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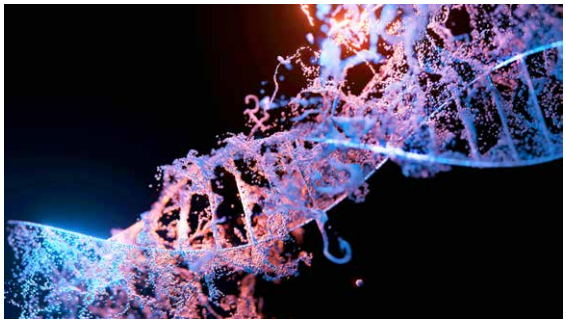

Legislative Study on Biosafety Mainstreaming

Integrating the Cartagena Protocol on Biosafety into National Sectoral and Cross-Sectoral Policies, Laws and Institutional Frameworks

Convention on
Biological Diversity

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CBD BIOSAFETY TECHNICAL SERIES 06

Legislative Study on Biosafety Mainstreaming

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Foreword

The Convention on Biological Diversity addresses biosafety in various provisions and provided the basis for the negotiations on the Cartagena Protocol. The Protocol is an international agreement dedicated to biosafety which aims towards ensuring the safe handling, transport and use of living modified organisms, considering risks to human health.

The importance of biosafety for the conservation and sustainable use of biological diversity has been recognized in the Kunming-Montreal Global Biodiversity Framework through the inclusion of Target 17 on biosafety and biotechnology.

In adopting the Implementation Plan for the Cartagena Protocol on Biosafety in 2022, Parties to the Protocol recognized the complementarity of the Plan to the Kunming-Montreal Global Biodiversity Framework and its potential to contribute to achieving the goals and targets of the Global Biodiversity Framework relevant to biosafety.

The inclusion of biosafety in the Framework offers an opportunity to strengthen concerted efforts under the Convention and the Protocol to implement effective biosafety measures. These efforts would benefit from the integration of biosafety concerns into policies, laws, decision-making processes and management practices of relevant production sectors. Under Target 14 of the Framework, this need is recognized through the call for the full integration of biodiversity and its multiple values into policies, regulations, planning and development processes across all levels of government and across all sectors. The food and agriculture sectors, where biotechnologies are widely applied, deserve special attention in this regard.

Agricultural biodiversity provides humans with food, raw materials, incomes and livelihoods. Moreover, agricultural biodiversity performs ecosystem services such as soil and water conservation, maintenance of soil fertility and biota, and pollination – all of which are essential to human life.

Living modified organisms are widely used in the food and agriculture sectors. While they provide opportunities for those sectors, including for food security, their use and release require regulation, management and control of potential associated risks to biodiversity.

The present study undertakes an analysis of how several Parties to the Cartagena Protocol have mainstreamed biosafety into cross-sectoral and sectoral legislation, policies and institutional frameworks, focusing especially on instruments and institutions relevant to the food and agriculture sectors. The examples presented showcase the progress made by Parties towards achieving the mainstreaming objectives under the Implementation Plan for the Cartagena Protocol and ensuring the synergetic and coordinated implementation of the Cartagena Protocol and the Convention on Biological Diversity, thereby contributing to the conservation and sustainable use of biological diversity. The lessons learned from these experiences will help other Parties in their efforts towards attaining the full implementation of the Cartagena Protocol

and achieving the Implementation Plan, including its mainstreaming elements, as well as Target 14 of the Kunming-Montreal Global Biodiversity Framework.

From 2016 to 2020, the Government of Japan, through the Japan Biodiversity Fund, has actively supported Parties in their biosafety mainstreaming efforts through activities at the national, regional and global levels. The best practices and lessons learned that were documented in that context have now been incorporated in this practical guide. It is intended to assist legislators and policymakers in finding practical ways to mainstream biosafety into legislation, policies and institutional frameworks relevant to the food and agriculture sectors and represents a critical addition to the suite of tools previously developed to support Parties to the Protocol in their mainstreaming efforts.

The present study contains several examples, among many others, of how Parties have mainstreamed biosafety into their national biodiversity strategies and action plans. These examples will help to guide Parties in their efforts to revise those strategies and action plans so as to align them with the goals and targets under the Kunming-Montreal Global Biodiversity Framework, including Target 17 on biosafety and biotechnology.

The study has been prepared in collaboration with the Food and Agriculture Organization of the United Nations (FAO) and the Montevideo Programme on Environmental Law under the United Nations Environment Programme (UNEP) as a pendant to a publication on biodiversity mainstreaming in law.

The publication of the present study coincides with the start of a collaborative project between the FAO Development Law Service, the Montevideo Programme on Environmental Law and the Secretariat of the Convention on Biological Diversity through which several Parties to the Cartagena Protocol will be supported in the strengthening of their biosafety legislation.

I would like to thank the Government of the Kingdom of the Netherlands and the Government of Japan, through the Japan Biodiversity Fund, for their generous support for the mainstreaming project and this publication. Moreover, I would like to express my gratitude to the Parties that were actively engaged in the project and shared their experiences. I wish to thank Miranda Geelhoed, who was involved in the work on biosafety mainstreaming as a member of the team at the University of Strathclyde and put together the present study. Finally, I would like to thank the Secretariat staff who were involved in the development of the present study, as well as colleagues from FAO and UNEP, who provided comments on the drafts of the publication.

Astrid Schomaker:
Executive Secretary,
Convention on Biological Diversity

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Abbreviations

FAO	Food and Agriculture Organization of the United Nations
GMO	genetically modified organism
LMO	living modified organism
OECD	Organisation for Economic Co-operation and Development

1. Executive summary

The present legislative study on the mainstreaming of biosafety was commissioned by the Secretariat of the Convention on Biological Diversity.[1] In the present study, the term "biosafety mainstreaming" refers to the integration of biosafety in domestic cross-sectoral and sectoral legislation, policies and institutional frameworks, taking into account national circumstances and priorities. Through in-depth analysis of international and national laws and policies and domestic examples of biosafety mainstreaming, the study provides a comprehensive overview of biosafety obligations and the practical ways in which biosafety measures can be mainstreamed into the national laws, policies and institutional frameworks of the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity,[2] the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety[3] and the Convention on Biological Diversity. This legislative study aims at assisting Parties in achieving the integrated implementation of the Cartagena Protocol. Its target audience may include both those engaged, at the national level, in the development and implementation of biosafety-related legislation, and those engaged in the development and implementation of cross-sectoral and sectoral policies and laws that are indirectly relevant to biosafety.

Living modified organisms (LMOs) are defined in section 3 of the present study, with a specific focus on their relevance for food and in agriculture,. Taking into account the potential benefits of LMOs for the food and agriculture sectors, the study considers the importance of biosafety in providing protection against their potential risks, notably for the environment and human health. In section 4 the topic of biosafety is placed in an international legal context through the outlining of provisions of the Convention on Biological Diversity that relate directly to LMOs and biosafety and key legal obligations and procedures under the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol. Also in section 4, brief consideration is given to the relevance of other international instruments for biosafety, notably international trade law.

In sections 5 and 6, the case is made for biosafety mainstreaming. In section 5 the reasons why countries would mainstream biosafety are discussed. First, biosafety mainstreaming may help to ensure synergies between and within national and international frameworks, including the Convention on Biological Diversity and the Kunming-Montreal Global Biodiversity Framework.[4] Second, biosafety

1 United Nations, *Treaty Series*, vol. 1760, No. 30619. The Convention on Biologicl Diversity was adopted on 22 May 1992 and entered into force on 29 December 1993)

2 Ibid., vol. 2226, No. 30619. The Cartagena Protocol was adopted on 29 January 2000 and entered into force on 11 September 2003

3 Ibid., vol. 3240, No. 30619. The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety is contained in the annex to decision BS-V/17 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol of 15 October 2010, The Supplementary Protocol was adopted on 15 October 2010 and entered into force on 5 March 2018.

4 Annex to decision 15/4 of the Conference of the Parties to the Convention on Biological Diversity.

mainstreaming may help to facilitate the establishment, development and strengthening of effective national biosafety frameworks. Furthermore, biosafety mainstreaming may help in implementing the Convention and the Cartagena Protocol in a more resource-efficient manner, for example, through sharing of expertise and resources.

In section 6, the key steps towards mainstreaming biosafety at the domestic level are outlined. Those steps include formulation of a mainstreaming vision; identification of entry points, opportunities and activities for mainstreaming; engagement of authorities and stakeholders; identification of non-legislative tools; and creation of an enabling environment for biosafety mainstreaming. In subsections 6.2–6.4, the question of how biosafety can be mainstreamed into cross-sectoral and sectoral policies, legislation and legal institutional frameworks is considered. A multitude of examples of biosafety mainstreaming at the national level are presented, including example provisions, with the aim of illustrating how biosafety may be mainstreamed in domestic contexts and helping readers to identify opportunities for mainstreaming at the national level. Further examples of mainstreaming of biosafety into policies, legislation and institutional frameworks are included in annex III to the present study, entitled "Overview policy and legislative examples of biosafety mainstreaming".

This legislative study builds on the work previously undertaken on biosafety mainstreaming by the Secretariat of the Convention on Biological Diversity and 19 countries that were part of the pilot project on integrated implementation and mainstreaming of biosafety (2015–2016) and the project on integrated implementation of the Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress and the Convention on Biological Diversity (2017–2018). While the national desk studies that were drafted by those countries provided the foundations for the identification of key examples of biosafety mainstreaming at the national level, the present analysis was complemented by in-depth examination of the texts of laws and policies and review of the literature and enhanced through identification of other and more recent examples associated with the 19 pilot countries through the FAOLEX database. Parts of the present study also built upon information that is included in the modules on biosafety mainstreaming which are available on the Biodiversity e-Learning Platform.[5] <

5 See https://scbd.unssc.org/course/index.php?categoryid=14>.

2. Objectives and methodology

In the present study, as noted above, the term "biosafety mainstreaming" refers to the inclusion of biosafety in domestic cross-sectoral and sectoral policies, legislation and institutional frameworks. This legislative study on biosafety mainstreaming was drafted for the Secretariat of the Convention on Biological Diversity. It introduces the concept of mainstreaming in legislation, policy and institutions and outlines the international legal framework for biosafety mainstreaming.

The study analyses how countries have mainstreamed biosafety into domestic cross-sectoral and sectoral policies, legislation and institutional frameworks and provides example clauses in this regard. The study was developed with feedback from the Food and Agriculture Organization of the United Nations (FAO) Development Law Service, the United Nations Environment Programme (UNEP) Montevideo Programme on Environmental Law and the Secretariat of the Convention on Biological Diversity. Parties to the Cartagena Protocol provided input to the development of examples based on their national legislation and policies. Where appropriate, specific consideration has been given to mainstreaming biosafety in the context of food and agricultural policy and legislation. Section 6 of the present study includes more information about the types of legislation and policies relevant to biosafety mainstreaming, including, notably, primary and secondary legislation, policies, strategies, programmes and plans and legal institutional frameworks that set out biosafety-related institutional mandates.

2.1. Objectives and target audience

The purpose of this practical legislative study is to assist Parties with the integrated implementation of the Cartagena Protocol. Improved implementation of the Protocol may help to support Parties in achieving the Sustainable Development Goals, for example, in relation to food security and sustainable agriculture.[6] Mainstreaming biosafety is relevant not only for Parties to the Cartagena Protocol on Biosafety but also to Parties to the Convention on Biological Diversity, with respect to facilitating the implementation of the biosafety-related obligations in the Convention and to give effect to the international commitments on biosafety and biotechnology reflected in the Kunming-Montreal Global Biodiversity Framework (in particular under Target 17). While the study strives to speak most notably to those involved, at the national level, in the development and implementation of biosafety-related legislation, it may also benefit those involved in the development and implementation of cross-sectoral and sectoral policies and laws that are indirectly relevant to biosafety. The present study seeks to be accessible to Parties at different stages of implementation of international regulatory requirements on biosafety. It contains a wide variety of examples of biosafety mainstreaming at the national level, which showcase implementation of biosafety

6 See, for example, decision CP-10/3 of 19 December 2022 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, entitled "Implementation Plan for the Cartagena Protocol on Biosafety", annex, paras. 4–5. See also sect. 5.2.1 below.

obligations or enhancement of national biosafety frameworks through mainstreaming. Countries may use the present study and the examples provided to inform the development of a national vision for biosafety mainstreaming, while taking into consideration their specific national circumstances and needs.

2.2. Relation to previous work undertaken on biosafety mainstreaming

The present study builds on the work previously undertaken under the pilot project on integrated implementation and mainstreaming biosafety (2015-2016) and the project on integrated implementation of the Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress and the Convention on Biological Diversity (2017-2018). Both projects were implemented by the Secretariat of the Convention on Biological Diversity with generous support from the Government of Japan through the Japan Biodiversity Fund.

The pilot project involved nine Parties to the Cartagena Protocol on Biosafety. Those Parties drafted desk studies in which the extent to which biosafety had been integrated into existing national policies and laws, as well as institutional structures, was analysed. Where information was available, the processes that had led to the successful mainstreaming of biosafety in these instruments and institutions were described in the studies. Each desk study was presented at a national round-table meeting where stakeholders from different sectors provided input. The final desk study was presented at a national awareness building seminar which targeted decision makers and politicians. Representatives of the Parties involved in the pilot project shared their experiences at a global workshop held in Chisinau, Republic of Moldova, in October 2016. The subsequent integrated implementation project involved 10 Parties to the Cartagena Protocol. Those Parties analysed the extent to which biosafety was integrated into existing national policies, legislation and institutional structures and identified opportunities for further strengthening of mainstreaming efforts. The draft desk studies were presented at national seminars.[7]

The projects funded by the Japan Biodiversity Fund involved the development of a synthesis report and three online learning modules for biosafety mainstreaming. The Strathclyde Centre for Environmental Law and Governance was commissioned by the Secretariat of the Convention on Biological Diversity to undertake the project. The online modules, which were developed by Elisa Morgera, Miranda Geelhoed and Elsa Tsioumani, comprise:

- The synthesis report on the national desk studies developed in the pilot phase of the Project[8]
- Module: Introduction to mainstreaming biosafety[9]
- Toolkit: Practical guidance for mainstreaming biosafety[10]
- Application: Develop a strategy for biosafety mainstreaming[11]

2.3. Methodology and case studies

The present study has been developed on the basis of independent analysis of primary and secondary sources related to biosafety, biosafety mainstreaming, international law and the implementation of biosafety-related obligations in national frameworks. Sections 3 to 5 on living modified organisms, biosafety mainstreaming and international legal frameworks benefited from previous research conducted for the development of the online learning modules

7 For more information on the pilot project and the integrated implementation project, see Convention on Biological Diversity, "Mainstreaming biosafety: activities and resources", available at https://bch.cbd.int/protocol/issues/mainstreaming_activities.shtm (accessed on 28 June 2024).

8 Miranda Geelhoed, Elisa Morgera and Elsa Tsioumani, "Capacity-building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level", Synthesis report – National Desk Studies (Strathclyde Centre for Environmental Law and Governance, 13 March 2017).

9 See Convention on Biological Diversity, "Biodiversity e-Learning Platform: Biosafety/mainstreaming biosafety" (2018), available at https://scbd.unssc.org/course/index.php?categoryid=14 (accessed on 28 June 2024). The online learning modules are freely available (after registration).

10 Ibid.

11 Ibid.

for biosafety mainstreaming. In section 6, further, in-depth analysis was provided of the final national desk studies developed by the 19 Parties that were involved in the pilot project (Belarus, Burkina Faso, China, Ecuador, Malawi, Malaysia, Mexico, Republic of Moldova and Uganda) and integrated implementation project (Cambodia, Cameroon, Cuba, Ghana, Mongolia, Nigeria, Peru, Togo, Venezuela (Bolivarian Republic of) and Viet Nam) in 2015-2018.

Where examples of mainstreaming were described in the national desk studies, the author of the present study identified and analysed the texts of relevant policies and legislation, including in relation to institutional frameworks. That research was complemented by general searches for updates on the implementation of biosafety legislation and biosafety mainstreaming in the 19 Parties and targeted keyword searches in the FAO legislative and policy database (FAOLEX)[12] with a view to identifying examples of biosafety mainstreaming in cross-sectoral and sectoral instruments after 2016 and 2018, respectively. A great number of examples of biosafety mainstreaming and key enabling and supportive tools for biosafety mainstreaming were identified through this research, more than 50 of which have been included in the present study. The examples are included for their value in showcasing different ways in which biosafety can be mainstreamed. The national examples are not intended to provide a comprehensive overview of the regulation of biosafety and biosafety mainstreaming in each country. While some examples may reflect historic rather than current biosafety policies, they have been included for their technical value. Parties were given the opportunity to contribute to the case studies.

Each example consists of a descriptive segment and the relevant provision in the national legislation or policy. Provisions in English, French or Spanish are presented in the original language, with a link to the official English translation, if available. Where the text of the provision is provided in French or Spanish, an explanation is provided in English in the descriptive segment of the example. Examples in languages other than Spanish or French are provided in English, unless an English translation from an official source was not available.

12 FAO, FAOLEX database, available at www.fao.org/faolex/en/ (accessed on 28 June 2024).

3. Living modified organisms, their potential benefits and risks

The main international legal instrument for the regulation of biosafety is the Cartagena Protocol on Biosafety. Biosafety, as regulated under the Cartagena Protocol, encompasses the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology.[13] Such organisms have potential for human well-being but only if they are developed and used with adequate safety measures for the environment and human health in place, given the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity and the risks to human health.[14] .

The present section provides a brief explanation of what LMOs are and how they are used, including in the food and agriculture sectors, and a description of how biosafety addresses potential risks posed by these organisms.

3.1. Introduction to the subject of living modified organisms

Biosafety is concerned with the risks posed by certain organisms that have been genetically modified to create a novel combination of genetic material. Such organisms are referred to as living modified organisms (LMOs). Under the Protocol, biosafety refers to the protection of biological diversity from the possible adverse effects of LMOs, taking also into account risks to human health.

3.1.1. What are living modified organisms?

A living modified organism is defined under the Cartagena Protocol as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology".[15] Under the Protocol, a living organism is defined as "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids".[16]

In the context of the Protocol, genetic material has been interpreted as referring specifically to nucleic acids of plant, animal, microbial or other origin that contain genetic information.[17] This understanding of genetic material is compatible with but narrower than the definition given in Article 2 of the Convention on Biological Diversity. A novel combination of genetic material can thus be understood as a novel combination of nucleic acids containing functional units of heredity. Novel combinations may arise from introduction of genetic material from a different species

13 Cartagena Protocol, Article 1. See also sect. 4.1 below on how biosafety is understood under the Convention on Biological Diversity.
14 For the potential benefits and risks of modern biotechnologies, see the preamble to the Cartagena Protocol.
15 Cartagena Protocol, Article 3 (g).
16 Ibid., Article 3 (h).
17 Ruth Mackenzie and others, *An Explanatory Guide to the Cartagena Protocol on Biosafety* (Gland, Switzerland, IUCN, 2003), p. 43, para. 199.

or potentially from rearrangement of genetic material from the same species.[18]

The novel combination of genetic material must be obtained through the use of modern biotechnology, which is defined in the Protocol as the application of "in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or 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".[19] Recombinant DNA techniques have for a long time been the most commonly used form of modern biotechnology. They are based on techniques developed in the 1970s that allow for isolation and reorganization of individual genes and the introduction of genes into cells of another organism.[20] Use of recombinant DNA involves the selection of a donor plant or animal organism, or microorganism, with a desirable characteristic. One or more genes within the organism, which are responsible for the particular trait, are identified and extracted. Copies are made of the isolated gene or genes, which are then combined with other pieces of DNA to control expression within the recipient organism. These assemblies of pieces of DNA are called gene constructs or cassettes. The gene construct is inserted into the recipient organism. The selection of LMOs that have incorporated the desirable characteristics of the donor organism is the last step before further application.[21]

Following the adoption of the Cartagena Protocol, new biotechnology techniques started to emerge within the field of synthetic biology, which applies engineering principles in the context of biology.[22] Both DNA techniques and synthetic biology techniques are "based on common enabling technologies and involve the assembly of DNA sequences that are based on/are analogous to existing genetic material, and involve the transfer of genetic material into an existing living recipient cell/host".[23] Various genome editing tools linked to synthetic biology are being developed which use nucleases to bind to DNA sequences in a sequence-specific manner to introduce specific modifications into the genome. These tools often utilize CRISPR (clustered regularly interspaced short palindromic repeats).[24] Use of such genome editing technologies is held to be more precise and cost-effective than use of other modern biotechnologies.[25] A topic that has been of specific interest to the Conference of the Parties to the Convention on Biological Diversity and the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol is the possibility of using synthetic biology to create "engineered gene drive" systems, that is to say, systems that bias the inheritance of a particular DNA sequence.[26] They are intended for use in wild populations to "spread traits aimed at the suppression or extirpation of populations of disease vectors"[27] or to control or eradicate invasive species.[28] While applications may support human health, environmental and agricultural objectives. it has been recognized within the context of the Convention and the Protocol that there could be potential unintended adverse consequences.[29]

3.1.2. How are living modified organisms used for food and in agriculture?

Modern biotechnologies date back to the 1970s, when a series of experiments led to the production of the first molecules of recombinant DNA and the first

18 Ibid., p. 45.

19 Cartagena Protocol on Biosafety, Article 3 (i).

20 Convention on Biological Diversity, "Biodiversity e-Learning Platform: Biosafety/mainstreaming biosafety", Introduction to mainstreaming biosafety module (2018), available at https://scbd.unssc.org/course/index.php?categoryid=14 (accessed on 28 June 2024).

21 On the staged process of LMO development, see the e-learning module "Introduction to mainstreaming biosafety"; see also Mackenzie and others, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, pp. 48–49.

22 Felicity Keiper and Ana Atanassova, "Regulation of synthetic biology: developments under the Convention on Biological Diversity and Its Protocols", *Frontiers in Bioengineering and Biotechnology*, vol. 8, No. 310 (April 2020), p. 5.

23 Ibid., p. 6.

24 W. Craig, R. Sara and F. Moronta-Barrios, *Synthetic Biology*, CBD Technical Series, No. 100 (Montreal, Canada, Secretariat of the Convention on Biological Diversity,, April 2022).

25 Keiper and Atanassova, "Regulation of synthetic biology", p. 7.

26 The Royal Society, "Gene drive research: why it matters" (London, November 2018), p. 3.

27 Conference of the Parties to the Convention on Biological Diversity, "Potential positive and negative impacts of components, organisms and products resulting from synthetic biology techniques on the conservation and sustainable use of biodiversity, and associated social, economic and cultural considerations", note by the Executive Secretary (UNEP/CBD/COP/12/INF/11), 24 September 2014, p. 6.

28 The Royal Society, "Gene drive research", p. 5.

29 Craig, Sara and Moronta-Barrios, *Synthetic Biology*.

Photo by Trisha Downing on Unsplash

genetically engineered bacteria.[30] The techniques were used for the development of pharmaceuticals for humans, notably insulin initially.[31]The trialling of industrial applications in the agricultural sector began in the 1980s and continued into the 1990s, notably in relation to genetically modified plants.[32] Through genetic modification, pest- and herbicide-resistant traits have been introduced into a variety of plants used as key agricultural crops. LMOs can make their own pest-resistance proteins. The first pest-resistance gene to be isolated and inserted into a crop came from *Bacillus thuringiensis* (Bt), a soil bacterium,.[33] Examples of herbicide-resistant crops include Roundup Ready LMOs, notably Roundup Ready soybeans, which contain a form of the plant enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), a gene isolated from a strain of a common soil bacterium, which allows the soybeans to survive an otherwise lethal application of glyphosate, the active ingredient in the herbicide Roundup.[34] Distinctions have been made between crops with enhanced input traits (e.g. herbicide tolerance and resistance to droughts, pests and diseases), crops with enhanced output traits (e.g. better micronutrient availabilities) and crops for non-traditional uses (e.g. production of pharmaceuticals or biofuels).[35] Industrial adoption has been limited mostly to crops in the first category.[36] For example, commercial applications in the arable and vegetable sectors include

30 Kathryn Garforth, Worku Damena Yifru and Mai Fujii, "Biosafety, the Cartagena Protocol, and sustainable development", in *Legal Aspects of Implementing the Cartagena Protocol on Biosafety*, Marie-Claire Cordonier Segger, Frederic Perron-Welch and Christine Frison, eds. (Cambridge, United Kingdom, Cambridge University Press 2013), p. 20.

31 Brooke Glass-O'Shea, "The history and future of genetically modified crops: frankenfoods, superweeds, and the developing world", *Journal of Food Law and Policy*,, vol. 7, No. 1 (2011), p. 8.

32 Garforth, Yifru and Fujii, "Biosafety, the Cartagena Protocol, and sustainable development", p. 20.

33 Glass-O'Shea, "The history and future of genetically modified crops", p. 9.

34 See UN Environment and Convention on Biological Diversity, Biosafety Clearing-House, "Living modified organism identity: Roundup Ready™ soybean". Available at https://bch.cbd.int/en/database/14796 (accessed on 10 October 2023).

35 Organisation for Economic Co-operation and Development (OECD), *Concentration in Seed Markets: Potential Effects and Policy Responses* (Paris, 2018), p. 29.

36 Ibid.

drought-tolerant LMOs (e.g. maize),[37] and disease-resistant LMOs (e.g. cotton and potatoes).[38]

The global market for living modified crops was valued at $21.08 billion in 2022 and this figure is expected to increase to $28.03 billion in 2027.[39] In 2015, LM crops were grown in 28 countries and on 179.7 million hectares, representing over 10 per cent of the world's arable land.[40] The main LM crops globally are soybeans (94 million hectares (ha) in 2017), maize (60 million ha in 2017) and cotton (24 million ha in 2017).[41] In 2017, the countries with the largest area of land under LMO cultivation were the United States of America (75 million ha, or 40 per cent of the global total), Brazil (50 million ha, or 26 per cent of the global total) and Argentina (24 million ha, or 12 per cent of the global total).[42]

While the dominant application of modern biotechnologies within the context of agriculture and food production is in the production of crop plants with novel combinations of genetic material, other applications are being developed. These include the engineering of bacteria, fungi insects, and viruses, mostly for the control of insect pests or diseases,[43] as well as the genetic modification of microorganisms such as growth-promoting rhizobacteria, which act as biofertilizers.[44] Furthermore, modern biotechniques can be used to introduce novel combinations of genetic material in animals, including livestock and fish. Some regional institutions have developed specific guidance for the risk assessment of LM animals.[45] The AquAdvantage Salmon developed by AquaBounty Technologies was the first genetically engineered animal approved for human consumption in the United States and Canada,[46] and, more recently, GalSafe pigs, which produce meat that is safe for consumption for people with certain allergies, were approved in the United States.[47]

3.2. Biosafety: managing (potential) risks to biodiversity and human health

The objective of the Cartagena Protocol on Biosafety 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".[48] "[i]n accordance with the precaution-

37 Eric Adee and others, "Drought-tolerant corn hybrids yield more in drought-stressed environments with no penalty in non-stressed environments", *Frontiers in Plant Science*, vol. 7, No. 17 (12 October 2016). The authors reference the application of DroughtGard technology in maize, which introduces a transgenic trait for greater drought tolerance.

38 U.S. Food and Drug Administration, "GMO crops, animal food, and beyond" (03/05/2024). Available at www.fda.gov/food/agricultural-biotechnology/gmo-crops-animal-food-and-beyond (accessed on 10 October 2023).

39 See The Business Research Company, *Genetically Modified Crops Global Markets Report 2023* (Boston, Massachusetts, 2023).

40 The Royal Society, "What GM crops are currently being grown and where?" (2016). Available at https://royalsociety.org/topics-policy/projects/gm-plants/what-gm-crops-are-currently-being-grown-and-where/#:~:text=The%20GM%20crops%20grown%20commercially,and%20cotton%20(15%20countries (accessed on 10 October 2023).

41 OECD, *Concentration in Seed Markets*, p. 28.

42 Ibid.

43 K.E. Hokanson and others, "Not all GMOs are crop plants: non-plant GMO applications in agriculture",*Transgenic Research*, vol. 23, No. 6 ((17 November 2013), pp. 1057-1068.

44 See, for example, Bio-FIT, "Nanofertilizers: genetically engineered microbes as biofertilizers – genetically modified bacteria for agricultural purposes" (2015). Available at www.bio-fit.eu/q7/lo4-nano-fertilizers-and-genetically-engineered-microbes?start=1 (accessed on 10 October 2023).

45 See, for example, European Food Safety Authority, *Guidance on the Environmental Risk Assessment of Genetically Modified Animals*, *EFSA Journal*, vol. 11, No. 5 (Parma, Italy, 2013). See also Antonella Ingrassia, Daniele Manzella and Elzbieta Martyniuk, *The Legal Framework for the Management of Animal Genetic Resources*, FAO Legislative Study, No. 89 (Rome, Food and Agriculture Organization of the United Nations (FAO), 2005), pp. 14-16, on the application of the Cartagena Protocol on Biosafety in the context of the management of LM animals.

46 Convention on Biological Diversity, Biosafety Clearing-House, "Living modified organism identity: AquAdvantage® Salmon" (13 March 2013). Available at https://bch.cbd.int/en/database/record?documentID=104725 (accessed on 10 October 2023).

47 Convention on Biological Diversity, Biosafety Clearing-House, "Living modified organism identity: GalSafe® pig" (,2023). Available at https://bch.cbd.int/en/database/record?documentID=263132 (accessed on 10 October 2023); U.S. Food and Drug Administration, "FDA approves first-of-its-kind intentional genomic alteration in line of domestic pigs for both human food, potential therapeutic uses: alteration intended to eliminate alpha-gal sugar on surface of pigs' cells" (2020). Available at www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-intentional-genomic-alteration-line-domestic-pigs-both-human-food (accessed on 28 June 2024).

48 Cartagena Protocol, Article 1.

ary approach contained in Principle 15 of the Rio Declaration on Environment and Development".[49] The Protocol recognizes the potential of modern biotechnology for human well-being, as well as the need for adequate safety measures for the environment and human health.[50] The debate on the benefits and risks of modern biotechnology continues to this day.

While the Cartagena Protocol is dedicated specifically to biosafety, the Convention on Biological Diversity does contain some provisions relating to biosafety. The Convention requires Parties, as far as possible and as appropriate, to "establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health".[51] Risks of LMOs are case-specific and depend on a variety of factors including the type of LMO, the intended use of the LMO and the specifics of the receiving environment. The Cartagena Protocol contains provisions on risk assessment and risk management as well as an annex dedicated to risk assessment.[52] Furthermore, guidance on risk assessment of LMOs sheds light on some of the environmental risks involved, as risk assessment involves the identification of potential adverse effects.[53]

49 Ibid.
50 Cartagena Protocol, Preamble.
51 Convention on Biological Diversity, Article 8 (g).
52 Cartagena Protocol, annex III.
53 "Guidance on risk assessment of living modified organisms" (30 July 2012) (UNEP/CBD/BS/COP-MOP/6/13/Add.1), p. 14. See also "Guidance on risk assessment of living modified organisms and monitoring in the context of risk assessment" (14 December 2016) (UNEP/CBD/BS/COP-MOP/8/8/Add.1), p. 27.

4. International law on biosafety

At the time of the opening for signature of the Convention on Biological Diversity, during the United Nations Conference on Environment and Development, held in June 1992, Agenda 21, a programme of action for sustainable development, was adopted by 178 Governments.[54] One chapter of Agenda 21 was devoted to the "environmentally sound management of biotechnology".[55] In that chapter, the potential of biotechnology for contributing to a number of objectives across sectors was considered, including better health care, enhanced food security through sustainable agricultural practice, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes.[56] Moreover, in Agenda 21, the need was identified to ensure safety in biotechnology development, application, exchange and transfer, particularly in relation to health and environmental considerations, to be achieved through close international cooperation.[57]

LMOs may be subject to trade and transboundary movement, while environmental and health impacts of LMOs may transcend national borders or exert an impact on conservation of biological diversity or plant genetic resources for food and agriculture. International law on biosafety has been developed primarily in the context of the Convention on Biological Diversity, notably under the Cartagena Protocol on Biosafety (173 Parties[58]), which focuses specifically on transboundary movement of LMOs, and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (54 Parties[59]).

The present section on international law relevant to biosafety outlines the provisions of the Convention that relate directly to LMOs and biosafety and the key legal obligations and procedures under the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol. The relevance of other international instruments for biosafety, in particular international instruments in the field of trade law and food safety standards, is also briefly considered in this section.

While the focus of this section is on biosafety instruments and provisions that have been developed in the context of the international legal framework on biodiversity, it is worth noting that there are other international instruments that are relevant to biosafety.

54 *Report of the United Nations Conference on Environment and Development, Rio de Janeiro, 3–14 June 1992*, vol. I, *Resolutions Adopted by the Conference* (United Nations publication, Sales No. E.93.I.8 and corrigendum), resolution 1, annex II.

55 Agenda 21, chap. 16. See also in this regard Garforth, Yifru and Fujii, "Biosafety, the Cartagena Protocol, and sustainable development", p. 21

56 Agenda 21, para. 16.1.

57 Ibid., paras. 16.29–16.31.

58 Number of Parties at the time of writing. Up-to-date information is available at https://bch.cbd.int/protocol (accessed on 28 June 2024).

59 Number of Parties at the time of writing. Up-to-date information is available at https://bch.cbd.int/protocol/supplementary (accessed on 28 June 2024).

In particular, biosafety is an issue that is often perceived as being at the nexus of environmental and trade law. Furthermore, certain human rights and environmental agreements are relevant to aspects of biosafety.

4.1. Convention on Biological Diversity

The Convention on Biological Diversity was adopted in 1992. Its objectives are:[60]

- The conservation of biological diversity
- The sustainable use of its components
- The fair and equitable sharing of the benefits arising out of the utilization of genetic resources

The Convention contains three provisions that relate directly to LMOS. Article 8 (g) requires Parties, as far as possible and as appropriate, to:

> "*Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.*"

Transfers of LMOs between Parties to the Convention are regulated under Article 19 (4), which includes an obligation to provide information by stipulating that:

> "*Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above,*[61] *provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.*"

Articles 8 (g) and 19 (4) thus lay out international obligations in relation to LMOs and biosafety that apply to all 196 Parties[62] to the Convention, regardless of whether they have become a Party to the Cartagena Protocol, and include domestic use.[63]

Furthermore, Article 19 (3) of the Convention, laid the foundations for the negotiation of the Cartagena Protocol by providing that:

> "*The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.*"

In decision II/5 of 17 November 1995, entitled "Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms" (now retired), the Conference of the Parties to the Convention provided the mandate for "a negotiation process to develop, in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".[64] In the same decision, the Conference of the Parties affirmed that international action on biosafety had the potential to offer an efficient and effective framework for the development of international cooperation aimed at ensuring safety in biotechnology, taking into account Articles 8 (g) and 19 (4) of the Convention.[65] The Cartagena Protocol on Biosafety, the outcome of that negotiation process, was adopted by the Conference of the Parties on 29 January 2000 at its only extraordinary meeting.[66]

60 Convention on Biological Diversity, Article 1.

61 Paragraph 3 of Article 19 refers to living modified organisms resulting from biotechnology.

62 Number of Parties at the time of writing. Up-to-date information is available at www.cbd.int/information/parties.shtml (accessed on 28 June 2024).

63 See also in this regard, Mackenzie and others, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, paras. 5–6.

64 Decision II/5, para. 1.

65 Ibid., preamble.

66 See decision EM-I/3 of the Conference of the Parties, entitled "Adoption of the Cartagena Protocol and interim arrangements".

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4.2. Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety entered into force on 11 September 2003. Its objective is, in accordance with the precautionary approach, "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".[67]

The present section briefly outlines some of the key components of the Cartagena Protocol, including its scope, key regulatory procedures, institutional frameworks and administrative requirements.[68] This section also briefly outlines components of the Nagoya-Kuala Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

A tool kit for implementing the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol is provided in annex I to the present study. The development of the tool kit was based on the implementation tool kit contained in annex III to decision BS-I/5 of 27 February 2004 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety. Additional elements were added relating to the implementation of the Supplementary Protocol. The tool kit facilitates the analysis of the extent of implementation of the Cartagena Protocol and the Supplementary Protocol in domestic legislation.

4.2.1. Scope of the Cartagena Protocol

The Cartagena Protocol applies "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".[69] Without prejudice to any right of a Party to

67 Cartagena Protocol on Biosafety, Article 1.

68 A full and comprehensive analysis of the articles of the Protocol is provided in Mackenzie and others, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, developed by the IUCN Environmental Law Centre.

69 Cartagena Protocol, Article 4.

subject all living modified organisms to risk assessment prior to the making of decisions on import, the Protocol "[does] not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations".[70] The principal relevant entity in this area is the World Health Organization.[71] While products of LMOs (e.g. processed materials of LMOs origin) are also not included, they are referenced in relation to risk assessment, in so far as those products contain "detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology".[72]

4.2.2. Decision-making procedures under the Protocol according to intended use of specific living modified organisms[73]

4.2.2.1. Living modified organisms intended for intentional introduction into the environment

Through the advance informed agreement procedure, the Protocol regulates the first transboundary movement of LMOs intended for intentional introduction into the environment.[74]

Requirements in relation to the handling, transport, packaging and identification of LMOs intended for introduction into the environment are discussed in section 4.2.3 below.

4.2.2.2. LMOs intended for direct use as food or feed, or for processing

Article 11 of the Cartagena Protocol lays out the requirements that apply specifically to LMOs intended for direct use as food or feed, or for processing. The focus is on creating a multilateral procedure for the exchange of information regarding LMOs as food or feed, or for processing.

The Protocol requires a Party that makes a final decision regarding domestic use, including placing on the market, of an LMO that may be subject to transboundary movement for direct use as food or feed, or for processing,[75] to notify the Parties through the Biosafety Clearing-House within 15 days of making that decision.[76] The minimum requirements for information concerning such LMOs are set out in annex II to the Protocol. The information required includes, inter alia, information on approved uses of the LMO intended for direct use as food or feed, or for processing and a risk-assessment report consistent with annex III of the Protocol.

A Party may require prior consent for import of LMOs intended for direct use as food or feed, or for processing under its domestic regulatory framework, provided that the framework is consistent with the objective of the Cartagena Protocol.[77] Where such a domestic regulatory framework is not yet in place, developing country Parties or Parties with economies in transition may declare through the Biosafety Clearing-House that they will take a decision on the first import of an LMO intended for direct use as food or feed, or for processing, in accordance with a risk assessment and within a predictable time frame not exceeding 270 days.[78] Similar to the provision under the advance informed agreement procedure, when there is lack of scientific certainty, Parties may adopt a precautionary approach when taking a decision.[79]

Requirements in relation the handling, transport, packaging and identification of LMOs intended for direct use as food or feed, or for processing, are discussed in section 4.2.3 below.

4.2.2.3. LMOs in transit and destined for contained use

Article 6 of the Cartagena Protocol stipulates that the advance informed agreement procedure shall not apply to LMOs in transit and LMOs destined for

70 Ibid., Article 5.
71 Mackenzie et others, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, para. 237.
72 Cartagena Protocol, annex III, para. 5.
73 An overview of those procedures is provided in subsections 4.221–4.223.
74 See Cartagena Protocol, Article 7 (1).
75 Field trials are to be treated as introduction into the environment and should follow the advance informed agreement procedure (see sect. 4.2.2.1 above).
76 Cartagena Protocol on Biosafety, Article 11 (1).
77 Ibid., Article 11 (4).
78 Ibid., Article 11 (6).
79 Ibid., Article 11 (8).

BOX 1: Key components of the advance informed agreement procedure

Notification: The advance informed agreement procedure obliges a Party of export to notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import of the first international transboundary movement of an LMO for intentional introduction into the environment of the Party of import.[a] Minimum information requirements in that regard are set out in annex I to the Cartagena Protocol and Parties are obliged to ensure that there is a legal requirement for the accuracy of information provided by the exporter.[b] The Party of import shall acknowledge receipt of notification, in writing, within 90 days of receipt and as part of the acknowledgement, the Party of import is to indicate to the notifier whether to proceed according to the domestic regulatory framework of the Party of import (which must be consistent with the Protocol) or according to the decision procedure specified in Article 10 of the Protocol.[c]

Decision procedure: According to the decision procedure in Article 10 of the Protocol, within 270 days of receiving notification, the Party of import must communicate its decision to the notifier and to the Biosafety Clearing-House:[d]

- Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism
- Prohibiting the import
- Requesting additional relevant information in accordance with its domestic regulatory framework or annex I of the Protocol
- Informing the notifier that the period specified in Article 10 (3) is extended by a defined period of time

Failure by the Party of import to communicate its decision on time shall not imply its consent. Article 10 (6), provides that, when there is lack of scientific certainty, Parties may take a precautionary approach when taking a decision.

Risk assessment: The decision by the Party of import must be based on a risk assessment.[e] Risk assessment requirements are set out in Article 15 of the Protocol, which provides that risk assessments shall be carried out in a "scientifically sound manner, in accordance with annex III and taking into account recognized risk assessment techniques".[f] The objective of the risk assessment is "to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health".[g] It shall be based, at a minimum, on information provided by the exporter and other available scientific evidence.[h] Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.[i] Guidance on risk assessment of living modified organisms was developed under the Protocol in 2016 and provides further details on steps to be taken when conducting risk assessments and guidance on risk assessment for specific types of LMOs (LM plants with stacked genes or traits, LM plants with tolerance to abiotic stress, LM trees and LM mosquitoes).[j]

Risk management: Parties are obliged under the Protocol to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks that are identified in risk assessment associated with the use, handling and transboundary movement of living modified organisms.[k] Risk-management measures shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health.[l] The 2016 guidance on risk assessment of living modified organisms and monitoring in the context of risk assessment constitutes an important basis for risk management.

[a] Cartagena Protocol, Article 8 (1).
[b] Ibid., Article 8 (2) and annex I.
[c] Ibid., article 9 (1) and (2) (c).
[d] Ibid., Article 10 (3).
[e] Ibid. Articles 10 (1) and 15.
[f] Ibid., Article 15 (1).
[g] Ibid., annex III, para. 1.
[h] Ibid., Article 15 (1).
[i] Ibid., annex III, para. 4.
[j] "Guidance on risk assessment of living modified organisms and monitoring in the context of risk assessment" (14 December 2016) (UNEP/CBD/BS/COP-MOP/8/8/Add.1).
[k] Cartagena Protocol, Article 16 (1).
[l] Ibid., Article 16 (2).

contained use. The Protocol confirms that Parties maintain the right to regulate the transport/transit of LMOs through their territory and the right to subject all LMOs to risk assessment prior to decisions on import and set standards for contained use within their jurisdiction.[80] Contained use is understood, under the Protocol, to mean: "any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment".[81]

Requirements in relation to the handling, transport, packaging and identification of LMOs for contained use are discussed in section 4.2.3 below.

4.2.3. Handling, transport, packaging and identification

Under Article 18 (1) of the Protocol, Parties shall take necessary measures to require that all LMOs that are subject to intentional transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards. The aim of this requirement is to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.[82] Article 18 (2) sets out requirements regarding the information that must be provided in documentation that accompanies the LMO. According to the Explanatory Guide to the Cartagena Protocol: "This information provides a means to identify and track transboundary movements of LMOs; gives information to the Party of import at the border; and offers a contact point for further information about the consignment in question."[83]

Specific documentation requirements apply to different categories of LMOs and documentation requirements have been set out in further detail in decisions of the Conference of the Parties serving as the meeting

80 Ibid., Article 6.
81 Ibid., Article 3 (b).
82 Ibid., Article 18 (1).
83 Mackenzie et others, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, para. 503.

BOX 2: Scope of the Cartagena Protocol and the advance informed agreement procedure (Articles 4–7)[a]

LMOs that are subject to the provisions of the Protocol:

- All LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4)

LMOs that are subject to provisions under the advance informed agreement procedure :

- LMOs intended for intentional introduction into the environment (Article 7 (1))

LMOs that are excluded from the provisions of the Protocol with respect to the advance informed agreement procedure :

- LMOs in transit (Article 6 (1))
- LMOs destined for contained use in the Party of import (Article 6 (2))
- LMOs intended for direct use as food or feed, or for processing (Article 7 (2))
- LMOs identified in a decision of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol as being not likely to have adverse impacts (Article 7 (4))

LMOs that are excluded from the provisions of the Protocol with respect to transboundary movements:

- LMOs that are pharmaceuticals for humans that are addressed by other international organizations or agreements (Article 5)

[a] Adapted from Ruth Mackenzie and others, *An Explanatory Guide to the Cartagena Protocol on Biosafety* (Gland, Switzerland, IUCN, 2003).

of the Parties to the Cartagena Protocol, particularly decision BS-III/10.[84]

The Organisation for Economic Co-operation and Development (OECD) developed guidance for the designation of a unique identifier for transgenic plants",[85] which had been referenced by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol in its decision BS-1/6 of 27 February 2004 and made available through the Biosafety Clearing-House. The OECD unique identifier system can be used to make information on LMOs available through the Biosafety Clearing-House. Examples of the integration of information requirements into existing documents, such as commercial invoices or other document required or utilized by existing documentation systems, are provided in decision BS-1/6 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol of 27 February 2004.

4.2.4. Unintentional and illegal transboundary movements of living modified organisms

The Protocol obliges Parties to take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of an LMO.[86] Parties shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States.[87] Specific notification requirements are set out in Article 17 (3) of the Protocol. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, Parties shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.[88]

The Protocol also provides rules in relation to illegal transboundary movements, which are transboundary movements of LMOs in contravention of domestic measures to implement the Cartagena Protocol. Parties are under obligation to adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing such illegal transboundary movements.[89]

4.2.5. Institutional and administrative requirements

The Protocol requires each Party to designate one or more competent national authorities , which shall be responsible for performing the administrative functions required by the Protocol and which shall be authorized to act on its behalf with respect to those functions.[90] The Protocol obliges Parties to designate one national Focal Point to be responsible on its behalf for liaison with the Secretariat.[91] The Protocol allows for one single entity to fulfil the functions of both competent national authority and national focal point.[92]

4.2.6. Biosafety Clearing-House

The Protocol establishes a Biosafety Clearing-House to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs and to assist Parties in implementing the Protocol.[93] The Biosafety Clearing-House also serves as a means through which information is made available.

84 Decision BS-III/10 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol of 17 March 2006, entitled "Handling, transport, packaging and identification of living modified organisms: paragraph 2 (a) of Article 18".

85 "OECD guidance for the designation of a unique identifier for transgenic plants" (2006 revised version), in *Safety Assessment of Transgenic Organisms, OECD Consensus Documents, Volume 3* (2010), part 3, sect. 1.

86 Cartagena Protocol on Biosafety, Article 16 (3).

87 Ibid., Article 17 (1).

88 Ibid., Article 17 (4).

89 Ibid., Article 25.

90 Ibid., Article 19 (1).

91 Ibid.

92 Ibid.

93 Ibid., Article 20 (1) (a) and (b).

BOX 3: Documentation requirements under Article 18 of the Cartagena Protocol

Article 18 (2) (a): Living modified organisms intended for direct use as food or feed, or for processing

Parties shall take measures to ensure that documentation accompanying LMOs intended for direct use as food or feed, or for processing clearly identifies that they "may contain" LMOs and are not intended for international introduction into the environment, as well as a contact point for further information. Under Article 18 (2) (a), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol are obliged to take a decision on detailed information requirements for LMOs that are intended for direct use as food or feed, or for processing, including specification of their identity and any unique identification. On 17 March 2006, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol adopted decision BS-III/10, in which further information requirements were set out. In paragraph 4 of that decision, Parties to the Protocol were requested and other Governments urged to take measures ensuring that documentation accompanying LMOs intended for direct use as food or feed, or for processing, clearly state:

(a) In 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;

(b) In cases where the identity of the living modified organisms is not known through means such as identity preservation systems, that the shipment may contain one or more living modified organisms that are intended for direct use as food or feed, or for processing;

(c) That the living modified organisms are not intended for intentional introduction into the environment;

(d) The common, scientific and, where available, commercial names of the living modified organisms;

(e) The transformation event code of the living modified organisms or, where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code;

(f) The Internet address of the Biosafety Clearing-House for further information.

Article 18 (2) (b): LMOs destined for contained use

Parties shall take measures to ensure that documentation accompanying LMOs destined for contained use clearly identifies them as LMOs; and specifies any requirements for their safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned. In its decision BS-VI/8 of 5 October 2012, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol requested Parties to implement those requirements under Article 18 (2) (b) through the use of commercial invoices or other documents required or utilized by existing documentation systems or documentation required by domestic regulatory and/or administrative frameworks.

Article 18 (2) (c): LMOs intended for intentional introduction into the environment and any other LMOs

Parties shall take measures to ensure that documentation accompanying LMOs intended for intentional introduction into the environment of the Party of import and any other LMOs within the scope of the Protocol identified as LMOs, specifies their identity and relevant traits and/or characteristics; any requirements for safe handling, storage, transport and use; the contact point for further information; and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter. In its decision BS-VI/8, the Conference of the Parties serving as the meeting of the Parties to the Protocol, requested Parties to implement those requirements under Article 18 (2) (c) through the use of commercial invoices or other documents required or utilized by existing documentation systems or documentation required by domestic regulatory and/or administrative frameworks.

Under Article 20, Parties are required to make the following types of information available to the Biosafety Clearing House:[94]

- Laws, regulations and guidelines for implementation of the Protocol
- Any bilateral, regional and multilateral agreements and arrangements
- Summaries of risk assessments
- Their final decisions regarding the importation or release of LMOs
- National reports submitted pursuant to Article 33 of the Protocol

Under several other Articles, Parties are required or encouraged to make available other types of information. Under Article 19 (2), for example, a Party is required :

- To notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities
- To convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of its competent national authorities, where that Party designates more than one competent national authority. At a minimum, such information shall specify which competent authority is responsible for which type of LMO
- To notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities

Other obligations in relation to making information available to the Biosafety Clearing-House are included in the Protocol, as outlined in the tool kit for implementing the Cartagena Protocol on Biosafety and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, which is contained in annex I to the present legal study. These obligations include:

- Specification of cases in which import may take place at the same time as the movement is notified to the Party of import (Article 13 (1) (a))
- Specification of imported LMOs to be exempted from the advance informed agreement procedure (Article 13 (1) (b))
- Notification of domestic regulations that shall apply with respect to specific imports (Article 14 (4))
- Making available the relevant details on its point of contact for receiving information from other States on unintentional transboundary movements (Article 17 (2))
- Making available information concerning cases of illegal transboundary movements (Article 25 (3))

4.2.7. Socioeconomic considerations

Parties to the Cartagena Protocol, in reaching a decision on import may take into account, consistent with their international obligations, socioeconomic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous peoples and local communities.[95] Integration of socioeconomic considerations is discretionary and relevant implementing measures apply only to Parties that choose to integrate socioeconomic considerations.[96] Voluntary guidance on the assessment of socioeconomic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety, developed under the Protocol, assists Parties in giving effect to Article 26.[97]

4.2.8. Public awareness, education and participation

Under the Protocol, Parties have committed to promoting and facilitating public awareness, education and participation concerning the safe transfer, handling and use of LMOs in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human

94 Ibid., Article 20 (3).

95 Cartagena Protocol on Biosafety, Article 26 (1).

96 Decision CP-10/3 of the Conference of the Parties to the Convention of 19 December 2022, appendix, goal A 9.

97 In decision CP-9/14 of 28 November 2018, the Conference of the Parties to the Convention serving as the meeting of the Parties to the Cartagena Protocol took note of the voluntary guidance on the assessment of socioeconomic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety, as contained in the annex to document CBD/CP/MOP/9/10.

health.[98] In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies.[99] Parties shall endeavour to ensure that public awareness and education encompasses access to information on LMOs.[100]

Moreover, Parties shall consult the public in the decision-making process regarding LMOs and make the results of decisions available to the public.[101] These obligations are qualified by the fact that consultation must be in accordance with respective domestic laws and regulations, while respecting rules concerning confidential information, as set out in the Protocol.[102]

The provisions under the Protocol on public awareness, education and participation have been interpreted against the backdrop of principle 10 of the Rio Declaration on Environment and Development[103] which states:

> *Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.*

Access to information and public participation rights have been recognized in a large number of international environmental instruments as well as regional instruments, notably the Economic Commission for Europe Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters .[104] Parties to that Convention recognize the concern of the public about the deliberate release of LMOs into the environment and the need for increased transparency and greater public participation in decision-making in that field.[105] Its provisions on public participation in decisions on specific activities shall be applied by Parties to the Aarhus Convention, within the framework of their national law and to the extent feasible and appropriate, to decisions on whether to permit the deliberate release of LMOs into the environment.[106] The Regional Agreement on Access to Information, Public Participation and Justice in Environmental Matters in Latin America and the Caribbean (Escazú Agreement)[107] is another example of a regional legal instrument with relevance to Article 23 of the Cartagena Protocol. Although the Escazú Agreement does not refer explicitly to living modified organisms or genetically modified organisms, many of its provisions on access to information and participation in decision-making would also apply within a biosafety context. While the Protocol does not specify how requirements for public participation should be implemented, participation activities often involve the following: notice to stakeholders; public consultation, including hearings; and a "consideration of public concerns" phase following consultation.[108]

4.2.9. Capacity-building and cooperation

Under Article 22 of the Cartagena Protocol, Parties commit to cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of the Protocol.[109] Under this provision, it is thus recognized that cooperation and capacity-building are activities that can support

98 Cartagena Protocol on Biosafety, Article 23 (1) (a).
99 Ibid.
100 Ibid., Article 23 (1) (b).
101 Cartagena Protocol on Biosafety, Article 23 (2).
102 Ibid.; and Article 21.
103 *Report of the United Nations Conference on Environment and Development, Rio de Janeiro, 3–14 June 1992*, vol. I, *Resolutions Adopted by the Conference* (United Nations publication, Sales No. E.93.I.8 and corrigendum), resolution 1, annex I.
104 United Nations, *Treaty Series*, vol. 2161, No. 37770. The Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention) was adopted on 25 June 1998 and entered into force on 30 October 2001.
105 Aarhus Convention, preamble.
106 Ibid., article 6 (11).
107 United Nations, *Treaty Series*, vol. 3398, No. 56654.
108 Mackenzie and others, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, , para. 597.
109 Cartagena Protocol on Biosafety, Article 22 (1).

the implementation of the requirements under the Protocol and, similarly to public awareness, education and participation, cooperation and capacity-building contribute to creating an enabling environment for effective implementation.[110]

Further, in relation to cooperation and capacity-building on biosafety, under Article 22 of the Protocol, the needs of developing country Parties for financial resources and access to and transfer of technology and know-how are considered, in accordance with the relevant provisions of the Convention on Biological Diversity.[111] Cooperation in capacity-building is determined to include scientific and technical training in the proper and safe management of biotechnology and in the use of risk assessment and risk management for biosafety and the enhancement of technological and institutional capacities in biosafety.[112]

Action plans for capacity-building have been developed under the Protocol to guide Parties in their capacity-building efforts, the most recent being the Capacity-building Action Plan for the Cartagena Protocol on Biosafety, which was adopted by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol in 2022.[113] The purpose of the Capacity-building Action Plan for the Cartagena Protocol is to facilitate the development and strengthening of the capacities of Parties to implement the Protocol. Outlined in the Action Plan are key areas for capacity-building related to the goals of the Implementation Plan for the Cartagena Protocol on Biosafety, adopted, also in 2022, by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol .[114]

In the Capacity-building Action Plan, reference is made to the long-term strategic framework for capacity-building and development, adopted by the Conference of the Parties to the Convention in decision 15/8 of 19 December 2022 and welcomed by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol in decision CP-10/4, which provides an overarching framework for addressing capacity-building and development as well as technical and scientific cooperation.

4.3. Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was adopted on 15 October 2010 and entered into force on 5 March 2018. Its objective is "to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to living modified organisms".[115] The Supplementary Protocol supplements the Cartagena Protocol and neither modifies or amends the Protocol, nor does it affect the rights and obligations of the Parties to the Supplementary Protocol under the Convention on Biological Diversity and the Cartagena Protocol.[116]

The present section briefly outlines the key components of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, namely, its scope, response measures and the discretionary power of providing rules and procedures on civil liability. In essence, the Supplementary Protocol places obligations on Parties to provide, in their domestic law, for rules and procedures that address damage.[117] A tool kit for implementing the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol is provided in annex I to the present study and provides opportunities to check implementation at the domestic level.

110 See, e.g., sect. 4.2.8 above and decision CP-10/3 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol of 19 December 2022, para. 7.

111 Cartagena Protocol on Biosafety, Article 22 (2). See notably in this regard, Articles 16-18 of the Convention on Biological Diversity.

112 Cartagena Protocol on Biosafety, Article 22 (2).

113 See decision CP-10/4, annex.

114 See decision CP-10/3, annex.

115 Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, Article 1.

116 Ibid., Article 16 (1) and (2).

117 For further information, see Convention on Biological Diversity, "About the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress" (2018). Available at https://bch.cbd.int/protocol/supplementary/about/#tab=1 (accessed on 28 June 2024).

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4.3.1. Scope of the Supplementary Protocol on Liability and Redress

The Supplementary Protocol applies to damage resulting from LMOs which find their origin in a transboundary movement and that started after the entry into force of the Supplementary Protocol for the Party into whose jurisdiction the transboundary movement was made.[118] The LMOs referred to are LMOs (a) intended for direct use as food or feed, or for processing; (b) destined for contained use; and (c) intended for intentional introduction into the environment.[119] With regard to intentional transboundary movements, the Supplementary Protocol applies to damage resulting from any authorized use of those LMOs,[120] as well as damage resulting from unintentional and illegal transboundary movements.[121] The Supplementary Protocol applies to damage that occurs within the limits of a Party's national jurisdiction, including damage caused by transboundary movement from non-Parties.[122]

Damage is defined under the Supplementary Protocol as an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, that (a) is measurable or otherwise observable taking into account, wherever available, scientifically established baselines recognized by a competent authority that takes into account any other human-induced variation and natural variation; and (b) is significant.[123] Whether damage is a "significant" adverse effect is to be determined on the basis of factors such as: (a) the long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time; (b) the extent of the qualitative or quantitative changes that adversely affect the components of biological diversity; (c) the reduction of the ability of components of biological diversity to provide goods and services; and (d) the extent of any adverse effects on human health in the context

118 Supplementary Protocol, Article 3 (1) and (4).
119 Ibid., Article 3 (1).
120 Ibid., Article 3 (2).
121 Ibid., Article 3 (3).
122 Ibid., Article 3 (5) and (7).
123 Ibid., Article 2 (2) (b).

of the Cartagena Protocol.[124] Under article 4 of the Supplementary Protocol on causation requires that a causal link be established between the damage and the LMO in question in accordance with domestic law.

4.3.2. Response measures in the event of damage or a sufficient likelihood of damage

The central obligation of Parties under the Supplementary Protocol is to provide for response measures in the event of damage resulting from LMOs. Response measures[125] refer to reasonable actions to prevent, minimize, contain, mitigate or otherwise avoid damage, as appropriate; and restore biological diversity through actions to be undertaken in the following order of preference: restoration of biological diversity to the condition that existed before the damage occurred, or its nearest equivalent, and, where the competent authority determines this is not possible, restoration by, inter alia, replacing the loss of biological diversity with other components of biological diversity for the same or for another type of use either at the same or, as appropriate, at an alternative location.

Parties are required to place responsibility for relevant obligations with the appropriate operator or operators, that is to say, any person in direct or indirect control of the LMO which could, as appropriate and as determined by domestic law, include, inter alia, the permit holder, the person who placed the LMO on the market, the developer, the producer, the notifier, the exporter, the importer, the carrier or the supplier.[126]

Parties shall require that:

- An operator, in the event of damage, subject to the requirements of the competent authority, (a) immediately inform the competent authority; (b) evaluate the damage; and (c) take appropriate response measures[127]
- Where relevant information, including available scientific information or information available in the Biosafety Clearing-House, indicates that there is a sufficient likelihood that damage will result if timely response measures are not taken, an operator take appropriate response measures so as to avert such damage[128]

The competent authority is required to: (a) identify the operator which has caused the damage; (b) evaluate the damage; and (c) determine which response measures should be taken by the operator.[129] Decisions of the competent authority requiring the operator to take response measures should be reasoned and such decisions should be notified to the operator[130] and the operator should be informed of available remedies, including administrative or judicial review, that are required to be provided under domestic law.[131]

Competent authorities may themselves implement appropriate response measures, including, in particular, when the operator has failed to do so.[132] The competent authority has the right to recover from the operator the costs and expenses of, and incidental to, the evaluation of the damage and the implementation of any such appropriate response measures.[133]

4.3.3. Rules and procedures in relation to civil liability

The Supplementary Protocol is focused primarily on an administrative approach for addressing damage.[134] Article 12 of the Supplementary Protocol does, however, contain provisions on civil liability. Pursuant to that article, Parties are provided with the opportunity, when implementing their obligations in relation to response measures, to apply existing domestic law, including, where applicable, general rules and procedures on civil liability, or apply or develop civil liability

124 Ibid., Article 2 (3).
125 Ibid., Article 2 (2) (d).
126 Ibid., Articles 2 (2) (c) and 5 (1).
127 Ibid., Article 5 (1).
128 Ibid., Article 5 (3).
129 Ibid., Article 5 (2).
130 Ibid., Article 5 (6).
131 Ibid.
132 Ibid., Article 5 (4).
133 Ibid., Article 5 (5).
134 Peter Gailhofer, "The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety", in *Corporate Liability for Transboundary Environmental Harm: An International and Transnational Perspective*. Peter Gailhofer and others, eds. (Springer, 2023); and Secretariat of the Convention on Biological Diversity, "The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: an introductory mote in preparation for signature and ratification", available at https://bch.cbd.int/nkl_suppl_protocol/introductorynote.pdf?download.

rules and procedures specifically for that purpose or apply or develop a combination of both.[135] Under Article 12, Parties are obliged to continue to apply existing general law on civil liability or apply civil liability law developed specifically for the purpose of providing adequate rules and procedures on civil liability for material or personal damage associated with the damage as defined in the Supplementary Protocol.[136]

Under the Supplementary Protocol, it is prescribed that, when developing civil liability law, Parties shall, as appropriate, address, inter alia: (a) damage; (b) standard of liability, including strict or fault-based liability; (c) channelling of liability, where appropriate; and (d) the right to bring claims.[137]

135 Supplementary Protocol, Article 12 (1).
136 Ibid., Article 12 (2).
137 Ibid., Article 12 (3).

5. The case for biosafety mainstreaming

In the present study, biosafety mainstreaming refers to the integration of biosafety concerns into cross-sectoral and sectoral legislation, policies and institutional frameworks, taking into account national circumstances and priorities.[138] Mainstreaming can facilitate the building of synergies between actions on biosafety and biodiversity and other areas of international and national law, facilitate effective implementation of international obligations on biosafety and contribute to resource-efficient implementation of the Cartagena Protocol.[139]

The present section addresses the following questions: what is biosafety mainstreaming and why is biosafety mainstreaming into cross-sectoral and sectoral legislation, policies and institutional frameworks important?

5.1. What is mainstreaming of biosafety?

Efforts to mainstream biosafety are part of a wider progression towards an integrated approach developed within the framework of international biodiversity law. In Article 6 (b) of the Convention on Biological Diversity, Parties are c called uponon t to "[i]ntegrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies". In this regard, it is recalled that the objective of the Cartagena Protocol on Biosafety 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.[140] Mainstreaming biodiversity has been understood as ensuring that biodiversity, and the services that it provides, are appropriately and adequately factored into policies and practices that rely and have impact on it.[141] A link can be made between mainstreaming and the ecosystem approach, which – considering the complexity of biodiversity management – calls for the involvement of all relevant sectors of society and scientific disciplines, at the local, national, regional and international levels, as appropriate.[142]

138 Convention on Biological Diversity, Cartagena Protocol on Biosafety, "About biosafety mainstreaming" (2018). Available at https://bch.cbd.int/protocol/issues/mainstreaming/about/> (accessed on 28 June 2024).

139 Convention on Biological Diversity, "Biodiversity e-Learning Platform: Biosafety/mainstreaming biosafety", Introduction to mainstreaming biosafety module (2018). Available at https://scbd.unssc.org/course/index.php?categoryid=14 (accessed on 28 June 2024).

140 Cartagena Protocol on Biosafety, Article 1.

141 Secretariat of the Convention on Biological Diversity, "Mainstreaming biodiversity: concept and work under the Convention" (2013); and Convention on Biological Diversity, note by the Executive Secretary entitled "Strategic actions to enhance implementation of the Convention and the Strategic Plan for Biodiversity 2011-2020" (UNEP/CBD/SBI/1/5), para. 8.

142 See decision VII/11 of the Conference of the Parties to the Convention of 20 February 2004, entitled "Ecosystem approach", annex I, principle 12. On the implications for the implementation of the ecosystem approach within the context of law and policies on agriculture, see Miranda Geelhoed, "Agroecology and EU law: finding potential for agroecology at the nexus between biodiversity law and human rights law", PhD dissertation, Strathclyde Centre for Environmental Law and Governance, 2022.

In 2010, at its tenth meeting, the Conference of the Parties to the Convention adopted its revised and updated Strategic Plan for Biodiversity. Strategic goal A of the plan was to "[ad]dress the underlying causes of biodiversity loss by mainstreaming biodiversity across government and society",[143] with four Aichi targets organized under and in support of that strategic goal.[144] The Cancun Declaration on Mainstreaming the Conservation and Sustainable Use of Biodiversity for Well-being was adopted on 3 December 2016 during the high-level ministerial segment of the thirteenth meeting of the Conference of the Parties,.[145] In the declaration, ministers and other heads of delegation committed to "[e]nsure that sectoral and cross-sectoral policies, plans and programmes, as well as legal and administrative measures and budgets established by [their] Governments, integrate in a structured and coherent manner actions for the conservation, sustainable use, management and restoration of biological diversity and ecosystems".[146] Moreover, the Cancun Declaration provides guidance for mainstreaming conservation and sustainable use of biodiversity in the agriculture, forestry, fisheries and tourism sectors. This includes activities that resonate with the multifaceted meaning of biosafety (see sect. 3.2 above) such as the promotion of sustainable agriculture for food security, human nutrition, health, economic development and environmental protection; the conservation and cultivation of native varieties, as well as farmers' landraces, locally adapted breeds and underutilized species, including those threatened by intensification of production; and effective management and conservation of pollinators.[147]

The achievement of the Sustainable Development Goals is supported by The Kunming-Montreal Global Biodiversity Framework, adopted in 2022, which charts an ambitious pathway towards reaching the global vision of a world living in harmony with nature by 2050. The Global Biodiversity Framework takes a "whole-of-government and whole-of-society approach", as its success "requires political will and recognition at the highest level of government and relies on action and cooperation by all levels of government and by all actors of society".[148] The Framework includes 23 action-oriented targets, clustered into three main themes: reducing threats to biodiversity; meeting people's needs through sustainable use and benefit-sharing; and tools and solutions for implementation and mainstreaming. Regarding the last-mentioned theme, Target 14 aims to "[E]nsure the full integration of biodiversity and its multiple values into policies, regulations, planning and development processes, poverty eradication strategies, strategic environmental assessments, environmental impact assessments and, as appropriate, national accounting, within and across all levels of government and across all sectors, in particular those with significant impacts on biodiversity, progressively aligning all relevant public and private activities, and fiscal and financial flows with the goals and targets of this framework". Target 14 can be broken down into several areas of concern. First, biodiversity has multiple values, as it underpins a wide range of services that support economies, food production systems, secure living conditions and human health and is central to many cultures and worldviews.[149] Second, while various decision-making frameworks, such as for policies, regulations, processes, strategies, assessments and national accounting, guide public and private activities extending from the national to the local level, often they do not account appropriately for biodiversity or its values.[150] Third, action to fully integrate biodiversity and its multiple values should be taken across all levels of government and across sectors, with a focus on those with significant impact on biodiversity.[151]

In its decision XIII/3 of 17 December 2016, entitled "Strategic actions to enhance the implementation of the Strategic Plan for Biodiversity 2011–2020 and

143 See Decision X/2 of the Conference of the Parties to the Convention of 29 October 2010, annex.

144 Those targets encompassed people's awareness of biodiversity (target 1); integration of biodiversity into national and local development and poverty reduction strategies (target 2); elimination, phasing out and reform of incentives that are harmful to biodiversity (target 3); and implementation of plans for sustainable production and consumption (target 4).

145 Document UNEP/CBD/COP/13/24.

146 Ibid, commitment 1.

147 Ibid, annex.

148 Decision 15/4 of the Conference of the Parties to the Convention, sect. C, para. 7.(c).

149 Secretariat of the Convention on Biological Diversity, Guidance notes for Target 14: the multiple values of biodiversity are integrated into decision-making at all levels (2023) Available at www.cbd.int/gbf/targets/14/ (accessed on 12 May 2024).

150 Ibid.

151 Ibid.

Photo by Peter Lowe/Centro Internacional de Mejoramiento de Maíz y Trigo

the achievement of the Aichi Biodiversity Targets, including with respect to mainstreaming and the integration of biodiversity within and across sectors", the Conference of the Parties to the Convention on Biological Diversity welcomed the Cancun Declaration on Mainstreaming and recognized the role and relevance of, inter alia, the Cartagena Protocol on Biosafety in contributing to sustainable food systems and agriculture. As discussed in section 4.1 above, the Protocol has been developed within the framework of the Convention and contributes to its aims, as it seeks to contribute to ensuring adequate protection against adverse effects on the conservation and sustainable use of biological diversity.[152] The Protocol itself has been interpreted in legal scholarship as embracing integrated aspects when explored through the lens of sustainable development, including, in particular, risk assessment and management, public awareness and public participation and socioeconomic considerations and procedures for LMOs intended for direct use as food or feed, or for processing (see sect. 4.2 above).[153] Within this context, mainstreaming of biosafety and the elements of the Protocol refers to "the integration of biosafety concerns into cross-sectoral and sectoral legislation, policies and institutional frameworks, taking into account national circumstances and priorities".[154] As discussed in further detail in section 5.2 below, mainstreaming has the potential to help to ensure synergies in processes for drafting, adopting and implementing legislation and policies, including in relation to the Protocol, the Convention and other international legal instruments. Biosafety mainstreaming may facilitate the establishment, development and strengthening of effective national biosafety frameworks and help Parties to implement the Protocol in a more resource-efficient manner.

Mainstreaming of biosafety is ultimately a practical process which involves the building of bridges between a range of institutions through facilitation of relations

152 Cartagena Protocol, Article 1. See also the Convention on Biological Diversity, Article 1.

153 Garforth, Yifru and Fujii, "Biosafety, the Cartagena Protocol, and sustainable development" (see sect. 3.1.2).

154 Convention on Biological Diversity, Cartagena Protocol on Biosafety, "About biosafety mainstreaming".

and conversations to identify shared objectives, opportunities for collaboration and complementary expertise and resources. Parties may find that they are already involved in mainstreaming activities on an ad hoc basis since, in many instances, mainstreaming of biosafety as an integrated approach to law-, policy- and decision-making makes sense from the perspective of effective and efficient implementation. However, mainstreaming should ideally be a planned process which involves the development of a mainstreaming vision and mainstreaming goals, the selection of relevant laws, policies and institutional frameworks (entry points), the engagement of authorities and stakeholders, the dedication of resources, the identification of non-legislative tools and the creation of an enabling environment involving, inter alia, awareness-raising, outreach, public participation and education and capacity-building activities. These steps will be discussed further in section 6.1 below.[155] The examples in sections 6.2–6.4 and annex III illustrate what types of cross-sectoral and sectoral legislation, policies and institutional frameworks could be relevant to biosafety mainstreaming and the different features that can be mainstreamed into policy and legal provisions. Mainstreaming activities could include, for example, integration of commitments and actions in relation to international and national biosafety obligations into cross-sectoral or sectoral policies, the establishment of links between biosafety and cross-sectoral and sectoral objectives, the inclusion of the key elements of the Protocol in cross-sectoral or sectoral legislation, the inclusion of cross-sectoral or sectoral representatives in biosafety-specific institutional frameworks or the inclusion of biosafety-specific representatives in cross-sectoral or sectoral institutional frameworks and the creation of coordination mechanisms.

5.2. Why is biosafety mainstreaming important?

In 2016, the e-learning module on biosafety mainstreaming was published on the website of the Secretariat of the Convention, following completion of the pilot project on the integrated implementation of the Cartagena Protocol on Biosafety.[156] The e-learning module was commissioned by the Secretariat of the Convention and developed by the Strathclyde Centre for Environmental Law and Governance in cooperation with the Secretariat. It identifies three complementary motivations (explained in the subsections below) for mainstreaming of biosafety into cross-sectoral and sectoral policies, legislation and institutional frameworks, which are:

- To ensure synergies within the context of international law, including the Convention on Biological Diversity and the Kunming-Montreal Global Biodiversity Framework
- To facilitate the establishment, development and strengthening of effective national biosafety frameworks
- To implement the Convention and the Protocol in a more resource-efficient manner

5.2.1. Ensure synergies within the context of international biodiversity law, including the Convention on Biological Diversity and the Kunming-Montreal Global Biodiversity Framework

Mainstreaming of biosafety is important for ensuring a consistent and synergetic approach to the implementation of international obligations in relation to biosafety and biodiversity at the national level. Such obligations can be relevant to a great number of different policy areas and different sectors. As explained in section 4 above, the Convention and the Protocol share partly overlapping objectives, notably the conservation of biodiversity and the sustainable use of its components.[157] Implementation of the objectives under the Protocol contributes to the implementation of the objectives of both the Convention and the wider international agenda for sustainable development which integrates environmental, economic and social

155 Ibid.

156 Convention on Biological Diversity, "Biodiversity e-Learning Platform: Biosafety/mainstreaming biosafety", (2018), available at https://scbd.unssc.org/course/index.php?categoryid=14 (accessed on 28 June 2024). Upon registration, the e-learning module can be accessed on this website.

157 Convention on Biological Diversity, Article 1; and Cartagena Protocol on Biosafety, Article 1.

considerations.[158] In the Implementation Plan for the Cartagena Protocol, adopted in 2022, it is explicitly recognized that the Implementation Plan may help to support Parties in achieving the Sustainable Development Goals, for example, Goal 2 (end hunger, achieve food security and improved nutrition and promote sustainable agriculture) and Goal 3 (ensure healthy lives and promote well-being for all at all ages).[159] The Conference of the Parties serving as the meeting of the Parties to the Protocol recognized the complementarity of the Implementation Plan and the Kunming-Montreal Global Biodiversity Framework and that the Implementation Plan could contribute to the achievement of the goals and targets relevant to biosafety in the Kunming-Montreal Global Biodiversity Framework.[160]

The relevance of biosafety for implementing international biodiversity obligations follows from the fact that the Convention includes international obligations in relation to LMOs and biosafety that apply to all Parties to the Convention, regardless of whether those countries have become a Party to the Cartagena Protocol, and include domestic use.[161] Under Article 8 (g) of the Convention, Parties are required, as far as possible and appropriate, to establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs. Moreover, under Article 19 (4) of the Convention, Parties are required to provide information about the use and safety regulations for the handling of LMOs. The achievement of Target 17 under the Kunming-Montreal Global Biodiversity Framework, which bears a specific relation to those biosafety obligations under the Convention, will contribute to the realization of the vision of the Framework, which is a world where, "by 2050, biodiversity is valued, conserved, restored and wisely used, maintaining ecosystem services, sustaining a healthy planet and delivering benefits essential for all people".[162] Target 17 of the Framework reads as follows:

> "*Establish, strengthen capacity for, and implement in all countries, biosafety measures as set out in Article 8 (g) of the Convention on Biological Diversity and measures for the handling of biotechnology and distribution of its benefits as set out in Article 19 of the Convention*".

In the Implementation Plan for the Cartagena Protocol on Biosafety, it is specifically recognized that the Plan "is anchored in and complementary to the Kunming-Montreal Global Biodiversity Framework".[163] Improved implementation of international biosafety obligations through mainstreaming can contribute to the achievement of many other targets beyond Target 17 within the Framework. For example, integration of biosafety into relevant cross-sectoral laws and policies that govern protected areas, to ensure that use of modern biotechnologies is consistent with conservation outcomes, could contribute to the achievement of Target 3 on the conservation and management of ecologically representative, well-connected and equitably governed systems of protected areas. Moreover, biosafety has an important role to play in the achievement of Target 10 whose aim is to ensure that areas under agriculture, aquaculture, fisheries and forestry are managed sustainably, in particular through the sustainable use of biodiversity. Integration of biosafety into relevant cross-sectoral and sectoral laws and policies in relation to agriculture, forestry, fisheries, food and overarching development policies will be key to ensuring sustainable use of biodiversity in these sectors.

Overall, coordinated implementation of the objectives and obligations under the Convention and the Cartagena Protocol on Biosafety, the Kunming-Montreal Global Biodiversity Framework and the Implementation Plan for the Cartagena Protocol, through mainstreaming, can lead to strengthened implementation at the national level. Through the inclusive processes that underpin mainstreaming activities – connecting and facilitating cooperation

158 See, for example, Agenda 21 and the Sustainable Development Goals, set out in General Assembly resolution 70/1, entitled "Transforming our world: the 2030 Agenda for Sustainable Development", of 25 September 2015, notably Goal 15.9.

159 Decision CP-10/3 of 19 December 2022 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, entitled "Implementation Plan for the Cartagena Protocol on Biosafety", annex, paras. 4–5.

160 Ibid., para. 3.

161 See sect. 4.1 above; and Mackenzie and others, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, paras. 5–6.

162 Decision 15/4, annex, para. 10.

163 Decision CP-10/3, annex, para. 4.

among biodiversity, biosafety and other cross-sectoral and sectoral representatives and stakeholders – the potential is created to identify gaps or conflicts in implementation, to avoid duplication and to share knowledge and resources.

This potential is best illustrated through examining national biodiversity strategies and action plans. Article 6 of the Convention on general measures for conservation and sustainable use obliges Parties to "[d]evelop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in [the] Convention relevant to the Contracting Party concerned". National biodiversity strategies and action plans can serve as particularly important cross-sectoral vehicles for mainstreaming biosafety and ensuring synergies between the Protocol and the Framework, as well as achieving the broader cross-sectoral and sectoral objectives that inform the content of the national biodiversity strategies and action plans, for example, agricultural aims in relation to pesticide use or genetic diversity.

Two examples of the mainstreaming of biosafety into national biodiversity strategies and action plans are provided below. Additional examples can be found in

BOX 4: The national focal point for biosafety was included in the task team responsible for drafting the national biodiversity strategy and action plan (2015–2025) of Malawi[a]

The task team responsible for drafting the national biodiversity strategy and action plan (2015–2025) of Malawi included the national focal point for biosafety. The aim was to ensure that targets on biosafety would be linked up with the broader objectives of the biodiversity strategy of Malawi. Furthermore, consultations were conducted during which institutions addressing issues related to biosafety were asked to contribute input on biosafety to the national biodiversity strategy and action plan.

Biosafety was thereby mainstreamed into the national biodiversity strategy and action plan (2015–2025) of Malawi. Under target 14, it is provided that, by 2025, the level of protection on safe handling, transfer and use of LMOs resulting from modern biotechnology that may have adverse impacts on biodiversity, would be strengthened, taking into account risks to human health. Actions directed towards achieving this target include revision of the Biosafety Act, development of a national biosafety capacity-building plan, establishment of national systems for documentation, management and information-sharing on biosafety and establishment of an effective detection and monitoring system for biotechnology. Consultations on the revision of the Biosafety Act are currently ongoing.

[a] Available at www.cbd.int/doc/world/mw/mw-nbsap-v2-en.pdf (accessed on 28 June 2024).

***Example clause:* national biodiversity strategy and action plan (2015–2025) of Malawi**

Target 14: By 2025, the level of protection on safe handling, transfer and use of living modified organisms resulting from modern biotechnology that may have adverse impacts on biodiversity is strengthened, taking into account risks to human health.

Actions:
(a) Revise the Biosafety Act and regulations;
(b) Conduct public awareness campaigns on biosafety legislation;
(c) Develop and implement a national biosafety capacity-building plan;
(d) Establish national systems for documentation, management and information-sharing on biosafety;
(e) Establish an effective detection and monitoring system for biotechnology.

Output indicators:
(a) Biosafety Act and regulations revised;
(b) Public awareness campaigns on biosafety legislation conducted;
(c) A national biosafety capacity-building plan developed and implemented;
(d) A biosafety clearing-house mechanism developed and operationalized;
e) An effective monitoring system for biotechnology established.

BOX 5: The strategy on biological diversity of the Republic of Moldova for the period 2015–2020[a] and the action plan for enforcing it provided a vehicle for cross-sectoral coordination and the pooling of resources for biosafety

The strategy on biological diversity of the Republic of Moldova for the period 2015–2020 and the action plan for enforcing it provided a vehicle for cross-sectoral coordination and the pooling of resources for biosafety. The strategy and action plan constituted an important instrument for cross-sectoral coordination of biosafety mainstreaming and included the objective of reducing the pressure on biodiversity to ensure sustainable development. This would be achieved through development of risk assessment procedures for the introduction of LMOs and establishment of an advisory centre.

The various governmental bodies involved in the implementation of the strategy on biological diversity and the action plan for enforcing it were obliged to mobilize resources to bring their sectoral legislation into compliance with the strategy and action plan. Those bodies included the Ministries of the Environment, Health and Agriculture and the Food Industry. The various ministerial departments were tasked with the development of annual working plans, including for implementation of the strategy and action plan, under the coordination of the Ministry of the Economy.

[a] Available at www.cbd.int/doc/world/md/md-nbsap-v2-en.pdf (accessed on 28 June 2024).

***Example clause:* Strategy on biological diversity for 2015–2020 of the Republic of Moldova (2015)**

The overall objective of the strategy: Decrease the current loss rate of biodiversity as a contribution to reducing poverty and as a benefit to all forms of life on earth.
Specific objective B: By 2020, reduce the pressure on biodiversity to ensure sustainable development through: […],

B3: Implementing biological security measures by developing risk assessment procedures for the introduction of genetically modified organisms in the environment and the establishment of an advisory centre

section 6.2 and example clauses are included in annex III to the present study, entitled "Overview policy and legislative examples of biosafety mainstreaming".

Although the focus of the present section is on biosafety and biodiversity obligations and their implementation at the national level, it is worth noting that coordinated approaches may also create synergies between biosafety laws and policies and other areas of international and national law and policy, for example, in relation to implementation of obligations that follow from other multilateral environmental agreements or in relation to international trade law.

5.2.2. Facilitate the establishment, development and strengthening of effective national biosafety frameworks.

Mainstreaming of biosafety may: strengthen existing national biosafety frameworks; help to (temporarily) address gaps in the implementation of key elements of the Cartagena Protocol and the Supplementary Protocol; and contribute to the creation of an enabling environment for the implementation of the Cartagena Protocol and the Supplementary Protocol. Examples of mainstreaming can be found in section 6.2 below and example clauses are included in annex III to the present study.

First, the mainstreaming of biosafety into cross-sectoral and sectoral legislation, policies and institutional frameworks may strengthen national biosafety frameworks. In this regard, the objectives that are pursued through biosafety frameworks are integrated into relevant policies and legislation, such as national biodiversity strategies and action plans or policies for sustainable development, agriculture, food and health, to ensure synergies between biosafety objectives and cross-sectoral and sectoral aims. Cross-sectoral and sectoral legislation may integrate or reference biosafety requirements that follow from biosafety-specific laws, for example, in relation to risk assessment, to ensure broad understanding of the risks of modern biotechnology for the environment and human health in the sectors that are most likely to use modern biotechnologies. Moreover, Parties may wish to go beyond the obligations under the Cartagena Protocol to achieve comprehensive biosafety objectives within the relevant cross-sectoral and sectoral contexts. For

example, Parties may wish to mainstream labelling requirements into legislation on consumer protection. Mainstreaming into institutional frameworks may involve the inclusion of biosafety authorities in cross-sectoral or sectoral frameworks, or the inclusion of biosafety-specific representatives in cross-sectoral or sectoral institutional frameworks, with a view to going beyond "one-off" mainstreaming activities to achieve an integrated approach which is underpinned by a long-term mainstreaming vision.

Second, biosafety mainstreaming may contribute to the creation of an enabling environment for the implementation of the Cartagena Protocol. As reflected in the Implementation Plan, an enabling environment can be created by reinforcing capacity-building, resource mobilization, cooperation, education and participation and raising public awareness. Providing access to information is another objective in the creation of an enabling environment. Mainstreaming activities in support of an enabling environment can vary widely, some of which will be discussed in the next section, although not all activities aimed at creating an enabling environment are of a legal nature. The Implementation Plan considers the importance of mainstreaming in the context of the goal of Parties to "promote and facilitate public awareness, education and participation on the safe transfer, handling and use of LMOs, in accordance with Article 23 of the Protocol".[164] The Plan includes the following objective: Parties facilitate sectoral and cross-sectoral coordination and cooperation at the national level to mainstream biosafety, a key accomplishment

164 Decision CP-10/3 of 19 December 2022 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, entitled "Implementation Plan for the Cartagena Protocol on Biosafety", appendix, Goal B.3 and indicators.

BOX 6: Permission for introduction into the environment is a requirement for patent applications for LMOs under the Law on the Protection of Plant Varieties of the Republic of Moldova[a]

The Law on the Protection of Plant Varieties of the Republic of Moldova (2008) regulates the creation, legal protection and use of plant varieties. Mainstreaming of biosafety into the law was initiated upon recommendation of the Parliamentary Commission for public administration, regional development, environment, and climate change. Specifically, the law requires that applications for patents for LMO plant varieties be accompanied by permission for introduction into the environment in accordance with national biosafety legislation. It clarifies that this means that permission to introduce a LMO into the environment must be provided simultaneously with the filing of the patent application or within two months of the date of completion of the substantive examination of the patent application.

By making permission for introduction into the environment a requirement under the patent application procedure for LMO plant varieties, the Law on the Protection of Plant Varieties effectively integrated the procedure outlined in chapter IV, on the deliberate release into the environment of genetically modified organisms, of the Law on Biological Safety of the Republic of Moldova (2001),. A new Law on the Regulation and Control of Genetically Modified Organisms (2022) will enter into force in 2024.

[a] Available at www.wipo.int/wipolex/en/text/498052.

***Example clause:* Law on the Protection of Plant Varieties of the Republic of Moldova (2008)**

Article 33: Criteria which a patent application must satisfy [...]

(2) The following shall accompany the application: [...]

(g) Permission for introduction into the environment, granted by a competent national body in accordance with legislation in the field of biological security, where the variety is a genetically modified organism.

Article 35: Filing date of the application [...]

(4) Permission to introduce a genetically modified organism into the environment shall be provided simultaneously with the filing of the application or within two months of the date of completion of the substantive examination.

BOX 7: Legislation and technical regulations of Ecuador for consumer protection include labelling requirements for LMOs

The *Ley Orgánica de Defensa del Consumidor (2000)* of Ecuador[a] includes two provisions in relation to the labelling of LMOs.

Article 13 of the law provides that products that are intended for consumption by humans or livestock should include a warning if they have been obtained or improved through genetic modification. Article 14 of the law sets minimum requirements for the labelling of food for human consumption, without prejudice to technical standards, which should include an indication whether the food is artificial, irradiated or genetically modified.

Furthermore, the *Reglamento Técnico: Rotulado de Productos Alimenticios Procesados, Envasados y Empaquetados (2014)* provides that processed foods containing transgenic ingredients must be labelled as "contains transgenic", as long as the LM material exceeds a threshold of 0.9 per cent of the product.

[a] Available at https://faolex.fao.org/docs/pdf/ecu139405.pdf (accessed on 28 June 2024).

***Example clause: Ley Orgánica de Defensa del Consumidor* of Ecuador (2000)**

Article 13. PRODUCCION TRANSGÉNICA. Si los productos de consumo humano o pecuario a comercializarse han sido obtenidos o mejorados mediante transplante de genes o, en general, manipulación genética, se advertirá de tal hecho en la etiqueta del producto, en letras debidamente resaltadas.

Art. 14. ROTULADO MINIMO DE ALIMENTOS. Sin perjuicio de lo que dispongan las normas técnicas al respecto, los proveedores de productos alimenticios de consumo humano deberán exhibir en el rotulado de los productos, obligatoriamente, la siguiente información:
[...]
l) Indicación de si se trata de alimento artificial, irradiado o genéticamente modificado.

for achieving the associated goal: Parties enhance cooperation and coordination on biosafety issues at the national, regional and international levels.[165] These objectives have been reinforced in the Capacity-building Action Plan for the Cartagena Protocol on Biosafety.[166] Activities aimed at creating an enabling environment for biosafety mainstreaming are discussed in section 6.1 below.

Third, where gaps remain in the implementation of functional national biosafety frameworks [167], the integration of key elements of the Protocol and the Supplementary Protocol in cross-sectoral and sectoral legislation may address such gaps, even if only temporarily. For example, the drafting or revision of existing cross-sectoral or sectoral laws on the environment, biodiversity, agriculture and seeds may provide opportunities for putting in place safeguards to ensure the safe transfer, handling and use of LMOs and/or mandate the constitution of biosafety-specific or cross-sectoral institutions tasked with ensuring biosafety. Importantly, such activities should not lead to the fragmented implementation of the obligations under the Cartagena Protocol across several laws and policies, risking overlapping, contradictory or conflicting provisions or aims and miscommunications or inefficiencies. Where risks of fragmentation appear, provision should be made for permanent solutions for implementation of biosafety obligations, notably through biosafety-specific laws. However, temporary inclusion of key elements in relevant cross-sectoral and sectoral laws and policies may still have long-term benefits for an integrated approach to implementing the Protocol. Such activities may lead to both a broad understanding of biosafety across cross-sectoral and sectoral institutions and to future legislative and policy activities that strengthen biosafety frameworks even when specific laws are put in place, as long as biosafety capacity is maintained across cross-sectoral and sectoral institutions.

165 Ibid., Goal B.4 and objective B.4.3.
166 See decision CP-10/4, appendix.
167 See annex I to the present study, entitled "Tool kit for implementing the Cartagena Protocol on Biosafety and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress".

BOX 8: Integration of biosafety in the Law on Biodiversity of Viet Nam (2008)[a] provided a basis for inter-ministerial cooperation and development of biosafety-specific rules and guidance

Viet Nam became a Party to the Cartagena Protocol in 2004, with the Ministry of Natural Resources and Environment assigned to the role of national focal point. In this capacity, the Ministry was involved in the drafting process of the Law on Biodiversity (2008) and, with the aim of protecting human health and biodiversity, proposed the inclusion of a section on biosafety management based on the precautionary principle. The Law outlines responsibilities for managing risks caused by LMOs to biodiversity, the procedure for the making and appraisal of risk assessments and the granting of certificates on LMO safety, obligations for publishing information on LMOs and responsibilities for management of databases on LMOs. The Law provides a basis for cross-ministerial cooperation on the issue of biosafety and development of biosafety-specific rules and guidance, as it stipulates that the Government shall specify responsibilities of ministries, ministerial-level agencies, organizations and individuals for managing risks caused to biodiversity by LMOS. For example, representatives from the Ministry of Natural Resources and Environment, the Ministry of Agriculture and Rural Development, the Ministry of Industry and Trade, the Ministry of Health and the Ministry of Science and Technology are involved in the appraisal of risk assessments for LMOs, and advise the competent national authorities on risk management.

The promulgation of the Law on Biodiversity led to the issuance of governmental decrees with more specific rules in relation to biosafety, notably Decree No. 69 on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms (2010). Relevant cross-sectoral ministries have developed and issued circulars for guidance on biosafety management related to LMOs according to their functions and responsibilities. For example, the Ministry of Science and Technology has issued guidance in relation to general biosafety in research and technology development related to LMOs, while the Ministry of Natural Resources and Environment has published guidance on the procedures for granting and revoking biosafety certificates.

[a] Available at www.cbd.int/doc/measures/abs/msr-abs-vn-en.pdf (accessed on 28 June 2024).

Example clause: **Law on Biodiversity of Viet Nam (2008)**

Section 3: Management of risks caused to biodiversity by genetically modified organisms and genetic specimens of genetically modified organisms.

Article 65: Responsibilities for managing risks caused to biodiversity by genetically modified organisms and genetic specimens of genetically modified organisms.

1. Responsibilities for managing risks caused to biodiversity by genetically modified organisms and genetic specimens of genetically modified organisms are defined as follows:
(a) Organizations and individuals that research and create genetically modified organisms or genetic specimens of genetically modified organisms shall register with the Ministry of Science and Technology and satisfy conditions on material and technical foundations, technologies and professionals under regulations of the Ministry of Science and Technology;
(b) Organizations and individuals that import genetically modified organisms or genetic specimens of genetically modified organisms shall obtain permission of competent State agencies;
(c) Organizations and individuals that research, import, purchase, sell or release genetically modified organisms or genetic specimens of genetically modified organisms shall publicize information on the risk level and risk management measures under Article 67 of this Law.
2. The Government shall specify responsibilities of ministries, ministerial-level agencies, organizations and individuals for managing risks caused to biodiversity by genetically modified organisms or genetic specimens of genetically modified organisms. […]

BOX 9: Integrated and coordinated enforcement in Malaysia to give clarity about roles related to enforcement of biosafety laws and sharing of responsibilities, tasks and resources

Owing to the cross-cutting nature of biosafety, enforcement involves various types of enforcement officers operating under different laws. In Malaysia, the mandate for coordinated enforcement action was provided under section 38 of the Biosafety Act (2007).[a] This includes actions by police officers, agricultural inspection officers, food safety officers, customs officers, port officers, fisheries officers, plant protection officers, veterinary authorities and quarantine and inspection officers.

Based on the provisions in various relevant laws, an integrated enforcement matrix was developed by the relevant Malaysian enforcement agencies. The matrix outlines the roles and responsibilities of all enforcement agencies and the overlap of the various laws. This participatory approach ensures that all agencies are aware of their jurisdictional powers and legal obligations in relation to biosafety enforcement. Sharing responsibilities and tasks on the basis of the matrix thus not only strengthens enforcement but also lessens pressures on the capacities of those agencies, avoiding duplication of efforts and allowing for the sharing of resources.

Formalization of coordinated enforcement has been achieved with the establishment of the Officer Level Integrated Committee for LMO Monitoring and Enforcement (Technical Committee on LMO Enforcement) by the National Biodiversity Council in 2016. Furthermore, there is an intention to establish a high-level integrated committee for LMO monitoring and enforcement of (National Committee on LMO Enforcement), to be chaired by the Deputy Prime Minister and to be tasked with review and implementation of relevant policies.

[a] *Available at https://faolex.fao.org/docs/pdf/mal74258.pdf (accessed on 28 June 2024).*

Example clause: **Biosafety Act of Malaysia (2007)**

Section 38. Enforcement officers

The following officers may exercise the powers under this Part:
(a) an enforcement officer of the Board;
(b) officers specified in the Third Schedule; and
(c) any other officer of the Board or any other public officer authorized in writing by the Board. […]

Third Schedule: Enforcement Officers

1. Any police officer not below the rank of Inspector, as provided for in the Police Act 1967.
2. Any Inspecting Officer of the Department of Agriculture, as defined in section 2 of the Plant Quarantine Act 1976.
3. Any authorized officer, as defined in section 2 of the Food Act 1983.
4. Any Officer of customs, as defined in section 2 of the Customs Act 1967.
5. Any port officer, as defined in section 2 of the Merchant Shipping Ordinance 1952.
6. Any fisheries officer, as defined in section 2 of the Fisheries Act 1985.
7. Any authorized officer, as defined in section 2 and appointed under section 53 of the Protection of New Plant Varieties Act 2004.
8. Any veterinary authority, as defined in section 2 of the Animals Act 1953.

5.2.3. Implement the Convention on Biological Diversity and the Cartagena Protocol in a more resource-efficient manner

Practical considerations may underpin national activities for mainstreaming biosafety into cross-sectoral and sectoral institutional frameworks, legislation and policies. Activities under the Convention on Biological Diversity and the Cartagena Protocol should be coordinated, complementary and non-duplicative. Integration at the international and domestic levels may contribute to averting potential conflicts within and beyond the international biodiversity framework.

The Kunming-Montreal Global Biodiversity Framework has emphasized the importance of mainstreaming for strengthening resource mobilization and the effective and efficient use of resources, in order to support the conservation and sustainable use of biodiversity.[168] An integrated and coordinated approach may allow for more efficient use of resources, through the sharing of costs and resources between biosafety and biodiversity institutions and cross-sectoral and sectoral departments. Where biosafety is integrated into a broader policy that is a national priority and is well-supported by public resources, this may benefit the delivery and achievement of biosafety objectives and outcomes and the implementation of biosafety-related obligations. Resources that could potentially be shared for biosafety-related purposes include funding, facilities such as laboratories and technical equipment, expertise and human resources, including monitoring and enforcement capacities, and human-generated intelligence such as research results and risk assessments.

168 See, in this regard, decision 15/7 of the Conference of the Parties to the Convention, entitled "Resource mobilization", of 19 December 2022, with its reference to Targets 14, 15, 16 and 18 of the Framework.

BOX 10: High-level political and financial support for implementation of national biodiversity strategy and action plan II (2015–2025) of Uganda, including biosafety-related public awareness, education and participation targets

The national biodiversity strategy and action plan II (2015–2025) of Uganda included the following targets: By 2018, public awareness, education and participation in biotechnology and biosafety are enhanced and by 2020, national capacity for biotechnology applications and use is adequate. To implement those targets, under the national biodiversity strategy and action plan of Uganda, a number of activities were proposed, including a baseline study on levels of public awareness and education on the benefits and risks of biotechnology and biosafety, specialized training in biosafety for regulators and inspectors, training in biotechnology and biosafety for women and men and support for the development of skilled human resources for biotechnology and biosafety.

Implementation of the national biodiversity strategy and action plan II and integration of biosafety benefited from high-level political and financial support. Implementation of national targets was to be achieved by target champions, that is to say, government institutions whose mandate directly related to the specific national targets. The Ministry of Finance in its circular on preparation of the budget framework papers and preliminary budget estimates guided and advised sectors on implementation of national biodiversity strategy and action plan II targets, including those relating to biosafety. ,

6. Mainstreaming biosafety into domestic cross-sectoral and sectoral policies, laws, and institutional frameworks

In the present study, biosafety mainstreaming refers to the integration of biosafety in domestic cross-sectoral and sectoral legislation, policies and institutional frameworks, taking into account national circumstances and priorities.[169] It follows from the discussion in section 5 that mainstreaming may serve different but often complementary objectives, depending on evolving international targets and specific national policy and legislative contexts. As outlined in that section, biosafety mainstreaming may help to ensure synergies within the international biodiversity framework and between the implementation of biosafety obligations and implementation of other international obligations (related, for example, to biodiversity, environment and trade) at the national level. Biosafety mainstreaming may facilitate the establishment, development and strengthening of effective national biosafety frameworks and support more resource-efficient implementation.

The present section identifies key steps for mainstreaming of biosafety into cross-sectoral and sectoral policies, legislation and institutional frameworks and provides examples of mainstreaming from the 19 Parties to the Cartagena Protocol that were involved in the pilot project on biosafety mainstreaming and integrated implementation project. The presentation in this section may therefore help other Parties to explore options for mainstreaming biosafety in their country.

6.1. Key steps to mainstreaming biosafety at the domestic level

Through a four-year consultative and stakeholder-driven process, the Secretariat of the Convention, in collaboration with the Strathclyde Centre for Environmental Law and Governance, worked with 19 Parties to the Cartagena Protocol to identify and document best practices for biosafety mainstreaming. This led to the development of a method for biosafety mainstreaming which involves the formulation of a mainstreaming vision and goals, identification of national entry points and opportunities for mainstreaming, identification of mainstreaming aspects and mainstreaming activities, engagement of relevant authorities and stakeholders, identification of tools for mainstreaming and creation of an enabling environment for mainstreaming. An online application developed by the Convention Secretariat and the Strathclyde Centre for Environmental Law and Governance, which provides step-by-step guidance for development of a mainstreaming strategy at the national level, is available through the Secretariat Biodiversity e-Learning Platform.[170] Further

169 Convention on Biological Diversity, Cartagena Protocol on Biosafety, "About biosafety mainstreaming" (2018). Available at https://bch.cbd.int/protocol/issues/mainstreaming/about/ (accessed on 28 June 2024).

170 'Convention on Biological Diversity, "Biodiversity e-Learning Platform: Biosafety/mainstreaming biosafety" (2018), available at https://scbd.unssc.org/course/index.php?categoryid=14 (accessed on 12 May 2023).

information is available on the "About biosafety mainstreaming" page of the Convention website.[171]

Key steps to biosafety mainstreaming are provided below to help readers of sections 6. 2–6.4, which include national examples of biosafety mainstreaming), to understand how those examples could be relevant to their national contexts and to identify opportunities for mainstreaming at the domestic level. A printable basic template of a national mainstreaming strategy which captures key elements of such a strategy is provided in annex II to the present study, entitled "Template for developing a national biosafety mainstreaming strategy".

It is to be noted that mainstreaming can take many different forms depending on national needs and circumstances. The method for biosafety mainstreaming presented in the present study was developed in collaboration with Parties to the Cartagena Protocol and constitutes one of many possibilities for biosafety mainstreaming. It is not meant to be prescriptive, nor are its elements meant to be exhaustive.

The steps to mainstreaming biosafety at the national level are the following:

1. Formulate a mainstreaming vision and goals
2. Identify national entry points and opportunities for mainstreaming
3. Identify specific aspects to be addressed within each entry point and the necessary activities or actions
4. Engage authorities and stakeholders when implementing mainstreaming activities and dedicate adequate resources to realize mainstreaming objectives
5. Identify tools for biosafety mainstreaming
6. Create an enabling environment for biosafety mainstreaming

171 Convention on Biological Diversity, Cartagena Protocol on Biosafety, "About biosafety mainstreaming" (2018). Available at https://bch.cbd.int/protocol/issues/mainstreaming/about/ (accessed on 12 May 2024).

Information on each of those steps is provided below.

1. FORMULATE A MAINSTREAMING VISION AND GOALS

A national vision for biosafety mainstreaming is important for guiding national action. Such a vision enables the setting of clear and realistic goals for biosafety mainstreaming. A national mainstreaming vision enables the prioritizing of mainstreaming goals and the planning for mainstreaming activities, taking into account national capacities and needs. In the formulation of a biosafety mainstreaming vision, other relevant national goals and priorities need to be considered in order to ensure consistency.

Following the formulation of a mainstreaming vision, goals may be developed. Those goals can be set while taking into consideration opportunities to facilitate biosafety mainstreaming that are expected to arise. A vision, goals and opportunities allow for prioritization of activities. A national vision and national goals may be adapted over time in the light of changes in national policy, priorities and opportunities.

2. IDENTIFY NATIONAL ENTRY POINTS AND OPPORTUNITIES FOR MAINSTREAMING

Mainstreaming activities are aimed at addressing biosafety issues across cross-sectoral and sectoral legislation, policies and institutions. It is crucial to identify early on in the mainstreaming process the instruments where biosafety would need to be better addressed. The instruments and institutions identified may be referred to as mainstreaming "entry points".

As introduced under section 5.2.1, a logical point of departure for biosafety mainstreaming may be the national biodiversity strategy and action plan, which functions as the national implementation strategy under the Convention. The integration of aspects of biosafety in the national biodiversity strategy and action plan would reflect the interconnected objectives of the Protocol and the Convention and could give an impetus to biosafety mainstreaming within the context of national actions related to biodiversity. Furthermore, the national biodiversity strategy and action plan could be used to highlight the national

Photo by Peter Lowe/Centro Internacional de Mejoramiento de Maíz y Trigo

mainstreaming vision and foster mainstreaming across cross-sectoral and sectoral instruments.

Policy or legal instruments related to environmental protection, trade, consumer protection, sustainable development, agriculture, food and land use, health care, forestry, fisheries, energy and research are other possible entry points for biosafety mainstreaming.

Moreover, several relevant institutions may serve as entry points, including biosafety-specific institutions such as competent national authorities and other national biosafety institutions, as well as cross-sectoral and sectoral government bodies, platforms for cooperation and advisory bodies. Mainstreaming biosafety in institutions may involve the inclusion of biosafety experts or a representative of competent authorities for biosafety in sectoral or cross-sectoral institutions or the establishment of coordination mechanisms.

It may be necessary to prioritize certain entry points over others, depending on opportunities and resources and in the light of the national vision for biosafety mainstreaming and related goals.

Examples of entry points for mainstreaming will be provided hereafter (section 6. 2-6. 4).

3. IDENTIFY SPECIFIC ASPECTS TO BE ADDRESSED WITHIN EACH ENTRY POINT AND THE NECESSARY ACTIVITIES OR ACTIONS

Once the policies, legislation and institutional frameworks for mainstreaming have been identified, it would be important to formulate the aspects of biosafety that need to be addressed within each entry point. It may be useful to decide which aspects of biosafety can be best addressed for each entry point so that the mainstreaming goal can be achieved most effectively and efficiently. For example, labelling requirements may be best addressed in consumer protection legislation, whereas punitive and administrative sanctions may be best addressed in relevant criminal and administrative laws.

The examples provided in sections 6.2–6.4 below illustrate aspects of biosafety that could be relevant within cross-sectoral and sectoral legislation, policies and institutional frameworks.

Activities and actions will be required to achieve successful mainstreaming of aspects of biosafety into the policies, legislation and institutional frameworks which have been identified as entry points. These practical steps may include preparatory activities such as research; participatory activities including engagement of working groups, meetings and consultations to gather information and incorporate different perspectives on biosafety; and drafting activities including preparation of proposals and amendments that focus on specific aspects of biosafety.

4. ENGAGE AUTHORITIES AND STAKEHOLDERS WHEN IMPLEMENTING MAINSTREAMING ACTIVITIES AND DEDICATE ADEQUATE RESOURCES FOR REALIZING MAINSTREAMING OBJECTIVES

Formulating and implementing a strategy for mainstreaming biosafety also involve addressing practical issues, including identification of the authorities that may be best placed to take mainstreaming actions and activities forward and the resources that would be necessary to undertake mainstreaming actions and activities and achieve relevant goals. Including activities and actions to support biosafety mainstreaming into work programmes of relevant authorities and ongoing or scheduled processes may allow for and facilitate efficient use of resources. It is to be noted, however, that assigning clear mainstreaming responsibilities to authorities that are in control of specific entry points may not always be possible. Where cross-sectoral or sectoral authorities are not yet involved in biosafety (mainstreaming) activities, responsibilities may be assigned to those that are already involved, notably biosafety-specific institutions, so as to create an understanding of the importance of biosafety mainstreaming and help to build capacity.

Engaging public authorities, private stakeholders and the public in mainstreaming processes is important for raising awareness of biosafety and ensuring that diverse interests and perspectives are included in biosafety mainstreaming activities, in relation, for example, to agriculture, health, the environment and socioeconomic concerns. Wide engagement can help to ensure that proposed provisions and activities are ambitious as well as practical and feasible and enjoy broad stakeholder and public support. Awareness-raising, training and education and capacity-building activities in the context of specific mainstreaming activities may be required to ensure full and effective involvement of all relevant authorities, stakeholders and the public.

When stakeholders and interest groups are being included, special attention should be given to indigenous peoples and local communities, in accordance with international obligations under biodiversity and human rights law.

5. IDENTIFY TOOLS FOR BIOSAFETY MAINSTREAMING

The four steps outlined above are key building blocks for drafting and implementing a national strategy for mainstreaming biosafety into legislation, policies and institutional frameworks.

In sections 6.2–6.4 below, examples derived from countries where biosafety mainstreaming has already taken place are provided to illustrate the features of potential entry points and mainstreaming activities. Whereas these policy and legislative examples are the focus of the present study, for the purpose of comprehensiveness it is worth noting that non-legislative tools and approaches may also hold potential for biosafety mainstreaming and for supporting legislative biosafety mainstreaming efforts. Use of non-legislative tools and approaches may contribute to facilitating engagement of authorities and stakeholders in relation to specific biosafety mainstreaming activities (see step 4 above) and the creation of an enabling environment for biosafety more generally (see step 6 below).

To illustrate the potential of non-legislative tools for mainstreaming, examples of the use of guidance documents, memorandums of understanding and research funding in support of biosafety mainstreaming are presented in boxes 11–13 below. Other examples of non-legislative tools for biosafety mainstreaming include standards and certification, for example,

technical standards or standards for private sustainability certification such as organic certification which integrate biosafety and LMO labelling requirements. Non-legislative tools may include networks and databases to support cooperation and implementation of biosafety obligations, for example, networks of laboratories for LMO detection and identification and or information systems that facilitate cooperation, for example, between biosafety authorities and border control.

6. CREATE AN ENABLING ENVIRONMENT FOR BIOSAFETY MAINSTREAMING

Implementation of biosafety obligations and mainstreaming of biosafety are often hampered by a lack of coordination of efforts across cross-sectoral and sectoral institutions or a lack of capacity, awareness and resources. Creating an enabling environment through which to overcome such barriers is an essential step for successful mainstreaming of biosafety.

Capacity-building, resource mobilization, cooperation, and public awareness, education and participation are building blocks for the creation of an enabling environment for the implementation of biosafety obligations, as recognized in the Implementation Plan for the Cartagena Protocol on Biosafety,[172] and for mainstreaming biosafety. Some of the building blocks that contribute to creating an enabling environment are enshrined in provisions of the Cartagena Protocol (see sects. 4.2.8–4.2.9 above).

Where activities target private stakeholders, those stakeholders may include industry actors, researchers, farmers, indigenous peoples and local communities and the public at large.

Key elements of an enabling environment for biosafety regulation and mainstreaming, include:

- **Capacity-building**, for example, through cooperation, training workshops, manuals, and guidelines and technical, regulatory and policy advice
- **Resource mobilization**, including adequate human, technical and financial resources
- **Cooperation and coordination**, at local, national, bilateral, regional and multilateral level
- **Public awareness-raising**, **public education, public participation in decision-making on LMOs and access to information**, for example, through briefing sessions, information events, documents, consultations and education programmes

Examples of activities that have contributed or have potential to contribute to the creation of an enabling environment for biosafety mainstreaming are included in the text boxes 14–17 below.

172 Decision CP-10/3 of 19 December 2022 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, entitled "Implementation Plan for the Cartagena Protocol on Biosafety", annex, para. 7.

BOX 11: The national laboratory biosafety and biosecurity guidance (2019)[a] developed by the Ministry of Public Health of Cameroon aims at ensuring that laboratory practices conform with biosafety standards and harmonizing practices at the national level

Through the development of the national laboratory biosafety and biosecurity guidance in Cameroon in 2019 the Ministry of Public Health of Cameroon has sought to ensure that laboratory practices conform with biosafety standards and to harmonize practices at the national level. The aim of the guidance is to ensure that laboratory practices conform with international standards and guidelines on biosafety; to provide information on the safe handling, transport and disposal of equipment and organisms associated with biological hazards; and to harmonize current laboratory practices at the national level.

In general terms, the guidance serves as a reference for laboratory practitioners on precautions to be taken in the handling, transporting and storing of pathogens, toxins and radioactive agents in Cameroon. It supports compliance by existing or new laboratories with physical standards on containment, operating standards and those relating to verification and performance tests. A dedicated section on safety and DNA recombination technologies outlines potential hazards associated with contained LMO use and integrates key elements of risk assessment. The guidance emphasizes that "[R]esearchers must comply with the regulations, restrictions and requirements for working on genetically modified organisms in Cameroon".

[a] Available at https://dpml.cm/images/Publications/GuideBonnePratique/Laboratory_Biosafety_and_Biosecurity_Guidance_in_Cameroon.pdf (accessed on 28 June 2024).

BOX 12: Memorandums of understanding between the National Biosafety Management Agency of Nigeria and public bodies as a foundation for inter-agency collaboration and the mainstreaming of biosafety in legislative and non-legislative instruments

The National Biosafety Management Agency of Nigeria has developed memorandums of understanding to facilitate inter-agency collaboration among relevant ministries, departments and agencies for the effective implementation of the regulation of LMOs. The memorandums of understanding regulate cooperation between the National Biosafety Management Agency and nine public bodies: the Federal Competition and Consumer Protection Commission, the Federal Ministry of Agriculture and Rural Development through its Veterinary and Pest Control Department, the Federal University of Petroleum Resources, the National Agency for Food and Drug Administration and Control, the National Agricultural Seeds Council, the National Varietal Release Committee, the Nigeria Agricultural Quarantine Service, the Nigerian Customs Services and the Standard Organization of Nigeria.

The memorandums of understanding were used to operationalize the inter-agency pathway for collaboration on release of genetically modified organisms in Nigeria, a harmonization strategy. The collaborative work that underpins the memorandums of understanding has led to mainstreaming into legislative frameworks and other non-legislative tools. For example, cooperation with the National Agricultural Seeds Council led to mainstreaming of biosafety into the National Agricultural Seeds Council Act (2019). Furthermore, cooperation with the Nigerian Customs Services led to integration of the National Biosafety Management Agency into the Nigeria Integrated Customs Information System II in September 2023. The aim of that integration was to ensure that imports and exports would be monitored for LMO presence and that no LMO seeds or grains would be imported or exported without the approval of the National Biosafety Management Agency. Moreover, cooperation with the National Varietal Release Committee led to integration of biosafety into the authority's operational guidelines and procedures, which means that the Committee now requests an Agency biosafety permit from applicants before certifying new LM plant varieties.

BOX 13: The Intersecretarial fund for biosafety research of Mexico is resourced by and equipped to respond to the research needs of cross-sectoral and sectoral institutions

The *Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados* of Mexico (CIBIOGEM)is made up of the heads of the secretariats of agriculture, livestock, rural development, fisheries and food; environment and natural resources; health; economy; public education; and finance and public credit; and the Director General of the National Council of Science and Technology. CIBIOGEM is tasked with establishing policies related to biosafety with respect to the use of LMOs. The secretariats that are part of CIBIOGEM contribute financial resources to the Fondo CIBIOGEM, a national fund that supports academic research projects in the field of biosafety.

The Fondo CIBIOGEM f is considered to be an efficient means of providing funding for biosafety research since projects must respond to an identified need for information in relation to biosafety, which may include information needs of the cross-sectoral and sectoral institutions involved with CIBIOGEM. First, economic support is provided for activities that are directly linked to the *programa para el desarrollo de la bioseguridad y la biotecnología*, the national scientific programme on biosafety and biotechnology. Under article 29 of the *Ley de Bioseguridad de Organismos Genéticamente Modificados (2005)*,[a] the National Council of Science and Technology of Mexico is tasked to develop the programme on the basis of the proposals presented by the secretariats that compose CIBIOGEM and other public agencies. Second, alignment between the content of research projects and the needs of decision makers has been held to follow from the fact that the secretariats that make up CIBIOGEM contribute their own resources to the fund (pursuant to article 31 of the *Ley de Bioseguridad de Organismos Genéticamente Modificados (2005)*). While projects may generate knowledge concerning the environmental and health risks of LMOs, they may also focus on socioeconomic considerations. For example, the focus of one project was the perceptions and attitudes of the Mexican urban population regarding the production and consumption of LMOs. The responsiveness of the Fondo to the needs of the secretariats signifies that there is potential for dedicated funding of projects whose aim is to address information gaps that currently inhibit cross-sectoral and sectoral mainstreaming activities (in this regard, see step 4 above on preparatory activities for mainstreaming which may include research).

Results of research undertaken with support from the Fondo CIBIOGEM are made publicly available through seminars, workshops, the CIBIOGEM website, scientific journals and academic conferences. For research that is part of the *programa para el desarrollo de la bioseguridad y la biotecnología,* article 30 of the *Ley de Bioseguridad de Organismos Genéticamente Modificados (2005)* provides that results are made available to seed companies of peasant and producer organizations in an accessible manner.

[a] Available at https://faolex.fao.org/docs/pdf/mex64015.pdf. The English translation (Law on Biosafety of Genetically Modified Organisms) is available at https://conahcyt.mx/cibiogem/images/cibiogem/eng/Docs/Ing_LBOGM_P.pdf (accessed on 28 June 2024).

***Example clause: Ley de Bioseguridad de Organismos Genéticamente Modificados* of Mexico (2005)**

ARTÍCULO 29. – Para lograr el fomento a la investigación científica y tecnológica en materia de bioseguridad y de biotecnología se establecerá un programa para el desarrollo de la bioseguridad y la biotecnología que será considerado como un programa cuya formulación estará a cargo del CONACyT con base en las propuestas que presenten las Secretarías y las demás dependencias y entidades de la Administración Pública Federal que apoyen o realicen investigación científica y desarrollo tecnológico. En dicho proceso se tomarán en cuenta las opiniones y propuestas de las comunidades científica, académica, tecnológica y sector productivo, convocadas por el Foro Consultivo Científico y Tecnológico, y de la CIBIOGEM.

Dicho programa formará parte del Programa Especial de Ciencia y Tecnología que establece la Ley de Ciencia y Tecnología. […]

ARTÍCULO 30. – […]El Ejecutivo Federal, por conducto de las Secretarías competentes, se asegurará de poner a disposición de las empresas semilleras de las organizaciones de campesinos y de productores, de manera preferente y accesible, los resultados de la investigación científica y de innovación y desarrollo tecnológico contenidos en el Programa para el desarrollo de la bioseguridad y la biotecnología.

ARTÍCULO 31. – El CONACyT constituirá un Fondo para el Fomento y Apoyo a la Investigación Científica y Tecnológica en Bioseguridad y Biotecnología conforme a la Ley de Ciencia y Tecnología, al cual se destinarán los recursos fiscales que aporten las dependencias y entidades para tal fin, recursos de terceros e ingresos que por concepto de derechos determinen las disposiciones fiscales, que deriven de actos realizados en aplicación de esta Ley.

BOX 14: The National Coordination Biosafety Centre of Belarus, provides consultative services and training to build capacity on biosafety among ministries and other public bodies

The National Coordination Biosafety Centre of Belarus was established in 1998 under the aegis of the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus, which is the supreme State scientific institution and the body for the coordination of all subjects that are the focus of scientific research.

One of the key objectives of the National Coordination Biosafety Centre is to provide consultative services to ministries and other republican bodies of the State administration for the development of draft legislative acts in relation to biosafety. Those services allow for capacity-building through the sharing of biosafety-related knowledge. For example, the Biosafety Centre supported the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food and the National Centre of Legislation and Legal Research in the drafting of the Law on Safety in Genetic Engineering Activity (2006). The Biosafety Centre supported the same public institutions in the mainstreaming of biosafety into administrative and criminal frameworks for the purpose of enforcing biosafety obligations (see also sect. 6.3.1 below).

Moreover, the National Coordination Biosafety Centre initiates capacity-building activities such as training workshops and seminars for members of groups engaged in biosafety-related activity, such as LMO developers, biosafety experts, staff members of the LMO detection laboratories and members of public associations, as well as the representatives of all relevant national government institutions.

BOX 15: Promotion of joint initiatives on biosafety to stimulate cooperation and coordination among countries that are part of the Andean Community of Nations

The Andean Community of Nations integrates a number of countries in the Andes region of South America into a free trade area. The aim of the Community, which was created in 1969 upon the signature of the Andean Subregional Integration Agreement (Cartagena Agreement), is to promote harmonious development through economic and social cooperation. In 2012, when the Community included Bolivia (Plurinational State of), Colombia, Ecuador and Peru, the Community approved the Environmental Andean Agenda 2012–2016, a planning tool which guided and supported sustainable development in the region through coordination of policies and community strategies. In relation to biodiversity, the agenda included the explicit objective of promoting joint initiatives on biosafety. Under this goal, countries that are part of the Community are tasked with generating cooperation tools and strengthening institutional frameworks to improve the regulation of LMOs at the regional and subregional levels.

BOX 16: The Biosafety communication strategy of Malawi to build public awareness on biosafety

The aim of the biosafety communication strategy of Malawi is to ensure awareness and understanding, among the members of the public, of biosafety issues, the regulation of biosafety in Malawi and the mandate of the National Biosafety Regulatory Committee. The strategy provides a framework for delivering key messages and activities that target specific audiences. The implementation of the strategy is coordinated by the biosafety registrar, which identifies key partners for its delivery. A lack of funding, however, has hampered the effective implementation of the biosafety communication strategy.

BOX 17: Legislation on consultation with indigenous peoples and local communities is a part of the framework for the regulation of biosafety of the Bolivarian Republic of Venezuela.

The *Ley Orgánica de Pueblos y Comunidades Indígenas (2005)*[a] of the Bolivarian Republic of Venezuela builds upon the principle of respect for the cultural integrity of indigenous peoples and local communities, as enshrined in the country's Constitution. The law is considered to be part of the framework of legislation relevant to biosafety in the Bolivarian Republic of Venezuela.

Provisions in particular on prior and informed consultation establish that any activity that may directly or indirectly affect indigenous peoples and local communities must involve consultation with them. The consultation must be conducted in good faith, taking into account languages and spirituality of indigenous peoples and local communities and the legitimate authorities and communication and information systems of the indigenous peoples and communities involved.

[a] *Available at https://faolex.fao.org/docs/pdf/ven174043.pdf (accessed on 28 June 2024).*

6.2. Mainstreaming biosafety into cross-sectoral and sectoral policies

Mainstreaming biosafety into cross-sectoral and sectoral policies allows for its integration at the policy level through inclusion in relevant objectives, goals, outcomes, targets and indicators. Moreover, mainstreaming is an effective vehicle for engagement with multiple sectors. Relevant cross-sectoral policies (see sect. 6.2.1 below for a further discussion) may include national biodiversity strategies and action plans and policies that relate to the environment, sustainable development, climate change, social well-being, land use, rural development, customs and trade. Relevant sectoral policies (see sect. 6.2.2 below for a further discussion) may include those relating to agriculture, food and food safety, forestry, fisheries, consumer protection, tourism, health, transport, water and research.

The present section, which provides examples of biosafety mainstreaming in cross-sectoral and sectoral policies, is based upon in-depth analysis of examples of biosafety mainstreaming that were identified for the 19 Parties that had participated in the pilot project and integrated implementation project between 2015 and 2018. Use of this inductive method signifies that not all of the potential cross-sectoral and sectoral policies have been included. Instead, the focus is on policies for which strong sample provisions could be identified, notably policies relevant to food and agriculture, whose lessons could be transferred or extended to other policy areas.

Further examples of biosafety mainstreaming into cross-sectoral and sectoral policies are included in annex III below.

6.2.1. Examples of biosafety mainstreaming in cross-sectoral policies, including the national biodiversity strategy and action plan

Cross-sectoral policies, strategies, programmes and plans play a special and significant role as entry points for mainstreaming. As cross-sectoral policies, by definition, cover more than one sector, drafting processes as well as implementation processes for cross-sectoral policies will usually reflect a wide representation of public institutions that are responsible for regulating different sectors. The ability to bring biosafety into discussions on the drafting and implementation of cross-sectoral policies may offer possibilities for inter-institutional awareness-raising and capacity-building. Furthermore, successful mainstreaming of biosafety into a cross-sectoral policy may provide a foundation for further biosafety mainstreaming in other entry points. For example, if the relevance of biosafety in relation to sectoral objectives and targets for sustainable agriculture or agrobiodiversity is considered under a cross-sectoral policy, this may lead to further mainstreaming of biosafety into sectoral legislation and policies on agriculture, including regulations on

Photo by United Soybean Board

organic certification and the authorization and use of pesticides.

National examples of biosafety mainstreaming are particularly prevalent in cross-sectoral policies on sustainable development and the environment, reflecting opportunities for implementation of the Sustainable Development Goals and evolving environmental priorities through comprehensive protection against biosafety risks. Another example of cross-sectoral policies that are of particular significance for biosafety mainstreaming are national biodiversity strategies and action plans, as introduced in section 5.2.1 above. Under Article 6 of the Convention on Biological Diversity, Parties are required to develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity. To date, 194 of the 196 Parties to the Convention (99 per cent) have developed at least one national biodiversity strategy and action plan.[173]

National biodiversity strategies and action plans are the principal policy instrument for implementing the Convention at the national level. A national strategy will "reflect how the country intends to fulfil the objectives of the Convention in the light of specific national circumstances, and the related action plans will constitute the sequence of steps to be taken to meet these goals".[174] National biodiversity strategies and action plans usually contain objectives, activities, indicators and outcomes for a range of biodiversity issues. As illustrated by the examples of biosafety mainstreaming into national biodiversity strategies and action plans provided in section 5.2.1, they hold great potential for linking activities aimed at implementing and mainstreaming biosafety obligations to the fulfilment of the partly overlapping objectives of the Convention and the Cartagena Protocol, notably conservation and sustainable use of biodiversity. As illustrated by the example of national biodiversity strategy and action plan-related mainstreaming offered in section 5.2.3, implementation of national biodiversity strategies and action plans may be better

173 See Convention on Biological Diversity, National biodiversity strategies and action plans (NBSAPs), "What's new?" (2023). Available at www.cbd.int/nbsap/ (accessed on 11 November 2023).

174 Ibid., "What is an NBSAP?" (2023). Available at www.cbd.int/nbsap/introduction.shtml (accessed on 11 November 2023).

resourced by countries than implementation of standalone national policies on biosafety, which could allow for mobilization of resources for the implementation of biosafety activities and efficient sharing of resources.

To ensure that achievement of biosafety objectives and outcomes and proposed activities on biosafety in cross-sectoral policies, including national biodiversity strategies and action plans, are adequately resourced, it is important that they be made explicit. Furthermore, while biosafety may be integrated throughout the cross-sectoral policy, it could be useful to bring goals and objectives, activities, indicators and outcomes that relate to biosafety together within the strategy document to ensure that responsibilities across cross-sectoral and sectoral institutions for achieving relevant goals and undertaking activities are clear and mutually supportive and that adequate resources are dedicated to implementation.

Biosafety mainstreaming into national biodiversity strategies and action plans, environmental policies and sustainable development policies may, for example, involve integration of commitments and actions to implement key elements of international and national obligations on biosafety. Biosafety mainstreaming may also involve the establishing of explicit links between biosafety objectives and activities and other national objectives and activities relevant to biodiversity conservation and sustainable use, in relation, for example, to invasive alien species, ex situ and in situ conservation of biological diversity, protected areas and conservation of genetic resources. In this regard, cross-referencing of biosafety-specific policies in cross-sectoral policies on, for example, the environment or biodiversity may be a useful mainstreaming technique for integrating commitments and actions. Boxes 18–20 include detailed examples of biosafety mainstreaming into cross-sectoral policies which were identified through analysis of policies formulated in the Parties that participated in the projects on biosafety mainstreaming under the Secretariat of the Convention.

Additional examples of biosafety mainstreaming into cross-sectoral policies are included in annex III below.

BOX 18: Commitments and actions to develop and implement key obligations for a national biosafety framework in the national biodiversity conservation strategy and action plan (2011–2030) of China[a]

The aim under the national biodiversity conservation strategy and action plan (2011–2030) of China, which was issued by the Ministry of Environmental Protection, is to implement relevant provisions of the Convention on Biological Diversity in order to strengthen biodiversity conservation in China and enable new problems and challenges associated with biodiversity conservation to be addressed effectively.

The national biodiversity conservation strategy and action plan identifies the management of LMOs as a priority area of work. China, under action 24 of priority area 7 of its strategy and action plan, commits to "[e]stablish and complete technical systems and platforms for biosafety assessment, inspection and monitoring of transgenic organisms". Proposed activities for implementing this action include the development of assessment techniques for environmental risk analysis; development of sampling and high-throughput detection technology and full traceability technology; and development of techniques and standards for LMO release, production and application; import and export safety monitoring and risk management; establishment of centres for biosafety assessment; and the gradual establishment of an inspection and monitoring system for biosafety of LMOs.

The national biodiversity conservation strategy and action plan is providing the basis for local and regional action on biosafety. Provinces in China that are taking actions on LMO management include Shandong Province which has made carrying out LMO safety assessment and developing LMO inspection methods and monitoring techniques one of its priorities. Tianjin has asked for strengthened monitoring and entry-exit inspection and quarantine of LMOs. Ningxia Hui Autonomous Region has decided to improve its LMOs management mechanism through enhancing detection procedures and establishing an LMO safety assessment, inspection and monitoring system.

The Biosecurity Law of China was adopted in October 2020 and took effect on 15 April 2021. The Law is broad in scope and aims, inter alia, for the purposes of maintaining national security, towards preventing and responding to biosecurity risks, safeguarding the lives and health of the people, protecting biological resources and ecology and the environment and promoting the sound development of biotechnology. After adoption of the Biosecurity Law, the Ministry of Agriculture and Rural Affairs indicated that rules for agricultural biotechnology would be revised, although no further information was available at the time of writing.

[a] Available at www.cbd.int/doc/world/cn/cn-nbsap-v2-en.pdf (accessed on 28 June 2024).

***Example clause:* National biodiversity conservation strategy and action plan (2011–2030) of China (2010)**

Priority Area 7: Strengthen biosafety management of invasive alien species and genetically modified organisms. […]

Action 24: Establish and complete technical systems and platforms for biosafety assessment, inspection and monitoring of transgenic organisms.
- Focus on developing assessment techniques of environmental risk analysis of transgenic organisms, and safety of GMOs for food and feed.
- Develop transgenic organism sampling and high-throughput detection technology, and undertake research on and develop related criteria, inspection equipment, facilities and products and research on full traceability technology.
- Develop techniques and standards of transgenic organism release, production and application, import and export safety monitoring and risk management, and technology of risk warning and safe disposal.
- Establish centres for biosafety assessment of GMOs and gradually establish an inspection and monitoring system of biosafety of transgenic organisms and implement real-time detection and tracking.
- Actively participate in international negotiation in fields related to biosafety.

BOX 19: The *Plan Nacional para el Buen Vivir (2013–2017)*[a] of Ecuador included commitments and actions to guarantee biosafety through development and implementation of biosafety regulations and protocols

The *Plan Nacional para el Buen Vivir (2013–2017)* of Ecuador was prepared by the National Planning and Development Secretariat in its capacity of Technical Secretariat of the National Decentralized Participatory Planning System. The drafting was supported by representatives of the Ministries of Environment, Agriculture and Health, the National Secretariat of Higher Education, Science, Technology and Innovation and other entities that were part of the Monitoring Committee of the project entitled "Implementation of the national biosafety framework". Those institutions were able to bring significant awareness and capacity related to biosafety to the table.

Under its objective of guaranteeing the rights of nature and promoting environmental sustainability globally, Ecuador committed to guaranteeing biosecurity, safeguarding the health of people, other living beings and nature. Relevant activities included the development of biosafety regulations based on the precautionary principle; implementation of protocols to prevent and manage adverse effects that modern biotechnology may have on human health, food sovereignty and the conservation and use of biodiversity; and implementation of measures and safeguards to promote the involvement and participation of communities, people and nationalities in the processes that affect their cultures and natural environments.

[a] Available at https://faolex.fao.org/docs/pdf/ecu139396.pdf. The English translation of the document (Good Living National Plan 2013–2017: A Better World for Everyone) is available at www.oneplanetnetwork.org/sites/default/files/from-crm/ecuador_national_plan_of_good_live_2013_-_2017.pdf (accessed on 28 June 2024).

***Example clause: Plan Nacional para el Buen Vivir (2013–2017)* of Ecuador (2013)**

Objetivo 7: Garantizar los derechos de la naturaleza y promover la sostenibilidad ambiental, territorial y global.

7.5. Garantizar la bioseguridad precautelando la salud de las personas, de otros seres vivos y de la naturaleza

a. Generar normativa sobre bioseguridad basada en el principio de precaución, para afrontar y reducir los riesgos asociados a la presencia y al uso de organismos vivos modificados.
b. Desarrollar y aplicar un sistema nacional de bioseguridad integral para el control de los potenciales peligros y riesgos en la transferencia, manipulación, liberación y utilización de los resultados de la biotecnología.
c. Implementar protocolos que permitan prevenir y manejar los efectos adversos que pueda generar la biotecnología moderna en la salud humana, la soberanía alimentaria y la conservación y el uso de la biodiversidad.
d. Fomentar la investigación, la educación, la capacitación, el entrenamiento y la comunicación sobre la bioseguridad, la biotecnología y los organismos genéticamente modificados.
e. Aplicar medidas y salvaguardas para fomentar el involucramiento y la participación de las comunidades, pueblos y nacionalidades en los procesos que afecten a sus culturas y entornos naturales como resultado de las prácticas de manipulación biotecnológica.

BOX 20: The *Estrategia Nacional de Diversidad Biológica al 2021 y su Plan De Acción (2014–2018)*[a] of Peru led to the development of a multisector plan for surveillance of LMOs

In its *Estrategia Nacional de Diversidad Biológica al 2021 y su Plan De Acción (2014–2018)* Peru committed to reducing direct and indirect pressures on biological diversity and its ecosystemic processes (objective 3). This involved more effective control and oversight in the use of biodiversity and increased regulatory mechanisms for threatened species and invasive alien species (goal 8). To achieve this goal, the national biodiversity strategy and action plan included an action to establish a control system for restricting the entry of LMOs into the country. The national biodiversity strategy and action plan also included an action which had great potential for further mainstreaming of biosafety across sectors, as Peru committed through that action to developing a multisector surveillance and early warning plan for the release of LMOs.

The *Plan Multisectorial de Vigilancia y Alerta Temprana* was adopted in 2016.[b] Under the plan, the following ministries were made jointly responsible for surveillance of LMOs: the Ministry of the Environment, the National Institute of Agricultural Innovation, the National Fisheries Health Organization and the Environmental Assessment and Supervision Agency. Control and surveillance activities for the release of LMOs are reported by the relevant authorities on an annual basis, under the coordination of the Ministry of the Environment.

[a] Available at www.cbd.int/doc/world/pe/pe-nbsap-v2-es.pdf (accessed on 28 June 2024).

[b] Further information may be found in the document entitled "Control y vigilancia de OVM" (Ministry of the Environment of Peru, n.d.), available at https://bioseguridad.minam.gob.pe/normatividad/implementacion/control-y-vigilancia-de-ovm/ (accessed on 28 June 2024).

***Example clause: Estrategia nacional de diversidad biológica al 2021 y su plan de acción (2014–2018)* of Peru (2014)**

Objetivo Estratégico 3. Reducir las presiones directas e indirectas para la diversidad biológica y sus procesos ecosistémicos.

Meta 8. Al 2021 se habrá mejorado la efectividad del control, supervisión y fiscalización en el aprovechamiento de la biodiversidad, e incrementado los mecanismos regulatorios de las especies amenazadas y las especies exóticas invasoras.

Submeta 8. Al 2018 se habrá mejorado en un 30 % la efectividad del control, supervisión y fiscalización en el aprovechamiento de la biodiversidad, e incrementado los mecanismos regulatorios de las especies amenazadas y las especies exóticas invasoras. […]

Acción 84. A finales del primer semestre del 2015 se cuenta con un plan multisectorial de vigilancia y alerta temprana relativa a la liberación de los OVM.

BOX 21: A strategy to create an enabling environment for biosafety as part of the national biodiversity strategy and action plan (2016–2020) of Cambodia[a]

Under the national biodiversity strategy and action plan of Cambodia (2016–2020), several key actions were identified which were to be facilitated and coordinated as part of the responsibilities of the following ministries and institutions: the Ministry of Environment, the National Council for Sustainable Development, the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Commerce, the Ministry of Economy and Finance, the Ministry of Planning, the Ministry of Health, the Ministry of Rural Development and the Ministry of Mines and Energy.

Under the theme "Industry, technology and services", the aim of the national biodiversity strategy and action plan was to further the implementation of the national action plan on biosafety and biotechnology (2010–2014) notably through providing a comprehensive list of actions in relation to the creation of an enabling environment for implementing biosafety obligations. Those actions included the development of capacity-building action plans (well coordinated at the local and national levels), the establishment of a national directory of human resources trained and/or working on subjects concerning biotechnology and biosafety and mobilization of additional financial resources and technical support for the implementation of the Cartagena Protocol.

[a] Available at www.cbd.int/doc/world/kh/kh-nbsap-v2-en.pdf (accessed on 28 June 2024).

Example clause: **National biodiversity strategy and action plan (2016–2020) of Cambodia (2016)**

Theme 17: Industry, Technology and Services (Manufacturing, Biotechnology and Biosafety, and Tourism).

Strategic objective 1: Further the implementation of the National Action Plan on Biosafety and Biotechnology (2010–2014) and revise it in the context of the Cartagena Protocol on Biosafety and its Strategic Plan, and assess the contribution of these activities to the conservation and sustainable use of biodiversity, sustainable development and poverty reduction in Cambodia.

Key actions

1.1. Develop biosafety capacity-building action plans, well coordinated at the local and national levels, for implementing the Cartagena Protocol on Biosafety and the Nagoya- Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

1.2. Establish a national directory of human resources trained and/or working on subjects concerning biotechnology and biosafety, and assess capacity building needs, including training and institutional needs.

1.3. Raise public awareness, and promote training, education and participation concerning the safe transfer, handling and use of living modified organisms (LMOs).

1.4. Establish regulatory (national biosafety legislation and related guidelines) and administrative (administrative rules and procedures for handling notifications and requests for approval of imports of LMOs intended for direct use as food or feed, or for processing; contained use; and for introduction into the environment) rules consistent with the Protocol.

1.5. Establish a system for enforcement of the Cartagena Protocol on Biosafety. Adopt and widely use guidance on risk assessment and risk management.

1.6. Integrate biosafety issues and the implementation of the Protocol into the relevant sectors.

1.7. Carry out research to provide relevant guidance on socioeconomic considerations that may be taken into account in reaching decisions on import of living modified organisms.

1.8. Mainstream biosafety into national development plans and relevant sectoral policies, strategies and programmes, including development assistance programmes.

1.9. Mobilize additional financial resources and technical support for the implementation of the Protocol, as one of the major prerequisites of successful implementation of activities planned in the Protocol and within the overall framework of the Strategy for Resource Mobilization in support of the Convention on Biological Diversity.

6.2.2. Examples of biosafety mainstreaming in sectoral policies

Sectoral policies regulate specific sectors and provide the mandate and direct the activities of sectoral institutions. As there may be important synergies between biosafety and sectoral objectives, mainstreaming into sectoral policies may allow for synergetic implementation. For example, for the agricultural sector, biosafety may be relevant to national priorities related to protecting agrobiodiversity or promoting subsectors such as the organic sectors which rely on effective implementation of obligations concerning the safe handling, packaging and transport of LMOs to protect their LMO-free status and place in the market.

Similar observations could be made in relation to other sectors, including: (a) the health and food sectors, as the Protocol takes into account risks to human health and the work of the Codex Alimentarius Commission aims towards protecting consumers against food safety risks; and (b) the research sector, as the Protocol provides for obligations in relation to contained use of LMOs which may help to avoid the unintentional spread of LMOs and the mixing with or cross-contamination of other biological matters. The steps to be taken to draft and implement national strategies for biosafety mainstreaming (sect. 6.1), notably identification of entry points and key aspects (steps 2 and 3), allow for the establishment of synergies between biosafety and sectoral aims. Synergetic implementation may lead to strengthening of national biosafety frameworks and resource-efficient implementation of policies, including shared capacities.

Biosafety mainstreaming may, for example, involve inclusion of commitments and actions to implement biosafety obligations or strengthen or revise national biosafety frameworks in sectoral policies, considering their potential contributions to achieving sectoral aims. Sectoral policies may provide clarifications on how biosafety regulations and activities are intended to be implemented in relation to sectoral objectives and actions and those policies may seek to build bridges between sectoral objectives and biosafety aims. Moreover, sectoral policies (similarly to cross-sectoral policies, as outlined in some of the examples provided above) may offer opportunities for elaboration of commitments and actions to support the creation of an enabling environment for biosafety. Boxes 22–24 below present detailed examples of biosafety mainstreaming into sectoral policies which were identified through analysis of policies of the Parties that had participated in the projects on biosafety mainstreaming under the Convention Secretariat.[175]

Further examples of biosafety mainstreaming into cross-sectoral policies are included in annex III below.

175 See objectives and methodology section above, where more information about these projects is provided.

BOX 22: The *programa sectorial de agricultura y desarrollo rural (2020–2024)*[a] commits to strengthening the biosafety policy of Mexico to protect national agrobiodiversity

The *programa sectorial de agricultura y desarrollo rural (2020–2024)* of Mexico specifies the objectives, priorities and policies that govern the actions of the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food. The programme is designed in accordance with article 12 of the *Ley Nacional de Desarrollo Sustentable (2001)*, which is focused on promotion of sustainable rural development and consideration of the public interest in this context, including planning and organization of agricultural production.

Mexico, under priority strategy 1.5 of the Programme, commits to strengthening the health of agriculture and aquaculture fisheries and the safety of healthy and nutritious foods. A specific action based on this priority is strengthening the biosafety policy of Mexico for the protection of national agrobiodiversity.

[a] Available at https://faolex.fao.org/docs/pdf/mex196247.pdf (accessed on 28 June 2024).

***Example clause: Programa Sectorial de Agricultura y Desarrollo Rural (2020–2024)* of Mexico (2020)**

Estrategia prioritaria 1.5 Fortalecer la sanidad agropecuaria y acuícola-pesquera, y la inocuidad para la producción de alimentos sanos y nutritivos.

Acción puntual
[…]
1.5.5 Fortalecer la política de bioseguridad para la protección de la agrobiodiversidad nacional.

BOX 23: The *Programa Especial de Ciencia, Tecnología e Innovación (2021–2024)*[a] of Mexico puts forward a multidisciplinary and multisectoral vision for achieving biosafety

The *Programa Especial de Ciencia, Tecnología e Innovación (2021–2024)* is a public policy instrument that is concerned with the state of the sector for science, technology and innovation of Mexico and offers solutions for problems identified under the *Plan Nacional de Desarrollo.* The legislative basis for the programme includes the *Ley de Bioseguridad de los Organismos Genéticamente Modificados (2005)*.

The aim under the first priority objective of the *Programa Especial de Ciencia, Tecnología e Innovación (2021–2024)* of Mexico is to promote the training of high-level specialists in the areas of scientific, humanistic, technological and socioeconomic research that contributes to the development of comprehensive biosafety protection directed towards the solution of prioritized national problems, including climate change, thereby contributing to social welfare. Proposed activities include programmes in secondary and higher education and the establishment of exchange agreements with Mexican scientists, technologists and humanists residing abroad with a view to consolidating international networks for knowledge exchange.

The aim under the third priority objective of the programme is to bring together those persons in the scientific, public, private and social sectors who are involved in the production of humanistic, scientific and technological knowledge in order to solve prioritized national problems through a multidisciplinary, multisectoral, complex systems and comprehensive biosafety vision. In this regard, the programme, recognizing the structural and dynamic complexities that are associated with multidisciplinary and multisectoral work, aims towards creating mechanisms for collaboration, which would bring together members of the scientific community with persons in other public and private sectors to effectively address national-scale problems.

[a] Available at www.siicyt.gob.mx/index.php/normatividad/nacional/programa-especial-de-ciencia-tecnologia-e-innovacion-peciti/programa-especial-de-ciencia-tecnologia-e-innovacion-peciti-2/4965-programa-especial-de-ciencia-tecnologia-e-innovacion-peciti-2021-2024/file (accessed on 28 June 2024).

***Example clause: Programa Especial de Ciencia, Tecnología e Innovación (2021–2024)* of Mexico (2021)**

6. Objetivos prioritarios
6.1.- Promover la formación y actualización de especialistas de alto nivel en investigación científica, humanística, tecnológica y socioeconómica que aporten a la construcción de una bioseguridad integral para la solución de problemas prioritarios nacionales, incluyendo el cambio climático y así aportar al bienestar social. […]

6.3.- Articular a los sectores científico, público, privado y social en la producción de conocimiento humanístico, científico y tecnológico, para solucionar problemas prioritarios del país con una visión multidisciplinaria, multisectorial, de sistemas complejos y de bioseguridad integral.

6.3. Mainstreaming biosafety into cross-sectoral and sectoral legislation

Mainstreaming of biosafety into new or existing cross-sectoral and sectoral legislation allows for the integration of biosafety into instruments that are legally binding in nature. As noted above, mainstreaming activities may help to strengthen national biosafety frameworks to ensure synergies between biosafety and cross-sectoral and sectoral objectives and obligations, to build a broad understanding of biosafety across legislative frameworks and to create integrated legislative frameworks with provisions that are supportive of legal biosafety obligations, or that even include additional or more stringent requirements. While mainstreaming may also help to address current gaps in the implementation of functional national biosafety frameworks, it is important that mainstreaming activities do not lead to a fragmented implementation of the obligations under the Cartagena Protocol across several laws and policies, risking overlapping, contradictory or conflicting provisions or objectives (see also sect. 5.2.2 above). Further information on the key components of national biosafety frameworks is found in annex I below.

Photo by Peter Lowe/Centro Internacional de Mejoramiento de Maíz y Trigo

In the present section, several cross-sectoral and sectoral legal instruments into which biosafety has been integrated will be examined. Compared with the examples of integration of biosafety into policy instruments showcased in previous subsections, the examples of integration of biosafety into legislation seem to indicate that legal instruments are well suited to implementation of aspects of biosafety at an advanced level of detail. It is to be noted that the examples included in this section do not provide an exhaustive overview of how biosafety can be mainstreamed in cross-sectoral and sectoral legislation, as they are limited to those that could be identified within the legal contexts of the 19 Parties that had participated in the Convention Secretariat pilot project and integrated implementation project between 2015 and 2018.

Relevant cross-sectoral legal instruments (discussed further in sect. 6.3.1 directly below) may include constitutional instruments and legislation that relates to the environment, sustainable development, climate change, international cooperation, well-being and community development, enforcement, local governance, human rights, land use and planning, rural development, health, customs, and trade. Relevant sectoral legislation (discussed further in sect. 6.3.2 below) may include legislation that relates to agriculture, food and food safety, forestry, fisheries, consumer protection, tourism, health, transport, water and research.

6.3.1. Examples of biosafety mainstreaming in cross-sectoral legislation

Cross-sectoral legislation is a particularly important entry point for mainstreaming of biosafety because the implementation of cross-sectoral laws often requires cooperation between the various authorities responsible for the sectors addressed in that legislation. Integration of considerations on biosafety in processes for the drafting and implementation of cross-sectoral legislation may therefore offer possibilities for inter-institutional awareness- raising and capacity-building which may allow for further mainstreaming in other cross-sectoral and sectoral instruments for which those public authorities are responsible.

Environmental laws may constitute important entry points for the mainstreaming of biosafety obligations

because of the close connection and partial overlap in scope of biosafety measures and environmental measures, particularly those relating to the conservation and sustainable use of biodiversity. Environmental laws are entry points for biosafety provisions relating to both substantial issues and procedural issues. In this regard, the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (see sect. 4.2.8 above) provides an example of mainstreaming at the regional level, as it includes provisions on access to environmental information (including on the state of biological diversity and its components, including genetically modified organisms) and public participation in decision-making on the deliberate release of LMOs.[176]

Biosafety mainstreaming into cross-sectoral legislation may involve, for example, the integration of fundamental objectives and priorities of national biosafety policy in a constitution or other overarching laws, as well as the mainstreaming of biosafety obligations, relating, inter alia, to the assessment, management and monitoring of environmental or health risks in environmental laws or laws relevant to human, animal or plant health. Moreover, administrative and criminal laws may provide for specific procedures and sanctions for violation of biosafety legislation. Boxes 24–29 below present several detailed examples of biosafety mainstreaming into cross-sectoral legislation which were identified through in-depth analysis of legislation of the Parties that participated in the Convention Secretariat projects on biosafety mainstreaming.

Further examples of biosafety mainstreaming into cross-sectoral legislation are included in annex III.

176 Articles 2 (3) (a) and 6 (11).

BOX 24: The *Código Orgánico del Ambiente*[a] of Ecuador[a] sets out the country's approach to biosafety and the implementation of risk-assessment obligations through solid scientific procedures

The aim under the *Código Orgánico del Ambiente (2017)* of Ecuador is to guarantee the right of people to live in a healthy and ecologically balanced environment and to protect the rights of nature.

The code includes a chapter dedicated specifically to biosafety which provides that biosafety standards will regulate the products of modern biotechnology, with the aim of contributing to the conservation and sustainable use of biodiversity and guaranteeing the rights to human health and the environment. The code makes the national environmental authority, in coordination with the competent institutions, responsible for establishing standards, public policies and biosafety plans for controlling biosafety risks. The code provides that risk assessment of modern biotechnology will be carried out through solid scientific procedures.

[a] Available at https://faolex.fao.org/docs/pdf/ecu167116.pdf (accessed on 28 June 2024).

***Example clause: Código Orgánico del Ambiente* of Ecuador (2017)**

Artículo 75.- (De la bioseguridad) Las normas de bioseguridad regularán los productos de la biotecnología moderna, con el objeto de contribuir a la conservación y el uso sostenible de la biodiversidad y de garantizar los derechos a la salud humana y al ambiente.

La Autoridad Ambiental Nacional, en coordinación con las instituciones competentes, establecerá las normas, las políticas públicas y los planes de bioseguridad para el control de los riesgos de los productos de la biotecnología moderna. […]

Artículo 77.- Evaluación del riesgo. La evaluación del riesgo a los productos de la biotecnología moderna se realizará con base en procedimientos científicos sólidos y en principios ambientales reconocidos en la Constitución y en este Código, así como en los instrumentos internacionales aplicables.

BOX 25: The *Ley de Gestión de la Diversidad Biológica*[a] of the Bolivarian Republic of Venezuela (2008) considers the management of biotechnology and biosafety in relation to national priorities on, for example, poverty, human rights and biodiversity

The *Ley de Gestión de la Diversidad Biológica (2008)*, the overarching biodiversity law of the Bolivarian Republic of Venezuela, considers biosafety in relation to the country's national priorities and thereby integrates socioeconomic and ethical concerns. Article 44 of the law holds that the management of biotechnology must contribute to the reduction of poverty, respect for dignity, human rights and the well-being of humanity.

This provision under the biodiversity law, together with provisions that set out fundamental principles for biodiversity management (namely, autonomy, libertarian and ecological extensionism and conservation ethics, under article 46) more broadly, offers guidance on carrying out the responsibilities of the State. Those responsibilities entail preventing or averting any threat to biological diversity and its components that follows from the use of biotechnology, especially threats to biodiversity arising from the development, management, transportation, use, transfer and release of LMOs (article 47).

[a] Available at https://faolex.fao.org/docs/pdf/ven89953.pdf (accessed on 28 June 2024).

***Example clause: Ley de Gestión de la Diversidad Biológica* of the Bolivarian Republico of Venezuela (2008)**

Propósito
Artículo 44. La gestión de la biotecnología debe contribuir con la reducción de la pobreza, el respeto a la dignidad, los derechos humanos y el bienestar de la humanidad.

Medidas preventivas
Artículo 47. El Estado establecerá las medidas para prevenir y evitar cualquier amenaza a la diversidad biológica y sus componentes, derivada del uso de la biotecnología, en especial aquellas relacionadas con el desarrollo, el manejo, el transporte, la utilización, la transferencia y la liberación de los organismos resultantes de la aplicación de la biotecnología moderna.

BOX 26: The Constitution of Ecuador[a] prohibits the use of LMOs that are harmful to human health, food sovereignty or ecosystems and makes the State responsible for regulating the use and development of modern biotechnologies under biosafety standards

Ecuador maintains a strict level of regulation of LMOs. This national priority is reflected in several provisions of the Constitution of Ecuador (2008, revised 2021), which was approved by the electorate in a constitutional referendum.

Under article 15 of the Constitution, the development, production, possession, commercialization, import, transport, storage and use of LMOs that are harmful to human health, food sovereignty or ecosystems are prohibited. Food sovereignty and the achievement of self-sufficiency with respect to health and culturally appropriate foods are strategic constitutional objectives (articles 281). The State is therefore responsible for regulating, under biosafety standards, the use and development of modern biotechnology, including its experimentation, use and commercialization article 401).

The Constitution provides that Ecuador is free of LMO crops and seeds and that only in the case of duly substantiated national interest may LMO seeds and crops be introduced (article 401).

[a] Available at www.defensa.gob.ec/wp-content/uploads/downloads/2021/02/Constitucion-de-la-Republica-del-Ecuador_act_ene-2021.pdf. The English translation of the Constitution' of Ecuador is available at www.constituteproject.org/constitution/Ecuador_2021 (accessed on 28 June 2024).

***Example clause:* Constitution of Ecuador (2008, revised 2021)**

Art. 15.- El Estado promoverá, en el sector público y privado, el uso de tecnologías ambientalmente limpias y de energías alternativas no contaminantes y de bajo impacto. La soberanía energética no se alcanzará en detrimento de la soberanía alimentaria, ni afectará el derecho al agua. Se prohíbe el desarrollo, producción, tenencia, comercialización, importación, transporte, almacenamiento y uso de armas químicas, biológicas y nucleares, de contaminantes orgánicos persistentes altamente tóxicos, agroquímicos internacionalmente prohibidos, y las tecnologías y agentes biológicos experimentales nocivos y organismos genéticamente modificados perjudiciales para la salud humana o que atenten contra la soberanía alimentaria o los ecosistemas, así como la introducción de residuos nucleares y desechos tóxicos al territorio nacional. [...]

Art. 281.- La soberanía alimentaria constituye un objetivo estratégico y una obligación del Estado para garantizar que las personas, comunidades, pueblos y nacionalidades alcancen la autosuficiencia de alimentos sanos y culturalmente apropiado de forma permanente.

Para ello, será responsabilidad del Estado: [...]
9. Regular bajo normas de bioseguridad el uso y desarrollo de biotecnología, así como su experimentación, uso y comercialización.

Art. 401.- Se declara al Ecuador libre de cultivos y semillas transgénicas. Excepcionalmente, y sólo en caso de interés nacional debidamente fundamentado por la Presidencia de la República y aprobado por la Asamblea Nacional, se podrán introducir semillas y cultivos genéticamente modificados. El Estado regulará bajo estrictas normas de bioseguridad, el uso y el desarrollo de la biotecnología moderna y sus productos, así como su experimentación, uso y comercialización. Se prohíbe la aplicación de biotecnologías riesgosas o experimentales.

BOX 27: The Environmental Management Act of Malawi (2017)[a] integrates measures and actions to conserve biodiversity and promote biosafety, through measures and guidelines for in situ conservation and ensuring that risk assessments are conducted for LMO permits

The revision of the Environment Management Act of Malawi (2017) allowed for consultation of the national focal point for biosafety and the Convention on Biological Diversity focal point, which provided opportunities for biosafety mainstreaming. Article 69 of the Act provides for a general mandate whereby the Malawi environment protection authority shall prescribe measures and issue guidelines to promote the in situ conservation of biological resources, in consultation with relevant lead agencies. This includes conservation in relation to the "safe handling, transfer, and use of living modified organisms resulting from modern biotechnology that may have adverse impact on biodiversity, human health, and the environment". Furthermore, the authority shall, in consultation with relevant agencies, take measures for the control, eradication or management of alien or invasive species in order to "ensure that environmental and risk assessments are conducted for purposes of permits under the Biosafety Act" (Article 71).

[a] Available at https://faolex.fao.org/docs/pdf/mlw169354.pdf (accessed on 28 June 2028).

Example clause: **Environment Management Act of Malawi (2017)**

Article 69 (on conservation of biological resources in situ)

The Authority shall, in consultation with relevant lead agencies, prescribe measures and issue guidelines to promote the conservation of biological resources in situ in relation to-- [...]
(g) safe handling, transfer, and use of living modified organisms resulting from modern biotechnology that may have adverse impact on biodiversity, human health, and the environment.

Article 71 (on the control and management of alien and invasive species)

(1) The Authority shall, in consultation with relevant lead agencies, take measure for control, eradication or management of alien and invasive species in order to [...]
(d) ensure that environmental and risk assessments are conducted for purposes of permits under the Biosafety Act.

BOX 28: The National Environment Act of Uganda (2019)[a] provides a mandate for issuing guidelines and providing measures in relation to biosafety and liability and redress

The National Environment Act of Uganda (2000) provided measures for the conservation of biological diversity but did not include any specific provisions in relation to biosafety. Biosafety was addressed during the review of the Act and the drafting process for the National Environment Bill in 2016. This process was led by the Uganda National Environment Management Authority which consulted with the National Council for Science and Technology as the competent national authority of Uganda for the Cartagena Protocol. The involvement of the National Council alongside scientists and individuals with knowledge on biosafety was considered instrumental for mainstreaming biosafety in the National Environment Act (2019).

Article 63 of the Act provides that the National Environment Management Authority may provide guidelines and prescribe measures in relation to biosafety and liability and redress in relation to LMOs.

[a] Available at https://faolex.fao.org/docs/pdf/uga192395.pdf (accessed on 28 June 2024).

Example clause: **National Environment Act of Uganda (2019)**

63. Management of genetically modified organisms.

The Authority may, in consultation with the relevant lead agency, issue guidelines and prescribe measures—
(a) for the protection of the environment and management of risks to human health from the development, access, use and transfer of Genetically Modified Organisms; and
(b) for liability and redress in relation to genetically modified organisms.

BOX 29: The enforcement framework of Belarus includes procedures and sanctions for violation of biosafety legislation in general administrative and criminal laws.

The Code of the Republic of Belarus on Administrative Offenses (2021) and the Criminal Code of the Republic of Belarus (1999) provide for specific sanctions for violations of LMO provisions. Article 16.4 of the Administrative Code and relevant implementing measures provide that violation of safety rules when handling genetically engineered organisms, biological or chemical substances entails a fine, the level of which is dependent on whether the violation was committed by an individual entrepreneur or a legal entity. Article 278 of the Criminal Code provides for criminal sanctions in relation to the violation of safety rules for the production, storage, use, transportation, burial or other handling of genetically engineered organisms, biological or chemical substances. Sanctions apply when violations have been committed in an environmentally unfavourable territory or have resulted in intentional or careless infliction of damage on a large scale or, through negligence, illness of people. It includes separate sanctions if the violation resulted in the death of a person.

***Example clause: Кодекс Республики Беларусь об Административных Правонарушениях* of Belarus (2021)[a]**

Статья 16.4. Нарушение правил безопасности при обращении с генно-инженерными организмами, биологическими или химическими веществами,

Нарушение правил безопасности производства, хранения, использования, транспортировки, захоронения или иного обращения с генно-инженерными организмами, биологическими или химическими веществами –влечет наложение штрафа в размере от десяти до тридцати базовых величин, на индивидуального предпринимателя – от двадцати до двухсот базовых величин, а на юридическое лицо – от пятидесяти до тысячи базовых величин.

[a] Available at https://etalonline.by/document/?regnum=hk2100091 (accessed on 28 June 2024).

***Example clause:* Уголовный кодекс Республики Беларусь of Belarus (1999)[b]**

Статья 278. Нарушение правил безопасности при обращении с генно-инженерными организмами, биологическими или химическими веществами

1. Исключена.

2. Нарушение правил безопасности производства, хранения, использования, транспортировки, захоронения или иного обращения с генно-инженерными организмами, биологическими или химическими веществами, совершенное на экологически неблагополучной территории либо повлекшее умышленное или по неосторожности причинение ущерба в крупном размере либо по неосторожности заболевания людей, -

наказывается исправительными работами на срок до двух лет, или ограничением свободы на срок до трех лет, или лишением свободы на тот же срок с лишением права занимать определенные должности или заниматься определенной деятельностью или без лишения.

3. Нарушение тех же правил, повлекшее по неосторожности смерть человека, -

наказывается ограничением свободы на срок до пяти лет или лишением свободы на срок от одного года до семи лет с лишением права занимать определенные должности или заниматься определенной деятельностью или без лишения.

[b] Available at https://continent-online.com/Document/?doc_id=30414984#pos=2350;-58 (accessed on 28 June 2024).

6.3.2. Examples of biosafety mainstreaming in sectoral legislation

Sectoral legislation responds to the legislative needs of specific sectoral areas by, for example, providing obligations and rights that are relevant only to specific sectors such as agriculture and forestry. The importance of biosafety in specific sectors, including the agriculture and food sectors, and the potential for synergies between biosafety and sectoral objectives have been outlined in section 5.2.1. For example, while LMOs may provide potential gains in efficiency and yields for the agricultural sector, LMOs may negatively impact agricultural genetic resources or agrobiodiversity owing to persistence in agricultural areas and increased invasiveness in natural habitats. Biosafety may therefore be an important consideration in the context of national legislative frameworks on agriculture. Moreover, as biosafety is intrinsically linked with food safety, relevant regulations may seek to ensure synergies between general and specific food safety laws and rules and regulations on biosafety relating to LMOs.

Biosafety mainstreaming into sectoral legislation may include, for example, linking relevant sectoral obligations and objectives with objectives and obligations in biosafety legislation. Mainstreaming may also involve integration of biosafety obligations relating to the assessment and management of environmental and health risks into legislation on plant seeds and animal genetic resources, including laws on the production, import and export, packaging, marketing and patenting of varieties and seeds.[177] Labelling requirements for LMOs and LMO products may be included in legislation on food safety or consumer protection (see sect. 5.2.2 above on Codex Alimentarius principles in relation to the labelling of LMOS).[178] Boxes 30–34 below provide several detailed examples of biosafety mainstreaming into cross-sectoral legislation which were identified through analysis of legislation of the Parties that had participated in the Convention Secretariat projects on biosafety mainstreaming.

Further examples of biosafety mainstreaming into cross-sectoral legislation are included in annex III.

177 For an example of mainstreaming of biosafety in relation to protection of plant varieties and patenting, see the Law on the Protection of Plant Varieties of the Republic of Moldova (2008), discussed under sect. 5.2.2 above.

178 See, notably, Codex Alimentarius Commission, "Principles for the risk analysis of foods derived from modern biotechnology" (CAC/GL 44-2003).

BOX 30: The *Loi d'orientation agro-sylvo-pastorale, halieutique et faunique* of Burkina Faso[a] aims at achieving food sovereignty and food security and commits to guaranteeing biosafety in relation to living modified organisms

Biosafety of modern biotechnology is regulated in Burkina Faso under a number of legal instruments, notably the *loi No. 064-2012/AN portant régime de sécurité en matière de biotechnologie*. The *loi No. 070-2015/CNT d'orientation agro-sylvo-pastorale, halieutique et faunique* of Burkina Faso was adopted in 2015. The law, which is concerned with agro-sylvo-pastoral, fisheries and wildlife activities, reflects the importance of the biosafety regime in relation to its overarching aims of achieving food sovereignty and food and nutritional security as a contribution to sustainable development in Burkina Faso.

The fact that biosafety was considered at the outset of the drafting process followed from the involvement of cross-sectoral and sectoral institutions, notably the Ministry of Research and Innovation in its capacity as national biosafety authority.

In article 4 of Loi No. 070-2015/CNT biosafety is defined as comprising measures taken to reduce or eliminate potential risks arising from the development of modern biotechnology and the use of its products. Article 82 of the law provides that the State: (a) encourages agroecology, including organic agriculture, because of its positive impacts on the environment and (b) guarantees biosafety in the context of LMO cultivation by evaluating the effects of LMO cultivation on ecosystems and soil fertility and human and animal health in consultation with stakeholders.

[a] Available at https://faolex.fao.org/docs/pdf/bkf198258.pdf (accessed on 28 June 2024).

***Example clause: Loi d'orientation agro-sylvo-pastorale, halieutique et faunique* of Burkina Faso (2015)**

Article 4 : Au sens de la présente loi, on entend par: [...]
- Mesures prises pour réduire ou éliminer les risques potentiels découlant du développement de la biotechnologie moderne et l'utilisation de ses produits; [...]

Article 82: L'agriculture conventionnelle s'exerce dans le respect de l'environnement.
L'État encourage l'agriculture agro-écologique ou l'agro-écologie, y compris l'agriculture biologique en raison de son impact positif sur l'environnement et en collaboration avec les autres acteurs, en assure la promotion à travers entre autres, la fixation de prix rémunérateurs incitatifs. Il garantit la biosécurité dans le cadre de la culture d'organismes génétiquement modifiés, en évaluant, de manière permanente, en concertation avec les autres acteurs, les effets et impacts de la culture d'organismes génétiquement modifiés sur les écosystèmes, la fertilité des sols ainsi que la santé humaine et animale.

BOX 31: The *Decreto-Ley De Recursos Fitogenéticos para la Alimentación, la Agricultura y Las Semillas* of Cuba[a] cross-references biosafety procedures that apply to LM seeds

The *Decreto-Ley No. 190/99 de la Seguridad Biológica of Cuba (1999)* provides the legal basis for the regulation of biological organisms that may pose biosafety risks for the environment, including LMOs. The law outlines the responsibilities of the Ministry of Science, Technology and Environment in this regard.

The objectives of the *Decreto-Ley De Recursos Fitogenéticos para la Alimentación, la Agricultura y Las Semillas*, which was adopted in 2019, include the control, conservation and regulation of the use of plant genetic resources for food and agriculture. The law and its supplementary regulations cross-reference biosafety procedures set out in biosafety laws in relation to LM seeds. Article 69 provides that the import of LM seeds or exotic species requires prior authorization from the competent authority in accordance with national legislation and international agreements. Article 81 provides that the Ministry of Agriculture approves crop varieties that are intended for use in commercial production of LMOs, while Article 104 provides that the import of LM seeds requires the approval of competent authorities.

[a] Available at https://faolex.fao.org/docs/pdf/cub222156.pdf (accessed on 28 June 2024).

***Example clause: Decreto-Ley De Recursos Fitogenéticos para la Alimentación, la Agricultura y Las Semillas* of Cuba (2019)**

Artículo 69. La importación de semillas de variedades genéticamente modificadas o de especies exóticas, requieren la autorización previa de la autoridad competente en este campo de regulación, en correspondencia con la legislación vigente en la materia y en los convenios internacionales. […]

Artículo 81. El Ministerio de la Agricultura aprueba las variedades de los diferentes cultivos que se emplean como material de partida para la obtención de variedades genéticamente modificadas, destinadas para la producción comercial, una vez admitida por la autoridad competente.

Artículo 104. La importación de semilla de variedades genéticamente modificadas requiere la aprobación de las autoridades competentes.

BOX 32: The legal regime for food and food safety of Mongolia requires risk assessment and registration of raw materials and foods derived from LMOs

The National Biosafety Committee of Mongolia worked together with the Ministry of Food, Agriculture and Light Industry to include biosafety clauses in the Law on Food (2012) and the Law on Food Safety (2012).[a] The draft laws were discussed in a meeting organized by the Parliamentary Standing Committee on Food, Agriculture and Environment, which included decision makers, scientists and stakeholders representing civil society, private sectors and other professional organizations.

Biosafety is mainstreamed into a provision that requires risk assessment and registration of raw materials and food products derived from LMOs under procedures that are approved jointly by the State administrative authorities in charge of health, food and the environment. Supply of LM raw materials and foods that have not undergone risk assessment and registration is prohibited.

[a] Available at https://faolex.fao.org/docs/pdf/mon167073.pdf (accessed on 28 June 2024). The English translation of this article was provided by Mongolia in their national desk study on "Mainstreaming Biosafety in Mongolia".

***Example clause:* Law on Food Safety of Mongolia (2012)**

Article 14. Raw materials and food products derived from LMOs.
14.1. Procedures for performing risk assessment and registering raw materials and food products derived from LMOs shall be jointly approved by the State Administrative Authorities in charge of Health, Food and Environment.
14.2. The Inspection Body shall conduct inspection on first-time imports, and on domestically produced raw materials and food products derived from LMOs.
14.3. It is prohibited to supply raw materials and food products derived from LMOs that did not undergo risk assessment and registration processes as specified in Article 14.1.

BOX 33: Labelling requirements with a 5 per cent threshold are included in the decree on elaboration of some articles of the Law of Food Safety of Viet Nam.[a]

The decree on elaboration of some articles of the Law of Food Safety (2020) of Viet Nam provides that the manufacturers and sellers of foods that contain more than 5 per cent LM ingredients must contain information about the LMO on their label. Exemptions apply, notably for unpackaged LM foods that are sold directly to consumers and LM foods that are served as part of the recovery from a natural disaster or epidemic.

[a] Available at https://faolex.fao.org/docs/pdf/vie214418.pdf (accessed on 28 June 2024).

Example clause: **- Decree on elaboration of some articles of the Law of Food Safety of Viet Nam (2020)**

Article 10. Labelling of goods containing GMO and GMO products used as foods.
1. Manufacturers and sellers of foods the content of GM ingredients in which exceeds 5 per cent of total ingredients, in addition to compliance with common
regulations of law on goods labelling, the goods label must contain information about the GMOs, except for the cases specified in Clause 2 of this Article.

2. Labelling of GM foods is exempted in the following cases:
a) The prepackaged GM food contains GM ingredients without discovery of the modified gene or products of the modified gene in the food;
b) Fresh GM foods, unpackaged processed GM foods sold directly to consumers;
c) GM foods serving recovery from a natural disaster or epidemic.

BOX 34: The National Agricultural Seeds Council Act of Nigeria[a] provides for penalties in relation to import or export of LM seed in contravention of the country's biosafety regulations

The National Agricultural Seeds Council Act of Nigeria (2019),[a] which replaced the National Agricultural Seeds Act (2004), aims at strengthening the legal and regulatory framework for high-quality seed, with an expected outcome of enhanced agricultural productivity, increased food security and improvement of the livelihoods of rural farmers. The main aim of the Act was to establish the national agricultural seed council which formulates programmes, policies and actions regarding seed development and the seed industry. Moreover, the Council is responsible for implementing an official seeds quality control and certification service.

In relation to LMOs, the act requires compliance with the biosafety regulations of Nigeria insofar as they regulate the import, for commercial or research purposes, of LM seeds. The act requires notification of the Council prior to importation. Import or export of LM crop seeds in contravention of the provisions of the act is considered an offence and *lex specialis* penalty provisions are provided in article 42 in relation to such offences.

[a] Available at https://seedcouncil.gov.ng/wp-content/uploads/2020/02/Seed-Act-2019.pdf (accessed on 28 June 2024).

Example clause: **National Agricultural Seeds Council Act of Nigeria (2019)**

36.-(2) A person intending to import, for commercial or research purposes, seed of a genetically modified variety shall comply with the biosafety regulation of Nigeria and notify the Council prior to the importation.

41.-(1) A person who contravenes the provisions of this Act or any regulation made under it commits an offence. [...]

42.-(1) A person who commits an offence under this Act is liable upon conviction-
(a) as a first offender: to imprisonment for a term not exceeding one year or a fine not exceeding N 1,000,000; and
(b) in the event of such person having been previously convicted under this section, he is liable to imprisonment for a term not exceeding two years or a fine of N 2,000,000 or both.
(2) Where a person has been convicted under this Act, the seed in respect of which the contravention occurred may be forfeited to the Federal Government.
(3) Where an offence under this Act is committed by a company, any officer who, at the time the offence was committed; was in charge of the conduct of the business of the company, as well as the company, is deemed to be guilty and liable. Provided that nothing contained in this subsection shall render such person liable to any punishment if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of the offence.
(4) Where an offence under this Act is committed by a company with the consent or connivance of, or is attributable to any neglect on the part of any director, manager, secretary or officer of the company, such director, manager, secretary, or officer is deemed to have committed the offence and is liable.

6.4. Mainstreaming biosafety into institutional frameworks

Many national institutions can be relevant with respect to implementing biosafety obligations and strengthening national biosafety frameworks. Some institutions, for example, competent national authorities, have specific responsibilities for implementing international and national biosafety obligations. Other cross-sectoral and sectoral institutions have responsibilities for implementing cross-sectoral and sectoral policy and legislative instruments within which biosafety is mainstreamed. Where the mandates and responsibilities of institutions are set out in legal institutional frameworks, the design and reform of such frameworks provide possibilities for integrating relevant knowledge and expertise on biosafety or cross-sectoral and sectoral knowledge and expertise relevant to biosafety. As observed in section 5.2.3 above, an integrated and coordinated approach to implementing biosafety obligations may allow for more efficient use of resources through the sharing of costs and resources between biosafety and biodiversity institutions and cross-sectoral and sectoral departments. Furthermore, including cross-sectoral and sectoral representatives in the formulation and implementation of biosafety obligations may ensure that measures are feasible and in accordance with cross-sectoral and sectoral best practice, for example, technical standards. Identifying relevant institutional frameworks and understanding their potential with respect to biosafety constitute an important step in the design and implementation of national visions for biosafety mainstreaming (see sect. 6.1, step 1).

There are important links between biosafety mainstreaming into institutional frameworks and biosafety mainstreaming into cross-sectoral and sectoral policies and legislation (sects. 6.2–6.3). Where biosafety is mainstreamed into cross-sectoral and sectoral policies and legislation, this may bring into focus the need to build internal capacity to achieve biosafety objectives and implement obligations, which may require biosafety mainstreaming into the legal frameworks of institutions that are responsible for implementing entry points. For example, if cross-sectoral or sectoral legislation makes a cross-sectoral or sectoral institution responsible for monitoring compliance with biosafety regulations (for example, in relation to import or export of LM seeds), the institution may wish to integrate legal and technical biosafety expertise into its institutional frameworks. At the same time, mainstreaming of biosafety into institutional frameworks may help to build internal awareness and capacity and may allow for cooperation and coordination in support of further mainstreaming. For example, if biosafety authorities are represented in cross-sectoral and sectoral institutions, they may be able to flag opportunities for mainstreaming when policies and laws are drafted, amended or reformed.

While the focus of the present section is both on bringing institutional knowledge on biosafety into cross-sectoral and sectoral institutional frameworks and on bringing cross-sectoral and sectoral institutional knowledge into biosafety frameworks, it should be noted that these efforts must be complemented by activities designed to include the public and biosafety, cross-sectoral and sectoral private actors, for example, industry, research institutions and environmental non-governmental organizations, in decision-making on LMOs. This may be achieved through participatory processes including access to information and consultation (see sect. 6.1, step 6, on creating an enabling environment).

6.4.1. Examples of biosafety mainstreaming in institutional frameworks

The focus of this legislative study is on examples of public institutions and mechanisms that are anchored in legislation and may require mainstreaming at the legislative level to ensure that biosafety is adequately addressed at the institutional level. It is to be noted, however, that not all activities relevant to mainstreaming of biosafety in cross-sectoral and sectoral institutions and governance structures will have a basis in legislation. In Nigeria, for example, the National Biosafety Management Agency has requested the designation of "biosafety desk officers" across the country's 36 State ministries on the environment, which would allow for effective and easy communication on biosafety issues across States and increased awareness and capacity in the context of biosafety issues. This example and other non-legislative arrangements (such as cooperation based on a memorandum of understanding) could be considered in the context of non-legislative tools for biosafety mainstreaming or

an enabling environment for biosafety and biosafety mainstreaming (see sect. 6. 1, steps 5 and 6).

Biosafety mainstreaming into legislative institutional frameworks may entail, for example, inclusion of cross-sectoral and sectoral representatives in biosafety-specific institutions. These biosafety institutions may be responsible for decision-making on LMOs, although biosafety institutions can also include technical advisory bodies. Moreover, biosafety mainstreaming may involve inclusion of biosafety-representatives in cross-sectoral and sectoral institutional frameworks. On occasion, countries have sought to integrate biosafety expertise into the governance structures of semi-public and private institutions. Furthermore, biosafety mainstreaming may involve the establishment of coordination mechanisms for providing strategic direction on biosafety matters for decision-making on LMOs or monitoring and enforcement. The text boxes 35–40 below include some detailed examples of biosafety mainstreaming into legislative institutional frameworks which were identified through analysis of legislation in the Parties that participated in the projects on biosafety mainstreaming under the Convention Secretariat.

Further examples of biosafety mainstreaming into cross-sectoral legislation are included in annex III to the present study, entitled "Overview policy and legislative examples of biosafety mainstreaming".

BOX 35: The National Biosafety Authority, governing body of the competent national authority of Ghana, includes cross-sectoral and sectoral public and private representatives.

The Biosafety Act of Ghana (2011)[a] constituted the National Biosafety Authority which acts as the national focal point for the Cartagena Protocol and the competent national authority. The National Biosafety Authority is responsible for receiving, processing, responding to and making decisions on applications under and in conformity with the Biosafety Act (article 4). The governing body of the Authority is a board, whose membership is clearly set out in the Act and includes representatives of the Ministry responsible for Science, the Ministry of Food and Agriculture, the Ministry of Health and the customs division of the Ghana Revenue Authority, alongside experts, academics, industry representatives and representatives of non-governmental organizations.

[a] Available at https://faolex.fao.org/docs/pdf/gha136733.pdf (accessed on 28 June 2024).

***Example clause:* Biosafety Act of Ghana (2011)**

Establishment of the National Biosafety Authority
Article 3. (1) There is established by this Act a body corporate to be known as the National Biosafety Authority.

Functions of the Authority
Article 4. The function" of the Authority are
(a) to receive, process, respond to and to make decisions on applications under and in conformity with this Act,
(b) to establish administrative mechanisms to ensure the appropriate handling and storage of documents and data in connection with the processing of applications and any other matters covered by this Act,
(c) to act as the National Focal Point responsible for liaising with any other agency or international organizations concerned with biotechnology and biosafety, and
(d) to promote public awareness, participation and education concerning the activities of the Authority under this Act.

The governing body
Article 5. (1) The governing body of the Authority is a Board consisting of:
(a) an expert in biotechnology and related biological sciences including biosafety, as the chairperson,
(b) the chairperson of the technical advisory committee established under section 27,
(e) one representative of the Ministry responsible for Science not below the rank of Director,
(d) one representative of the Association of Ghana Industries,
(e) one legal practitioner of not less than ten years standing, who has a sufficient background knowledge relevant to the subject matter of this Act,
(j) one representative of non-governmental organizations,
(g) the chief executive officer of the Authority,
(h) two members from academia who are persons with a sufficient background knowledge relevant to the subject matter of this Act, at least one of whom is a woman,
(i) one representative of the Council for Scientific and Industrial Research not below the rank of a Director,
(j) one representative of the Ministry of Food and Agriculture not below the rank of a Director,
(k) one representative of the Ministry of Health not below the rank of a Director, and
(I) one representative from the Customs Division of the Ghana Revenue Authority.

BOX 36: The Ministry of Environment and Forestry Resources of Togo is assisted by a scientific committee comprising cross-sectoral and sectoral representatives

The Scientific and Technical Biosafety Committee (Comité Scientifique et Technique de Biosecurité) of Togo assists the Ministry of Environment and Forestry Resources as the competent national authority. It is responsible for preparing LMO risk assessment reports prior to any import, export, transit, contained use, development, production, storage, deliberate release and placing on the market of LMOs. Personal appointments of members of the Committee are provided in the *Arrêté portant mise en place du comité scientifique et technique de biosécurité (2020)*.[a] They include members of the Ministry of Higher Education and Research, the Ministry of Health, Public Hygiene and Universal Access to Care, the Ministry of Maritime Economy, Fisheries and Coastal Protection and the Ministry of the Environment and Forestry Resources.

[a] *Arrêté No. 0029/MEDDPN/SG/DRF* was provided by Togo to the Convention Secretariat) (accessed on 28 June 2024).

***Example clause: Arrête portant mise en place du comité scientifique et technique de biosécurité* of Togo (2020)**

Article 1: Le présent arrête met en place le comité scientifique et technique de biosécurité (CSTB).

Article 2: Le CSTB a pour mission d'examiner et de donner son avis sur les demandes d'autorisation relatives au développement, à l'utilisation confinée, à l'importation, à l'exportation, au transit, à la production, au stockage, à la dissémination volontaire ou involontaire dans l'environnement et à la mise sur le marché des organismes génétiquement modifiés (OGM).

Article 3: Les personnes dont les noms suivent désignées membres du CSTB :
- Ministère de L'Enseignement Supérieur et de La Recherche (MESR)
- Ministère de la Sante et de l'Hygiène Publique (MSHP)
- Ministère de l'Agriculture, de la Production Animale et Halieutique (MAPAH)
- Ministère de l'Environnement, du Développement Durable et de la Protection de la Nature (MEDDPN)

Article 4: Le comité scientifique et technique de biosécurité peut faire appel à toute personne ayant des expériences avérées dans des disciplines pertinentes liées aux biotechnologies modernes et à la biosécurité et dont la compétence est jugée nécessaire pour la réalisation de sa mission.

BOX 37: The Biosafety Registrar of Malawi is tasked with raising awareness and building capacity on biosafety regulations among relevant cross-sectoral and sectoral institutions

Regulation 8 of the Biosafety (Management of Genetically Modified Organisms) Regulations (2007) of Malawi[a] provides for the appointment of a Biosafety Registrar who acts as the secretariat for the National Biosafety Regulatory Committee, which is the technical committee responsible for evaluating applications concerning or related to the use of LMOs and products thereof and which make recommendations to the minister responsible for the environment. The office of the Biosafety Registrar is part of the Environmental Affairs Department in the Ministry of Natural Resources and Climate Change, which is the department responsible for the general supervision and coordination of all matters relating to the management of the environment and natural resources.

The Biosafety Registrar is tasked, among other activities, with ensuring that the provisions of the Biosafety Act (2012) are known to the relevant authorities and the general public. The Registrar maintains a register of all biotechnological activities in Malawi and all licences and permits issued, which may support cross-sectoral and sectoral capacity on biosafety.

[a] Available at https://faolex.fao.org/docs/pdf/mlw117649.pdf (accessed on 28 June 2024).

Example clause: **Biosafety (Management of Genetically Modified Organisms) Regulations of Malawi (2007)**

Regulation 8 - Appointment of the Biosafety Registrar
(1) There shall be appointed, in the public service, a Biosafety Registrar and such other suitably qualified officers as may be required for the administration of these Regulations.
(2) The Biosafety Registrar shall exercise such powers and perform such duties as may be conferred upon him by the Minister, and the Committee.

9. Functions of the Biosafety Registrar
(1) The Biosafety Registrar shall—
(a) ensure that the provisions of the Act and these Regulations are known to the relevant authorities and the general public;
(b) maintain a register of all biotechnological activities in Malawi and all licenses and permits issued under the Act;
(c) receive all documents relating to applications and appeals and transmit them to the Committee and the Minister;
(d) liaise with the Secretariat of the Convention on Biological Diversity;
(e) transmit information on biosafety to the Biosafety Clearing House Mechanism;
(f) facilitate and ensure the training of all inspectors in relevant aspects of biosafety and biotechnology;
(g) maintain a register of experts in biotechnology and biosafety; and
(h) perform any other functions as may be conferred upon him by the Minister or the Committee.

BOX 38: The intersectoral coordination of national policies on biosafety in CIBIOGEM of Mexico

Under the *Ley de Bioseguridad de Organismos Genéticamente Modificados* of Mexico (2005),[a] the Intersecretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM) is put in charge of formulating and coordinating national policies on biosafety of LMOs. The aim of this intersectoral approach is to allow for integrated management of biosafety matters across seven public institutions: the secretariats of agriculture, livestock, rural development, fisheries and food; environment and natural resources; health; economy; public education; and finance and public credit; and the National Council of Science and Technology.

Policy decisions relating to the national strategy on biosafety are taken at the highest level of CIBIOGEM, which involves the secretariats of the seven institutions. The presidency of CIBIOGEM is rotated among three secretariats: the secretariats of agriculture, livestock, rural development, fisheries and food; environment and natural resources; and health. The *Ley de Bioseguridad* allows CIBIOGEM to invite other agencies to participate.

[a] Available at https://faolex.fao.org/docs/pdf/mex64015.pdf. The English translation (Law on Biosafety of Genetically Modified Organisms (February 2005)) is available at https://conahcyt.mx/cibiogem/images/cibiogem/eng/Docs/Ing_LBOGM_P.pdf (accessed on 28 June 2024).

***Example clause: Ley de Bioseguridad* of Mexico (2005)**

ARTÍCULO 19.- La CIBIOGEM es una Comisión Intersecretarial que tiene por objeto formular y coordinar las políticas de la Administración Pública Federal relativas a la bioseguridad de los OGMs, la cual tendrá las funciones que establezcan las disposiciones reglamentarias que deriven de esta Ley, conforme a las siguientes bases:

I. La CIBIOGEM estará integrada por los titulares de las Secretarías de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación; Medio Ambiente y Recursos Naturales; Salud; Educación Pública; Hacienda y Crédito Público, y Economía, así como por el Director General del CONACyT;

II. La CIBIOGEM tendrá una Presidencia que será rotatoria entre los titulares de las Secretarías de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, de Medio Ambiente y Recursos Naturales y de Salud, y cuyo ejercicio, funciones y duración se determinarán en las disposiciones reglamentarias correspondientes. También habrá una Vicepresidencia cuyo titular será el Director General del CONACyT, quien presidirá las sesiones en ausencia del Presidente, coadyuvará con la Comisión y con el Secretario Ejecutivo en el ejercicio de sus funciones y realizará las actividades que le encomiende la propia CIBIOGEM en los términos que establezcan las disposiciones reglamentarias que deriven de la presente Ley;

III. La CIBIOGEM podrá invitar a otras dependencias a participar, con voz, en los acuerdos y decisiones de los asuntos que tengan relación con su objeto, así como a los miembros del Consejo Consultivo;

IV. La CIBIOGEM contará con un Secretario Ejecutivo que será designado por el Presidente de la República, a propuesta del Director General del CONACyT, aprobada por la propia CIBIOGEM. Tendrá las atribuciones y facultades que se determinen en las disposiciones reglamentarias que deriven de este ordenamiento, y ejecutará y dará seguimiento a los acuerdos de la propia Comisión y ejercerá las demás funciones que se le encomienden;

V. La Secretaría Ejecutiva de la CIBIOGEM contará con la estructura orgánica que se apruebe en los términos de las disposiciones aplicables, y será considerada una unidad administrativa por función del CONACyT, de conformidad con la Ley Orgánica de dicha entidad paraestatal, y

VI. La CIBIOGEM también contará con un Comité Técnico integrado por los coordinadores, directores generales o equivalentes competentes en la materia que designen los titulares de las dependencias y entidades que formen parte de la CIBIOGEM. Dicho Comité podrá proponer la creación de subcomités especializados para la atención de asuntos específicos y tendrá las atribuciones que se determinen en las disposiciones reglamentarias que deriven de esta Ley.

BOX 39: The National Commission for the Use of Genetically Modified Organisms in Agriculture of Cuba serves as a coordination and harmonization mechanism for decision-making on the use of LMOs in agriculture across sectoral institutions

The *Decreto-Ley de la Comisión Nacional Para el Uso de Los Organismos Genéticamente Modificados en la Agricultura Cubana (2020)*[a] provides for the creation of the National Commission for the Use of Genetically Modified Organisms in Agriculture of Cuba. The Commission is made up of representatives from the country's competent authorities: the Office of Environmental Regulation and Safety (representing the Ministry of Science, Technology and Environment as national focal point), the Directorate of Plant Health, the Directorate of Animal Health, the Directorate of Seeds and Plant Genetic Resources (representing the Ministry of Agriculture), the Directorate of Environmental Health and the National Institute of Hygiene, Epidemiology and Microbiology (representing the Ministry of Public Health).

Among other functions, the Commission is responsible for harmonizing decision-making on the use of LMOs in agriculture. Articles 10-14 of the decree outline the responsibilities of the different competent authorities in fulfilling the functions of the Commission. For example, as President of the Commission, the Ministry of Science, Technology and Environment is tasked with coordinating decision-making on LMOs, overseeing processes and ensuring the soundness of work undertaken by scientific institutions. The Ministry of Agriculture is tasked with assessing the feasibility of LMO use in agricultural production, taking into account agronomic attributes, potential increases in yields, adaptation and the technologies used. To fulfil this function, the Ministry of Agriculture has created an internal commission made up of representatives from the agriculture, plant health, seeds and plant genetic resources, soils and land control and science, technology, innovation and environment directorates.

[a] Available at https://bch.cbd.int/en/database/LAW/BCH-LAW-CU-115874 (accessed on 28 June 2024).

Example clause: Decreto-Ley de la Comisión Nacional Para el uso de Los Organismos Genéticamente Modificados en la Agricultura Cubana (2020)

Artículo 1. El presente Decreto-Ley tiene como objetivo la creación de la Comisión Nacional para el uso de los Organismos Genéticamente Modificados, dirigida a armonizar el proceso de toma de decisiones entre las diferentes autoridades en esta materia para su uso en la agricultura, y lograr que la incorporación de dichos organismos en los programas de desarrollo agrícola, se produzca de manera ordenada y segura. [...]

Artículo 3. Se crea la Comisión Nacional para el uso de los Organismos Genéticamente Modificados en la Agricultura, en lo adelante la Comisión, presidida por el Ministro de Ciencia, Tecnología y Medio Ambiente, en su carácter de organismo rector de la seguridad biológica en el país y de punto focal nacional para el Protocolo de Cartagena sobre Seguridad de la Biotecnología.

Artículo 4. La Comisión está integrada, por representantes de las autoridades competentes de los ministerios de Ciencia, Tecnología y Medio Ambiente, de la Agricultura y de Salud Pública.

Artículo 5. En la Comisión se adoptan las decisiones relacionadas con los Organismos Genéticamente Modificados, de interés para la alimentación y la agricultura.

Artículo 6. Las autoridades competentes que conforman la Comisión, son las siguientes:
1. Oficina de Regulación y Seguridad Ambiental, en representación del Ministerio de Ciencia, Tecnología y Medio Ambiente.
2. Dirección de Sanidad Vegetal, Dirección de Sanidad Animal y Dirección de Semillas y Recursos Fitogenéticos, en representación del Ministerio de la Agricultura.
3. Dirección de Salud Ambiental y el Instituto Nacional de Higiene, Epidemiología y Microbiología, en representación del Ministerio de Salud Pública.

BOX 39: continued...

Artículo 7. La Comisión tiene las funciones siguientes:
a) Adoptar decisiones relacionadas con la investigación, desarrollo, producción, uso, importación y exportación de los Organismos Genéticamente Modificados, de manera coordinada;
b) propiciar la participación de las entidades de ciencia, tecnología e innovación, las universidades, las empresas productoras, los órganos, organismos de la Administración Central del Estado, las entidades nacionales y otras instituciones que resulten pertinentes como parte del soporte científico de las decisiones;
c) realizar o encargar estudios técnicos e investigaciones que se estimen necesarios para acometer su función; y
d) recopilar y brindar la información requerida, para cumplir las obligaciones que emanan de los instrumentos internacionales, en particular, las del Protocolo de Cartagena sobre Seguridad de la Biotecnología y las recomendaciones del CODEX Alimentarius, en correspondencia con las regulaciones vigentes en materia de inocuidad alimentaria. [...]

Artículo 10. Corresponde al Ministro de Ciencia, Tecnología y Medio Ambiente, en su carácter de presidente de la Comisión, ejecutar las acciones siguientes:
a) Coordinar el trabajo de la Comisión para la toma de decisiones sobre Organismos Genéticamente Modificados;
b) convocar a las instituciones científicas y académicas, según sea pertinente, para garantizar la eficacia y la solidez del proceso;
c) garantizar que se observen los términos y plazos acordados para las evaluaciones y la toma de decisiones;
d) garantizar que la información necesaria para el proceso que obra en los expedientes técnicos, una vez completados por los solicitantes, esté a disposición de las autoridades, en aras de agilizar los trámites administrativos; y e) dirimir las diferencias que puedan surgir entre las autoridades competentes en relación con la decisión final.

Artículo 11. Corresponde al Ministro de la Agricultura, evaluar la factibilidad del uso de los Organismos Genéticamente Modificados en las producciones agrícolas, como una alternativa más, como parte de los estudios previos a la utilización comercial de este material y para ello tiene en cuenta en cada variedad lo siguiente:
a) Sus atributos agronómicos;
b) el potencial incremento en el rendimiento agrícola;
c) su adaptación a factores edafoclimáticos limitantes; y
d) la tecnología en su utilización.

BOX 40: The institutional biosafety committees as a mechanism for integrating biosafety into organizations undertaking modern biotechnology research, including public and private research institutions, as part of the national biosafety laws of Malaysia and Ghana

The Biosafety (Approval and Notification) Regulations (2010) of Malaysia provide that the National Biosafety Board may direct any organization that undertakes modern biotechnology research and development to establish an institutional biosafety committee, including public and private research institutions and private companies that have a research facility involved in the handling of LMOs. The institutional biosafety committees provide guidance on the safe use of modern biotechnology, monitor activities relating to modern biotechnology, establish and monitor procedures for the implementation of policies and procedures for the purpose of handling LMOs and determine the classes of biosafety levels related to contained use activity for the purpose of modern biotechnology research and development undertaken within a facility where the institutional biosafety committee is established. An institutional biosafety committee must be registered with the National Biosafety Board and provide oversight at the institutional level. Institutional biosafety committees are required to submit an annual report to the National Biosafety Board on behalf of the organization through its biological safety officer

In a similar vein, the Biosafety Regulations (2019) of Ghana oblige public and private institutions that wish to engage in modern biotechnology research to set up an institutional biosafety committee. Certification of an institutional biosafety committee comes with a cost but exceptions are provided; for an institution that is unable to constitute its own institutional biosafety committee may request another biosafety committee to help to monitor and supervise the biosafety aspects of its work. In this case, a formal agreement must be put in place and the National Biosafety Authority of Ghana must be notified. Membership of an institutional biosafety committee is intended to be diverse, as stipulated in regulation 7. Among other functions, an institutional biosafety committee monitors the regulated work under progress within the institution, reports infractions to the institutional head or to the Authority , determines additional biosafety measures and organizes training.

Example clause: **Biosafety (Approval and Notification) Regulations of Malaysia (2010)[a]**

Regulation 5 on Establishment of an institutional biosafety committee
(1) The Board may, in exercising its functions under paragraph 5 (1) (b) and subsection 5 (2) of the Act, direct any organization that undertakes modern biotechnology research and development to establish an institutional biosafety committee for the purpose of:-
(a) providing guidance for safe use of modern biotechnology;
(b) monitoring activities relating to modern biotechnology;
(c) establishing and monitoring the implementation of policies and procedures for the purpose of handling living modified organisms; and
(d) determining the classes of Biosafety Levels for contained use activity for the purpose of modern biotechnology research and development undertaken within a facility where the institutional biosafety committee is established.
(2) The institutional biosafety committee which has been established upon the direction of the Board under subregulation (1) shall be registered with the Board in a manner as the Board may determine.
(3) Any organization that fails to comply with the direction made under subregulations (1) and (2) commits an offence.

[a] Available at https://faolex.fao.org/docs/pdf/mal99066.pdf (accessed on 28 June 2024).

BOX 40: continued...

Example clause: **Biosafety (Management of Biotechnology) Regulations of Ghana (2019)**[b]

4. (1) A public or private institution or organization, engaged in or with the intent to engage in the acquisition, development, propagation or field release of genetically modified organisms or products of genetically modified organisms for purposes of research, shall
(a) each establish an institutional biosafety committee, and
(b) support the needs and demands of the committee for the effective performance of its functions.
(2) Despite subregulation (1), an institution which is unable to constitute its own institutional biosafety committee may request any other biosafety committee to help monitor and supervise the biosafety aspects of its work.
(3) A request under subregulation (2) shall be in the form of a written Agreement entered into between the parties involved and the Authority shall be notified of the Agreement.
(4) A representative of the institution requesting assistance shall maintain close ties with the respective institutional biosafety committee or serve as a member on the supporting institutional biosafety committee.

Certification of the Institutional Biosafety Committee
5. (1) The Authority shall
(a) prepare and provide to the institutional biosafety committees, the various notification and assessment forms, appropriate guidelines and any other relevant documents;
(b) provide assistance to the institutional biosafety committees and advise them on the various notification and assessment forms, biosafety guidelines and other relevant documents; and
(c) certify each institutional biosafety committee to undertake monitoring functions for contained use and confined use activities for certain levels of classified risks to be issued periodically through guidelines.
(2) For the purposes of certification, the completed notification forms of an institutional biosafety committee, detailing the academic and professional history of each member appointed to the Committee, shall contain information relating to
(a) members of the institutional biosafety committee,
(b) the designated Biosafety Officer where applicable,
(c) a list of current projects indicating the risk assessment category,
(d) a list of the laboratories approved for biotechnological work indicating the category of containment, and
(e) a list of greenhouses and animal facilities of the institution, certified and intended for work with genetically modified organisms, indicating the category of containment. [...]

Composition of the institutional biosafety committee
7. (1) An institutional biosafety committee shall include
(a) four members of the institution with expertise in biosafety regulation and the environmental effects of biotechnological work;
(b) the Biosafety Officer of the institution;
(c) a representative each from a cognate organization or institution; and
(d) two other members who are not affiliated with the institution and represent the interest of the community such as
(i) members of Government, public health or environmental agencies,
(ii) persons active in human, plant or animal health concerns, and
(iii) persons active in environmental concerns, and who do not require a previous affiliation with the institution.
(2) The head of the institution shall appoint members of the institutional biosafety committee and shall designate a chairperson and a secretary for the effective performance of the functions of the committee.

[See also regulations 8 and 9 on the functions of the Institutional Biosafety Committee and the Biosafety Officer]. [c]

[b] Available at https://nba.gov.gh/wp-content/uploads/2020/09/L-I-2383.pdf (accessed on 28 June 2024).

[c] Ibid.

7. Concluding remarks

Target 14 of the Kunming-Montreal Global Biodiversity Framework brings into focus the reason why an integrated approach to law- and policymaking is essential for tackling complex global issues in a holistic manner, with a view to achieving the objectives of the Convention on Biological Diversity. Activities that exert an impact on biodiversity are often outside the remit of biodiversity policy and in order to ensure that biodiversity and the opportunities derived from its conservation and sustainable use are recognized and reflected in decision-making, biodiversity needs to be integrated into relevant cross-sectoral and sectoral policies and legislation. Along similar lines and considering that the Cartagena Protocol on Biosafety and the Convention have partly overlapping objectives and contain related provisions, mainstreaming of biosafety into cross-sectoral and sectoral policies, legislation and (legal) institutional frameworks is important for achieving an adequate level of protection against potential adverse effects of living modified organisms (LMOs) on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Biosafety is integral to the conservation and sustainable use of biodiversity and environmental protection more broadly but can be realized only through involvement of sectors that may wish to use LMOs resulting from modern biotechnology, including the food and agricultural sectors in particular.

The present practical legislative study argues that biosafety mainstreaming may help to ensure synergies between and within international and national legal regimes. Mainstreaming is an inclusive process which requires connections and cooperation between biodiversity, biosafety and other cross-sectoral and sectoral public sector representatives, and private sector actors. Mainstreaming processes and activities may therefore help to create opportunities to identify gaps and conflicts in implementation of biosafety and other cross-sectoral and sectoral objectives and obligations and to ensure efficient implementation of biosafety obligations through the sharing of knowledge and expertise, capacity and resources. Moreover, mainstreaming may facilitate strengthened implementation of and compliance with national biosafety frameworks.

With the aim of assisting Parties in carrying out the integrated implementation of the Cartagena Protocol on Biosafety, the present study has provided important guidance to support mainstreaming of biosafety in domestic contexts. Building upon online resources that were developed by the Secretariat of the Convention on Biological Diversity in collaboration with the Strathclyde Centre for Environmental Law and Governance,[179] the study has outlined key steps for mainstreaming biosafety in cross-sectoral and sectoral legislation, policies and institutional frameworks. It has focused on identifying examples of biosafety mainstreaming at the national level in the

179 Convention on Biological Diversity, "Biodiversity e-Learning Platform: Biosafety/mainstreaming biosafety" (2018), available at https://scbd.unssc.org/course/index.php?categoryid=14 (accessed on 28 June 2024).

Photo by Nick Fewings on Unsplash

19 countries that participated in the pilot project of the Secretariat on biosafety mainstreaming and the integrated implementation project. Those examples reveal which cross-sectoral and sectoral instruments could be viewed as entry points to biosafety mainstreaming and what kinds of aspects and activities could address biosafety within different entry points. The analysis includes biosafety mainstreaming into national biodiversity strategies and action plans as cross-sectoral policy instruments which may offer opportunities for inter-institutional awareness-raising and capacity-building. Moreover, sectoral instruments such as seed, agricultural and food safety laws may offer opportunities for integrating elements of risk assessment and risk management or integrating labelling requirements. The section of the study on institutional frameworks has focused on institutions that are anchored in legislation, providing examples of governance models that integrate cross-sectoral and sectoral representatives in biosafety institutions and governance models that integrate biosafety representatives in cross-sectoral and sectoral institutions, as well as coordination mechanisms.

The study has described how biosafety mainstreaming into legislation, policy and institutional frameworks can be facilitated by creating an enabling environment, for example, through awareness-raising among relevant institutions of the importance of biosafety (including for delivery of cross-sectoral and sectoral objectives) and strengthening capacity to mainstream biosafety into relevant cross-sectoral and sectoral instruments.

For the present study to be used as a supportive tool for biosafety mainstreaming, it is recommended that it be read in conjunction with the online tools developed by the Secretariat of the Convention on the topic of biosafety mainstreaming which provide further guidance on how to create an enabling environment for biosafety mainstreaming. Elements of those tools are included in the annexes to the study, Notable in this

regard is the application entitled "Develop a strategy for biosafety mainstreaming", the template of which is included as annex II below. Further guidance supporting the implementation of the Cartagena Protocol on Biosafety and the creation of an enabling environment is provided in the Implementation Plan for the Cartagena Protocol on Biosafety[180] and the Capacity-building Action Plan for the Cartagena Protocol on Biosafety.[181]

180 Decision CP-10/3 of 19 December 2022 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, entitled "Implementation Plan for the Cartagena Protocol on Biosafety", annex.

181 Decision CP-10/4 of 19 December 2022 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, annex.

Annex I

Tool kit for implementing the Cartagena Protocol on Biosafety[182*] and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

Obligations under the Cartagena Protocol on Biosafety	Article of Cartagena Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
I. Administrative tasks						
1. Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19 (1), (2)					
2. Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19 (1), (2)					
3. Provide to the Biosafety Clearing-House: ▪ Any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMOs-FFP; and ▪ Any bilateral, regional or multilateral agreements or arrangements.	20 (3) (a)–(b), 11 (5), 14 (2)					
4. Specify to the Biosafety Clearing-House cases in which import may take place at the same time as the movement is notified.	13 (1) (a)					
5. Specify to the Biosafety Clearing-House imports of LMOs exempted from the advance informed agreement procedures.	13 (1) (b)					

182 *Based on the implementation tool kit contained in annex III to decision BS-I/5 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety of 27 February 2004.

Obligations under the Cartagena Protocol on Biosafety	Article of Cartagena Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
6. Notify the Biosafety Clearing-House if domestic regulations shall apply with respect to specific imports.	14 (4)					
7. Provide the Biosafety Clearing-House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17 (2)					
8. Notify the Secretariat if there is a lack of access to the Biosafety Clearing-House and hard copies of notifications to the Clearing House should be provided.	(e.g. 11 (1))					
Follow-up actions						
9. Provide to the Biosafety Clearing-House: ▪ Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Article 15; ▪ Final decisions concerning the import or release of LMOs; and ▪ Article 33 reports.	20 (3) (c)(e)					
10. Make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements.	25 (3)					
11. Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33					
12. Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.						
II. Legal requirements and/or undertakings						
1. Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2 (2)					

Obligations under the Cartagena Protocol on Biosafety	Article of Cartagena Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
2. Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMOs-FFP.	8 (2) 11 (2)					
3. Ensure that any domestic regulatory framework used in place of the advance informed agreement procedures is consistent with the Protocol.	9 (3)					
4. Ensure that advance informed agreement decisions are taken in accordance with Article 15.	10 (1)					
5. Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15 (1), (2)					
6. Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16 (1)					
7. Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16 (3)					
8. Endeavour to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16 (4)					

Obligations under the Cartagena Protocol on Biosafety	Article of Cartagena Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
9. Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17 (1)					
10. Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18 (1)					
11. 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; and ▪ Provides a contact point for further information.	18 (2) (a)					
12. Take measures to require that documentation accompanying LMOs destined for contained use: ▪ Clearly identifies them as LMOs; ▪ Specifies any requirements for their safe handling, storage, transport and use; ▪ Provides a contact point for further information; and ▪ Provides the name and address of individuals or institutions to which they are consigned.	18 (2) (b)					

Obligations under the Cartagena Protocol on Biosafety	Article of Cartagena Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
13. Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: ▪ Clearly identifies them as LMOs; ▪ Specifies the identify and relevant traits and/or characteristics; ▪ Provides any requirements for the safe handling, storage, transport and use; ▪ Provides a contact point for further information; ▪ Provides, as appropriate, the name and address of the importer and exporter; and ▪ Contains a declaration that the movement is in conformity with the requirements of the Protocol.	18 (2) (c)					
14. Provide for the designation of confidential information by notifiers, subject to the exclusions set forth in Article 21(6).	21 (1), (6)					
15. Ensure consultation with notifiers and review of decisions in the event of disagreement regarding claims of confidentiality.	21 (2)					
16. Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21 (3), (5)					
17. Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21 (4)					
18. Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23 (1) (a)					
19. Endeavour to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23 (1) (b)					

Obligations under the Cartagena Protocol on Biosafety	Article of Cartagena Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
20. In accordance with relevant domestic laws, consult with the public in decision-making under the Protocol, while respecting confidential information.	23 (2)					
21. Endeavour to inform the public about the means of public access to the Biosafety Clearing-House.	23 (3)					
22. Adopt appropriate measures aimed at preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25 (1)					
23. Dispose, at its expense, LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25 (2)					
III. Procedural requirements: advance informed agreement						
1. Notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1.	8 (1)					
2. Provide written acknowledgement of receipt of notification to notifier within 90 days, including: ▪ Date of receipt of notification; ▪ Whether notification meets requirements of Annex I; ▪ That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; OR ▪ Whether the import may proceed after 90 days without further written consent.	 9 (2) (a) 9 (2) (b) 10 (2) (a), 9 (2) (c) 10 (2) (b)					

Obligations under the Cartagena Protocol on Biosafety	Article of Cartagena Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
3. Communicate in writing to the notifier, within 270 days of receipt of notification: ▪ Approval of the import, with or without conditions; ▪ Prohibition of the import; ▪ A request for additional relevant information in accordance with domestic regulatory framework or Annex I; or ▪ Extension of the 270-day period by a defined period of time; AND Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.	10 (3) (a)–(d) 10 (4)					
4. Provide in writing to the Biosafety Clearing-House the decision communicated to the notifier.	10 (3)					
5. Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12 (2), (3)					
IV Procedural requirements: living modified organisms for direct use as food, feed, or for processing						
1. Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing-House within 15 days of making that decision, including the information listed in Annex II.	11 (1)					
2. Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing-House.	11 (1)					

Obligations under the Cartagena Protocol on Biosafety	Article of Cartagena Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
3. Provide additional information contained in paragraph (b) of annex II about the decision to any Party that requests it.	11 (3)					
4. In response to the posting of a decision by another Party, a Party that decides to import may take a decision on the import of LMOs-FFP: ▪ Either as approved under the domestic regulatory framework consistent with the Protocol; OR ▪ In the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.	11 (4), (6)					

Legal components under the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety	Article of the Supplementary Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
I Response measures						
1. Require that an operator, subject to any requirements of the competent authority, in the event of damage resulting from LMOs that find their origin in a transboundary movement, as defined under the Supplementary Protocol: (a) immediately inform the competent authority; (b) evaluate the damage; and (c) take appropriate response measures.	5 (1)					
2. Require that an operator take appropriate response measures where there is sufficient likelihood that damage will result if timely response measures are not taken.	5 (3)					

Legal components under the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety	Article of the Supplementary Protocol	Biosafety legislation	Biosafety Policy	Other cross-sectoral legislation	Other sectoral legislation	Comments and explanatory notes
3. Ensure that the competent authority: (a) identifies the operator that has caused the damage; (b) evaluates the damage; and (c) determines which response measures should be taken by the operator.	5 (2)					
4. Require that decisions by the competent authority requiring the operator to take response measures should be reasoned and that the competent authority shall inform the operator that remedies are available, including administrative or judicial review of such decisions.	5 (6)					
5. Put in place a requirement whereby the competent authority itself may implement appropriate response measures, in particular in situations where the operator has failed to do so.	5 (4)					
6. Provide that the competent authority has the right to recover from the operator costs and expenses incurred in relation to the implementation of the response measures.	5 (5)					
II Civil liability						
1. Continue to apply existing general law on civil liability and/or develop and apply or continue to apply civil liability law specifically for the purpose of providing adequate rules and procedures in domestic law on civil liability for material or personal damage associated with damage as defined under Article 2 (b) of the Supplementary Protocol.	12 (2)					
2. Address, as appropriate, when developing civil liability law for material or personal damage associated with damage as defined under Article 2 (b) of the Supplementary Protocol, inter alia: (a) damage; (b) standard of liability, including strict or fault-based liability; (c) channelling of liability, where appropriate; and (d) right to bring claims.	12 (3)					

Annex II

Template for developing a national biosafety mainstreaming strategy

For further information on the key steps to mainstreaming biosafety, see section 6.1 above. For further instructions on how to develop a strategy for mainstreaming biosafety in your country, see the online application entitled "Develop a strategy for biosafety mainstreaming".[183]

A printable template for developing a national biosafety mainstreaming strategy is provided below.

Vision:
Long-term goals:
Short-term goals:

183 See Convention on Biological Diversity, "Biodiversity e-Learning Platform: Biosafety/mainstreaming biosafety", available at https://scbd.unssc.org/course/index.php?categoryid=14.

Entry points and tools	Mainstreaming actions	Responsible authority	Stakeholders to be engaged	Timeline	Resources	Opportunities
National biodiversity strategy and action plan						
Cross-sectoral policies:						
Sectoral policies:						

Entry points and tools	Mainstreaming actions	Responsible authority	Stakeholders to be engaged	Timeline	Resources	Opportunities
Cross-sectoral Legislation:						
Sectoral legislation:						

Entry points and tools	Mainstreaming actions	Responsible authority	Stakeholders to be engaged	Timeline	Resources	Opportunities
Institutional frameworks:						
Activities: Capacity-building:						
Activities: Awareness-raising:						

Activities: Education:
Activities: Cooperation and coordination:
Activities: Public participation and access to information:

Annex III

Overview policy and legislative examples of biosafety mainstreaming

Mainstreaming of biosafety in cross-sectoral policies

The *Estrategia Nacional para la Conservación y Uso Sustentable de los Polinizadores* of Mexico[a] includes an objective and action for integration of goals for the protection of pollinators and LMO risk assessment procedures

The *Estrategia Nacional para la Conservación y Uso Sustentable de los Polinizadores* of Mexico considers the possible impacts of LMOs on pollinators and the potential of biosafety procedures for protecting pollinators. The strategy includes the objective of averting the widespread and indiscriminate use of pesticides, herbicides and other highly toxic substances as well as LMOs in order to prevent the loss of pollinators and associated flora and fauna and impacts on human health. The strategy also includes an action to review and, where appropriate, update or develop risk assessment procedures for LMOs, under a precautionary approach, to take into account sublethal and indirect effects on both wild and managed pollinators. The ministries of agriculture, environment and health are jointly responsible for delivering these actions.

[a] Available at www.gob.mx/cms/uploads/attachment/file/629651/ENCUSP_calidad_media_corregido.pdf (accessed on 28 June 2024).

***Example clause: Estrategia Nacional para la Conservación y Uso Sustentable de los Polinizadores* of Mexico (2019)**

8.2. Evitar el uso masivo e indiscriminado de plaguicidas, herbicidas y otras sustancias altamente tóxicas, así como organismos genéticamente modificados.

Objetivos específicos

- *Evitar la pérdida de polinizadores, así como de la flora y fauna asociadas.*
- *Evitar las consecuencias a la salud humana. […]*

Acciones 8.2.3 Revisar y en su caso, actualizar o desarrollar los procedimientos de evaluación de riesgos de los plaguicidas, otras sustancias altamente tóxicas, así como de los organismos vivos genéticamente modificados, bajo un enfoque de precaución, conforme a las atribuciones y competencias de cada instancia, para tener en cuenta los efectos subletales e indirectos, tanto en los polinizadores silvestres como en los gestionados.

The *Estrategia Nacional sobre Biodiversidad y Plan de Acción (2016-2030)* of Mexico[b] includes actions to strengthen the biosafety frameworks of Mexico through research, monitoring and sharing of information.

The *Estrategia Nacional sobre Biodiversidad y Plan de Acción (2016-2030)* of Mexico was drafted with support from the national focal points of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. A draft version was coordinated with different institutions and experts and developed with the involvement of stakeholders through consultations. The national biodiversity strategy and action plan mainstreams biosafety in a provision that seeks to promote and guide research on biotechnology and biosafety topics for the sustainable use and conservation of biodiversity. The national biodiversity strategy and action plan, among other actions, provides for the development of a monitoring strategy for detecting possible effects of LMOs in a timely manner.

[b] Available at https://bioteca.biodiversidad.gob.mx/janium/Documentos/12890.pdf (accessed on 28 June 2024).

***Example clause: Estrategia Nacional sobre Biodiversidad y Plan de Acción (2016-2030)* of Mexico (2016)**

Acciones - 1.1.10. Promover y orientar la investigación en biotecnología y bioseguridad en temas estratégicos para el uso sustentable y conservación de la biodiversidad.

- *Desarrollar investigación y paquetes tecnológicos que contribuyan al uso sustentable y conservación de la biodiversidad bajo un enfoque de bioseguridad de acuerdo a las disposiciones de la Ley de Bioseguridad de los Organismos Genéticamente Modificados, la Ley de Ciencia y Tecnología y la normativa aplicable.*
- *Coadyuvar con la Red Nacional de Monitoreo de OGM para detectar oportunamente posibles efectos de los organismos genéticamente modificados.*
- *Evaluar los beneficios y riesgos de la biotecnología sobre la diversidad biológica y cultural del país.*
- *Desarrollar una estrategia de monitoreo de la biodiversidad para detectar oportunamente posibles efectos de los organismos genéticamente modificados (OGM).*
- *Promover el uso del Sistema Nacional de Información sobre Bioseguridad (SNIBIOS), y generar los enlaces a bases de datos y repositorios de información sobre diversidad genética, facilitando el acceso libre, dirigido al público y a los tomadores de decisiones.*
- *Crear un sistema nacional de información genética de acceso libre, dirigido al público y a los tomadores de decisiones.*

The national biodiversity strategy to 2020, vision to 2030 of Viet Nam[a] considers the importance of biosafety for biodiversity objectives and commits to strengthening national frameworks, notably through enhanced cooperation and investment.

The responsibility for drafting the national biodiversity strategy to 2020, vision to 2030 of Viet Nam was assigned to the Ministry of Natural Resources and Environment. The ministry established a drafting Board and an editorial team which included representatives of ministries, agencies and research institutions and leading experts in the field of environmental protection and biodiversity. Biosafety was mainstreamed under the objective of controlling activities that have negative impacts on biodiversity by including a commitment to enhance biosafety management through actions such as enhanced cooperation and increased investment in measures to monitor and control risks.

[a] Available at www.cbd.int/doc/world/vn/vn-nbsap-v3-en.pdf (accessed on 28 June 2024).

***Example clause:* National biodiversity strategy to 2020, vision to 2030 of Viet Nam (2015) -**

3.1.4. Control activities that have negative impacts on biodiversity. [...]
c) Control, halt and prevent the damage caused by invasive alien species: and enhance biosafety management of genetically modified organisms.

Actions:

- *Enhance cooperation, exchange and learning from experience on the biosafety management of genetically modified organisms, to improve technical and professional expertise of biosafety management agencies and units at all levels;*
- *Increase investment in infrastructure and resources for implementation of measures to monitor and control the risks of genetically modified organisms to the environment and biodiversity;*
- *Develop and promulgate legal documents on redress and liability in biosafety management activities of GMOs;*
- *Assessment of status of the release of GMOs and products containing GMOs to the environment, and their appearance in the market.*

The national biodiversity strategy and action plan (2015-2025) of Mongolia[a] considers the importance of biosafety for the protection and sustainable use of genetic resources and highlights opportunities for integrated research and information dissemination.

The Ministry of Environment and Tourism and National Biosafety Committee of Mongolia, rather than develop a separate national biosafety programme, agreed on the mainstreaming of national objectives on biosafety within the national biodiversity strategy and action plan (2015-2025). Precautionary measures for biosafety are considered indicators for achievement of the goal of creating a legal environment notably for the protection and sustainable use of genetic resources and implementing sustainable use, and protection from genetic erosion and depletion. Connections between biosafety and biodiversity aims are highlighted under objective 6 which commits to creating knowledge and experience related to registering genetic resources and GMOs, with outputs highlighting opportunities for integrated research and information dissemination.

[a] Available at www.cbd.int/doc/world/mn/mn-nbsap-v2-en.pdf (accessed on 28 June 2024).

Example clause: **National biodiversity strategy and action plan (2015-2025 of Mongolia (2015)**

Goal 3: Create a legal environment for the protection, sustainable use, and fair and equitable sharing of benefits arising from widely used and economically significant genetic resources, and to implement sustainable use, and protection from genetic erosion and depletion. […]

Indicators:

- *A legal environment for the use of and sharing of benefits arising from genetic resources.*
- *Types and number of source materials contained in the genetic resource database.*
- *Types and dissemination frequency of intersectoral and public information pertaining to genetic resources and their utilization.*
- *Number of actions ensuring and taking precautionary measures for biosafety.*

Objective 6 -Register genetic resources and GMO and create a genetic resource bank. […]
Outputs: By 2018, knowledge and experience of registering genetic resource, GMO and database establishment is created.

- *By 2020, methods of research and assessment technique for endemic plants, animals and organisms, their genetic resources and derived genetically modified organisms are developed.*
- *By 2025, a system and dissemination scheme for information regarding genetic resources, genetically modified organisms and their use is created.*

The national biodiversity strategy and action plan II (2015-2025) of Uganda[a] seeks to provide a comprehensive strategy for creating an enabling environment for biosafety within the wider biodiversity framework.

The national biodiversity strategy and action plan II (2015-2025) of Uganda included the following targets: by 2018, public awareness, education and participation in biotechnology and biosafety are enhanced and by 2020, national capacity for biotechnology applications and use is adequate. Those targets were accompanied by activities to create an enabling environment for biosafety. Uganda committed to having the national biotechnology and biosafety law in place by 2018. The National Biosafety Act was adopted in 2017.

[a] Available at www.cbd.int/doc/world/ug/ug-nbsap-v2-en.pdf (accessed on 28 June 2024).

Example clause: **National biodiversity strategy and action plan II (2015-2025) of Uganda (2015)**

Thematic area six: Harnessing benefits from modern biotechnology
Strategic objective 6: To harness modern biotechnology for socio-economic development with adequate safety measures for human health and the environment.

National target 6.1: By 2018, public awareness, education and participation in biotechnology and biosafety are enhanced.
National target 6.2: By 2020, national capacity for biotechnology applications and use is adequate.
National target 6.3: By 2018, the national biotechnology and biosafety law in place.
National target 6.4: By 2018, the Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety in operation and implemented.
National target 6.5: By 2020, there is widespread application and use of biotechnology and its products for national development.

Strategies for biotechnology and biosafety in Uganda include:
(a) Assess national capacities in biotechnology and biosafety;
(b) Enhance the availability and exchange of information on biotechnology and biosafety;
(c) Establish a mechanism(s) for continuous human and infrastructural resource capacity development, deployment and retention;
(d) Develop a fully functional national biosafety system;
(e) Enhance regulatory performance of the National Biosafety Committee and the institutional biosafety committee;
(f) Establish a national repository for plant and animal genetic resources;
(g) Promote research in medical, agricultural, environmental and other areas of biotechnology and biosafety;
(h) Update information on biotechnology and biosafety.
(i) Establish a strong and effective monitoring system for biotechnology use and application;
(j) Undertake environmental impact assessments or risk assessments on biotechnology policies, programmes or projects that are likely to have significantly negative impacts on human health and the environment including biodiversity;
(k) Develop mechanisms for sharing costs and benefits of biotechnology;
(l) Promote integration of biotechnology values into macroeconomic frameworks;
(m) Develop and disseminate biotechnology awareness materials.

Mainstreaming of biosafety in sectoral policies

The national food safety policy of Ghana (2022)[a] outlines the role and responsibilities of the National Biosafety Authority in relation to supporting the delivery of sectoral objectives and actions.

The national food safety policy of Ghana (2022) aims at building a responsive and resilient food safety system which assures the right to quality food. In relation to biosafety, the policy considers that use of modern biotechnologies could contribute to improving food quantity and quality but only when biosafety is ensured. The policy references the National Biosafety Act 2011 and outlines the role of the National Biosafety Authority in promoting food safety, including the consideration and determination of applications for LMO development, transfer, handling and use, coordination of monitoring and research activities, identification of capacity-building needs and advising of the Government on legislation and awareness and education. The policy states that an effective collaboration mechanism will be established to ensure coordination among various public bodies working on food safety, including the National Biosafety Authority, under the general responsibility of the Ministry of Health.

[a] Available at https://faolex.fao.org/docs/pdf/gha211470.pdf (accessed on 28 June 2024).

Example clause: **National Food Safety Policy of Ghana (2022)**

5.4. Roles of various sectors in promoting food Safety

5.4.16 Role of National Biosafety Authority.
a. Consider and determine applications for approval for the development, transfer, handling and use of genetically modified organisms and related activities in accordance with the provisions of the Biosafety Act.
b. Coordinate and monitor activities relating to safe development, transfer, handling and use of genetically modified organisms in order to ensure that such activities do not have adverse effect on human beings and the environment.
c. Coordinate research and surveys in matters relating to the safe development, transfer, handling and use genetically modified organisms and collect, collate and disseminate information about the findings of such research investigations or survey.
d. Identify national requirements for manpower development and capacity-building in biosafety.
e. Advise the Government on legislation and other measures relating to the safe development, transfer, handling and use of genetically modified organisms.
f. Promote awareness and education among the general public in matters relating to biosafety.
g. Establish and maintain a biosafety clearing house to serve as a means through which information is made available to facilitate exchange of scientific, technical, environmental and legal information, and experience with living modified organisms.
h. Perform any other function which is incidental to the performance of any other foregoing functions.

Mainstreaming of biosafety in cross-sectoral legislation

The Swiss Federal Constitution[a] provides for protection against the misuse of gene technology.

In 1992, Switzerland voted in favour of introducing an article on genetic engineering into the Swiss Federal Constitution. Article 120 of the Constitution provides that human beings and their environment shall be protected against the misuse of gene technology and that the Confederation shall legislate on the use of reproductive and genetic material from animals, plants and other organisms. In doing so, it shall take into account the dignity of living beings as well as the safety of human beings, animals and the environment and shall protect the genetic diversity of animal and plant species. Biosafety regulations were introduced in Switzerland in 1995.

[a] Available at www.fedlex.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/1999/404/20210307/en/pdf-a/fedlex-data-admin-ch-eli-cc-1999-404-20210307-en-pdf-a-1.pdf (accessed on 28 June 2024).

***Example clause:* Swiss Federal Constitution (1999)-**

Art. 120 Non-human gene technology

1 Human beings and their environment shall be protected against the misuse of gene technology.
2 The Confederation shall legislate on the use of reproductive and genetic material from animals, plants and other organisms. In doing so, it shall take account of the dignity of living beings as well as the safety of human beings, animals and the environment and shall protect the genetic diversity of animal and plant species.

The *Ley Federal de Sanidad Animal* of Mexico[a] integrates biosafety requirements (including inspection, certification, documentation and authorization) in relation to the import and experimental use of LMOs which may pose animal health risks.

The *Ley Federal de Sanidad Animal (2007)* of Mexico provides that biological agents for any use, including LMOs, are subject to inspection in accordance with applicable animal health provisions and to the issuance of a zoo sanitary certificate for import at the point of entry into the country (article 24). These obligations apply to biological agents for any use including LMOs (Article 24). The Law also provides that the secretariat of agriculture, livestock, rural development, fisheries and food will issue animal health provisions determining the characteristics and specifications for products made from LMOs which represent a zoosanitary risk (Article 95). The secretariat needs to authorize experimental use, piloting and commercial use of LMOs or use of LMOs for the control and eradication of diseases or pests (Article 98).

[a] Available at https://faolex.fao.org/docs/pdf/mex9444.pdf (accessed on 28 June 2024).

Example clause: Ley Federal de Sanidad Animal of Mexico (2007)

Artículo 24.- La importación de las mercancías que se enlistan a continuación, queda sujeta a la inspección de acuerdo a las disposiciones de sanidad animal aplicables y a la expedición del certificado zoosanitario para importación en el punto de ingreso al país: [...]
III. Agentes biológicos para cualquier uso incluyendo organismos genéticamente modificados de acuerdo con la Ley correspondiente, así como los materiales y equipos utilizados para su manejo, uso o aplicación; […]

Artículo 95.- La Secretaría expedirá disposiciones de sanidad animal en las que determinará las características y especificaciones zoosanitarias que deberán reunir: [...]
II. Los productos elaborados a base de organismos genéticamente modificados cuando representen riesgo zoosanitario; […]

Artículo 98.- La aplicación, uso o manejo de organismos genéticamente modificados en programas experimentales, pilotos, comerciales o en el control y erradicación de enfermedades o plagas, requerirá de la autorización correspondiente que expida la Secretaría y estará sujeta a los procedimientos de verificación e inspección previstos en esta Ley y en las disposiciones de sanidad animal respectivas, sin perjuicio de lo que establezcan otros ordenamientos.

The *Ley de Bioseguridad*[a] *and Ley General del Equilibrio Ecológico y la Protección al Ambiente*[b] of Mexico provide for synergized mainstreaming of restrictions on LMO activities in protected areas and core areas of protected areas.

In relation to biosafety and protected areas, the biosafety and environmental laws of Mexico provide for synergized mainstreaming. Article 89 of the Ley de Bioseguridad (2005) provides that only LMO activities that aim at providing for bioremediation, in the case of the presence of plagues or contaminants, will be allowed in protected areas but not in the core areas (*zonas núcleo*) of the protected area. Similarly, the *Ley General del Equilibrio Ecológico y la Protección al Ambiente (1988)* provides that introduction of exotic specimens or LMOs is expressly prohibited within the core areas of protected areas (Article 49).

[a] Available at https://conahcyt.mx/cibiogem/images/cibiogem/eng/Docs/Ing_LBOGM_P.pdf) (accessed on 28 June 2024).
[b] Available at https://faolex.fao.org/docs/pdf/mex5750.pdf (accessed on 28 June 2024).

***Example clause: Ley de Bioseguridad* of Mexico (2005) -**

ARTÍCULO 89.- En las áreas naturales protegidas creadas de conformidad con lo dispuesto en la materia, sólo se permitirán actividades con OGMs para fines de biorremediación, en los casos en que aparezcan plagas o contaminantes que pudieran poner en peligro la existencia de especies animales, vegetales o acuícolas, y los OGMs hayan sido creados para evitar o combatir dicha situación, siempre que se cuente con los elementos científicos y técnicos necesarios que soporten el beneficio ambiental que se pretende obtener, y dichas actividades sean permitidas por la SEMARNAT en los términos de esta Ley.

Para los efectos de lo dispuesto en el párrafo anterior, queda prohibido realizar actividades con OGMs en las zonas núcleo de las áreas naturales protegidas.

En caso de que algún centro de origen o centro de diversidad genética se ubique dentro de alguna área natural protegida, las declaratorias de creación y los programas de manejo de dichas áreas se modificarán en los términos de la legislación de la materia, conforme se realicen las determinaciones a que se refiere el Artículo 86 de la presente Ley.

***Example clause: Ley General del Equilibrio Ecológico y la Protección al Ambiente* of Mexico (1988)**

ARTÍCULO 49.- En las zonas núcleo de las áreas naturales protegidas quedará expresamente prohibido: […]
IV. Introducir ejemplares o poblaciones exóticos de la vida silvestre, así como organismos genéticamente modificados, [...]

Integration of LMOs in the regulation of protected areas in the *Reglamento al Código Orgánico del Ambiente* of Ecuador,[a] and of biosafety in the environmental management system of Ecuador.

The supplementary Reglamento al Código Orgánico del Ambiente (2019) provides the structures and regulations required to effectively implement the Código Orgánico del Ambiente of Ecuador (2017). Article 240 of the Regulations to the Code establishes "restriction zones" for LMOs based on national protection goals and risk analysis. Designation takes into consideration possible risks from LMOs to centres of origin and genetic diversity, the national system of protected areas and national forests, special areas for the conservation of biodiversity, fragile ecosystems and other zones as defined by the relevant authority. Within the zones, activities relating to LMOs are restricted.

Article 241 of the Regulations to the Code establishes the *sistema nacional de bioseguridad*, which is part of the national decentralized environment management system and includes all processes, entities, actors and instruments responsible for the guidance, interaction, coordination, cooperation and monitoring of biosafety policies, projects and programmes in relation to the regulation of LMOs and exotic and invasive alien species. The Regulations to the Code provide that the National Biosafety Committee will act as an inter-institutional coordination body for the national biosecurity system.

[a] Available at https://faolex.fao.org/docs/pdf/mex5750.pdf (accessed on 28 June 2024).

***Example clause: Reglamento al Código Orgánico del Ambiente* of Ecuador (2019)**

Art. 240. Zonas de restricción.- Con base en las metas nacionales de protección y los resultados del proceso de análisis del riesgo, las autoridades nacionales competentes, coordinarán el establecimiento de zonas restringidas para actividades con organismos genéticamente modificados resultantes de la biotecnología moderna, considerando los posibles riesgos que podría generar su uso en los centros de origen y diversidad genética, el Sistema Nacional de Áreas Protegidas, el Patrimonio Forestal Nacional, las áreas especiales para la conservación de la biodiversidad, los ecosistemas frágiles y demás zonas definidas por la Autoridad Ambiental Nacional.

Art. 241. Sistema Nacional de Bioseguridad SINABIO.- El Sistema Nacional de Bioseguridad es parte del Sistema Nacional Descentralizado de Gestión Ambiental, y comprende el conjunto de procesos, entidades, actores e instrumentos que permiten la orientación, interacción, coordinación, cooperación, supervisión y seguimiento de la políticas, proyectos y programas en materia de bioseguridad; para lo que, entre otros, tratará los siguientes temas:

1) Especies exóticas e invasoras;
2) Organismos genéticamente modificados resultantes de la biotecnología moderna; y,
3) Otros establecidos por las autoridades competentes.
El Comité Nacional de Bioseguridad actuará como instancia de coordinación interinstitucional del Sistema Nacional de Bioseguridad.

Mainstreaming of biosafety in sectoral legislation

The Food Regulations of Malaysia[a] require approval from the Director of the Food Safety and Quality Division of the Ministry of Health before food or food ingredients obtained through modern biotechnology can be imported, prepared or advertised for sale or sold.

The Food Regulations of Malaysia (1985, amended 2010) regulate all import, manufacturing, advertisement, sale, use of additives, packaging and standards for a range of food and drinks. The Regulations were amended in 2010 to include a new part on the approval and sale of food obtained through modern biotechnology and mandatory LMO labelling, which requires that written approval be obtained from the Director of the Food Safety and Quality Division of the Ministry of Health before LMOs are imported, prepared or advertised for sale or sold. In practice, coordination of enforcement requires that LMOs and LMO products be initially reviewed and assessed by the National Biosafety Board. Only after an approval is granted will the LMO and the product be allowed to be released and if the LMO is a food product, it will be under the oversight of the Director of the Food Safety and Quality Division of the Ministry of Health and will require written approval.

[a] Available at https://faolex.fao.org/docs/pdf/mal27305.pdf (accessed on 28 June 2024).

***Example clause:* Food Regulations of Malaysia (1985, amended 2010 -**

Regulation 3A. Approval for sale of food obtained through modern biotechnology.

No person shall import, prepare or advertise for sale or sell any food and food ingredients obtained through modern biotechnology without the prior written approval of the Director.

***Example clause: -* Biosafety Act of Malaysia (2007)[b]**

Section 2. Act to be read together with other laws
(1) The Act shall be read together with any other written law relating to import and export, human, plant and animal health, the environment and biological diversity, and the provisions of this Act shall be in addition to, and not in derogation of, the provision of such other written laws.

[b] Available at https://faolex.fao.org/docs/pdf/mal74258.pdf (accessed on 28 June 2024).

The *Ley General de Pesca y Acuacultura Sustentables* of Mexico[a] applies the provisions of national biosafety law to the import of fishing and aquaculture resources.

The *Ley General de Pesca y Acuacultura Sustentables* of Mexico (2007, amended 2018) aims to regulate, promote and manage the use of fishing and aquaculture resources in areas of national jurisdiction. Article 95 of the law provides that the import of seeds, eggs, fry, larvae, post-larvae, algae strains, reproducers or any other stage of wild, cultivated or laboratory species requires an aquaculture health certificate from the national health service for food safety and food quality. In the case of LMOs, the provisions of the *Ley de Bioseguridad de Organismos Genéticamente Modificados* apply, meaning that the health service is required to carry out a risk assessment before an aquaculture health certificate can be issued.

[a] Available at https://faolex.fao.org/docs/pdf/mex72880.pdf (accessed on 28 June 2024).

***Example clause: Ley General de Pesca y Acuacultura Sustentables* of Mexico (2007, amended 2018) -**

ARTÍCULO 95.- Para la importación de semillas, ovas, alevines, larvas, postlarvas, cepas algales, reproductores o cualquier otro estadio de especies silvestres, cultivadas o de laboratorio, se deberá adjuntar a la solicitud el certificado de sanidad acuícola otorgado por el SENASICA. En el caso de organismos genéticamente modificados se sujetará a lo dispuesto en la Ley de Bioseguridad de Organismos Genéticamente Modificados.

The *Ley Orgánica de Salud* of Ecuador (2006)[a] requires the demonstration of the safety of food intended for human consumption that consists of or contains LMOs.

Article 149 of the *Ley Orgánica de Salud* of Ecuador (2006) provides that the development, treatment, processing, production, application, handling, use, storage, transport, distribution, import, marketing and sale of food for human consumption consisting of or containing LMOs requires the demonstration of safety for consumption to the competent authority through technical and scientific studies. Moreover, Article 150 of the law provides that food donations containing LMOs in food aid programmes will be accepted only if their safety has been demonstrated to the national health authority through technical and scientific studies.

[a] Available at https://faolex.fao.org/docs/pdf/ecu154951.pdf (accessed on 28 June 2024).

***Example clause: Ley Orgánica de Salud* of Ecuador (2006) -**

Art. 149.- El desarrollo, tratamiento, elaboración, producción, aplicación, manipulación, uso, almacenamiento, transporte, distribución, importación, comercialización y expendio de alimentos para consumo humano que sean o contengan productos genéticamente modificados, se realizará cuando se demuestre ante la autoridad competente, mediante estudios técnicos y científicamente avanzados, su inocuidad y seguridad para los consumidores y el medio ambiente.

Art. 150.- La donación de alimentos que contengan productos genéticamente modificados, así como su utilización, uso y manejo en planes y programas y planes de ayuda alimentaria, serán aceptados si es que mediante procedimientos técnicos y científicamente avanzados, demuestren su inocuidad y seguridad ante la autoridad sanitaria nacional.

The *Ley de Salud Agrícola Integral* of the Bolivarian Republic of Venezuela[a] regulates the release into the environment, production, distribution, exchange and marketing of LMOs, taking into consideration the absence of scientific certainty.

The *Ley de Salud Agrícola Integral* of the Bolivarian Republic of Venezuela (2008) provides that the National Executive, through its competent bodies and entities, regulates the release into the environment, production, distribution, exchange and marketing throughout the national territory of LMOs and by-products, given the absence of scientific certainty as to the environmental safety and consumption of these products and the possible irreversible damage that they could cause to human health or the natural equilibrium. The law also provides that, exceptionally, for strategic health reasons and when compliance with biosafety standards can be guaranteed, research that includes LMOs will be allowed in absolute confinement. Article 47 of the law provides that an importer of LMOs must present a sworn statement to declare the presence/use of LMOs in cases where they will be processed for human and animal consumption.

[a] Available at https://faolex.fao.org/docs/pdf/ven83245.pdf (accessed on 28 June 2024).

***Example clause: Ley de Salud Agrícola Integral* of the Bolivarian Republic of Venezuela (2008)**

Regulaciones relativas a los organismos vivos modificados
Artículo 46. El Ejecutivo Nacional, a través de sus órganos y entes competentes, regulará la liberación al ambiente, producción, distribución, intercambio y comercialización en todo el territorio nacional de organismos vivos modificados, productos y subproductos, dada, la ausencia de certeza científica sobre la inocuidad ambiental y consumo de estos productos y sobre los posibles daños irreversibles que pudiera provocar a la salud de las personas o al equilibrio natural. Excepcionalmente por razones estratégicas en materia de salud y cuando se garantice el cumplimiento de normas de bioseguridad, se permitirá la investigación con organismos vivos modificados en absoluto confinamiento.

Declaración jurada
Artículo 47. Toda persona natural o jurídica dedicada a la importación de alimentos, insumos, materia prima o material genético susceptible de ser empleado en la alimentación, en los cuales se han empleado organismos vivos modificados; deberá presentar declaración jurada que indique de manera expresa tal circunstancia, cuando se trate de alimentos procesados, mezclados o industrializados para el consumo humano o animal, de conformidad con lo establecido en el presente Decreto con Rango, Valor y Fuerza de Ley, sus reglamentos y normas técnicas de salud agrícola integral.

Mainstreaming of biosafety in institutional frameworks

The National Biosafety Board of Malaysia, the decision-making body under the national biosafety frameworks, consists of members of cross-sectoral and sectoral institutions.

The National Biosafety Board was established under the Biosafety Act of Malaysia (2007).[a] Its responsibilities include decision- making on all LMO applications, alongside monitoring activities relating to LMOs and products of LMOs and promotion of research, development, education and training. The Board, which falls under the Ministry of Natural Resources and Environmental Sustainability, is chaired by the Secretary-General of this Ministry and includes representatives from six sectoral and cross-sectoral ministries: the Ministry of Agriculture and Food Security, the Ministry of Health, the Ministry of Plantation and Commodities, the Ministry of Domestic Trade and Costs of Living, the Ministry of Investment, Trade and Industry and the Ministry of Science, Technology and Innovation. The name of each ministry will be amended to its current name in the next revision of the law.

[a] Available at https://faolex.fao.org/docs/pdf/mal74258.pdf (accessed on 28 June 2024).

Example clause: **Biosafety Act of Malaysia (2007)**

Section 4. Establishment of the National Biosafety Board
(1) A board by the name of the "National Biosafety Board" is established.
(2) The Board shall consist of the following members who shall be appointed by the Minister Biosafety Act 2007:
(a) the Secretary General of the Ministry of Natural Resources and Environment who shall be the Chairman;
(b) a representative from the Ministry of Agriculture and Agro-based Industry;
(c) a representative from the Ministry of Health;
(d) a representative from the Ministry of Plantation Industries and Commodities;
(e) a representative from the Ministry of Domestic Trade and Consumer Affairs;
(f) a representative from the Ministry of International Trade and Industry;
(g) a representative from the Ministry of Science, Technology and Innovation; and
(h) not more than four other persons who have the knowledge or experience or both in any of the disciplines or matters relevant to this Act.
(3) The provisions of the First Schedule shall apply to the Board.
(4) The Director General shall be the Secretary of the Board and shall carry out such duties as may be imposed by the Board.
(5) The Board shall be responsible to the Minister.

Section 5. Functions of the Board
(1) The functions of the Board shall be as follows: (a) to decide on all applications and matters under Part III and Part IV;
(b) to monitor activities relating to living modified organisms and products of such organisms;
(c) to promote research, development, educational and training activities relating to biosafety;
(d) to establish mechanisms to facilitate the collection, storage and dissemination of data relating to living modified organisms and products of such organisms and biosafety; and
(e) where so directed by the Minister, to perform or provide for the performance of the obligations arising from agreements, conventions or treaties relating to biosafety to which Malaysia is a party where such agreements, conventions or treaties relate to the purposes of this Act.
(2) The Board shall have power to do such things as the Board thinks fit to enable it to perform its functions effectively or which are incidental to the performance of its functions.

The National Biosafety Committee of Cameroon serves as a consultative body to the Ministry of Environment, Nature Protection and Sustainable Development and comprises key cross-sectoral and sectoral institutions relevant to biosafety.

The National Biosafety Committee of Cameroon supports the Ministry of Environment, Nature Protection and Sustainable Development in the development and implementation of the country's regulatory framework on biosafety. The Committee, which is charged with examining requests and monitoring biosafety activities in Cameroon, comprises key institutions relevant to biosafety, such as the Ministry of Environment, Nature Protection and Sustainable Development, the Ministry of Agriculture and Rural Development, the Ministry of Forestry and Wildlife, the Ministry of Scientific Research and Innovation, the Ministry of Public Health and the Ministry of Livestock, Fisheries and Animal Industries. The Committee includes stakeholders from private sector organizations such as research institutions, consumer rights associations and biotechnology associations, which are designated by the ministers responsible for trade and the environment. The Minister of Environment, Nature Protection and Sustainable Development may also invite natural or legal persons based on their skills or experience on issues of biosafety. Thematic working groups may be set up within the Committee to examine specific problems linked to biosafety.

***Example clause: Arrêté portant création, organisation et fonctionnement du Comité National de Biosécurité* of Cameroon (2012)**[a]

Article 1 – Le présent arrêté porte création, organisation et fonctionnement du Comité National de Biosécurité, en abrégé CNB et ci-après désigné "le Comité" […]

Article 3 – (1) Le Comité est composé ainsi qui suit :
Président : Le Ministre de l'Environnement, de la Protection de la Nature et du Développement Durable ou son représentant.

Membres :
- *un représentant du Ministère chargé de l'agriculture et du développement rural ;*
- *un représentant du Ministère chargé des forêts et de la faune ;*
- *un représentant du Ministère chargé de la recherche scientifique et de l'innovation ;*
- *un représentant du Ministère chargé de la santé publique ;*
- *un représentant du Ministère chargé de l'enseignement supérieur ;*
- *un représentant du Ministère chargé du commerce ;*
- *un représentant du Ministère chargé de l'élevage, des pêches et des industries animales ;*
- *un représentant du Ministère chargé du développement technologique ;*
- *le Point Focal du Protocole de Carthagène sur la prévention des risques biotechnologiques ;*
- *un représentant de l'Agence Nationale des Normes et de la Qualité (ANOR) ;*
- *un représentant du Centre de Biotechnologie de l'Université de Yaoundé I ;*
- *un représentant de l'Institut de Recherche Agricole pour le Développement (IRAD)*
- *un représentant de l'Institut de Recherches Médicales et d'Études des Plantes Médicinales (IMPM) ;*
- *un représentant des associations de défense des droits des consommateurs ;*
- *un représentant des associations opérant dans le domaine de biotechnologie.*

(2) Les Membres du Comité sont désignés par les administrations et organismes auxquels ils appartiennent.
(3) Les représentants des associations sont désignés respectivement par le Ministre chargé du commerce et le Ministre chargé de l'environnement.
(4) Le Président du Comité peut inviter toute personne physique ou morale, en raison de ses compétences ou de son expérience sur les questions à examiner, à prendre part aux travaux du Comité avec voix consultative.
(5) Le Président du Comité peut, lorsque les circonstances l'exigent, constituer en son sein des groupes de travail thématiques, éventuellement avec le concours d'experts, en vue d'examiner des problèmes spécifiques liés à la biosécurité.
(6) La composition du Comité est constatée par décision du Ministre chargé de l'environnement.

[a] The text of the decree was provided by Cameroon to the Convention Secretariat upon request (accessed on 28 June 2024).

The Scientific Advisory Team that advises the Cambodian Ministry of Environment is composed of scientific specialists from across public and private institutions.

The Scientific Advisory Team of Cambodia was set up under the Subdecree on Mechanisms and Procedures for Implementing the Law on Biosafety (2010).[a] While based within the Ministry of Agriculture, Forestry and Fisheries, it is chaired by a representative of the Ministry of Environment. The Team is responsible for the review of risk assessments that accompany requests for approval of LMOs for import/export, and for making recommendations to the Ministry of Environment on whether additional risk assessments are required. The Scientific Advisory Team is composed of scientific specialists from a number of public and private institutions, including the Ministry of Environment (Chair), the Ministry of Agriculture, Forestry and Fisheries (Vice-Chair), the Ministry of Commerce, the Ministry of Industry, Mine and Energy, the Ministry of Health and the Ministry of Education, Youth and Sport. While the actual composition is decided by the Government, the Team may request additional national or international scientists in relevant fields to assist with its work.

[a] Available at www.fao.org/fileadmin/user_upload/gmfp/docs/Sub%20Decree%20on%20Mechanisms%20and%20Procedures%20for%20Implementing%20the%20Law%20on%20Biosafety.pdf (accessed on 28 June 2024).

Example clause: **Subdecree on Mechanisms and Procedures for Implementing the Law on Biosafety of Cambodia (2010)**

Article 13:-
A Scientific Advisory Team (SAT) shall be established, which is written in short S.A.T and based at the Ministry of Agriculture, Forestry and Fisheries.

Article 14:-
The SAT is composed of the following scientific specialists:
(i) One representative from the Ministry of Environment, Chair
(ii) One representative from the Ministry of Agriculture, Forestry and Fishery, Vice-Chair
(iii) One representative from the Ministry of Commerce, Member;
(iv) One representative from the Ministry of Industry, Mine and Energy Member;
(v) One representative from the Ministry of Health, Member;
(vi) One representative from Ministry of Education, Youth and Sport, Member;
(vii) One representative from the Royal Academy, Member;
(viii) One representative from the university, Member;
(ix) One representative from relevant laboratories.

Actual composition of the SAT shall be determined by the Government. The S.A.T may request the Ministry of Environment for additional national or international scientists to assist their works within relevant fields in which additional expertise may be required, including, but not limited to: ecology, seed science, environmental toxicology, animal breeding and genetics, virology, microbiology, molecular biology, biotechnology, physiology, and plant breeding.

Article 15:-
The S.A.T has the following duties and responsibilities:
(i) Reviewing risk assessments that accompany requests for prior approval to apply for an import/export permit and recommending to the Ministry of Environment whether additional risk assessment is required;
(ii) Reviewing additional risk assessments that the Ministry of Environment may direct to be prepared by independent experts;
(iii) Keeping any confidential information identified and presenting recommendations to the Ministry of Environment to take strict measures, monitoring procedures as appropriate and providing scientifically sound evidence;
(iv) Proposing risk management measures;
(v) Assisting the production of scientific information for improving public awareness activities;
(vi) Fulfilling the other duties assigned by RGC or the Ministry of Environment.

The technical advisory committee of Ghana includes public representatives and experts, and its tasks include the carrying out of risk assessments and advising the ministries and appropriate bodies on matters concerning LMOs.

The technical advisory committee under the Biosafety Act of Ghana[a] *is the national advisory body on matters concerning or related to LMOs. The committee carries out risk assessments and audits of applications at the request of the board of the National Biosafety Authority of Ghana. The committee advises ministries and appropriate bodies on matters relating to, for example, the introduction of LMOs into the environment, the contained use of LMOs and the import and export of LMOs, as well as proposed regulations and guidelines. No more than 11 persons are appointed to the committee, for a period not exceeding three years. The Biosafety Act sets out requirements in relation to the structure of the committee, which must include representatives from a number of ministerial departments and public bodies and experts appointed for their scientific expertise and knowledge of socioeconomic matters relevant to LMOs.*

[a] Available at https://faolex.fao.org/docs/pdf/gha136733.pdf (accessed on 28 June 2024).

Example clause: **Biosafety Act of Ghana (2011)**

Technical advisory committee

Section 27 (i) In addition to any other committees that the Board may establish under the First Schedule, there is hereby established a technical advisory committee consisting of not more than eleven persons appointed by the Board for a period not exceeding three years as follows:
(a) one representative each from (i) the Council for Scientific and Industrial Research, and (ii) the Atomic Energy Commission,
(b) two persons one of whom is a woman, who are persons knowledgeable in the fields of science applicable to ecology and the development and release of genetically modified organisms,
(c) two persons one of whom is a woman who are knowledgeable in socio-economic matters and genetically modified organisms, and
(d) one representative each from the (i) Ghana Revenue Authority, (ii) Environmental Protection Agency, (iii) Food and Drugs Board,
(iv) Veterinary Services Directorate, and
(v) Plant Protection and Regulatory Services Directorate. [...]

Functions of the committee.

Section 28. (i) The technical advisory committee shall (a) act as the national advisory body on matters concerning or related to genetic modification of organisms, and carry out risk assessment and audit of applications at the request of the Board, and (b) advise, on request or of its own accord, the Minister and through the Board and the Minister advise the Ministries and appropriate bodies, on matters concerning the genetic modification of organisms including
(i) aspects relating to the introduction and development of genetically modified organisms into the environment,
(ii) proposals for specific activities or projects concerning genetic modification of organisms,
(iii) aspects concerning the contained use of genetically modified organisms,
(iv) the importation and exportation of genetically modified organisms, and
(v) proposed Regulations and written guidelines.
(2) The committee shall annually submit a budget to the Board.
(3) The committee may appoint subcommittees to deal with specific matters as required.

The Biosafety Act of Malawi provides for coordination of enforcement, compliance and monitoring efforts among sectoral institutions.

The Biosafety Act of Malawi (2002) provides that the Minister shall, for the purpose of ensuring compliance with the Act, appoint a number of inspectors who are issued a certificate of authority. A person shall not be qualified for appointment as an inspector unless he is competent in biotechnology or biosafety. The Biosafety Regulations (2007)[a] provide that inspectors are appointed by the public institutions represented on the National Biosafety Regulatory Committee, which includes heads of institutions such as the Secretary for Agriculture and Food Security, the Secretary of Health, the Secretary for Industry and Trade, the Director of Forestry and the Secretary for National Parks and Wildlife. The inspectors will work under the general direction and instructions of the Committee. These stipulations aim towards ensuring coordination of enforcement, compliance and monitoring efforts among institutions.

[a] Available at www.fao.org/fileadmin/user_upload/gmfp/docs/Biosafety%20Regulations%20for%20Malawi.pdf (accessed on 28 June 2024).

Example clause: **Biosafety Regulations of Malawi (2007)**

Article 10.
(1) Subject to the provisions of section 30(2) and (3) of the Act, the institutions represented on the Committee shall nominate from their institutions suitably qualified public officers for appointment as inspectors by the Minister in accordance with the section 30 of the Act.
(2) Where the Committee has ascertained or suspects, on reasonable grounds, that genetically modified organisms are being imported or locally produced or used contrary to the provisions of the Act, these Regulations or the conditions of a license or permit issued thereunder, the Committee shall instruct inspectors to -
(a) Require the cessation of any genetic modification activity at the facilities where the provisions of the Act or the conditions of the license or permit have not been or are not being complied with;
(b) ensure that appropriate measures are undertaken by all users at all times with a view to protect human health and the environment from hazards;
(c) serve notice upon any person by whom or on whose behalf genetically modified organisms are being imported into, produced or used in Malawi contrary to the Act or these Regulations, for the removal of such genetically modified organisms, to a place or facility and in a manner prescribed by the Committee, or
(d) destroy such genetically modified organisms or cause them to be destroyed, subject to procedures stipulated in the guidelines issued by the Minister.

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