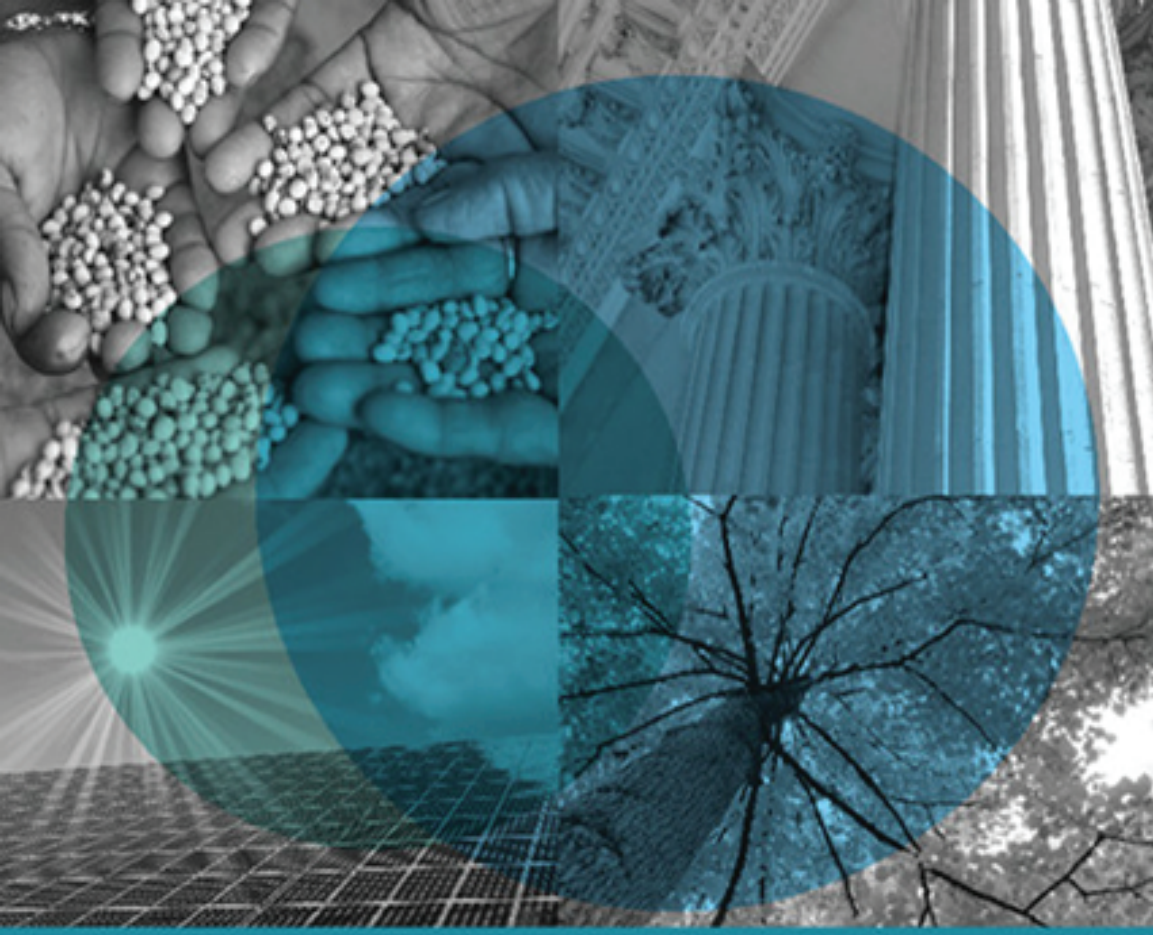

Legal Aspects of Implementing the Cartagena Protocol on Biosafety

Edited by

Marie-Claire Cordonier Segger,
Frederic Perron-Welch, Christine Frison

CAMBRIDGE

LEGAL ASPECTS OF IMPLEMENTING THE CARTAGENA PROTOCOL ON BIOSAFETY

This book, the first in a new series that focuses on treaty implementation for sustainable development, examines key legal aspects of implementing the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) at national and international levels. The book provides a serious contribution to the current legal and political academic debates on biosafety by discussing key issues under the Cartagena Protocol on Biosafety that affect the further design of national and international law on biosafety and analysing recent progress in development of domestic regulatory regimes for biosafety. This text also examines the legal, political, economic, and practical challenges and solutions encountered in recent efforts to develop and implement domestic biosafety regulations, with a focus on developing countries. Coming after the fifth Conference of the Parties serving as the meeting of the Parties (COP-MOP) to the Cartagena Protocol on Biosafety (COP-MOP 5), where the Parties adopted a new Nagoya – Kuala Lumpur Protocol on Liability and Redress, this timely book examines recent developments in biosafety law and policy.

Marie-Claire Cordonier Segger is the Head of Economic Growth and Trade at the International Development Law Organization (IDLO) in Rome, Italy. She co-edits the Treaty Implementation for Sustainable Development series with Cambridge University Press, and has authored or edited more than eighty publications, including fourteen books in three languages: Sustainable Development in World Investment Law (2010) and Sustainable Development in World Trade Law (2005) with Dr. M. Gehring; Sustainable Development Law: Principles, Practices and Prospects (2004) with A. Khalfan; and Sustainable Justice: Reconciling Economic, Social and Environmental Law (2004) with H. E. Judge C. G. Weeramantry. In an academic capacity, she also serves as Senior Director of the Centre for International Sustainable Development Law (CISDL) in Montreal, Canada; as Affiliated Fellow of the Lauterpacht Centre for International Law (LCIL) at Cambridge University, and as a Visiting Professor at the University of Chile Faculty of Law.

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TREATY IMPLEMENTATION FOR SUSTAINABLE DEVELOPMENT

Over the past three decades, a series of international treaties have entered into force to address pressing global concerns – social and economic development and environmental protection. On climate change, biodiversity and biosafety, desertification, agriculture and seeds, and trade and investment liberalisation, new regimes have been established to implement global commitments related to sustainable development, many with nearly universal membership.

Successful domestic implementation of these international treaty regimes is one of the most significant challenges facing international law today. Although much has been written on the content and form of treaty law, there is relatively little that examines the transition from international legal theory and treaty texts to domestic regulation and practice.

This series of books addresses this need and provides a serious contribution to ongoing global debates by conducting a detailed analysis of how myriad new treaty regimes that cover the future's most pressing concerns can be made to work in practice. It is dedicated to our mentor and first Chairman of the Board of Governors of the Centre for International Sustainable Development Law (CISDL), The Honourable Mr. Justice Charles Doherty, Puisne judge on the Supreme Court of Canada from February 1, 1989, to August 1, 2003.

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Legal Aspects of Implementing the Cartagena Protocol on Biosafety

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Prior to joining the Secretariat in February 2001, he worked for 12 years on environment and development issues at different government positions in his native country, Ethiopia. He was the head of Policy and Legislation Department at the Environmental Protection Agency of Ethiopia. He was once the Director of Ethiopian Conservation Strategy Initiative, which resulted in the development and adoption of the Environmental Policy of Ethiopia. He coordinated the drafting of the basic environmental laws of Ethiopia, which were passed by the government in 2002. He was a member and a legal advisor of the Ethiopian delegation in a number of international environmental negotiations, including the negotiations for the Cartagena Protocol on Biosafety and the International Treaty on Plant Genetic Resources for Food and Agriculture. Mr. Yifru holds a master's degree (LL.M.) in Environmental Law from the London School of Economics and Political Science (1995) and a bachelor's degree in law (LL.B.) from the Law Faculty of Addis Ababa University (1988).

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With regard to genetic resource issues, she has participated in negotiation of international and regional agreements and prepared advisory white papers on all sides of the issues, including the application of biodiversity, sustainable development, environmental protection, commercial, resource development and conservation, and coastal zone management law in the context of LMOs and genetic resources for the United Nations. She has been named by the Global Environment Facility as the legal expert on the international expert team tapped to perform the external evaluation of UNEP-GEF's implementation of the Cartagena Protocol and has led an international expert team tasked by the UN Food and Agriculture Organisation to undertake the external evaluation of international instruments and processes within FAO's mandate. Ms. Young also serves as Editor of Environmental Policy and Law (IOS Press) and has served as an adjunct professor in several contexts, including at the University of San Francisco School of Law. She is a graduate of Hastings College of the Law (1981) and the University of Southern California (1978). At Hastings, she served as an editor of the *Hastings International and Comparative Law Review*.

Foreword

Emerging from the outcomes of the 1992 United Nations Conference on Environment and Development, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and its Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress respond to the realities of biotechnology development across the world. Advancements in biotechnology continue to push the boundaries of science in search of solutions to global problems and there is no question that the application of biotechnology continues to gain ground worldwide. Nonetheless, this field is relatively new, and questions remain about the short- and long-term biological and social effects of living modified organisms. Countries, concerned about their ability to manage these risks in a world of increasingly liberalized trade, negotiated the Cartagena Protocol and the Nagoya – Kuala Lumpur Supplementary Protocol to enable more sovereign control over the use of biotechnology.

The Cartagena Protocol and the Nagoya – Kuala Lumpur Supplementary Protocol are important instruments for implementing the Convention. They establish how Parties can regulate, manage, and control risks associated with the transfer, handling, and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biodiversity, thus contributing to the first two objectives of the Convention.

Sound implementation of the Protocols encourages both sustainable development and the careful use of biotechnology. It does this by not only empowering Parties to exercise precaution in the regulation of living modified organisms, but also by requiring a higher level of transparency in the production and movement of such organisms.

Implementation of the Protocols is a continuing process and, in many cases, a challenge. The development of appropriate laws and administrative measures is ongoing for many countries. For implementation to be successful, stakeholders and participants at all levels need to share their knowledge and experiences in a spirit of co-operation, engagement, and innovation. This book makes an important

contribution to such a dialogue. By bringing together authors with a variety of views, this book explores the range of issues and perspectives that need to be considered in the implementation of the Cartagena Protocol.

The insights of experts who contributed to this book will serve as valuable tools for governments, researchers, and lawmakers everywhere, all of whom play important roles in building the capacity of Parties to implement the sustainable development commitments imbedded in the Cartagena Protocol and the Nagoya – Kuala Lumpur Supplementary Protocol.

This book is a valuable contribution to the body of shared knowledge, and crucial debates, on biosafety.

Braulio Ferreira de Souza Dias
UN Executive Secretary of the Secretariat of
the Convention on Biological Diversity
September 2012

Preface

Emerging from the outcomes of the 1992 United Nations Conference on Environment and Development, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted by the Conference of the Parties to the Convention on 29 January 2000. The Protocol has its roots in Article 19.3 of the Convention, which obliged Parties to consider the need for and modalities of a protocol setting out appropriate procedures for the safe handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity. It entered into force on 11 September 2003 and currently has 163 Parties. On 15 October 2010 at the Fifth Conference of the Parties serving as the meeting of the Parties to the Protocol in 2010, the Parties adopted the Nagoya – Kuala Lumpur Supplementary Protocol to the Cartagena Protocol on Biosafety. The Supplementary Protocol was opened for signature on 7 March 2011 and will enter into force nintey days after the deposit of the 40th instrument of ratification, acceptance, approval, or accession.

These Protocols respond to the reality of biotechnology development across the world. Some of these technologies promise to address malnutrition or other medical problems, or to overcome the challenges of conventional agriculture. There is no question that they are gaining ground worldwide. Nonetheless, these technologies are relatively new, and questions remain about their short- and long-term biological and social effects. Parties to the Convention, concerned about their ability to manage these risks in a world of increasingly liberalized trade, negotiated the Cartagena Protocol and Nagoya – Kuala Lumpur Supplementary Protocol to enable more sovereign control over the sustainable use of biotechnology. The Cartagena Protocol and Nagoya – Kuala Lumpur Supplementary Protocol are important tools for implementing the Convention. They establish how Parties can regulate, manage, and control risks associated with the transfer, handling, and use of LMOs that may have adverse effects on the conservation and sustainable use of biodiversity – the first two objectives of the Convention.

Sound implementation of the Protocols encourages both sustainable development and the careful use of biotechnology. It does this by not only by empowering Parties to exercise precaution in the regulation of such technologies within their borders, but also, as a consequence, by requiring a higher level of transparency in the production and movement of the products of biotechnology.

Implementation will be an on-going process that requires the development of appropriate laws and administrative measures. Many Parties, especially developing countries, have faced challenges in implementing the full scope of their commitments. The UNEP-GEF Biosafety Project has helped countries develop national biosafety frameworks (NBFs). Many of the authors in this book participated in the project in various capacities and have used this opportunity to share their experiences in the national implementation of the Protocol.

These legal expert authors' insights will serve as valuable tools for government departments, experts, researchers, and lawmakers everywhere, all of whom play important roles in building the capacity of all Parties to implement the sustainable development commitments in this important Convention and its Protocols effectively. For this process to be successful, stakeholders and participants at all levels need to share their knowledge and experiences in a spirit of co-operation, engagement, and innovation. This book is a valuable contribution to that body of shared knowledge, and these crucial debates.

Dedication and Acknowledgements

This is the first book in a new series of volumes that focuses on the implementation of international treaty commitments on sustainable development, edited by Marie-Claire Cordonier Segger and Markus Wilheim Gehring, and published by Cambridge University Press. The editors respectfully dedicate this series to the memory of the Honourable Justice Charles Doherty Gonthier, who served for many years on the Supreme Court of Canada and was the founding Chairman of the Board of Governors of the Centre for International Sustainable Development Law (CISDL).

We would like to express our gratitude to those who contributed in the legal experiences and practice, collaborative research, drafting, and editing that were essential tasks to the preparation of this volume. First, we are deeply indebted to every contributor for taking the time to share their expertise and knowledge. We also sincerely thank the dedicated and experienced senior government officials from more than 80 countries, the United Nations Environment Programme (UNEP), and the Global Environment Fund (GEF) for their collaboration on the National Biosafety Framework Development Project for the reviews of National Biosafety Frameworks between 2002 and 2008.

This book would not have happened without the research and support of many brilliant and dedicated members of the CISDL and the McGill University Faculty of Law, who assisted in the research, drafting, development, and review of the manuscript, including Patrick Reynaud, Jennifer S. Bond, Dob Feldman, Kathryn Garforth, Olivier Rukundo, Christine Toczeck Skarlatakis, Alexandra Keenan, Freedom-Kai Phillips, Giselle Davidan, and Aleksandra Bojovic. The collaboration and kindness of knowledgeable professors and practitioners from the Lauterpacht Centre for International Law (LCIL) at Cambridge University Faculty of Law, particularly Sir Eli Lauterpacht, Professors James Crawford and Marc Weller, and Dr Joanna Gomula and Anita Rutherford, are acknowledged. We further recognize and appreciate the engagement and support of the dedicated rule of law experts and legal specialists at the International Development Law Organization, including the

Director-General Irene Khan and Giulio Zanetti, Ilaria Bottigliero, Judit Arenas, Charles E Tucker, and previously Tom McInerney and Robert Buergenthal, as well as the entire team of economic and sustainable development lawyers. We would also like to recognize the support and guidance of the Centre de Philosophie du Droit, Université catholique de Louvain, and of the Centre for Intellectual Property Rights, Katholieke Universiteït Leuven.

Last but not least, we were encouraged all through the process with the love, support, and faith of our families, in particular when we were under tight time pressure and constraint to work late nights. To everyone, we sincerely thank you.

Introduction

Marie-Claire Cordonier Segger, Frederic Perron-Welch, and Christine Frison

The exponential growth in the use and trade of living modified organisms (LMOs) has made the safe use of biotechnology (i.e., biosafety) an issue of global relevance.[1] Modern biotechnology has the potential to further development and improve human welfare, but the possible impact of environmental releases of LMOs on other species and varied ecosystems also implies significant and unexplored risks. The adoption of the Cartagena Protocol on Biosafety[2] (Cartagena Protocol) contributes to the development of an international regulatory framework to enable international trade in environmentally sound applications of biotechnology.[3]

This Protocol, as a legal instrument that aims to promote sustainable development and use of biological resources, is part of the emerging body of sustainable development law, integrating economic and social development and environmental protection by setting an international regime in place to govern the transboundary movements of LMOs.[4] Globalisation has greatly broadened the need for biosafety and has complicated its pursuit. In spite of multilateral initiatives for the implementation of national biosafety frameworks, the implementation of international

[1] Global use of biotech crops has grown rapidly – approximately 94-fold from 1996 to 2011 – to 160 million hectares of cropland cultivated by millions of farmers in 29 different countries. Most biotech crops are grown in the USA, but developing countries are rapid adopters and are expected to soon grow the majority of biotech crops. Successful crops (e.g. soybeans, cotton, corn, and canola) have seen high levels of market penetration. See Clive James, *Global Status of Commercialized Biotech/GM Crops: 2011*, International Service for the Acquisition of Agri-biotech Applications (ISAAA) Brief No 43 (Ithaca, NY: ISAAA, 2011).

[2] *Cartagena Protocol on Biosafety*, 2226 UNTS 208; 39 ILM 1027, 29 January, 2000 (entered into force 11 September 2003) [*Cartagena Protocol*].

[3] Secretariat of the Convention on Biological Diversity (SCBD), *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes* (Montreal, Canada: SCBD, 2000) at Introduction.

[4] Marie-Claire Cordonier Segger, "The Role of International Forums in the Advancement of Sustainable Development" (2009) 10(1) *Sustainable Development Law & Policy* 4 at 8; Marie-Claire Cordonier Segger and Ashfaq Khalfan, eds, *Sustainable Development Law: Principles, Practices and Prospects* (Oxford, UK: Oxford University Press, 2004) at 2 [Sustainable Development Law].

biosafety obligations remains a challenge for developing countries, especially for those with limited scientific, human, technical, and financial resources.

This book analyses the legal aspects of implementing the Cartagena Protocol and provides a serious contribution to current legal and academic debates on biosafety by reviewing key issues under the Cartagena Protocol that affect the design and implementation of national biosafety regulatory regimes. The book takes into account the principles of sustainable development law, and informs future evolution of the international biosafety regime. The text also examines recent experiences with domestic laws and regulations on biosafety, canvassing the practical, legal, political, and economic challenges encountered in the design and implementation of these regulatory schemes, while placing special emphasis on diverse law and policy approaches taken in developing countries.

Overall, this book addresses the legal avenues that are available to implement international law on biosafety by focusing on three particular objectives. First, the book identifies the aspects of international law on biosafety that are pertinent to and reflective of the treaty objective of sustainable development and use of biotechnology and genetic resources, as well as related principles of international law. Second, the book analyses the national implementation of international law on biosafety, focusing on the design and enforcement of biosafety regulations from a sustainable development law perspective, and examines the practical, legal, political, and economic challenges and achievements encountered in implementing international biosafety obligations. Last, the book discusses the future legal practice and research agenda in this field, providing both recommendations to encourage successful implementation of biosafety regulations and insights into international institutions that oversee and further develop international law on biosafety.

DEVELOPMENT OF THE CARTAGENA PROTOCOL

Due to emerging debates on biotechnology and its potential impact on the environment, the topic of biosafety was raised in the 1992 Earth Summit in Rio de Janeiro. Discussions did not result in a treaty on the subject, but negotiators decided that biosafety should be addressed under the aegis of the Convention on Biological Diversity (CBD).[5] The CBD requires Parties to establish or maintain means to regulate risks arising from biotechnology, taking into account those associated with the use and release of LMOs, which are likely to have adverse environmental impacts that could affect conservation and sustainable use of biotechnology, or present risks to human health.[6] Parties also committed to consider the need for a Protocol setting out procedures for the safe transfer, handling, and use of LMOs that might have adverse effect on the conservation and sustainable use of biological diversity, including

[5] *Convention on Biological Diversity*, 5 June 1992, 31 ILM 818 (entered into force 29 December 1993) [CBD].

[6] *Ibid* at art 8(g).

arrangements for advance informed agreement (AIA) prior to the import/export of LMOs.[7]

The first Conference of the Parties (COP) of the CBD in 1994 initiated consideration of a Protocol, focusing on possible objectives, definitions, scope, application of the AIA procedures, relation to agreements other than the protocol, aspects of risk, relevant national authorities, capacity building, illegal traffic, liability and redress, and the financial mechanisms and resources.[8] In 1995, the second COP to the CBD adopted Decision II/5, launching the Open-ended Ad-Hoc Working Group on Biosafety. This Working Group met six times between 1996 and 1999, concluding with the submission of a draft Protocol to be considered at the first Extraordinary Meeting of the COP (convened with the purpose of adopting a Protocol on biosafety to the CBD).

The Extraordinary Meeting, which was held in two sessions in 1999 and 2000, resulted in the adoption of the Cartagena Protocol and the establishment of the Ad-Hoc Intergovernmental Committee for the Cartagena Protocol (ICCP) to undertake the preparations necessary for the first meeting of the Parties.[9] The Protocol entered into force on 11 September 2003 and by 31 January 2012 engaged 161 Parties. The CBD Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) acts as the governing body.[10] By 2010, the COP-MOP had met five times. These meetings made significant contributions to the elaboration of international law on biosafety and sustainable development.

The first meeting of the COP-MOP was held in Kuala Lumpur, Malaysia, from 23 to 27 February 2004. Fundamentally, it succeeded in setting up the operational framework required for the long-term effective implementation of the Protocol.[11] The most notable developments included the creation of procedures and mechanisms that would facilitate decision making by Parties of import, a group that includes developing countries, economies in transition, and centres of origin and centres of genetic diversity,[12] and the establishment of an information-sharing mechanism: the Biosafety Clearing-House (BCH).[13] In addition, a roster of experts was created

7 *Ibid* at Art. 19(3).

8 Patricia Birnie, Alan Boyle, and Catherine Redgwell, *International Law & the Environment*, 3rd ed. (Oxford, UK: Oxford University Press, 2009) at 629 [International Law & Environment].

9 *Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety*, UN Doc UNEP/CBD/ExCOP/1/3, Dec EM-I/3.

10 *Cartagena Protocol*, *supra* note 2 at art 29(1). The list of the Parties to the Protocol is available online: http://bch.cbd.int/protocol/parties.

11 International Institute for Sustainable Development (IISD), Earth Negotiations Bulletin (ENB), Vol 9, No 289, *Summary of the First Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety*, online: http://www.iisd.ca/vol09/enb09289e.html.

12 SCBD, *Global Biosafety: From Concepts to Action: Decisions from the First meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety* (Montreal, Canada: SCBD, 2004), Dec BS-I/2.

13 *Ibid*, Dec BS-I/3.

for the purpose of capacity building in developing countries;[14] the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol was launched;[15] and the group made first steps toward establishing identification requirements for LMOs intended for direct use as food or feed, or for processing.[16] Finally, that first meeting resulted in the establishment of procedures and mechanisms on compliance,[17] provision of guidance on transboundary movement of LMOs with nonparties,[18] the creation of a medium-term programme of work for the COP-MOP,[19] and the funding of capacity building and implementation measures through the Global Environment Facility.[20]

The following year, the second meeting of the COP-MOP took place in Montreal, Canada, from 30 May to 3 June 2005. Noticeable progress was made on three key issues under the Protocol. First, discussions on risk assessment and management led to the creation of the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment.[21] Second, major decisions were made relating to the operations and activities of the Biosafety Clearing House, capacity-building activities, and the financial mechanism/resources.[22] Third, the Parties recognized and emphasized the importance of public awareness and participation.[23] The main point of contention during the negotiations, however, was documentation for the transboundary movement of LMOs.[24] Discussions between the Parties did result in the articulation of measures to elaborate documentation for the contained use and intentional introduction of LMOs into the environment,[25] but no decision was made regarding documentation for LMOs meant for food, feed, or processing (LMO-FFP) as required by Article 18.2(a) of the Protocol.[26]

COP-MOP 3 was held in Curitiba, Brazil, from 13 to 17 March 2006. The main result of that meeting was the adoption of a compromise package on LMO-FFP documentation requirements.[27] Other major decisions taken included the

[14] *Ibid*, Dec BS-I/4.
[15] *Ibid*, Dec BS-I/5.
[16] *Ibid*, Dec BS-I/6.
[17] *Ibid*, Dec BS-I/7.
[18] *Ibid*, Dec BS-I/11, Annex.
[19] *Ibid*, Dec BS-I/12.
[20] *Ibid*, Dec. BS-I/15.
[21] SCBD, *Facing the Biosafety Challenge: Towards Effective Implementation of the Protocol: Decisions of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety* (Montreal, Canada: SCBD, 2005), Dec BS-II/9 at para 4.
[22] *Ibid*, Dec BS-II/2, BS-II/3, BS-II/4 and BS-II/5.
[23] *Ibid*, Dec BS-II/13.
[24] *Ibid*, at v.
[25] *Ibid*, Dec BS-II/10.
[26] IISD, ENB, Vol 9, No 320, *Summary of the First Meeting of the Ad Hoc Group on Liability and Redress and the Second Meeting of the Parties to the Cartagena Protocol on Biosafety*. Online: <http://www.iisd.ca/vol09/enb09320e.html>.
[27] IISD, ENB, Vol 9, No 351, *Summary of the Third Meeting of the Parties to the Cartagena Protocol on Biosafety*, online: <http://www.iisd.ca/vol09/enb09351e.html>; SCBD, *Biosafety: Building Further*

adoption of an updated version of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety,[28] directions relating to the financial mechanism,[29] further discussion on guidance and capacity building for risk assessment and risk management,[30] and the adoption of a monitoring and reporting format to help fulfill obligations under Article 33 of the Protocol.[31]

At COP-MOP 3 the Parties decided to meet every two years rather than every year; thus COP-MOP 4 was held in Bonn, Germany from 12 to 16 May 2008. One major achievement was the decision to further elaborate international rules and procedures for liability and redress resulting from the transboundary movement of LMOs.[32] Furthermore, the Parties issued a comprehensive decision on risk assessment and risk management, agreeing to the development of training activities and the establishment of an Ad Hoc Technical Expert Group on Risk Assessment and Risk Management.[33] These initiatives were in addition to the adoption of measures to promote long-term biosafety education and training and to strengthen the Coordination Mechanism to support those measures.[34]

The fifth meeting of the COP-MOP took place from 11 to 15 October 2010 in Nagoya, Japan. The Parties focused on adopting rules and procedures pertaining to liability and redress, and concluded the meeting with the adoption of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol.[35]

At COP-MOP 5, the Parties also adopted a ten-year strategic plan for the implementation of the Protocol from 2011 to 2020 with a focus on five main areas: 1) facilitating the establishment and further development of effective biosafety systems for the implementation of the Protocol; 2) capacity-building; 3) compliance and review; 4) information sharing; and 5) outreach and cooperation.[36] Due to the work done at COP-MOP 5, the Parties, in cooperation with relevant organizations,

Consensus for Action: Decisions of the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (Montreal, Canada: SCBD, 2007), Dec BS-III/10.

28 *Ibid*, Dec BS-III/3.

29 *Ibid*, Dec BS-III/5.

30 *Ibid*, Dec BS-III/11.

31 *Ibid*, Dec BS-III/14.

32 SCBD, *Biosafety: Taking Further Steps Towards Effective Implementation of the Protocol. Decisions of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety* (Montreal, Canada: SCBD, 2008), Dec BS-IV/12.

33 *Ibid*, Dec BS-IV/11.

34 *Ibid*, Dec BS-IV/3.

35 *Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety*, Annex to Dec BS-V/11, online: http://bch.cbd.int/protocol/NKL_text.shtml.

36 SCBD, *Biosafety: Setting a New Agenda: Decisions of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biodiversity* (Montreal, Canada: SCBD, 2011), Dec BS-V/16, at Annex I, at para 7.

are also approaching the adoption of a roadmap for risk assessment, as well as guidelines on the elements and procedures of risk assessments for different LMO types, to help countries make informed decisions about the development, handling and use of LMOs.[37]

SUSTAINABLE DEVELOPMENT LAW AND THE CARTAGENA PROTOCOL

Sustainable development law refers to a set of legal instruments and related principles that include, among their objectives, the realization of sustainable development.[38] To date, most sustainable development law has been adopted through "hard law" treaty regimes, although there is also a body of emerging customary principles of law on sustainable development. The process of identifying and promoting respect for these principles of law has been reasonably complex and continues to be the subject of debates in 2010.[39] In 2002, however, at the 70th Conference of the International Law Association (ILA), a resolution by the Committee on the Legal Aspects of Sustainable Development, the ILA New Delhi Declaration of Principles of International Law Relating to Sustainable Development, which was annexed to the outcomes of the 2002 World Summit on Sustainable Development (WSSD), provided an important benchmark that is used in much of the relevant academic and legal literature today.[40]

The New Delhi Declaration elaborates on seven central principles that are common to most international treaties related to sustainable development, many of which were recognized and reaffirmed in the 2002 Johannesburg Plan of Implementation from the World Summit.[41] In this book, these principles provide a benchmark against which the Cartagena Protocol can be analyzed to assess its commitment to the realization of sustainable use of biological resources, and ultimately, to sustainable development. These principles include the duty of States to ensure sustainable use of resources; the principle of equity and the eradication of poverty; the principle of common but differentiated responsibilities; the principle of the precautionary approach to human health, natural resources, and ecosystems; the principle of public participation and access to information and justice; the principle of good governance; and the principle of integration and interrelationship, in particular as these relate to human rights and social, economic, and environmental objectives.

37 *Ibid*, Dec BS-V/12.

38 *Sustainable Development Law*, *supra* note 4 at 103.

39 Cordonier Segger, "The Role of International Forums in the Advancement of Sustainable Development," *supra* note 4 at 10.

40 *ILA New Delhi Declaration of Principles of International Law Relating to Sustainable Development*, UN Doc A/CONF.199/8, Annex [*New Delhi Declaration*].

41 Cordonier Segger, "The Role of International Forums in the Advancement of Sustainable Development," *supra* note 4 at 10.

Principle of Integration and Interrelationship

The principle of integration and interrelationship provides the context for international law on sustainable development by emphasizing the interdependence among economic development, social and human rights, and environmental priorities in international law.[42] The 1992 Rio Declaration from the United Nations Conference on Environment and Development (UNCED) states that "[i]n order to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it."[43] In the WSSD, this principle was arguably broadened to recognize that human rights and social development priorities also constitute an integral part of this balance.[44] It is essential that sustainable development be implemented at all sectors of society and governance.[45] To respect this principle, States may seek to resolve overlaps or perceived conflicts between economic, social, and environmental concerns either through the activation of existing institutions or the establishment of new ones that can balance the competing goals.[46]

The Cartagena Protocol is a prime example of the principle of integration and interrelationship because it is a treaty regime that attempts to address social, economic, and environmental themes in a balanced and holistic fashion. This recognized, it is clear that the Cartagena Protocol permits and even encourages the economic development of biotechnology, attempting to promote safe, equitable, and environmentally sound uses. The negotiation of the Protocol served as an attempt to reconcile competing narratives on modern biotechnology through the creation of a regime that promoted the environmentally sound application of biotechnology. The Protocol's preamble makes this objective clear, since it recognizes the great potential of modern biotechnology while also expressing awareness of its rapid expansion and the resulting growing public concern over its potential adverse effects on biodiversity and human health. It also recognizes that trade and environment agreements should be mutually supportive, with the aim of achieving sustainable development.[47] Additionally, several provisions in the Protocol allow for economic considerations to receive priority, such as the exemption of LMOs in transit from the advance informed agreement procedure,[48] and LMOs intended for contained use in accordance with the importing Party's standards.[49] Similarly,

[42] *New Delhi Declaration*, *supra* note 40 at Principle 7.1; *Sustainable Development Law*, *supra* note 4 at 102.

[43] *Rio Declaration on Environment and Development*, UN Doc A/CONF.151/26 (Vol I), 31 ILM 874 (1992) at Principle 4.

[44] *Sustainable Development Law*, *supra* note 4 at 103.

[45] *New Delhi Declaration*, *supra* note 40 at Principle 7.2.

[46] *Ibid* at Principle 7.3.

[47] *Cartagena Protocol*, *supra* note 2 at Preamble.

[48] *Ibid* at art 6(1).

[49] *Ibid* at art 6(2).

a distinct procedure for commodities (LMOs–FFP) is provided for, rather than the standard advance informed agreement procedure.[50] The Protocol also reflects the principle of integration and interrelationship through its integration of social considerations by the application of socioeconomic considerations in the risk assessment process.[51] Although the Protocol recognizes and attempts to integrate environmental and social concerns into the process of developing and using biotechnology, and even activates economic instruments to achieve social and environmental aims, it remains far from clear whether the current interrelationships among economic, social, and environmental nuances in the treaty could be described as adequately balanced.

Principle of Sustainable Use of Natural Resources

In principle, States have a duty to ensure sustainable use of natural resources, particularly in a transboundary context. This duty stems from the recognition that the sovereign right of States to manage their own natural resources comes with the responsibility to ensure that activities within their jurisdiction or control do not cause significant environmental damage elsewhere.[52] This principle encourages States to manage their natural resources sustainably to contribute to the development of their peoples, with particular regard for the rights of indigenous peoples, and to the conservation and sustainable use of natural resources and the protection of the environment, including ecosystems.[53] The principle also emphasizes that the protection, preservation, and enhancement of the natural environment, and biological diversity in particular, is a common concern of humankind.[54] This principle is reflected in many international treaties and legal instruments in the field of sustainable development.[55]

Fundamentally, the Cartagena Protocol was conceived with this duty in mind. This is clear from its objective, which holds that the Protocol's aim is to contribute to ensuring an adequate level of protection in the safe transfer, handling, and use of LMOs that could have adverse effects on the conservation and sustainable use of biological diversity.[56] The Parties themselves are also obliged to ensure that the development, handling, transport, use, transfer, and release of LMOs is undertaken in a manner that prevents or reduces the risks to biological diversity.[57] In essence, the Cartagena Protocol is seeking to contribute to the sustainable use of biotechnology and biological resources, in particular LMOs.

[50] *Ibid* at art 11.
[51] *Ibid* at art 26.
[52] *New Delhi Declaration*, *supra* note 40 at Principle 1.1.
[53] *Ibid* at Principle 1.2.
[54] *Ibid* at Principle 1.3.
[55] *Sustainable Development Law*, *supra* note 4 at 120.
[56] *Cartagena Protocol*, *supra* note 2 at art 1.
[57] *Ibid* at art 2(2).

Principle of Equity and the Eradication of Poverty

The principle of equity – both inter- and intragenerational – is central to the attainment of sustainable development.[58] Although the present generation has a right to use and enjoy the resources of the Earth, this generation is also under an obligation to take into account the long-term impact of its activities and to sustain the resource base and the global environment for the benefit – in its broadest meaning – of future generations.[59] The right to development must be implemented to meet developmental and environmental needs of present and future generations sustainably and equitably. This includes exercising the duty to cooperate for the eradication of poverty in accordance with Chapter IX on International Economic and Social Co-operation of the Charter of the United Nations and the Rio Declaration on Environment and Development, as well as the duty to cooperate for global sustainable development and the attainment of equity in the development opportunities of developed and developing countries.[60] The principle of equity is reflected in different ways in many international treaties and legal instruments in the field of sustainable development.[61] Although it is the primary responsibility of the State to aim for conditions of equity within its own population, and to ensure, at a minimum, the eradication of poverty, both the UN Charter and the 2000 U.N. Millennium Declaration recognize that all States that are in a position to do so have a further responsibility, to assist in the global achievement of this objective.[62] In attempting to protect the rights of future generations to safe food and a sound environment, the Cartagena Protocol reflects a certain respect for the principle of equity. By making possible the safer import and use of drought-resistant varieties of plants, high-yield food crops, and other beneficial LMOs, it could be argued that the Cartagena Protocol is also contributing in certain ways to reducing poverty. Furthermore, by attempting to balance the need of exporters of LMOs for a stable regulatory climate and the need of importers to be able to manage the risks and potential impacts of biotechnology on their populations, especially in poor or rural areas, the Protocol also has the potential to address imbalances, thereby securing greater equity.

Principle of Common but Differentiated Responsibilities

The principle of common but differentiated responsibilities is a manifestation of general principles of equity. States and other relevant actors have a common responsibility for the achievement of global sustainable development and protection of the environment, but each stakeholder's differing circumstances must be taken into

[58] *New Delhi Declaration*, *supra* note 40 at Principle 2.1.
[59] *Ibid* at Principle 2.2.
[60] *Ibid* at Principle 2.3.
[61] *Sustainable Development Law*, *supra* note 4 at 122.
[62] *New Delhi Declaration*, *supra* note 40 at Principle 2.4.

account when examining their contribution toward those goals.[63] All States have a duty to cooperate in the achievement of global sustainable development and the protection of the environment, and international organizations, corporations (including in particular transnational corporations), nongovernmental organizations, and civil society should also be a part of this global partnership. Corporations have a role pursuant to the "polluter-pays" principle.[64]

Differentiation of responsibilities, although principally based on the contribution that a State has made to the emergence of environmental problems, must also take into account the economic and developmental situation of the State, in recognition of the special needs and interests of developing countries and of countries with economies in transition, particularly least-developed countries and those affected adversely by environmental, social, and developmental considerations.[65] Developed countries bear a special burden of responsibility in reducing and eliminating unsustainable patterns of production and consumption and in contributing to capacity building in developing countries by providing financial assistance and access to environmentally sound technology. In particular, developed countries should play a leading role and assume primary responsibility in matters of relevance to sustainable development.[66]

The Protocol recognizes that centres of origin and centres of genetic diversity are of crucial importance to humankind and takes into account the limited capacities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with LMOs.[67] The Protocol's capacity-building measures, resources, and financial mechanism may also contribute to the realization of this principle in the treaty.[68]

Principle of the Precautionary Approach

The precautionary approach to human health, natural resources, and ecosystems requires that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent degradation.[69] This requires States, international organizations, and nongovernment actors to avoid activities, in light of scientific uncertainty, that could cause significant harm.[70] The approach includes accountability for harm caused, planning based on clear criteria and well-defined goals, consideration of

[63] *Sustainable Development Law*, *supra* note 4 at 132–3.
[64] *New Delhi Declaration*, *supra* note 40 at Principle 3.1.
[65] *Ibid* at Principle 3.2 and 3.3.
[66] *Ibid* at Principle 3.4.
[67] *Cartagena Protocol*, *supra* note 2 at Preamble.
[68] *Ibid* at arts 22 and 28.
[69] Cordonier Segger, "The Role of International Forums in the Advancement of Sustainable Development," *supra* note 4 at 12.
[70] *New Delhi Declaration*, *supra* note 40 at Principle 4.1.

all possible means to achieve an objective when completing an environmental impact assessment, and establishing an appropriate burden of proof on the person or persons carrying out, or intending to carry out, activities that could cause serious long-term or irreversible harm.[71] Decision-making processes should adopt a precautionary approach to risk management and appropriate precautionary measures in particular.[72] Last, precautionary measures should be based on up-to-date and independent scientific judgment and be transparent, and not used as a cover for economic protectionism. Transparent structures that involve all interested parties, including nonstate actors, in the consultation process should be established, and appropriate review by a judicial or administrative body made available.[73]

The Cartagena Protocol is founded on the precautionary approach, with express reference made in the preamble and article 1, and implicit reference found in the conditional "may have an adverse effect" on biodiversity and/or human health.[74] The AIA procedure is the primary mechanism used to ensure that Parties are provided with the information necessary to make informed decisions before agreeing to the import of LMOs.[75] It must be considered with the Protocol's risk assessment and risk-management provisions for safe use, handling, and transboundary movement; emergency measures in the event of unintentional release; and provisions on handling, transport, packaging, and identification.[76]

The flexibility to maintain a multidisciplinary case-by-case approach to LMOs for the purpose of risk assessment is provided for by the Protocol, but decision making must still be grounded in sound science; nonscientific factors alone will not provide unchallengeable grounds for refusal to import LMOs.[77] In general, the Protocol requires Parties to ensure that the development, handling, transport, use, transfer, and release of LMOs are undertaken in a manner that prevents or reduces the risks to biodiversity, taking also into account risks to human health.[78] It does not prevent a Party from taking action that is more protective of the conservation and sustainable use of biodiversity than called for, provided that the action is consistent with the objective and provisions of the Protocol and is in accordance with that Party's obligations under international law.[79] The rules contained in the Protocol are a minimum standard rather than a ceiling, meaning that Parties can adopt a more precautionary approach if they deem fit.[80]

[71] *Ibid* at Principle 4.2.
[72] *Ibid* at Principle 4.3.
[73] *Ibid* at Principle 4.4.
[74] International Law & Environment, *supra* note 8 at 640.
[75] *Ibid* at 640; See *Cartagena Protocol*, *supra* note 2 at art 7.
[76] *Ibid* at 641; See *Cartagena Protocol*, *supra* note 2 at arts 15, 16, 17, and 18.
[77] *Ibid* at 644–5.
[78] *Cartagena Protocol*, *supra* note 2 at art 2(2).
[79] *Ibid* at art 2(4).
[80] Ruth Mackenzie et al, *An Explanatory Guide to the Cartagena Protocol on Biosafety* (Gland, Switzerland and Cambridge, UK: IUCN and FIELD, 2003) at para 184 [IUCN Guide].

Principle of Public Participation and Access to Information and Justice

The principle of public participation and access to information and justice requires States to ensure that people have proper access to appropriate, comprehensive, and timely information concerning sustainable development that is held by public authorities and the opportunity to participate in decision-making processes, as well as effective access to judicial and administrative proceedings, including redress and remedy.[81] It is a condition for responsive, transparent, and accountable governments; the active engagement of civil society organizations, including industrial concerns and trade unions; and ensuring that women can play their vital role in sustainable development in every country.[82]

Public participation is based on the effective protection of the human right to hold and express opinions and to seek, receive, and impart ideas. This is predicated on access to appropriate, comprehensible, and timely information held by governments and industrial concerns on economic and social policies regarding the sustainable use of natural resources and the protection of the environment, access that does not impose undue financial burdens on the applicants and that gives due consideration for privacy and adequate protection of business confidentiality.[83] The empowerment of peoples in the context of sustainable development also depends on access to effective judicial or administrative procedures in the State where the measure has been taken to challenge such measure and to claim compensation. States should ensure that where transboundary harm has been or is likely to be caused, individuals and groups affected have nondiscriminatory access to the same judicial and administrative procedures as would individuals and groups of the State in which the harm is caused.[84]

Public awareness and participation play a prominent role in the Protocol. There are likely to be a wide range of stakeholders consulted in the field of biosafety, and Parties are required to ensure that the public is actively consulted on LMOs and biosafety, with the objective of promoting transparency and informed decision making, in accordance with their respective laws and regulations.[85] The Biosafety Clearing-House (BCH) is a publicly accessible information- sharing mechanism to facilitate the exchange of scientific, technical, environmental, and legal information.[86] The Protocol's BCH and capacity-building provisions are designed to facilitate developing states' participation. The Protocol also allows for the protection of business confidentiality, balancing social with economic considerations.[87] Last,

[81] Cordonier Segger, "The Role of International Forums in the Advancement of Sustainable Development," *supra* note 4 at 12.
[82] *New Delhi Declaration*, *supra* note 40 at Principle 5.1.
[83] *Ibid* at Principle 5.2.
[84] *Ibid* at Principle 5.3.
[85] *Cartagena Protocol*, *supra* note 2 at art 23; International Law & Environment, *supra* note 8 at 642.
[86] *Ibid* at art 20.
[87] *Ibid* at art 21.

it mandates measures for the adequate handling, packaging, transport, and identification of LMOs.[88]

Principle of Good Governance

The principle of good governance commits States and international organizations to adopt democratic and transparent decision-making procedures and financial accountability, take effective measures to combat official or other corruption, respect the principle of due process in their procedures, and observe the rule of law and human rights.[89] Citizens can expect good governance by States and international organizations, whereas nonstate actors should be subject to internal democratic governance and to effective accountability.[90] The application of the principle can evoke the need for corporate social responsibility and a global market aimed at a fair distribution of wealth among and within communities.[91]

The Cartagena Protocol contains numerous aspects that reflect the principle of good governance at both the domestic and international level. Its first general provision explicitly requires each Party to take the necessary and appropriate legal, administrative, and other measures to implement its obligations.[92] Second, it establishes a transparent and procedurally sound decision-making process to govern the first intentional transboundary movement of LMOs for intentional introduction into the importing Party's environment – the advance informed agreement (AIA) procedure.[93] Third, the Protocol establishes notification and consultation requirements on Parties relating to unintentional transboundary movements of LMOs,[94] as well as requiring appropriate domestic measures aimed at preventing and penalizing illegal transboundary movements.[95] Fourth, each Party is required to monitor the implementation of its obligations and report to the COP-MOP on its implementation measures.[96] Fifth, the COP-MOP is required to consider and approve cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of noncompliance, including provisions to offer advice or assistance when appropriate.[97] Last, the COP-MOP is required to undertake an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes, at least every five years.[98] The COP-MOP shall also

[88] *Ibid* at art 18.
[89] *New Delhi Declaration*, *supra* note 40 at Principle 6.1; Cordonier Segger, "The Role of International Forums in the Advancement of Sustainable Development," *supra* note 4 at 12.
[90] *Ibid* at Principle 6.2.
[91] *Ibid* at Principle 6.3.
[92] *Cartagena Protocol*, *supra* note 2 at art 2(1).
[93] *Ibid* at art 7(1).
[94] *Ibid* at art 17.
[95] *Ibid* at art 25(1).
[96] *Ibid* at art 33.
[97] *Ibid* at art 34.
[98] *Ibid* at art 35.

keep under regular review the implementation of the Protocol and shall make decisions necessary to promote its effective implementation, including considering and adopting amendments to the Protocol and annexes that are deemed necessary for its implementation.[99] A broad list of observers is allowed, including any body or agency, whether national or international, governmental or nongovernmental, that is qualified in matters covered by the Protocol.[100]

Conclusion

In summary, the Cartagena Protocol on Biosafety shares an important objective with the CBD – the conservation of biological diversity and sustainable use of its components. These components include genetic resources and technologies, and in particular, the Protocol seeks to secure the safe and sustainable use of LMOs, which form a significant part of the growing field of biotechnology. The principles of international law on sustainable development, as enshrined in soft law instruments such as the 1992 Rio Declaration and analyzed in the work of scholarly bodies such as the ILA 2002 New Delhi Declaration, are both recognized and made operational in the Cartagena Protocol in certain ways, often through the establishment of specific mechanisms or instruments. The key challenge, at this point, is to analyze and monitor outcomes to give effect and implement this key Protocol. This endeavour may be able to improve the abilities of the Parties to comply with their obligations within their diverse territories and broaden understanding of the overall regime, contributing to its eventual refinement and evolution internationally.

BIOSAFETY BECOMES BINDING

This volume is presented in five parts. Part I (Essentials of Biosafety and Sustainable Development Law) lays the foundations for the book. It begins with Chapter 1 by Kathryn Garforth, Worku Damena Yifru, and Mai Fujii. This chapter establishes the historical and legal context of international biosafety law, defines biotechnology, and explains why modern biotechnology is a common concern. This chapter also provides a general explanation of the key obligations in the Cartagena Protocol, with emphasis on its main decision-making provisions. The next chapter, by Christine Frison, Sylvestre-José-Tidiane Manga, and Marie-Claire Cordonier Segger, outlines certain challenges faced in the development of National Biosafety Frameworks (NBF) and related regulatory regimes and comments on the role of such national policies and laws in the promotion of sustainable development. Part I concludes with a chapter by Greg Jaffe that details the components and characteristics of a functional and protective biosafety regulatory system.

[99] *Ibid* at art 29(4)(d).
[100] *Ibid* at art 29(8).

Part II (Sustainable Development Law and Policy on Biosafety) expands on the constituent elements of the Cartagena Protocol and in many cases discusses how these provisions both reflect important principles of international law on sustainable development and seek to contribute to the safe and sustainable use of genetic resources. It begins with Chapter 4, by Ryan Hill, which addresses issues and challenges related to risk assessment and risk management in the context of LMOs. Chapter 5, by Worku Damena Yifru, Mai Fujii, and Kathryn Garforth, examines the relevance and validity of the AIA procedure and related procedure for LMOs intended for direct use as food or feed or for processing. Chapter 6, by Thomas Redick, examines key issues regarding the handling, transport, packaging, and identification of LMOs bound for use as seed or in food, feed, or processing, and the ways in which these issues affect trade. Chapter 7, by Julian Kinderlerer and Christine Toczeck, explores the question of public participation in the debate over the safe use of biotechnology, explaining the importance of meaningful public participation and transparency in decision-making processes. Chapter 8, by Frederic Perron-Welch, discusses the role and importance of the Biosafety Clearing-House. Chapter 9, by Tomme Rosanne Young, considers progress in the implementation of the Biosafety Clearing-House, drawing on a careful analysis of recent domestic legislative experiences to constructively highlight important legal and policy challenges for the regime. Chapter 10, by Frederic Perron-Welch, examines socioeconomic considerations that relate to biosafety in the context of the Cartagena Protocol and how they can play a role in decision-making to help promote sustainable development. Chapter 11, by Veit Koester, discusses the implications and effectiveness of compliance procedures and mechanisms under the Cartagena Protocol. Finally, Chapter 12, by Frederic Perron-Welch and Olivier Rukundo, examines issues of liability and redress in the context of biotechnology and the *Nagoya – Kuala Lumpur Protocol on Liability and Redress to the Cartagena Protocol*.

Part III (Domestic Implementation of Biosafety Regulatory Aspects) conducts a detailed analysis of the implementation of the Cartagena Protocol on Biosafety through the development of national biosafety frameworks. It opens with a discussion of legislative options for national implementation in Chapter 13, by Tomme Rosanne Young. Through the analysis of the experiences of various countries and regions in Chapter 14, by Liina Eek and David Duthie, on Central and Eastern Europe; Chapter 15, by Gregory Jaffe and Papa Miessa Dieng, on West Africa; Chapter 16, by Gregory Jaffe, on East Africa; Chapter 17, by Nizar Mohamed, on Asia; and Chapter 18, by Jorge Cabrera Medaglia, on the Americas, this third part identifies specific problems related to the development of national biosafety regulatory regimes and seeks to outline key lessons for future capacity-building activities in biosafety.

Part IV (Case Studies of Domestic Regimes and Sustainable Development) builds on the analysis in Part III with case studies of specific legislative approaches to the Cartagena Protocol. This part opens with an overview of various responses to key aspects of the Protocol in Chapter 19, by Tomme Rosanne Young. Chapter 20, by

Jorge Cabrera Medaglia, explains Costa Rica's legal framework concerning GMOs in the agricultural sector. Chapter 21, by Frederic Perron-Welch, describes New Zealand's biosafety framework in the context of that country's unique history and geography. In Chapter 22, by Kathryn Garforth and Paige Ainslie, the issue of liability and redress in Canadian case law is investigated by following the case of a group of organic farmers seeking to bring a class action suit against Monsanto and Bayer for damages allegedly caused by the companies' genetically modified varieties of canola. Last, Chapter 23, by Konstantia Koutouki and Paula Honorato Marin, discusses the implications of GMOs in Chile for the protection of Indigenous culture.

Part V (Global Policy Trends in Biosafety) explores global policy trends in the implementation of the Cartagena Protocol on Biosafety. Chapter 24, by Frederic Perron-Welch, Marie-Claire Cordonier Segger, Christine Frison, and Jorge Cabrera Medaglia, draws on the experience of the authors in reviewing the design of numerous national biosafety frameworks and regulatory regimes to draw certain conclusions about the diverse approaches being adopted by Parties to the Protocol. The chapter identifies key future legal research questions and priorities, and provides preliminary recommendations regarding the future design and implementation of biosafety rules in the context of sustainable development law. Chapter 25, by Marie-Claire Cordonier Segger and Markus Gehring, examines the findings and corresponding implications for sustainable development of the *European Communities Biotech Dispute* submitted to the World Trade Organization (WTO). Chapter 26, by Martin Endicott, explores the fraught relationship between food aid and biosafety.

This book concludes with a final scholarly and practical legal analysis of implementation of the Cartagena Protocol, from a sustainable development law perspective, summarizing key conclusions on the strengths and weaknesses of implementation efforts across the world, and offering advice to the over 160 countries seeking to set laws and policies in place related to biosafety, and to further refine their international regime for biosafety.

PART I

Essentials of Biosafety and Sustainable Development Law

1

Biosafety, the Cartagena Protocol, and Sustainable Development

Kathryn Garforth, Worku Damena Yifru, and Mai Fujii

As one of a growing number of multilateral instruments that seek to promote sustainable development, the *Cartagena Protocol on Biosafety*[1] (Cartagena Protocol) represents, in many respects, an interesting development in the law of sustainable development.[2] The Protocol is not solely economic, environmental, or social but incorporates elements of each of these pillars of sustainable development.[3] The Cartagena Protocol has strong links to environmental law through its foundation in the precautionary principle and the development of sound science; links to social and human rights law through its elements of public awareness, public participation, and the public right to know, as well as by permitting consideration of the socioeconomic impacts of living modified organisms (LMOs); and links to trade law because of its focus on the transboundary movement of LMOs.

The sections that follow examine the context in which the Cartagena Protocol was developed and describe some of the different aspects of the Protocol through the lens of sustainable development.

CONTEXT

Biosafety "refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology."[4] As this definition

[1] *Cartagena Protocol on Biodiversity*, 29 January 2000, 2226 UNTS 208 (entered into force 11 September 2003) [*Cartagena Protocol*].

[2] UP Thomas, "The CBD, the WTO, and the FAO: The Emergence of Phytogenetic Governance" in Philippe G LePrestre, ed, *Governing Global Biodiversity: The Evolution and Implementation of the Convention on Biological Diversity* (Burlington, VT: Ashgate Publishing Co, 2002) 177 at 200.

[3] Marie-Claire Cordonier Segger and Ashfaq Khalfan, eds, *Sustainable Development Law: Principles, Practices and Prospects* (Oxford, UK: Oxford University Press, 2004) at 50.

[4] Secretariat of the Convention on Biological Diversity (SCBD), *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes* (Montreal, Canada: SCBD, 2000) at 1.

illustrates, biosafety is intricately bound to biotechnology. In turn, *biotechnology* is a broad term that can encompass a range of activities in a variety of different fields. The scope of the Cartagena Protocol is limited, however, to "modern biotechnology," which is defined as the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.[5]

The field of biosafety stems from the development of these modern techniques of biotechnology. In the early 1970s, American scientists Herbert Boyer and Stanley Cohen collaborated on a series of experiments that resulted in the creation of the first molecules of recombinant DNA and the first genetically engineered bacteria.[6] The early transformations of bacteria and viruses in the laboratory raised concerns among scientists, leading to the development of guidelines for recombinant DNA research focusing particularly on containment measures for laboratory experiments.[7]

By the end of the 1970s, the field of biotechnology began to shift from experiments in the laboratory to industrial applications in the field. The first environmental releases of genetically modified bacteria began in the 1980s, as did field trials for genetically modified plants.[8] As the science advanced, the risks became more complex, leading to concerns about the possible hazards posed by recombinant DNA.

Until this point, biotechnology was primarily the domain of developed countries. Recombinant DNA experiments were conducted in the laboratories of industrialized countries, and genetically modified organisms (GMOs) were being created to meet needs in developed countries. These industrialized countries also implemented some of the first regulatory regimes for GMOs, such as Canada's National Biotechnology Strategy, created in 1982, or the Coordinated Framework for the Regulation of Biotechnology, published in the United States in 1986.[9]

In this context began the negotiations on the *Convention on Biological Diversity*[10] (CBD) in 1987. The emerging role and potential value of genetic resources in the world economy were becoming increasingly obvious. The United States was

[5] *Cartagena Protocol*, *supra* note 1 at art 3(i).
[6] Susan R Barnum, *Biotechnology: An Introduction* (Scarborough, ON: Scarborough, Canada: Wadsworth Publishing Company, 1998) at 21.
[7] See, for example, the outcomes from the Asilomar Conference on Recombinant DNA Molecules held in February 1975 and the "Guidelines for research involving recombinant DNA molecules," (1976) 41 Federal Register 131 at 27911–27943 developed by the U.S. National Institutes of Health; Barnum, *ibid* at 22–5.
[8] Barnum, *ibid* at 25–6.
[9] Barnum, *ibid* at 192.
[10] *Convention on Biological Diversity*, 5 June 1992, 31 ILM 818 (entered into force 29 December 1993 [CBD].

beginning to grant patents on genetically modified life forms,[11] and the debate over Plant Breeders' Rights versus Farmers' Rights had been raging at the Food and Agriculture Organization of the United Nations since 1980. From the very beginning of the discussions that led to the CBD, developing countries insisted that biotechnology be one of the key issues addressed in the Convention.[12]

Developing countries' insistence about this issue was successful and led to the inclusion of Article 19 in the CBD, which discusses the "handling of biotechnology and distribution of its benefits." The article provides that Parties to the CBD are to take measures to include countries that provide genetic resources in biotechnology research activities, share access to the results and benefits of biotechnology, and provide information about LMOs to Parties where they are to be introduced. Paragraph 3 of Article 19 obliges the Parties to the Convention to consider the need for a protocol on LMOs resulting from biotechnology that could have adverse effects on the conservation and sustainable use of biodiversity. This paragraph was somewhat controversial during the negotiations because some countries wanted to make the development of a protocol mandatory and not simply something for further consideration.[13]

At the same 1992 United Nations Conference on Environment and Development (UNCED), where the CBD was opened for signature, more than 140 governments agreed to *Agenda 21*.[14] Section II of *Agenda 21* is devoted to the "conservation and management of resources for development" and includes chapter 16 on the "environmentally sound management of biotechnology." The chapter focuses on five areas within biotechnology: increasing the availability of food, feed, and renewable raw materials; improving human health; enhancing protection of the environment; enhancing safety and developing international mechanisms for cooperation; and establishing enabling mechanisms for the development and environmentally sound application of biotechnology. The fourth of these areas is of particular relevance here because it calls for

> further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level. Only when adequate and transparent safety and border-control procedures are in place will the community at large be able to derive

[11] The U.S. Supreme Court decision in *Diamond v Chakrabarty*, 206 USPQ 193 (USSC 1980) granted a patent on a genetically modified microorganism and found that whether something is living is not relevant in determining whether it is patentable. In 1987, the US Patent and Trademark Office issued a statement declaring that "nonnaturally occurring non-human multicellular living organisms" are patentable subject matter, US PTO 1077 Official Gazette 24 (21 April 1987).

[12] Désirée M McGraw, "The Story of the Biodiversity Convention: From Negotiation to Implementation" in LePrestre, *supra* note 2, 7 at 34.

[13] Ruth Mackenzie et al, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN Environmental Policy and Law Paper No 46 (Gland, Switzerland: IUCN, 2003) at para 11 [IUCN Guide].

[14] *Report of the United Nations Conference on Environment and Development*, UN Doc A/CONF.151/26/Rev.1 (Vol 1), 31 ILM 874 (1992) [UNCED Report].

> maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology.[15]

Three years after UNCED, the United Nations Environment Programme released the International Technical Guidelines for Safety in Biotechnology.[16] According to the Preface, these guidelines are intended as a contribution to the implementation of *Agenda 21*. They were developed "on the basis of common elements and principles derived from relevant existing regional and international instruments and national regulations and guidelines, drawing upon experience already gained through their preparation and implementation."[17] The guidelines "provide technical guidance on evaluating biosafety, identifying measures to manage foreseeable risks and to facilitate processes such as monitoring, research and information exchange."[18] The same year, the Parties to the CBD agreed to establish an Ad Hoc Working Group on Biosafety to elaborate a protocol on biosafety.[19] The Working Group was to endeavour to complete its work in 1998.

In the end, it took until the year 2000 for the negotiating countries to reach agreement on the text of a protocol. The negotiations were rocky and reached the brink of failure when no agreement had been reached by the February 1999 meeting in Cartagena, Colombia. The meeting was adjourned, and a resumed session of the first extraordinary meeting of the Conference of the Parties was called for January 2000 in Montreal, at which consensus finally was achieved. Three and a half years later, in September 2003, the Cartagena Protocol on Biosafety entered into force, having received the fifty necessary ratifications. To date, of the 193 Parties to the CBD, 163 also have become Parties to the Protocol.[20]

As other chapters in this book explore, some of the most contentious issues during the negotiations included the scope of the advance informed agreement procedure under the Protocol and the types of organisms it would cover; inclusion of the precautionary principle in the operational text of the Protocol, the allowance for socioeconomic considerations in decision making under the Protocol, and the relationship between the Protocol and other international agreements, particularly those of the World Trade Organization (WTO).

Although the text of an international treaty might appear to be static, in fact the understanding and application of the words in any agreement are constantly

[15] *Ibid* at para 16.29.

[16] United Nations Environment Programme, "International Technical Guidelines for Safety in Biotechnology" (1995), online: United Nations Environment Programme, http://www.unep.org/biosafety/Documents/Techguidelines.pdf.

[17] *Ibid* at ix.

[18] IUCN Guide, *supra* note 13 at para 119.

[19] CBD Dec II/5, "Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms".

[20] As of 11 July 2012, online: Biosafety Clearing-House, "List of Parties" http://bch.cbd.int/protocol/parties. Only Parties to the CBD may become Parties to the Protocol, see art 32(1) of the CBD.

evolving. Much work takes place to flesh out the meaning of a treaty. In the case of the Cartagena Protocol, this work is led by its governing body – the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP). The COP-MOP has met five times to date: Kuala Lumpur, Malaysia, 23 to 27 February 2004; Montreal, Canada, 30 May to 3 June 2005; Curitiba, Brazil, 13 to 17 March 2006; Bonn, Germany, 12 to 16 May 2008; and Nagoya, Japan, 11 to 15 October 2010.

The COP-MOP adopts decisions on different aspects and issues of the Protocol. In addition to exploring the relationship between the Protocol and sustainable development, the discussion that follows also examines the role of the COP-MOP in elaborating on the provisions of the Protocol.

THE CARTAGENA PROTOCOL AND THE THREE PILLARS OF SUSTAINABLE DEVELOPMENT

Much of this text is devoted to detailed explorations of the different facets of the Cartagena Protocol. Our intention in this chapter is to provide a brief overview and introduction to these facets and to describe what the Protocol does – and does not – do. The book explores the different aspects of the Cartagena Protocol through the lens of sustainable development to demonstrate the treaty's integrative nature.

The concept of sustainable development[21] has been incorporated into various international instruments, including multilateral environmental agreements, since the 1980s. Although sustainable development may be critiqued as having become an "umbrella term for a host of disparate issues,"[22] or a "rhetorical mantra, often repeated but seldom truly understood,"[23] the notion clearly has obtained broad support in the international community. Since the World Summit on Sustainable Development in Johannesburg in 2002, environmental protection and economic and social development have been considered "interdependent and mutually reinforcing" pillars of sustainable development.[24] It is a common understanding that attaining all three of these pillars concurrently is essential to achieve genuine sustainable development.[25]

[21] The notion of sustainable development was originally defined as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs," World Commission on Environment and Development, *Our Common Future* (Oxford, UK: Oxford University Press, 1987) at 43.

[22] International Law Association, "International Law on Sustainable Development" in *Report of the Seventy-First Conference: Berlin* (London: International Law Association, 2004) 566 at 576.

[23] International Law Association, "International Law on Sustainable Development" in *Report of the Seventy-Third Conference: Rio de Janeiro* (London: International Law Association, 2008) 895 at 900.

[24] *Plan of Implementation of the World Summit on Sustainable Development*, WSSD Res 2, 17th plenary meeting, (4 September 2002) in United Nations, *Report of the World Summit on Sustainable Development* (New York, UN, 2002) at para 2, online: United Nations: Johannesburg Summit 2002, http://www.johannesburgsummit.org.

[25] International Law Association, "International Law on Sustainable Development" in *Report of the Seventy-Second Conference: Toronto* (London: International Law Association, 2006) 467 at 472.

The Cartagena Protocol contains all three pillars in its provisions. Implementation of the Protocol moves from rhetorical mantra to actual integration of the three components and promotion of sustainable development.

The scope and limitations of the Protocol are largely set out in its first five articles. Article 1 defines the objective of the Cartagena Protocol as follows:

> In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

There are a few key things to note from this objective. First, the Protocol concerns LMOs rather than the more commonly used term *genetically modified organisms*. This is because the primary concern of countries was the possible environmental impact of the release of new organisms into the environment. The ability of living organisms to reproduce and spread independently led to their being the focus of the Protocol. A second aspect to note is that the objective includes the phrase "taking also into account risks to human health." The Protocol includes human health within its ambit, though the meaning and effect of this phrase has not yet been well defined.

A final aspect to note is that the Protocol focuses specifically on transboundary movements. Although some provisions in the Protocol concern domestic development of LMOs (e.g., Article 16 on risk management), the Protocol mostly addresses what should or could happen when an LMO is moved from one country to another.

These parameters are also reflected in the scope of the Protocol as set out in Article 4: "This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health." Although the scope states that the Protocol applies to *all* LMOs that might have adverse effects on the conservation and sustainable use of biodiversity, Article 5 on pharmaceuticals may limit this somewhat. The article states that the Protocol does not apply to the transboundary movement of LMOs that are pharmaceuticals for humans when these LMOs are addressed by other relevant international agreements or organizations.

With the basic framework of the Protocol set, we now turn to examining the interlinkages among the provisions of the Protocol and the three pillars of sustainable development. By necessity, this exploration is somewhat simplified, because several individual aspects of the Protocol can themselves be understood as cutting across economic, social, and environmental concerns. Nonetheless, it is a useful exercise for understanding the Cartagena Protocol as an integrative instrument that has

environmental protection as its fundamental goal but also recognizes the social and economic dimensions necessary for achieving this goal.

Environment

The environmental dimension of sustainable development can be found most particularly in the risk assessment requirements of the Cartagena Protocol. The Protocol sets out provisions on risk assessment (Article 15 and Annex III) and risk management (Article 16) to identify, evaluate, regulate, manage, and control possible adverse effects and risks of LMOs. The risk assessment provisions are tied most closely – although not exclusively – to the advance informed agreement (AIA) procedure of the Protocol. This procedure is set out in Articles 7 through 10 and 12 and applies "prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import."[26] It requires that decision making be based on a risk assessment[27] that is "carried out in a scientifically sound manner . . . taking into account recognised risk assessment techniques."[28] Annex III sets out the risk assessment requirements in more detail, providing the objective, general principles, methodology, and points to consider in the conduct of risk assessment.

Article 16 requires Parties to, among other things, adopt measures and strategies for preventing adverse effects and for managing and controlling risks identified by risk assessments. When scientific certainty about the extent of the potential adverse effects of an LMO is lacking, a Party may take precautionary action to avoid or minimize the potential adverse effects.[29]

Discussions on risk assessment under the Protocol have led to agreement that there is a need for additional guidance on specific aspects of risk assessment and risk management, and to this end, an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management was established at COP-MOP 4. The AHTEG developed "Guidance on Risk Assessment of Living Modified Organisms," which includes a roadmap on the steps for conducting a risk assessment as well as guidance on specific types of LMOs and traits.[30] An open-ended online forum on specific aspects of risk assessment was also established, and several real-time online conferences were conducted to provide input to the AHTEG.

At COP-MOP 5, the Parties welcomed the guidance developed by the AHTEG. They agreed to undertake a scientific review of the guidance and also to extend the open-ended online forum and the AHTEG. In 2011 and 2012, the AHTEG

[26] *Cartagena Protocol*, *supra* note 1 at art 7(1).
[27] *Ibid* at art 10(1).
[28] *Ibid* at art 15(1).
[29] *Ibid* at art 10(6).
[30] Executive Secretary of the Convention on Biological Diversity, "Risk Assessment and Risk Management (Articles 15 and 16)," UN Doc UNEP/CBD/BS/COP-MOP/5/12 (30 July 2010) at Annex III.

contributes to the scientific review and testing of the guidance and also develops further guidance on new specific topics of risk assessment.[31]

The risk assessment and risk management requirements of the Protocol concern the intentional transboundary movements of LMOs. Article 17 addresses the situation in which a transboundary movement is unintentional. The article requires a Party to take notification measures as soon as it knows of an occurrence under its jurisdiction resulting in a release that leads or might lead to an unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biodiversity.[32] It also sets out specific types of information that should be included in the notification.[33] The article closes by asking each Party under whose jurisdiction a release occurs to consult the affected or potentially affected States immediately "to enable them to determine appropriate responses and initiate necessary action, including emergency measures."[34]

The ultimate purpose of Article 17 is to reduce the impact of unintentional transboundary movements of LMOs on biodiversity. Also evident in the language of the article are echoes of Principles 18 and 19 of the *Rio Declaration on Environment and Development*,[35] which similarly call for states to notify each other in cases of "natural disasters or other emergencies that are likely to produce sudden harmful effects on the environment of [other] States" (Principle 18) and to notify and consult with each other "on activities that may have a significant adverse transboundary environmental effect" (Principle 19).

Society

Public awareness and public participation are essential elements to achieve sustainable development. In international environmental forums, transparency and broad public participation in governmental decision making are required to ensure not only social development itself but also the integration of environmental, social, and economic considerations.[36] Public participation in the context of sustainable development is a broad concept that also includes elements of access to information.

The Protocol includes provisions on information sharing, confidential information, and public awareness and participation. Article 20 of the Protocol establishes

[31] Cartagena Protocol, COP-MOP 5, Dec BS-V/12, "Risk assessment and risk management (Articles 15 and 16)" (2010).

[32] *Cartagena Protocol*, *supra* note 1 at art 17(1).

[33] *Ibid* at art 17(3).

[34] *Ibid* at art 17(4).

[35] UNCED Report, *supra* note 14.

[36] An Expert Group Workshop on International Environmental Law aiming at Sustainable Development convened by the United Nations Environment Programme in 1996 recognized "that the integration of environmental, social and economic policies requires transparency and broad public participation in governmental decision-making." See Final Report of the Expert Group Workshop on International Environmental Law Aiming at Sustainable Development, UN Doc UNEP/IEL/WS/3/2 (1996) at para 35(d).

a Biosafety Clearing-House (BCH) as a tool for information sharing and exchange among Parties and other stakeholders. Parties are required to make certain information available through the BCH, such as laws, regulations, and guidelines for the implementation of the Protocol,[37] decisions taken under the AIA procedure,[38] and decisions on domestic use of LMOs intended for direct use as food or feed, or for processing.[39] The BCH also includes a Biosafety Information Resource Centre where users can post biosafety-related materials.

The BCH is unique because it was the first Internet-based information exchange mechanism mandated by a multilateral environmental agreement. Furthermore, as the power of the Internet grows, so does the functionality of the BCH. In recent years, the BCH has served as the platform for online discussion forums and real-time online conferences, complementing the more traditional meeting formats used in the United Nations.

Balancing the access to information facilitated by the BCH is Article 21 on confidential information. This article requires, among other things, a Party of import to allow a notifier to identify information that is to be treated as confidential when it is submitted to the Party of import.[40] The Party of import must protect confidential information received under the Protocol.[41] The Party of import must also consult the notifier if it decides that information identified by the notifier as confidential does not qualify as such, and, prior to any disclosure, the Party of import must inform the notifier of its decision, providing reasons on request as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.[42]

Article 23 of the Protocol requires Parties to promote and facilitate public awareness and education, including access to information, about the safe transfer, handling, and use of LMOs. It also requires Parties to consult the public in the decision-making process, to make public the final decision taken, and to inform the public about the means of access to the BCH. This obligation to involve the public in decision making on LMOs is qualified by a reference to national laws and regulations.

Overall implementation of Parties' obligation to promote and facilitate public awareness, education, and participation faces major challenges, however.[43] COP-MOP 5 thus adopted a programme of work on public awareness, education, and participation concerning the safe transfer, handling, and use of LMOs for the period

37 *Cartagena Protocol*, *supra* note 1 at art 20(3).
38 *Ibid* at art 10(3).
39 *Ibid* at art 11(1).
40 *Ibid* at art 21(1).
41 *Ibid* at art 21(3).
42 *Ibid* at art 21(2).
43 Executive Secretary of the Convention on Biological Diversity, "Public Awareness and Participation: Interim report on the status of implementation of public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms (Article 23, paragraph 1(a))," UN Doc UNEP/CBD/BS/COP-MOP/4/16 (3 March 2008) at para 25.

2011–2015.[44] The programme of work includes several elements and suggested activities directed toward Parties, civil society, and educational institutions.

It is also worthwhile mentioning the *Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters*[45] (i.e., the Aarhus Convention). In 2005, the Parties to the Aarhus Convention adopted an amendment "on public participation in decisions on deliberate release into the environment and placing on the market of genetically modified organisms."[46] Once the amendment enters into force,[47] it requires Parties to provide for "early and effective information and public participation prior to making decisions on whether to permit the deliberate release into the environment and placing on the market of genetically modified organisms."[48] A new annex to the Convention would set out the modalities for Parties to follow in providing early and effective information and public participation. The Secretariats of the Aarhus Convention and the CBD are already collaborating and have undertaken joint activities such as an international workshop on access to information, public participation, and access to justice regarding GMOs that was held in Cologne, Germany, in May 2008.

A final and somewhat separate aspect of the Cartagena Protocol that supports the society pillar of sustainable development is Article 22, on capacity building. Similar to several other multilateral environmental agreements, the Cartagena Protocol requires Parties to cooperate in developing or strengthening human resources and institutional capacities in biosafety in developing country Parties and Parties with economies in transition.[49] According to paragraph 2 of Article 22, capacity building must be needs driven and should include scientific and technical training in the proper and safe management of biotechnology, the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety.

The Parties have adopted numerous extensive decisions on capacity building. These include an Action Plan for Building Capacities for the Effective Implementation of the Protocol, which was initially adopted at COP-MOP 1 and then revised at COP-MOP 3. Even prior to the Protocol's entry into force, the Global Environment Facility – the financial mechanism of both the CBD and the Cartagena

44 Cartagena Protocol, COP-MOP 5, Decision BS-V/13, "Public awareness, education and participation" (2010).

45 *Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters*, 25 June 1998, 38 ILM. 517 (entered into force 30 October 2001) [*Aarhus Convention*].

46 Aarhus Convention, MOP 2, Decision II/1, "Genetically modified organisms" (2005). UN Doc ECE/MP.PP/2005/2/Add.2.

47 Article 14(4) of the Aarhus Convention requires that three-quarters of the Parties to the Aarhus Convention ratify, approve, or accept the amendment in order for it to enter into force. As of 20 June 2012, there were 46 Parties to the Convention and 27 Parties (59%) to the amendment on public participation in decisions on the deliberate release into the environment and placing on the market of GMOs.

48 Dec II/1, *supra* note 46 at Annex, art 6bis(1).

49 *Cartagena Protocol*, *supra* note 1 at art 22(1).

Protocol – undertook an extensive capacity-building project for the development and implementation of national biosafety frameworks to facilitate national compliance with the Cartagena Protocol. More than 120 countries were involved in the project, which formed the basis of many of these countries' national approach to biosafety.

Economy

The Cartagena Protocol permits the inclusion of socioeconomic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity in deciding whether to allow the import of these organisms.[50] The inclusion of socioeconomic considerations in Parties' decision making must be consistent with their other international obligations.

The provision's wording reflects a compromise among the different economic interests at stake. During the negotiations, countries that were developers and exporters of LMOs were concerned that socioeconomic considerations could be used as a trade barrier by other countries to block the import of LMOs. Conversely, other countries wanted to assess whether the import of LMOs would be in their social and economic best interests before agreeing to adopt the technology. As a result, the language in paragraph 1 of Article 26 tries to balance the right of Parties to include socioeconomic considerations in decision making with their other obligations under international (trade) law.

The provision on socioeconomic considerations is one of the least elaborated aspects of the Protocol. To date, the COP-MOP has largely restricted its consideration of the issue to discussions on cooperation on research and information exchange on socioeconomic impacts of LMOs as required by paragraph 2 of Article 26. At COP-MOP 5, however, the Parties agreed to a number of activities on socioeconomic considerations in the context of capacity building.[51] These include regional online conferences and a workshop – activities to be carried out in 2011 and 2012. The Parties also included an operational objective on socioeconomic considerations in the Strategic Plan for the Protocol.[52]

The Cartagena Protocol is not unique, however, in allowing for socioeconomic considerations in decision making. Paragraph 3 of Article 5 of the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures*[53] requires WTO Members to take certain economic factors into account when assessing a risk and determining the measure to protect against the risk. The International Plant Protection Convention's International Standard for Phytosanitary Measures (ISPM)

[50] *Ibid* at art 26(1).

[51] Cartagena Protocol, COP-MOP 5, Decision BS-V/3, "Status of capacity-building activities" (2010), see, in particular, section IV of the decision, "cooperation on identification of capacity-building needs for research and information exchange on socio-economic considerations."

[52] Cartagena Protocol, COP-MOP 5, Decision BS-V/16, "Strategic plan for the Cartagena Protocol on Biosafety for the period 2011–2020" (2010), see operational objective 1.7.

[53] *Agreement on the Application of Sanitary and Phytosanitary Measures*, 15 April 1994, being part of Annex IA to the *Agreement Establishing the World Trade Organization*, 15 April 1994, 33 ILM 1144.

No. 11 on "Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms" includes provisions on the assessment of potential economic consequences as part of the pest risk assessment.[54] Furthermore, the World Organisation for Animal Health includes consideration of both biological and economic consequences in its definitions of risk and risk assessment.[55]

Although the allowance for socioeconomic considerations might be the most obvious way in which the Cartagena Protocol integrates the economic pillar of sustainable development, at least three other aspects of the Protocol demonstrate this as well: the procedure for LMOs intended for direct use as food or feed, or for processing (LMOs-FFP); the handling, transport, packaging, and identification of LMOs; and liability and redress.

Article 11 of the Protocol establishes the procedure for LMOs-FFP. It provides that a "Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House" (Article 11(1)). Annex II to the Protocol sets out the minimum information that must be provided to the BCH. Parties may then take decisions on the import of LMOs-FFP under their domestic regulatory framework that is consistent with the objective of the Protocol (Article 11(4)).

Developing country Parties and Parties with economies in transition also have the option to use the decision-making process provided for in paragraph 6 of Article 11 if they do not have a domestic regulatory framework. The process requires a Party to declare (through the BCH), prior to the first import of an LMO-FFP, that its decision will be made according to a risk assessment undertaken in accordance with Annex III of the Protocol and made within a predictable timeframe, not exceeding 270 days. To date, only two Parties – Barbados and Saint Lucia – have declared through the BCH that they will follow the process in paragraph 6 of Article 11. Paragraph 8 of Article 11 allows Parties to take precautionary decisions when faced with scientific uncertainty because of insufficient information.

The distinction between LMOs for intentional introduction into the environment and LMOs-FFP emerged only late in the Protocol's negotiation. At its core, the distinction is economic. Developers of LMOs, the shipping industry, and exporting countries did not want to hamper bulk trade in commodities (e.g., corn, canola, and soy) by onerous and lengthy decision-making processes that required a risk assessment for every import of every LMO. The procedure for LMOs-FFP is intended to

[54] See, for example, sections 2.1.1.5 and 2.3 in ISPM No. 11, "Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms" (2004).

[55] *Aquatic Animal Health Code* (2011) online: http://www.oie.int/international-standard-setting/terrestrial-code/access-online/ and *Terrestrial Animal Health Code* (2011) online: http://www.oie.int/international-standard-setting/terrestrial-code/access-online.

be "relatively speedy while allowing an importing country to exercise some degree of sovereignty and control over the regulation of imports of LMO-FFP commodities."[56] Creating a legal distinction between LMOs-FFP and LMOs for intentional introduction into the environment was not without controversy, however, because some countries argued that ensuring that LMOs-FFP would not be introduced into the environment was impossible.

One of the most difficult aspects of the Protocol both during its negotiation and following its entry into force was its provision on the handling, transport, packaging, and identification of LMOs – Article 18. Paragraph 1 of Article 18 requires each Party to "take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged, and transported under conditions of safety, taking into consideration relevant international rules and standards." Paragraph 2 of the article goes on to set more specific documentation requirements for three categories of LMOs: LMOs-FFP,[57] LMOs for contained use,[58] and LMOs for intentional introduction into the environment.[59] Finally, paragraph 3 requires the COP-MOP to "consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies." Several economic issues are bound up in this article; we shall focus on those associated with LMOs-FFP.

Paragraph 2(a) of Article 18 states that Parties are to take measures to require that documentation accompanying LMOs-FFP clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment, as well as a point of contact for further information. The paragraph also specifies that the COP-MOP is to take a decision on the detailed requirements for this purpose, including specification of the identity of the LMOs and any unique identification, no later than two years after the date of entry into force of the Protocol. This was the last issue to be resolved during the negotiation of the Protocol and agreement was possible only by punting the details of the issue to COP-MOP for them to resolve.

Although the details of the debate around documentation for LMOs-FFP are quite complex, at its most basic the issue encompasses two economic concerns: first, the current structure of the international trade in bulk commodities, and second, the desire to label genetically modified foods. To understand this, imagine the modern international trade in bulk commodities as an hourglass shape. At the very top are the farmers who grow crops on their individual farms. Their harvests are gradually aggregated through on-farm storage, grain elevators, and transportation terminals, where they are loaded onto ships, trains, or trucks, leaving the country

[56] Francois Pythoud & Urs P Thomas, "The Cartagena Protocol on Biosafety" in LePrestre, *supra* note 2 at 48.

[57] Cartagena Protocol, *supra* note 1 at art 18(2)(a).

[58] *Ibid* at art 18(2)(b).

[59] *Ibid* at art 18(2)(c).

of origin to travel to the importer country, which is the narrowest point in the hourglass. Once the goods arrive in the importing country, they are distributed to processing companies that produce and package new goods, which end up in stores for consumers – the very bottom of the hourglass – to purchase. Throughout this chain, the different consignments of the same commodity generally are considered interchangeable. The effect is that if one farmer grows genetically modified corn, for example, but his neighbour does not, the two harvests are treated the same and mixed together after they leave the farm. The system is not set up to segregate genetically modified crops from non-genetically modified crops. Part of the opposition to strict documentation requirements for LMOs-FFP was due to the added costs that would have been required to create separate streams of products.

On the other side were countries that wanted to be able to label genetically modified foods. The desire to label such foods is partly economic – facilitating consumer choice – but also goes beyond this , because consumers wanting to avoid genetically modified foods often do so for social or environmental reasons. Although foods per se are outside the scope of the Protocol, labeling them requires knowledge of the ingredients and therefore documentation to this effect must accompany the shipment of the commodity.

As described, paragraph 2(a) of Article 18 left it to COP-MOP to sort out the details of the documentation requirements for shipments of LMOs-FFP no later than two years after the date of entry into force of the Protocol, which effectively meant by COP-MOP 2. The Parties were, however, unable to reach a compromise at that meeting. The debate continued at COP-MOP 3, at which a deal was finally struck – in the form of decision BS-III/10 – after nearly 48 hours of continuous negotiations.

The text of decision BS-III/10 does include more details on the documentation to accompany LMOs-FFP. For example, documentation should clearly state "[i]n cases where the identity of the living modified organisms is known through means such as identity preservation systems, that the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing."[60] When the identity is not known, however, the documentation should clearly state "that the shipment may contain one or more living modified organisms that are intended for direct use as food or feed, or for processing."[61] Paragraph 7 of the decision states that Parties are to consider a decision at COP-MOP 6 "to ensure that documentation accompanying living modified organisms intended for direct use as food or feed, or for processing covered by paragraph 4 clearly states that the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing." At COP-MOP 5, however, the Parties noted the limited experience in the implementation of decision BS-III/10 and decided to postpone the decision

[60] Cartagena Protocol, COP-MOP 3, Dec BS-III/10 at para 4(a).
[61] *Ibid* at para 4(b).

referred to in paragraph 7 to COP-MOP 7.[62] In essence, the issue has been punted forward again.

At their most basic, questions of liability and redress concern who is responsible for damage and what they must do to remedy the problem. In the case of the Cartagena Protocol, there was insufficient time during the negotiation of the Protocol itself to elaborate the rules on liability and redress. Instead, the Protocol includes an enabling clause in Article 27 that required the Parties at their first meeting to "adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, and . . . [to] endeavour to complete this process within four years." Six years of negotiations drew to a close at the COP-MOP 5 in Nagoya with the adoption of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress. The Supplementary Protocol provides for a so-called administrative approach and its key provision is Article 5 on response measures. It largely addresses actions to be taken by operators and competent authorities to respond to damage caused by LMOs. The Supplementary Protocol also includes one provision on civil liability, namely Article 12.[63] The Supplementary Protocol was open for signature from 7 March 2011 to 6 March 2012 and will enter into force ninety days after the deposit of the fortieth instrument of ratification, acceptance, approval, or accession.

It might also be noted that six of the largest biotechnology developers – Monsanto, Syngenta, BASF, Bayer CropScience, Dow AgroSciences, and DuPont/Pioneer – have banded together to back their products financially. They have developed a private contractual compensation mechanism concerning recourse in the event of damage to biological diversity caused by LMOs – known as *the Compact* – that would provide redress (primarily remediation rather than monetary compensation) to states in cases in which the release of one of the companies' products causes damage to biodiversity.[64]

CONCLUSION

Much progress has been made in the implementation of the Cartagena Protocol, but much work remains to be done. As with all international agreements, issues and points of contention evolve. Research in the field of biotechnology is expanding. Most commercial applications of the technology are still for agricultural crops, but increasing work is being done on organisms such as insects and fish. Furthermore,

[62] Cartagena Protocol, COP-MOP 5, Dec BS-V/8, "Handling, transport, packaging and identification of living modified organisms: paragraph 2(a) of Article 18" (2010) at para 6.

[63] Cartagena Protocol, COP-MOP 5, Dec BS-V/11, "International rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms" (2010).

[64] For more details, see online: Crop Life International, http://www.croplife.org/the_compact.

countries' priorities and needs change as they gain experience with biotechnology and their associated regulatory regimes. The key is for the Protocol to remain a flexible instrument that can address new challenges as they arise. With its provisions that integrate social, economic, and environmental considerations, the Protocol is well suited to the task.

2

Implementing Sustainable Development through National Biosafety Frameworks

Christine Frison, Sylvestre-José-Tidiane Manga, and Marie-Claire Cordonier Segger

The international community is facing significant economic, social, and environmental challenges. In 1992, Agenda 21 of the Rio Conference on Environment and Development[1] emphasized the need for a coherent understanding of biodiversity, biotechnology, and sustainable development. Almost twenty years later, scholars still identify an urgent need for support to countries so that they can be helped in materializing the "ambitious prognosis in Agenda 21 of the benefits of sustainable development of biotechnology."[2] Addressing this need through the Cartagena Protocol on Biosafety (Cartagena Protocol) requires structured implementation plans, monitoring, and enforcement.

Implementing the Cartagena Protocol, taking into account the various and often conflicting environmental, social, and economic interests at stake, is not an easy task, especially for developing countries. To help Parties to pursue implementation with a sustainable development approach, the Global Environment Facility (GEF)[3] adopted an Initial Strategy on Biosafety in November

[1] Agenda 21, Report of the United Nations Conference on Environment and Development, Rio de Janeiro, 3–14 June 1992, UN Doc. A/CONF.151/26, Vols. I-III, 12 Aug 1992.

[2] Catherine Redgwell, "Biotechnology, Biodiversity and Sustainable Development," in Francesco Francioni and Tullio Scovazzi, eds, *Biotechnology and International Law* (Hart Publishing, 2006) at 78.

[3] The Global Environment Facility (GEF) unites 182 member governments – in partnership with international institutions, nongovernmental organizations, and the private sector – to address global environmental issues. As an independent financial organization, the GEF provides grants to developing countries and countries with economies in transition for projects related to biodiversity, climate change, international waters, land degradation, the ozone layer, and persistent organic pollutants. These projects benefit the global environment, linking local, national, and global environmental challenges and promoting sustainable livelihoods.

This chapter builds on the experiences of the CISDL in the development of national biosafety frameworks through the UNEP-GEF Biosafety Initiative, expanding on Martin Endicott, Christine Frison, and Kathryn Garforth with Marie-Claire Cordonier Segger, Jorge Cabrera, and Sylvestre-José-Tidiane, *Innovations in Biosafety Law: A CISDL Working Paper* (Montreal: Centre for International Sustainable Development Law, 2005). Thanks are due to Chris Briggs and the other members of the UNEP-GEF Biosafety Initiative, as well as many national stakeholders and decision makers whose sincere and courageous efforts inspired this chapter.

2000.[4] This strategy aims to assist countries preparing for the implementation of the Cartagena Protocol through the establishment of National Biosafety Frameworks (NBFs). The objectives of the GEF Initial Strategy on Biosafety Are to assist in the development of NBFs through capacity-building initiatives; to promote information sharing and collaboration, especially at the regional and subregional level; and to promote collaboration with other organizations to assist capacity building for the Protocol. Various activities have been proposed to implement these strategies, including assisting developing Parties in NBF development and implementation, supporting countries to participate in the Biosafety Clearing-House (BCH), coordinating with other organizations to provide biosafety-related assistance, and enhancing scientific and technical advice to GEF on biosafety issues.[5]

The United Nations Environment Programme (UNEP) joined the GEF to run three activities and to implement the GEF Strategy under the mandate of the UNEP-GEF Biosafety Unit. The UNEP-GEF Biosafety Unit Projects aim to implement the strategy by assisting countries in establishing their NBFs; promoting information sharing and collaboration, especially at the regional and subregional level; and promoting collaboration with other organizations to assist capacity building for the Protocol. These activities include assisting 123 countries to develop their own NBFs, to implement those NBFs in some cases, and to allow 139 countries to participate in and benefit from the BCH. As of July 2009, 111 countries had completed their draft NBFs, 8 countries had completed the implementation of their NBFs, 11 countries began the implementation phase, and 122 countries are currently setting up their participation in the BCH.[6]

The Centre for International Sustainable Development Law (CISDL) partnered with the UNEP-GEF on the Development of National Biosafety Frameworks project. This global project was designed to help countries comply with the Cartagena Protocol and aims to enable countries to make technical, political, and administrative decisions on the safe transfer, handling, and use of living modified organisms (LMOs), and to meet the requirements of the Cartagena Protocol.

Indeed, legal and regulatory structures are required to implement the Cartagena Protocol. NBFs seek to build and implement an effective normative structure at a national level for research and trade in products containing LMOs. Although NBFs vary from country to country, they contain several common components. These include a government policy on biosafety, which is usually part of a broader policy such as policy on biotechnology in general, agricultural production, health care, or environmental protection; a regulatory regime for biosafety, which often is a combination of an act or decree, complemented by implementing technical regulations and guidelines; and a system to handle notifications or requests

[4] GEF Council, *Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety*, November 1–3, 2000, UN Doc. GEF/C.16/4/Rev.1, online: http://www.unep.org/biosafety/Documents/GEF_strategy.pdf.

[5] *Ibid* at paras 20–21.

[6] See UNEP, "About Biosafety Unit," online: http://www.unep.org/biosafety/About.aspx.

for authorizations for certain activities, such as releases of GMOs into the environment. Such systems typically include administrative functions, risk assessment, decision making, and public participation; and systems for follow-up, such as enforcement and monitoring for environmental effects. *Monitoring* is a term used for evaluating actual impacts on the environment and human health, whereas *enforcement* typically focuses on compliance with the regulatory regime and approaches for public information and public participation, that is, informing and involving stakeholders in the development and implementation of the national biosafety framework.[7]

CISDL participated closely in the preparatory phase of the project by contributing to the design of the technical material proposed to contracting parties to help in implementing the Protocol. This technical material, designed as a toolkit for countries, contained three phases, titled the Biosafety Project:

Phase 0 – Starting the project
Phase 1 – Taking stock
Phase 2 – Consultation and analysis
Phase 3 – Drafting the NBF
    Part I: Formulation of the regulatory regime
    Part II: Designing the administrative systems for handling applications and notification

The aim of the toolkit is to provide a practical "how-to" guide for countries to assist them in developing and implementing NBFs, in particular new regulatory regimes. CISDL assisted more than thirty developing countries participating in the UNEP-GEF project, including in Francophone Africa, Latin America, Asia, and the Middle East, by providing an independent, technical, and legal review of the draft NBFs, and in many cases, draft legislation. The first part of this chapter discusses best practices and lessons learned in the design and implementation of NBFs. The second part comments on principal challenges faced by many of the Parties, taking into consideration the basic requirements of the provisions of the Cartagena Protocol. This commentary includes a section examining aspects of the biosafety partnership and a section on the commercial, sanitary, and phytosanitary aspects of emerging national frameworks on biosafety from a global perspective.

THE UNEP-GEF BIOSAFETY PROJECT

The UNEP-GEF Biosafety Project has supported developing countries in designing NBFs since 2001. This support to developing countries was a priority for the Parties

[7] UNEP-GEF Biosafety Unit, *Biosafety Project: Phase 3 – Drafting the NBF – Part I: Formulation of the regulatory regime* at 56–7, online: http://www.unep.org/biosafety/Toolkit.aspx. See Annex I to this book for a figure on the components of a National Biosafety Framework (NBF) [Biosafety Toolkit – Phase 3 – Part I].