



MAINSTREAMING BIOSAFETY IN MONGOLIA

Desk report

2018

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List of Acronyms

AFCCP	Authority for Fair Competition and Consumer Protection
BCH	Biosafety Clearing House
BRI	Biosafety Research Institute
CPB	Cartagena Protocol on Biosafety
CBD	Convention on Biological Diversity
FSC	Food Safety Council
GASI	General Agency of Specialized Inspection
GCO	General Customs Office
GEF	Global Environment Facility
GIA	General Intelligence Agency
LMO	Living Modified Organism
MAS	Mongolian Academy of Science
MBA	Mongolian Biotechnological Association
MECS	Ministry of Education, Culture, Science and Sports
MEGD	Ministry of Environment & Green Development (former name)
MET	Ministry of Environment and Tourism
MFALI	Ministry of Food, Agriculture and Light Industry
MFA	Ministry of Foreign Affairs
MH	Ministry of Health
MMHI	Ministry of Mining and Heavy Industry
MNE	Ministry of Nature & Environment (former name)
MSUA	Mongolian State University of Agriculture
MUST	Mongolian University of Science and Technology
NKLSP	Nagoya – Kuala Lumpur supplementary protocol on liability and redress
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NDA	National Development Agency

NEA	National Executing Agency
NEMA	National Emergency Management Agency
NFMCA	National Federation of Mongolian Consumer Association
NUM	National University of Mongolia
NUSPCR	National Union of Societies for the Protection of Consumer Rights NGO
PHC	Public Health Center
UNEP	United Nations Environment Programme

Executive Summary

Mongolia is a Party to the Convention on Biological Diversity since September 30, 1993 and Party to the Cartagena Protocol on Biosafety since October 20, 2003. The Ministry of Environment and Tourism (MET) has been appointed as National Focal Point for the Protocol.

In January 26, 2012 Mongolia signed and in 21 May, 2013 Mongolia has ratified the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

Law on Living Modified Organisms was approved by the Parliament of Mongolia on June 18, 2007 in order to create a legal environment for biosafety in Mongolia. The law has 4 chapters and 20 articles and became legal base for National Biosafety Committee. Biosafety main issues are included in the revised and updated **Mongolian National Security Concept** in 2010.

NBC worked together with Ministry of Agriculture & Light Industry to include additional clauses regarding LMOs and LMO derived products in the revised **Law on Food** and the newly proposed legislation of the **Law on Food Safety** and both updated by Parliament of Mongolia on December 20, 2012 with necessary changes including LMOs and LMO derived products.

Biosafety national action plan included into Mongolian NBSAP which was approved in 2015 by Mongolian Government.

Current legal framework in Mongolia not updated in accordance with the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress.

- LMOs and LMO derived products related regulations which are currently operational in Mongolia;
- General regulation on registration and monitoring of LMOs and their derived food products (2003);
- Government resolution for border check points for transboundary movements of LMOs (2010);

Institutional Framework

According to Law on LMOs Mongolia has established a National Biosafety Committee (NBC) at the Ministry of Nature & Environment on April 24, 2008 to manage and organize activities regarding biosafety in Mongolia. The Committee will be led by the minister of the Nature and Environment and operates with 19 members from related organizations and with one NBC Secretary.

The NBC will be in charge of transboundary movement of living modified organisms; general requirements on transboundary movement of LMOs and all LMO related activities; additionally, in the scope of NBC including laboratory biosafety and biosecurity issues in Mongolia.

National Biosafety Committee in order to make professional decision making on risk assessment and management have Scientific Council with 9 members. Scientific council members selected from related professional laboratories, institutes and universities. Till date none risk assessment and risk management has been carried out. Also no request has been submitted to NBC for risk assessment of LMOs from importers and private sector.

Few incidences were registered on illegal introduction into environment of LMOs in Mongolia. Because of the lack of knowledge and awareness about LMOs and biosafety issues in Mongolia, especially in agricultural sector there are many risk probabilities for unintentional introduction of LMOs into the environment.

Four national standards which are translated and developed by NBC and Capacity building for Building Implementation for Mongolia project was approved by Mongolian Agency for Standards and Metrology from 2011 to 2013. These standards were very useful tools for identification and determination of LMOs in Mongolia for all biotech laboratories, especially for General Laboratory of GASI and Laboratory of GCO for reliable and standardized results.

Lessons learnt

Despite many capacity building activities and efforts by NBC and related projects there are still lack of understanding and knowledge about biosafety issues at the policy and implementation level in Mongolia. Regular meetings, workshops and trainings for officials especially at the policy levels are very important for mainstreaming biosafety in Mongolia specially to raise decision makers' awareness on biosafety.

Studies on the site which are carried out by NBC together with related organizations are the good examples of capacity building of the human resource on the site and mainstreaming biosafety into Inspection agencies and research organization.

Organizing international workshops on Biosafety in Mongolia was very useful for sharing different countries' real experiences and challenges on mainstreaming biosafety into NBF.

Major challenges

In last few years Mongolia is facing severe economic difficulties. Significant cuts in the sectoral expenditures in which MET is included. That's why Mongolia still has very limited capacity and insufficient funding to implement this Law on LMOs. Also frequent structure change of the MET is affecting NBC sustainable activities and finding.

In order to fully operationalize Law on LMOs, related Laws and supporting regulations/rules there is urgent need for sustainability of National Biosafety Committee (only one staff, but still under question, also in charge of other issues – NBC secretary) and sustain existing capacity, human resources. Also biosafety activities within the NBSAP should be reflected annually in the state budget.

Followings are the major challenges on biosafety in Mongolia:

- *Insufficient capacities and funding for detection, monitoring and risk assessment of LMOs;*
- *Lack of information and understanding of decision makers, general public and related stakeholders regarding the economic, legal and social impacts of LMOs.*

Necessary further steps

Revision, assessment and mainstreaming possibilities of NBC structure and function against newly approved Development policies and strategies of Mongolia (Sustainable and Green Development Policies). Strengthen the cross sectoral cooperation through regular NBC meeting to keep NBC members

updated and well informed about current biosafety situation in Mongolia and through improved management tools. Increase civil society organization participation in biosafety activities.

To develop suitable improved tools for mainstreaming biosafety into cross sectoral legislation and policy. Regularly organize public awareness activities for decision makers and general public. Increase regional networking and cooperation on biosafety through BCH, Asian Biosafety Framework and through other tools.

To develop and to find external donors who will fund funding for Biosafety activities in Mongolia for capacity building, technical support, public awareness, risk assessment & risk management of LMOs, liability & redress, socio-economic consideration and decision making etc.

To organize monitoring activities agricultural sector for crops like rapeseed etc. and to work on awareness raising activities for private sector.

Also to establish and apply appropriate rules and procedures on liability and redress for damage resulting from the transboundary movements of living modified organisms, in accordance with the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress in Mongolia.

Introduction

Mongolia is a Party to the Convention on Biological Diversity since September 30, 1993 and Party to the Cartagena Protocol on Biosafety since October 20, 2003. The Ministry of Environment and Tourism (MET) has been appointed as National Focal Point for the Protocol.

In January 26, 2012 Mongolia signed and in 21 May, 2013 Mongolia has ratified the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

Mongolia made significant efforts towards having a functional biosafety system. From 2002-2005, Mongolia successfully completed a draft NBF under the UNEP/GEF funded global project on “Development of National Biosafety Frameworks”. The project GEF/2716-02-4527 entitled “Development of the National Biosafety Framework” financed by the GEF, had the aim of developing the National Biosafety Framework in agreement with the provisions of the CPB. The draft NBF formed the basis of a new law and which was enacted in November 2007.

National Biosafety Committee established in 2008 according to Law on LMOs at Ministry of Nature & Environment.

Limited capacity for LMOs derived using genetic engineering has led to the implementation of the medium level project for “Capacity building for Building Implementation for Mongolia” jointly organized by GEF, UNEP and Government of Mongolia from May 01, 2011 to April 30, 2014. This capacity building project provided the mainly capacity building activities and foundation of the Biosafety national action plan.

However, the NBF in Mongolia still requires additional efforts and regular financing to allow the country to take advantage of development and use of LMOs as well as to minimize the possible negative effects that they could have.

There are still needs related to local capacity for LMO monitoring, surveillance, detection and consecutive public awareness activities; issues that were just started and some of them not addressed during the former implementation project.

Similarly, issues related to Liability and Redress (L&R) and Socio-Economic Considerations (SEC) have not been addressed and are of great importance for the Mongolia and as well as the recent ratification of the Supplementary Protocol on Liability and Redress, in alignment with CBD COP-MOP decision VIII/11.

National circumstances and national biosafety-related legal, policy and institutional frameworks

Laws

Law on Living Modified Organisms was approved by the Parliament of Mongolia on June 18, 2007 in order to create a legal environment for biosafety in Mongolia, therefore becoming the first such legal document regarding biosafety in Mongolia. The law has 4 chapters and 20 articles and addresses the following: goals, definitions, scope of activities and legal base for National Biosafety Committee.

Biosafety main issues are included in the revised and updated **Mongolian National Security Concept** in 2010.

NBC worked together with Ministry of Agriculture & Light Industry to include additional clauses regarding LMOs and LMO derived products in the revised **Law on Food** and the newly proposed legislation of the **Law on Food Safety** and both updated by Parliament of Mongolia on December 20, 2012 with necessary changes including LMOs and LMO derived products. Several discussion meetings were organized for working group on Law development & update including all related stakeholders. Final discussion on draft Laws was organized for Parliamentary Standing Committee on Food, Agriculture and Environment, decision makers, scientists, civil society, private sector and professional organization. Draft law introduced to the general public through newspaper and related websites for comments and suggestions for two months. Good experience was NBC worked very closely with Ministry of Agriculture & Light Industry on these Laws.

Following articles related to Biosafety included in Laws below:

Law on Food (revised edition, 2012)

Article 7. Foods originating from living modified organisms

7.1. Living modified organism food products means any foodstuffs that originate from living modified organisms, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

7.2. Living modified organism food products shall be registered by the central administrative body in charge of foodstuffs according to sub-article 14.1 of the Law on Food Safety.

7.3. Public awareness on the importation of living modified organism foodstuffs will be raised by the central administrative body in charge of food monitoring (hereinafter referred to as the “monitoring body”) and the organization in charge of biosafety using electronic means.

7.4. Living modified organism foodstuffs are prohibited to be purchased using foreign aid and loans.

Law on Food Safety (2012)

Article 12. Packaging and labeling of raw materials and food products

12.5.3. Internationally and/or domestically recognized signs and codes must be present for food additives and organic food, and if the raw materials and/or food products are derived from LMOs.

Article 14. Raw materials and food products derived from LMOs

14.1. Procedures for performing risk assessment and registering raw materials and food products derived from LMOs shall be jointly approved by the State Administrative Authorities in charge of Health, Food and Environment.

14.2. The Inspection Body shall conduct inspection on first-time imports, and on domestically produced raw materials and food products derived from LMOs.

14.3. It is prohibited to supply raw materials and food products derived from LMOs that did not undergo risk assessment and registration processes as specified in Article 14.1.

Article 19. Liabilities to be imposed for violators of the Law

19.1.7. For placing raw materials and food products derived from LMOs on the market in violation of Article 14.3 of this Law, the guilty person shall be fined the amount equal to 20 times minimum monthly wages.

Current legal framework in Mongolia not updated in accordance with the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress.

Regulations

LMOs and LMO derived products related **regulations** which are currently operational in Mongolia:

1. General regulation on registration and monitoring of LMOs and their derived food products (2003);
2. Government resolution for border check points for transboundary movements of LMOs (2010);

Regulation on Registration and RA of food and raw materials derived from GMOs developed and on the approval stage. The regulation should be approved by 3 Ministries, currently approved by MET and Ministry of Health and waiting for approval from Ministry of Food, Agriculture and Light Industry.

Institutional Framework

According to Law on LMOs Mongolia has established a National Biosafety Committee (NBC) at the Ministry of Nature & Environment on April 24, 2008 to manage and organize activities regarding biosafety in Mongolia. The Committee will be led by the minister of the Nature and Environment and operates with 19 members from related organizations and with one NBC Secretary.

The NBC will be in charge of transboundary movement of living modified organisms; general requirements on transboundary movement of LMOs and all LMO related activities; border check point for LMOs transboundary movement, production and manufacture of LMOs; risk assessment of living modified organisms; technology confidentiality; to ensure biosafety, use of LMOs, rights and obligations of individuals, business entities or organizations in regard of biosafety and to prevent from damages caused by LMOs; Biosafety funding and finance; professional inspection of LMOs on use and transboundary movement; registration of LMOs; and liability.

Additionally, in the scope of NBC including laboratory biosafety and biosecurity issues in Mongolia.

National Biosafety Committee in order to make professional decision making on risk assessment and management have Scientific Council with 9 members. Scientific council members selected from related professional laboratories, institutes and universities. Till date none risk assessment and risk management has been carried out. Several studies are carried out by research institutions, universities and private sector on LMO development but none of them on risk assessment level yet. Also no request has been submitted to NBC for risk assessment of LMOs from importers and private sector.

Few incidences were registered on illegal introduction into environment of LMOs in Mongolia. Because of the lack of knowledge and awareness about LMOs and biosafety issues in Mongolia, especially in agricultural sector there are many risk probabilities for unintentional introduction of LMOs into the environment. On every incidence NBC worked according to the Law on LMOs.

Four national standards which are translated and developed by NBC and Capacity building for Building Implementation for Mongolia project was approved by Mongolian Agency for Standards and Metrology from 2011 to 2013. These standards were very useful tools for identification and determination of LMOs in Mongolia for all biotech laboratories, especially for General Laboratory of GASI and Laboratory of GCO for reliable and standardized results.

4 national standards are:

1. Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Qualitative nucleic acid based methods MNS ISO 21569: 2011;
2. Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - General requirements and definitions MNS ISO 24276:2013;
3. Foodstuffs – Methods of analysis for detection of genetically modified organisms and derived products – Qualitative nucleic acid based methods MNS ISO 21570:2013;
4. Foodstuffs – Methods of analysis for the detection of genetically modified organisms – Protein based MNS ISO 21572:2013.

Description of processes and practical steps taken

National Biosafety Committee

Mongolia established a National Biosafety Committee at the Ministry of Nature & Environment on April 24, 2008 for purposes of fulfilling its obligations to the agreement, and to manage and organize activities regarding biosafety in Mongolia.

The NBC is led by the Minister of the Environment and consist of 19 non-staff members ensuring the cross-sectoral coordination with all related organizations, such as:

- Ministries of Environment and Tourism;
- Ministry Food, Agriculture and Light Industry;
- Ministry of Health;
- Ministry of Foreign Affairs;
- Ministry of Education, Culture, Science and Sports;
- General Agency for Specialized Investigation;
- General Customs Administration;
- General Intelligence Agency;
- National Emergency Management Agency;
- National Centre for Zoonotic Diseases;
- National Centre for Communicable Disease;
- Public Health Center;
- Food Safety Council;
- Representatives from related scientific organizations;
- NGOs representatives.

The committee's membership was updated due to Government structure change by Environmental Ministerial Order A-27 of the Minister of Environment and Tourism, also on August 31, 2010 and membership again updated by Order A-03 of the Minister of Environment and Green Development on January 3, 2013.

Since establishment National Biosafety Committee (NBC) has met 11 times in total, discussing and developing recommendations over on 40 biosafety issues.

In addition to this, the government has fostered local research and development in biosafety and biotechnology, which has led to start the generation of local expertise.

Through Capacity Building for Biosafety Implementation for Mongolia project (UNEP-GEF) NBC developed and implemented capacity building program for related and targeted stakeholders. The capacity building program contributed mainstreaming biosafety into policy and implementation level in Mongolia and also helped for awareness raising of the general public. For example, the capacity of custom officers and GASI inspectors has been strengthened through previous GEF-UNEP project with basic training and sensitization activities on biosafety and the Cartagena Protocol, although capacity building for customs officers is still needed in order to apply biosafety measures such as sampling of imports, detection, etc.

By subscription of National Biosafety Committee, the Mongolian Biotechnology Association (NGO) conducted assessment of laboratory biosafety level which are operating in the field of molecular biology, genetics, microbiology, pharmaceuticals, bio-supplements and biotechnology in 2011 and 2014 from State budget.

4 ISO standards for detection of LMOs and derived products have approved from Government and project funding from 2011 to 2013.

In January 26, 2012 Mongolia signed and in 21 May, 2013 Mongolia has ratified the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

By subscription of National Biosafety Committee, the Mongolian Biotechnology Association (NGO) and Mongolian Academy of Science conducted a research & monitoring project to determine whether food and feed crops in selected agricultural area contain any transferred genes or LMOs in 2013-2014. The project funded from State budget. To register the identified LMOs to database and do monitoring, other activities according to related Laws. This activity led for a next step cooperation with NBC and MFALI further according to National biosafety action plan. Database currently don't have open access to the public only open for Governmental and research organizations.

Capacity Building for Biosafety Implementation project

From 2002-2005, Mongolia successfully completed a draft NBF under the UNEP/GEF funded global project on "Development of National Biosafety Frameworks". The project GEF/2716-02-4527 entitled "Development of the National Biosafety Framework" financed by the GEF.

While Mongolia has approved laws and procedures regarding LMOs and established a Governmental unit to ensure biosafety under the Ministry of Environment and Tourism, limited capacity for LMOs derived using genetic engineering has led to the further implementation of the medium level project for "Capacity building for Building Implementation for Mongolia" jointly organized by GEF, UNEP and Government of Mongolia from May 01, 2011 to April 30, 2014.

This capacity building project provided the initial capacity foundation of Biosafety in Mongolia. Through trainings, workshops and seminars gave general understanding of NBF, LMOs and possible transboundary movements of LMOs to the general public, decision makers, related officials and experts and NGOs etc. Through Capacity building for Building Implementation for Mongolia project cross sectoral stakeholders started to understand biosafety issues in Mongolia and started to contribute in their respective sector at the policy and implementation level. By Capacity building for Building Implementation for Mongolia project Mongolia developed short and long term biosafety strategy and action plan together with all related stakeholders. The draft of Biosafety National Program (biosafety national action plan) was developed through Capacity building for Building Implementation for Mongolia project.

Phase II project for Capacity building for Biosafety Implementation for Mongolia's preparation is currently underway.

Capacity building activities



Despite NBC official meetings about 30 national workshop, training and seminars were organized so far: for decision makers; for inspectors of customs and state specialized inspection agency; for officers of MEGD, MFALI, AFCCP and NUSPCR; for experts from universities and research institutes; for journalists and for representatives of GO and NGO etc.

Two high level meeting was organized by NBC together with Capacity building for Building Implementation for Mongolia project.

A “Biosafety and modern biotechnology” high level meeting was held from March 23-24, 2012 together with Parliament Secretariat, Parliamentary Standing Committee on Environment, Food & Agriculture, Parliament Research Center and a total of 35 advisors, specialists, and researchers. Main goal of the high level meeting was to introduce modern biotechnology, living modified organisms, their uses, socioeconomic trends, biosafety issues, Convention on biological diversity, Cartagena Protocol on Biosafety and the activities of the National Biosafety Committee to the decision makers. This discussion meeting has led to necessity for development of Biosafety action plan in Mongolia.

A “Food and feed safety” discussion which was held at the Parliament House on October 17, 2012 organized by the Parliamentary Standing Committees on Environment, Food & Agriculture and Social Policy, Security and Foreign Policy together with the MFALI, UNFP, MEGD, National Biosafety Committee, and Project for “Capacity Building for Biosafety Implementation”. The topics discussed were food safety policies; the legal environment; production in Mongolia, present day food supply and its current and future trends and problems, the current situation and future goals concerning of food and food disorders in Mongolia; world malnutrition, international experiences in combating malnutrition; food safety and risk assessment and analysis; modern biotechnology and living modified organisms; current status and challenges facing biosafety; breakthroughs in genetic engineering; positive and negatives of living modified organisms; standardization of nanotechnology and Nano safety; biosafety legal environment and urgent need of necessary regulations. This discussion has led to the mainstreaming biosafety into approval and renewal of Law on Food and Law on Food safety by Parliament of Mongolia on 20th December, 2012.

First National Training on risk assessment and risk management of LMOs



First national LMO detection and verification training was organized from 30 October to 02 November 2012 in Ulaanbaatar, Mongolia. The training session was organized by the Institute of Molecular and LMO detection laboratory, General and Experimental Biology, Mongolian Academy of Science together with Dr Dmitrii Dorokov, an expert at Centre for Bioengineering, Russian Academy of Science. A total of 45 researchers and specialists from the PHC, NCZD, MSUA, MUST, MAS, GASI, GCA, Institute of Plant & Agriculture, Monchemo LLC, AFCCP and Consumer Rights Protection Union.

Through this training research organizations and private laboratories are mainstreamed in biosafety issues in the world & in Mongolia, also in internationally recognized main methods for detection of LMOs.

11th Asia Regional Capacity-building Workshop for National Managers of Biosafety Projects



From July 1-5, 2013 the 11th National coordinators workshop was organized including representatives from Capacity building projects for Biosafety in the Asian region in Ulaanbaatar, Mongolia in order to share good practices and exchanging information on achievements, issues faced and mechanisms for ensuring biosafety concerning living organisms derived using genetic engineering.

With a unique and fragile biodiversity adapted to an extreme climate it Mongolia was an important milestone as the country is putting great emphasis on biosafety activities and taking precautionary measures against risks from LMOs to human health, environment and national socioeconomic factors. It was good opportunity to introduce current biosafety situation in Mongolia to the countries in Asian region and to share difficulties and experience related with Biosafety implementation in Mongolia. This five-day consultative meeting was organized by the UNEP-GEF Biosafety team, Mongolian Government, and the National Biosafety Committee, with representatives from Bhutan, Laos, Cambodia, Mongolia, Indonesia, Bangladesh, Tajikistan, Malaysia, and India.

Mongolian biosafety team learned a different kind of strategies and tools for mainstreaming biosafety into NBF from countries in the Asian region through this workshop.

Asia Regional Capacity-building Workshop on Mainstreaming Biosafety into National Biodiversity Strategies and Action Plans and Resource Mobilization

The Asia Regional Capacity-building Workshop on “Mainstreaming Biosafety into National Biodiversity Strategies and Action Plans and Resource Mobilization” was held from February 9-13, 2015 in Ulaanbaatar.

The aim of the workshop was to improve coordination in the National Biodiversity Strategic Action Plan, providing leadership to human and financial resources, and capacity building.

The workshop funded by Japanese Government, the workshop was jointly organized by the Secretariat of the Convention on Biological Diversity, Ministry of Environment, Green Development and Tourism of Mongolia and National Biosafety Committee, with participation from representatives from 16 countries from Asian region (Bhutan, Cambodia, India, Iran, China, Laos, Malaysia, Moldova, Mongolia, Philippines, Pakistan, South Korea, Sri-Lanka, Thailand, Vietnam, Nepal), who set out to identify tools, strategies and opportunities for improving methods for protecting biodiversity and ensuring biosafety by incorporating biosafety measures in national strategies for biodiversity and its implementation plan.

Mongolia introduced main steps on mainstreaming biosafety into National Biodiversity Strategies and Action Plan and also learned from other countries experiences, especially in resource mobilization.

Mainstreaming Biosafety National Program to National Biodiversity Strategic Action Plan (NBSAP)

By 2014 National Biosafety Committee together with Capacity Building for Biosafety Implementation project developed the draft National Biosafety Program and it was on approval stage by Mongolian Government. But just before Government of Mongolia assessed all National Programs in Mongolia which are implemented at that period and revealed that most of the National Program implementation were insufficient. Government of Mongolia decided to combine some related National Programs into one in order to sufficiently use funds and human resources. After this decision at the Ministerial (MET) level it was decided to mainstream draft National Biosafety Program into the National Biodiversity Strategies and Action Plan. NBC and MET officials with related stakeholders are officially agreed on mainstreaming biosafety issues into NBSAP by NBC meeting. The working group was organized from all related stakeholders for mainstreaming Biosafety into NBSAP and work on approval of NBSAP. Mongolian NBSAP approved on 4th August, 2015. Biosafety issues are mainstreamed under the **Goal 3: Create a legal environment for the protection, sustainable use and fair and equitable sharing of benefits arising from**

widely used economically significant genetic resources and to implement sustainable use, and protection from genetic erosion and depletion of the Mongolian NBSAP.

Biosafety funding mechanism is mainstreamed Biodiversity resource mobilization. But there is still need to expand NBC structure by human resources by already gained experts & administration staff. Currently NBC funding source is only state budget. But along with the mainstreamed Biodiversity resource mobilization Government contribution expected to increase and also can raise and propose project funding from donor organizations.

There are also laboratories, institutes and universities who are receiving government grants on LMO development or LMOs monitoring activities every year from State budget, MET or Science & Technology funds, for example on development of drought and pest tolerant tree species, evergreen grass – LMO development experiments, regular monitoring activities of LMOs and its derived products by professional institution, experts by subscription NBC and MET etc.

General Agency for Specialized Inspection is also have annual budget for monitoring of LMOs according to the Law on LMOs.

Activities for Technical Capacity Improvement

Determining transferred genes using molecular biology and genetic engineering methods and performing risk assessment is a basic requirement for ensuring biosafety. In Mongolia's case, the level of activity in molecular biology and genetic engineering is not yet at the level of developed countries, but some basic research is still being conducted.

An example is the Molecular Biology Laboratory at the General and Experimental Biology Institute, Mongolian Academy of Science. The laboratory was first established in 1983 as the Molecular Genetics laboratory, changing its name to its current form from 1988. Research performed here since its inception over 30 years ago include liver cancer, molecular biological research on viruses that cause liver cancer, diagnosis, vaccines, mitochondrial DNA and Y chromosome analysis of Mongolian populations, molecular biological research of Mongolian horses and wild horses (Przewalski's horse), cancer inducing genes among the Mongolian population, using molecular biology techniques in biology and medicine, molecular biological research of hepatitis viruses and cancers, biotechnological studies on some species of plants, molecular factors in developing cancer, molecular mechanisms for developing liver cancer, cell culturing of plant-derived biologically active compounds, impacts to gene expression dynamics, and studies of molecular mechanisms of some substances to cancer cell culture methods. The laboratory contains a cell base of over 30 stable eukaryotic cells grown in vitro, a highly skilled, experienced expert staff, and considerable cooperation with international research organizations.



The project for “Capacity Building for Biosafety Implementation” jointly implemented by GEF, UNEP, and the Mongolian government determined that the laboratory had adequate technical and human resources for LMO detection and risk assessment, and established a LMO detection laboratory for technical capacity improvement. Laboratory equipment, additional substances and reagents were obtained with a total expenditure of 46,500 USD from the Capacity Building for Biosafety Implementation project. This LMO detection laboratory has been working in cooperation with the National Biosafety Committee in detecting transferred genes for necessary samples.

Description of the major challenges/difficulties encountered and the lessons learnt in mainstreaming biosafety

Lessons learnt

Despite many capacity building activities and efforts by NBC and related projects there are still lack of understanding and knowledge about biosafety issues at the policy and implementation level in Mongolia. Regular meetings, workshops and trainings for officials especially at the policy levels are very important for mainstreaming biosafety in Mongolia.

Following two studies which are carried out by NBC together with GASI and Mongolian Biotechnological Association are the good examples of capacity building of the human resource on the site and mainstreaming biosafety into Inspection agency and research organization.

Studies on labelling of LMO derived food products were conducted (2010) by National Biosafety Committee, together with the General Agency for State Inspection named “Study and inspection on the labelling of LMO derived food products” assessing the implementation of the “Law on Living Modified Organisms” (2007).

With direction from the inspection guidelines established by the General Agency for State Inspection, the study was performed on 162 imported foodstuffs of 6 types (chocolate, coffee milk, vegetable oil, nuts, ham, and instant noodles) that were suspected of having ingredients derived from LMOs at Nomin, Tenger, Urbanik, and Sky wholesale shopping centers. The results were:

1. Though the study only comprised 162 foodstuffs of 6 categories, only 13 or 8% had special markings, with over 60% of the other foods having a high likelihood of having ingredients derived from LMOs (based on soy & corn ingredients).
2. Organizing public awareness activities to store owners and customers, and monitoring implementation of legislation regarding foodstuffs and raw ingredients that may derive from LMOs is very important and these activities should be strengthened in the future (including Law on Food (2012), Law on Food safety (2012) & Law on LMOs (2007)). Some imported foodstuffs have labels in uncommon languages, hindering customers from gaining useful information from them. Therefore, implementing and strengthening various monitoring activities regarding LMOs and its derived products should be a high priority.

In recent years, oil and animal feed crops, namely rapeseed, corn, alfalfa, soy, and oat have been grown to a larger scale in Mongolian agricultural areas like Tuv, Selenge, Bulgan, and Darkhan-Uul provinces.

A research project (2013-2014) to determine whether food and animal feed crops contain transferred genes was jointly carried out by the Mongolian Biotechnology Association NGO and Laboratory of Molecular Biology, Institute of General and Experimental Biology, Mongolian Academy of Sciences. The results showed from 53 samples (agricultural plants) studied in the laboratory 11 samples or 20.8% were plants with transferred genes.

Organizing international workshops on Biosafety like

- 11th Asia Regional Capacity-building Workshop for National Managers of Biosafety Projects;

- Asia Regional Capacity-building Workshop on Mainstreaming Biosafety into National Biodiversity Strategies and Action Plans and Resource Mobilization

in Mongolia was very useful for sharing different countries' real experiences and challenges on mainstreaming biosafety into NBF.

Mongolian decision makers always think that biosafety is not the priority issue in Mongolia, by regular national and international activities on biosafety Mongolian team should further work to change the altitude of the decision makers.

Major challenges

In last few years Mongolia is facing severe economic difficulties. Significant cuts in the sectoral expenditures in which MET is included. That's why Mongolia still has very limited capacity and insufficient funding to implement this Law on LMOs.

In order to fully operationalize Law on LMOs, related Laws and supporting regulations/rules there is urgent need for sustainability of National Biosafety Committee (only one staff, but still under question, also in charge of other issues – NBC secretary).

Followings are the major challenges on biosafety in Mongolia:

There is no single accountability provision concerning living modified organisms in the Criminal Code which entered into force from July 1, 2017. Also because renewed Law on Secrecy of Civil Service - Law on LMOs updated accordingly in Dec 01, 2016 & entered into force Sep 01, 2017.

Insufficient capacities for detection, monitoring and risk assessment of LMOs

- Lack of capacity to detect, identify and evaluate possible adverse impacts from LMOs in a timely manner (i.e. before impacts are widespread or severe)
- Lack of monitoring and surveillance capacity to enforce national regulations in relation to LMOs, in particular in the field and at custom level; In addition, Mongolia have only partial technical capacity to detect LMOs, and LMOs (only one official laboratory) could enter the country without detection and prior risk assessment;
- Due to the lack of appropriate laboratories and monitoring systems and to perform any safety assessment on modern biotechnology applications, it is difficult to obtain data on adverse effects associated to LMOs;
- the risk analysis of LMOs is based only in expert criteria and a small amount of studies conducted by scientific institutions in the country especially when agricultural sector is very well developing in the country and there is no sufficient monitoring system of LMOs;
- Limited financial resources for capacity building in monitoring and surveillance;
- Although customs and GASI personnel have been sensitized on biosafety, there is no technical capacity or systems at customs or at GASI to actually manage biosafety issues. For instance, there are no procedures on how to take neither samples nor the necessary equipment and customs laboratory staffs didn't have related adequate trainings;

- Need for establishing national digital database on LMOs & derived products and immediate registration of additional products and raw materials used in food & pharmaceutical sector;

Lack of information and understanding regarding the economic, legal and social impacts of LMOs

- Most of the private sector representatives are not informed and don't have any understanding about biosafety and LMOs. Capacity to handle, transporting, packaging & identification of LMOs needs strengthening and overall whole biosafety management system in Mongolia should be operationalized;
- Public awareness, participation and decision making procedures should be improved because most of the decision makers have no understanding about biosafety and if some of them have they think biosafety issues are not priority issue in Mongolia and also public doesn't have enough knowledge and understanding about biosafety issues;
- Socio-economic impacts are not considered in LMO decision-making, which is mainly guided so far by scientific risk assessment;
- Limited knowledge on possible implications of the use of GMOs on local communities;
- Lack of technical parameters to measure the economic and social damage caused by LMOs;
- Baseline out of date (Diversity in crops that have been modified by modern biotechnology, related species existing in Mongolia, its use in the economy and culture, etc.);
- Absence of a common position among the authorities on whether or not socio-economic conditions are important for LMO decision-making, even though the CPB calls for it on article 26;
- Lack of knowledge and information on the staff of the authorities on how to address the socio-economic related issues;
- Lack of public awareness activities for the general public on LMOs and its derived products.

Recommendations

Concerning the legal framework:

- To do Policy Legal Review of the related laws, regulations and to determine gaps and urgent missing legal tools for mainstreaming biosafety in Mongolia, updating relevant Laws, approving necessary regulations and standards accordingly including financial resources;
- Biosafety issues already integrated to NBSAP but should be regularly reflected (included) to State budget and further should be integrated to the Development policies like Sustainable Development Policy and Green Development Policy as one of the indicators;

Concerning institutional framework:

- NBC sustainability is essential, at least 2 permanent staffs should be working at the NBC and to develop for better cross-sectoral coordination tools for mainstreaming biosafety in Mongolia;
- Regular funding should be secured annually for NBC activities in order to implement activities stated in the Mongolian NBSAP;

- To create an initiative together with MFALI on LMOs in agricultural sector for food & feed crops. It is important to reflect LMOs issues in agricultural policy and planning for crop cultivation by obtaining samples from agricultural lands with unregistered oil and animal feed crops possibly containing transferred genes and that have not undergone risk assessment, subjecting them to tests, and determine if transferred genes are present as stated in the Law on LMOs, Law on Food and Law on Food Safety;
- Urgent need for further technical assistance or capacity building project from donor organizations in order to retain existing capacity & human resource;

Concerning registration and monitoring of oil and animal feed crops:

- Perform medium to long term planning and monitor implementation of this planning of oil crops and other crops with transferred genes that may be hazardous to the surrounding environment and soil fertility;
- Develop a more efficient, productive precautionary monitoring and registering framework. Economic entities should switch to a framework to conduct experiments and verify crop seeds in advance of planting;
- A unified informational database on registration and monitoring should be developed in order to cut costs on planning and monitoring, especially for inspectors from GASI & customs;

Concerning transferred genes in oil and animal feed crops:

- In order to ensure biosafety and identify effects of genetically modified plants on the environment, risk assessment to human health and environment must be performed on oil and animal feed crops found to have transferred genes by monitoring or study;
- Agricultural seeds should be examined for transferred genes before the planting season each year by a newly established or existing system, the multi-year results of which can be used for determining policy development in environmental and agricultural sector;
- National Biosafety Committee should organize more public awareness activities on biosafety and LMOs in order to mainstream biosafety issues for decision makers, farmers, private business owners, and local experts on agriculture and also general public;
- Herbarium and samples collected during the study, DNA sample materials, detailed depictions of geograPHCc location, hereditary information on genetically modified plants, and genomes should be stored and preserved in the national gene bank using relevant methods. The genetic resources preserved in the gene bank should be accessible by research organizations, biotechnology and agricultural enterprises, and other economic entities;
- Identification, registration and risk assessment of LMOs should be organized and performed in agricultural areas like Zavkhan, Khovd, Khalkh river basin in Dornod province, all other emerging areas in agriculture.

Conclusion

Policy and Laws

Law on LMOs approved in 2007 by Mongolian Parliament. Law on LMOs

National Security Concept updated in 2010, biosafety issues mainstreamed and included.

Mongolia have National Biosafety Framework in place. Biosafety issues are mainstreamed in agricultural sector into Law on Food and Law on Food Safety in 2012.

Biosafety national action plan are included into Mongolian NBSAP which was approved in 2015 by Mongolian Government.

But due to other new law approval and related Law updates like Criminal Code of Mongolia and the Law of Mongolia on Violations - the Law on Living Modified Organisms was updated by the parliament on December 04, 2015 and also renewal Law on Secrecy of Civil Service - Law on LMOs updated accordingly in Dec 01, 2016 & entered into force Sep 01, 2017.

Even though legal responsibilities in the laws enforced in Mongolia have been improved through amendment, there is need to make additional changes as required to liabilities of the operators in the Nagoya-Kuala Lumpur protocol are subject to, so that making it better adaptable to different circumstances.

As per the Law on Living Modified Organisms as well as the Law on Violations, individuals, businesses and legal entities which produced living modified organisms are subject to certain liabilities and responsibilities. There should be detailed legal regulations clearly specifying involvement of the operators, in which operators' liabilities should vary depending on their involvement to damages caused. Moreover, both the law and the protocol specified to "compensate for necessary measures to redress the damage", however, it is still unclear how to estimate amount of the compensation and how to tackle interdependent and harmful relation which was stated in the Civil law.

Legal framework in Mongolia not yet updated in accordance with the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress.

Institutional arrangement

Mongolia have NBF in place but still lack at implementation stage because of insufficient financing, lack of human resource, training absence and necessary equipment etc. But Mongolia have only one acting (permanent) staff member – Secretary of NBC and all others are non-staff members. NBC funding only from State budget and its insufficient, there is need to increase possible financial sources. Due to budget cut from 2015 NBC secretary is in charge of other environmental issues beside biosafety.

NBC is good example of the sectoral & cross-sectoral cooperation in Mongolia. Through NBC members the biosafety issues are successfully mainstreamed into sectoral & cross-sectoral legislations and policy.

Due to country economic situation Mongolian Government is reducing its structure and budget for all sector including biosafety. There is urgent need to sustain existing capacity, human resources and

maintain the NBC. Also biosafety activities within the NBSAP should be reflected annually in the state budget.

NBC couldn't organize the committee meeting since January 2016 because of uncertainty of NBC legal position and lack of financing, only in September 2018 NBC could organize the regular meeting about current biosafety situation in Mongolia to the committee members. Also most of the NBC members are renewed because of the staff change in Government organization, generally due to elections.

Therefore, the next phase of the Capacity Building Biosafety Implementation for Mongolia project or any other related project or program funded by donor organizations is necessary. Draft project proposal already drafted and going at the submission level at the UNEP. By these activities Mongolia can upscale biosafety issues to the next level and to increase public awareness on biosafety issues, also bring decision makers' attention on biosafety, biodiversity and science innovation.

Necessary further steps

Maintain NBC as stated in Law on LMOs and ensure sustainable activities by Minister of Environment & Tourism. Update Law on LMOs and related Laws and approve regulations and standards to ensure fully functional NBF in Mongolia, especially related with the cross sectoral policies/Laws.

Revision, assessment and mainstreaming possibilities of NBC structure and function against newly approved Development policies and strategies of Mongolia (Sustainable and Green Development Policies). Strengthen the cross sectoral cooperation through regular NBC meeting to keep NBC members updated and well informed about current biosafety situation in Mongolia and through improved management tools. Increase civil society organization participation in biosafety activities.

To develop suitable tools for mainstreaming biosafety into cross sectoral legislation and policy. Regularly organize public awareness activities for decision makers and general public.

Increase regional networking and cooperation on biosafety through BCH, Asian Biosafety Framework and through other tools.

To find external donor funding for Biosafety activities like capacity building, technical support, public awareness, risk assessment & risk management of LMOs, liability & redress, socio-economic consideration and decision making etc.

To organize monitoring activities agricultural sector for crops like rapeseed etc. and to work on awareness raising activities for private sector.

Also to establish and apply appropriate rules and procedures on liability and redress for damage resulting from the transboundary movements of living modified organisms, in accordance with the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress in Mongolia.

There urgent need to implement activities like:

- Analysis of existing national policies, laws and institutional mechanisms to determine how they address or could address the requirements of the Supplementary Protocol;
- Establishment of new, or amendment of existing, domestic legal and administrative frameworks to implement the requirements of the Supplementary Protocol;

- Development of guidance to assist competent authorities in discharging their responsibilities under the Supplementary Protocol;
- Organization of training activities to strengthen the scientific and technical capacity of the competent authorities to be able to evaluate damage, establish causal links and determine appropriate response measures;
- Establishment of databases and knowledge management systems to facilitate the establishment of baselines and monitoring of the status of biodiversity at genetic, species and ecosystem levels;
- Strengthening national capacity to provide for administrative or judicial review of decisions on response measures to be taken by the operator in accordance with Article 5.6 of the Supplementary Protocol.

Entry points for biosafety mainstreaming

Possible entry points for biosafety mainstreaming in Mongolia:

- Integrating and mainstreaming biosafety into country's development policies like Sustainable and Green Development;
- Law on the Environment;
- Customs and trade policy;
- General Agency for Specialized Inspection;
- Criminal Law;
- Options for establishing or strengthening national inter-sectoral coordination mechanisms to facilitate a coordinated approach to the implementation of the Convention and the Protocol;
- Implementation of the Supplementary Protocol and integration of its provisions into existing regimes concerning liability and redress;

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