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# Synthesis Report – National Desk Studies

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Capacity-building to promote integrated implementation of the  
Cartagena Protocol on Biosafety and the Convention on Biological  
Diversity at the national level.

The Strathclyde Centre for Environmental Law and Governance,  
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## 2 Introduction

This report provides a synthesis of the desk studies prepared by nine pilot countries (Belarus, Burkina Faso, China, Ecuador, Malaysia, Malawi, Mexico, Republic of Moldova, Uganda) 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’. The project aims to strengthen the capacity of the nine pilot countries to develop and test practical measures to promote the integrated implementation of the Cartagena Protocol on Biosafety (CPB) and the Convention on Biological Diversity (CBD) and to mainstream biosafety into national biodiversity strategies and action plans (NBSAPs) and other sectoral and cross-sectoral legislation, policies and institutional frameworks. In their national desk study, each pilot country provides an overview of the national legal, policy and institutional framework relevant to biosafety and an analysis of the extent to which these frameworks address biosafety. The desk studies also provide an analysis of lessons learnt, remaining gaps, as well as recommendations to improve the mainstreaming of biosafety in existing frameworks. The project was implemented from February to December 2016 with the financial support of the Government of Japan, through the Japan Biodiversity Fund.<sup>1</sup>

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 key examples, good practices and lessons learnt on biosafety mainstreaming.**
4. Common challenges encountered by the pilot countries.
5. Recommendations to further improve the mainstreaming of biosafety.
6. Conclusions

This synthesis report provides a short description of each of the desk studies, focusing on good practices and key examples provided, lessons learnt and conclusions. In section 4, a general description of the main challenges to biosafety mainstreaming is presented. Section 5 provides a final overview of the main recommendations and lessons learnt from the different desk studies. The summary descriptions have been prepared by the University of Strathclyde, Centre for Environmental Law and Governance,<sup>2</sup> and were further elaborated and completed by the pilot countries.

Drawing on the results of the national desk studies and on additional information provided, the Secretariat of the Convention on Biological Diversity (SCBD), in cooperation with the University of Strathclyde, Centre for Environmental Law and Governance, is preparing an e-learning module and a toolkit for capacity building on mainstreaming biosafety into NBSAPs and other cross-sectoral and sectoral legislation, policies and institutional frameworks. The e-learning module and toolkit are expected to be made available in the spring of 2017 on the CBD e-learning platform.<sup>3</sup>

## 3 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

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<sup>1</sup> For the purpose of this synthesis report, additional information was obtained from pilot countries during a global workshop organized in the context of the project and in follow-up exchanges, where necessary.

<sup>2</sup> <http://www.strath.ac.uk/research/strathclydecentreenvironmentallawgovernance/>.

<sup>3</sup> <https://scbd.unssc.org/>.

(e.g. the *National Coordination Biosafety Centre* in Belarus and the *Biosafety Committee of Agricultural LMOs* in China); authorization procedures (including risk assessment and management) for the import and export, the intentional introduction into the environment or the contained use of living modified organisms (LMOs) (e.g. *Ley de Bioseguridad de Organismos Genéticamente Modificados* in Mexico); 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 in place functioning biosafety legislation where there is none, improving biosafety legislation in cases it is not considered effective or comprehensive, and improving implementation of specific aspects, such as risk assessment and risk management. In general, they indicate to be 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 of the Cartagena Protocol on Biosafety in general and consider mainstreaming as a second step in the implementation process. Some countries acknowledge 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 LMOs biosafety in the country, with guidelines for analysis under a multi-sectoral and multidisciplinary approach."

The desk studies identify a broad range of relevant legislation and policies which could be used for biosafety mainstreaming. Examples of cross-sectoral mainstreaming cover legislation 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 civil, administrative and criminal law (liability, enforcement and penalties). Examples of sectoral mainstreaming include legislation and policies in the fields of agriculture, food, land use, health care, forestry, fisheries, energy and mining, academia and research. Although the desk studies identify a large number of potential legal, policy and institutional instruments that could be used to mainstream biosafety (entry points), only few of these are reported to have successfully been used for mainstreaming biosafety. It appears that mainstreaming practices are still at a modest level and have been particularly focused on legislation 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 focused 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 of relevance mentioned in the desk studies 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.

## 4 Summary of National Desk Studies and Key Examples

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) are not intended to provide an all-inclusive overview, but are meant to identify particular areas of focus, key examples, best practices and lessons learnt.

### 4.1 Belarus

#### A. Introduction

Belarus has provided a comprehensive overview of its biosafety legislation, notably its Law on Safety in Genetic Engineering Activity (2006), which was jointly developed and implemented by the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food, the National Co-ordination Biosafety Centre, the National Centre of Legislation and Legal Research and subordinated authorities to the relevant ministries. Aspects of implementation of biosafety regulations discussed in 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, public awareness and participation, and information exchange through the Biosafety Clearing House.

#### B. Key examples and good practices on biosafety mainstreaming

##### ***Cross-Sectoral and Sectoral Entry Points***

Belarus has taken a cooperative and consultative approach to the development and implementation of its regulatory framework on LMOs that seeks to implement the Cartagena Protocol. This has allowed for extensive mainstreaming into cross-sectoral and sectoral legislation and policies, as the responsible ministries identified mainstreaming as a prerequisite to secure implementation.

Examples can be found across the board, and include sectoral laws and policies: the Law On Cooperation of the Republic of Belarus and International Organizations (2002 – International Cooperation) which provides for a liaison with the SCBD, the Law on some issues of provision of information to consumers on food raw material and food products (2005 – Consumer Protection), with provisions on LMO labelling, the Resolution on some Issues related to Sanitary and Epidemiological Welfare of Population (2006 – Health), with a list of products which are potentially dangerous to life and health, including LMOs, as well as some provisions of the Administrative Violation Code of the Republic of Belarus (2003 – Administrative Law) and the Criminal Code of the Republic of Belarus (1999 – Criminal Law) which provide for specific sanctions for violations of legislation on LMOs.

##### ***National Coordination Biosafety Centre: Scientific Information and Advice***

The National Coordination Biosafety Centre (NCBC) was established in 1998 under the aegis of the Institute of Genetics and Cytology of the National Academy of Sciences (NAS) of Belarus, which is the Supreme State Scientific Institution and the body for the coordination of all subjects involved in scientific research. The NCBC is the lead independent scientific institution of the country in the field of fundamental and applied research on transgenic organisms. It collects, analyzes and systematizes information on biosafety legislation and scientific investigations of biosafety issues, including field tests. Additionally, it often initiates meetings related to LMO issues, and training workshops and seminars for groups engaged in biosafety-related activity, such as LMO developers, biosafety experts,

staff members of the LMO Detection Laboratories and public associations, as well as the representatives of all relevant national government institutions.

Furthermore, according to the Resolution of the Council of Ministers № 963, 1998, the NCBC provides advice to ministries and other governmental bodies on draft legislation related to import and export and safe use of genetically engineered organisms and products, manuals for risk assessment and prevention, safety instructions for genetic engineering laboratories, as well as on bilateral, regional and international agreements.

#### ***Inter-agency Expert Council: Cross-Sectoral Decision-Making Body***

The Inter-Agency Expert Council is the Expert Board on Biosafety decides upon the admissibility of LMOs for release into the environment. Although the Agency falls under the Ministry of Natural Resources and Environmental Protection, it also includes representatives from the Ministry of Agriculture and Food, different scientific institutions (e.g. the Republican Research Unitary Enterprise “Belarusian Research Centre “Ecology” of the Ministry of Natural Resources and Environmental Protection, the Institute of Genetics and Cytology, the Institute of Forest, the Institute of Microbiology, the Institute of Experimental Botany at the Academy of Sciences of Belarus, the Scientific and Practical Centre of Hygiene and the Republican Research and Practical Centre for Epidemiology and Microbiology of the Ministry of Health and other scientific institutes), the NCBC and the State Institute of Metrology. The Council uses the knowledge and experience from all these institutions to decide on applications and risk assessment and management, including the use of monitoring methods.

#### ***Tools for Mainstreaming: Databases, Border Control Standards, Guidelines, Pest Management and Research Funding***

Various tools for mainstreaming – legal or non-legal instruments that can complement or anticipate mainstreaming into entry points – were mentioned in Belarus’ report and during the workshops.

One of the tasks of the National Coordination Biosafety Centre was the development of an electronic and automated National Information Databank, as an integral part of the National Biosafety Database, which is now available at: <[biosafety.org.by](http://biosafety.org.by)>. The databank contains information on risk assessments and field trials, descriptions of varieties, a collection of laws and by-laws and educational materials.

By resolution of the State Customs Committee, a procedure for the submission of data, including a form, was developed for the intended import and export of LMOs. Laboratories for LMO detection are located in border regions and border control officers recognize their role as gatekeepers.

A set of voluntary standards for food safety and certification were developed within the context of the Eurasian Economic Union: The Technical Code of Practice on Food Products. Labelling Rules for Marking by the Label "Natural Product" (2008), and the Technical Regulations on Food Safety (2011) and the Technical Regulation on Food Products in Terms of their Labelling (2011). The standards aim to ensure uniformity across the customs union and are also used to implement legislative requirements regarding, for example, mandatory labelling of LMOs.

Similarly, international and national methodological guidelines for LMO risk assessment and standards for qualitative and quantitative detection help the implementation of the legal framework. The guidelines and standards are used by the 18 accredited laboratories that operate under the Ministry of Health, the Ministry of Agriculture and Food and the National Academy of Sciences.

Additionally, Belarus' Law on Quarantine and Plant Protection (2016), which imposes protection and quarantine measures for all plants for pest management, could be used for control of LMOs.

Biosafety considerations have also been included in research programs. The State Program 'Innovative Biotechnologies' 2010-2012, extended up to 2015, for example, included a sub-program on agricultural biotechnology, with a view to fostering biosafety research and in particular risk assessments. However, funding is distributed on a competitive basis and is not only targeted to risk assessments and biosafety, and the low number of research projects funded is considered a critical issue.

#### ***Public Awareness: Media Dissemination***

The NCBC uses media like radio and television to communicate on biosafety on a regular basis. It also publishes in journals, including its own journal 'Science and Innovations,' explaining matters regarding, for example, release of LMOs into the environment, public participation in accordance with national legislation, relevant organizations and access to information.

#### ***Education: Conference on Education, Courses and Training Activities***

An International Conference on 'Experience Sharing in Public Education and Awareness of Biosafety Issues' was held in 2013, with the political support of the Deputy Minister of Natural Resources and Environmental Protection, the Director of the Institute of Genetics and Cytology of the National Academy of Sciences and the representative of the Secretariat of the Aarhus Convention.

The conference was a great opportunity for representatives of State bodies, non-governmental organizations and scientists to share experiences on biosafety-related issues, including public involvement. Belarusian practices that were highlighted included, for example, the organization of special courses upon request on GMO safety by NCBC, for primary, secondary, and tertiary education pupils, as well as graduate and postgraduate students, crop breeders, developers etc. For students at the Belarusian State University, a training course is organized by NCBC as part of the course on Microbiology. A special course on 'Genomics and Biotechnology' is organized at the Institute for of Scientific Personnel Training of the National Academy of Sciences, with a specific lecture on 'Genetically Modified Organisms and Biosafety'. All courses are organized in collaboration with the Aarhus Centre.

### **C. Key Lesson Learnt and Conclusion**

The National Co-ordination Biosafety Centre, as an independent scientific institute, has proven to be an important instrument to promote implementation of the Cartagena Protocol, and has enabled mainstreaming efforts of government agencies, the scientific community and non-governmental organizations, as well as access to information on LMOs for citizens.

Furthermore, Belarus' mapping exercise and the organized roundtable, helped identify some priority entry points for further mainstreaming. These include, in particular, the Strategy for conservation and sustainable use of biological diversity for 2011-2020 and the Strategy for scientific and technological and innovation activity in the area of environmental protection and efficient use of natural resources for 2014-2015 and for the period up to 2025. Belarus identified how biosafety could be included into these documents, to further mainstreaming into related legislative fields.

## 4.2 Burkina Faso

### A. Introduction

Burkina Faso has provided an extensive overview of legislation and policies related to biosafety mainstreaming, notably the 'Loi portant régime de sécurité en matière de biotechnologie' (2012) and the 'Décret portant règles nationales en matière de sécurité en biotechnologie' (2004). Mainstreaming practices are, however, still limited, and this is attributed to the fact that most other relevant legislation pre-dates the biosafety framework. Burkina Faso has recognized this gap and has identified and described in detail the necessary steps that it intends to take to integrate biosafety considerations into relevant legislation, including draft provisions and strategies for capacity building and resource mobilization.

### B. Key Examples and Good Practices

#### ***Generating Political Support and Recognizing Opportunities for Mainstreaming***

In the 1990s Burkina Faso, as the region's largest producer of cotton, saw production threatened by droughts and pests. A solution was offered by a foreign producer of GM cotton, resistant to the most common pest, the bollworm. A trusted public-private partnership was created with Burkina Faso's agricultural research institute: the Institute of Environment and Agricultural Research. Openness was, furthermore, given from the very beginning as to the potential environmental risks involved. This allowed the Ministry of Research and Innovation, now in charge of biosafety, to put biosafety considerations on the agenda against the backdrop of the proposed production of BT cotton - which was commercially released in 2008 - and to communicate the significance of biosafety within the context of broader conservation and sustainable development discussions.

#### ***Selecting Entry Points: Agro-Forestry and the Guidelines for Local Authorities***

Two examples of mainstreaming, adopted after the biosafety regime was developed, were provided in the desk study: the law on agro-forestry (loi d'orientation agro-sylvo-pastorale, halieutique et faunique) and the general code for local authorities (code général des collectivités territoriales). Burkina Faso's agro-forestry law provides for a legal State obligation, in cooperation with other actors, to ensure biosafety in the use of LMOs in agriculture, through constant assessment of their impacts on ecosystems, soil fertility, and human and animal health. The general code for local authorities sets out the main framework for decentralization, including the powers and authorities involved. The code provides local authorities with competences in the area of economic development and planning, and the responsibilities to implement them in line with broad guidance from the central government. Such competences include general biosafety-related considerations, linking them to regional spatial planning, the management of natural resources and economic development, although it is believed that the responsibilities of local authorities could have been set out more clearly and firmly.

Both pieces of legislation were developed by the respective ministries of Agriculture and Territorial Administration. Taking the example of the agro-forestry legislation, it was recognized from the very beginning that biosafety is a subject that had to be approached in an integrated manner, involving actors in the agriculture, forestry and animal resources sectors. The negotiations provided an avenue for the involvement of different actors in the law-making process and thus a forum for the Ministry of Research and Innovation in its capacity as the national biosafety agency to convince all stakeholders of the relevance of biosafety. Aiming for a cross-sectoral, legal instrument was, moreover, recognized as preferable in order to allow for continuous and maximum impacts, due to the binding and lasting nature of legislation (over policies) and the fact that further implementation

would be necessary within the respective sectors (trickling-down effect). Indeed, a strategy paper and action plan are currently being developed to allow for efficient and effective implementation.

***Tools: Regional Networks and Projects (within NEPAD and WAEMU) for Capacity Building***

The African Biosafety Network of Expertise (ABNE), falling under the New Partnership for Africa's Development (NEPAD), is a biosafety resource network for African regulators and policy makers. The overall goal of ABNE is to enhance the capacity of African countries to build functional biosafety regulatory systems. ABNE is a continent-wide service network that has buy-in from African governments and that fulfils the recommendation of the High-Level African Panel on Modern Biotechnology. ABNE's biosafety capacity building services target National Biosafety Committees (NBCs), Institutional Biosafety Committees (IBCs), Plant Quarantine Officers (PQs), and policy makers. Science-based biosafety information is shared with these groups, and with farmers and the media. The network draws on available expertise, resources and infrastructure, and develops capacity and linkages with institutions within Africa and globally.

Other capacity building initiatives were developed within the context of the West African Economic and Monetary Union (WAEMU).<sup>4</sup> From 2007 to 2013, the West Africa Regional Biosafety Project, mainly funded through GEF and WAEMU, was run. The project comprises the following components: adoption and dissemination of regional methodologies to assess and manage risks, the establishment of a national reference laboratory with a regional dimension for biosafety in Burkina Faso, the development and implementation of a regional biosafety framework and the adoption of capacity building activities. The biosafety laboratory was established in Burkina Faso with a loan from the World Bank. Eight additional laboratories were set up with funds from WAEMU, creating a network led by the national laboratory of Burkina Faso. Furthermore, consultations are currently ongoing to extend the biosafety framework to 17 countries by mid-2017.

***Cross-Sectoral Monitoring Body: National Observatory on Biosecurity***

The National Observatory on Biosafety (Observatoire National de Biosécurité) ensures the implementation of monitoring and surveillance systems linked to the use of GMOs in terms of their health, nutritional, agricultural, ethical, socio-economic and environmental risks. It alerts and advises the National Biosafety Agency (l'Agence nationale de biosécurité) on such risks. Additionally, the Observatory provides for public awareness raising, information and education activities.

The Observatory has 33 members, ensuring a cross-sectoral membership. 20 are ministry representatives, coming from the Prime Minister office, and the Ministry of Scientific Research, Higher Education, Health, Agriculture, Water, Animal Resources, Justice, Territorial Administration, Culture, Defense, Finance, Trade, Human Rights, Advancement of Women and Gender, Communication, the Economic and Social Council, and the National Biosafety Agency. 12 representatives come from civil society: consumer organizations, environmental NGOs, biotechnology, agricultural, health and livestock associations, traditional and customary chieftainship, human rights associations, economic operators, religious denominations, and communication associations.

The Observatory has a permanent secretariat in the Ministry of Research and Innovation.

**C. Key Lesson Learnt and Conclusion**

Burkina Faso has found that the successful regulation of biosafety and the taking of first mainstreaming steps was the result of circumstances promoting adoption of modern biotechnology

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<sup>4</sup> WAEMU members are: Benin, Burkina Faso, Cote d'Ivoire, Guinea-Bissau, Mali, Niger, Senegal and Togo.

in the country, combined with the existence of a functional institutional framework and the allocation of sufficient resources.

Mainstreaming efforts are still ongoing. The activities under this project highlighted the need for development of a national biosafety strategy to guide further action. Steps are taken to move biosafety and biosafety mainstreaming up on the agenda of the Ministry of Finance and at WAEMU/ECOWAS level, and to mobilize more resources from existing GEF and other international funds. A 'Green economy' vision of the new government is also recognized and seized as an opportunity to integrate biosafety in sustainable development agendas. However, Burkina Faso recognizes that mainstreaming efforts are only a first step and that operational guidelines and commitments to implementation are needed to make integration efforts a success.

## 4.3 China

### A. Introduction

China's desk study provides an outline of China's well-developed system of biosafety legislation, including the Regulations on Administration of Agricultural Genetically Modified Organisms Safety and the Regulation on Inspection and Quarantine of Import and Export of Genetically Modified Products. Examples of mainstreaming into legislation and policies are not distinguished as such, but some references in cross-sectoral and sectoral legislation and policies can be found. With biosafety aspects being included in the National Biodiversity Conservation Strategy and Action Plan (2011-2030) and the Plan for Major Programme of Biological Diversity Conservation (2014-2020), it is expected that mainstreaming of biosafety will be taken to the next level. Of particular interest is, furthermore, China's experience with cross-sectoral institutions and platforms for cooperation.

### B. Key Examples and Good Practices

#### ***An Overarching Framework: NBSAP and the Major Programme of Biological Diversity Conservation***

Reviewed and adopted by a State Council executive meeting, China's National Biodiversity Conservation Strategy and Action Plan (2011-2030) was issued by the Ministry of Environmental Protection. The document identifies LMO management as a priority area of work and lists the following strategic tasks related to LMOs: advancing research on environmental release, risk assessment and environmental impact assessment of LMOs, and improving related technical standards and regulations. The NBSAP's Implementation Plan for a Major Programme of Biological Diversity Conservation (2014-2020) was approved by the National Committee of Biodiversity Conservation (NCBC) with the allocation of 70 million USD. Its implementation involves 100 institutions, including ministries, universities, research institutes, local governments and local communities. Mainstreaming biosafety was included in the capacity building part.

Additionally, and supported by the NCBC, local governments issued their own biodiversity conservation strategies, which include LMOs management. For example, in Shandong Province, LMO safety assessment and development of LMO inspection methods and monitoring techniques are priority actions. Four priority projects have been set up, which consider research and development techniques, standards, equipment for LMOs sampling, detecting and tracing, monitoring and risk management techniques for environmental release, commercialization, import and export, precaution measures and safe treatment of LMOs. As part of these projects, pilot studies address evaluation, detection and monitoring methods of LMOs, and establishment of detecting and tracing systems on transgenic aquatic organisms and feed in the provincial context. 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 LMO safety assessment, inspection and monitoring systems. Fujian Province plans to set up and improve a technical system for LMO inspection and monitoring. Hubei Province has planned to put in place an inspection system for the entry and exit of LMOs, and build up its capacity in early warning, emergency response and monitoring. Heilongjiang Province has decided to set up a system and platform for LMO safety assessment, inspection and monitoring techniques.

***Entry Points: Trade and Customs and Forestry***

China's study provides two examples of mainstreaming into trade and customs, and forestry legislation, respectively. In 2004, the General Administration of Quality Supervision, Inspection and Quarantine of China issued the Regulation on Inspection and Quarantine of Import and Export Genetically Modified Products. The regulation seeks to enhance administration on import and export genetically modified products, protect human health and the safety of animals, plants and microorganisms, and conserve the ecological environment, and cross-references already existing laws on customs and quarantine. The regulation covers the whole country, but it is implemented by provincial inspection and quarantine institutions, which are mainly funded through national budgets.

In December 2013, the State Forestry Administration issued the Regulation on Biosafety Monitoring of Genetically Modified Forest Trees, which is valid until the 31<sup>st</sup> of January 2019. The Regulation covers forest plants in which the genome composition was changed by genetic engineering techniques, and for the purposes of forestry production and processing. The regulation provides for mandatory, standardized and science-based investigation, inspection, analysis of monitoring of environmental and health risks associated with the contained use, environmental release and production and commercialization of LMOs. These activities are carried out by the State Forestry Administration and those eligible institutions appointed by the Administration.

***High-Level Platform for Cooperation: The National Committee for Biodiversity***

Established in June 2011, the National Committee for Biodiversity Conservation is the highest body for the coordination of biodiversity management, including biosafety management in China. It is composed of representatives from 25 ministries and institutions: the Propaganda Department of the Central Committee of the Communist Party of China, the Ministry of Foreign Affairs, the State Development and Reform Commission, the Ministry of Education, the Ministry of Science and Technology, the Ministry of Public Security, the Ministry of Finance, the Ministry of Land Resources, the Ministry of Environmental Protection, the Ministry of Housing and Urban-Rural Development, the Ministry of Water Resources, the Ministry of Agriculture, the Ministry of Commerce, State Administration of Customs, State Administration for Industry and Commerce, the General Administration of Quality Supervision, Inspection and Quarantine, the State Administration of Press, Publication, Radio, Film and Television, the State Forestry Administration, the State Intellectual Property Office, the Xinhua News Agency, the Chinese Academy of Sciences, the State Oceanic Administration, the State Administration of Traditional Chinese Medicine and two newspapers, the People's Daily and GUANGMING Daily.

Its responsibilities include coordinating biodiversity conservation actions at national level, assisting in the compilation of biodiversity conservation plans and carrying out conservation and management work, and implementing the CBD, other relevant conventions and the NBSAP (2011-2030). The highest decision-making mechanism is the National Committee plenary, which has been held twice as of February 2017.

### ***Inter-institutional Coordination Body: Joint Conference and Coordinating Group***

Another high-level mechanism for cooperation on biosafety is the joint conference established by the State Council. The mechanism includes all ministries responsible for studying and coordinating major policy and legal issues concerning biosafety management of agricultural LMOs: agriculture, technology, environmental protection, health, quality inspection and food and drugs. China has established a regulatory system comprising a State Council regulation and five department-level regulations, covering risk assessment, product licensing, business licensing, product labelling and import/export approval.

The conference complements the work done by the Ministry of Environmental Protection, and notably the Coordinating Group on Biological Diversity, which manages and coordinates efforts to implement the CBD and the Cartagena Protocol. Its members come from 25 ministries and institutions, including the Chinese Academy of Sciences, and two newspapers, the People's Daily and the GUANGMING Daily.

### ***Expert Body: Biosafety Committee of Agricultural GMOs***

The Biosafety Committee is composed of 75 academics and experts in fields such as research and development of LMOs, production, processing, inspection and quarantine, health and environmental protection, from research institutes and universities. It is in charge of the risk assessment of both domestically developed and imported LMOs. The risk assessment covers different evaluation stages, including environment release, productive test and safety certification. The conclusions of the risk assessment are used as a basis of decision making and reported to the Ministry of Agriculture. The Biosafety Committee of Agricultural GMOs meets three times a year to conduct risk assessment on LMOs applications.

### ***Tools: Research Funding***

In 2008, the State Council approved the Science and Technology Major Project for Breeding New Varieties of LMOs. The project aims to foster research in three areas: development of LMO varieties for agriculture purpose, biosafety management (risk assessment, detection and monitoring) and commercialization. 10% of funds are allocated every five years, through the central government budget, for the development of biosafety technologies. This ensures that researchers who are interested in biosafety technology developments have a stable financial support to continue their studies.

### ***Awareness Raising: Workshops and Media Outreach***

In April 2012, the Minister of Agriculture Department of Science and Education organized a national training workshop for journalists on biosafety management of GMOs, in collaboration with China Society of Science Editors and Journalists of Evening Newspapers, China Journal of Health Standard and Management, Shanghai Municipal Society of Science Communication and Beijing Association of Science Journalists and Editors. Nearly one hundred editors and journalists from major national media attended this training workshop.

Additionally, the agrogene network ([www.agrogene.cn](http://www.agrogene.cn)), established in June 2013, communicates information related to agricultural biotechnology development, reports in a timely manner events related to GM technologies and disseminates knowledge related to GMOs, through on-site reporting, internet advertising, social media interaction and organizing off-line activities. Technical support and website content for this network are provided by China Society of Biological Engineering, China Plant

Protection Society, China Crops Society, China Plant Physiology and Molecular Biology Society, Beijing Zhongguancun Alliance of Agricultural Biotechnological Industries and Capital Alliance of Seed Industry Service and Innovation. Similarly, S & T Channel ([www.people.com.cn](http://www.people.com.cn)) organized in 2013 four panel discussions on GMO-related sciences. Scientists undertaking GMO research and experts of biosafety management were invited to answer questions focusing on four topics, including GMO science and safety, GM food safety, GMOs in foreign countries and whether GMOs disturb ecological balance.

#### ***Capacity Building: Training Workshops on State and Provincial Level***

The Ministry of Environmental Protection organizes training workshops for environmental managers on the biosafety management of GMOs every year. From 2012-2015, more than 100 managers were trained. In the same period, the key lab on biosafety received an investment of over 2 million USD. These funds were used for building bases, improving lab conditions and purchasing equipment and instruments needed.

The Ministry of Agriculture organizes every year training workshops for local agricultural departments and personnel involved in the testing and monitoring of agricultural GMOs. More than 800 people have been trained in total. Meanwhile, the Ministry has also strengthened capacities for testing by upgrading testing equipment and building the capacity of personnel involved, as well as developing and issuing standards for testing and risk assessment.

The National Health and Family Planning Commission has provided lab equipment and facilities for biosafety management as required by relevant laws and regulations, has strengthened training in relevant knowledge and skills for professionals at various levels and for lab managers, and has actively participated in international exchanges in the field of biosafety.

The State General Administration of Quality Supervision, Inspection and Quarantine has invested considerable human, financial and technical resources into the development of a series of technical standards for biosafety management and guidelines for testing, the establishment of labs undertaking verification of GM composition and the provision of relevant equipment. It has also organized seminars and training workshops on sampling and testing of GMOs for personnel involved.

The State Forestry Authority has organized lectures and training workshops on forestry-related biosafety issues for more than 300 biosafety managers and scientists within the forestry sector.

#### ***Education: Undergraduate and Postgraduate Courses on Biosafety***

With regard to public education, institutions of higher education under the Ministry of Education have established programs on biosafety for undergraduates and training of professionals for biosafety management. For example, Southwest University, Sichuan University, Nanjing University, Hunan Agricultural University, and Fujian University of Agriculture and Forestry have established undergraduate programs on biosafety. Among them, Hunan Agricultural University has established a college of science and technology for biosafety. Zhejiang University and Yangzhou University have courses on GM biosafety. Shenzhen University offers an optional course on "biosafety and human life". In addition, the Chinese Academy of Agricultural Sciences has set up a postgraduate program on biosafety of genetic modification, with a view to training professionals on tracing, testing, and assessing risks of GMOs. Fujian University of Agriculture and Forestry and East China Insect Society have jointly published "A Journal of Biosafety", which is intended to promote information exchange and research in the field of biosafety.

## C. Key Lesson Learnt and Conclusion

Through long-term exploration and practice, China has gained some experience in biosafety mainstreaming, which could be shared with other countries. National experience shows that that biosafety mainstreaming should be country and sector-driven. Biosafety management is considered an issue of social concern and public attention, and a public welfare matter, and relevant sectors have an essential role in mainstreaming. In addition, biosafety mainstreaming into biodiversity conservation planning, and economic and social development planning, at all levels of government, is expected to filter down into more specific, operational legislation and policies. Finally, the joint sectoral coordination mechanisms such as the National Committee of Biodiversity Conservation and the Coordination Group have a key role to play in biosafety mainstreaming.

## 4.4 Ecuador

### A. Introduction

Ecuador has presented an extensive analysis of its legal framework, including references to biosafety in cross-sectoral and sectoral legislation and policies. The Constitution has declared Ecuador free of transgenic crops and seeds, with the exception of cases of national interest duly substantiated by the Presidency. There is no specific biosafety law, and 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. Current efforts for the drafting of biosafety-specific legislation and the establishment of biosafety institutions also take a multi-sectoral and multidisciplinary approach, thus supporting biosafety mainstreaming.

### B. Key Examples and Good Practices

#### ***Overarching Departure Points: National Plan for Living Well (2013-2017) and NBSAP (2015-2020)***

Successful mainstreaming of biosafety into cross-sectoral and sectoral legislation, policies and institutional frameworks started with the National Plan for Living Well (2013-2017) and the National Biodiversity Strategy 2015-2020, as high-level departure points. The National Plan for Living Well, in particular, is a practical instrument setting clear guidelines for public policies and public investment. Among other issues, it aims to ensure biosafety, thereby safeguarding the health of people, other living beings and nature, through five actions: generating regulations based on the precautionary principle; developing and implementing a comprehensive national biosafety system for the control of potential hazards and risks in the transfer, handling, release and use of the results of modern biotechnology; implementing protocols to prevent and manage potential adverse effects; promoting research, education, training, coaching and communication on biosafety; and implementing measures and safeguards in order to promote the involvement and participation of potentially affected communities and people. The National Plan for Living Well thus sets goals for the regulation of biosafety, through development and implementation of a national biosafety system, with processes aiming to promote public and institutional awareness and to encourage participation and involvement of key sectors of society.

Bringing cross-sectoral and sectoral legislation into compliance with these overarching strategic documents has led to biosafety mainstreaming across a number of different entry points. However, due to the time-bound nature of the policies, questions have arisen regarding the next phase and the extent to which biosafety will be recognized in future development policies.

#### ***Policies for Coordination: National Environmental Policy and the Draft Organic Environmental Code***

In addition to these overarching departure points, Ecuador is also developing policies for legislative coordination for environmental, including biosafety, mainstreaming. The National Environmental Policy and the Draft of the Organic Environmental Code are legal instruments that apply across legislation, in strict adherence to the provisions of the Constitution. The instruments provide guidelines for specific actions under the leadership of the Environmental Authority, and seek to systematize and avoid contradictions between legislation and the work of the various bodies that deal with different environmental issues. They promise to provide legal support for the integral management of biosafety in Ecuador, with guidelines for the adoption of a multi-sectoral and multidisciplinary approach in that regard.

***Entry Points: Agriculture, Food and Seeds, Consumer Protection and Health***

Cross-references to legal requirements for the use of LMOs can be found in the legislation on consumer protection, agriculture and food production, and health, which have been approved and elaborated in accordance with the new Constitution. The Organic Law on Food Sovereignty declares Ecuador free of transgenic crops in principle and sets out strict conditions for possible derogation. The Organic Law for Consumer Protection and the Organic Health Law provide for labelling requirements and prohibit the use of LMOs in infant and baby food. The by-law of the Regulation for Agricultural Organic Production, furthermore, prohibits the use of LM seeds, seedlings and propagating material under the organic produce labels. Applying the principles set out in the Constitution, the proposed Organic Law for Agrobiodiversity and Seed, which aims to regulate the use and conservation of agricultural biodiversity in relation to plant genetic resources for food and agriculture, also prohibits the commercialization, planting, storing and releasing of transgenic seed without compliance with legal requirements. According to this law, the seeds will be ‘forfeited and incinerated, in addition to the cancellation of the registration of importer or responsible for their introduction and this shall be penalized as a very serious infringement’ and ‘public action is granted to denounce the introduction of GM seeds for food and agriculture’.

Mainstreaming into these legislative acts aimed to ensure compliance with the 2008 Constitution and the National Plan for Living Well, as well as the 1999 Environmental Management Act and to lay the groundwork for a future National Biosafety Framework.

***Inter-Institutional Decision-Making Body: National Biosafety Commission (CONABIO)***

The National Biosafety Commission (CONABIO - Comisión Nacional de Bioseguridad) is responsible for the coordination, formulation and implementation of the National Biosafety Policy. It is composed of delegates from the Ministries of the Environment, Agriculture, Livestock, Aquaculture and Fisheries, Public Health, as well as the Secretariat of Higher Education, Science, Technology and Innovation. CONABIO decisions are implemented through each of the member institutions. Its main functions include: proposing a National Policy on Biosafety and a biosafety agenda; proposing plans and projects for the proper management of LMOs; negotiating with competent organizations regulations related to LMOs; supervising all assessment procedures, risk management and control mechanisms; creating and maintaining updated records of, amongst others, biosafety experts and imported LMOs; promoting capacity building and awareness raising; and liaising nationally and internationally for technical support.

The institution in its current form (with its competences having been updated in 2015) is, however, not yet operational. The proposal for a Biosafety Regulation, which are currently submitted for analysis to the Legal Secretariat to the Presidency, seeks to change that.

***Cross-Sectoral Advisory Body: Biosafety Unit within the Ministry of the Environment***

The Biosafety Unit within the Ministry of the Environment provides expertise and advice on biosafety, especially to decision makers in the Environmental Ministry. It consists of four professionals: three biologists and one biotechnologist. It provides advice on biosafety matters upon request by the Ministry and on its own initiative.

### ***Awareness Raising and Capacity Building***

A Plan and Communication Strategy on biotechnology, genetically modified organisms and biosafety 2013-2014 was developed, aiming to inform and facilitate the creation of conceptual knowledge in targeted populations, in particular indigenous peoples and environmental NGOs. Several communication materials were developed, such as a radio spot and information guides on biotechnology, GMOs and biosafety, training workshops for members of the press, a comic book titled 'Dr. Experiment explains ...' for college students, an audio-visual informative medium and introductory workshop.

With regard to capacity-building, the 2012-2017 Quinquennial Training Plan has been generated for education and training in the regulation, management and safe use of GMOs. This document provides the basis and necessary elements for the preparation of annual training plans and their monitoring, as well as suggestions for achieving sustainability of training, funding mechanisms, strategic and learning approaches and specific actions for each year with an estimate for training of staff and required funding. Based on this Plan and although there are no long-term training programs, 39 training sessions have been organized, including workshops, courses, breakfast meetings, forums and national seminars, where approximately 469 individuals were trained from National Secretariats, Coordinating and Sectoral Ministries, Control Agencies, and Public Research Institutes, among others. A database was created to document professionals trained under the plan, to allow for the exchange of expertise.

### **C. Key Lessons Learnt and Conclusion**

Examples of successful mainstreaming of biosafety in Ecuador can be found policy and legal frameworks, and capacity building of local professionals. High-level 'departure points', such as the National Plan on Living Well, and high-level political support helps foster mainstreaming. However, Ecuador's experience has also emphasized the importance of 'continuity' as an additional criterion for the selection and prioritization of entry-points, as well as the importance of alliances with non-political actors, such as scientists, to ensure that biosafety remains a regulatory and political priority when political powers and agendas change.

## **4.5 Malawi**

### **A. Introduction**

Malawi's national desk report outlines laws and policies relevant for biosafety mainstreaming. The report provides a great number of relevant examples of instruments that may function as future entry points for mainstreaming. However, current practices and examples of mainstreaming in these instruments appear to be limited. The report indicates that mainstreaming biosafety in Malawi has happened in two ways: as a process, through engaging various stakeholders in biosafety activities, and as an output, through inclusion of biosafety in relevant sectoral strategies and legislation.

### **B. Key Examples and Good Practices**

#### ***An Overarching Biosafety/Biodiversity Vision: Mainstreaming into the NBSAP (2015-2025)***

The National Biodiversity Strategy and Action Plan (NBSAP) 2015-2025 is a tool for achieving long-term goals on conservation and sustainable use of biodiversity in accordance with Malawi's Constitution and its National Environmental Policy. Target 14 of the NBSAP aims to ensure that biosafety and prevention of negative impacts on biodiversity and human health are prerequisites for the use of biotechnology for economic growth and social development. The NBSAP lists actions and output indicators to be achieved by 2025, including: revising the Biosafety Act and Regulations; conducting public awareness campaigns on biosafety legislation; developing and implementing a National Biosafety Capacity Building Plan; establishing national systems for documentation, management and information sharing on biosafety; and establishing an effective detection and monitoring system.

Various factors have been identified as contributing to successful biosafety mainstreaming in the case of the NBSAP: the National Focal Point for Biosafety was included in the NBSAP task team to ensure integration of targets on biosafety; public consultations were conducted during the NBSAP's development, including with institutions dealing with issues related to biosafety.

Malawi is also participating in the Capacity-Building Project to promote Integrated Implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the National Level.

#### ***Selecting Entry Points: Environment Management Bill 2016 and EIA Regulations/Guidelines***

Malawi has taken advantage of ongoing processes for the revision and development of legislation and regulations to ensure that biosafety is incorporated in upcoming legislative documents. A good example is the revision of the Environment Management Act (1996), which created an opportunity to integrate provisions on biosafety as a result of extensive stakeholder consultations. Section 71(g) of the resulting Environment Management Bill (2016) states that the Authority shall, in consultation with relevant lead agencies, prescribe measures and issue guidelines to promote the conservation of biological diversity *in situ* in relation to 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.

During the revision of the Environmental Management Act, both the National Focal Point for Biosafety and the CBD Focal Point were part of the team that was consulted. This involvement gave the officers an opportunity to ensure that their areas of interest are addressed.

Similarly, the current revision of Malawi's EIA Regulations and Guidelines has allowed putting biosafety higher on the environmental-regulatory agenda. The draft guidelines were sent to various stakeholders for comments, including the CBD Focal Point, which, in consultation with the National Focal Point for Biosafety. Malawi included a section on the need to screen projects for risks associated with introducing LMOs.

#### ***Cross-Sectoral, Participatory Advisory Body: National Biosafety Regulatory Committee***

Regulation 3 of the Biosafety Regulations creates a National Biosafety Regulatory Committee whose functions include: evaluating all applications concerning or related to GMOs and products thereof and making recommendations to the Minister in that regard; and advising, upon request or on its own initiative, the Minister on matters concerning genetic modification. The Committee includes government representatives from cross-sectoral and sectoral departments, NGOs and private institutions: The Ministries of Agriculture and Food Security, Health, Industry and Trade, Labor, Justice, Women and Children Affairs, and Nutrition, HIV and Aids, the Department of Forestry, Director of Parks and Wildlife, Council for NGOs, Revenue Authority, Police Services, and Consumer

Association. In addition to its advisory role, the Committee also liaises, through relevant institutions, with international groups or organizations concerned with biosafety.

#### ***Tools: Networks for Detection and Testing***

Malawi, together with other selected Southern Africa Development Community (SADC) countries, participates in a Sub-Regional Project on LMO detection and testing in cooperation with the Regional Agricultural and Environment Innovations Network-Africa, with funding from the Global Environment Facility. Through the project, Malawi and other countries have assessed their needs in detection and testing of LMOs. It is hoped that participation in the project will assist in improving the country's infrastructure for detecting, testing and monitoring LMOs, upgrading institutional laboratories and convincing government to finance infrastructure for biosafety. Malawi will involve stakeholders from customs, agriculture, academia and trade in the implementation process, to enhance participation and capacity building, and ensuring that these sectors participate in future biosafety programs.

#### ***Cross-Sectoral Monitoring Network for Coordination and Compliance***

Malawi's regulatory system provides for licensing and compliance monitoring by trained inspectors from different sectors. The system enables continuous consideration of biosafety issues and ensures that biotechnology activities are inspected in a coordinated way.

The Biosafety Act 2002 (Section 30) provides for the requirements for inspectors, and their appointment by the Minister of Environment, to ensure compliance with the provisions of the Act. Regulation 10 of the Biosafety (Management of Genetically Modified Organisms) Regulations 2007 further stipulates that institutions represented in the National Biosafety Regulatory Committee nominate officers with competence in biotechnology and biosafety, to serve as biosafety inspectors. This seeks to ensure the coordination of enforcement, compliance and monitoring efforts amongst institutions. Coordination of efforts is further facilitated through the Biosafety Registrar at the Environmental Affairs Department which also serves as Secretariat to the NBRC, which receives all documentation regarding LMO applications and appeals and which maintains a register of biotechnological activities in Malawi and all licenses and permits issued.

#### ***Awareness: Biosafety Communication Strategy***

The communication strategy was developed to help ensure that the public is made aware of, and understands biosafety issues and the mandate of the National Biosafety Regulatory Committee. The strategy provides a framework for delivering key messages and proposes awareness-raising for specific target audiences, including government agencies, NGOs, the private sector, development partners and the general public. The Biosafety Registrar is the overall coordinator of the strategy's implementation through identification of key partners to ensure that society in Malawi as a whole is well informed about biosafety. Information includes modern biotechnology activities in Malawi and how they are regulated; and the role and mandate of the National Biosafety Regulatory Committee as provided for in the Biosafety Act 2002 and the Biosafety (Genetically Modified Organisms) Regulations 2007.

The strategy focuses on the use of the most effective channels of communication to reach the target audiences with key messages, through government department websites, workshops/meetings, bulletins and publications, radio and television programs, as well as other social media.

### **C. Key Lesson Learnt and Conclusion**

Seeking interlinkages between biosafety objectives and broader environmental (conservation) objectives may greatly foster mainstreaming. Malawi has sought to foster such linkages through:

strong collaboration between the CBD and Cartagena Protocol focal points, which reside in the same institution; inclusion of biosafety experts in the development and revision of relevant legislation and policies, like the NBSAP; and importantly, inclusion of biosafety issues in the national budget, thus raising its priority status. However, inadequate awareness and communication, and thus lack of understanding of benefits results in lack of mainstreaming in most sectoral policies.

## 4.6 Malaysia

### A. Introduction

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. The prevailing instrument for implementation of biosafety measures, including through mainstreaming, is the Biosafety Act 2007. The desk study further documents Malaysia's wide experience in awareness raising and capacity building activities, which were funded through government resources provided to the Ministry of Natural Resources and Environment after the adoption of the Biosafety Act, as well as the Global Environment Facility (GEF) through the project: 'Capacity Building for Implementation of Malaysia's National Biosafety Framework'.

### B. Key examples and Good practices

#### ***Mainstreaming into National Policies on Biodiversity (1998 and 2016)***

Malaysia has pioneered the mainstreaming of biosafety in its National Policies on Biological Diversity, both the original 1998 document and the revised version for 2016-2025. The 2016 Policies take into consideration the Convention of Biological Diversity (CBD) Strategic Plan for Biodiversity, adapting it in the context of the current and future needs of Malaysia. Drafting sessions and workshops during the Policies' negotiation process served to spread the message to cross-sectoral and sectoral representatives, scientists and civil society representatives. Adoption of the 2016 Policies and their subsequent endorsement by the Prime Minister during the 4<sup>th</sup> plenary of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services held in 2016 in Kuala Lumpur highlights Malaysia's efforts to bring forward biosafety within the context of the priority objective of conservation.

The 2016 Policies give greater attention to biosafety than the 1998 Policies, incorporating it as a policy target with three action plans. Biosafety is addressed under Goal 3 on Safeguarding all key ecosystems, species and genetic diversity, which states that, while the country could benefit from modern biotechnology, the products of modern biotechnology should not pose unacceptable risks. Target 12 subsequently states that 'a comprehensive biosafety system inclusive of a liability and redress regime is to be in place to manage potential adverse impacts of modern biotechnology on the conservation and sustainable use of biodiversity and human health'.

#### ***Inter-Institutional Decision-Making Body: The National Biosafety Board***

The National Biosafety Board was established in 2010 and is tasked with biosafety regulation. It falls under the Ministry of Natural Resources and Environment and is chaired by the Secretary General of this ministry, with members from six sectoral and cross-sectoral ministries: the Ministries of Agriculture and Agro-based Industry, Health, Plantation Industries and Commodities, Domestic Trade Cooperatives and Consumerism, International Trade and Industry and the Ministry of Science, Technology and Innovation. It decides on the applications for release and contained use of LMOs and LMO products, monitors relevant activities, enforces the biosafety legislation, promotes research, development and educational and training activities, establishes mechanisms to facilitate collection

and storage of relevant data (including providing information to international databases such as the Biosafety Clearing House and the FAO GM Foods Platform) and implements international obligations. It is advised by a scientific body of experts called the Genetic Modification Advisory Committee, which is comprised of experts from various science-based disciplines and other relevant disciplines such as public health, coming from the academia, research institutes, and government agencies, as well as an industry and an NGO representative. The Department of Biosafety, with 25 staff members, is the secretarial and operational arm of the National Biosafety Board.

#### ***Integrated Enforcement Matrix and Integrated Committee on Monitoring and Enforcement***

Due to the cross-cutting nature of biosafety, enforcement involves officers from many agencies. Based on various legislative provisions, an integrated enforcement matrix was developed by the Department of Biosafety together with four departments under the Ministry of Agriculture and Agro-based Industry: the Departments of Veterinary Services, Malaysian Quarantine and Inspection Services, Agriculture, and Fisheries; as well as three divisions under the Ministry of Health: the divisions of Food Safety and Quality, Disease Control, and Pharmaceutical Services. The matrix aims to identify various aspects of modern biotechnology that are regulated and outlines the roles and responsibilities of respective agencies. It represents an important reference for the regulation of release, import, export, and contained use of LMOs and LMO products.

Additionally, successful efforts were made to raise awareness at ministerial level on the possible imminent risks resulting from the presence of unapproved LMOs, in particular during a briefing on 9 August 2016 of the National Biodiversity Council, Malaysia's highest decision-making body on biosafety. Subsequently, a high-level committee was established to provide policy guidance, coordinate and harmonize inter-agency efforts to implement biosafety measures. The committee will formalize the Integrated Enforcement Matrix among government agencies and enable the formation of the Integrated Committee on Enforcement and Monitoring of LMOs, which will be comprised of senior officers from the agencies listed in the Matrix. Each member is expected to promote awareness on biosafety and ensure its integration within their respective agencies' enforcement framework.

#### ***General and Targeted Activities to Raise Public Awareness and Foster Participation***

Formulation and implementation of the Biosafety Act 2007 followed a consultative process involving various groups of stakeholders, such as industry, NGOs and researchers. The process aimed to identify the best way forward to regulate modern biotechnology, but indirectly allowed for communicating the importance of biosafety in biotechnology advancements to all involved. Similar progress was made in the development of implementation mechanisms, such as the establishment of Institutional Biosafety Committees in consultation of researchers, which, put the topic of biosafety management on the radar and agenda of relevant institutions.

The Department of Biosafety has, moreover, conducted programs to raise awareness on biosafety. Priority target groups were identified for the effective use of limited public resources, notably industry representatives and researchers on modern biotechnology. An ad-hoc committee was set up to initiate discussions to help industry comply with the terms and procedures related to use of LMOs for food or feed and processing. Similarly, explanatory notes on application forms and sample forms were made available to researchers and several training sessions were held, providing guidance on using the forms. These methods have successfully improved the awareness of the prioritized target groups.

Other outreach activities include a biosafety education video, produced in both the national language and in English, Biosafety Q+A pocket-sized booklets with basic information on biosafety, and training sessions for members of the media on biosafety issues (Biosafety & DNA & U' Workshop). Advanced technical workshops related on LMO detection were also organized through the Department of Chemistry, which is located within the Ministry of Science, Technology and Innovation.

Other efforts to foster public participation are integrated into the LMOs approval process, as the Biosafety Act 2007 requires inviting the public to submit feedback on any applications for release, which is considered and decided upon by the National Biosafety Board. Any technical matters brought up through the public consultations are referred to the Genetic Modification Advisory Committee to edify the risk assessment process.

#### ***Activities to Raise Governmental Awareness and Build Capacity***

The Department of Biosafety has taken the lead in organizing training workshops to increase the knowledge and competency among staff in government agencies and institutions that are involved, both directly and indirectly, in the implementation and enforcement of the Biosafety Act 2007. A training module was developed by the Department of Biosafety, in consultation with the Genetic Modification Advisory Committee, to provide training for Institutional Biosafety Committees. The government also organized workshops to enable participants to understand the format of the Biosafety Clearing House and the procedures for registering and publishing biosafety-related records.

Additionally, the consultative and inclusive process that led to the adoption of the integrated enforcement matrix helped raise awareness across enforcement agencies. Malaysia aims to continue extending this awareness to other agencies and relevant local authorities.

#### ***Education: University Courses and Training Sessions***

Integration of biosafety into education has occurred through the incorporation of a biosafety module in a Masters Degree in one of the local universities. More universities are developing similar modules to incorporate biosafety. The Department of Biosafety regularly conducts the Biosafety Training Workshop in collaboration with the various Institutional Biosafety Committees in their respective institutes. The Department of Biosafety officers also become resource persons for any biosafety components in seminars and events organized by other organizations. Yet, additional work is proposed as Malaysia recognizes that biosafety awareness should begin in schools, for example at the secondary level, where biosafety can be introduced as part of the science syllabus in fundamental topics such as genetics.

#### ***Tools: Research Grants***

The Ministry of Science, Technology and Innovation and the Ministry of Agriculture and Agro-Based Industry, in partnership with the Department of Biosafety, have made it compulsory for funding applicants to obtain prior approval from institutional biosafety committees before application. This mechanism ensures that all projects funded by these ministries involving modern biotechnology comply with the Biosafety Act 2007.

### **C. Key Lesson Learnt and Conclusion**

Malaysia's experience shows that strong political will is needed to drive biosafety mainstreaming forward. A high-level representative with good understanding of biosafety issues may pursue such political will by becoming a biosafety champion. This can reach higher-level government officials, to gain traction for resource allocation and implementation of plans and proposals. Due to its

preventive nature, biosafety is often not considered an issue of current, therefore high political priority. Awareness raising and education measures are critical to this regard.

## 4.7 Mexico

### A. Introduction

Mexico has provided detailed information on its biosafety framework, at the core of which is the Biosafety Law on Genetically Modified Organisms 2005, which sets out the competences and roles of the national competent authorities. The study provides examples related both to general implementation efforts and to mainstreaming. The latter 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 legislation) are promoted and organized.

### B. Key examples and Good practices

#### ***Inter-Sectoral Coordination, Management and Decision-Making Body: CIBIOGEM***

The Inter-secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM) is in charge of formulating and coordinating the national policies on biosafety of genetically modified organisms. The benefit of this multi-sectorial approach is an integrated management of biosafety, coordinated actions and better efficiency on biosafety mainstreaming among seven agencies: the Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food; the Secretary of Environment and Natural Resources; the Secretary of Health, the Secretary of Economy; the Secretary of Public Education ; the Secretary of Treasury; and the National Council of Science and Technology . Policy decisions on biosafety are taken at the highest level at CIBIOGEM, which is composed by the secretaries of state of these agencies. Moreover, three of the secretaries are also the national competent authorities under the Biosafety Law on Genetically Modified Organisms 2005, and thus in charge of the implementation of the regulation and approvals (including issuing authorizations and permits) of LMOs. The presidency of CIBIOGEM rotates between the three authorities every two years.

The agencies and consultative bodies that constitute the CIBIOGEM are coordinated through an Executive Secretariat, which follows up on the decisions that the Commission takes. The Executive Secretariat also facilitates the information exchange and collaboration. The communication and cooperation activities among national competent authorities are explicit in the Law and the specific mechanisms for interaction among the operative areas are also described in the Operative Rules of the CIBIOGEM. The Internal Regulation of the Secretaries involved on biosafety was also adjusted starting in 2005 to generate the necessary legal provisions for installing coordinated actions. Lastly, the Biennial Working Program of CIBIOGEM is a policy document that structures and coordinates concrete actions and activities by the different secretaries on biosafety of LMOs.

The secretaries forming CIBIOGEM provide financial resources on behalf of the federal government, according to the provisions of the 2005 Biosafety Law into the 'FONDO CIBIOGEM': a fund for the development of biosafety activities, capacity building and development of research on biosafety and the safe use of biotechnology.

#### ***Cross-Sectoral Plans and Strategies: The National Development Plan***

The procedures for integration into all national plans and strategies and the responsible institutions are set out in the National Planning Law. The law provides for participatory procedures and consultations and for fundamental principles for the drafting of plans and strategies, including

cultural feasibility, equality, and respect of human rights. The Federal Executive coordinates and promotes the public consultation activities within the 32 federal entities.

Adoption of the National Development Plan 2013-2018, which is revised every six years, was preceded by broad consultations, with input collected from 228,949 participants, through discussion panels, sectoral workshops, online fora etc. Particular stakeholder groups that were identified include legislators, representatives of the three levels of government, young citizens, indigenous communities, people with disabilities, civil society organizations, academic institutions and private sector groups. The potential of biotechnology for social development has been recognized by different sectors. The importance of biosafety was put forward by the state secretaries that make up the CIBIOGEM, and notably by the three competent authorities, whose mandate under the Biotechnology Law includes an obligation for biosafety mainstreaming. Also, the Presidency Consultative Science Council, at the time led by specialists with strong background in biotechnology, the National Academy of Science and the National Council of Science and Technology provided input to the drafting process, flagging biosafety as a priority issue.

#### ***Other Cross-Sectoral and Sectoral Plans and Strategies: Environment, Health and Agriculture***

Similarly, to the National Development Plan, the Biosafety Law on Genetically Modified Organisms 2005 makes compulsory the integration of biosafety into other cross-sectoral and sectoral plans. Examples can be found in the Sectoral Program for the Environment and Natural Resources (2013-2018), the Agricultural Development Sector Program (2013-2018) and the Health Sector Program (2013-2018).

Mainstreaming biosafety into these plans and strategies builds upon the structures of the National Development Plan, and notably public participation and consultation, as well as the fact that the secretaries are represented in the structures of CIBIOGEM and act as competent authorities. Sometimes, additional avenues were created, for example in the case of the Agricultural Sector Plan, which organized its own public consultations with farmer organizations, researchers, farmers, producers and legislative representatives.

#### ***Other Entry Points: Natural Protected Areas (Environment)***

Article 89 of the Biosafety Law on Genetically Modified Organisms 2005, reflecting the precautionary principle, links biosafety to the protection of natural reserves. It provides that the intentional release of LMOs is restricted in Natural Protected Areas (NPAs).<sup>5</sup> A specific exception applies for cases where the LMO is intended for bioremediation.

#### ***Advisory Fora for Legislative Bodies***

The Mexican Legislative chambers have frequent dialogs with relevant stakeholders on the potential uses of modern biotechnology and the importance of biosafety at the technical, regulatory and political level. Members of congress use various fora for information exchange including the commissions of agriculture, science, and rural development. The current President of the Commission on Science and Technology at the Senate was also previously vice-president of CIBIOGEM.

#### ***Public Participation: Indigenous Peoples***

Indigenous communities that have territories in areas where applications for environmental release are made, can participate in decision-making on the basis of article 108 of the Biosafety Law, in

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<sup>5</sup> <http://www.gob.mx/conanp/acciones-y-programas/sistema-nacional-de-areas-protegidas-sinap>.

accordance with their rights as recognized in the Mexican Constitution. The participatory process involves several phases: first, the community is contacted by the government through its authorities and representatives, and a work plan is drafted; then information on biosafety and the specific LMOs is provided to the community on the basis of their customary forms, cultural pertinence and respective language; after that, the community examines the information provided and manifest any doubts or requests. This is then followed by a consultative phase; and the follow up of any agreements reached along the process. Processes are often observed by human rights organizations and NGOs. Companies have so far not participated, but they may be included in the future.

#### ***Capacity Building: Draft Inter-Institutional Platform for Information-Sharing***

The establishment of proper coordination and information-sharing mechanisms is considered a priority for the main competent secretaries. A unified platform for sharing information on biosafety has been under preparation since 2008, but finalization has proven difficult due to the large amount and diversity of information topics submitted under different processes, the distinct capacities of the institutions involved and the different internal systems. The latest CIBIOGEM working program has, however, put the initiative back on the agenda. Once established, the Platform would complement the already existing coordination and information sharing mechanisms. For instance, it will lay down the obligations to consult the different authorities on the distinct LMO authorization processes, and the opportunities for the six secretariats involved in CIBIOGEM to comment on the activities under the Biennial Working Program.

#### ***Education: Activities run by the Secretary of Public Education***

The Secretary of Public Education is a member of CIBIOGEM, with federal powers on academic plans and educational activities at the national level. Given the importance that these activities have on mainstreaming biosafety, there is the need to strengthen its role within the Commission.

Activities that have been initiated in a sporadic manner include: capacity building for teachers (elementary school and technological education), workshops for university students on biosafety, and updated curricula in some academic programs, for example biology and biotechnology, to include biosafety in study plans.

#### ***Tools: National Laboratory Network on GMO Detection***

Over the years, Mexico has increasingly strengthened its national laboratories for LMO detection and identification. To synergize efforts and enhance the capacity of laboratories through the exchange of knowledge and expertise, a National Laboratory Network on GMO Detection was established. Guidance was developed in a collaborative process to ensure a high standard of work across all laboratories. This network includes a central node of government-certified laboratories from different sectors as well as laboratories in universities and public research institutions, which are interested in collaborating with the government. The laboratories of the central node periodically organize short and long term training courses. Altogether, by using reference controls, blind sample testing and sharing results and facing common challenges, the laboratories have built capacities to follow quality control processes to detect, identify and quantify LMOs

#### ***Tools: Internal Biosafety Commissions and Bioethics Committees***

Mexico's Biosafety Law establishes that notification to competent authorities has to precede the contained use of LMOs. The law further requires that with the notification, academic researchers and institutions carrying out activities on confinement with LMOs must also provide proof of the establishment of an internal Biosafety Commission at the institution. Many of these institutions

already have a functioning Bioethics Committee, the tasks of which can be extended to also consider biosafety issues.

#### **Tools: Pre-Existing Databases**

Several databases already existing in Mexico can be used and adapted for biosafety purposes. These include databases on the distribution of wild relatives of GM crops, non-target organisms, the distribution of pest organisms, and research laboratories. Examples of these databases include the following:

- Endemic species<sup>6</sup>
- Weeds<sup>7</sup>
- Species monitor<sup>8</sup>
- Information system for biodiversity centers<sup>9</sup>

#### **Tools: Public Funding for Biosafety-Relevant Research**

As noted above, the FONDO CIBIOGEM, funded by the different state secretaries, supports academic research projects in the field of biosafety. Research results funded by the FONDO CIBIOGEM are made publicly available and are communicated through seminars, workshops and at the CIBIOGEM website, as well as scientific journals and academic conferences. The projects approved for funding need to respond to an identified need for information, including from regulators, which has been submitted to the Technical Committee of CIBIOGEM. The Scientific Consultative Council revises submissions and, with the approval of CIBIOGEM, research proposals are invited for submission on the approved topics. A recent example is the project 'Perceptions and attitudes of the Mexican urban population on the production and consumption of genetically modified organisms' which resulted in a book publication.

### **C. Key Lesson Learnt and Conclusion**

A strong legal framework that explicitly expresses the need to consider the inclusion of the safe use of biotechnology in national plans and specific programs allows for functional biosafety mainstreaming processes, upon the responsibility of federal agencies, and relatively independently from political changes. Institutional competences grounded in law, together with a coordination framework amongst the involved government agencies, allow for an integrated, multi-sectoral approach towards the inclusion of biosafety in national policies. Biosafety is not viewed from the point of view of a single institution, but instead, is addressed transversally in several objectives and action lines, as part of the National Development Plan.

However, even with a strong legal framework, education, information and communication remain big challenges to be addressed, as lack thereof may impede proper implementation.

## **4.8 Moldova**

### **A. Introduction**

Moldova's desk study identifies, and provides a detailed analysis of, a broad range of potential entry points for mainstreaming (12 policy and 24 legal instruments) in the field of: environmental protection, agriculture and food processing, health care, trade, custom services, consumer protection

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<sup>6</sup> <http://www.biodiversidad.gob.mx/especies/endemicas/endemicas.html>.

<sup>7</sup> <http://www.conabio.gob.mx/malezasdemexico/2inicio/home-malezas-mexico.htm>.

<sup>8</sup> <http://www.biodiversidad.gob.mx/especies/mespecies/index.html>.

<sup>9</sup> <http://www.sinarefi.org.mx/sistemas/sibg/germocallihomepage.php>.

and public information. Current practices and practical examples of how biosafety has been mainstreamed in these instruments appear to be at a modest level. Examples of mainstreaming are mostly based on the overarching National Biosafety Law 2001 and its implementing regulations, legislation which is currently under revision. Most examples of mainstreaming relate to the agricultural sector.

## B. Key examples and Good practices

### ***Overarching Departure Point: NBSAP 2015-2020***

The National Strategy on Biodiversity for the period 2015-2020 and Action Plan (NBSAP) is an important mechanism for cross-sectoral coordination of biosafety mainstreaming. The NBSAP includes references to institutional and financial resources, including budgetary and external resources for its implementation. It further includes specific provisions for implementation of the Cartagena Protocol on Biosafety, and its objective 1.4 identifies the need for the development and promotion of regulation on GMOs' deliberate release into the environment and market authorization, in accordance with EU legislation.

Various governmental bodies are involved in the implementation of the NBSAP, and are obliged to mobilize resources to bring their sectoral legislation in compliance, including the Ministries of the Environment, Health, and Agriculture and Food Industry. These bodies develop annual working plans, including steps for NBSAP implementation, under the coordination of the Ministry of Economy.

### ***Entry Points: A Consultative Approach to Integration in Agricultural and Related Health Regulations***

Various examples of biosafety mainstreaming in the agricultural and food sector provides can be found in Moldova. The Law on Agro-Food Ecological Production 2005 includes a reference to LMOs; the Law on the Protection of Plant Varieties 2008 includes requirements for LMO authorization and patents; the Law on Seeds 2013 includes provisions on GM seed production, their marketing, import, export, re-export, packaging and labelling, with cross-reference to the National Biosafety Law. The Law on Food Products 2004 includes LMOs labelling requirements; and the Law on sanitary-veterinary activity has some provisions on the presence and control of LMOs in animal products and feed – an activity for which the Ministries of Agriculture and Food Industry, Health, and the Environment are responsible.

Different actors and processes were involved in the mainstreaming of biosafety into these particular instruments. Mainstreaming into the Law on Seeds and the Law on the Protection of Plant Varieties was initiated upon recommendation of the Parliamentary Commission for public administration, regional development, environment and climate change. The Laws on agro-food ecological production, food products and sanitary-veterinary activity were amended primarily with a view to implement Moldova's Association Agreement with the EU, and notably ensure compliance with Directive/2001/18/EC (EU) on the deliberate release of GMOs.

The legislative process, moreover, allows for broad stakeholder participation and the expression of biosafety concerns by the public. Consultations are publicly announced, and new drafts and revisions are made available to the public. Consulted parties include all relevant sectors' ministries.

Lastly, a working group within the Ministry of Agriculture and Food Industry was established for better implementation of the Law on agro-food ecological production, and included a representative of the Ministry of the Environment, in charge of the coordination of biodiversity and biosafety activities.

### ***Institution: Cross-Sectoral Interdisciplinary Decision-Making Body***

The National Biosafety Committee is responsible for the examination and decision-making on applications for LMOs. It also monitors LMO activities and collaborates with governmental authorities and scientific institutions. The Committee operates as the inter-ministerial authority and consists of 14 members, including two members from the Ministry of the Environment, which have the functions of the Chairman and the Secretary of the National Committee respectively, four members from the Academy of Sciences, three members from other scientific institutions and universities with biological or medical profiles and one member from each of the national ministries for economy, agriculture and food industry, health care, standardization and metrology, as well as from environmental NGOs.

### ***Institution: Independent, Non-Profit Biosafety Organization for Capacity-Building***

The Biosafety Office is an independent non-commercial, non-profit organization, established by order of the Ministry of the Environment. It seeks to promote and strengthen government, academic and civil society capacities to implement activities on biosafety. Amongst others, the Biosafety Office: helps design and implement biosafety legislation; provides risk assessment of socio-economic impacts; facilitates the creation of databases and monitoring systems; and implements awareness and information activities for civil society, relevant specialists and decision makers.

### ***Public Participation: Regulation on Public Information and Consultation***

The Regulation on information and public consultations of 2002 provides for the provision of information to the broader public during the consultation phase of the decision-making process on LMO authorizations, including which information may not be kept secret upon confidentiality grounds. The regulation was developed based on the Aarhus Convention and the Cartagena Protocol.

### ***Education: University Courses***

Moldova has promoted education initiatives to integrate biosafety in the university curricula and long term training. These include a university course on “Genetically Modified Organisms” for undergraduate students, as well as special courses on “Biosafety and Sustainable Development” and “Modern and classic biotechnology” for master degree students, as part of the molecular biology university curricula in the State University of Moldova, Faculty of Biology and Soil Sciences. A course on biosafety knowledge and the Cartagena Protocol on Biosafety (Juridical aspects of the international law) is also part of university courses in molecular biology at the University of the Academy of Sciences of Moldova, as well as of the agronomy faculty of the Agrarian University of Moldova.

A special master degree on biosafety is currently awaiting approval in the Faculty of Biology and Soil Sciences of the State University. It takes a multidisciplinary approach, including courses from specializations like botany, zoology, molecular biology, ecology, microbiology, algology, animal physiology and sanocreatology, medicine, geography, soil sciences etc.

## **C. Key Lesson Learnt and Conclusion**

The mapping exercise under this project has shown that Moldova needs to focus its attention on bringing together stakeholders to improve cross-sectoral dialogues and clarify different roles.

Mechanisms to strengthen mainstreaming include: increasing political support through consultation and awareness raising; improving cross-sectoral cooperation and generating more financial resources; developing a roadmap for mainstreaming and training mechanisms for new personnel;

and further working on biosafety education and strengthening regional and sub-regional cooperation.

## 4.9 Uganda

### A. Introduction

The National Biotechnology and Biosafety Policy 2008 is currently the core instrument on biosafety in Uganda, in absence of specific legislation. The policy will be operationalized by the draft National Biotechnology and Biosafety Bill 2012, once passed into law. The new bill would provide for clear legal rules on biosafety research and development in accordance with the Cartagena Protocol. It would also establish a Competent Authority and a National Focal Point, a National Biosafety Committee and Institutional Biosafety Committees.

Although current efforts regarding the regulation of biosafety have focused on the drafting and implementation of the legislation, Uganda's study also recognizes successful mainstreaming practices, as well as the opportunities that the drafting of new legislation may provide for further mainstreaming into cross-sectoral and sectoral instruments. Such activities are, furthermore, put on the political agenda against the backdrop of ongoing field trials by Uganda's National Agriculture Research Organization and increasing numbers of applications; and are strategically guided from integration of biosafety consideration into the National Biodiversity Strategy and Action Plan.

### B. Key examples and Good practices

#### ***Overarching Departure Point: NBSAP 2015-2020***

Uganda has extensive experience with the mainstreaming of biosafety on a strategic level, for example into the National Biodiversity Strategy and Action Plan 2015-2025 (NBSAP II). During the review and updating of the previous NBSAP, NBSAP I, a working group was constituted to collect and synthesize information on the status of biotechnology and biosafety in Uganda. Based on the information obtained, and with guidance from the national focal points for the Cartagena Protocol and the CBD, the working group proposed national targets on biotechnology and biosafety to be included in NBSAP II. Its objective is to harness modern biotechnology for socio-economic development, with adequate safety measures for human health and the environment, including biodiversity. The tools for achieving this objective, will include an Environment and Social Impact Assessment (ESIA) for biotechnology policies and projects, once the Bill is passed into law, the promotion integration of biotechnology value in macroeconomic frameworks. Implementation of national targets is to be achieved by target champions. These target champions are Government institutions whose mandate directly relates to the specific national targets.

The review and updating of NBSAP II provided the opportunity to create awareness on biosafety, which allowed for further mainstreaming of biosafety into other strategic policy frameworks. Such activities are supported by the Ministry of Finance, which in its First Budget Call Circular on Preparation of the Budget Framework Papers and Preliminary Budget Estimates 2017-2018 guided and advised sectors to implement the national biodiversity targets stipulated in NBSAP II, including those on biosafety.

#### ***Strategic, Priority Entry Point: Uganda Vision 2040 and the National Development Plan II***

The National Vision 2040 intends to transform Uganda from a peasant to a modern and prosperous country by 2040. It singles out biotechnology as a key innovative pathway, but also identifies the challenges posed to the environment and natural resources emanating from the use of LMOs. Biosafety and Biotechnology were mainstreamed in the Uganda Vision 2040 as a result of national,

sectoral and local government consultations. Widespread consultation processes were undertaken among state and non-state actors (private sector and civil society) who play key roles in its implementation.

The Vision is a broadly formulated strategic document and does not provide detailed provisions on biosafety, but together with NBSAP II, it has provided the basis for further integration into Uganda's revised National Development Plan II (NDP II). Integration of biosafety was made possible with support from the National Planning Authority, and the President, support which was generated by emphasizing the economic losses associated with biodiversity losses. As biosafety was not included prominently in the NDP I, NDP II presented the opportunity to renew Uganda's commitment to biosafety by clearly enumerating various strategic interventions aimed at promoting biosafety.

The NDP II is a high-level priority instrument for Uganda's government. It was recognized from the beginning that mainstreaming into this cross-sectoral plan could spark further mainstreaming on a sectoral level and lower levels of regulation, particularly if supported by strong budget allocations. Uganda sought and succeeded to link biosafety to the development goals within the plan, including environmental goals of sustainable use of natural and genetic resources, health and development, and to highlight biosafety as an essential condition for biotechnological innovations for national development.

#### ***Ongoing Activities: a Consultative Approach to Mainstreaming into Environmental Laws and Policies***

The current National Environment Act, which does not include provisions on biotechnology and biosafety, is currently under revision. The proposed National Environment Bill 2016 provides that the National Environment Management Authority (NEMA), being the CBD National Focal Point, may, in consultation with the National Competent Authority, issue guidelines and prescribe measures for the protection of the environment and management of risks to human health from genetically modified organisms, and on liability and redress in respect to damage inflicted on biological diversity and / or the environment arising from genetically modified organisms. The Bill was drafted in consultation with the Uganda National Council for Science and Technology, scientists and experts and the CBD National Focal Point. It was presented to different stakeholders including at national and sub-national level to obtain comments from experts, political leaders and public.

The activities regarding the National Environment Bill 2016 are complemented by the revision of the National Environment Management Policy 1994. The policy provides a framework policy broadly addressing management of all matters relating to environment and natural resources in Uganda. The policy is reviewed to take into account the prevailing environmental circumstances in Uganda since 1994, and also to capture new and emerging issues. Wide stakeholder consultations were conducted at the national and district level, as well as focused group discussions with technical officers and experts in biotechnology and biosafety. This approach made it possible to identify gaps and mainstream biosafety and biotechnology in the final draft. The draft policy was presented to the Ministry of Water and Environment and to the Policy Committee, which is comprised of ministers representing: natural resources; agriculture, animal industry and fisheries; finance and economic development; education; health; lands, housing and urban development; local government; gender and community development; tourism, wildlife and antiquities; and trade and industry. The Committee is chaired by the Prime Minister and, with the National Environment Management Authority appointed as the Secretariat, the Committee provides opportunities for biodiversity and biosafety mainstreaming. The draft policy aims to ensure the safe application of biotechnology and promote use of biotechnology for socio-economic development while managing concerns associated

with its application, to be implemented through relevant laws and regulations. It contains precautionary measures, the drafting and implementation of the new Biosafety Bill and capacity building and awareness raising on biosafety.

### C. Key Lesson Learnt and Conclusion

Uganda has learnt that mainstreaming of biosafety into overarching strategic frameworks like the National Biodiversity Strategy and Action Plan II and the National Development Plan II can catalyze further mainstreaming on sectoral and district (sub-national) legislative levels. Targeting high-level, development-focused entry points may, furthermore, allow for easier budget generation. Moreover, awareness amongst the public and government agencies is crucial for mainstreaming, and, as still very limited in Uganda, a targeted priority.

## 5 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 in 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 legislation, 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. Lastly, **unbalanced representation of interests** within institutional frameworks has been noted as a concern that would impede proper cooperation and coordination of efforts on mainstreaming.

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. 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 legislation 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.

The studies make several recommendations as to how to address the identified challenges (above 5). It must be noted, however, that such recommendations often reflect good intentions for improvements that have not yet been implemented. The lessons that follow from the good practices of other countries may provide more valuable sources of inspiration to tackle persistent problems. Links between the challenges of one country and the experiences of another were made during the workshops in Moldova. A few noteworthy lessons for biosafety mainstreaming can be identified.

## 6 Recommendations and Lessons Learnt

At the very core of a strong regulatory and institutional framework on biosafety mainstreaming one will find: ample **awareness** on biosafety amongst the public and authorities, with a strong **legal framework** which supports continuous action and sufficient **financial resources** to implement actions. There is not a simple solution where elements are lacking, thus inhibiting action on the mainstreaming of biosafety, as a multitude of national circumstances, factors and interests will come into play.

However, some general lessons may be drawn from the desk studies for inspiration on how to deal with the challenges specific to a country. Firstly, the studies stress the importance of **an overarching vision** on mainstreaming and a framework of action on biosafety, setting out general objectives, specific targets with possibly indicators for success, as well as realistic timelines and a division of tasks. Whereas a strategic document in this regard may serve to increase political awareness and support, the drafting processes, if undertaken in a participative manner involving cross-sectoral and sectoral government representatives through consultations and roundtables, may also have this effect.

The importance of awareness-raising, as well as capacity-building, public participation and education, must also be stressed within the broader context of mainstreaming into selected cross-sectoral and sectoral legislation, policies and institutional frameworks. **Awareness-raising** activities to enhance a general understanding of biosafety and targeting a broad range of stakeholders like government institutions, research community, industry, indigenous people and local communities and environmental NGOs, may include briefing sessions and workshops, roundtables for discussion and media outreach through radio, television and booklets. **Capacity-building** activities to generate the specific knowledge needed for the proper implementation of the biosafety framework and actions on mainstreaming by government authorities, laboratories and border control agencies, may include the organization of legal and technical training workshops, distribution of manuals and guidelines, the setting up of networks and platforms for knowledge exchange and the provision of advice and technical support upon request. **Education** activities for students and professionals include the organization of biosafety courses and modules on all levels of education, and guest-seminars by biosafety authorities. Lastly, **public participation** activities include the consultation of the public in decision-making on LMOs, in the drafting or revision of biosafety legislation or the entry points for mainstreaming and may in particular aim to involve indigenous people and local communities.

**Success stories of mainstreaming into institutional frameworks** include examples like internal and external technical advisory bodies on biosafety to cross-sectoral and sectoral government agencies, cross-sectoral coordination bodies for action on biosafety, cross-sectoral decision-making bodies on LMOs and biosafety, cross-sectoral legislative bodies, integrated committees and networks for monitoring and formalized platforms for cooperation. Yet, other than success stories, these institutional frameworks, with appropriate mandates, also provide fora to facilitate knowledge exchange, raise awareness and communicate on biosafety in a consultative and coordinated manner.

Joint work on biosafety is one way of **generating political support**, to be complemented by active communication on the linkages between biosafety, national priorities and sectoral objectives, such as the importance of biosafety for conservation and sustainable development, and the building of alliances with public and private champions (e.g. authorities and scientists) to take the message forward. **Selecting and prioritizing entry points** for mainstreaming is a diligent exercise, where one may seek to aim high with smaller chances of success (target high-value cross-sectoral legislation and policies with potential for further mainstreaming) or pick the low-hanging-fruit with short term results, but which may lack lasting impacts. Much will be dependent on the particular circumstances, yet it will be important to recognize and take advantage of **opportunities for mainstreaming**, such as changes in the political field, drafting or revision processes, the emergence of a hazard and the organization of relevant high-level events to communicate your message and generate support for mainstreaming.