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**GLOBAL WORKSHOP ON INTEGRATED IMPLEMENTATION OF  
THE CARTAGENA PROTOCOL ON BIOSAFETY AND THE  
CONVENTION ON BIOLOGICAL DIVERSITY**Chisinau, Republic of Moldova, 31 October - 4 November 2016  
Agenda item 6 of the provisional agenda\***SYNTHESIS REPORT OF NATIONAL DESK STUDIES****PRELIMINARY VERSION***Note by the Executive Secretary*

1. In its decision BS-V/16, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety adopted the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020 (Strategic Plan) and urged Parties to review and align with the Strategic Plan, as appropriate, their national action plans and programmes relevant to the implementation of the Protocol, including their national biodiversity strategies and action plans (NBSAPs). In decision BS-VII/5, paragraph 10, the Conference of the Parties serving as the meeting of the Parties to the Protocol further urged Parties and invited other Governments to integrate and prioritize biosafety within their national biodiversity strategies and action plans and national development plans and programmes, as appropriate.
2. Furthermore, in decision BS-VII/9, the Conference of the Parties serving as the meeting of the Parties to the Protocol, recognizing that the work under the Cartagena Protocol had increasingly become separated from the work of the Convention on Biological Diversity resulting in biosafety receiving less attention in implementation and funding, and recognizing also that limitations existed in the current organization of the meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol back-to-back with the meetings of the Conference of the Parties to the Convention, in terms of achieving a meaningful integration of the work of the Cartagena Protocol into the work of the Convention, decided to hold its future ordinary meetings concurrently with the meetings of the Conference of the Parties to the Convention in the same two-week period. In the same decision, the Conference of the Parties serving as the meeting of the Parties to the Protocol also took note of recommendation 5/2 of the Ad Hoc Open-ended Working Group on Review of Implementation of the Convention, regarding integrated approaches to the implementation of the Convention and its Protocols with a view to improving efficiencies.
3. At its twelfth meeting, the Conference of the Parties to the Convention also recognized the need for integrated implementation of the Convention and its Protocols to improve efficiency and effectiveness and adopted a number of decisions in this regard. The Conference of the Parties encouraged Parties to integrate biosafety and access and benefit-sharing into NBSAPs, national development plans and other

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\* UNEP/CBD/BS/MB/WS/2016/2/1

relevant sectoral and cross-sectoral policies, plans and programmes, and to strengthen national coordination mechanisms to facilitate a coordinated approach to the implementation of the Convention and its Protocols (decision XII/29, paras. 9 and 11).

4. Against this background, and with the generous support of the Government of Japan, through the Japan Biodiversity Fund, the Secretariat developed the project entitled “Capacity-building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level”. The project aims at strengthening capacity in pilot countries to develop and test practical actions to promote integrated implementation of the Cartagena Protocol and the Convention. Within the pilot countries, the project seeks to facilitate the integration of biosafety into NBSAPs and other sectoral and cross-sectoral policies, plans and programmes, and to strengthen national intersectoral coordination mechanisms.

5. Following a call for expression of interest and a selection process, nine Parties to the Cartagena Protocol are participating in the project and have carried out a number of national activities. As part of the project activities, each participating country has developed a national desk study that provides an analysis of the extent to which policy and legal instruments as well as institutional frameworks at the national level promote integrated implementation of the Biosafety Protocol and the Convention. The studies also draw lessons from national experiences and identify needs to further improve integrated implementation. On the basis of the desk studies, the Secretariat, in collaboration with the University of Strathclyde, is developing an e-learning module and toolkit on integrated implementation of the Biosafety Protocol and the Convention.

6. In close collaboration with the Republic of Moldova as host, the Secretariat is organizing a global workshop, targeting the project countries, on integrated implementation of the Cartagena Protocol and the Convention at the national level, to be held in Chisinau, Republic of Moldova, from 31 October to 4 November 2016. Resource persons from the Strathclyde Centre for Environmental Law and Governance, University of Strathclyde, Glasgow, United Kingdom of Great Britain and Northern Ireland, are providing support throughout the workshop.

7. The objective of the workshop is to enable focal points of the Cartagena Protocol and Convention, as well as national project coordinators, to present the desk study results and share experiences and lessons learned at the national level. The draft e-learning module on integrated implementation will also be presented at the workshop and participants will be invited to use it and provide input for its finalization. Participants will also provide feedback on the content of the associated draft toolkit. Finally, participants will be developing short national action plans, enriched by the discussions on national lessons learned and recommendations.

8. The University of Strathclyde, in cooperation with the Secretariat, has developed a preliminary version of a synthesis report of the national desk studies (preliminary synthesis report). The preliminary synthesis report provides initial summaries of the national desk studies and provides general observations, an overview of challenges and recommendations made in the different national desk studies. The preliminary synthesis report also includes country-specific questions that have been shared with the countries to obtain further information to be included in the final national desk studies and to facilitate the development by the participating countries of executive summaries of the national desk studies. The final synthesis report will be prepared on the basis of the final national desk studies and executive summaries prepared by the participating countries and will be made available on the Biosafety Clearing-House.

9. The preliminary synthesis report is presented in the annex to the present document.

*Annex*

Synthesis Report of the National Desk Studies  
*preliminary version*

Prepared by

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*In cooperation with the Secretariat of the Convention on Biological Diversity*

With the generous support of the  
Government of Japan through the Japan Biodiversity Fund

## Synthesis Report of the National Desk Studies *preliminary version<sup>2</sup>*

### Introduction

This report provides a synthesis of the desk studies prepared by nine pilot countries, within the framework of the project ‘Capacity-building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level’, regarding the mainstreaming of biosafety into national biodiversity strategies and action plans (NBSAPs) and other sectoral and cross-sectoral laws, policies and institutional frameworks. The project aims to strengthen the capacity of the nine pilot countries to develop and test practical measures to promote integrated implementation of the Cartagena Protocol on Biosafety (CPB) and the Convention on Biological Diversity (CBD). The nine selected pilot countries are: Burkina Faso, Malawi and Uganda (Africa); China and Malaysia (Asia); Ecuador and Mexico (Latin America); and Belarus and Moldova (Europe).

This synthesis report is structured in the following way:

1. Introduction
2. General observations on the national biosafety frameworks of the pilot countries
3. Summaries of the national desk studies **including country-specific follow-up questions.**
4. Common challenges encountered by the pilot countries.
5. Recommendations to further improve the mainstreaming of biosafety.
6. **Request for further information for all pilot countries**

Drawing on the results of the national desk studies prepared by the pilot countries and on additional information provided, the Secretariat of the Convention on Biological Diversity (SCBD), in cooperation with consultants from the University of Strathclyde, Centre for Environmental Law and Governance, will prepare an e-learning module and a toolkit for capacity building on mainstreaming biosafety into NBSAPs and other cross-sectoral and sectoral laws, policies and institutional frameworks.

### General Observations

Seven out of 9 pilot countries report to have biosafety-specific legislation. Such legislation may, among other things, provide for the establishment and mandate of biosafety-specific institutions (e.g. the *National Coordination Biosafety Centre* in Belarus and the *Biosafety Committee of Agricultural GMOs* in China), for authorisation procedures (including risk assessment and management) for the import and export, the intentional introduction into the environment or the

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<sup>2</sup> This report has been prepared by the Strathclyde Centre for Environmental Law and Governance, University of Strathclyde, Glasgow, United Kingdom of Great Britain and Northern Ireland, under a small scale funding agreement concluded with the Secretariat of the Convention on Biological Diversity in the context of project “Capacity-building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level”, with the generous support of the Government of Japan, through the Japan Biodiversity Fund. The final version of the summary report will be prepared on the basis of the additional information requested in the preliminary synthesis report.

contained use of living modified organisms (LMOs) (e.g. *Ley de Bioseguridad de Organismos Genéticamente Modificados* in Mexico), for public participation and liability (e.g. *The Biosafety Act 2002* in Malawi),) and packaging and labelling (e.g. *The National Biosafety Law* in Moldova). The two pilot countries that do not yet have biosafety-specific legislation in place, Ecuador and Uganda, report to be developing draft legislation (the proposed *Law and Regulation on Biosafety* in Ecuador and the draft *National Biotechnology and Biosafety Bill 2012* in Uganda respectively). The desk studies identify efforts by countries to improve their national legal framework for biosafety, putting into place functioning biosafety laws where there are none, improving biosafety laws where they are not considered effective or comprehensive, improving implementation of specific biosafety aspects, such as risk assessment and risk management, and in general engaging in efforts to bring legislation in line with international obligations and notably the Cartagena Protocol. The desk studies seem to suggest that some pilot countries, to varying degrees, are primarily focusing on implementation in general and consider mainstreaming as a second step in the implementation process. Some countries acknowledged that general implementation efforts can contribute to mainstreaming. Of particular interest in this regard is Ecuador's work on the Proposal for a *Law and Regulation on Biosafety*, which, in addition to providing consolidated, biosafety specific regulations, also provides "legal support to the integral managing of GMOs biosafety in the country, with guidelines for analysis under a multi-sectoral and multidisciplinary approach."

The desk studies identify a broad range of relevant laws and policies which could be used for biosafety mainstreaming. Examples of cross-sectoral mainstreaming cover laws and policies in the fields of biodiversity, notably NBSAPs, environmental protection more generally, trade and customs, consumer protection, public awareness and participation, sustainable development, international cooperation, climate change, and general private, administrative and criminal laws (liability, enforcement and penalties). Examples of sectoral mainstreaming include laws and policies in the fields of agriculture, food and land use, health care, forestry, fisheries, energy and mining, academia and research. Although the desk studies identify a large number of laws and policies as potential entry points, only few of these entry points are reported to have been used for mainstreaming biosafety. It appears that mainstreaming practices are still at a fairly modest level and have been particularly focussed on laws and policies in the field of biodiversity and the environment, agriculture and health, with few examples of mainstreaming in other areas.

Examples regarding biosafety mainstreaming into institutional frameworks in particular focussed on the inclusion of government representatives from sectoral and cross-sectoral departments in biosafety-specific institutions (e.g. *Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados* in Mexico and the *National Biosafety Commission* in Ecuador) and, conversely, on the inclusion of biosafety experts in cross-sectoral institutional frameworks (e.g. the *task team* for the revision of Malawi's NBSAP).

It must be noted, however, that many sectoral and cross-sectoral instruments into which biosafety could be mainstreamed pre-date the Cartagena Protocol and the development of national biosafety frameworks. The amendment of these sectoral and cross-sectoral instruments depends on multiple interests and factors.

## Summaries of National Desk Studies and Follow-up Questions

This section provides a summary of the approach and content of the national desk studies, in light of the terms of reference of the project. The summaries of the national desk studies below (in

alphabetical order) do not intend to provide for all-inclusive overviews, but are intended to identify particular areas of focus, list key points and best practices and identify gaps in information provided in light of the terms of reference for the desk studies.

## Belarus

**Overview:** Belarus has provided a comprehensive overview of its biosafety legislation, notably its *Law on Safety in Genetic Engineering Activity* (2006). Aspects of implementation of biosafety regulations discussed by the report, including those falling under the scope of the Cartagena Protocol, cover, among others, the establishment of biosafety institutions and procedures on import, contained use and deliberate release of LMOs. The study touches upon mainstreaming of biosafety considerations into general enforcement laws and laws and standards on consumer protection.

**Key points:** Belarus' study contains a reference to the National Coordination Biosafety Centre, which is tasked with the delivery of information on biosafety issues to the involved Ministries through, among others, a National Biosafety Database. Belarus is, furthermore, the only pilot country which has provided examples of mainstreaming into general legislation on criminal and administrative penalties. Lastly, examples were provided of GMO provisions in labelling standards for consumer protection.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o Article 15.4 of the Administrative Violations Code of the Republic of Belarus
  - o Article 278 of the Criminal (Penal) Code of the Republic of Belarus
  - o Technical Code of Common Practice on Food Products
  - o Technical Regulation TS 022/2011
- **Cross-sectoral institutions (section 0, sub c):**
  - o National Coordination Biosafety Centre
- **Other country-specific questions:**
  - o It seems to follow from your report that rules on GMO labelling are of a voluntary nature, captured in private standards. Why were these instruments chosen for mainstreaming and do you expect further mainstreaming into consumer laws?

**Areas of the terms of references that would benefit from further inputs:** The national desk study would benefit from drawing clearer distinctions between general implementation efforts and challenges and those that are specific for biosafety *mainstreaming* across sectoral and cross-sectoral laws and policies (see relevant fields of law and policy above under 0). If available, it would be useful if additional examples are provided of biosafety mainstreaming into laws, policies and institutional frameworks, in particular the NBSAP, including the processes and practical steps that supported mainstreaming. Furthermore, and particularly if additional examples are not readily available, we would welcome a description of the major challenges/difficulties encountered in mainstreaming biosafety and recommendations to further improve mainstreaming biosafety.

## Burkina Faso

**Overview:** Burkina Faso has provided an extensive overview of laws and policies related to biosafety mainstreaming. Current mainstreaming practices are, however, still limited, while most laws pre-date

the biosafety framework. Burkina Faso has recognised these current gaps and has identified and described in detail the necessary steps that it intends to take to integrate biosafety considerations, including draft provisions and strategies for capacity building and resource mobilisation.

**Key points:** One of Burkina Faso’s particularly interesting examples of biosafety mainstreaming into laws and policies are its legal provision on the obligation of the state to ensure biosafety in the use of GMOs in agriculture, through constant assessment of the impacts of GMOs’ cultivation on ecosystems, soil fertility, and human and animal health, in cooperation with other actors (“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”) in its law on agroforestry; and the references to biosafety in the guidelines for local authorities on the implementation of development policies and plans. In addition, the study’s sections on a plan for integration activities and the development of a national biosafety strategy, and on strategies for capacity building and resource mobilisation provide recommendations for further mainstreaming.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o Article 82 Loi n° 070-2015/CNT portant loi d’orientation agro-sylvo-pastorale, halieutique et faunique au Burkina Faso
  - o Loi N° 055-2004/AN du 21 décembre 2004 portant code général des collectivités territoriales au Burkina Faso
- **Other country-specific questions:**
  - o Could you share any progress in the implementation of the plan for integration activities and the development of a national biosafety strategy, and the strategies for capacity building and resource mobilisation, and, if applicable, any lessons learnt? In particular, your plans describe a stage of assistance for integration (‘assistance à l’intégration’), falling within the responsibility of the National Biosafety Agency (French acronym “ANB”); how is this organised and which tools are used for cooperation?
  - o How do your plans and recommendations to increase public and governmental awareness and enhance capacity aim to contribute to biosafety mainstreaming?

## China

**Overview:** China’s desk study provides an outline of China’s well-developed system of biosafety legislation. Examples of mainstreaming into laws and policies are not distinguished as such, but some references in cross-sectoral and sectoral laws and policies can be found. Of particular interest is China’s experience with cross-sectoral institutions and platforms for cooperation.

**Key points:** China has developed two biosafety-specific legal instruments in the fields of trade and customs, and forestry. Additionally, the study touches upon well-established cross-sectoral institutions, the CBD Implementation Office of China and the coordination group, which are joined by 25 Ministries, for the promotion of the implementation of the Protocol and a mechanism of joint

conference of relevant ministries, which is responsible for coordinating major policy and legal issues on biosafety.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o Regulation on Inspection and Quarantine of Import and Export Genetically Modified Commodities.
  - o Regulation on Biosafety Monitoring of Genetically Modified Forest Trees.
- **Cross-sectoral institutions (section 0, sub c):**
  - o CBD Implementation Office of China and the coordination group
  - o Mechanism of joint conference established by the State Council
- **Other country-specific questions:**
  - o In answering the questions under section 6.1, sub b for the Regulation on Biosafety Monitoring of Genetically Modified Forest Trees, are there any possible links to biodiversity conservation and climate change objectives?

**Areas of the terms of references that would benefit from further inputs:** The national desk study would benefit from drawing clearer distinctions between general implementation efforts and challenges and those that are specific for biosafety *mainstreaming*, across sectoral and cross-sectoral laws and policies (see relevant fields of law and policy above under 0). It would also be helpful to add information on some examples of mainstreaming, in particular on the processes and practical steps taken that supported mainstreaming. It would also be helpful to provide additional examples of biosafety mainstreaming, if any are available.

## Ecuador

**Overview:** Ecuador has presented an extensive analysis of its legal framework, including references to biosafety in cross-sectoral and sectoral laws and policies. The Constitution has declared Ecuador free of transgenic crops and seeds, with the exception of introduction in case of national interest duly substantiated by the Presidency. In absence of a specific biosafety law, mainstreaming across a wide-range of instruments, including those related to environment, consumer protection, sustainable development, agriculture and health, has been the primary method for the regulation of biosafety in Ecuador. Current efforts for the drafting of biosafety-specific legislation and the establishment of biosafety institutions also take a multisectoral and multidisciplinary approach, thus supporting biosafety mainstreaming.

**Key points:** Particularly interesting examples of biosafety mainstreaming into Ecuador's cross-sectoral and sectoral laws and policies include the strategic guidelines under the *National Plan for Living Well* and the *National Biodiversity Strategy 2015-2020*, which set out goals for biosafety (e.g. develop and implement a comprehensive national biosafety system and to raise public and institutional awareness and foster public participation). Cross-references to legal requirements for the use of GMOs, as well as self-standing labelling rules and prohibitions on GMO uses can be found in various laws for consumer protection, agriculture and food production, and health. Furthermore, two policy documents, which include provisions on biosafety, create a framework for exploring



relations between environmental laws, and the creation and revision of environmental standards. The Proposal for a Law and Biosafety Regulation, moreover, promises to “provide legal support to the integral managing of GMOs biosafety in the country, with guidelines for analysis under a multisectoral and multidisciplinary approach”. As to biosafety mainstreaming into institutional frameworks, a cross-sectoral institution, the National Biosafety Commission, is responsible for the coordination and implementation of biosafety laws, whereas a Biosafety Unit with personnel trained on the subject is established under the Ministry of Environment. Lastly, Ecuador has experience with various training programs to enhance biosafety capacity.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o Organic Law for Consumer Protection, Official Gazette S. 116 (2000);
  - o Substitute Health Regulation for Labelling of Processed Foods for Human Consumption, Official Gazette 2nd. S 318 (2014);
  - o The Organic Law on Food Sovereignty, Official Gazette No. 349 (2010);
  - o Bylaw of the Regulation for Agricultural Organic Production;
  - o Official Gazette 384 (2006), Instructional for General Regulations to Promote and Regulate Organic, Official Gazette No. 34 (2013);
  - o Proposed Organic Law for Agrobiodiversity and Seed.
  - o Organic Health Law, Official Gazette Supplement 423 (2006).
  - o Institutional: Biosafety Unit (within the Ministry of the Environment)
- **Cross-sectoral institutions (section 0, sub c):**
  - o National Biosafety Commission
- **Other country-specific questions:**
  - o Could you provide additional information on the National Environmental Policy and the Draft Organic Environmental Code? How do these documents aim to contribute to mainstreaming, and are examples of mainstreaming impacts available? To the extent that impacts are lacking, which factors do you think are accountable for this?
  - o Could you provide details on how the draft Law and Biosafety Regulation and the underlying guidelines aim to support the integral management of biosafety, through a multisectoral and multidisciplinary approach? Which tools does the draft Law seek to employ to further biosafety mainstreaming? Which “different actors of public sector, industry and academic circles, linked to the issue” were involved in the development of the Law and which tools (e.g. communication and cooperation mechanisms) were used to allow for participatory work?
  - o Do you have any empirical evidence of the positive impacts of your training programs, e.g. the Quinquennial Plan the Interagency training agreements to mainstreaming?

## Malawi

**Overview:** Malawi’s national desk report provides an overview of laws and policies relevant to biosafety mainstreaming. The report provides a wealth of relevant examples of instruments that may function as future entry points for mainstreaming, although current practices and examples of mainstreaming in these instruments appear to be limited.

**Key points:** Of particular interest is Malawi's approach to the revision of its NBSAP, which included the National Focal Point for Biosafety in the task team for the revision, as well as the consultation of institutions dealing with issues related to biosafety and the sharing of information on biosafety and needs assessment. Further examples were provided on the integration of biosafety issues into annual budgets and the GEF5. Explicit references to biosafety mainstreaming are included in laws and policies in the fields of the environment, consumer protection, and agriculture. Also, the study identifies various cross-sectoral institutions, notably the *National Biosafety Regulatory Committee* and the *Agricultural Technology Clearing Committee (ATCC)*, which include government representatives from cross-sectoral and sectoral departments, NGOs and private institutions and actors.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o Revised Environment Management Bill;
  - o Consumer Protection Act No. 14 (2003);
  - o The Guidelines for the Release of New Agricultural Technologies (2000).
  - o Annual budget of the government
  - o The Global Environment Facility (GEF) 5
- **Cross-sectoral institutions (section 0, sub c):**
  - o National Biosafety Regulatory Committee
  - o The Agricultural Technology Clearing Committee (ATCC)

**Other country-specific questions:**

- In answering question a) below (section 0), could you provide detailed information on the approach to the revision of the NBSAP 2015-2020, as an example of effective mainstreaming?

## Malaysia

**Overview:** Malaysia's desk study provides a comprehensive overview of its national framework for the implementation of the Cartagena Protocol, and other instruments relevant to biosafety. Of particular interest is Malaysia's wide experience with biosafety training workshops for government institutions. While the country has an advanced legal framework on biosafety implementation, some additional information would be helpful in clarifying to what extent biosafety has been (explicitly) mainstreamed into the listed sectoral and cross-sectoral acts.

**Key points:** Malaysia has pioneered the mainstreaming of biosafety through its National Policies on Biological Diversity, with both the original 1998 document and the revised version for 2016-2025 including objectives on biosafety. Proposed actions include the adoption of an environmental impact assessment (EIA) procedure for biotechnology research and activities, including the assessment on safety and social impacts, and the establishment of an enforcement unit on biosafety. With regard to the latter, an integrated enforcement matrix was developed as an effort to strengthen enforcement across all related agencies (to be complemented by a proposed Integrated Committee on Enforcement and Monitoring of LMO). Under the National Policies on Biological Diversity, a large variety of awareness-raising and capacity-building events and trainings were launched. Also, a large number of relevant regulations in the field of trade and customs, agriculture, fisheries and health are

listed, although it is not always evident to what extent biosafety has been mainstreamed into these instruments. Of particular interest is Malaysia's experience with partnerships with research funders, making it compulsory for funding applicants to notify and obtain approval from biosafety authorities.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o Acts and Regulations related to biosafety listed in Table 2-3, only to the extent that they explicitly mainstreaming biosafety (please specifying the content of the provision).
  - o Integrated enforcement matrix
  - o Partnerships between the Department of Biosafety and public funders of research (Ministries), subjecting funding applicants to biosafety requirements.
- **Cross-sectoral institutions (section 0, sub c):**
  - o Department of Biosafety

**Other country-specific questions:**

- In answering question a) below (section 0), could you specify how the National Policy on Biological Diversity 1998 has contributed to mainstreaming into cross-sectoral and sectoral laws and policies?
- To the extent that the EIA procedure proposed under the National Policy on Biological Diversity 1998 has been put in place, could you provide information on its functioning and your experiences (positive and negative) on the use of this tool?
- Could you share your experiences on the functioning of the integrated enforcement matrix in practice? How will the envisaged Integrated Committee on Enforcement further help with biosafety mainstreaming and which practical steps and processes are planned to set it up?
- Which of your awareness-raising activities (pp 3-10 and 3-12) and training workshops have contributed particularly to mainstreaming (rather than the general implementation of biosafety laws), and how? What were the practical steps and processes taken to develop these activities, which actors and institutions were involved and which impacts can be seen?
- The desk study states: "Agencies charged with the responsibility for biodiversity should play a more prominent role in providing input on risk management to protect native species and protected areas". Do you have an idea how this could be made operational: which practical steps would need to be taken and which institutions would need to be involved?

## Mexico

**Overview:** Mexico has provided detailed information on its biosafety framework. The study provides both examples related to general implementation efforts and examples of mainstreaming. The mainstreaming examples show how the inclusion of biosafety into cross-sectoral and sectoral strategic documents and projects, together with the work of cross-sectoral biosafety institutions, has created a framework through which further mainstreaming efforts (notably into cross-sectoral and sectoral laws) are promoted and organised.

**Key points:** Mexico's mainstreaming efforts have focussed on the mainstreaming of biosafety into national and sectoral plans and strategies, as frameworks for further integration of biosafety into relevant laws and institutional frameworks within those fields. Additionally, projects and programs to

address capacity needs – e.g. to increase expertise on biosafety and foster information exchange – have been implemented in Mexico.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o Plan Nacional de Desarrollo (2013-2018)
  - o Programa Sectorial de Medio Ambiente y Recursos Naturales (2013-2018)
  - o Programa Sectorial de Agropecuario (2013-2018)
  - o Programa Sectorial de Salud (2013–2018)
  - o Iniciativa de SAGARPA para establecer una red de comunicación interinstitucional
- **Cross-sectoral institutions (section 0, sub c):**
  - o Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)
- **Other country-specific questions:**
  - o Could you explain how the projects on the fostering of biosafety research (e.g. FONDO CIBIOGEM, PDBB) aim to contribute to biosafety mainstreaming, by providing examples of specific perceived and/or planned impacts? To the extent that positive contributions to mainstreaming are expected, could you specify the institutions involved in these projects and the practical steps that preceded their launch?
  - o Could you explain how the planned activity aiming to promote public participation processes and consultation processes for indigenous communities ('para promover procesos participativos entre la población y procesos de consultas a comunidades indígenas') aims to contribute mainstreaming? Which processes and institutions are involved?
  - o Do you have examples of impacts on how the initiatives by SAGARPA to establish a network for inter-institutional communication (para establecer una red de comunicación interinstitucional) contributed to mainstreaming?

**Areas of the terms of references that would benefit from further inputs:** The national desk study could benefit from clearer distinctions between general implementation efforts and those particularly directed at biosafety mainstreaming. The study provides clear and detailed information on the extent of biosafety mainstreaming into cross-sectoral and sectoral *strategies*, and it would benefit from examples – if available – on how the integration into these strategies has resulted into further mainstreaming into cross-sectoral and sectoral *laws* (and institutional frameworks), and the practical steps involved.

## Moldova

**Overview:** Moldova's desk study identifies, and provides a detailed analysis of, a broad range of potential entry points for mainstreaming. Currently existing practices and practical examples of how biosafety has been mainstreamed in these instruments appear to be at a modest level. Most examples of mainstreaming relate to the agricultural sector.

**Key points:** Considerable efforts regarding biosafety mainstreaming have been made within laws on agriculture. Examples include cross-references to biosafety laws in agricultural laws, self-standing requirements for the release of GMOs and their use in particular products and labelling. An inter-ministerial authority is, moreover, in charge of the examination and notification of GMOs.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o The Law on Seeds (2013)
  - o The Law on Agro-Food Ecological Production (2005)
  - o The Law on Protection of Plant Varieties (2008)
  - o The Law on Sanitary-Veterinary Activity (2007)
  - o The Law on Food Products (2004)
- **Cross-sectoral institutions (section 0, sub c):**
  - o National Biosafety Committee
- **Other country-specific questions:**
  - o The NBSAP identifies the establishment of ‘biosafety and protected areas’ as a tool for the achievement of its objectives. Has any progress been made on the integration of biosafety into protected areas, and, if so, which institutions were involved, which practical steps were made and what impacts have been made so far?
  - o How do the Regulation on information and public consultations on GMOs, aim to contribute to biosafety mainstreaming (if possible – could you illustrate this with examples)?

## Uganda

**Overview:** Although it follows from Uganda’s desk study that current efforts have focussed on the drafting and implementation of biosafety-specific legislation, the study identifies a broad range of laws and policies that serve as possible entry points for mainstreaming. Moreover, biosafety mainstreaming is already strong on a strategic level, with prominent recognition in the National Vision 2040, NBSAPs and NDPs.

**Key points:** Uganda’s NBSAP II provides evidence of a high level of biosafety mainstreaming. “The review and updating of the NBSAP provided the platform for creating awareness on biotechnology and biosafety. A working group was constituted during the review and updating of NBSAP to collate and synthesize information on the status of biotechnology and biosafety; and based on the information obtained, the working group proposed national targets on biotechnology and biosafety to be included in the NBSAP. [...] Implementation of national targets in NBSAPII is by target champions, [...] government institutions whose mandate directly relates to the national targets.” The NBSAP II identifies various strategies and tools for the achievement of its objectives. These include “EIA 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,” as well as the employment of various tools to increase public and governmental awareness and capacity.

Since the revision of Uganda’s NBSAP, biosafety has also been mainstreamed into Uganda’s National Vision 2040 and the National Development Plan II. It is considered “a mile stone and ... a strong basis

for mainstreaming biosafety into other sectors". Furthermore, biosafety is mainstreamed into environmental laws and policies, which are currently in draft form, and agricultural law.

**Follow-up on key points:** To allow the SCBD to discern lessons from your best practices and processes, we would request additional information regarding the key points identified. Please see below, **section 0, sub b and c**, for guiding questions to help you in preparation of the additional information, on:

- **Laws, policies and institutional frameworks (section 0, sub b):**
  - o National Vision 2040
  - o National Development Plan II
  - o Draft: New National Environment Management Policy
  - o Draft: National Environment Bill
  - o The Plant Protection Act and Plant Variety Protection Act 2014
  
- **Other country-specific questions:**
  - o Can you specify how 'EIA or risk assessments on biotechnology policies, programmes or projects', and tools for awareness and capacity development under the NBSAP II aim to contribute to biosafety mainstreaming? To the extent that these mechanisms are operational, could you provide evidence of positive mainstreaming impacts ?
  - o The NBSAP II identifies the establishment of 'a national repository for plant and animal genetic resources' as one of its strategies on biosafety. Is this repository already operational and if so, does it include GM varieties and breeds? If so, are any biosafety considerations taken into account before their inclusion? Is the process of inclusion into the repository linked to an EIA or risk assessment of biotech projects?
  - o How is the NDP II used as a basis for mainstreaming into other sectors?
  - o The desk study suggests that integrating biosafety in the NDPII makes it possible to justify budgetary allocation for biosafety". Have budget allocations been made for biosafety (mainstreaming)? If so, how? And who was involved?

## Major Challenges

The studies identify a range of challenges that countries have encountered in biosafety mainstreaming, which may be divided into challenges of a legal or institutional nature and capacity-related issues.

With regard to legal and institutional challenges, the **absence of an overarching legal framework** of biosafety- specific legislation or **shortcomings in the implementation** of existing biosafety legislation were identified by many desk studies as a major challenge. This has led to some extent to diverting attention from (further) mainstreaming of biosafety into cross-sectoral and sectoral laws, policies and institutional frameworks, as the primary concern is the development of such overarching (legal) frameworks. Also, and sometimes even when biosafety- specific legislation is in place, pilot countries reported that they were **lacking an overall national biosafety vision** to guide national action in an integrated manner and to increase political awareness among cross-sectoral and sectoral institutions.

Additionally, challenges within the institutional framework were identified regarding the **absence of formal frameworks and effective mechanisms to enhance cooperation, communication and the exchange of information** between relevant authorities – including biosafety and cross-sectoral and sectoral authorities. As a consequence, a **lack of coordination** in the development and

implementation of different legal and policy instruments relevant to mainstreaming was sometimes observed.

In terms of issues related to capacity needs, the desk studies showed that **financial limitations** inhibit effective mainstreaming of biosafety. Reference was made in this regard to a lack of funding made available to develop and implement mainstreaming strategies and to train and engage experts. In relation to the latter, issues with regard to **a lack of human capacities and expertise** were observed. Other challenges that were mentioned in the studies are lack of **awareness and expertise** amongst government staff in relevant departments. The pilot countries did, however, not always differentiate between capacities needed to improve the general implementation of biosafety legislation and specific capacities needed to foster mainstreaming. Countries report that it is of particular importance to increase awareness among sectoral institutions regarding the contribution of biosafety to the conservation of biological diversity and sustainable development and to build capacity on specific methods and techniques for mainstreaming, are particularly relevant. It was recognized that there is a **lack of capacity-building activities** in this regard, **and effective training materials** translated into local languages, as well as having relevant laws translated into local languages.

Lastly, some pilot countries observed **a lack of mechanisms for public participation and awareness**. To the extent that such mechanisms are considered as tools to enhance awareness and political will among cross-sectoral and sectoral decision-makers, their absence constrains biosafety mainstreaming.

## Recommendations

The pilot countries have made several recommendations to further biosafety mainstreaming and to address the major legal and institutional challenges and capacity needs identified above. To a large extent the recommendations identify current gaps (above 0), and, in broad terms suggest ways to address them.

Possible suggestions to improve biosafety mainstreaming include:

- Development of an action plan/strategy/framework on mainstreaming of biosafety into cross-sectoral/sectoral laws, policies and institutional frameworks, where one is lacking.
- Identification of 'opportunities' for mainstreaming, such as scheduled revision and amendments of entry points (laws/policies/institutional frameworks) for biosafety mainstreaming and actors ('champions') which could promote mainstreaming.
- Participation of biosafety departments into cross-sectoral and sectoral national committees and, vice versa, extend sectoral representation in biosafety departments.
- Development of mechanisms for coordination of activities and projects across national authorities (on biosafety, and within sectoral and cross-sectoral departments).
- Development of mechanisms for consultation and cooperation between authorities (on biosafety, and within sectoral and cross-sectoral departments).
- Organisation of consultations on the revision of biosafety laws, including with other sectors and government departments, to raise awareness among different institutions.

- Identification of an authority responsible for the provision of mainstreaming assistance.
- Organization of trainings and capacity-building activities for sectoral specialists and sectoral and cross-sectoral decision-makers, on mainstreaming and relevant tools.
- Development of a mechanism to encourage the sharing of information and experiences.

## Request for Information: Practical Steps and Lessons Learnt

Countries have provided a lot of information in their national desk studies. This includes overviews of national biosafety-related legal, policy and institutional frameworks, evidence of mainstreaming across cross-sectoral and sectoral laws, policies and institutional frameworks (e.g. reference to biosafety in sectoral legislation as the 'end result' of national mainstreaming processes), the identification of major challenges and national capacity needs and recommendations to address some of these challenges and needs.

In order to learn from these experiences and draw lessons for future application, it would be important to obtain more information on the processes followed and steps taken that led to the successful mainstreaming of biosafety.

Additional information would therefore be helpful, in order to identify the practical steps and processes that supported the mainstreaming of biosafety to the extent that evidence of that has been provided. Identification of such practical steps and processes, as well as the lessons learnt during the process of biosafety mainstreaming (the 'dos and don'ts'), allows others to learn from your experiences and for the replication of step-by-step best practices to further biosafety mainstreaming in your country.

The questions below aim to help you in providing information and empirical evidence on practical steps and processes. In answering these questions, please take into consideration the challenges that have been identified in the studies, as well as recommendations made for further mainstreaming action, to see how your experiences - including best practices and lessons learnt - may be helpful to others.

### General Follow-Up Questions

In conjunction with the country-specific questions above (under 'follow up on key points' from your national desk studies), these general follow-up questions aim to assist you in the finalisation of your national desk studies, the drafting of an executive summary and the preparation for the workshops.

- a) For your **National Biodiversity Strategy and Action Plan**, to the extent that it provides for mainstreaming;  
And,
- b) **For each of the key examples of mainstreaming of biosafety** into cross-sectoral and sectoral laws, policies and institutional frameworks identified in your national desk studies (see above under 0), and for additional examples that were not (yet) included in the study, **describe:**
  - In general terms, the process that led to the mainstreaming of biosafety in the particular instrument/institution and the administrative actions taken.
  - What political support was available and how was that support generated?
  - Was there an 'opportunity' that contributed to the creation of space to mainstream (e.g. scheduled review of laws/policies, ongoing amendment processes etc.)?



- Which competent authorities were involved in the mainstreaming process and what was their role?
  - Which resources contributed to the mainstreaming process and how were these resources generated?
  - Did public participation and awareness raising play a role in this process?
  - What do you believe to be the determining factor(s) for successful mainstreaming in this instance (consider timing, institutions and people involved, stakeholder and public involvement, available resources)? Which lessons can be learned?
- b) For each of the **cross-sectoral institutions** identified in your national desk study (see above under 0), and for additional examples that were not (yet) identified, **describe**:
- Briefly, the members (notably sectoral representatives) and institutional mandates
  - Available mechanisms to foster inter-departmental communication and cooperation
  - Examples of how the work of the institutions contributed to biosafety mainstreaming
- c) Please provide examples of **resource efficiencies** gained by biosafety mainstreaming, describing the instruments and/or institutions involved and the nature and scale of the gains.
- d) What is the **key lesson** about biosafety mainstreaming your country wishes to share with other countries?