving the

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<sup>37</sup> <<http://www.millenniumassessment.org/en/index.aspx>>.

<sup>38</sup> <<http://www.un.org/secureworld/High%20Level%20Panel%20Report%20on%20TCC>>.

MDGs. The report highlights economic and social issues, including poverty and environmental degradation, within its clusters of global threats, underscoring the necessity of preventive measures and to act “early, decisively and collectively.” The Panel stresses the need to address poverty, disease and environment issues in more integrated and coherent ways, to effectively promote renewable energy and address climate change, and to place the MDGs at the centre of national and international poverty-reduction strategies.

The report defined “threat to international security” as any event or process that leads to large-scale death or lessening of life chances and undermines States as the basic unit of the international system; and identified six clusters of threats, with which the world must be concerned now and in the decades ahead:

- Economic and social threats, including poverty, infectious diseases and environmental degradation;
- Inter-State conflict;
- Internal conflict, including civil war, genocide and other large-scale atrocities;
- Nuclear, radiological, chemical and biological weapons;
- Terrorism; and
- Transnational organized crime.

Environmental issues are included in the section on “Poverty, infectious disease and environmental degradation.” The report noted that environmental degradation has enhanced the destructive potential of natural disasters and in some cases hastened their occurrence, highlighting in particular that climate change produces more acute flooding, heat waves, droughts and storms, and that this pace may accelerate. It also remarked that rarely are environmental concerns factored into security, development or humanitarian strategies and that rarely is there coherence in environmental protection efforts at the global level, so that most attempts to create governance structures to tackle the problems of global environmental degradation have not effectively addressed climate change, deforestation and desertification. It called for new negotiations to produce a new long-term strategy for reducing global warming beyond the period covered by the Kyoto Protocol.

If the report had the undisputable value of injecting for the first time environmental issues into the security dialogue, specifically focusing on climate change, it regrettably disregarded other security issues linked to environmental resources, such as conflicts over scarce resources or the illegal exploitation of natural resources.

On the basis of the findings of the UN High-Level Panel, the UN Secretary General issued his report “In Larger Freedom”<sup>39</sup> in March 2005, containing his recommendations for a coherent package of decisions at the September Summit in four areas: development, security, human rights, and global institutions (UN reform). The report had a strong focus on UN reform and security-related issues, as well as development issues and MDGs.

Based on the Annex to “In Larger Freedom”, closed informal consultations within the General Assembly have been held over the last several months on developing an Outcome Document for the 2005 World Summit, under the chairmanship of the President of the General Assembly, Jean Ping of Gabon. The negotiations were organized in four clusters (according to the sections of “In Larger Freedom”): Cluster I: “Freedom from want” – poverty reduction and global prosperity; Cluster II: “Freedom from fear” – action against threats to international peace and security; Cluster III: “Freedom to live in dignity”, including human rights; and Cluster IV: The imperative for collective action: strengthening the United Nations.

From an environmental perspective, the Secretary General’s report included recommendations stressing the importance of investing in resource management, including integrated water resource management, the need for broad policy reforms at the national level, and the importance of ensuring environmental sustainability as a priority issue for the international community, particularly the three Rio conventions (desertification, biodiversity and climate change). Specifically, concerning biodiversity, the report urged the implementation of the CBD and its 2010 commitment, and on climate change, expanded on the recommendation of the High Level Panel on Threats, Challenges, and Change, urging a more inclusive framework beyond 2012 with broader participation, including developing countries, and with a focus both on emissions reductions and on mitigation. The report also referred to the need to develop a stronger UN Environmental programme (UNEP), drawing from a French proposal for UNEP reform. As a consequence, among the clusters of negotiations, environmental issues were initially envisaged as: “implementation of the Johannesburg outcome” and “Framework for climate change beyond 2012” in cluster I; and “environmental governance” in Cluster IV.

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<sup>39</sup> <<http://www.un.org/largerfreedom>>.

### **The French Proposal for the establishment of a UN Environmental Organization**

The discussions on a French proposal for UNEP reform had already occurred for quite some time within UNEP itself, under the agenda item on “international environmental governance.” Such discussions never reached the level of support hoped by the French Government, which decided to bring its proposal to a higher political level already in 2003, when a French position was announced by President Chirac to the UN General Assembly on transforming UNEP into a UN Environment Organization (UNEO).<sup>40</sup> The pre-2005 Summit process gave further visibility to the need for UN reforms in various sectors, thus providing the ideal stage for continuing discussions on the French proposal under Cluster IV.

In November 2004, the French Ministry of Foreign Affairs proposed to Prof. Pierre-Marie Dupuy to prepare a legal analysis of the proposed UNEO, in which were involved also: Prof. Francesco Francioni, Massimiliano Montini, Ricardo Pavoni, Federico Lenzerini, Francesca Devittor and Elisa Morgera.<sup>41</sup> The project<sup>42</sup> identified as the preferred option for strengthening international environmental governance the establishment of a new specialized agency of the United Nations with specific and exclusive competence in the environmental field. To ensure the political feasibility of this option, the project suggested that UNEO inherit some of the competences that are presently owned and exercised by UNEP, along with its budget and funds, premises and staff, and develop innovative functions for the coordination of environmental initiatives within the UN System as an umbrella organization. As its main task, UNEO will provide a global, overall coordination among existing multilateral environmental agreements (MEAs). It will perform innovative tasks that are not provided by MEA Secretariats individually (such as annual global cluster coordination meetings, overall integrated assessment of MEA national reports, and support to national integrated MEA implementation) without prejudice to the decision-making and budgetary independence of MEA Secretariats. Thus, the creation of UNEO will not affect in any way the current functions and status of the MEA Secretariats and will not create obligations or impact on rights of States parties to certain MEAs but non-parties to the UNEO Constitution. The UNEO Constitution would invite MEAs to accept the overall support offered by the UNEO, particularly in terms of the consideration of crosscutting issues at the global level. Support of the MEAs to the UNEO Constitution could be achieved by a decision of the Conference of the Parties of the MEA, thus eliminating the need to renegotiate the text of pre-existing MEAs.

In addition, UNEO will play a central role within the UN System for the development and implementation of environmental law at the international and national levels, through a central, integrated legal service. UNEO will emerge as the main permanent multilateral forum for environmental negotiation, through the identification of gaps in the protection already provided for by existing MEAs. It will provide legislative and institutional technical assistance and capacity building to member States, particularly developing countries, for the integrated implementation at the national level of MEAs obligations. It will also provide: capacity building to national judiciaries for the effective enforcement of environmental laws, assistance in the development of regional and bilateral agreements for the management of shared natural resources and other transboundary environmental issues; and legal advice on the resolution of environmental disputes at the regional and international level. In terms of monitoring, UNEO will periodically undertake field visits for the preparation of national/regional reports on integrated MEA implementation and contextually identify areas for support to the member States, particularly developing countries. Furthermore, it will broaden UNEP’s areas of technical assistance, targeting specifically developing countries, in the areas of: early warning and emergency; technology transfer; data collection and information; and scientific advice.

The UNEO will have a strengthened institutional status within the UN System. The UNEO will build cooperative relationships with the other international organizations with environmental competences/programmes (such as the UN Food and Agriculture Organization, the UN Development Programme (UNDP), the Commission on Sustainable Development, and the World Bank, to name but a few) on equal footing, without impinging upon their acquired competences in the environmental field. Rather, the UNEO will conclude cooperation agreements to ensure, on mutually agreed terms, an effective distribution of responsibilities and possibilities of institutional learning and ongoing consultations through common services and common arrangements as to training, interchanges of staff, joint programmes or projects. To this end, the

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<sup>40</sup> <<http://www.diplomatie.gouv.fr/frmonde/onue-en/index.html>>.

<sup>41</sup> For a more in-depth discussion on this project, see Federico Lenzerini’s contribution “The Reform of Environmental Governance in the United Nations: the French Proposal” in this Working Paper.

<sup>42</sup> <[www.diplomatie.gouv.fr/fr/IMG/pdf/Etudes\\_iddri\\_juridique\\_EN.pdf](http://www.diplomatie.gouv.fr/fr/IMG/pdf/Etudes_iddri_juridique_EN.pdf)>.

report suggested establishing an agreement with UNDP for a systematic joint management of the Global Environment Facility's (GEF) projects, in order to ensure to both organizations an equal share of the service fees whilst at the same time providing for a more cost-efficient task sharing. It will build stronger relationships with the other specialized agencies, through agreements that respect existing acquired competences in the environmental field, and allow for institutional learning and effective cooperation. Finally, it will play a multi-faceted role in environmental dispute prevention and resolution. It will prevent disputes through emergency response to environmental disasters and compliance monitoring systems. It will aid in resolving disputes through mediation and conciliation or through legal advice on judicial dispute settlement.

The UNEO should be established by a multilateral treaty, to be negotiated by an international conference, possibly within the framework of UNEP, with the participation of representatives of the UN member States, all the UN Programmes and Specialized Agencies having environmental competencies and/or programmes, the Secretariats of the MEAs, the World Bank, the GEF, the major international environmental NGOs and the private sector.

### **The Outcome of the 2005 World Summit**

Three aspects of the Outcome Document<sup>43</sup> of the 2005 World Summit are significant from an international environmental law perspective. First of all, an extensive section of the document has been devoted to "sustainable development: managing and protecting our common environment", besides other references to environmental protection and sustainable development, scattered in the text. Secondly, the document addressed, albeit to a very limited extent, the issue of possible reforms of international environmental governance. And thirdly, a commitment to develop and implement MDG-based national development strategies may also have an impact on the international protection of the environment.

It is interesting to note that the agreed Outcome Document devotes a quite extensive section to environmental protection, particularly if compared with the initial drafts. General Assembly President Ping's initial text, prepared after consultations with governments in early July 2005, referred to sustainable development only twice (once in the paragraph on environment and once in the section on international environmental governance), and to four environmental issues (climate change, desertification, biodiversity and freshwater). The final document uses the term 'sustainable development' twenty-five times and addresses nine environmental issues (sustainable consumption and production, climate change, desertification, biodiversity, freshwater, forests, chemical and hazardous wastes, oceans and seas, and the transportation of radioactive materials by sea through SIDS). Respect for nature is also included in the opening section of the Outcome Document on values and principles, and sustainable development is considered "a key element of the overarching framework of United Nations activities."<sup>44</sup>

The commitments mainly collect language previously agreed in other international fora, such as the 2002 World Summit on Sustainable Development (WSSD) and the 2005 Mauritius International Meeting on Small Island Developing States (SIDS). Many NGOs expressed their disappointment at the "watered-down Summit Declaration, at best a mere regurgitation of commitments long adhered to" with "no sense of urgency."<sup>45</sup> Nonetheless, it is indeed a victory for the environmental community that all these interrelated environmental issues have been included in what is expected to be the agenda for the next ten years' intergovernmental cooperation, and that 151 Heads of State and Government have re-confirmed their agreed commitments to address global environmental challenges collectively.

With regard specifically to climate change, the commitment to "initiate negotiations to develop a more inclusive international framework on climate change post-2012", which was among the most pressing issues in the Summit process, has been replaced by softer language on recognizing that the UN Framework Convention on Climate Change (UNFCCC) is the appropriate framework for addressing future action on climate change, at the global level (para. 51) and on calling for widest possible cooperation and participation in an effective and

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<sup>43</sup> 2005 World Summit Outcome (A/60/1, 15 September 2005).

<sup>44</sup> The same language was agreed upon in the Report of the World Summit on Sustainable Development, Plan of Implementation of the World Summit on Sustainable Development (A/CONF.199/20, 4 September 2002), Resolution 2, para. 125, at the 2002 World Summit on Sustainable Development.

<sup>45</sup> Vicente García-Delgado, CIVICUS' UN Representative.



appropriate international response within the principles of the UNFCCC (para. 53). With regard to the transportation of radioactive materials by sea through SIDS, it is interesting to note that the Outcome Document reproduces *verbatim* para. 25 of the Mauritius Strategy, which was one of the most controversial to be agreed upon at the Mauritius International Meeting.

In terms of possible reforms of international environmental governance, the Outcome Document devotes one paragraph (para. 169) to this issue, under the somewhat disappointing title of “environmental activities.” States recognized the need for more efficient environmental activities in the UN system, and agreed to “explore the possibility of a more coherent institutional framework to address this need, including a more integrated structure, building on existing institutions, and internationally agreed instruments, as well as the treaty bodies and the specialized agencies.” Although the French proposal to create a UNEO was not endorsed at the Summit, or received with a strong commitment to promptly consider the matter at a later stage, the Outcome Document leaves the door open for future intergovernmental negotiations on this matter. Even in the face of such a limited result, the UN Summit led to two advantages: first of all, it offered an opportunity for this French initiative to become a EU proposal,<sup>46</sup> which will certainly contribute to increasing its political leverage; secondly, it brought the discussion to a higher political level, since the issue is no longer only on the agenda of UNEP itself, but also on that of the General Assembly.

Finally, the Outcome Document embodies a commitment, in para 22 (a), to adopt, by 2006, and implement comprehensive national development strategies to achieve the internationally agreed development goals and objectives, including the Millennium Development Goals. Although there is no reference to the integration of environmental sustainability in these MDG-based development strategies (which was included in earlier versions of the draft), this still remains an aim for the UN treaties and bodies devoted to environmental protection. This is particularly necessary given the little discussion at the national level on environmental issues in the framework of MDGs, as documented by the 2005 UNDP report on “Environmental Sustainability in 100 MDG Country Reports,” according to which more than sixty countries view environment issues as constraints to development. UNEP has already undertaken a series of consultations with MEAs and other partners to find ways of ensuring environmental integration in MDG-related development cooperation, using the concept of “ecosystem services” as a bridge between MDG-7 and all the other goals, and building upon a renewed interest for economic instruments for environmental protection.<sup>47</sup>

In conclusion, the 2005 World Summit Outcome Document did not provide innovative language on international environmental protection, did not initiate intergovernmental negotiations on pressing environmental issues, and did not even succeed in providing the much-needed high-level support to the post-Kyoto phase of global climate politics or to the much-needed reform of international environmental governance. Nonetheless, it managed to embed into the intergovernmental cooperation agenda for the next ten years a significantly vast array of environmental issues, much beyond the vision of the UN High-Level Panel and of the UN Secretary General. It managed to confirm and possibly reinforce, at the highest global political level, commitments already agreed up in previous, much more environmentally aware, fora. Whether these positive, albeit modest, results will have an impact on the ongoing negotiations in the international environmental arena and in the intergovernmental efforts to support sustainable development remains to be seen.

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<sup>46</sup> EU Presidency Statement at the UN 2005 World Summit (14 September 2005: New York), found at <[http://europa-eu-un.org/articles/en/article\\_5026\\_en.htm](http://europa-eu-un.org/articles/en/article_5026_en.htm)>.

<sup>47</sup> <[http://www.unep.org/dec/support/mdg\\_meeting\\_lon.htm](http://www.unep.org/dec/support/mdg_meeting_lon.htm)>.

**Climate Change**

**How to Prevent Babies from Being Thrown Away with the Bathwater:  
Perspectives on the International Climate Regime  
from Buenos Aires to the Future**

Kati Kulovesi\*

The objective of this contribution, which builds on my presentation on 21 April 2005, is to share some practical experiences from the tenth Conference of the Parties (COP-10) to the United Nations Framework Convention on Climate Change (UNFCCC),<sup>48</sup> held from 6 to 18 December 2004, in Buenos Aires, Argentina, and reflect these in light of some broader issues relating to the international climate change regime. I focus on a question that assumed an important role during COP-10 even though it was too controversial to be included in the official agenda: the future of the international climate regime beyond 2012, when the first commitment period under the Kyoto Protocol ends.

The political momentum to consider the future of the international climate regime has been growing steadily since Buenos Aires. Parties to the UNFCCC met in May 2005 to discuss the topic informally,<sup>49</sup> and the first Meeting of the Parties (MOP-1) of the Kyoto Protocol should start considering future commitment periods in December 2005.<sup>50</sup> Also the latest climate research, including the Arctic Climate Impact Assessment, emphasises the need to formulate long-term climate policies and adopt stricter emissions controls. In any case, the existing international instruments were always known to be insufficient to achieve the objective of "stabilization of greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system."<sup>51</sup> The main contribution of the UNFCCC and its Kyoto Protocol was therefore to establish a legal and administrative framework for further action against global warming. International climate negotiations are, however, a complicated game, and it is not certain how fast, and in what direction, the process will continue from here.

**The long journey from Kyoto to Buenos Aires**

Before it even entered into force in 2005, the Kyoto Protocol had travelled a long and difficult journey. When the treaty was adopted in December 1997 in Kyoto, Japan, its birth was celebrated as an important landmark. The Protocol prescribes, for the first time, binding targets for industrialised countries and economies in transition (known as Annex I countries) to reduce their greenhouse gas emissions by an average of 5% from 1990 levels during the first commitment period between 2008 and 2012. Other remarkable features in the Kyoto Protocol include possibilities for its flexible and cost-efficient implementation through the

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<sup>48</sup> The United Nations Framework Convention on Climate Change, (New York, 9 May 1992).

<sup>49</sup> The Seminar of Governmental Experts was held on 16 and 17 May 2005, at the Maritim Hotel in Bonn, Germany.

<sup>50</sup> Kyoto Protocol to the United Nations Framework Convention on Climate Change, (New York, 16 March), Article 3(7).

<sup>51</sup> UNFCCC, Article 2.

'Kyoto Mechanisms,' namely international emissions trading (Article 17), Joint Implementation (JI) (Article 6), and the Clean Development Mechanism (CDM) (Article 12). The latter two are based on projects implemented to reduce emissions, or to remove greenhouse gases by carbon sinks, following strict international rules and procedures.

However, ensuring a sufficient number of ratifications for the Kyoto Protocol to enter into force proved difficult, and there was a major defeat along the way. The U.S. Congress has never been the biggest admirer of the Kyoto Protocol. One of the key reasons is the principle of common but differentiated responsibilities, according to which developing countries are not required to limit their greenhouse gas emissions during the first commitment period. The Clinton Administration thus attempted to convince some of the most advanced developing countries to take voluntary emissions targets in order to make Kyoto more acceptable to American congressmen.<sup>52</sup> The Bush Administration chose a different path, however, and dealt a huge blow to international climate cooperation by announcing in March 2001 that the U.S. would not ratify Kyoto as it was "fatally flawed in fundamental ways" and contrary to American economic interests.<sup>53</sup> Instead of cutting absolute emissions by 7% from 1990 levels as required by the Kyoto Protocol, Bush launched a climate programme focused on reducing the greenhouse gas intensity of the U.S. economy.<sup>54</sup> As a result, American emissions currently exceed the Kyoto target by some 20%, and it is therefore not realistic to expect the U.S. ever to join the Protocol in its current form.<sup>55</sup> Also Australia withdrew from the Kyoto Protocol; in Canada, Kyoto's ratification was preceded by a lengthy debate; and a member of the Japanese delegation once told me that the main reason Japan, the country with the most ambitious emissions target, ended up ratifying the Protocol was that the instrument was born in Japan and given the name "Kyoto."

The U.S. refusal to ratify Kyoto twisted the plot in the international climate story in two significant respects. First, the U.S. is the world's largest emitter of greenhouse gases. Its share of industrial country emissions in Kyoto's chosen base year of 1990 was 34%, and its share of global total emissions is currently around 24%.<sup>56</sup> To effectively address global warming, American participation would thus be crucial. The U.S. withdrawal also caused some formal difficulties. According to Article 25(1) of the Kyoto Protocol, its entry into force required ratification by Annex I countries representing at least 55% of the total emissions of those countries in 1990. The only prospect for Kyoto to enter into force without the U.S. was to be ratified by the Russian Federation, accounting for 17.4% of the required emissions. Following Bush's shock announcement, all eyes therefore turned to Moscow, and the hottest topic in international climate circles between March 2001 and October 2004 was Russian climate

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<sup>52</sup> Argentina, for instance, adopted a voluntary target to reduce the growth of its greenhouse gas emissions.

<sup>53</sup> "President Bush discusses global climate change," *White House Press Release*, 11 June 2001, found at <<http://www.whitehouse.gov/news/releases/2001/06/20010611-2.html>>.

<sup>54</sup> On U.S. Climate Policy, see the U.S. Department of State web site, found at <<http://www.state.gov/g/oes/rls/fs/2004/38641.htm>>.

<sup>55</sup> According to the latest U.S. emissions inventory under the UNFCCC, American greenhouse gas emissions were 13 % above 1990 levels in 2003. *Executive Summary of the Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2003*, at 3, found at <<http://yosemite.epa.gov/oar/globalwarming.nsf/content/ResourceCenterPublicationsGHGEmissionsUSEmissionsInventory2005.html>>. The Kyoto target for the U.S. would have been 7 % below 1990 levels between 2008 and 2012.

<sup>56</sup> Based on U.S. official energy statistics, found at <<http://eia.doe.gov/>>.

policy. The Russian Government made the long-awaited announcement a few weeks before COP-10, marking the most important development in the year 2004. None of the decisions adopted in Buenos Aires came close to being as significant. A rumour has it that climate change may not have been the driving force behind the Russian ratification, but that the motivation came from a link that the EU allegedly made between Russia's membership in the World Trade Organization and its ratification of the Kyoto Protocol.<sup>57</sup> Be that as it may, the Kyoto Protocol finally entered into force on 16 February 2005, and has currently been ratified by 156 countries, including the most economically advanced developing countries such as Argentina, Brazil, China, India, Mexico and South Korea, and excluding, most notably, the U.S. and Australia.

### **And yet another long journey from Buenos Aires to the future**

The Russian decision to ratify the Kyoto Protocol inevitably left its mark on the tenth gathering of the parties to the UNFCCC. Had the Russians not announced their ratification just prior to COP-10, speculation over the fate of the Kyoto Protocol would have undoubtedly dominated the conference. However, now that short-term uncertainty concerning the international climate regime was finally over, attention could be directed to other issues. Contrary to what one might have expected, the mood in Buenos Aires was not one of accomplishment and celebration. Instead, a new concern seemed to already occupy people's minds: the prospects of the regime beyond Kyoto's first commitment period. To most people, the Kyoto Protocol is, after all, just an inadequate first step laying down the foundations for a stricter regime with broader participation. However, the next step in the regime-building exercise will be difficult to complete.

I have described Kyoto's teething troubles precisely in order to illustrate why the future of the global climate regime is such an important but also an incredibly problematic topic. To put it frankly, after some 15 years of international climate negotiations, countries are yet to find a format that would be both effective and acceptable for all the major players. The Buenos Aires COP confirmed just how difficult it is to haul all the relevant countries around the negotiation table to discuss future commitments. The question of commitments beyond 2012 was too controversial to be included on the agenda at COP-10. After lengthy negotiations nicknamed "talks about talks about talks",<sup>58</sup> the host country Argentina, strongly supported by the EU, managed to persuade the more reluctant counterparts, including Brazil, China, India, Saudi Arabia and the U.S., to agree to an informal seminar to discuss the future of the climate regime.

This Seminar for Governmental Experts was held in Bonn in May 2005 without any formal mandate to feed into the climate process. Given how difficult it was to reach an agreement on the Seminar at COP-10, expectations prior to the event were rather pessimistic and skeptical. It came therefore as a pleasant surprise that the Seminar managed to inspire a rather frank and open exchange of views amongst the participants. The atmosphere was relaxed and countries felt they could honestly elaborate their concerns and explain their positions.<sup>59</sup> However, the presentations also revealed a plethora of diverse visions for a future climate regime, starting

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<sup>57</sup> "Russia forced to ratify Kyoto Protocol to become WTO member," *Pravda*, 26 October 2004, found at <[http://english.pravda.ru/main/18/88/354/14495\\_kyoto.html](http://english.pravda.ru/main/18/88/354/14495_kyoto.html)>.

<sup>58</sup> In other words, "negotiations on how to organize seminars that discuss future climate negotiations."

<sup>59</sup> 12: 261 *Earth Negotiations Bulletin*, found at <<http://www.iisd.ca/vol12/enb12261e.html>>.

from either binding or non-binding emissions targets; travelling through the explosive territory of climate equity, historical responsibility and convergence of *per capita* emissions; and ending with a rather different system that would focus on cleaner fossil fuel technologies and carbon capture and storage. Reaching an agreement on the post-2012 period will thus be extremely difficult. This impression has been reinforced by subsequent developments: in July 2005 some of the most significant emitters, including Japan (that has the most difficult Kyoto target), the U.S. and Australia (that have not ratified Kyoto), and China, India and South Korea (that do not have quantitative commitments under Kyoto) announced plans for a new international climate pact outside the existing UN framework.<sup>60</sup> Even if this cooperation never leads to anything substantive and serious, it illustrates that the divide between the key actors in the UN climate regime is currently wide, and some of them are considering other options.

Two other themes that were close to the surface at COP-10 in Buenos Aires were adaptation (to the extent that the Conference was nicknamed 'Adaptation COP') and the Clean Development Mechanism. Interestingly, these two topics also touch upon questions that will be crucial in the long-term. It is becoming increasingly clear that global warming cannot be completely avoided. Therefore, policies, measures and considerable amounts of money are needed to adapt to its consequences, including extreme weather events. Since the most serious impacts of climate change are predicted to take place in some of the world's poorest regions, 'adaptation' involves a strong development dimension. However, also adaptation was a politically charged topic at COP-10, with Saudi Arabia and some other oil-producing developing countries insisting that also negative impacts of climate mitigation measures (i.e. declining oil revenues) must be compensated in this context. Apart from instructing the Subsidiary Body for Scientific and Technological Advice to draw a five-year programme on adaptation, COP-10 merely affirmed decisions by previous COPs. Further struggles on adaptation are therefore sure to follow.

As to the CDM, its contribution to the transfer of cleaner technologies to developing countries to avoid a carbon-intensive path of economic growth similar to what the industrialized countries followed is a small but nevertheless significant step in action against climate change. Given that the CDM has been operational since 2000, there were already practical experiences to discuss at COP-10. Opinions voiced in Buenos Aires revealed that several countries, and especially private actors involved in project implementation, are far from satisfied with the CDM and its Executive Board. This is largely due to complicated and time-consuming procedures and difficulties in demonstrating project 'additionality.' Concerns were also raised over the uneven geographical distribution of projects - there are only very few in Africa but plenty in Latin America. CDM projects have also tended to focus on the most potent greenhouse gases, methane and hydro-fluorocarbons, thus offering cheap carbon credits for investors but often making only a very small contribution towards the sustainable development of the host country. However, despite the critiques, it was clear that the basic concept underlying the CDM still enjoyed broad support from industrialised and developing countries, as well as the private sector. Thus, one of the very few things that looks certain is that a mechanism similar to the CDM is likely to find its way to a future climate treaty.

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<sup>60</sup> "Announcing the Asia-Pacific Partnership on Clean Development" *U.S. State Department Press Release*, 28 July 2005, found at < <http://www.state.gov/s/d/rem/50326.htm>>.

### **Signposts for the future journey**

Even when it was born, the Kyoto Protocol always had its flaws. In December 1997 it was already known that its modest emissions cuts would not come close to meaningfully addressing global warming. After the largest emitter withdrew from the treaty, Kyoto's contribution is even less significant. Furthermore, it has been estimated that several EU countries parties to the Protocol and committed to combating climate change, including Denmark, Greece, Italy, the Netherlands, Portugal and Spain, will face difficulties in reaching their Kyoto targets.<sup>61</sup> Formulating detailed rules and procedures for implementing the Kyoto Protocol has also been an incredibly bureaucratic exercise. Thus, Kyoto's main achievement so far seems to be a highly complicated jargon that makes even the most dedicated climate nerds struggle: it is not always easy to understand all the complexities involved in establishing assigned amounts, greenhouse gas inventories and greenhouse gas registries; fulfilling the eligibility criteria for the flexibility mechanisms and applying approved baseline methodologies and additionality requirements for the project-based mechanisms, trading and generating different types of registry units (AAUs, RMUs, ERUs and CERs);<sup>62</sup> and interacting with expert review teams and the facilitative and executive branches of the compliance committee.

When considering the future, one of the big question marks thus hanging in the ominously warming air is whether we are talking about a "post-2012" period - or a "post-Kyoto" period. The strongest support for continuing the Kyoto regime seems to be coming from environmental NGOs and the EU. However, doubts have recently been voiced even from within the EU ranks. Prime Minister Tony Blair, once the most vocal supporter of Kyoto, first failed to fulfil his (rather unrealistic) promise of persuading President Bush back onboard, and now Blair seems to be backing down himself, mostly because also the United Kingdom may have troubles meeting its emissions target.<sup>63</sup> Also, as a representative of the European Commission pointed out in May 2005, the fact remains that the EU only accounts for (a declining) 14% of global greenhouse gas emissions and thus "even closing down the European economy would not stop climate change."<sup>64</sup> To put it in another way, it does not make much sense for the EU to insist on continuing with the Kyoto Protocol beyond 2012 if this means cutting emissions all by itself.

On the other hand, the Kyoto Protocol and its detailed rules have taken years and painstaking efforts to finalize. It would be pure madness to throw the baby away with the bathwater. At the end of the day – there is no magical remedy that would do away with all the difficulties encountered under the current regime. To mitigate global warming, greenhouse gas emissions must be cut. This requires international cooperation and joint efforts. Non-binding targets advocated by the U.S. have already been proven unsuccessful: the target stipulated in Article 4(2) of the UNFCCC for industrialised countries to return to their 1990 emissions levels has

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<sup>61</sup> They can, however, use Kyoto's flexibility mechanisms to meet any shortage. The Netherlands, for instance, has decided to meet half of its Kyoto target by carbon credits purchased by using the Kyoto mechanisms.

<sup>62</sup> AAU = Assigned Amount Unit used in emissions trading under Article 17; RMU = Removal Unit resulting from a sink projects; ERU = Emissions Reduction Unit resulting from JI projects under Article 6; CER = Certified Emissions Reduction resulting from CDM projects under Article 12.

<sup>63</sup> "Blair signals shift over climate change" *The Guardian*, 2 November 2005, found at <<http://www.guardian.co.uk/climatechange/story/0,,1606602,00.html>>.

<sup>64</sup> Presentation by Artur Runge-Metzger "Winning the battle against global climate change" *ENB on the Side*, 19 May 2005, found at <<http://www.iisd.ca/climate/sb22/enbots/19may.html>>.

not had any practical impact on global emissions, with the U.S. itself exceeding the 1990 emissions levels by some 13%. Mandatory targets, in turn, require reliable greenhouse gas inventories and transparent reporting with a possibility for an independent review and penalties for non-compliance in order for the regime to be fair and credible. All of these elements have already been created under the Kyoto system. Kyoto's flexibility mechanism, and especially the CDM, may have turned out to be bureaucratic and very complicated to implement, but the underlying ideas of flexibility and cost-efficiency are essential components in any future climate regime.

Thus, even though the post-2012 climate regime may well require some new elements, such as an increased focus on the creation and transfer of climate-friendly technologies, many of the other necessary details have already been negotiated under the Kyoto framework. What the post-2012 regime most desperately needs is broader participation and therefore innovation in terms of defining emissions targets and categorising countries. Against this background, the magic potion for international climate negotiations is, first and foremost, a critical but open-minded examination of the virtues and flaws of the Kyoto Protocol. A healthy dose of realism and common sense would also help in bridging the gap between those who still belittle anthropogenic climate change, and those who tend to overlook the fact that when designing an effective regime, economic needs and realities must be taken into consideration. However, as the adverse impacts of global warming are becoming more visible and the need for effective action is growing more urgent, also creative thinking, good negotiation skills, and heroic acts will be needed during what promises to be a long and painful delivery of the post-2012 climate regime.

### **The Climate Change Regime: Recent Developments at the International, EU and Italian level**

Massimiliano Montini\*

The legal regulation of climate change and the coordination of the international efforts in this sense among different actors around the world represents a top priority at various levels. The aim of the present contribution is to briefly describe some recent developments in the evolution of the climate change regime at the international and European levels, before addressing some specific issues related to the implementation of those regimes into the Italian legal order.

#### ***THE INTERNATIONAL CLIMATE CHANGE REGIME: WHERE DO WE STAND?***

At the international level the climate change regime is at a crossroad. The Kyoto Protocol (KP) to the United Nations Framework Convention on Climate Change (UNFCCC), which currently represents the greatest effort ever put in place by the international community to curb greenhouse gas (GHG) emissions and tackle climate change, finally entered into force in February 2005, following the long-awaited ratification by the Russian Federation.

At the first COP/MOP (Conference of the Parties serving as the Meeting of the Parties to the Kyoto Protocol), which will be held in Montreal from 28 November to 9 December 2005, together with COP-11 (Conference of the Parties to the UNFCCC) however, there will be no time for celebration. This is due to several reasons.



Firstly, the KP, which was originally signed in 1997, has lost along the way some of its original signatory States. Notably, the USA, the largest GHG emitter on the planet, as it is well known, has decided not to ratify the Protocol, and whilst not denying the existence of a climate change problem, holds that the KP does not represent the right response to the issue. According to the US administration, the fight against climate change should not be based on such a costly regime, but should rather be pursued through the promotion of a slow and voluntary reduction of GHG emissions by all affected sectors of the economy pushed by new low-carbon intensive technology to be gradually put on the market. The main supporter of this alternative vision, along with the USA, is presently represented by Australia, but a great interest for the achievement of GHG emissions reductions commitments by means of a market-based effort, rather than by a Government-imposed series of binding targets for both the public and private sector, as represented by the rigid system envisaged by the KP for the most industrialised countries around the world, is shared by many other States. An example in this sense is the “Asia-Pacific Partnership for Clean Development and Climate” announced in July 2005 by the USA together with five countries of the Asian-Pacific Region – namely Australia, India, Japan, China and South Korea.<sup>65</sup>

Secondly, since the KP presently foresees binding reduction commitments of GHG emissions by industrialized countries (Annex I Parties) only for the period 2008-2012, the discussion on the future commitment periods is already started at COP-10 in 2004. Officially, Parties to the UNFCCC met in Bonn in May 2005 within the framework of the Seminar of Governmental Experts requested by COP-10 to the Secretariat, in order to promote an informal exchange of information on actions as well as policies and measures to develop effective and appropriate responses to climate change with a look at the post-2012 targets. Such a discussion will be then reopened in Montreal at COP/MOP-1 later this year, but has in fact already been addressed informally in several other international fora, such as a few recent meetings within the framework of the G8, the group of the most industrialised countries in the world, which has recently paved the way for a transformation of the post-2012 discussion into a post-Kyoto discussion. In this sense, several States have started arguing that, rather than establishing other commitments for the present group of States, which already have existing commitments for the period 2008-2012, the international community should try to overcome the shortcomings of the Kyoto Protocol and work out a completely new agreement, which may find wider support in the global community, including most of the important countries that presently do not have binding GHG reduction commitments, such as the USA and Australia among the industrialised countries, and China and India among the group of developing countries with high GHG emissions rates.

### ***THE EUROPEAN CLIMATE POLICY: THE WAY FORWARD***

The European Community and its member States are both members to the UNFCCC and in Annex B to the Kyoto Protocol they agreed on a global -8% of GHG reduction, with the understanding that such a global amount of reduction would have been then re-assigned among the members States by means of a separate and internal agreement. This was done later on through the so-called “burden sharing agreement”, contained in an *EC Environment Council Decision* of June 1998.

The EC and its member States then ratified the Kyoto Protocol in 2002, through the *Council Decision 2002/358/EC of 25 April 2002 concerning the approval, on behalf of the European Community, of the Kyoto Protocol to the United Nations Framework Convention on Climate Change and the joint fulfilment of commitments thereunder*. The Kyoto Protocol, as well as many other international environmental agreements, are “mixed agreements”, in the legal wording of EU law, insofar as it is ratified both by the EC and its member States, each one of them being responsible within the limits of its competence in the environmental field.

However, the EU had already started the implementation of a specific Climate Change Policy before the ratification of the Kyoto Protocol. Apart from some examples of early actions to tackle climate change, the first official basis for EU Climate Policy has been the first European Climate Change Programme (ECCP), adopted in 2000, which defines in general terms EU policies and measures to address climate change, with regard, in particular, to the energy, transport and industry sectors (see *Communication on EU policies and measures to reduce greenhouse gas emissions: Towards a European Climate Change Programme (ECCP), COM (2000) 88*).

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<sup>65</sup> See Kati Kulovesi’s contribution “How to Prevent Babies from Being Thrown Away with the Bathwater: Perspectives on the International Climate Regime from Buenos Aires to the Future” in this Working Paper.

The EU Climate Policy has also paved the way for the introduction of a climate change legal regime, mainly based on two EC Directives. The first one is Directive 2003/87/EC, which has instituted a EU-wide emissions trading scheme (ETS) (see *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*); the second one is Directive 2004/101/EC, the so-called “EU Linking directive”, which has put in place a system for the direct transfer of credits from Joint Implementation (JI) and Clean Development Mechanism (CDM) projects into the EU ETS (see *Directive 2004/101/EC of the European Parliament and of the Council of 27 October 2004 amending Directive 2003/87/EC establishing a scheme for greenhouse gas emission allowance trading within the Community, in respect of the Kyoto Protocol's project mechanisms*).

The implementation of Directive 2003/87/EC on the EU ETS is of particular importance and it represents a milestone on the way to reaching the Kyoto targets by the European Community. The extent to which the EU ETS will contribute to the EU climate policy largely depends on the correct elaboration of the National Allocation Plans (NAPs), to be drafted by the member States and sent to the European Commission for approval. The NAPs identify the quantity of allowances initially allocated by each State to the operators of the installations covered by the directive, on the basis of objective and transparent criteria established under Annex III to the directive.

In February 2005, the European Commission announced the launch of a new phase of the European Climate Change Programme (ECCP II) with the Communication *Winning the battle against climate change* (COM (2005) 35). In October 2005, it organised a stakeholder conference in preparation for the start of the second European Climate Change Programme, which should revise and update the first European Climate Change Programme, with a specific focus on tackling transport emissions and more support for carbon capture and storage. Within the framework of ECCP II, three working groups will be created in order to produce by mid-2006 a set of “policy orientations that might be able to go to legislation.” The three groups will deal with aviation, road transport and carbon capture.

### ***ITALY AND THE INTERNATIONAL AND EUROPEAN CLIMATE CHANGE REGIMES***

The implementation in Italy of the International and European climate change regimes has raised several issues in recent years.

National strategy on climate change mitigation set up by the Ministry for Environment and Territory (MET) is based on two key framework instruments:

- 1) National Plan for the Reduction of GHG (NRP), based on the following acts:
  - *Deliberazione CIPE (Interministerial Committee for the Economic Programme) 137/1998*, which contains national policies and measures to reduce greenhouse gas emissions;
  - *Law 120/2002*, on the ratification and implementation of the Kyoto Protocol;
  - *Deliberazione CIPE 123/2002*, with a revision of the national policies and measures to reduce greenhouse gas emissions contained in *Deliberazione CIPE 137/1998*).
- 2) National Allocation Plan, as required under Article 9 of directive 2003/87/EC establishing a greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.

As far as the European climate change regime is concerned, Italy has shown more than a problem in the implementation of the EU Emissions trading directive: firstly in the issuance of the national implementing legislation, failing to transpose the EU provisions on time; and secondly in the adoption of the NAP, officially submitted just in February 2005 (deadline of 31 March 2004) and approved with conditions by the European Commission in May 2005, which however has not been definitively issued by the Italian Government yet.

Both such issues, namely the lack of operational rules and the saga of the Italian NAP, not yet adopted almost one year after the date in which it had to become operational, to allow national installations to participate in the Emissions Trading scheme, are causing an unacceptable delay to those Italian companies which would have liked to start operating on the market since the beginning – 1 January 2005 - thus seriously undermining the competitiveness of national industrial sectors covered by the scheme with respect to their EU counterparts.

Beyond the NAP, a further brief comment can be made on the Italian climate change policy. In Italy, many commentators argued from the very beginning that the 6,5% reduction of GHG emissions target as agreed under the KP, as supplemented by the EC “burden sharing agreement”, appeared to be very challenging for the national energy and industrial system and quite difficult to achieve. This notwithstanding, in the past few years, while awaiting the entry into force of the KP, insufficient efforts were undertaken to pursue an effective policy for the reduction of GHG emissions at the national level. As a consequence, Italy is currently well behind the schedule set up by the mentioned international and European climate regimes, with a tendency to increase rather than decrease emissions and a growing distance from its agreed target.

In such a situation, where the implementation of the KP flexible mechanisms will be needed to meet international and European targets, the Italian Government is pursuing an international campaign to get carbon credits from JI/CDM projects, both through the establishment of several informal (Memoranda of Understanding) with other countries in the world and with the establishment and participation in a few carbon funds administered by the World Bank, including the *Italian Carbon Fund*.

**Biodiversity and Biotechnology  
and the Governance of Risk**

## **Access and Benefit-sharing in Natural Plant and Human Genetic Resources for the Production of Medicines**

Hélène Boussard & Aphrodite Smagadi\*

The regulation of natural plant genetic resources and the successive regulation of human genetic resources raise some common issues centred on the recognition of sovereignty or property rights, the choice of adopting the qualification of common heritage of mankind and the implementation of the principle of benefit-sharing. The specificity of the two fields justifies different legal constructions based on the same legal concepts.

### **1. INTRODUCTION**

This contribution is an attempt to draw a parallel between the regulation of the utilization of natural plant genetic resources (NPGR), on the one hand, and human genetic resources (HGR), on the other, for the production of medicines. In other words, it deals with the regulation of genetic resources, with the exception of animal genetic resources and microorganisms, in the so-called “red biotechnology”- that is the application of biotechnology in medicine.<sup>66</sup> Also excluded from this analysis are genetic resources out of state jurisdiction. First, Part 1 describes the access and benefit-sharing international framework in the field of NPGR and explores the implementation trajectories of the Convention on Biological Diversity (CBD) principle on access and benefit-sharing and pinpoints some issues. Next, Part 2 discusses the international construction with respect to the use of HGR in the production of medicines. Finally, a conclusion is offered, with the principal differences and analogies. It is important, however, to bear in mind the obvious difficulties and limitations of developing in the short space of this presentation more than the basic outlines of an analysis on a subject of this nature and complexity.

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<sup>66</sup> The “red biotechnology” is distinguished from the “green” and the “white” biotechnologies, which refer respectively to the agricultural and industrial application of biotechnology. The legal treatment of NPGR used for food and agriculture is a complex issue that does not readily fall within the bilateral framework contemplated under the CBD for access and benefit-sharing. A multilateral system has been recently established to put into practical effect the access and benefit-sharing principle in the context of the global system for NPGR, i.e. FAO International Undertaking and International Treaty. Regarding HGR, they are potentially interesting not only in scientific research and biomedical applications (genetic screening, counseling and therapy), but also in the production of medicines: all these applications are part of the “red biotechnology” (medical application *lato sensu*) and issues such as the principle of benefit-sharing are discussed with the same understanding.

## **2. ACCESS AND BENEFIT-SHARING IN THE USE OF NPGR IN THE DRUGS INDUSTRY<sup>67</sup>**

This part first introduces some concepts and terms and then takes up two principal considerations raised in the access and benefit-sharing context: the sovereignty/property rights over genetic material and the indigenous peoples' permanent sovereignty over natural resources.

### ***2.1. DEFINITIONS AND THE PROBLEM***

What is biodiversity: Biological diversity or biodiversity can be described very briefly as the number and variety of living organisms on earth, including ecosystems, species and genes. Biodiversity is a very difficult term to define, because it involves features that distinguish it from conventional management resources: it is renewable, if it is used sustainably, but species/resources can become extinct, if they are not used sustainably. Plants, animals, fungi and microorganisms and human genetic resources form part of the biological diversity of the planet. The Conference of the Parties (COP) to the CBD interpreted the access and benefit-sharing provisions of the CBD in such a way as to exclude human genetic resources from the CBD scope.<sup>68</sup> However, this aspect of access to genetic resources raises profound ethical questions and remains largely unregulated. Biodiversity can also be "bad": the genetic distinctiveness of the human immunodeficiency virus (HIV) or the boundless proliferation of fungal crop diseases are undesirable biodiversity expansions. Biodiversity does not only involve a material aspect, namely the variety of tangible animals, plants and ecosystems, and the interrelationships between these elements; it also reflects a concept that stands for the variability of life, the diversity of all the living organisms and their interdependence, the evolutionary capacity of the system through space and time.

What is bioprospecting: Biodiversity prospecting (or bioprospecting) is the exploration/search of biodiversity and collection of its resources for commercial purposes. The main industries active in bioprospecting are the pharmaceutical, botanical medicine, cosmetic and personal care, biotechnology, seed and crop protection, chemicals, and horticulture industries. In "red biotechnology", very often the production of a medicine by private companies is based on genetic resources from plants, microbial sources, animal genetic resources, marine organisms and insects that lie within the borders of developing countries rich in biotas. Lately, human genetic resources (like human proteins produced by rDNA techniques) have attracted considerable attention in medicinal uses.<sup>69</sup>

What is biopiracy: "Biopiracy" has emerged as a term to describe the ways corporations from the developed world claim ownership of, free ride on, or otherwise take advantage of, the genetic resources and traditional knowledge and technologies of developing countries. In the

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<sup>67</sup> Part 1 has been written by Aphrodite Smagadi working on the doctoral thesis: "The Utilization of Natural Plant Genetic Resources and Benefit-sharing for the Production of Medicines: the Impact of the Implementation of the Convention on Biological Diversity." The current contribution to the EUI WGEL Working Paper aims at presenting as concisely as possible the use of plant genetic resources in red biotechnology.

<sup>68</sup> Decision II/11 Access to Genetic Resources, Second Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, 6-17 November 1995 – Jakarta, Indonesia.

<sup>69</sup> See under Part 2.

field of NPGR, many species and crops, like quinine, rubber and cocoa, were “smuggled” in the past. Very often, genetic resources alone are hardly useful if not accompanied by the knowledge and experience of the local communities. These communities or individuals provide the bioprospectors with precious guidance, “traditional medicinal knowledge”, concerning the qualities of plant genetic material, and, hence, they facilitate the efforts of researchers in the drug development process. Biopiracy (and biocolonialism) refers to the expropriation of both the tangible (genetic resources) in as much as the intangible (traditional knowledge) components by the companies. In other words,<sup>70</sup> for the production of a drug, the natural products branch of a company may use the genetic material from the plants collected (tangible component) and sometimes also the indigenous knowledge associated to the medicinal properties of the material (intangible component). When the use of either the material or the knowledge takes place without the permission of the owner of the land where the material was collected or without the consent of the provider of the knowledge, and no benefits for their contributions are granted in the end, we are talking about biopiracy and biocolonialism. These terms are broadly used by NGOs and developing countries, but they remain rather controversial and imprecise.<sup>71</sup>

## 2.2. THE CBD ON ACCESS AND BENEFIT-SHARING

In 1992, the CBD came to correct the market failure caused by the illegal access and use of genetic resources. Accordingly, the objectives of the CBD, as stated in its Article 1, are not only the conservation of biological diversity and the sustainable use of its components; but also “the fair and equitable sharing of the 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.”

Further, CBD Article 15 (Access to Genetic Resources) sets the framework for the implementation of the access and benefit-sharing principle of the CBD. It is premised on three fundamental principles: (1) *sovereignty* over genetic resources, (2) reaching *mutually agreed terms* (MATs), and (3) *prior informed consent* (PIC).

In addition, Article 8(j) contains a provision to encourage the equitable sharing of the benefits arising from the utilization of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity.

These principles provide the international legal basis for a *quid pro quo* arrangement between the CBD Parties: access to genetic resources in exchange for a fair and equitable share of the benefits derived from their use. Both international and national laws are key tools in achieving this goal. These CBD provisions are also linked to the provisions on access to and transfer of technology (Art. 16), exchange of information (Art. 17), technical and scientific cooperation

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<sup>70</sup> For the production of a drug, the natural products branch of a company may use the genetic material from the plants collected (tangible component) and sometimes also the indigenous knowledge associated to the medicinal properties of the material (intangible component). When the use of either the material or the knowledge takes place without the permission of the owner of the land where the material was collected or without the consent of the provider of the knowledge, and no benefits for their contributions are granted in the end, we are talking about biopiracy and biocolonialism.

<sup>71</sup> There is no commonly accepted definition of “biopiracy.” Instead of this word some experts prefer to use the terms “illegal access and use”, both of which are used in the recently adopted Bonn Guidelines.

(Art. 18), the handling of biotechnology and distribution of its benefits (Art. 19 (1) and (2), and financial resources and financial mechanism (Art. 20 and Art. 21).

Unfortunately, the access and benefit-sharing provisions of the CBD lack clarity. Apart from the general foundation of the principles, the Convention does not offer any details on how these principles should be further put into action. The interpretation and legal implementation at the national level of the rules set by the CBD for a “fair and equitable” sharing of the benefits is currently a matter of discussion among specialists around the world in various international fora. The central issue is the equity and fairness of the process and of the distribution of the benefits, an issue that raises a lot of questions of a political and philosophical nature.

In sum, defining the rights and obligations, in order to strike a balance of the multiple interests in the production of medicines deriving from plant genetic resources, is still at an embryonic stage.

### 2.3. IMPLEMENTATION OF THE CBD OBJECTIVES: NORMATIVE CHOICES

Since, the CBD does not provide for definitions and guidance on how to apply “fair and equitable benefit-sharing” in bioprospecting activities, the question, put in very simple terms, is: how to interpret and make operational the CBD objectives, when the concepts of “fairness” and “equity” present different meanings through space and time and their understanding is not universal.

The possible implementation strategies are:

- International instruments (efforts for an international hard law instrument for the regulation of access and benefit-sharing, within the framework of the CBD, the Food and Agriculture Organization (FAO), World Intellectual property Organization (WIPO), and the World Trade Organization (WTO);
- Regional agreements/national measures addressing access and benefit-sharing;
- Private practices, such as institutional policies, corporate policies and professional society standards<sup>72</sup>, codes of conduct and research guidelines.

The implementation of the “fairness and equity” prerogatives is a very difficult task, because, first of all, there is a definition/valuation problem with genetic resources. The valuation is not objective, but it is ultimately a choice (uncertainty and redundancy among the leads), which consequently affects the regulatory effort. Furthermore, insofar as the benefits distribution is concerned, there are many stakeholders to be considered and this critically complicates the negotiations process. The experience gained from contracts between developing countries, research institutions and private drug companies highlight the complexity of the emerging benefit-sharing regime, but offer precious guidance for the future. This experience is evidently conducive for the drafting of regional and national legislation, and private corporations have started to develop corporate policies setting out their approach to compliance with the CBD.

### 2.4. THE CONTROL OF GENETIC MATERIAL: SOVEREIGNTY AND PROPERTY

Until 1992, when the CBD was signed, genetic resources were generally considered to belong to the commons. The International Undertaking (IU) of FAO, the first comprehensive international agreement dealing with access to plant genetic resources for food and agriculture (green biotechnology), recognized the *common heritage of*

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<sup>72</sup> This is the term used, see e.g. American Society of Pharmacognosy (ASP), International Society of Ethnobiology (ISE), Society for Economic Botany (SEB).



*mankind* (CHM) character of the resources. It should be noted here, however, that the characterization of NPGR as CHM before the CBD is contested; because NPGR are also located in the territory of the states, and the latter are entitled to decide on their regulation. It is claimed that the FAO IU, which proclaimed the CHM principle for plant genetic resources, was only a soft international instrument, and this further strengthens the argument that the customary law requirements were not fulfilled for the recognition of NPGR as CHM.

In 1992, the CBD came to clarify the situation, asserting state sovereignty over NPGR. Thus, the delineation of property and control over genetic resources rests with the State. The individual/entity that holds the ownership/possession/control is a stakeholder and can lay claims to participate in the process and to the profits deriving from the use of NPGR.

The character of genetic resources is decisive for the access and benefit-sharing arrangement, because it determines the stakeholders in the negotiation and benefits distribution processes. The situation is better demonstrated with the following example: The Andean Pact Decision 391, presently the most elaborate regional access and benefit-sharing instrument establishing a Common Regime on Access to Benefit-sharing for the Andean countries, provides:

**Article 5.-** The Member Countries exercise sovereignty over genetic resources and their by-products and consequently determine the conditions for access to them,...

...

**Article 6.-** The genetic resources and their by-products which originated in the Member Countries are *goods belonging to or the heritage of the Nation or of the State* in each Member Country, as stipulated in their respective national legislation.

Those resources are inalienable, not subject to prescription and not subject to seizure or similar measures, *without detriment to the property regime* applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component. (*emphasis added*)

There are two main observations to make. First, Decision 391 makes a clear distinction between genetic and biological resources.<sup>73</sup> Biological resources can be negotiated by anyone having a right over them; but only the state has rights over genetic resources and the state alone can negotiate benefit-sharing provisions from the use of genetic resources. Accordingly, any right given to a person or entity, like for instance a forest concession, over natural resources does not imply rights over genetic material found in the natural resources or the area over which the concession extends.

Second, Decision 391 tries to accommodate all the Andean countries constitutional provisions by designating genetic resources as goods owned by the nation or to those belonging to the heritage of the nation. In effect, there is a difference between ownership and patrimony of the nation; the former concept implies greater regulatory intervention than the latter. In the case of *national patrimony*, the State physically administers genetic resources in favor of all citizens and does not necessarily have an exclusive right to negotiate access agreements; the degree of private participation and freedom to negotiate an access procedure is then greater. In the case of *national property*, the state has the right to become the exclusive and only provider of genetic resources. State intervention is different in every case, but the final approval is made by the State.

The consequence of such a legal treatment of genetic resources in the elaboration of access and benefit-sharing laws is that extensive sovereign control over genetic resources (in combination with the trend for broad patents) risks creating the *tragedy of anticommons* for genetic resources, that is multiple individuals have rights of exclusion over genetic resources resulting in use below the social optimum. Too much state control and complex procedures in access and benefit-sharing (permits, bureaucracy, etc.) are driving companies away from the utilization of genetic resources of the area. This conclusion renders bioprospecting an inadequate tool for biodiversity conservation.

Finally, robust sovereign rights over raw genetic materials may threaten the autonomy and interests of individuals/communities. If the State decides on the use of the genetic resources and expects to acquire great profits, it might put pressure on local/indigenous communities to cooperate and grant consent.

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<sup>73</sup> CBD Use of Terms: "Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. "Genetic resources" means genetic material of actual or potential value.

### 2.5. INDIGENOUS PEOPLES' PERMANENT SOVEREIGNTY OVER NATURAL RESOURCES

It has been evidenced above, that at the heart of the debate on equitable sharing of benefits arising from the utilization of genetic resources is the matter of who is the owner of the resources. The definition of the owner/possessor/manager of the resources indicates the stakeholders, who give the prior informed consent and have claims from the benefits; and, it is at this point that the indigenous peoples' rights come into play.

Legal practice and contract design become a complex issue, when it comes to ownership, land tenure and use of resources and access to them in local/indigenous lands. Some local communities and indigenous peoples do not have ownership titles and some have systems of communal ownership. For this reason, the customary land tenure systems of those responsible for the protection and sustainable use of the resources must be respected. If bioprospecting arrangements fail to respect the indigenous peoples' rights, they do not meet the fairness and equity principles and fail to act as biodiversity conservation tools.

Permanent sovereignty of the indigenous peoples over natural resources is an acute problem in modern international law. The final report of the Special Rapporteur Erica-Irene Daes, issued on 13 July 2004, for the 56<sup>th</sup> session of the UN Sub-Commission on Human Rights (26 July-13 Aug. 2004) is indicative of the developments on indigenous peoples sovereignty over genetic resources. It is an analysis of all the existing national and international legal instruments and jurisprudence examining the evolution of the initial political claim for permanent sovereignty to a legal principle through human rights instruments. The conclusions of the report are revolutionary, because it is the first time that indigenous peoples' permanent sovereignty over natural resources is explicitly recognized as a "collective right by virtue of which States are obligated to respect, protect, and promote the governmental and property interests of indigenous peoples in their natural resources." This right derives from the exercise of the rights to self-determination.

The main human rights instruments providing a basis for the protection of indigenous peoples' rights in the access and benefit-sharing undertakings can be summarized as follows:

- The United Nations Declaration on Human Rights (UNDHR) (1948) Article 7:
  - .... All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination.
- GA Resolution 1803 (XVII) (1962), on the permanent sovereignty over natural resources (peoples and nations).
- The International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) common Article 1 (1966)
  1. All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.
  2. All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence.

together with the common ICESCR Article 25 and ICCPR Article 47:

Nothing in the present Covenant shall be interpreted as impairing the inherent right of all peoples to enjoy and utilize fully and freely their natural wealth and resources.

- The International Labour Organisation Convention 169 (ILO 169) concerning Indigenous and Tribal Peoples in Independent countries. The convention states that the rights of ownership and possession of the peoples over the lands they traditionally occupy must be recognized; hence, governments must take steps as necessary to guarantee effective protection of those ownership and protection rights. The rights of the peoples to the natural resources pertaining to their lands must be safeguarded, including the right to participate in the use, management and conservation. Finally, the governments are obliged to consult the peoples

concerned before undertaking any programs for the exploration of mineral or subsurface resources owned by the state, but located on the lands of the peoples concerned. The Convention, although ratified by many countries, has implementation problems.

- The Draft UN Declaration on the Rights of Indigenous Peoples implicitly incorporates the substance of this principle.

Thus, although there is no direct linkage with access and benefit-sharing, the development and implementation of an access and benefit-sharing regime under the CBD may have a positive or negative impact on the respect for and exercise of the rights embodied in these instruments, particularly with regards to the protection of the indigenous/local communities' rights.

## 2.6. FINAL REMARKS

It is submitted that the elaboration of a single hard law international instrument is unrealistic. It is a very difficult task, primarily because it is very difficult to set international standards of fairness and equity for the process and outcome in benefit-sharing arrangements. There is a wide range of international organizations involved, and opposed interests block the negotiations. Most importantly, the complexity of the different situations cannot be addressed by a single international treaty. If we end up with a treaty, this will suffer from interpretation and implementation problems again. Soft law instruments like the Bonn Guidelines on the CBD Article 15 are a better solution. A bilateral approach is more flexible and more adaptable to time and local particularities.

Private practices and professional society standards (codes of conduct) are an important element in formalizing biodiversity relationships, because they reflect the willingness of the user of genetic resources (drug industry) to comply with the CBD objectives.

However, a degree of state intervention and control is necessary to secure the rights of its citizens (*see indigenous communities*). The problem here is that states overestimate the value of genetic resources and try to strictly control access and benefit-sharing. Developing/source countries should shift the focus from stressing the remuneration for raw material to their opportunities to add value to such material, namely prioritize non-monetary over monetary benefits.

## **3. ACCESS AND BENEFIT-SHARING IN THE USE OF HGR IN THE DRUGS INDUSTRY<sup>74</sup>**

The principle of access and benefit-sharing comes to counterbalance the *invisible hand* of the regulation by the market. It belongs to the new paradigm of public health care which comes into play at the international level to ensure that developed and developing countries enjoy the benefits of scientific developments in life sciences and biomedicine. With the promise of genetic research, concepts such as interest sharing, benefit-sharing and burden sharing have been strengthened. HGR regulation, therefore, is considered primarily at the universal level and appears to be a step further in the protection of the biosphere. In providing some terminological precision the following section briefly presents the background of HGR regulation. I then introduce the current legal status of HGR and the possible implementation of an international regime.

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<sup>74</sup> Part 2 has been written by Hélène Boussard, author of the thesis "The Nature and Effectiveness of the Universal Declaration on the Human Genome and Human Rights" (UNESCO, 1997).

### 3.1 OLD CONCEPTS, NEW DEFINITIONS: HGR, THE LAST BASTION

While scientific progress extended to knowledge and utilization of HGR, concepts used in the field of NPGR found application or translation in HGR.

Biodiversity: The increasing recognition in the field of human rights law dealing with HGR that human beings are an integral part of the biosphere is used as a discussion-stopper in the recurrent debate between environmentalist and anthropocentric approaches. However, it seems that the principle of genetic diversity is used, rather than the concept of biodiversity, when HGR are in issue. In fact, although HGR are excluded from the scope of the CBD, the recognition of the genetic diversity of humanity that the CBD carries has been underlined in the UNESCO instruments dealing with HGR (the 1997 Universal Declaration on the Human Genome and Human Rights (UDHGHR) and the 2005 Universal Declaration on Bioethics and Human Rights (UDBHR)).

Bioprospecting: In a style reminiscent of prospectors of the past, bioprospectors are alerted to previously *undiscovered* resources derived from the plants and animals of developing countries and quickly apportion these materials for science, and in the case of pharmaceutical companies, for profit. The most popular and potentially profitable form of bioprospecting targets not just the plant life of developing countries, but those countries' indigenous human inhabitants. The Human Genome Diversity Project (HGDP), a poignant manifestation of this phenomenon started at the beginning of the 1990s, consists of an international consortium of scientists, universities, and governments organized to collect information on human genome variation in an effort to understand the genetic makeup of humanity.

Biopiracy or biocolonialism: refer to the appropriation of resources from the colonized to benefit the colonizing people, without proper compensation, as determined by the subject. In the field of HGR, it is the case of indigenous inhabitants, insofar as either drugs are developed to cure *northern* and not *southern* diseases, or the contributor cannot afford these drugs. There is no fatality in the field and pharmaceutical companies react increasingly to the accusation of biopiracy: in Iceland, Hoffman-Laroche accepted to distribute for free the drugs resulting from the genetic research on their databases.

### 3.2 Legal nature of the HGR: rejection of the proprietary rights

The principle today is that donors of genetic material retain no property or other rights to their DNA or with respect to the fruits of research employing their DNA. This stems from the general principle that individuals do not have any proprietary rights in relation to their own body and body parts. This leads to the system of *market inalienability*: sale is forbidden, gift is allowed. We also speak of *relativized commodification*. This principle was set down for the first time in the USA, in California (Moore v. Regents of University of California, Supreme Court of California, 51 Cal. 3d 120 (1990)): whereas most of the States of the USA consider themselves bound by this judgment, few States have enacted laws that expressly recognized property rights of a DNA donor (Colorado, Florida, Georgia, Louisiana). In both cases, the payment of valuable consideration in the acquisition of human research material is not excluded.

Quite the reverse, legal and ethical standards from EU countries and UNESCO feature several explicit bans on payment to tissue sources. Provisions of human rights documents from both the Council of Europe and UNESCO prohibit direct payment for, respectively, "the human body and its parts ... as such" (Article 21 European Convention on Biomedicine and Human Rights) or "the human genome in its natural state" (Article 4 UNESCO Universal Declaration on the Human Genome and Human Rights). In the United Kingdom, a 1995 report of the Nuffield Council on Bioethics opposed payment to human tissue sources as well. French bioethics laws stand firmly against compensation of human tissue sources under any conditions.

If individuals have no property right, they have the right to a free and informed consent to any sampling. It has been argued that the rights lying behind informed consent regimes are more plausibly explained as proprietary rights. Moreover it is realistic to say that it does not matter whether the law automatically provides proprietary rights in one's DNA, if donors will insist on having a say in the patenting of discoveries resulting from the research using their DNA as a contractual matter. The use of human tissue is in fact increasingly important in biomedical research and the discovery of products commercialized, without the individual sources of tissue seldom share in the ensuing profits.

The *no property right* paradigm is precarious, as the rewarding of some donors may lead to altruistic donation disappearing and create an inequality among contributors. The unfortunate prevalent argument against the recognition of property rights lies in the tragedy of the anti-commons: the biotechnology industry, which already bargains with holders of intellectual property rights,<sup>75</sup> could not waste time and money in bargaining with holders of tangible rights. This argument is unfortunate as it makes economic values prevail over ethical ones.

If the recognition of individual property right is impossible, there is an emerging norm, which tends to recognize collective compensation for indigenous people so as to fulfill the requirement of fair and equitable benefit-sharing in population genetic research. This solution is partial, since it raises the problem of defining the community and its members and does not solve the problem of the individual genetic donor. However, it constitutes a compromise between the Moore-based donation paradigm (no property right) and the market-based alternative (property right).

### 3.3 CHM QUALIFICATION AND UNIVERSAL APPROACH FOR HGR REGULATION

Human rights law has been chosen at the international and European level to regulate HGR. However, we witness a centrifugal internationalization in the field, resulting from the simultaneous reaction of governmental and non governmental international organizations. This creates a myriad of state and non-state actors with divergent approaches. The choice between international, bilateral or national instruments is dictated by different considerations. However, as long as we consider the implementation of the principle of fair and equitable benefit-sharing - that is the need to balance the interests of developed and developing countries- the choice between the proprietary rights system and the CHH regime leads to different normative and institutional choices.

In the field of HGR, the principle of fair and equitable benefit-sharing stems from the CHM regime and is to be understood in connection with the principle of non-commercialization of human body parts. The choice of the CHM regime requires a collective action from States, so as to ensure the sustainable development of resources for future generations.

First, there is a need for unification. The nature of the compensation, monetary or non-monetary, to ensure fair and equitable benefit-sharing remains to be decided at the international level so as to solve the dilemma of commodification of human body parts.

Then, there is a need for cooperation. If fair and equitable benefit-sharing can be considered as a procedural principle involving all stakeholders coming into play in each specific case, a bilateral approach is not the only solution to solve the complexity of the negotiations. The CHM regime would rather require that an international organization be entrusted with the task of deciding or supervising compensation in each case and of regulating the access to genes collected in the *biobank*. If such an organization cannot be created, the need for an international instrument harmonizing the procedure of compensation remains. What is important is to involve ethics committees in this procedure.

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<sup>75</sup> The issue of intellectual property rights (IPRs) on HGR goes beyond the scope of the present contribution, which focused on personal property. However it can be recalled that patents are granted not only on processes which allow the identification, isolation and purification of genes, but also on gene sequences whose nature and possible biological function are unknown. What is protected is the genetic information. Patent rights are rights to exclude others to exploit a process or a product without license, but they do not confer on inventors any positive right to make, use or commercialize an invention. IPRs can go both in favor (through the disclosure of knowledge) or against (exclusive monopoly is said to slow down research and to impede access to drugs) the principle of benefit-sharing.

Ethical guidelines have preceded the emergence of legal norms. The principle of non-commercialization of the human body and the right to free and informed consent are ethical principles proclaimed at the international level since the Nuremberg Code. Ethics committees are the main actors involved in the regulation of genetic research in terms of protection of human rights. To this end, their composition has to ensure the representation of all interests and the absence of conflict of interest, and their work has to be transparent. It is up to states to organize these committees. But the objective of fair and equitable benefit-sharing should be realized through international guidelines provided not only in ethical documents, but also in legally binding instruments. The emerging interaction between human rights and bioethics, as it appears from the work of UNESCO, should lead to new commitments from the side of states in the field of international human rights law.

#### 4. CONCLUSIONS

The present intends to be a modest contribution to such a future standard-setting exercise on the international and the regional/national ground for the regulation of utilization of genetic resources in the drugs industry. In both NPGR and HGR there is considerable international activity towards the development of norms that meet all concerned interests and correct present injustices.

In the use of NPGR, the typical scenario involves drug companies from developed countries, which obtained plant genetic material from biologically rich developing countries with very low collection/export permits and fees, or even with no compensation at all, because genetic material was long considered to belong to humanity; the genetic material is then developed into commercially valuable forms, protected by patents, and the resulting benefits never reach the source countries. The 1992 CBD has brought to the foreground the question of the relationship between conservation of biological diversity, sustainable use of its components and fair and equitable sharing arising from this use. That is to say, that if developing source countries receive part of the profits deriving from the commercialization of drugs based on PGRs within their jurisdiction, they will have an incentive to conserve and sustainably manage the biological wealth in their territory.

In the field of HGR, either individuals or indigenous groups, who have given an informed and prior consent, participate in research sponsored by private companies or industrialized countries. Their participation involves enrollment in clinical trials or contribution of blood samples for studies of the human genome. Sequences of human gene or medicines derived from human genetic samples are patented, without the authorization of the person(s) that has/have been involved in the research. The latter receive(s) neither remuneration nor compensation.

In both cases, the need to balance the interests of researchers, private investors and contributors, on the one hand, and the interests of developed and developing countries, on the other, requires some normative choices so as to achieve the principle of benefit-sharing.

*CHM in HGR vs. expansion of property and sovereignty boundaries in NPGR:* As the two parts of this presentation have sought to show, whilst the CBD deemed sovereignty/property recognition over genetic material a necessary step for fair and equitable sharing of the benefits arising from the utilization of NPGR, regulators in the use of HGR look askance at the eventual property rights allocation and commodification of the genetic material.

Concerning NPGR, until 1992, raw genetic material was considered to be a CHM component, whereas the improved plant varieties and medicines derived from NPGR were protected through intellectual property rights. The CHM qualification was favored by developed countries insofar as it implied free access to raw genetic material. In view of the general trend of property rights allocation for the protection of the environment (*tragedy of the commons*), the 1992 CBD repudiates the CHM qualification and explicitly recognizes state sovereignty over NPGR, whereby it leaves it to State discretion to decide on the actual status of the NPGR within their jurisdiction. This adjustment was expected to better realize the fair and equitable benefit-sharing principle.

For HGR, the stakes of the CHM qualification are different. First, the recognition of proprietary rights is not a sustainable alternative to the CHM regime: it raises numerous ethical issues and implies, *inter alia*, economic inefficiency, commodification of the person, distortion of clinical and research relationship and incompatibility with altruism. Then, the CHM qualification brings developed and developing countries into conflict not on free access to genetic material but on the principle of fair and equitable benefit-sharing. This time those who advocate the CHM legal concept are developing countries and developed countries would rather live without...

Accordingly, in both NPGR and HGR, the qualification of genetic resources as *common heritage of mankind* was considered. Whereas it has been abandoned for NPGR, it has been strengthened for HGR. What stands behind this antagonistic choice is not only the different understanding of the CHM legal concept; but most importantly the inherent character of the resources; whereas the trade of NPGR has been practiced since the very beginning of human traces in history and beyond and their commodification is acceptable, trade of humans beings, human organs and components thereof implies intricate ethical considerations that do not allow for their commodification and commercialization.

*Indigenous peoples:* Indigenous peoples rights are relevant in the efforts for the regulation of the utilization of both NPGR and HGR. In the case of NPGR, indigenous peoples have developed sustainable management systems and community control/possession customary rules, which should be fully taken into account in the negotiation and execution of bioprospecting agreements. There are at present several human rights instruments that corroborate the respect of indigenous peoples' rights in bioprospecting undertakings, namely, to negotiate in a fair process, grant PIC for NPGR in indigenous territories and enjoy part of the benefits.

In the case of HGR indigenous peoples' genes are scientifically interesting because their heightened isolation may have resulted in unique genetic traits of increased resistance or susceptibility to disease. What is at stake here is the recognition of collective interests and collective rights so that indigenous peoples can enjoy scientific benefits that they made possible. A legitimate concern is that any medical advances associated with genes will not benefit indigenous peoples. In fact it is unlikely that medical advances associated with genes will directly benefit those who provide the *raw materials* for the design of such knowledge. Moreover, if gene therapies were created, it is unlikely that indigenous peoples could afford them.

*Bilateralism vs. universality:* In light of these conclusions, especially in relation to the contention bearing on the issue of the status of genetic resources in international law, since the nature of the NPGR and HGR differ significantly, the legal constructions and the normative implementation choices vary in order to satisfy the same access and benefit-sharing principle. In the medicinal use of NPGR, the sovereignty/property rights are considered a more suitable normative route to protect biological diversity. Finally, attention should be drawn to the fact that there has always been, and there will always be, an NPGR market that favors bilateral agreements. State intervention is necessary to the degree of warranting

information, transparency and facilitation of bioprospecting agreements, but a single international access and benefit-sharing treaty seems to be a quixotic quest. If the current negotiations will end up in an access and benefit-sharing treaty, fear is expressed that this treaty will only give symbolic attention to developing countries' and indigenous/local communities' claims, and that its polite language of false concern will actually impend implementation.

On the contrary, CHM qualification and universal regulation go hand in hand and postulate a possible consensus if not on values, at least on the procedure to ensure the principle of benefit-sharing.



## **Biodiversity and Biotechnology: Consolidation and Strains in the Emerging International Legal Regimes**

Riccardo Pavoni \*

The present contribution deals with the basic legal principles and rules, which may be viewed as underlying the emerging international legal regime of biodiversity and biotechnology. As its title suggests, the contribution mainly focuses on the relationship between biotechnology and biodiversity, hence on the legal issues arising from the development of plant and agricultural biotechnology. However, I will endeavor to show the crosscutting nature of certain principles and rules, that is their applicability to human genomics and genetics as well.

For a number of reasons, this exercise might be considered inappropriate or, at least, premature. As a matter of fact, this area of international law is relatively new: leaving aside soft law instruments, the first pertinent treaty, i.e. the 1992 Biodiversity Convention (CBD), is only thirteen years old. At the same time, existing customary law – e.g. the duty to prevent transboundary environmental damage or the principle of permanent sovereignty over natural resources – surely applies to biodiversity and biotechnology, but its operation is ostensibly limited and inadequate to address the unprecedented challenges arising in this field.

Secondly, if it is true that since 1992 a huge bulk of legal instruments (treaties, declarations, resolutions, codes of conduct, and so on) have been adopted and that an increasingly high number of international organizations have taken on specific activities associated with biotechnology, the resulting legal framework nonetheless appears extremely fragmented. This makes the task of identifying the international legal regime of biotechnology particularly challenging; however, fragmentation is also an incentive to devise a coherent set of core principles and rules, which might hopefully inform a future global treaty on biotechnology, to be negotiated under the aegis of the United Nations. Thirdly, the same task seems problematic as it is well-known that fragmentation in this area does not only result in disconnected legal approaches, but also involves considerable tension between legal systems, such as between multilateral environmental agreements (MEAs) and the World Trade Organization (WTO) law. This tension, in extreme cases, may turn into veritable conflicts of norms and thus open up a Pandora's box of legal issues, which only rarely are amenable to solutions in line with the need for unity and coherence of the international legal order. Fourthly, the ongoing and far-reaching scientific advances of genetics and biotechnology, as well as the uncertainty over their long-term risks and benefits, inevitably results in this area of the law being in a perpetual state of flux.

If one adds to this picture the lack of relevant international judicial decisions, the perspective of this contribution might seem particularly naïve. However, the considerable amount of State practice which has rapidly accumulated in the field of biodiversity and biotechnology over the past few years cannot be underestimated. I am indeed convinced that some foundational

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principles and rules of an embryonic general regime of biodiversity and biotechnology may be extrapolated from this vast amount of practice. This general regime is composed of four conceptual pillars: *a) the principle of the common concern of humanity; b) the principle of equitable benefit-sharing; c) the precautionary principle; and d) the principle of mutual supportiveness of environmental and trade regimes.*

## **II. Common concern of humanity**

The principle of the common concern of humanity has become a popular formula in the international legal arena. It has been associated with “a consensus according to which respect for certain fundamental values is not to be left to the free disposition of States individually or *inter se* but is recognized and sanctioned by international law as a matter of concern to all States” (Simma, 1994). The principle thus marks a shift from the traditional synallagmatic conception of international legal obligations to a modern vision of rights and duties pertaining to a wider group of States or to the international community at large. Especially in the environmental field, common concern comes out as the conceptual matrix of a number of agreements aimed at the protection of essential components of the biosphere and evokes the idea of a global environmental responsibility. Biodiversity and biotechnology are no exception to this. Moreover, within the area of genetics and human rights, the 1997 *UNESCO Universal Declaration on the Human Genome* (UDHG) is based on the premise that the human genome “[i]n a symbolic sense, [...] is the heritage of humanity.” This symbolic reference to the concurrent principle of the common heritage discloses that States intended to avoid any impairment of the right to self-determination of human beings with respect to their genetic make-up. At the same time, however, it is clear that, in exercising this right, individuals do not enjoy absolute liberty, as they have to respect the principles and safeguards set forth in the Declaration *vis-à-vis*, not only their State of nationality, but the whole of humanity. In other words, research and interventions concerning the human genome are a common concern of humanity.

Coming back to the environmental context, I fully agree with those authors who underline the normative value of the common concern principle *vis-à-vis* a purely inspirational or interpretative function, and accordingly identify precise legal implications ensuing therefrom. These implications are most commonly reconnected to the *erga omnes* status of basic environmental precepts included in the pertinent treaty regimes and to a duty to protect the domestic environment. But, before examining how such legal implications come into play with respect to biodiversity and biotechnology, a preliminary crucial issue involves the determination of what actually constitutes the general interest of humanity in this area.

The references contained in the relevant treaties are no help in this regard. Nonetheless, I firmly believe that an accurate analysis of international practice clearly demonstrates that the common concern of humanity consists here in the promotion and enhancement of a rational, prudent and sustainable use of biodiversity *and biotechnology*. It would be naïve to assume that the whole rationale of international regulation in this field is to hinder or jeopardize the development of safe applications of modern biotechnology in the name of a misplaced desire for biodiversity preservation. Biotechnology is also part of the common concern due to its potential far-reaching benefits in the medical, pharmaceutical, environmental and agricultural sectors. Thus, in a recent report to the UN General Assembly, the UN Secretary General stresses that “[t]he Millennium Development Goals [e.g. eradication of poverty and infectious diseases, and food security] may be more easily met with the extensive application of modern biotechnology in agriculture and health” and that consequently “[i]t is in the *interest of*

*humanity*, in developed and developing countries, that safe biotechnology applications are used as widely as possible.” Such a characterization of common concern helps explain certain aspects of international rules in this area which at first sight might appear particularly ambiguous and disappointing from a purely environmental perspective.

i) The example of the *limits to the sovereign management of the domestic environment* purportedly arising from regimes based on the common concern principle is an emblematic one in this regard. The 2000 *Cartagena Protocol on Biosafety* (BSP) is unquestionably ambitious with respect to the regulation of living modified organisms (LMOs), but only insofar as their transboundary movements (i.e. interstate transactions) are concerned. By contrast, as I have tried to show elsewhere, the Protocol does not impose particularly stringent obligations and standards on the *domestic* handling of LMOs. This might be a reflection of the willful elaboration of an instrument with a focus and scope as narrow as possible, in conformity with the opportunity to lay down only those obligations that, while not unduly impairing the development of biotechnology, are necessary to ensure transparent and predictable international relations in the area of the export of LMOs. The “domestic standards” set out by other international agreements, such as the CBD or the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty), are similarly fraught with ambiguities and weaknesses. In sum, international regulation of biodiversity and biosafety does not provide convincing support to the existence of a customary rule imposing on States a duty of diligent and sustainable use of territorial natural resources that are a common concern of humanity;

ii) it is also very controversial that the basic treaty obligations existing in the area under consideration are – at least potentially – of an *erga omnes* character, namely that they are owed to the international community at large and thus legitimate, in case of a violation, the invocation of responsibility by any one State, no matter if it is directly injured. As is well-known, the solution included in the 2001 *International Law Commission Articles on State Responsibility* is not clear-cut in this respect. It retains the distinction between *erga omnes* obligations and *erga omnes partes* obligations. The latter category relates to obligations “owed to a group of States [...] and [...] established for the protection of a collective interest of the group.” The first candidate for inclusion in this category are obligations laid down in multilateral treaties. Significantly, Special Rapporteur J. Crawford, in his *Third Report on State Responsibility*, has posited that obligations existing in the area of biodiversity are to be considered of an *erga omnes partes* (collective) nature. Thus, if one accepts that such obligations are normally *treaty* obligations while their customary nature is exceptional and still needs evidence, the conclusion is that obligations pertaining to biodiversity are only owed as between State Parties to the relevant convention and may indeed be breached only by *those* Parties to the exclusion of any third State (such as the United States, that has notoriously refrained from ratifying any of the existing biodiversity and biosafety agreements).

In addition, if one looks at the relevant primary norms, it appears problematic to associate them with schemes of collective responsibility. Once again, the Cartagena Protocol provides a paradigmatic example in this respect. The Protocol allows (precautionary) restrictions on the import of certain biotech products (so-called living modified organisms) only as long as such restrictions are meant to prevent potential damage to biodiversity “in the Party of import.” Reaction to extraterritorial damage (i.e. to the environment of other States or to global commons) is thus precluded. With regard to secondary norms, this provision might clearly imply that only directly affected *Parties* may invoke the responsibility of wrongdoing *Parties*. This should not be taken as excluding altogether the relevance of the *erga omnes* doctrine for our purposes. After all, this doctrine is crucial with respect to human genetics and

biomedicine, where the pertinent norms draw from existing international human rights law, but, at least in the area of biosafety, its viability presupposes evidence of State practice (which for the time being is lacking) and a consensus relating to the very content and implications of the *primary* norms composing the regime of biodiversity *and* biotechnology;

*iii*) by contrast, the common concern principle considerably bears on the issue of the *status of biogenetic resources* in international law. Here, a distinction must be made between resources located within State territory and those located in areas beyond national jurisdiction (so-called global commons). With respect to the former, their assimilation (most notably, by the CBD and the FAO Treaty) to a common concern of humanity entails the maintenance of sovereign rights and circumvents the resistances and misunderstandings linked to the common heritage concept as originally retained by FAO. It should also be pointed out that the frequent references to the common heritage principle seem largely misplaced in this context, as long as some of its elements have never actually materialized in the international system, such as especially a truly international institution entrusted with administering the genetic heritage. Indeed, the regime of genetic resources prior to the CBD is best characterised as one of common property, thus essentially of freedom of access and reasonable exploitation. Secondly, due to the inapplicability of the common heritage principle, exclusive appropriation of genetic resources is at the disposal of the biotechnology industry for incorporation into inventions likely to be protected by patents and/or similar proprietary rights. Intellectual property rights (IPRs) are indeed an indispensable tool needed to foster the common concern associated with biodiversity *and* biotechnology. Provided such rights do respect the legitimate interests of territorial States (and especially their entitlement to a fair sharing of the benefits arising therefrom), the above appropriation should not be seen as infringing the principle of permanent sovereignty over natural resources. As a matter of fact, and this brings us to the third point, common concern is not co-extensive with permanent sovereignty. Sovereignty is not absolute here, as it entails common responsibilities and due regard for the general interest of humanity. Thus, prior informed consent under the CBD must not result in arbitrary and unreasonable prohibitions of access to territorial biogenetic resources likely to hinder biotechnological research with potential far-reaching benefits for human health, food security and similar public interests. More significantly, the 2001 FAO Treaty creates a *Multilateral System of Access and Benefit-Sharing*, according to which States are obliged to *facilitate* access to a negotiated list of crops and forages. This system is explicitly deemed as compatible both with the maintenance of sovereign rights and the common concern principle. The preceding remarks seem to a great extent applicable also to the regime of biotechnological activities taking place within areas of the sea that are subject to national jurisdiction, especially with regard to the access to the surplus of the allowable catch of living resources in the exclusive economic zone by States other than the coastal State. The most debated provision here is undoubtedly Art. 246(5)(a) of the United Nations Convention on the Law of the Sea (UNCLOS) on the so-called applied scientific research (an expression that certainly includes marine biotechnology) on the continental shelf and in the exclusive economic zone, wherein the power of coastal States to withhold at their discretion consent to the research activities is clearly established. I do not see, however, any particular problem in reconciling this provision with the regime of access related to terrestrial biodiversity. It seems to me that the cornerstone of the UNCLOS rules at stake corresponds once again to the sharing of the benefits arising from marine scientific research: whenever the specific terms of benefit-sharing provided for by Art. 249 are fulfilled, a coastal State has all the interest in granting access to its marine biodiversity.

With respect to the genetic resources located in parts of the sea beyond national jurisdiction, be they incorporated into fishery resources in the high seas or into living resources found in the vicinity of the deep sea-bed and ocean floor (the Area), I am not persuaded that they should be considered as a common heritage of humanity. Freedom of access and scientific research still provide the most accurate picture of present practices and applicable law. Here, the common concern principle may operate to mitigate such freedom and outlaw those practices that are ostensibly at variance with the general interest of humanity (i.e. unsustainable bioprospecting), just as it operates, in the domestic sphere, to qualify the power of States to grant access to the genetic resources subject to their sovereignty. Various examples of patents recognized over products derived from biological resources found in Antarctica, another territory belonging (though not unquestionably) to the global commons, reinforce the impression that resources beyond the limits of national jurisdiction are in principle freely subject to appropriation. It is true that, in relation to the marine living organisms found in the Area, there are sound policy reasons and legal arguments militating in favour of extending to them the common heritage regime applicable to mineral resources. However, in view of the existing legal gap, one cannot escape the conclusion that, as a matter of positive law and prevailing practices, even these resources are best characterised as a common concern of humanity;

iv) practice relating to biodiversity and biotechnology offers examples of further legal implications of the common concern principle. The fact that a certain treaty is grounded upon such principle leads to far-reaching interpretative consequences. At the judicial level, the most important decision is that of the European Court of Justice (ECJ) in the *Netherlands v. Parliament and Council* case, a case dealing with an action for annulment of Directive 98/44 on the legal protection of biotechnological inventions. In its judgment of 9 October 2001, the ECJ accepted to review the legality of the Directive in light of the Biodiversity Convention, as this Convention was “not strictly based on *reciprocal and mutually advantageous arrangements*” and notwithstanding the non self-executing character of its provisions. This finding, while disposing in a welcome manner of a particularly controversial issue of EC law, emphasizes the asymmetrical and multilateral (thus potentially *erga omnes partes*) nature of CBD obligations. This nature underlies the fundamental values protected by the CBD (thus, its common concern matrix) and requires that private parties and EC member States be entitled to rely judicially on CBD provisions as a ground of illegality of inconsistent EC measures;

v) in another topical context, that of WTO adjudication, the WTO Appellate Body (AB) has implicitly recognized the importance of regimes based on the common concern principle. In the celebrated *Shrimp/Turtle* case, the AB held that General Agreement on Tariffs and Trade (GATT) Art. XX (general exceptions) must be read “in the light of contemporary *concerns of the community of nations* about the protection and conservation of the environment.” In the facts of the case, this argument supported an evolutionary method of interpretation and the resulting conclusion, reached through an in-depth analysis of pertinent environmental instruments (CBD included), that Art. XX covers both living and non-living natural resources.

In the more recent *Korea – Beef* case, the AB substantially innovated the balancing test for assessing the fulfillment of the requirement of necessity as included in some of the exceptions of GATT Art. XX. The AB stated that one crucial factor in this balancing exercise is “the relative importance of the *common interests or values* that the law or regulation [...] is intended to protect”, and added: “The *more vital or important* those common interests or values are, the easier it would be to accept as ‘necessary’ a measure [...]” It is self-explanatory that such an approach may be interpreted as recognizing the special status in

WTO dispute settlement of MEAs grounded upon the common concern principle. These agreements are indeed emanations *par excellence* of vital interests shared by humanity as a whole. If one day tested for measures implementing such agreements, the same approach might at the very least facilitate a finding of consistency with the requirement of necessity.

### III. Equitable benefit-sharing

A growing number of international instruments dealing with biodiversity and biotechnology (including marine biotechnology) requires that benefits accruing from the use of biogenetic resources and traditional knowledge associated thereof (and thus *in primis* accruing from biotechnological inventions) be shared in a fair and equitable way with the States of origin of such resources, as well as with indigenous and local communities identifiable as holders of that knowledge. A critical feature of this principle of benefit-sharing is its *cross-cutting nature*, namely its relevance to biotechnology at large, including biomedicine, human genetics and human rights. Thus, according to the United Nations Educational, Scientific and Cultural Organization (UNESCO) International Bioethics Committee benefit-sharing constitutes “a truly urgent and universal issue” arising from advances in life sciences, while, in a similar vein, the UN High Commissioner for Human Rights’ Expert Group on Human Rights and Biotechnology considers “the linked issues of the ability to patent genetic material and the sharing of benefits deriving from commercial exploitation of that material to be the most important issues in the area of human rights and biotechnology at this time.” Forms of benefit-sharing are actually envisaged by the UDHG and especially by the 2003 *International Declaration on Human Genetic Data* (IDHGD). Moreover, there is no reason to doubt that the universal instrument on bioethics, currently being elaborated by UNESCO, will incorporate the principle at stake.

As I have tried to explain elsewhere, equitable benefit-sharing emerges as the cornerstone of the regime of access to biodiversity and of IPRs in biotechnological inventions. In effect, any international debates and confrontations in this area – including those relating to the purported conflict between the multilateral trade system and the pertinent MEAs – are mostly focused on the necessity to devise fair mechanisms of benefit-allocation among stakeholders. I have also tried to demonstrate that the duty of benefit-sharing is steadily *emerging as a rule of customary law*. Practice, indeed, looks impressive. First, in addition to the already-mentioned instruments, the principle at stake has been consistently recognized in various resolutions of the UN General Assembly, which, at the same time, has advocated the negotiation of an international regime on benefit-sharing. Secondly, there exist considerable instances of national legislation and policies endorsing benefit-sharing, the most recent (and crucial) examples being those of India and the European Community. Thirdly, statements and declarations made by State officials within the relevant international fora, such as the Trade-Related Aspects of Intellectual Property (TRIPs) Council or the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, constantly acknowledge the existence and importance of the principle of benefit-sharing. The only notable exception in this regard is unsurprisingly the United States, authentic persistent objector to the emerging customary rule. The US firmly opposes the elaboration of the above-mentioned international regime in the form of a *binding* instrument, since “any initiatives in this area must fully accord access to genetic resources and respect rights and obligations under international law.”

This statement highlights what the real concerns in the discourse over benefit-sharing are: the elaboration of definite, multilateral and binding standards of benefit-sharing is seen as

jeopardizing full access to genetic resources *and* concurrent international rules. These rules are mainly to be found in the WTO TRIPs Agreement, which recognizes (*rectius*: is interpreted as recognizing) the patentability of biotechnological inventions and the enjoyment of rights thereof with no exception arising from duties of benefit-sharing with, or prior informed consent of, countries of origin of genetic (raw) material. However, it should be noted that the granting of such controversial patents (*once* detected) increasingly meets with protests and threats of retorsion on the part of States of origin (and at times by not directly affected States as well), which frequently lead to their revocation (or to the withdrawal of patent applications). Moreover, it is not to be taken for granted that the TRIPs Agreement allows patents incompatible with such a core principle as that of benefit-sharing. The ongoing debates within the TRIPs Council on the relationship between the CBD and TRIPs are rather testimony to the efforts of the international community to develop consensual approaches to the interpretation of the latter (or to its *reform*) in line with the principle of equitable benefit-sharing.

Obviously, the outcome of the processes initiated within WTO, WIPO and the Conference of the Parties to the CBD will be a crucial test for the crystallization of the emerging duty of benefit-sharing. If these processes, as I hope, will not fail and will rather result in unambiguously obligatory standards of benefit-sharing, it is submitted that the already-existing abundant practice may be capable of unveiling a corresponding *opinio iuris*.

#### IV. Precaution

Much like benefit-sharing *vis-à-vis* access to genetic resources and patentability, the precautionary principle comes out as the cornerstone of biosafety, namely the regulation of risks associated with the release into the environment and marketing of genetically modified organisms (GMOs). Indeed, the most innovative aspect of this sector corresponds to the legitimation of the *right* of States to adopt, within a prior approval procedure, trade-restrictive environmental measures, even though there exists substantial scientific uncertainty and even though such measures are potentially inconsistent with WTO law. Other features of the biosafety regimes, such as the principles for risk assessment established by the BSP or the phasing-out of antibiotic resistance genes envisaged by the European Community (EC) legislation, clearly reflect a precautionary logic.

Precaution is a crosscutting principle of the international law relating to biotechnology. It applies to biotechnological activities impacting upon terrestrial biodiversity and *a fortiori* to those affecting marine biodiversity. But it also applies to the protection of human health and is thus extremely pertinent in biomedicine and human genetics. It is true that, within these fields, the principle is not as well developed as in the environmental context and is in fact not explicitly mentioned in any of the existing instruments. However, a precautionary rationale visibly underlies various provisions of these instruments. Take the example of persons not having the capacity to consent to research affecting his or her genome. According to the UDHG, such research “may only be carried out for [the person’s] direct health benefit”, while research that “does not have an *expected direct health benefit* may only be undertaken *by way of exception, with the utmost restraint*, exposing the person only to a *minimal risk* and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition [...], and provided such research is compatible with the protection of the individual’s human rights.” Thus, this kind of research presupposes sufficient scientific evidence showing direct health benefits to the disadvantaged person. When this evidence is absent or there exists a state of scientific

uncertainty, research may only be carried out in exceptional cases, pursuant to a cost-benefit analysis and if it involves *risk of the lowest degree*. Conversely, if science identifies more significant (yet uncertain) risks for human health, research just *cannot* take place. It is safe to assume that, pursuant to the precautionary principle, this requirement applies generally to human genetics. Unsurprisingly, precaution is endorsed by the current draft of a UNESCO declaration on universal norms on bioethics.

The following conclusions and reflections on the status, components and implications of the precautionary principle are however limited to the environmental context, where a considerable practice has emerged in relation to biosafety issues:

*i)* the Cartagena Protocol and the pertinent EC biosafety legislation undeniably demonstrate the evolution of the role of precaution from a purely interpretive principle to a *normative* one. In other words, the principle is fully operationalised within such regimes by means of positive rights and obligations;

*ii)* this normative value does not in anyway determine the long-standing debate over the customary *vis-à-vis* conventional status of the principle. Rather, it is submitted that the same controversial aspects that have long been considered as affecting the customary nature of precaution show up, at least to a certain extent, in the biosafety context as well. In the first place, no international judicial decision dealing with biosafety (or contiguous issues) has so far accepted the customary status of the principle. However, this is also due to the fact that the parties to the relevant disputes never actually relied on such alleged customary status. A special reference here must be made to the notable ECJ case law on biosafety and trade in GMOs. EC member States defending their precautionary measures in these cases have refrained from invoking precaution as a principle of *international law*. They have rather posited the existence of a *general principle of EC law* with no contradiction coming from the Court. Similarly, in the recent WTO *Japan – Apples* case, the AB has pointed out the failure on the part of Japan to invoke precaution “as a principle separate and distinct from the provisions of the Sanitary and Phytosanitary (SPS) Agreement.” This has probably paved the way to the rejection of the precautionary arguments raised by Japan itself.

Moreover, and perhaps more importantly, biosafety practice relating to the precautionary principle is not clear-cut. If, on the one hand, the quantity and quality of instruments and policy statements accepting precaution as their foundational and operative principle is certainly impressive, on the other, practice lacks that degree of uniformity necessary to the formation of customary law. Leaving aside the obvious example of the WTO, even EC practice (often viewed as the most proactive one with respect to precaution) looks contradictory, as long as the identification of the appropriate action to be taken in each particular case to implement the principle has invariably generated divisions and confrontations between EC institutions and member States authorities. The so-called *de facto* moratorium on the marketing of GMOs is an illuminating example thereof. It is right to consider this moratorium as a significant manifestation of regional practice based on a far-reaching conception of the precautionary principle. At the same time, however, it is well known that the moratorium is due to the initiative of a group of member States only, an initiative that was (and still is) not shared by the other members, nor by the EC institutions. The latter would have rather endorsed less radical measures deemed perfectly in line with the application of the principle at stake;

*iii)* another classical objection to the customary nature of the precautionary principle is the uncertainty over its real substance and constituent parts. Again, biosafety practice is



ambiguous in this respect. The Cartagena Protocol and the EC legislation endeavor to articulate the two fundamental components of precaution, namely scientific uncertainty and the seriousness of expected harm but, in the end, considerable doubts remain. On the one hand, the requirement of seriousness of harm is understated, since the above instruments envisage an apparently low threshold for invoking precaution, that is the threat of adverse effects to biodiversity *tout court*. This raises a question of coordination between the components of precaution emerging from the above instruments and those endorsed by other authoritative documents, chiefly by the 1992 Rio Declaration on Environment and Development (Principle 15).

Much more problematic is, however, the requirement of the state of scientific uncertainty. What incontestably transpires from the ECJ case law and, by way of analogy, from that of the WTO bodies, is that scientific uncertainty does *not* cover speculative, hypothetical or theoretical risks. On the contrary, a *prior risk assessment* capable of gathering scientific evidence (as partial and inconclusive as it might be) of a *plausible* risk of harm is a non-derogable requirement of precautionary measures. Conversely, these measures need not necessarily be based on majority scientific views; they may well conform to minority, yet recent and reliable, scientific opinions. In addition, scientific evidence must be *relevant*, that is relating to specific GMOs, specific situations and specific environmental or sanitary concerns. But, finally, what is scientific uncertainty about? May it refer to the very *existence*, nature or origin of the risk? Or exclusively to its *extent*, namely to a risk which, though not exactly quantified, is nonetheless clearly characterized in its essential aspects? Although certain key-provisions of the BSP lend weight to the second alternative, my opinion is that this must be rejected, as it would undermine the operation of the precautionary principle with respect to risks – such as, paradigmatically, those associated with GMOs – likely to be adequately appraised on a long-term basis only;

*iv)* the precise *nature* of legitimate precautionary measures is also controversial. Practice shows that an *a priori* categorization of such measures is not warranted. The legitimate measure to be imposed in each particular situation is rather subject to a case-by-case review and depends on the magnitude of risks that a State is willing to prevent or minimize. Therefore, precautionary measures may correspond either to radical restrictions, such as moratoria or generalized prohibitions, or to more focused precautions, such as prohibitions targeting particularly risky GMOs or labelling, traceability and monitoring requirements. At the same time, however, States do not enjoy an unfettered discretion in the selection of measures. While in this respect the Cartagena Protocol provides for an indefinite test of *appropriateness* of precautionary measures, the ECJ has held that such measures must be reasonably sustained by the findings of a risk assessment, however partial or preliminary this assessment might appear. There exists, in other words, a close relationship between the scientific assessment of risks and their political (precautionary) management, which, at the normative level, seems to introduce a requirement of *proportionality* between precautionary measures and the outcome of risk assessment. In the pertinent EC legislation, proportionality is indeed retained in its classic meaning, that is precautionary measures shall not go beyond what is necessary to achieve the sanitary or environmental objectives at stake.

However, the most debated issue in this context remains that of the *temporal scope* of precautionary measures. Need these measures be provisional? Or may they also be adopted for an indefinite period of time? As is well-known, the first option is retained by Art. 5(7) of the WTO SPS Agreement and by the safeguard clauses envisaged by the EC GMOs legislation. It is also retained by the definition of the precautionary principle set out in Art. 7 of EC Regulation No. 178/2002. Moreover, in both the SPS Agreement and EC Regulation No. 178/2002, compliance with the requirement of temporariness is ensured by a duty to

review precautionary measures within a reasonable period of time. What is doubtful here is the fate of measures which, after the expiration of such a reasonable period of time, still appear warranted in the light of *persistent* scientific uncertainty. If a State has in good faith undertaken periodic scientific assessments and constantly monitored the evolution of scientific knowledge, is it allowed to *maintain* the pertinent measure? Or is it obliged to repeal it? In my opinion, the temporariness of precautionary measures entails no more than a *duty to assess environmental risks on a continuous basis*, a duty that has been duly recognized by the International Court of Justice in the *Gabcíkovo-Nagymaros* case. The alternative view seems to a great extent capable of defeating the object and purpose of the precautionary principle. If, however, such a view were to correspond to the correct interpretation of the above SPS and EC provisions, this plainly means that the latter would not represent genuine examples of precautionary instruments. This finding is important to appraise the lawfulness of the several *non-provisional* moratoria and prohibitions on trade in GMOs currently in place in various national and regional contexts. In principle, such measures should be regarded as lawful, provided they are constantly updated in the light of new scientific insights;

v) on a more general level, the precautionary principle, as adopted within the biosafety legislation, marks the distinction between *risk assessment* and *risk management*. This unmistakably results in the power of States to take risk management measures that are different from those warranted under an exclusive reliance on scientific methods and with a view to controlling uncertain risks. Yet, as already pointed out, the separation between risk assessment and risk management is not clear-cut: indeed, the latter must at the very least generate decisions that are not manifestly disproportionate to the scientific evidence ensuing from the former. More precisely, the distinction at stake sheds light on the existence of *science policies* capable of influencing the purported neutrality of (scientific) risk assessment, for instance by giving more weight to some hypotheses rather than others or by discarding a given inference. Under these circumstances, it is reasonable to allow decision-makers to redress such imbalances and take measures contradicting the findings of risk assessors. The provisions of the Cartagena Protocol which prescribe *precautionary* scientific methods and principles are in this respect extremely significant, as they enhance the ongoing dialogue between science and politics;

vi) another legal implication frequently associated with the precautionary principle is a *reversal of the burden of proof* in relation to the risks that the pertinent measures aim at averting. If one looks at the jurisprudence of the ECJ and, by analogy, that of the WTO bodies on the SPS Agreement, such far-reaching consequence ought to be excluded. Within the review of member States measures taken pursuant to safeguard clauses, the ECJ has indeed confirmed that it is for the member States themselves to satisfy the burden of proving the existence and nature of risks. However, in the *Monsanto Italia* case, the Court appears to have accepted a lowering of the *standard* of proof by interpreting the expression “detailed grounds” as requiring mere “evidence which indicates the existence of a specific risk.”

Insofar as prior approval procedures of GMOs are concerned, it is true that they generally impose on producers and exporters the burden of performing a risk assessment, but I am not persuaded at all that this requirement corresponds to full proof of absence of non-negligible risks. Reversal of the burden of proof thus seems a mere aspiration not supported by practice;

vii) lastly, practice relating to biosafety stimulates reflections on the appropriate institutional level for implementing the precautionary principle. On the one hand, it is certainly true that States tend to perform a proactive function in this respect. They perceive themselves as the primary (if not exclusive) addressees of the right and duty to take precautionary measures.

This is supported by several provisions of the Cartagena Protocol and by the constant recognition in various fora (WTO *in primis*) of the sovereign right of States to establish the level of environmental and sanitary protection they deem appropriate within their territory. On the one hand, this State-centered conception of precaution is reasonable as long as State authorities are obviously best equipped to appraise the ecological, political and socio-economic peculiarities and priorities of their country. On the other hand, the absence of meaningful powers of supervision and control on the part of international institutions, such as the Meeting of the Parties to the Cartagena Protocol, entails risks of legal anarchy and proliferation of trade disputes.

This is all the more evident in particularly advanced contexts of regional economic integration like that of the European Community, given the operation of principles such as those of the indivisibility of the single market, fair cooperation between member States and institutions and uniformity of application of EC law. Therefore, it is unsurprising that the main theme of the whole practice and jurisprudence of the EC relating to biosafety and trade in GMOs coincides with the sharp confrontation that during the past ten years has opposed the EC institutions to several member States adopting radical unilateral actions in the name of precaution. Reliance on the above-mentioned principles and on the supervisory mechanisms established by EC law have, *to a certain extent*, controlled the phenomenon of unilateral measures. In doing so, EC practice has given an important contribution to the identification of the *limits* of precautionary measures. At the same time, however, the EC institutions have on some occasions held positions not acceptable from a legalistic point of view and stretched the principles of EC law to their utmost boundary. Visibly, the objective pursued has been the abrogation of unilateral measures by all means. I believe this approach to be mistaken as long as national measures may play (and have actually played) the essential role of catalysts of environmentally sound reforms of the law.

In short, it seems to me that, in light of the many outstanding uncertainties and ambiguities illustrated above, international and European practice relating to biosafety may not be seen as a real breakthrough with respect to the crystallization of the customary nature of precaution. However, this does not deprive precaution of its crucial role in the biosafety and analogous contexts. The constant recognition of such a role in a plethora of legal instruments and State declarations does have to be taken into account. The evolution of the regime of biotechnology is rather a valuable occasion to refine the substance of the principle with a view to reaching a universal consensus on its status and implications.

## **V. Mutual supportiveness between environmental and human rights instruments on biotechnology and the applicable WTO Agreements**

For international lawyers, the most intriguing issue arising in the context of biotechnology is probably that of the simultaneous existence of a plurality of applicable treaty regimes with a different nature, purpose and substance. This issue involves biotechnology at large. It has been mostly studied with regard to potential *inter-sectoral* conflicts as between the WTO system and (environmental) regimes on biodiversity and biosafety. But it is clear that this kind of potential conflict equally encompasses the relation of WTO law and instruments on human genetics and human rights. Moreover, *intra-sectoral* tensions also exist, that is tensions between treaties which have important objectives in common, such as the protection of the environment. As already noted, this second type of tension especially concerns the relation of the CBD and the UNCLOS with respect to the regulation of marine biotechnology.

Admittedly, the problem is more acute in the former case, as it calls into question the legally and politically-sensitive issue of the status of non-trade concerns in the WTO and must take into account the existence of a powerful dispute settlement system within the WTO itself. The WTO rules potentially affected by the trade-related environmental and human rights measures envisaged by the instruments on biotechnology and human genetics are wide-ranging. At the very least, one should mention the TRIPs Agreement with regard to prohibitions or limits on the granting of IPRs on genetic material (both human and non-human) and the WTO agreements relating to trade in goods (chiefly the GATT, SPS and TBT Agreements) *vis-à-vis* restrictions on the free movement of biotechnological products (such as GMOs or cloned animals) and human biological material (such as stem cells).

Particularly with respect to the environmental issues raised by biotechnology, I suggest that the most significant development in relation to the issue at hand is associated with the steady emergence of the concept of *mutual supportiveness* of environmental treaties (so-called MEAs) and the WTO system. This concept enshrines the requirement that States are under a duty to facilitate and enhance all processes and forms of multilateral cooperation that are able to ensure the pacific co-existence of allegedly conflicting regimes and prevent potential disputes originating therefrom. The reiterated and consistent acknowledgment, at all levels and in disparate institutional settings, of the duty to promote mutual supportiveness of environmental and trade regimes warrants the idea of an *emerging* rule of customary law.

The shift from an allegedly conflicting relationship to a mutually supportive one may also be seen in the omission by the operative provisions of the most recent pertinent agreements, namely the Cartagena Protocol and the FAO Treaty, of savings clauses purporting to provide an across-the-board solution to potential conflicts arising between the agreements themselves and other international obligations (including, of course, WTO obligations) in accordance with Art. 30(2) of the 1969 Vienna Convention. These agreements rather include a more articulated formula in their *preamble*, a portion of which only might be identified with a savings clause.

The same change of perspective is to be noted in relation to instruments on human genomics and genetics. The UDHG, though only in its preamble, contains a “without prejudice” clause allegedly aimed at giving precedence to the treaties in the field of intellectual property, first and foremost the TRIPs Agreement. By contrast, the 2003 IDHGD, again in its preamble, merely “recalls” a number of international agreements and declarations, including the TRIPs Agreement and, most interestingly, calls upon States to regulate “*in accordance with* their domestic law and *international agreements*, the cross-border flow of human genetic data, human proteomic data and biological samples [...]” This is not a savings clause plainly accepting the primacy of international agreements, but rather a reminder of the need to foster harmonious and mutually supportive relationships between the Declaration and such agreements.

In the end, the only remaining genuine savings clause is Art. 22 of the CBD setting out the primacy of other international agreements, except where the exercise of the rights and obligations envisaged therein “would cause a serious damage or threat to biological diversity.” In addition, the second paragraph of the same norm addresses potential conflicts between the CBD and *inter alia* UNCLOS, by stipulating that “Contracting Parties shall implement this Convention with respect to the marine environment *consistently* with the rights and obligations of States under the law of the sea.” It is self-evident that these clauses

are ambiguous in many respects and thus subject to differing interpretations. As for the relationship of the CBD and UNCLOS, it is worthwhile to add that the interaction, if any, of the two paragraphs of Art. 22 is particularly controversial and that the problem is further complicated by the parallel existence of a savings clause in UNCLOS itself. At any rate, the most important point with respect to CBD Art. 22 (and similar savings clauses) is that they are to be assimilated to *compatibility* clauses, rather than *subordination* clauses *stricto sensu*. As such, they should not be considered capable of ensuring primacy to the “saved” regimes over the conflicting rule. They should instead operate at the interpretive level by inviting a conciliatory application of both norms.

Before briefly outlining the legal implications of the principle of mutual supportiveness between the instruments on biotechnology and the applicable WTO agreements, let me submit that, notwithstanding a huge bulk of scholarly debate, the general problem of the relationship between MEAs and the WTO system still appears unsettled both at the positive and theoretical levels. At the positive level, all efforts undertaken so far within the WTO to reach a consensus on precise rules clarifying the relationship between MEAs and WTO law (including that between the TRIPs Agreement and the CBD) have failed. Conversely, for one reason or the other, scholarly contributions do not appear fully convincing. They can roughly be distinguished into two categories. The first includes those authors who do not exclude the existence of genuine normative conflicts and accordingly identify solutions, generally favorable to the priority of MEAs, in line with the applicable general principles, whereas the second category encompasses those authors who are more inclined to explain the relationship at stake in terms of mere tensions likely to be overcome by virtue of general interpretive principles (evolutive interpretation, presumption against conflict, treaty effectiveness). The former view seems problematic for a number of technical reasons related to the principles governing the conflict of norms in international law. I will just mention that reason which, perhaps, may be considered as the basic one. Is it convincingly demonstrated that there exist *genuine* conflicts, that is a mutual relationship of incompatibility between norms pursuant to the definition widely accepted in international law? If one looks at the practice in the field of biodiversity and biotechnology, the answer must be in the negative. The overwhelming majority of States and pertinent international bodies and organizations rather highlight the existence of a mere interrelation, interaction or intersection.

In many respects, the interpretive approach seems preferable. It is consistent with State practice and is certainly more protective of the integrity and unity of the international legal system (including the *pacta sunt servanda* rule). However, practice also shows that there exist *residual* hypotheses where a considerable tension between the agreements at stake arises, if not from their textual interpretation, at least from the persistence of controversial courses of actions formally justified under a given treaty. Crucially for our purposes, this is the case of the *patentability of genetic material illegally exported from the State of origin*, namely without the prior informed consent of that State as required under the CBD. The TRIPs Agreement arguably admits these patents and patent offices around industrialized countries are reluctant to deny protection. This phenomenon, often stigmatized as one of *biopiracy*, evidently entails the violation of the principle of equitable benefit-sharing as well.

Interpretive principles show their inherent limits here. Such practices cannot just be reconciled with the CBD. What is the way forward, then? Should the principle of mutual supportiveness of instruments on biotechnology and trade regimes be seen as a mere conceptual tool devoid of legal significance and justiciability, thus unhelpful in the situation at stake? I do not believe so. First, mutual supportiveness is contiguous with the principle of

*sustainable development*, particularly with its underlying requirement of integration between economic, environmental and social values. Therefore, mutual supportiveness may influence in a dispositive way the outcome of normative processes and judicial disputes, much as sustainable development does. Secondly, mutual supportiveness is closely linked to the overarching principles of *cooperation and good faith* in international relations. Thus, the conduct of a State consisting in an arbitrary and unreasoned dismissal of actions capable of safeguarding mutual supportiveness between regimes may be sanctioned as a wrongful act.

More ambitiously, could such arbitrary dismissal to pursue mutual supportiveness include the refusal to engage constructively in law-making processes aimed at amending controversial provisions of the trade system? Consider that, with respect to the problem of biotechnological patents inconsistent with the CBD outlined above, a wide-ranging group of developing countries (of enormous demographic importance) is indeed convinced that the TRIPs Agreement must be amended in order to provide for the disclosure of the origin of genetic material, evidence of prior consent and benefit-sharing as conditions of patentability. This course of action goes in the same direction as other recent developments. I refer especially to the thorny issue of the relationship between intellectual property and access to essential medicines by least-developed countries, an issue that, for obvious reasons, is extremely pertinent in the biotechnology context. It is well known that the solution devised at the WTO level is the adoption of apposite waivers to the TRIPs rules concerning compulsory licenses. The relevant decision provides that the waivers are to apply until they will be translated into corresponding *amendments* to the TRIPs Agreement.

Such a development may well be explained under a perspective of mutual supportiveness between concurrent regimes (*in casu*, the human rights and trade regimes). Indeed, they powerfully suggest that the principle at stake *does* have a normative value. In exceptional circumstances, mutual supportiveness seems to include an emerging duty to cooperate in good faith in order to facilitate amendments to trade rules likely to result in systemic conflicts with fundamental principles established by MEAs articulated around the common concern of humanity (such as the CBD and the FAO Treaty). It is remarkable that such a duty should be opposable also to States that are not parties to the MEA in question, but are members of the WTO. To a certain extent, then, this perspective circumvents what represents the intangible aspect of international law underlying all the scholarly analyses mentioned above, namely the sanctity of the *pacta tertiis neque prosunt neque nocent* rule.

## VI. Conclusion

The years to come will predictably be a crucial time for the elaboration of international regimes in the field of biotechnology and human genetics. Certain law-making processes are already underway and others will be probably started up to address emerging issues and challenges. In this context, the most pressing question that the international community has to tackle relates to the undesirable consequences resulting from an increasingly fragmented approach to the international regulation of biotechnology. The proliferation of international bodies with biotech-related competences and of “international regimes all addressing pieces of the biotechnology puzzle, yet [...] [un]capable of addressing the problem as a whole” requires streamlining, synergies and the creation of viable networks of co-operation, hopefully including relevant non-state actors and stakeholders.

The way forward could be the negotiation of a comprehensive biotechnology treaty under the aegis of the UN, laying down basic principles and procedures, addressing specific areas where

consensus can be reached and, crucially, providing for a mechanism of constant updating in light of new scientific findings and advances.

In this contribution, I have attempted to provide a modest contribution to such a future standard-setting exercise by focusing on some basic substantive principles of the international law of biotechnology that have emerged from the already abundant practice in this area. I am aware that some of my findings, for instance with respect to the customary nature of the duty of benefit-sharing, may seem particularly contentious and that other frameworks and approaches can be put forward. However, international practice is rarely clear-cut, especially in areas, such as biotechnology, that are not well-settled and are rather subject to ongoing developments. In most cases, then, it is submitted that the rules extrapolated from practice deeply reflect one's own policy and value judgments and this contribution is certainly not an exception thereof. I do hope, however, that this will not be interpreted as tantamount to a lack of a positivist approach.

**Science Goes to Court:  
Some Considerations on the Precautionary Principle  
in the Community Jurisprudence**

Patrycja Dabrowska and Patricia Quillacq\*

The following contribution aims at drawing attention to the Community Courts' burgeoning case law pertaining to the application of the precautionary principle,<sup>76</sup> particularly regarding the consequences of these cases for the discretion of public authorities both at the national and Community level, and for the scope of judicial review. The contribution will start by introducing briefly the Community legal framework of the precautionary principle in the first section; it will then proceed to the separate examination of the case law of the Court of First Instance (CFI) in section 2, and the European Court of Justice (ECJ) in section 3, before attempting to draw some conclusions in the last part.

### 1. The precautionary principle in EU law – introductory remarks

The Treaty establishing the European Community contains only one explicit reference to the precautionary principle (PP), namely Article 174(2), in title XIX on the Environment, which specifies that Community environmental policy should be based on it. Even though the principle has a long tradition in the environmental policies of many member States, above all in Germany where it is known as *Vorsorgeprinzip*, the Treaty or any other Community legislative instrument does not define its content. The usual understanding of precaution refers to the necessity of action or inaction when there is an uncertainty about risk of serious and irreversible damage to the environment and/or humans. Thus, the precautionary principle applies to regulatory situations when there is a need to protect the environment but available scientific data does not allow for the definitive evaluation of potential hazards, and thus decisions must be taken on 'uncertain risks'. Needless to say, the complexity of decision-making under circumstances of uncertainty and lack of any legal definition implies plenty of interpretative and legal doubts as to the scope, conditions of application and understanding of the principle as such.

In response to these doubts, and at the explicit request of the Council in its Resolution of 13 April 1999, the Commission published its guidance document explaining the content of the precautionary principle in EU law.<sup>77</sup> The principal goal of the Communication was to outline the Commission's approach to using the precautionary principle and to build up a common understanding of how to assess, appraise and manage risks that science is not yet able to fully

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<sup>76</sup> See: ECJ 5 May 1998, Case C-180/96, *UK v. Commission (BSE Judgment)*; ECJ 5 May 1998, Case C-157/96, *National Farmers' Union*; ECJ 11 September 2002, Case T-13/99, *Pfizer Animal*; ECJ 11 September 2002, Case T-70/99 *Alpharma*; ECJ 26 November 2002, Case T-74/00, *Artegodan*; ECJ 9 September 2003, Case C-236/01, *Monsanto Agricoltura Italiana*; ECJ 23 September 2003, Case C-192/01, *Commission v. Denmark*; ECJ 5 February 2004, Case C-24/00, *Commission v. France*; ECJ 2 December 2004, Case C-41/02, *Commission v. Netherlands*.

See also comments by W.T. Douma, 'Fleshing Out the Precautionary Principle by the Court of First Instance', 15:3 *Journal of Environmental Law* (2003), 394; C. MacMaoláin, 'Using the precautionary principle to protect human health: Pfizer v Council', 28 *European Law Review* (2003), 723; E. Vos, 'Antibiotics, the Precautionary Principle and the Court of First Instance', 11:2 *Maastricht Journal of European and Comparative Law* (2004), 187.

<sup>77</sup> Commission Communication of 2 February 2000 on the precautionary principle, COM(2000)1.



evaluate.<sup>78</sup> In addition, an explicit reference to the precautionary principle has been introduced in some Community laws in the field of health and environmental protection.<sup>79</sup> At the same time, the Community courts have started analysing and interpreting the precautionary principle in the context of EU policies.<sup>80</sup> As a result, its scope of application has become far broader to additionally cover consumer policy and human, animal and plant health.<sup>81</sup>

These developments did not remove all the legal controversies surrounding the principle, but its significance in EU law has grown noticeably. Moreover, after the recent decisions of the Community Courts that aim to define the precautionary principle, its interpretation (and comprehension) has gradually become well-settled in the Community case law.<sup>82</sup> Currently, it can be said that the Luxembourg Courts, in particular, the Court of First Instance, and many scholars tend to perceive the precautionary principle as a general principle of Community law. It is thus very interesting to examine more closely the recent judicial findings.

## **2. The precautionary principle before the Court of First Instance (Alpharma, Pfizer and Artegodan)**

### 2.1 The background of the disputes

In the three cases under analysis in this section, the applicants seek the annulment of Council Regulations, regarding the withdrawal of marketing authorisations of certain substances (either additives for animal feeding stuffs or medicinal products for human use). As noted in the introductory remarks, the precautionary principle is invoked when scientific knowledge is not established and uncertainty remains on a specific issue.

In *Pfizer and Alpharma*, the invocation of the precautionary principle derives from an important debate that animates the world scientific community. It concerns the development of bacteria resistance to antibiotics. Such resistance is seen as a serious threat to human health, since it could drastically reduce the utility of antibiotics as means to fight microbial infections.<sup>83</sup> Regular addition of antibiotics in animal foodstuff is recognized to be a cause of the development of acquired resistance. The real danger though, lies in the transfer of such acquired resistance to human beings, and in the nature of the danger since it is: a) an almost irreversible phenomenon; b) a phenomenon that might affect the totality of antibiotics that are available mainly due to the 'cross-acquired resistance', meaning the transfer of resistance between different types of bacteria by transmission of genetic material. This last point is the core of scientific discussion.

In *Artegodan*,<sup>84</sup> on the other hand, the scientific debate concentrates on the undesired and harmful effects of drugs used in medical treatment of obesity. A certain category of medicinal products containing amphetamine-like anorectic agents currently being used in treating obesity would induce a high risk of primary pulmonary hypertension, pathology, which, in the case of occurrence, is most of the time fatal to the patient. Furthermore, many professionals no longer consider that the therapeutic efficacy of this type of medicine outweighs the risks their consumption might create.

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<sup>78</sup> *Ibid.*, 4.

<sup>79</sup> E.g., Council Directive 2001/18/EC of 12 March 2001 on GMO Deliberate Releases, Article 1; Regulation (EC) No 2002/178 of 28 January 2002 on General Food Law, Article 7.

<sup>80</sup> See a discussion of the early case law of the European Courts J. Scott, E. Vos, 'The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO', in C. Joerges and R. Dehousse, *Good Governance in Europe's Integrated Market* (Oxford University Press, 2001).

<sup>81</sup> See ECJ, Case C-41/02, *Dutch nutrients*, n. 74 above, par. 45 and the case law cited therein.

<sup>82</sup> Interestingly enough, the parties in all the cases here considered do not dispute the application (therefore the validity) of the precautionary principle, but rather its interpretation.

<sup>83</sup> *Alpharma*, par. 266

<sup>84</sup> See n. 74 above.

## 2.2 The use of the precautionary principle and risk assessment procedures: the legal principle as a tool of risk management

For anyone who is familiar with the literature about PP, underlining the link between the PP and risk assessment might seem redundant. Yet, it might not be completely superfluous to note, from the CFI case law, that the PP has not and cannot be invoked in absolute terms, in the void of scientific background, on the basis of un-assessed fears or doubts, since it would amount to a justification for arbitrary decision-making. The Commission Communication underlines the difference between the preventive approach, which is at the very basis of the idea of risk assessment, and the use of the PP, which comes after the results of the risk assessment. The PP affirms itself as a legal tool for risk management and thus can only be invoked in cases where a scientific risk assessment procedure has taken place. Let's see then how the Court of First Instance has evaluated the action of Community institutions in assessing risks and scientific uncertainty.

## 2.3. Between uncertainty and speculation: preserving the effectiveness of the principle

Overall, the approach of the CFI on the use of the precautionary principle does not differ much from the Commission's view laid down in its 2000 Communication. Nevertheless, the CFI has taken a decisive step by favouring a concrete approach to the principle, seeking firstly to preserve the effectiveness of the principle (*l'effet utile*).

The cornerstone of the pragmatic interpretation of the CFI on the application of the PP lies in the full acceptance that

the fact that it is impossible to carry out a full risk assessment in the time available does not prevent the competent public authority from taking preventive protective measures if such measures appear essential, regard being had to the level of risk to human health which the public authority has decided is the critical threshold above which it is necessary to take preventive measures'.

And thus to assert, in order to protect the effectiveness of the principle:

if the Community institutions were unable to take any protective measures until such research was complete, the precautionary principle, the aim of which is to prevent the occurrence of any such adverse effects, would be rendered devoid of purpose. 85

A few comments can be made with regard to this passage. The first point is obviously the necessity of a 'full scientific risk assessment'. By 'full', the CFI intends the soundness of the process, not the absolute exhaustiveness of the data. The Court is thus called to control the correctness of the risk assessment. For instance, in both *Pfizer* and *Alpharma*, the CFI has clarified that the analysis of scientific data by a political committee, (independently of the qualification of its members) does not amount to a scientific opinion,<sup>86</sup> and therefore does not relieve the Community institutions from their duty to carry out a scientific risk assessment, that has to be conducted by a committee established for that purpose, and following the principles of independence, transparency and excellence.

The second important point is that incompleteness does not challenge the value of the risk assessment.<sup>87</sup> Nevertheless, the CFI stresses that no confusion shall be made between the lack of scientific data and a

*purely hypothetical approach to risk, founded on mere conjecture which has not been scientifically verified. It follows from the Community Courts' interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been fully demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken.*

Some authors regret that the Court has not seized the occasion to establish in the judgments a general and more precise criterion in order to draw a clear line between what is adequate data or mere speculation, and that the evaluation will be made on a case by case basis.<sup>88</sup> But the jurisprudence on the PP is very recent and wishing for more might be tantamount to asking the Court to play a role that goes beyond its judicial functions. The Court, in

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<sup>85</sup> *Pfizer*, par. 386

<sup>86</sup> *Pfizer*, par. 281-286; *Alpharma*, par. 238

<sup>87</sup> *Artgodan*, par. 183.

<sup>88</sup> K.-H. Ladeur, 'The introduction of the precautionary principle into EU law: a pyrrhic victory for environmental and public health law? Decision-making under complexity in multi-level political systems', 40 *Common Market Law Review* (2003), 1455; H.P. Sands, 'The precautionary principle: a European Perspective', 6:3 *Human and Ecological Risk Assessment* (June 2000), 445.

the three cases, demonstrates a willingness to verify that decisions are thoroughly built upon the most recent available scientific opinion. The Court does not require, though, that Community institutions endorse fully the scientific opinion, but that they duly take them into account in the decision-making and in the motivation of the decision.

Thirdly, the Court, in these cases has indicated some criteria to assess the measures taken upon the basis of the PP. The measures have to be *essential* regarding the level of the risk to human health. Can we imagine that the 'essential' character of the measures might be an additional element strengthening the proportionality principle as put forward by the Commission in its communication? The CFI wording might suggest at least that the link between the scientific advice and the measures need to be extremely clear. From that perspective, one aspect is likely to play an important role in the judicial assessment of those measures, namely, the prior definition of the accepted level of risk. In *Pfizer*, the Court indicates that it consists in the establishment of a '*critical threshold by public authorities*'. In *Alpharma*, the Court reaches further by defining it as a '*critical probability threshold for adverse effects on human health and for the seriousness of those possible effects*'. In *Artegodan*, this '*level of protection chosen by the competent authority*' is seen as a general rule that will determine whether to have recourse to the precautionary principle or not.<sup>89</sup>

The Court has suggested, *inter alia*, some factors that it might consider in assessing the level of the risk: <sup>90</sup>

- *The seriousness of the repercussion on public health, were the risk to occur.* In *Pfizer*, for instance, the Court considers that the fact that the risk may affect mainly a minority group, persons with a deficient or weakened immunity system, does not entail a reduction in the importance of the risk.

- *The long-term effects and the reversibility of the risk.* In *Pfizer* and *Alpharma*, the scientific evidence of the risk would be the materialization of the adverse effect that public authorities want to avoid, that is, the first colonisation of the human system by the resistant bacteria of animal origin, or even worse the first death due to such colonisation. The Court clearly rejects the eventuality of such an event, choosing to preserve the utility of the PP.<sup>91</sup>

- *The more or less acute perception of the risk.* One of the arguments of the applicants was that the regulation contested had been adopted with "the sole aim of creating a favorable political impression in the press and with public opinion." It is interesting to note, that while the CFI's ruling is mainly based on the scientific information that justifies the Community decision, the Court adds that "the restoration of consumer confidence can in such circumstances also be an important objective which may justify even substantial economic consequences for certain traders."<sup>92</sup>

- *The utility and/or necessity of the substance targeted by the measure taken by the EU institutions.* The applicants in *Pfizer* and *Alpharma* put forward several arguments concerning the side-benefits of antibiotics in animal production,<sup>93</sup> which the CFI dismisses them by concluding that the use of antibiotics is not strictly necessary in animal husbandry.<sup>94</sup>

- *The cost/benefit analysis*

Finally, the Court confirms many times that preventive protective measures taken by the authorities, deriving from a legitimate political decision are *provisional measures*, "pending the availability of additional scientific evidence and further action of the institutions."

#### 2.4. The scope of review of the CFI on Community Institutions Discretion

One of the pleas of the applicants in *Pfizer* was that Community institutions had made a manifest error of assessment of data and facts when performing the risk assessment, thus flawing the risk management measures, and misinterpreting the PP. To consider these arguments, the CFI screens the actions of the institutions,

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<sup>89</sup> *Artegodan*, par. 186

<sup>90</sup> *Pfizer*, par. 153.

<sup>91</sup> *Ib.*, par. 444.

<sup>92</sup> *Ib.*, par. 462.

<sup>93</sup> *Ib.*, par. 420-426.

<sup>94</sup> *Ib.*, par. 459.

searching for a manifest error of appreciation. In reviewing the action of the Community institutions, the ECJ - and the CFI by extension, has always focused on the control of the legality of the contested act, and on any possible violation of substantial forms. Accordingly, the first verification regards the powers of the Community institutions and the final objective that the Community has to pursue in using those powers. Do they have the powers to realise the scientific assessment in the instant cases? Without any doubt, the CFI acknowledges that it is for the Community institutions to determine: a) the level of risk, and b) the level of protection they deem appropriate. It is an important point, since it implies firstly that the Community holds the power and has the duty to carry out a specific risk assessment at the Community level, which is different from the national studies. Secondly, the '*Community is entitled to take public health measures, on the basis of as yet incomplete scientific knowledge, protective measures which may seriously harm legally protected positions, and they enjoy a broad discretion in that regard*'.<sup>95</sup> It has to be borne in mind that it is for the Community institutions to define the political objectives they intend to pursue "within the parameters of the powers conferred on them by the Treaty." Without any ambiguity, the Treaty states that Community institutions have to reach for a 'high level' of protection in environmental policy, human health and consumer protection.<sup>96</sup>

In all fields where the Community enjoys that type of discretion, as a direct consequence of the political responsibilities given to it by the Treaty (such as Competition or the Common Agricultural Policy) the Community courts have developed a functional analysis of the use of the Community institutions powers and a purposive interpretation of the texts. Such type of review has allowed the Court to ponder the use of that discretion, mainly through the obligation of motivation of Community Acts.<sup>97</sup> By means of reviewing compliance with the duty to motivate, the Court, using the principle of proportionality, has always looked for a sound balance between the acts, the adopted measures and the motivation of the act. In these cases analysed here, the Community Courts find themselves having to use those tools in complex cases where science plays a major role and where decision-making involves scientific opinions and experts committees.

In these cases, in order to assess that such discretion was substantiated, the Court has to retrace the *iter* of the decision-making process. While recalling that it is not the Court's duty to assess the merits of the scientific arguments of the parties, the CFI has nevertheless to scrutinize the content and the extent of such arguments, and is therefore called to give a reading of all documents that back-up the contested decision. In light of the documents, the Court is able to conclude that there existed "great uncertainty at the time of adoption of the contested decision." Considering that such uncertainty determines a "particularly complex and delicate situation", the CFI concludes: "it was for the Council to exercise its discretion and assume its political responsibilities."

The Court leaves no doubt about the fact that the risk management decision is a political decision, and that there are two possible way of reacting:

- a) taking immediate and provisional action (and pursue the studies); or
- b) calling for further studies until conclusive data is available to ground the decision (as had been the choice of the USA and Australia).

Accordingly the Community institutions cannot be blamed for adopting a different approach from that taken by other countries. As the Court points out, "risk management necessarily entails political choices which can vary from one society to another according to the threshold of risk deemed acceptable." It is also that same reason that enables the Community institutions to take a decision that disregards scientific opinion and entitled them to give priority to human health protection over market interests.<sup>98</sup>

The scope of the review of the CFI at this stage focuses on two main elements. First, as mentioned previously, the legality of the contested act: powers, legal basis, procedural requirements, proportionality of the measures. But it must be noted that the Court also gives particular attention to the soundness of the reasoning of the Community institutions and to the link with scientific data. The Community institutions are fully enabled to take

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<sup>95</sup> *Ib.*, par. 170.

<sup>96</sup> Treaty establishing European Community, Articles 95, 152 and 174.2; *Pfizer*, par. 114, 140, 200, 262, 340.

<sup>97</sup> See e.g. ECJ 14 March 1973, Case 57/72, *Westucker*, Rec. 321.

<sup>98</sup> See *Pfizer*, par. 457, where the Court recalls that it is settled case law that the freedom to pursue a trade or a business is not an 'unfettered prerogative but must be viewed in the light of its social function. Consequently, it may be restricted, provided that the restrictions imposed in fact correspond to objectives of general interest pursued by the Community'.

political decisions that do not endorse scientific advice,<sup>99</sup> but evidence must exist that they have done so on the basis of the risk assessment and that they have established a comprehensible link with scientific opinion. The final step for the Court is thus to review in detail the statement of reasons of the contested decision. The CFI considers that “the statement of reasons must be of a scientific level at least commensurate with that of the opinion in question.” In *Artegodan*, the CFI maintains that approach, by reviewing “the internal consistency of the opinion and the statement of reasons from which it is possible to ascertain the considerations on which the opinion is based, and whether it establishes a comprehensible link between the medical and or scientific findings and its conclusions.”<sup>100</sup> Whereas in *Pfizer* and *Alpharma* the CFI concluded that the Community institutions have not exceeded the bounds of their discretion in applying the precautionary principle and withdrawing the marketing authorizations, in *Artegodan*, the Court annulled the Commission decisions. In the latter case, the Court distinguishes between what is a new assessment criterion of the lack of therapeutic efficiency by the scientific community and the scientific data or information that validates such new assessment criterion. The shift towards a new scientific criterion, good clinical practices, incorporated into the last assessment does not provide any innovation when compared with the earlier assessment that authorized the marketing of the medicine.

### 3. The precautionary principle before the European Court of Justice: the judgments in *Monsanto* and *Nutrients* cases

As already indicated in the preceding sections, recently the CFI and the ECJ have had several occasions to rule on the discretion of public administration (and judicial review of such discretion) when protective measures based on the PP are employed.

At this point, it is worthy of note that, as a result of the structure of the Community judicial system, it was the CFI that assessed the measures of the European institutions in its judgments, whilst the ECJ gave rulings in cases which concerned measures taken by member States. Thus, after the appraisal of the decisions of the CFI, it is appropriate to turn to the analysis in the context of the case law of the ECJ.

The examination below is based on four cases recently decided by the ECJ, namely, the *Monsanto* judgement and three so-called *Nutrients* cases.<sup>101</sup> In the *Monsanto* case, the competent Italian authority invoked a safeguard clause from the Novel Food Regulation with the aim of blocking genetically modified novel foodstuffs on the Italian market.<sup>102</sup> Interestingly, it was the first case in which the Court invoked directly the PP regarding member States’ power to adopt a provisional prohibition on the marketing of GMO-derived novel foods.<sup>103</sup> In the *Nutrients* cases, on the other hand, the Commission sued Denmark, Holland and France for failing to fulfil their Treaty obligations under Article 28 and 30 (free movement of goods) because they introduced special conditions and/or administrative practices for marketing of foods fortified with vitamins in their national territories.<sup>104</sup> Again, as in the decisions discussed above, these cases concerned situations where scientific knowledge is not definitely established. In *Monsanto*, the issue was the potential risks of genetically modified products and in the *Nutrients* cases the dispute concerned uncertainty surrounding the nutritional value of vitamins added to foodstuffs (and the respective amount of these vitamins).<sup>105</sup>

<sup>99</sup> *Ib.*, par. 201, where the CFI values the legitimacy of the Commission against the scientific committee, which lacks democratic legitimacy and political authority, therefore concluding that scientific legitimacy cannot be a sufficient basis to exercise public authority.

<sup>100</sup> *Artegodan*, par. 200

<sup>101</sup> Part of the findings are based on P. Dabrowska, ‘GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the Day in the recent Judgment of the European Court of Justice?’, 5:2 *German law Journal* (2004).

<sup>102</sup> ECJ, Case C-236/01, *Monsanto*, n. 74 above.

<sup>103</sup> See however a similar case concerning GM maize and the Council Directive 90/220/EEC of 23 April 1990 on GMO deliberate releases, ECJ 21 March 2000, Case C-6/99, *Association Greenpeace France*.

<sup>104</sup> ECJ, Case C-192/01, *Danish nutrients*; ECJ, Case C-24/00, *French nutrients*; and ECJ, Case C-41/02, *Dutch nutrients*, par. 29 which refers to the previous two cases, n. 74 above.

<sup>105</sup> The outcome of the cases is discussed below, but it should be noted that in principle the ECJ did not accept national protective measures in the *Nutrients* cases, whilst in *Monsanto* it was left to the Italian Court to decide in view of the interpretative guidance the ECJ developed (which in fact annulled the protective ban).

### 3.1. Discretion of public administration in introducing national protective measures based on the precautionary principle

After close examination of the case law under consideration, it can be said that, in principle, national authorities have discretion in adopting measures based on the PP, which aim at protecting the environment and/or public health.<sup>106</sup> This discretion is especially wide when uncertainties exist in the current state of scientific research.<sup>107</sup> Still, this discretion is not unrestricted. The ECJ has taken this opportunity to explain in detail the conditions applying to national practices based on the PP.

Accordingly, it can be said that the Court has stipulated the substantive prerequisites legalising the temporal restriction or suspension of the marketing of products. Even though the ECJ used slightly different wording in each case, it was sufficiently similar to allow for their generalisation.

#### 3.1.1. *Common conditions*

The requirements which need to be met by national authorities when they introduce protective measures restricting trade by invoking precaution can be enumerated as follows:

1. the demonstration of the *existence of a risk* (“specific” or “real”) to public health (or the environment);
2. the measure must be “based on a *risk assessment* which is *as complete as possible* in the particular circumstances of an individual case”;<sup>108</sup> or “the object of risk assessment ... is to appraise the degree of probability of harmful effects on human health ... and the seriousness of those potential effects”;<sup>109</sup> and
3. the measure “may not properly be based on a purely hypothetical approach to risk” and “founded on mere suppositions, which are not yet scientifically verified.”<sup>110</sup>

Moreover, the outcome of the risk assessment must indicate that those protective measures are *necessary* in order to ensure that products do not present a danger for consumers or the environment). In other words, member States while exercising their discretion relating to the protection of public health must comply with the *principle of proportionality*.<sup>111</sup> Regarding the burden of proof it is the responsibility of member States. They need to prove that they have “detailed grounds” for considering that the use of products endangers human health or the environment and that the reasons that the member States present after they have carried out a risk assessment “cannot be of a general nature” (*Monsanto*). Thus, the burden of proof requirement is satisfied when the member States rely on “evidence which indicates the existence of a *specific risk*” which the novel foods concerned could involve or that the risk which marketing of certain foodstuffs poses must be “real.”<sup>112</sup>

It is only after detailed explanation of the requirements that national authorities must meet while exercising their discretion that the application of the PP comes into play. With respect to the understanding of the PP, the ECJ seems to be consistent throughout its case law and

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<sup>106</sup> *Dutch nutrients*, par. 42-45; *Monsanto*, par. 128, 133.

<sup>107</sup> *Dutch nutrients*, par. 43.

<sup>108</sup> *Monsanto*, par. 107.

<sup>109</sup> *Dutch nutrients*, par. 48-49; *Danish nutrients*, par. 47-48; *French nutrients*, par. 54-55.

<sup>110</sup> *Monsanto*, para. 105-106; *Danish nutrients*, para. 49; *Dutch nutrients*, par. 52.

<sup>111</sup> *Dutch nutrients*, par. 46-47; *Danish nutrients*, par. 45-46; *French nutrients*, par. 52-53. See generally G. de Búrca, ‘Proportionality and Subsidiarity as General Principles of Law’, in: U. Bernitz, J. Nergelius, *The General principles of EC Law* (Kluwer, 2000).

<sup>112</sup> *Dutch nutrients*, par. 47; *Monsanto* para. 108-109

usually recalls the explanation already well-settled in the case law of both European Courts: “where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent.”<sup>113</sup> The ECJ is well aware of the fact that “[s]uch uncertainty, which is inseparable from the precautionary principle, affects the scope of the Member State’s discretion and thus also the manner in which the precautionary principle is applied.”<sup>114</sup> Nevertheless, the Court’s interpretation of the *scope* of application of the principle in *Monsanto* and in the *Nutrients* cases seems to be slightly different.

### 3.1.2. *The precautionary principle and the safeguard clause in Monsanto case*

According to the ruling in *Monsanto*, the conditions for national authorities *must be interpreted with due regard to the precautionary principle*, because the safeguard clause gives specific expression to this principle.<sup>115</sup> Moreover, it must, where relevant, constitute an “integral part of the decision-making processes leading to the adoption of any measure for the protection of human health” when based on a safeguard clause.<sup>116</sup> As Joanne Scott rightly observes, the Court by this statement declared, albeit implicitly, that this principle could even impose on member States positive obligations to act by observing that this principle must be an integral part of decision-making in the event that the safeguard clause is invoked.<sup>117</sup> Therefore, the Court concluded that the interpretation of the safeguard clause in light of the precautionary principle permitted a certain relaxation of the above enumerated conditions. It may happen, according to the Court, that in particular circumstances it is impossible to carry out “as full a risk assessment as possible” because of “the inadequate nature of available scientific data.”<sup>118</sup> Still, the specific evidence resulting from the risk assessment accessible to national authorities should be based on “the most reliable scientific evidence available and the most recent results of international research.” Such evidence, without precluding scientific uncertainty, must still allow national authorities to reach the reasonable conclusion that implementation of preventive measures is necessary to avoid the presence on the market of products which can be potentially risky to human health. That is to say, when the responsible institution – Community or member State – needs to base its decision on the precautionary principle, a scientific risk assessment must first be carried out, and must be as complete as possible, account taken of the individual circumstances. Only then is the political risk management decision to follow.

### 3.1.3. *The precautionary principle and derogation under Article 30 in Nutrients cases*

In the *Nutrients* cases, the Court’s explanation of the application of the PP is similar in emphasising the importance of procedural steps, inconclusiveness of scientific data, and likelihood of real harm to public health, but it did not go as far as declaring that it must form an integral part of decision-making. The Court held that:

*A proper application of the precautionary principle requires, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly,*

<sup>113</sup> Par. 111-112; and, *inter alia*, *Pfizer* par. 139; *National Framers’ Union*, par. 63; *BSE Judgment*, par. 99.

<sup>114</sup> *Dutch nutrients*, par. 51.

<sup>115</sup> Par. 110.

<sup>116</sup> Par. 133.

<sup>117</sup> J. Scott, ‘Precautionary Principle before the European Courts’, in: R. Macrory, *Principles of European Environmental Law* (Europa Law Publishing 2004), 51.

<sup>118</sup> Par. 112; *Pfizer*, par. 162.

*a comprehensive assessment of the risk for health based on the most reliable scientific data available and the most recent results of international research*

*Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.*<sup>119</sup>

#### 3.1.4. Closing remarks on national protective measures and the PP

Finally, a few general points should be raised. First, the analogy which can certainly be drawn between these cases – national prohibitions of products potentially dangerous for human health and/or the environment based on the precautionary approach - illustrates that in “risky products disputes” it is, in principle, of no importance to the Court whether or not Community harmonisation is already in place. Protective measures, such as those in the Italian Decree on novel foods or national laws regulating marketing of vitamin-fortified foods, may be perceived to constitute a measure having equivalent effect to a quantitative restriction within the meaning of Art. 28 of the EC Treaty. The existence of Community harmonisation is relevant only in determining the legal base for the justification of such a measure, such as the relevant safeguard clause or Art. 30 of the EC Treaty. The Court acknowledged that the member States do have powers to adopt measures derogating from Community harmonisation by invoking a safeguard clause or introducing a prohibition justified in the light of Article 30 of the Treaty by invoking the PP to protect public health, but these protective measures are permitted only in so far as the outcome of the risk assessment interpreted in the light of the PP evidently indicates that implementation of such measures is necessary and in accordance with the principle of proportionality.

Secondly, when one examines the above mentioned case law of the ECJ in the context of discretion of national institutions to introduce any protective measures it is clear that member States are under an indisputable obligation to perform an *ex ante* scientific risk assessment.<sup>120</sup> In all cases, the Court emphasized the approach to risk that the member States should employ, which must not be purely hypothetical or based on suppositions which are not scientifically verified. In particular, the risk to public health must be “real.” The authority of this argument is clearly showed by the fact that in all the *Nutrients* cases, national legislation was found to be unlawful because it was, *inter alia*, based on an inadequate approach to risk, that is to say, an approach which was too hypothetical.<sup>121</sup> So the Court follows a quite strict scientific discipline, even though it admitted that the current state of scientific knowledge might be inadequate: it still recalled science as a verification of risk, and scientific evidence as grounds for the management of risk. However, what is very astonishing is that the Court, whilst giving legal meaning to scientific notions, did not specify what is meant by scientific experts or which would be the relevant scientific bodies.

Furthermore, having said that the PP continued to apply to protect human health, it should be mentioned that the Court seemed to be more conscious and more moderate about the extent of the discretion granted to the member States institutions than the CFI was towards Community institutions in its judgment. The statement that public values such as human health should

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<sup>119</sup> *Dutch nutrients*, par. 53-54; *Danish nutrients*, par. 51-52.

<sup>120</sup> *Dutch nutrients*, par. 48-56.

<sup>121</sup> *Danish nutrients*, where the *Monsanto* case is cited, par. 49, 56.



take precedence over economic considerations included in the CFI's judgments on the PP, does not appear in the present cases.<sup>122</sup> In addition, the Court did not include in its findings any observation or explanation that member States, while adopting preventive measures, should analyse the level of risk which could or could not be acceptable for their consumers (as it had in the previous judgments).<sup>123</sup> Here, member States should rather be able to conclude reasonably that such protective measures are necessary. In the *Danish nutrients* case, the Court observed that [s]uch measures must not be allowed unless they are non-discriminatory and objective", and in *Dutch nutrients* it ruled that national rules can be adopted if they "are necessary to give effective protection to the interests" of Article 30 of the Treaty (which is the legal basis for justifying measures where there is no Community harmonisation).<sup>124</sup>

Finally, it should be noted that, when the ECJ judgments in *Monsanto* and the *Nutrients* cases are compared, the discretion of national authorities in applying the PP seems to be somewhat reduced. Moreover, only in *Monsanto* did the Court, while leaving the final decision to a national court, exhibit a relatively moderate approach toward national discretion in the application of protective measures based on the PP. In other cases (*Nutrients*), the ECJ expressly declared that national practices were not acceptable and member States lost against the Commission. Interestingly, in light of the ECJ ruling in *Monsanto*, the national administrative Court (Italian Tribunale Amministrativo Regionale) decided to annul the governmental decree prohibiting GM products on the market, thus upholding the company's claim against protective measures based on the PP.<sup>125</sup>

### 3.2. The scope of judicial review

The second very important aspect of decision-making under the PP, which implies risk assessment and uncertainty of scientific findings, is the scope of judicial review, or, in other words, the role to be played by courts in assessing such situations. When one examines the case law of the ECJ in this context, it should be observed that, again like the CFI, the ECJ examines predominantly whether the required procedural steps were followed.

Generally, its discussion of scientific merits seems to be more limited than the CFI's discussion at the Community level, especially in the *Nutrients* cases. Still, there is a slight shift towards a more eager engagement in the analysis of risk assessment reasoning between the Danish and Dutch cases. In the Danish case, the Court simply stated that administrative practice was "disproportionate";<sup>126</sup> while in the case of the Netherlands it gave a quite elaborate analysis of the logic the Dutch authorities applied in the context of products risk assessment and national legislation.<sup>127</sup>

Interestingly as well, in the *Monsanto* case, the Court repeated the well-known phrase about the scope of judicial review in cases involving risk assessment:

*In a sphere in which the Community legislature is called on to undertake complex assessments, judicial review of the exercise of its powers must be limited to examining whether it is vitiated by a manifest error of assessment or a misuse of powers or whether the legislature has manifestly exceeded the limits of its discretion.*<sup>128</sup>

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<sup>122</sup> For example *Pfizer*, par. 456, 471.

<sup>123</sup> Cf. *Pfizer*, par. 150-153, 162.

<sup>124</sup> *Dutch nutrients*, par. 47; *Danish nutrients*, par. 53.

<sup>125</sup> See T.A.R LAZIO ROMA, Sez. I, 29 novembre 2004, n. 14477.

<sup>126</sup> *Danish nutrients*, par. 55.

<sup>127</sup> *Dutch nutrients*, par. 56-70.

<sup>128</sup> *Monsanto*, par. 135.

It also emphasised the role of national courts in deciding on the substantive merits of the case affecting its outcome (i.e. the issue of whether a particular GMO-derived product is substantially equivalent to conventional food). It did, however, not pay much attention to the fact that a similar determination might be undertaken at the Community level via the comitology structure, even though the importance of the latter possibility was stressed by the Advocate General.<sup>129</sup> Would this entail a willingness to increase the significance of judicial review in cases where political institutions are trapped in a regulatory impasse? Perhaps the Court would see a more robust judicial role, implying a greater significance for judicial review, as a desirable solution for difficult cases where decisions must be taken as to uncertain risks and where the precautionary principle applies. These issues can only be subject of guess and still remain undecided.

#### 4. Conclusion

The above analysis is by no means exhaustive, but just offers some considerations on the present interpretation of the PP by the European Courts. Generally, this jurisprudence should be welcomed, because in the current world there are more and more situations where science cannot provide an unambiguous response to challenges posed by technological developments as combined with natural risks. For example, the current threat posed by the H5N1 virus (highly pathogenic avian influenza), demonstrates how quickly the micro-organisms capacity to mutate develops, how they became capable of interacting among themselves, and most importantly of interacting with the human organism, and how the state of scientific knowledge must accordingly fluctuate. So we cannot avoid application of the PP if we want to protect human health and the environment.

The above examination of the respective case law of both European Courts led to some interesting findings. First, and by no means surprisingly, judgments given in two different governance contexts have many common points when discretion of public authorities (national or Community) is concerned. Both Courts try to define the conditions for protective measures under the applications of the PP, in order to balance the interest of market integration and protection of public health and the environment, both do it through proceduralisation of these conditions (full risk assessment, best available scientific evidence) and through (what may seem a tightened) application of the proportionality principle (and still to be confirmed in future cases).

Secondly, when the scope of judicial review is analysed, in both Court's decisions, it is also viewed similarly, as mostly the check of procedural steps (even if the CFI decisions are much more elaborate concerning the review of scientific merits). However, the two institutions come to different conclusions when applying their review. And these are the differing aspects of the two sets of judgments analysed above. Namely, the ECJ seems to be much less willing to acknowledge broad discretion of national authorities when taking protective measures in the light of PP, than the CFI vis-à-vis Community institutions. Moreover, until the above analysed case law on PP was decided, national authorities had never previously won a case by invoking the PP as a justification for national protective measures, whilst the Community institutions when invoking the PP in defence had only lost in *Artegodan*.<sup>130</sup> When deciding on national measures, the ECJ is also quite restrictive in discussing national bodies which should be politically responsible and defining the acceptable level of risk, and also what this level is for the member States.

Finally the jurisprudence can be open to criticism in that it did not establish more clearly what is to be understood as the "most reliable scientific evidence available" or identify the relevant Community scientific institution(s), such as the European Food Safety Authority. Broader elaboration on the role of scientific expertise in the present context would be desirable. Should we expect such elaboration to come from the Community Courts? The current state of the jurisprudence can also be read as not disrupting the role that the ECJ – and by extension the CFI, has traditionally attributed to itself. The Court holds powers and pursues functions that are superior to a simple judicial body; the Court is a main actor in the Community institutional architecture. Much has been said and written on the desirable role of the Community Judicial system and the role of the Courts. Yet,

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<sup>129</sup> AG Opinion in *Monsanto*, par. 135 and 150.

<sup>130</sup> See also ECJ 12 July 2005, Case C-154/04 *Nutri-Link*; and ECJ 12 July 2005, Case C-198/03 P, *Appeal in CEVA Sante Animale and Pfizer Enterprises*.

the Court has always favoured a rather strict conception of its own functions, that is, a judicial function. It is not foreseeable that scientific uncertainty could change this.

**The Aarhus Convention  
as an Instrument of Environmental Justice**

**Is legal symbiosis possible?**  
**The Coming Synergy between the Aarhus Convention and the European Court of Human Rights**

Patricia Quillacq\*

**Introduction**

From the early statutes on environmental impact assessment to the 1998 UN Convention on Access to Information, Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention), the idea that people have to be involved in a decision that might adversely affect their environment has grown beyond doubt. This core idea has led to a regulatory approach that designs steps and guarantees aiming to secure the participation of the public. This feature is often praised as a major contribution of environmental law to the development of national public law. Furthermore, one can affirm that the procedural dimension of environmental law has achieved what decades of intergovernmental and doctrinal discussion have not been able to conclude: the existence of an individual right to a sound environment.<sup>131</sup> Article 1 of the Aarhus Convention, despite the reservations made by some contracting parties (notably the UK), can indeed be read as the recognition of such a right, benefiting from the legal force of a binding international agreement.

In turn, the European Convention on Human Rights (ECHR) has been offering unexpected support to environmental protection, through the evolving case law of the European Court of Human Rights (ECtHR). Firstly, the individual human rights may be directly affected by adverse environmental factors, and applying its doctrine of positive obligations, States might be requested to act and take concrete measures to secure the human rights, and *par ricochet*, protect the environment. Secondly, environmental factors may give rise to certain procedural rights.

This contribution raises some points on how environmental law and human rights law are interacting with respect to the development of procedural rights, and provides a glimpse of how, in the future, the Aarhus Convention may enhance the ECHR, and vice-versa.

**1. Right to access and receive information**

The Court has stated a series of principles relating to access to information on environmental matters, mainly in relation to Article 8, but they appear to be valid as well for other articles.

In *McGinley & Egan v. the UK*,<sup>132</sup> the applicants, who had been exposed to radiations in the Pacific when the British Government carried out nuclear tests, were arguing non-disclosure of records relating to those tests. The Court firstly said Article 8 applies when there is a *sufficiently close link between private life and the question of access to information*. The restlessness and anxiety produced by ignoring the consequences of certain activities on one's own or one's family member's health could be an example of that link (§86). Even though not finding a breach of obligations in the instant case, the Court nevertheless established that when a government engages in hazardous activities which might have hidden adverse consequences on the health of those involved in such activities, respect for private and family life under Article 8 requires that an effective and accessible procedure be established which enables such persons to seek all relevant and appropriate information (§ 101).

The narrow majority of the decision regarding the extent of the positive obligation deriving from Article 8, the dissenting opinion of Judges De Meyer, Valticos & Morenilla, as well the dissenting opinion of Judge Pekkanen in this affair, deserve to be noted, as they represent an evolution with respect to the extent of the States' positive obligations regarding environmental information.<sup>133</sup>

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<sup>131</sup> For the latest failed attempt, Parliamentary Assembly of the Council of Europe, *Recommendation 1614 (2003) on Environment and Human Rights*.

<sup>132</sup> *McGinley & Egan v. the UK*, Judgment of 9 June 1998.

<sup>133</sup> The common dissenting opinion of De Meyer, Valticos and Morenillo suggests that States could be declared responsible of serious negligence when not collecting information on hazardous activities, and that interested

A similar example is provided by the *Guerra and Others v. Italy* case.<sup>134</sup> The applicants complained that they could not obtain the information about the risks and the measures to be adopted in the event of an accident at a local chemical factory. The Court considered that “particular emphasis should be placed on the public’s right to information”, and that “this right, which has already been recognised under Article 8, may also, in principle, be relied on for the protection of the right to life, particularly as this interpretation is supported by current developments in European standards” (§90). The Court, in appreciating the facts and the law, makes reference to the legal standards, and is sensitive to the international community consensus on those standards. It is relevant to note that the decision date is 19 February 1998, when the Aarhus Convention was not yet adopted and that at the time the reference was the 313/90 EC Directive on access to environmental information. It should, therefore, be noted that, while the 313/90 Directive does not mention the duty for authorities to collect and divulgate information, Article 5 of the Aarhus Convention imposes extended obligations to the States regarding the collection, possession, the availability and the flow of environmental information towards the public.

Anticipating these developments, in the *Guerra* case, the applicants also argued that Article 10 ECHR had been violated, but the Court refused to derive from a provision traditionally built as a freedom (of expression) a positive duty for the State to give information on its own initiative (§ 53 of the Judgement of 19 February 1998). Yet, the concurring common opinion of Judges Palm, Bernhard, Russo, MacDonald, Mackarzyk and Van Dyk already suggested a different path, indicating that: “under different circumstances, the State may have a positive obligation to make available information to the public and to disseminate such information which by its nature could not otherwise come to the knowledge of the public.”<sup>135</sup>

In a 2004 case, *Oneryildiz v. Turkey*,<sup>136</sup> where a methane-induced implosion in a municipal waste tip killed thirty-nine people, the ECtHR delivers its current view on the right to access to information:

*public authorities may be under a specific obligation to secure a right to access to information in relation to information on environmental issues in certain circumstances. This obligation arises from the procedural rights protected by Articles 2 and 8 of the Convention.*<sup>137</sup>

## 2. Human rights and public decision-making in environmental matters

The attention paid by the ECtHR to the procedural dimension of Article 8 is not exclusive to environmental affairs. It is present in all matters in which States possess a wide margin of discretion. The Court has always recognized the *bien-fondé* of the legitimacy of such a margin of discretion. Yet,

*whenever discretion capable of interfering with the enjoyment of a Convention right (...) is conferred on national authorities, the procedural safeguards available to the individual will be especially material in determining whether the respondent State has, when fixing the regulatory framework, remained within its margin of appreciation. Indeed it is settled case law that, whilst Article 8 contains no explicit procedural requirements, the decision-making process leading to measures of interference must be fair and such as to afford due respect to the interests safeguarded to the individual by Article 8.”*<sup>138</sup>

Land and environmental planning fall into that type of policy. Thus, the Court has stated that

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persons had the right to ask for information, which would have enabled them to assess the risks they were incurring.

<sup>134</sup> *Guerra and Others v. Italy*, Judgment of 19 February 1998.

<sup>135</sup> The Concurring opinion of Judge Bamberk also suggests a more open interpretation of Article 10 as regards environmental information: where a State does not, without good reason, give the information requested by potential victims of hazardous activities . such lack of action could amount to an interference with Article 10.2 of the ECHR.

<sup>136</sup> *Oneryildiz v. Turkey*, Grand Chamber, Judgment of 30 November 2004.

<sup>137</sup> The jurisprudence of the ECtHR regarding questions of information also includes a number of interesting cases regarding freedom of expression and the role of environmental associations. See for example *Vides Aizsardzibas Klubs v. Latvia*, (Judgment of 27 May 2004), *Steel & Morris v. UK* (Judgment of 15 February 2005), *Tierfabriken v. Switzerland* (Judgment of 20 May 1998).

<sup>138</sup> *Buckley v. the UK*, Judgment of 25 September 1996.

*where a State must determine complex issues of environmental and economic policy, the decision-making process must firstly involve appropriate investigations and studies in order to allow them to predict and evaluate in advance the effects of those activities which might damage the environment and infringing individuals rights and to enable them to strike a fair balance between the various conflicting interests at stake.*<sup>139</sup>

Faced with the wide margin of appreciation of the State, the Court retains its competence to appreciate if a State has committed a manifest error of appreciation.<sup>140</sup>

The *Hatton v. UK* case synthesises most principles established by the Court in this field. It concerned the noise generated by aircrafts taking off and landing at an international airport. Having to assess whether the decision to authorize supplementary night flights had bearing on the quiet enjoyment of the applicant's private and family life and home, the Court deemed that there are two aspects to the inquiry. First, the Court may assess the substantive merits of the government's decision, to ensure that it is compatible with Article 8. Secondly, and of interest to our discussion, it may "scrutinise the decision-making process to ensure that due weight has been accorded to the interests of the individual" (§ 99).

The Court is thus required to consider all the procedural aspects of the process leading to a decision of the authorities affecting individual human rights, from the type of policy or decision involved, the extent to which the views of individuals were taken into account throughout the decision-making procedure, mitigating measures, and the procedural safeguards available, that is whether it is possible to lodge a complaint as to the manner in which the decision-making procedure or an aspect of it was run. In addition, the Court often recalls that updated information is necessary in those types of cases and looks in detail at the relevance of the information sustaining the public decision.<sup>141</sup>

Let me finally mention a very recent case, *Taskin and Others v. Turkey*, where the Court has taken a step further in recognizing the link between environmental law and human rights. Confronted with the authorisation of the exploitation of a gold mine, the Court held that Article 8 was applicable because the decision allowing to proceed with the potentially dangerous effects of such activity, to which the individuals concerned were likely to be exposed, had been taken in the frame of a procedure of environmental impact assessment (EIA). So the mere fact of the existence of an EIA was a sufficient criterion to determine the application of Article 8.<sup>142</sup>

### 3. Access to justice

To give a complete picture of the relations that the Strasbourg case law may establish with the Aarhus Convention, we need to examine the question of access to justice. Article 9 of the Aarhus Convention requires contracting parties to provide access to justice to review decisions either by offering access to a court, or to another independent and impartial organ. Although the text of the ECHR alone does not contain a specific reference to access to a court, it is well-established by the case law that the right of access to a court (to be understood as the right to institute proceedings before courts in civil and criminal matters) is an inherent part of the fair trial guarantees provided by Article 6. But Article 13 of the ECHR completes that partial view, by requiring the existence of an effective remedy before a national authority. Both instruments cover, thus, the varied possibilities of "access to justice." But precisely because they cover different fields that, in some cases converge (environmental information, health issues, natural resource planning), there is a tremendous potential for synergy between them. The Aarhus Convention can inform the ECHR on what are the good practices and legal standards to be required in environmental cases. In turn, the ECtHR offers not only a forum for European citizens to bring claims and enforce their right of access to justice, including in environmental cases, but also the ECtHR case law is an important reference for all domestic judiciary systems on the interpretation of such rights.

A good way to demonstrate it is to consider the field of Article 9 of the Aarhus Convention. It guarantees access to justice for any person who considers that his or her request for information has been refused, inadequately answered or not dealt with in accordance with the provisions of Article 4 (access to information). Combining

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<sup>139</sup> *Hatton and others v. the UK*, Grand Chamber, Judgement of 8 July 2003, § 115.

<sup>140</sup> *Chapman v. the UK*, §92.

<sup>141</sup> *Katsoulis and others v. Greece*, Judgment of 8 October 2004.

<sup>142</sup> *Taskin and Others v. Turkey*, Judgment of 10 November of 2004, §113. This judgment will become final when the circumstances set out in article 44§2 of the ECHR will be satisfied.

Article 9 and Article 4 of the Aarhus Convention provides much information on the extent of the positive obligations of authorities regarding information. It could promote the advancement of the ECtHR case law in that field. But the field of the ECHR is much broader than Aarhus. Article 6 and Article 13 ECHR can apply to many cases concerning environmental questions, as demonstrated by the existing case law.

At the moment, the ECtHR considers that the right of access to a court applies if there is a sufficiently direct link between the environmental problem at issue and the individual right invoked. Mere tenuous connections or remote consequences are not sufficient (*Balmer-Schafroth v. Switzerland*, § 40). Therefore, Article 6 applies only when the individuals concerned have suffered, as a result of environmental deterioration, damage for which they are entitled to compensation under national legislation. In case of a serious, specific, and imminent risk, Article 6 may be invoked if the danger reaches a degree of probability, which makes the outcome of the proceedings directly decisive for the rights of those individual concerned.<sup>143</sup>

In particular, applicants will be able to rely on the right to have their physical integrity adequately protected, a right which is recognised under the domestic law of most European states. In *Balmer-Schafroth and others v. Switzerland*, and *Athanassoglou and other v. Switzerland*, the Court examined in detail whether the applicants could successfully invoke the right of access to a court in proceedings concerning the granting of operating licences for nuclear power plants, which, according to the applicants, were not meeting the current safety standards. Interestingly enough, the Court recognised that there had been a genuine and serious dispute between the applicants and the decision-making authorities, and the applicants had a “right” recognised under Swiss law to have their life, physical integrity and property adequately protected from the risks entailed by the use of nuclear energy. In addition, the mere fact that the decisions had to be based on technical data of great complexity did not in itself prevent Article 6 from being applicable. However, in the instant case the applicants did not establish clearly enough a direct link between the operating conditions of the power station and the right to protection of their physical integrity. The result of the *Balmer-Schafroth* decision is however debatable.<sup>144</sup> In *Taskin*, and more recently in *Okay v. Turkey*, the Court considered that the right to live in a healthy and balanced environment, enshrined in the Constitution, constitute a civil right within the meaning of Article 6.1 and therefore the applicants could maintain that they were entitled under Turkish law to protection against damage to the environment caused by the activities of the mine in question. Without any doubt, there was a genuine and serious dispute.<sup>145</sup>

The “civil right” approach and the direct link test used by the ECtHR raises major questions regarding standing issues, especially if we start looking at the associations’ situation, but space constraints preclude discussion of this issue in this contribution.<sup>146</sup>

#### **4. Indivisibility of human rights: rights and remedies**

Finally, we shall underline a unique feature of the ECtHR case law, which reiterates the indivisibility and interconnection of human rights. The environmental cases offer a new field where this interrelation manifests itself, and where the contribution of the ECHR, again, could be important for the implementation and enforcement of the Aarhus Convention. In the *Guerra* case, for example, the Italian Government objected that complainants should have exhausted domestic remedies, pointing to two judicial procedures. However, the Court dismissed this argument, insisting on the fact that:

- a) The government could not demonstrate that the remedies they were referring to had been used and proved successful in similar cases; and
- b) The remedies would not have secured the right of the applicants to obtain specifically the type of information they were asking for.

The Court, following its long tradition of defending a concrete and effective interpretation and implementation of the ECHR, offered by the same token a concrete and substantial defence of the right to access environmental information.

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<sup>143</sup> See *Balmer-Schafroth v. Switzerland*, Judgment of 26 August 1997; *Taskin and Others v. Turkey*, *Fadeyeva v. Russia*, Judgment of 30 November 2005.

<sup>144</sup> For more details, see the minority opinions: Dissenting opinion by Judge Pettiti, joined by Judges Golcuklu, Walsh, Russo, Valticos, Lopes Rocha and Jambrek; and Dissenting opinion of Judge Foighel.

<sup>145</sup> *Taskin and others v. Turkey* (§129), *Okay v. Turkey*, judgment of 12 July 2005 (not yet definitive).

<sup>146</sup> See for example *Gorraiz Lizarraga and Others v. Spain*, judgment of 27 April 2004.



Another example of that concrete and specific approach is offered in the first decision regarding the Hatton case, where the Court considered that the scope of review by the domestic courts, limited to classic English public law concepts, was insufficient to allow consideration on the effects of the increase of night flights, therefore finding a violation of article 13.<sup>147</sup> Finally, it is important to mention the emphasis of the ECtHR on the implementation of judicial decisions, crucial to give meaning to the letter of Article 6 and 13. In the Kyrtatos case, the State was found guilty of violation of Article 6.1 because, for a period of 7 years, the Greek authorities had not taken the necessary measures to implement two domestic judicial decisions.<sup>148</sup>

## 5. Conclusion: Enforcement issues

A human rights-based approach to environmental protection is not new. The Stockholm Declaration on the Human Environment emphasized the interconnection of these two spheres. Legal doctrine has promoted it. Yet, the same doctrine has underlined that uncertainty has marked the debates on the role of human rights law in the development of international environmental law in the last 30 years. Too often, the debate seemed to stumble over a recurrent question: the nature and scope of environmental rights. This is now partly solved: the Aarhus Convention Article 6 may be interpreted as the right to an environmental impact assessment. Nevertheless, the problem of the effective enforcement of the Aarhus Convention remains. The Meeting of the Parties has established a compliance mechanism, where the public is entitled to submit communications.<sup>149</sup> The Aarhus Compliance procedure, however, is not designed as a mechanism for redressing the violation of individual rights. It focuses instead on general issues of non-respect of the convention by the State. We are thus very far from the Strasbourg regime, where, ultimately, individuals can introduce a claim for violation of their rights. In light of the continuous and severe degradation of the environment, the integration of environmental factors in the case law of the ECtHR was unavoidable.<sup>150</sup> The present bulk of case law simply confirms past legal constructions and expectations, and may even go beyond them. The ECtHR case law discards the fear that international bodies would not have the competence to address complex environmental questions. The Court has not avoided assessing the facts and the law of sensitive or complex affairs: it is noteworthy. The human rights-based approach is not perfect, though. The Court's environmental case law oscillates between judicial activism and self-restraint. At the end of the day, it is one among other instruments for environmental protection, but it has important legal implications. For the citizens of 46 member States of the Council of Europe, the ECtHR represents a forum where the implications of environment degradation will not be lightly ignored. The Compliance Mechanism of the Aarhus Convention has now to demonstrate its value and usefulness. In the meantime, we expect that the environment will keep "greening" human rights in Europe and elsewhere, therefore contributing to achieving sustainable development by demonstrating that mutual support between international instruments is not only possible, but highly desirable.

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<sup>147</sup> *Hatton and others v. the UK*, Judgement of 2 October 2001, § 116.

<sup>148</sup> *Kyrtatos v. Greece*, Judgement of 22 August 2003, § 32.

<sup>149</sup> Meeting of the Parties, Decision I/7 on Compliance Mechanism.

<sup>150</sup> It must be noted that similar developments are visible in the African or South-American Human Rights systems. For a brief overview of jurisprudence of human rights bodies in that field, see Background Paper n°2 Joint UNEP-OCHR Expert Seminar on Human Rights and the Environment, 14-16 January 2002, available online at <[www.cedha.org.ar/docs/doc63/htm](http://www.cedha.org.ar/docs/doc63/htm)>.

## Procedural Environmental Rights and the Regulation of GMOs under the Aarhus Convention

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### 1. Introduction

The issue of the proceduralization of environmental regulation has been a popular one in the last decades. Procedural environmental rights are seen as mechanisms to achieve environmental protection through sound, sustainable decision-making. These rights may have an important role in a regulatory area such as the one dealing with genetically modified organisms (GMOs) where decision-making is very contentious and complex and the outcomes may represent a potential threat to the environment. This potential role was recognized within the Aarhus Convention, which regulates access to environmental information and participation in the decision whether to permit the deliberate release and placing on the market of GMOs.

This contribution will, initially, try to provide a framework for the role of procedural environmental rights in environmental regulation (which includes GMO related activities). Then, it will provide a general description of the access to environmental information and public participation in decision-making pillars of the Aarhus Convention. Lastly, the contribution will focus on public participation in decision-making in GMO related activities within the Aarhus Convention which was recently amended in this area.

### 2. Theoretical framework

#### 2.1. Public participation as a good governance vector

“Good governance”<sup>151</sup> has been frequently argued to be the ultimate solution for the legitimatization of international environmental law<sup>152</sup>. Still, what exactly “good governance” means nobody knows, since there are a myriad of definitions for this concept which leads many to question its usefulness. The vagueness added to the difficulty surrounding the conceptualization of “good governance” does not, however, preclude the importance of its underlying idea: the need for the democratization of environmental decision-making. Thus, for the purposes of this contribution “good governance” entails five basic principles, as defined at the EU level<sup>153</sup>, which are all inextricably linked. These principles are: openness, participation, accountability, effectiveness, and coherence.

Why, then, is there a need for “good governance” in international environmental decision-making? In general, environmental problems tend to get more complex and acute, thus a greater internationalization of environmental law is taking place. The issue of “good governance” and, consequently, the legitimacy of international environmental regulation crops up almost automatically.<sup>154</sup> Are international regulatory processes, which are mostly based on Nation-State’s choices, legitimate and do they need to be so?

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<sup>151</sup> The debate surrounding “good governance” is one that crosses many fields and levels of decision-making. It can be found at the EU level and in public international law, in general, or in more specific sectors of the law, such as environmental law.

<sup>152</sup> See *inter alia* A. Alkoby, “Non-State Actors and the Legitimacy of International Environmental Law”, 3:1 *Non State Actors and International Law* (2003), 23. D. Bodansky, “The Legitimacy of International Governance: a Coming Challenge for International Environmental Law”, 93:3 *American Journal of International Law* (1999), 596.

<sup>153</sup> See *European Governance: a White Paper* (COM (2001) 428 final).

<sup>154</sup> “But as decision-making authority gravitates from the national to the international level, the question of legitimacy will likely emerge from the shadows and become a central issue in international environmental law.” D. Bodanski., *supra* n.146, at 596.

Participation, as a core element of “good governance”, may enhance the legitimacy of international environmental regulation. Participation is rooted on the promotion of stakeholder involvement through the sharing of their lay knowledge or specific expertise. The ultimate goal should be to offer the public the actual possibility of influencing the process, either by providing information or an opinion concerning a particular policy or by monitoring compliance with a given agreement. This creates a sense of ownership in the process that would have a problem solving potential (acceptance of decisions would be easier) since the final outcome results from an interactive exercise where, in a material application of the principle of environmental participation<sup>155</sup>, all stakeholders presented their contributions (popular legitimacy).

Moreover, an interactive, open and communicative dialogue between different societal sectors would have an educational democratic prospective (social learning and awareness) which would contribute to a more active and engaged democracy. Democracy as such would only gain, since it is rooted in pluralism, and the adoption of such a principle would ensure that different zones of interest would be visible. Moreover, “this process seeks to ensure that alternative views are explored within the appropriate contextual matrix and contributes to a more legitimate and effective decision-making.”<sup>156</sup> Environmental participation would be a plus for Democracy (Participatory Democracy), providing it with an extra-tool of accountability other than the right to vote and by enhancing the transparency and fairness of democratic processes themselves.<sup>157</sup>

The above mentioned reasons make also a strong case for participation in the regulation of GMO-related activities since, although this a highly technical and complex field, it is also an area where different ethical, social, cultural and moral considerations exist and they should be especially taken into account along with scientific and economic factors. Scientists or regulators should not be the sole centre of decision-making power when it comes to as contentious and complex an issue as biotechnology. Biotechnology may irreversibly change and damage the environment, thus the public, as the representatives of intra- and inter-generational perspectives, together with scientists and regulators should make a sustainable decision.

## 2.2. Environmental human rights: substance *versus* procedure.

The existence or not of a substantive human right to environmental protection<sup>158</sup> has been the subject of a lengthy discussion and this is not the appropriate venue for its analysis. Still, whether one accepts or not the existence of a substantive environmental human right, the fact that a Convention has as subject matter procedural manifestations of such a right, such as access to information or public participation in environmental matters, makes it necessary to point out the human rights regime as another possible theoretical frame for the debate surrounding procedural environmental rights.

In a simplistic manner, there are two possibilities for placing these rights within a human rights regime. They may be seen as sub-manifestations of other consolidated human rights, such as the right to life (e.g. ECtHR jurisprudence), or as third generation human rights *in se* (collective in nature with regard to both object and subject), despite their substantive or procedural nature. This last approach seems to be the more realistic due to continuous references in international environmental law to them as third generation rights (hard law and soft law instruments, for instance).

## 2.3. Risk management

The environment is a pivotal focus of risk anxiety. One of the reasons for this is that environmental regulation is constantly faced with issues of a high degree of complexity and scientific uncertainty that need further understanding. Actually,

almost by definition environmental issues are those that sit at the intersection of complex natural, social and institutional phenomena. Complicated environmental media (atmospherical, hydrological,

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<sup>155</sup> A material application of the principle of environmental participation requires firstly, that all the stakeholders would have time to consider the subject open for discussion, especially if it involves difficult technical issues and, lastly, requires due account of the different contributions to the process.

<sup>156</sup> A. Ryall, *Effective Judicial Protection and the Environmental Impact Assessment Directive in Ireland*, Thesis/Law Department/European University Institute, June 2003, at 54.

<sup>157</sup> M. Appelstrand, “Participation and Societal Values: the Challenge for Lawmakers and Policy Practitioners”, 4:4 *Forest Policy and Economics* (2002), 281, at 285.

<sup>158</sup> See *inter alia* M. Fitzmaurice, “Some Reflections on Public Participation in Environmental Matters as a Human Right in International Law”, 2: 1 *Non State Actors and International Law* (2002), 1.

biological) render the derivation of optimal management strategies difficult and complex. Complicated social contexts (inter-personal, inter-generational, trans-national) render simple solution concepts inapplicable.<sup>159</sup>

The management of risk and uncertainties is a specifically acute subject in an area such as that of biotechnology where everything is new and uncertain and the risks to nature and humans are high. Science does not provide us with an accurate and definitive answer and other considerations (*see* above) definitely need to be taken into account.

The participation of all stakeholders would contribute to the internalization of these anxieties through a bottom-up, broad-based, not only technical approach.

### 3. The Aarhus Convention

The Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (hereafter the Aarhus Convention)<sup>160</sup> was concluded as part of the United Nations Economic Commission for Europe (UN/ECE) “Environment for Europe” process<sup>161</sup>. It entered into force on 30 October 2001.

The Aarhus Convention enables States and regional economic integration organizations (the only example being the European Community (EC)) to sign it and ratify it according to its Articles 17 and 19 respectively. At present, this international legal instrument has forty Signatories, the EC and thirty-nine European States, and thirty-seven Parties.

This Convention is a truly unique and revolutionary international environmental agreement that provides participatory rights to civil society, as defined in its Article 2 (4). These rights have a trilateral dimension: access to information, public participation in environmental decision-making and access to justice. These three procedural rights are tools to attain a substantive goal, that of environmental protection.

Moreover, the Aarhus Convention also concerns government accountability, transparency and responsiveness and it is considered as a pioneer governance device in the environmental field. This instrument entails a shift from a traditional democracy, where the citizen’s contribution rests primarily on the right to vote (representative democracy), to a more participatory and pro-active one, where all the stakeholders are entitled to contribute with their inputs to the defence of the environment.

From the desirability of enhancing participation linked to environmental matters expressed, in earlier times, via Principle 10 of the Rio Declaration or Agenda 21 (soft law instruments), these procedural rights have evolved into being the subject matter of this Convention.

#### 3.1. Access to information

This right is prescribed in Articles 4 and 5 and entails positive and negative obligations on public authorities that correspond respectively to a right of the public to accede to environmental information and a duty of the public authorities to collect and disseminate it. The effectiveness of this right depends on the one hand on the strict use of the exceptions [refusals: Article 4 (3, 4, 5)] and on the other hand practical issues such as the monetary charge required to have the information [Article 4 (10)].

This pillar is central to a participatory democracy: only a well-informed and environmentally educated public can make use of the integrated mechanism that this Convention provides (participation and access to justice).

#### 3.2. Participation *stricto sensu*

Articles 6, 7 and 8 foresee the right of public participation in three cases: decisions, plans and programmes (and policies) and, lastly, normative instruments, respectively.

The effectiveness of this right rests on the timely beginning of the process, when everything is still open to discussion so that the public can actually contribute with their views to the final outcome. It is particularly important that *the public’s inputs should be seriously taken into account* and somehow internalized.

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<sup>159</sup> T. Swanson (ed.), *An Introduction to the Law and Economics of Environmental Policy: Issues in Institutional Design, Research in Law and Economics*, Vol. 20 (Elsevier Science Ltd, 2002), at 1.

<sup>160</sup> <<http://www.unece.org/env/pp/treatytext.htm>>.

<sup>161</sup> <<http://www.unece.org/env/wgso/welcome.html>>.

#### 4. Public participation and GMOs

When the Aarhus Convention was adopted in June 1998, the signatories requested the first meeting of the Parties to further develop the application of the Convention in the field of the deliberate release of GMOs into the environment. At that time, no agreement was reached as to what would be the appropriate solution, thus leading to a compromise which resulted in a mere reference in the preamble (paragraph 20) and a single paragraph [ex-article 6 (11)] of “soft content.”

The first meeting of the Signatories (MOP-1), in 1999, established a Task Force on GMOs. The Task Force explored various options for developing the application of the Convention in the field of decision-making on GMOs, including a decision of the Parties, guidelines, an amendment of the Convention and the development of a protocol or an annex on GMOs. The work of the Task Force led to the establishment of a Working Group on GMOs.

As a result of these efforts, guidelines on public participation in decision-making on GMOs were adopted by MOP-1, in October 2002. The tensions between different Parties surrounding the choice of a legally binding option or a soft law solution in the GMO area were present throughout the entering into force of this legal instrument and have only recently been resolved with the adoption of an amendment to ex-Article 6 (11) of the Convention in MOP-2, in May 2005 leading to the appearance of the new Article 6 bis<sup>162</sup>. This Article together with Annex I bis now regulate public participation in decisions on the deliberate release into the environment and placing on the market of GMOs.

The new article and annex are improvements vis-à-vis former Article 6 (11). Despite the recognition of the importance of inserting some good governance practices, such as public participation, in the regulation of specific activities in the domain of biotechnology, the reference in the Preamble to GMOs (paragraph 20) together with ex-paragraph 11 of Article 6 were nothing but “wishful intentions” since their wording deprived them of legally binding content [see, for instance, the use of “to the extent feasible and appropriate” in ex-Article 6 (11)]. In short, the wording of ex-Article 6 (11) left the Parties with the choice of whether to apply or not to apply the public participation provisions in the process of authorization of deliberate release of GMOs.

The new article and annex, which still needs to be ratified by the Parties, establish a legally binding public participation solution for the permit of deliberate release and placing on the market of GMOs. Each Party shall establish a regulatory framework, which must obey some requirements, such as reasonable time frames for the public to get the information and effectively participate. Another important feature of the new regime is the fact that it considers some information may never be confidential, such as environmental risk assessments (Annex I bis, paragraph 4, c). Also, the decision along with its reasons and considerations has to be made publicly available (Annex I bis, paragraph 8).

Still, this solution falls somehow short on other issues such as the application of these provisions only to decision-making with regard to certain GMO-related activities (contained use is excluded). The lack of binding character of paragraph 7 of Annex I bis is also disappointing (“shall endeavour to ensure”...“due account is taken of the outcome of the public participation”) since the internalization of the public’s inputs is of key importance for a proper implementation of these rights.

The “honouring” of decision-making in specific activities related to GMOs with a specific, separate regulatory solution in the Aarhus Convention comes as no surprise and has been heralded by NGOs as a victory<sup>163</sup>. The amendment could be more ambitious but, given the political sensitivity and interests behind the regulation of GMOs, it is already quite a remarkable achievement that a compromise was reached.

#### 5. Concluding remarks

In general, public participation increases the accountability of the decision-maker leading to more legitimate and popularly accepted decisions concerning the environment. Greater public participation is likely to promote environmental justice together with awareness of the need to balance the interests of present and future generations in the protection of the environment.

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<sup>162</sup> <<http://www.unece.org/env/documents/2005/pp/ece/ece.mp.pp.2005.2.add.2.e.pdf>>.

<sup>163</sup> See *ENDS Report*, Issue 1888; and the press release of the European Eco Forum, 05.07.2005, available at <[www.eeb.org](http://www.eeb.org)>.

In the specific field of biotechnology, where the underlying risks, uncertainties and difference in values and concerns (ethical, political, legal, and economic) are even higher, public participation constitutes a bridge for the creation of common views or, at the very least, boosts discussion over sensitive and contentious issues which concern all communities, from the scientific to the entrepreneurial, from the regulator to the public *tout court*. The inclusive approach provided by the use of participatory mechanisms provides for legitimacy in decision-making in the regulation of risk areas, such as biotechnology.

The Aarhus Convention is a first step in bringing popular legitimacy and democratic diversity to the GMO regulatory process. Although, it is not a perfect solution, it is already a great achievement that in the future may well have a “spill-over effect” to other fora.



## **Environmental Liability**



**Environmental Liability:  
The European Approach – The 35/2004 EC Directive**

Emanuela Orlando\*

In the European Union (EU), the issue of environmental liability has been the object of increasing attention since the beginning of the 1990s, when the idea of a common legal framework harmonising the different national regimes of liability for environmental damage in Europe started to find positive support in light of both environmental and internal market considerations. However, only recently did the EU enact its own piece of legislation specifically and entirely devoted to the prevention and remedying of environmental damage, namely the *35/2004 Directive on Environmental Liability with regard to the Prevention and Remedying of Environmental Damage* (the ‘Environmental Liability Directive’ or ELD).

The Directive is the EU response to the very delicate and complex issue of environmental liability, and its adoption represents the first concrete step towards the establishment of a unitary legal framework across all EU member States in the field of environmental liability. This new piece of legislation intends to fill the gaps existing in the legislations of old and new member States and to achieve a minimum common starting point for the prevention and restoration of damage to the environment.

From an EU law perspective, the Directive is considered an effective way of implementing key principles of EC environmental policy laid down in Article 174, in particular the “polluter pays principle” and the “preventive action principle.”

Indeed, in the Commission’s opinion, the role that the ELD is expected to play in the promotion of the European Community overall environmental policy is twofold. On the one hand, the main aim of an environmental liability regime is to make the causer of damage to the environment (the polluter) financially liable, thus ensuring funding for appropriate reparation of the environmental harm caused. On the other, since in the Commission’s view environmental liability is deemed to have an important preventive effect, the Directive will also act as an incentive for regulatory compliance with existing and future Community environmental legislation and it will encourage economic actors, who may potentially become liable, to take greater care to avoid damage, and to invest in research and development to prevent further environmental harm.

This contribution will focus on the origins, the main characteristics, and issues of implementation and enforcement of the ELD.

**Origins of the Directive and the need for a Community wide regime**

The birth of the ELD has a rather long and controversial history. The first efforts to elaborate an EU-wide regime on civil liability for environmental damage go back as far as 1984, and were originally limited to the field of waste pollution damage<sup>164</sup>.

Since then, there has been considerable evolution in the political climate and, in 1993, the growing public concern over environmental matters led the Commission to refocus its efforts on developing a broader liability regime and to adopt a *Green Paper* on the issue of the remediation of environmental damage<sup>165</sup> with the aims of stimulating debate and collecting the views of various interested parties on the future regime.<sup>166</sup>

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<sup>164</sup> Council Directive 84/631/EEC of 6 December 1984 on supervision and control within the European Community of the transfrontier shipment of hazardous waste; pursuant to its article 11(3), the Council was under a duty to determine the conditions for implementing civil liability of the producer in case of damage. This first step was followed by Commission Proposal of 27 June 1991 for a Council Directive on Civil Liability for Damage caused by waste. However, after adoption of the ELD, which establishes a general scheme of environmental liability, the Commission proposal and related amendments have been withdrawn, Commission Communication, COM/2001/763/Final.

<sup>165</sup> Commission Communication of 14 May 1993, Green Paper on Remedying Environmental Damage, COM (93) 47.

<sup>166</sup> The usefulness of environmental liability has been underlined on subsequent occasions. In 1994, in its Resolution of 20 April 1994 on prevention and remedying environmental damage, the European Parliament called for legislation in this area and called on the Commission to submit a proposal for a directive on civil

The first serious reflection over a harmonised liability regime is represented by the White Paper on environmental liability, adopted by the Commission in February 2000. In the White Paper, the Commission explores the different possibilities of how such a regime could best be shaped and explains the main arguments in favour of the establishment of a EU harmonised environmental liability framework.

Firstly, the Commission notices that “environmental damage” and, in particular, damage to biodiversity is not adequately covered by member States’ national legislations. Most national law is operational only with respect to damage to human health or property, or contaminated sites and address only indirectly damage to natural resources. This is especially apparent in cases where damage is caused to natural resources which are not privately owned (the so-called orphan sites) and for which it is much more difficult to recover damages. Furthermore, the existence of substantial gaps and differences between member States legislation, with respect to their scope and clean up standards and objectives, could induce economic actors to exploit those legislative loopholes to circumvent liability and adopt more lenient environmental standards.

The final choice, among the possible options for Community action in this field, was the adoption of a Community directive. Notwithstanding all the important arguments in favour of a European liability regime for damage to the environment, the process leading to the adoption of the Directive was not straightforward. The reasons for the difficulties in designing the future environmental liability regime lie mostly in different views, between industry and environmental NGOs, on the need for and design of a liability instrument and on substantially different approaches to environmental liability between individual member States.

Indeed, the 2002 Commission’s proposal for a Directive on Environmental Liability<sup>167</sup> had been widely debated and only in March 2004 did the European Parliament and the Council finally reach a definitive agreement on the text of the ELD which was adopted and entered into force in April of the same year. It has been observed that the forthcoming enlargement played a role in speeding up the adoption of the Directive. Indeed, the European Parliament, the Council and the European Commission wanted to reach an agreement on the Directive before 1<sup>st</sup> May 2004, because waiting until enlargement would have meant recommencing the arduous process with a new council and a new parliament following the addition of ten new member States to the EU.

On the other hand, it is interesting to see the difference between the 2002 Proposal and the final text of the Directive, especially from the perspective of enforcement, member States’ duties and responsibilities<sup>168</sup> and the issue of access to justice for individuals and NGOs.

### **Structure and main characteristics of the Directive**

The Directive is the first European Community instrument aimed at dealing specifically with environmental damage. With respect to the other environmental liability instruments existing on the international level and to the traditional tort-based approach of national legal orders, the Directive presents some specificity, which renders an analysis interesting also from a comparative point of view.

To start with, the Commission chose to deal with environmental liability by adopting a *public law/regulatory approach*. Although entirely based on the principle of private operators’ liability, whereby the primary responsibility to identify the occurrence or imminent threat of damage and to take the necessary preventive or remedial actions is placed on the private operators, the Directive is, in its essence, a regulatory instrument. The decisive shift from the private law/ civil liability regime to a predominantly public one was made by the 2002 Commission Proposal and then retained by the final text of the Directive. Indeed, the analysis of the preparatory works and of all the various documents preceding the adoption of the Directive shows a progressive move from a civil liability based regime, as had been envisaged in the original proposal on waste and in the Green Paper, which were each quite properly described as proposals for harmonisation of member States’ rules on civil

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liability for environmental damage. See also, Commission Communication of 24 Nov.1999, ‘Europe’s environment: what Directions for the future?’, COM(99)543.

<sup>167</sup> Commission Proposal of 23 January 2002 for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage, COM (2002,) 17 final.

<sup>168</sup> As will be further highlighted below, member State duties and responsibilities are considerably lessened in the final text.

liability for “environmental damage” - towards one placing more emphasis on effective systems of administrative direction and administrative cost recovery.

The first corollary of this “public law” approach is the exclusion of traditional forms of damage, such as damage to goods, persons, private properties, from the compensable damage under the Directive. This exclusion was operated on the assumption that most member States national liability regimes (e.g. profits lost by hotel operators due to beach pollution by spilt oil) already cover those types of damages. The Directive, indeed, fully endorses the idea of the environment as a public good and recognises the duty to restore it for its own intrinsic value, independently from the occurrence of private property damages, health or personal injuries, which may occur as a consequence of an environmental harm. Article 3(3), in fact, specifies that “the Directive shall not give private parties a right of compensation as a consequence of environmental damage or of an imminent threat of such damage.” Consequently, separate actions of private economic loss or personal injury will have to be brought according to existing tort principles of national law.

The strong public law component of the Directive further emerges both from the definition of environmental damage and the restoration objectives to be pursued according to detailed guidelines set in Annex II. The notion of environmental damage constitutes one of the major novelties of the Directive, whose scope of application is defined with a strong reference to EC environmental legislation, both with respect to the definition of environmental damage and to the economic activities potentially giving rise to strict liability.

Article 2(1) of the ELD defines “environmental damage” as any measurable adverse change or impairment occurred to protected species and natural habitats designated by the 92/43/EC Habitats Directive and the 79/409/EC Wild Birds Directive or by national law, to water covered by the 2000/60/EC Water Framework Directive and land contamination which imposes a significant risk to human health.

Article 3 of the Directive differentiates the standards of liability, whether strict or fault-based, according to the nature of the economic activities causing the environmental damage and the nature of the damage. Strict liability is attached to environmental damage or imminent threat of such damage caused by the occupational activities listed in Annex III of the ELD. This Annex includes those economic activities deemed to be potentially dangerous and regulated by appropriate EC legislation<sup>169</sup>. By contrast, operators undertaking activities other than those listed in Annex III, may be rendered liable only in the case of fault or negligence and limited to cases of environmental damage to protected species and natural habitats.

As to the remediation of the damage, Annex II of the ELD specifies that the aim is not to repair losses privately suffered, but to restore the environment through appropriate remediation measures in order to re-establish, as much as possible, the *baseline* conditions (conditions had the harm not occurred).

The ELD covers both the hypothesis of actual occurrence of an environmental damage and that of an imminent threat of such damage and requires, accordingly, the operator to take the appropriate remedial or preventive measures. In the identification of a significant damage and in the determination of the necessary remedial or preventive measures, the ELD proposes an interesting approach based on mutual cooperation and information-sharing between the responsible operator and the member States competent authorities.

Remedial measures are defined in Article 2 of the ELD as including any action or combination of actions, including mitigating or interim measures to restore, rehabilitate or replace damaged natural resources, in accordance to the framework guidelines indicated in Annex II. Furthermore, when damage to the environment occurs, besides all the necessary remedial measures, the operator is required to immediately take all practicable measures for the containment and minimisation of the damage.

The Directive also provides for exceptions and defences. The distinction is crucial since, while a defendant operator bears the burden of proving that a defence applies, he does not have to prove that there is an exception to the liability scheme.

*Exceptions* (Article 4) include environmental damage or imminent threat of such damage caused by “an act of armed conflict, hostilities, civil war or insurrection” or a “natural phenomenon of exceptional, inevitable and irresistible character”; environmental damages arising from an incident in respect of which liability or compensation falls within the scope of the international conventions listed in Article 4(2) as well as nuclear risks or damages deriving from activities covered by the Treaty establishing the European Atomic Energy Community;

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<sup>169</sup> Among the activities listed in Annex III and regulated by apposite EC legislation, are included hazardous waste management operations (such as collection, transport, recovery and disposal), discharges of potentially hazardous substances into surface water and/or groundwater, preparation use, storage and release of dangerous substances, transport of dangerous goods, activities involving GMOs.

finally, liability is excluded in cases of pollution of a diffuse character where it is not possible to identify the polluter.

As to the *defences*, their introduction has been a highly debated issue during the drafting of the ELD. The final text distinguishes between “mandatory” defences, which must be allowed by all member States and those defences whose availability is left to the discretionary power of member States. Mandatory defences are provided in cases where the environmental damage was caused by third party intervention despite the adoption of adequate safety measures and in cases of operator compliance with a compulsory order of a public authority (Article 8, par.3). Although they do not exempt the private operator from taking the preventive or remedial measures, they nevertheless exclude liability and allow him to recover the relevant costs incurred from the member States.

Additionally, member States *may* decide to exempt the operators liability in case of : a) damage caused by an emission or event, occurred during one of the Annex III activities, and expressly authorised by national law implementing EC legislation and b) when the emission or activity in question was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when the emission was released or the activity took place (Article 8, par. 4, a-b). The availability of those discretionary defences, respectively called the “permit” defence and the “state of the art” defence, is subject to the operator proving that he was not at fault or negligent; for that reason they are also considered “real defences” by contrast to the mandatory ones which operate automatically.

The introduction of the latter defences has been strongly opposed by non-governmental organisations, which found its conceptual foundation contrary to the precautionary principle, which, instead, requires and justifies measures to prevent environmental impairment even in the absence of full scientific certainty of a causal link between the activity and the damage.<sup>170</sup>

Thirdly, another important aspect characterising the ELD and consistent with its regulatory nature is the *central role attributed to the member States competent authorities* in monitoring and ensuring the enforcement of the liability regime.

Pursuant to Article 11 of the ELD, the competent authorities shall identify the operator who caused the damage or the imminent threat thereof, evaluate the damage and assess whether it has reached the level of “significance” required in order to trigger liability, monitor and assess the adequateness of the preventive or remedial action taken by the operator and, eventually, require the operator to take further measures to ensure that the environment is restored. Articles 5 and 6 further confer on the authorities an important role in the prevention and remedying of the damage. Finally, in case of failure to act from the operator, the competent authorities may take the measures themselves, but then they shall recover the costs sustained by the operator.

### **Enforcement of the EC regime of environmental liability: what role for access to justice and what avenues for individuals and NGOs**

Ensuring access to justice for individuals and NGOs has proved to be so far one of the most effective means of enforcing European Community law. In the specific field of EC environmental law, the issue of access to justice has to be examined in light of the Aarhus Convention. The EC has recently ratified the Convention and is about to implement its third pillar by means of a prospective directive. Indeed a Proposal for a Directive has been presented by the Commission.

However, as far as the ELD is concerned, the issue of access to justice by public interest groups, environmental organizations and individuals represents its major weakness.

In fact, in case an environmental damage or an imminent threat of such damage occurs, under the scheme set up by the Directive member States’ competent authorities are the only ones exclusively entitled by Articles 5 and 6 of the Directive to require private operators to take the necessary preventive or remedial measures, while no direct action against the polluter is provided for individuals or NGOs.

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<sup>170</sup> G. Betlem and E. Brans, ‘The Future Role of Civil Liability for Environmental Damage in the EU’, 2, *Yearbook of European Environmental Law* (2002),183, at 198-99. For a more detailed analysis of the scope and meaning of the precautionary principle in the European Court of Justice’s jurisprudence and in International law, see respectively P.Dabrowska and P. Quillaq’s contribution, “Science Goes to Court: Some Considerations on the Precautionary Principle in the Community Jurisprudence” and R. Pavoni’s contribution “Biodiversity and Biotechnology: Consolidation and Strains in the Emerging International Legal Regimes” in this Working Paper.

Therefore, the potential impact of the Directive is undermined by the predominant role conferred on the member States' public authorities and the very limited power of action of private parties, i.e. individuals and environmental NGOs. Since no right of direct action against polluters is conferred to private parties, their role is limited to a "second step" request for review of the authorities' decision. Articles 12 and 13 envisage a "two-stages" approach whereby private parties are firstly entitled, under certain conditions, to file a request action with the competent authority against the polluter and *only afterwards* do they have a proper rights of access to judicial review before a court or another impartial and independent body to challenge the authority's decision or failure to act.

In practice, there are several obstacles to be overcome by individuals and NGOs before they will be effectively able to act on behalf of the environment under the ELD and which put into question the consistency of the Directive's provisions with the requirements of the Aarhus Convention.<sup>171</sup> First of all, obstacles stem, for instance, from the provisions of the Directive setting substantial and procedural requirements. In order to have their request to be considered by the competent authorities, at the first stage of this two-phases mechanism, private parties have to produce substantial evidence of their observations submitted in relation with the damage by supporting their request with all the relevant data and information in order to show in a plausible manner that environmental damage exists<sup>172</sup>. This might be very demanding and costly especially in light of the fact that, under the Directive, no compensation whatsoever is awarded to individuals and NGOs which, as Prof. Ludwig Kramer rightly observed, would then be required to undertake a sort of *pro bono* work on behalf of the environment.

In addition, difficulties may derive from the divergences existing between national legal orders with respect to the criteria of standing for individuals and, especially, NGOs. Although the ELD addresses this point by providing a minimum common definition (in Article 12.1) of the general standing requisites, in practice, there are still differences between distinct approaches taken by the national courts of the member States in determining the concrete meaning of "sufficient interests", "impairment of a right" or in ascertaining when private parties are likely to be affected by environmental damage<sup>173</sup>.

As far as standing of environmental NGOs is concerned, the main problem is that of their mutual recognition across the national legal orders of different member States. In fact, since Article 12.3 declares that the requisites of "sufficient interest" and "impairment of right" are presumed to be fulfilled by environmental NGOs with a *recognised status under the respective national legislations*, their legal capacity to act still largely depends on the law of the "home state" of association. The consequences in cases of cross-border environmental harm are going to be relevant.

It has also been argued<sup>174</sup> that lack of direct action of private parties against the polluters would contrast with the requirements of the Aarhus Convention. According to this reading of Article 9(3) of the Convention, the third pillar is not limited to public law, but would include also effective civil remedies for the public. However, this reading of Article 9 of the Convention is not unanimously shared by legal commentators<sup>175</sup>. What Article 9(4) of the Convention certainly requires is that the parties make *effective* remedies available, including injunctive relief, which are fair, equitable, timely and not prohibitively expensive. Therefore, focusing on effectiveness, rather than on the necessary availability of civil remedies, could provide the appropriate parameter against which to measure the consistency of the existing and future member States environmental legislation with the Convention. Unfortunately, even analysing Article 12 and 13 in this light, it is still difficult to see the option retained by the Directive as amounting to an effective remedy.

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<sup>171</sup> G. Betlem 'Environmental Liability and Private Enforcement – Lessons from International Law, the European Court of Justice and European mining Laws', in 4 *Yearbook of European Environmental Law* (2004), 117, at 127-130.

<sup>172</sup> Article 12, paragraphs 2 and 3 of the ELD

<sup>173</sup> However, it's possible to observe a general, albeit slow, tendency in national courts to reconsider and relax the general principles applicable to standing so as to made them more suitable for environmental cases. On this points, but with references more in general to access to justice under the Aarhus convention, J. Ebbesson, *Access to Justice in Environmental Matters* (Kluwer 2002), at 24.

<sup>174</sup> G. Betlem, *cit. fn.* 8, p.129.

<sup>175</sup> See, for instance, M. Lee and C. Abbott, "The Usual Suspects? Public Participation under the Aarhus Convention", 66 *Modern Law Review* (2003), 105.

In particular, the *monopoly* of public authorities in the enforcement of the Directive is not counterbalanced by any substantial obligations for them to repair or restore the environment. By contrast with the previous 2002 Directive's Proposal, under the final version of the Directive member States are not even obliged to take action themselves in case of the operator's failure to act.<sup>176</sup> Finally, it has to be noted that the wide discretion left to national authorities, the absence of direct actions for private interested parties and the exclusion of specific rights (or remedies for private losses) for individuals, coupled with the lack of any obligations whatsoever on the member States authorities deprive the Directive of direct effect and at the same time hinder the applicability of the *Francovich* line of case law.

### **Implementation of the ELD and its practical impact**

The Directive has to be implemented by member States by April 2007. According to the principle of *subsidiarity*, the ELD is a framework directive, in which the objectives are set by the EU, while member States are left with considerable flexibility in its implementation. Pursuant to Article 6 of the Directive as well as to Article 176 of the EC Treaty, member States may adopt stricter liability standards or impose liability on additional persons or add other activities.

This is consistent with the very nature of directives, which are binding for the member States as to the results to be achieved, but leave to national authorities the choice of forms and methods (art.249 EC Treaty). Accordingly, the text of the ELD leaves the member States with a large margin of discretion in the choice of the most adequate legal instrument for its transposition and practical application. The States' discretionary power in the introduction of the permit and state of the art defence has already been examined above.

Another issue left to the choice of member States concerns the nature of the "competent authorities." Despite the detailed description of their duties and the crucial role assigned to them in ensuring the effective functioning of the liability mechanism set up by the Directive, it is totally silent as to the question of their nature, whether administrative or judicial. Some clarification may be derived from the Explanatory Memorandum presented by the Commission together with the Directive's Proposal which, though recalling the principle of member States' procedural autonomy but in consideration of the specific tasks entrusted to the authorities, envisages the opportunity to appoint bodies provided with the relevant technical expertise<sup>177</sup>. It seems, then, that such a role is better suited for administrative authorities than for judicial bodies.

A wide debate is currently ongoing among legal scholars and practitioners over the practical impact of the Directive. The ELD undoubtedly constitutes an important step towards the setting-up of an effective environmental liability regime in Europe and contributes to the establishment of a minimum common liability standard across all EU member States, including those that traditionally have more lenient environmental legislation. Furthermore, were it to fulfil all the expectations which were placed on it, it is likely to have a positive impact in boosting the implementation and enforcement of the overall EC environmental policy.

However, the degree of harmonisation likely to be achieved by the Directive and its effectiveness in ensuring an equal minimum standard of environmental liability must be assessed in light of the differences which will inevitably arise in its enforcement by different competent authorities in different member States.

Once implemented into each national legal order, in fact, the Directive will interact, and in some cases overlap, with the already existing national legislations and legal principles relating to environmental damage. It will constitute an additional environmental liability tool besides the civil, administrative and criminal norms already in force. Therefore, it would have been of utmost importance to adopt very clear and well defined provisions so as to ensure some degree of coherence and consistency throughout the practical application of the Directive across the 25 different member States.

Nevertheless, being in most part the result of a political compromise among different political, civil and economic actors, each of them with different interests, some of the key provisions of the Directive are formulated in a very open manner and a wide margin of discretion is left to the national authorities. This is likely to produce uncertainties at the moment of its practical application and undermine its effectiveness.

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<sup>176</sup> Pursuant to Article 5 and 6 of the ELD the authorities are under a duty only to require that necessary measures are taken by the operators, but they do not oblige the authorities to take themselves those measures.

<sup>177</sup> Explanatory Memorandum attached to the Commission Proposal for a Directive on environmental liability, cit. above fn. 4.

In the first place, the competent authority's determination of the occurrence of a *significant impairment* amounting to an environmental damage and the identification of the relevant remedial measures implies in itself a certain kind of discretion.

Further problems are deemed to arise from the definition of "operator" adopted by the Directive. According to Article 2(6) of the ELD an economic operator is defined on the basis of the criteria of control or of decisive economic power. Since, under the ELD, the availability and the precise content of the latter criterion is to be determined according to the relevant national law, the notion of economic operator is likely to be the object of different interpretations by different courts in the various member States. This is also an example of how the Directive is likely to interact with and has to be interpreted in light of the existing private international law norms and the relevant case law.

Given the nature of the tasks conferred on the authorities and their margin of discretion in the evaluation of the damage and the identification of preventive and remedial measures, it would be desirable, once they will be established in each member State, to have some kind of coordination among them, in order to ensure consistency and a certain level of uniformity in the practical application of the Directive. To that purpose, it could be useful to consider the suitability of some of the instruments and bodies already existing at Community level. The European Network for the Implementation and Enforcement of Environmental Law (IMPEL), for instance, provides an interesting example of how a coordinated and decentralised approach, based on an informal network of the environmental authorities in the member States, could be a workable solution.

The above remark paves the way for some conclusive reflections about the opportunity of combining the substantive flexibility and decentralisation in the implementation and application of the ELD – which is also inherent in the nature itself of directives - with a somehow more centralized approach when it comes to its enforcement.

In particular, notwithstanding the above highlighted difficulties in enforcing the Directive by judicial means, *centralisation* of enforcement powers at the EU institutional level, for instance by strengthening the role of the European Environmental Agency (EEA),<sup>178</sup> could represent an option. Unfortunately, a previous attempt to confer specific enforcement powers on the EEA failed, mainly due to opposition from several Governments, but it is to be hoped that the issue of a stronger 'inspective' role for the EEA will be again taken up in the near future.

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<sup>178</sup> The European Environmental Agency (EEA) was set up, within the context of the V environmental Program, with the specific purpose of gathering information about its state of implementation in member countries.