

**CBD/CPB/UNEP
Ministry of Environment of the Republic of Moldova
Biosafety Office**

CBD/UNEP Project „Capacity –building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention of Biological Diversity at the national level”

**Republic of Moldova:
Final report desk study
on mainstreaming biosafety at national level**

Chisinau, 2016

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Abbreviations

AIPA	Investment and Agriculture Payment Agency
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CIS	Commonwealth of Independent States
CE	Council of Europe
CAPMU	Consolidated Agricultural Projects Implementation Unit
CPB	Cartagena protocol on Biosafety
CS	Custom Service
DCFTA	Deep and Comprehensive Free Trade Agreement
DDT	Dichlorodiphenyltrichloroethane
DRPC	Danube River Protection Convention
EC	European Community
EU	European Union
GD	Governmental Decision
GMO	Genetically Modified Organisms
GMMs	Genetically Modified Microorganisms
LMOs	Living Modified Organisms
LPA	Local Public Administration
MAFI	Ministry of Agriculture and Food Industry
ME	Ministry of Economy
MH	Ministry of Health
MoE	Ministry of Environment
NBC	National Bio-safety Committee
NBSAP	National Biodiversity Strategy and Action Plan
NCB	National Commission on Biosafety
OECD	Organisation for Economic Cooperation and Development
PD	Parliament Decision
PPP	Polluter Pays Principle
RASFF	Rapid Alert System for Food and Feed
RM	Republic of Moldova

Introduction

The CBD/UNEP Project “Capacity building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level” was implemented in the Republic of Moldova by the Ministry of Environment with support of the Biosecurity Office. The overall aim of the project is strengthening the capacity of the country to develop and test practical measures to promote integrated implementation of the Cartagena Protocol on Biosafety (CPB) and the Convention on Biological Diversity (CBD). In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans boundary movements.

This project was implemented simultaneous in 10 countries party at the Cartagena Protocol on Biosafety. Within each country project, seeks to facilitate the integration of biosafety into national biodiversity strategies and action plans (NBSAPs) and other sectorial and cross-sectorial policies, plans and programs and strengthen national inter-sectorial coordination mechanisms.

According the project requirements there is necessary to implement the following activities:

- analyse its existing national policies, strategies and activities relevant to biosafety,
- identify practical steps taken to integrate biosafety into NBSAPs and promote integrated implementation of the Cartagena Protocol and the Convention at the national level,
- document national experiences, good practices and lessons learned, and
- organize cross-sectorial meetings as well as awareness-raising activities for relevant policy makers, decision-makers and other key stakeholders.

The desk study has been developed based on analysis of actual status of implementation of Cartagena Protocol on Biosafety (CPB) in the RM, with a special focus paid to national sectors: (a) environmental protection, (b) agriculture and food processing, (c) health care, (d) trade, custom service, (e) consumer protection and public information. The main purpose of the study was to identify on what extent the objectives of biosafety are integrated in national policy and legislative framework, what is the institutional and administrative set up, existing mechanism for mainstreaming the biosafety, etc..

The desk study analysis was provided involving an overview of total number of 12 political documents and 24 legal and regulatory documents.

Results and findings of the desk study have been presented and discussed in a round table that was organized at 15 July 2016. The proposals and recommendations identified in the round table meeting were referring mostly to following type of activities as:

- improvement of the political framework,
- improvement of legal framework,
- measures for administrative/institutional framework.
- Improving coordination mechanisms.

The final desk study report and recommendations have been submitted to the sectorial authorities and stakeholders for further actions of mainstreaming biosafety at sectorial level.

A public information and awareness seminar organised for various stakeholders from governmental and non-governmental sectors to improve public consultation and participation in decision making.

1. Current state of Cartagena Protocol implementation

The Republic of Moldova has ratified the Convention on Biological Diversity in 1995, which refers to the conservation of the biodiversity, sustainable use of its elements and just and fair sharing of benefits that result from the use of genetic resources and access to these resources, taking into account all rights on the respective resources and thanks to an appropriate financing for the biodiversity conservation measures.

A framework convention, the *Convention on Biological Diversity* (CBD) provides only for general conservation and sustainable use measures, for the implementation of which it is necessary to develop strategies, national plans or programs or adapt those already in place, alongside the integration of conservation and sustainable use of biodiversity in the relevant sector or inter-sector plans, programs and policies, including biosafety mechanism.

The *Cartagena Protocol of the Convention on Biological Diversity* was signed by the Republic of Moldova as an integral part of the Convention on Biological Diversity at New York on 14 February 2001 and ratified by Law no. 1381-XV of 11 October 2002. The objective of the Protocol is to contribute to implementation of an adequate level of protection to ensure safe transfer, manipulation and use of Living Modified Organisms (LMOs) produced by modern biotechnology, which might have adverse effects upon conservation and sustainable use of biological diversity, with consideration of the risks for human health.

Genetically modified organisms can affect the natural ecosystems' biodiversity of The Republic of Moldova and is a potential threat for the ecosystems' stability. The risk of illicit penetration of genetically modified organisms into Moldova is quite high. The GMOs have already been found in agro-food products of soy-beans and corn. The assurance of an efficient biosecurity system, in line with international requirements, needs a continuous development of institutional capacities for preventing adverse risks on sustainable development of biological resources and human health.

The *National Biosafety Law*, that was adopted in 2001 covers all types of LMOs uses, including contained use, conditions for import/export of LMOs, special emphasis on trans boundary movement of LMOs, requirements regarding the packaging and labelling.

The provisions of mentioned law are applied for activities related to:

- Obtaining, multiplying, testing and use in isolate conditions with different purposes of microorganisms, plants and animals genetically modified through modern biotechnology technics;

- Deliberate introduction in the environment and on the market of GMOs including of each live structure which is able to reproduce a new organism as seeds, bulbs, cuttings, pollen, spores, etc.;
- Unintentional release into environment of GMOs;
- All kind of researches with GMOs, including laboratory researches, clinical, in the field, as production experiments;
- Deliberate operations of import/export with GMOs and with products resulted from this kind of organisms;
- Unintentional transboundary transportation of GMOs;
- Storage, burial, liquidation of GMOs and /or of products resulted from this kind of organisms, use of waste resulted from modern biotechnological technics.

In order to assess potential dangers for human health and the environment generated by activities regulated by the Law, a range of risk classes are specified for isolated systems of GMOs:

- Class I: Activities with negligible risks comparable to the risk of using non-pathogenic microorganisms, or without any risk;
- Class II: Activities with low risks comparable to the risk of using conventional pathogenic microorganisms;
- Class III: Activities with moderate risks comparable to the risk of using microorganisms potentially capable to spread infections;
- Class IV: Activities with grave risks comparable to the risk of using microorganisms capable to spread very dangerous infections.

Also, this law has provisions on labelling of products introduced on the market. Label shall include the words „This product contains genetically modified organisms”, which are obligatory both on the label and in accompanying documents. This law also is mentioning that the National Commission on Biosafety decides what competent public authority or scientifically institution shall do the risk evaluation. According the law, labelling is obligatory in cases when the contents of GMOs in the product is no less than 1%, and for seeds - 0,3% of the total product weight.

The imports/exports procedure provided by the Bio-safety Law is similar to the basic provisions of the Cartagena Protocol on Bio-safety, including the advance informed agreement procedure, the notification, acknowledgement of receipt and the decision making procedure.

A Risk assessment procedure is required in all procedures and must be based on two principles: scientific sound character and transparency. Risk assessment is performed by public authorities or scientific institutions selected by the Committee and paid for by the notifier.

The Law characterizes the risk assessment as an estimation of direct and indirect immediate and long-term consequences for the environment and human health of the release into the environment of GMOs or their components. Furthermore, it details risk management tasks, the development and application of comprehensive measures to monitor risks and emergency measures to be taken in the case of an accident.

The Law provides special rules for simplified procedures where a GMO is permitted for use in the EU. Article 19 (7) of the Law foresees that, in order to facilitate decision making for the deliberate release of GMOs that have already been notified and/or approved by an EU Member State or a member of the OECD, the notifier should submit to the NBC copies of the notification and the approving document to be eligible for the simplified authorization procedures. To ensure

transparency of the NBC activities, a special procedure on consultations with the public is provided for in the Biosafety law.

Since becoming party to the protocol, Moldova started to improve its legal framework for biosafety being developed national laws, regulations and guidelines related to biosafety, that have been made accessible also on the *Biosafety Clearing House platform*. Thus, some regulations have been developed in order to facilitate implementation of the Law on biosafety, as follows:

1) *Regulation on information, consultation and decision making in the field of GMO*, approved by the Ministry of Ecology ORDER no. 19 from 10.02.2004.

2) *Regulation on authorization of activities related to obtaining, testing, use and marketing of GMOs*, approved by GD no. 839 of 9.07.2008.

For example, the *Regulation on authorization of activities related to obtaining, testing, use and commercialization of GMOs*, adopted by the Governmental Decision Nr.1153 of 2003, stipulates the mechanism of authorization issue and cancellation in the following cases: (a) if the data presented for authorization are not in compliance with the reality; (b) if notifier does not respect the conditions stipulated in the domestic legislation and in authorization; (b) in case of heavy accident produced, for which a holder of authorization bears responsibility. At the same time, there are no specific stipulations in Moldovan regulation that establish mechanism for review of authorizations and decisions. The Regulation on authorization for the activities related to obtaining, testing, use and commercialization of LMOs, requires the elaboration of Action Plan of Emergency measures in case of accidents, including the methods and procedures for control of LMOs, methods of decontamination of affected zones, methods of GMOs elimination, isolation of affected zones, plans of human health and environment protection.

Other regulatory document is *Regulation on public information in the field of GMOs and public participation in decision-making process* that stipulates requirements to information which should be presented to broad public during the consultation process. At the same time, regulation has provisions that information that has to be presented to public should not be considered confidential. Up to now, there are no specific mechanisms elaborated to protect the confidential information regarding LMOS.

Following there will be characterized the new *Law on genetically modified organisms* that was approved by the Government of the Republic of Moldova on 30.03.2016.

In 2003, the Ministry of Environment was appointed as *National Competent Authority for Biosafety*. This decision was taken by the Governmental Decision No.197 of 2003. In the ministry was established a *Division of Natural Resources and Biodiversity* that is responsible for the biosecurity issues as well. At the same time, by Governmental Decision No.603 of 2003 was established the *National Biosafety Committee* as an intergovernmental body responsible for examination of notifications for GMOs.

It is also important to mention that additional protocol to the *Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Protocol on Liability and Redress* was signed by Moldova on 25 January 2012. The main objective of the additional Protocol Nagoya-Kuala Lumpur is to

contribute to the conservation and sustainable use of biological diversity, also taking into account risks to human health, by providing rules and procedures on international liability and redress for damage related to living modified organisms. Actually, the Nagoya Protocol is under the ratification procedure.

Example: In the context of the desk study report is relevant to mention that in 2015 (29 January) Republic of Moldova approved the import/use of the LMOs of soybean of several types, as:

- MON-89788-1 (resistant to herbicides glyphosate);
- MON-877 Ø 1-2 (resistant to diseases and pests –insects Lepidoptera);
- MON-Ø4 Ø32-6 (resistant to herbicides glyphosate).

The decision was taken for import/use of LMOs, especially for their direct use as feed for poultry farming, approval was conditioned – permit issued for a period of 6 months. As protocol requires, this information was placed on the BCH platform.

The basic national information on Biosafety is submitted via Biosafety Clearing House. It contains contact details, domestic regulations in the field of biosafety, institutional setting-ups, and publications. The National website on BCH www.biosafety.md is elaborated and available for the governmental decision makers and public. The following information is placed via the Biosafety Clearing-House:

1. Detailed contact information for authorized competent national authority and sectorial national bodies;
2. National Focal points for CP, BCH and Emergency situation, as well as coordination centers and individuals to be contacted in the case of emergency;
3. The national regulation in the field of Biosafety;
4. Publications on national language in the field of biosafety;
5. Capacity building (Biosafety projects);
6. Country needs and priorities;
7. Roster of national experts in the field of Biosafety.

Control and monitoring of LMOs activities are the duties of the *Ministry of Environment, Ministry of Health and Ministry of Agriculture, National Biosafety Committee* and specialized inspectorates. It is required that during notification, the Monitoring and Management Plan and Emergency measures should be provided by notifier. At the same time, there is no practical experience in conducting the risk management of LMOs in Moldova so far.

Also, for case of braking legal provisions related to proper management of the GMOs, there have been developed and submitted amendments to the Legal Code on administrative contravention that refers to economic entities and also to physical persons.

Draft Law on Genetically Modified Organisms

The draft Law on genetically modified organisms is developed in order to fulfil the provisions of the art. 172, point 2 of the *Association Agreement between the Republic of Moldova and the European Union and the European Atomic Energy Community and its Member States*, ratified by Law no.112 of 02.07.2014 (the *Official Gazette “Monitorul oficial”* no.185-199/442 of

18.07.2014) and in accordance with Cartagena Protocol provisions on Biosafety to the Convention on Biological Diversity (1992).

The draft law transposes the *Directive 2001/18/CE of European Parliament and of the Council of 12 March 2001 on deliberate release in the environment of genetically modified organisms and of repeal of Directive 90/220/CEE* of the Council, being the first stage of harmonization of the above-mentioned directive with national legislation.

The scope of this law is to ensure the necessary legal framework for implementation of activities related to LMOs on the territory of the RM, based on precautionary and ethical principles in order to insure protection of population health and of environment taking into account their impact on social-economical sector and on country population.

This draft law establishes general provisions for authorization of activities on introduction and use on the territory of the RM of LMOs. There are set down the responsibilities of central specialized bodies in relation with LMOs activities, as well as the responsibility of the National Commission on Biosafety for risk assessment on introduction of LMOs. Also, Law establishes the main notions and principles in the field, the procedure on elaboration and examination of notifications and the mechanism for public consultation and participation in decision making process towards notifications. For the ecological risk assessment procedure, the draft law foresees need to develop the Regulation regarding procedure for risk evaluation on introduction and use of LMOs.

For the scientifically research activity related to LMOs, the draft law establish the procedure on authorization of activities on introduction of LMOs as products themselves or as components of other products with the purpose of scientifically researches. These activities will be allowed only based on authorization issued free of charge by the competent authority for environmental protection sector.

The new law provides some restriction provisions, as ex. “ It is prohibited a deliberate release of LMOs in the natural environment (forestry, water, paludous, steppe and agricultural ecosystems) of genetically modified organisms On the territory of the Republic of Moldova. At the same time, taking into account the necessity to harmonize the national legal framework with the EU one in the field of GMOs, it is considered appropriate to put interdiction for introduction on the market and use of GMO as products itself or as component part of other products in proportion higher then 0,9% of total content of ADN and of proteins, till 31 December 2020, until establishing of all procedure, being included in legal and normative acts in field of agriculture and food industry and health sectors.

It is important to specify that this law is not regulating the authorization procedure for activities with involvement of GMOs in field of agriculture, food safety and health sector. This was done due to the fact that in accordance with the *Association Agreement between the Republic of Moldova and the European Union and the European Atomic Energy Community and its Member States*, of 27.06.2014, ratified by Law no.112 of 02.07.2014, in next 2-3 years it is foreseen to transpose in national legislation the following EU normative documents:

- Regulation (EC) no. 1829 of 22 September 2003 on genetically modified food and feed;
- Regulation (EC) no. 1830 of 22 September 2003 concerning the traceability and labelling of GMOs and the traceability of food and feed produced from GMOs;
- Directive 91/414 / EEC of 15 July 1991 concerning the placing on the market of phito-pharmaceutical products;
- Directive 2009 / 41 / EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified microorganisms, as well as bringing Moldovan legislation to other Community legislation and international treaties in GMO related areas.

Actually, the regime for testing, use and marketing of GMOs and of products resulted from GMOs are governed by *Law on biosafety* no. 755-XV of 21.12.200, which does not include resolutions and notifications, provisions taken within last years by Cartagena protocol and of EU legal framework. Thus, when the new *Law on GMOs* will enter into force (within 1 year from publication in the Official Monitor), the existing *Law on Biosafety* will be abrogated.

2. Review and analyze the national sectors political and legal framework in context of integration of the provisions of Cartagena Protocol on Biosafety.

In accordance with project TOR, each consultant had evaluated the national sector from the perspective of mainstreaming the biosafety issues in the sector policies and legal framework and prepared an overview with specification of policy and institutional set-up as well as cross-sectorial mechanisms for cooperation, institutional structure and responsibilities, as well as drafts of the legal documents for sectors.

The results of sectors assessment in context of biosafety related aspects could be seen in sub-chapter below.

2.1 Environmental protection sector

Policy documents

- The Strategy on Biological Diversity of the Republic of Moldova for 2015-2020 and the Action Plan approved by the Decree of the Government no. 274 of 18 May, 2015;
- Environmental Protection Strategy for 2014-2023 and the Action Plan, approved by the Governmental Decree no. 301 of 24 April, 2014;
- The Strategy on sustainable development of the forestry in the Republic of Moldova, approved by the Decision of the Parliament no. 350-XV of 12 June 2001;
- The draft Strategy on adaptation of the forestry sector to climate change for the period 2016-2025 and the Action Plan for its implementation.
- The National Programme on Establishing the National Ecologic Network for 2011-2018, approved by the Decree of the Government no. 593 of 1 August, 2011.

Domestic Legislation

- Law of the Republic of Moldova on environmental protection no. 1515-XII of 16.06.93
- Law on animal kingdom no. 439-XIII of 27.04.95

- Law on vegetal kingdom no. 239 of 08.11.2007
- Draft Law on GMOs

2.2 Agriculture and food industry sector

National policy

- National Strategy on Agriculture and Rural Development for years 2014-2020 (2014);
- The Strategy on development of rural extension services for the period 2012-2022 (2012).

Domestic Legislation

- Law on agro-food ecological production adopted in 2005
- Law on principles and general legal rules for the food security adopted in 2012
- Law on plant protection and phyto-sanitarian quarantine was adopted in 2004
- Law on food products adopted in 2013
- Law on seeds adopted in 2013
- Law on protection of plant varieties adopted in 2007
- Law on sanitary-veterinary activity was adopted in 2007
- Law on grape and wine adopted in 2006
- Law on tobacco and tobacco products adopted in 2007
- Law on horticulture adopted in 1996

2.3 Health care sector

National policy

- The national Strategy on public health for the period 2014-2020, approved in 2013
- The draft sectorial Strategy on adaptation of health system to climate change of 2015

Domestic Legislation

- Law on state supervision of health adopted in 2009
- Law on insurance the sanitary and epidemiological state of population adopted in 1993
- Law on drugs adopted in 1997
- Law on pharmaceutical activity adopted in 1993
- Draft Regulation on the contained use of genetically modified microorganisms

2.4 Trade and customs issues

National policy

- National Strategy for Integrated Border Management for the period 2015-2017 and the Action Plan for its implementation adopted in 2014

- The domestic trade development Strategy for the years 2014 - 2020 and the Action Plan for the years 2014-2016 adopted in 2013

Domestic Legislation

- Law on approval of Combined Nomenclature of goods approved in 2014
- Law on internal trade approved in 2010

2.5 Public information and consumer protection

National policy

- Strategy on consumer protection for the period 2013-2020 and the Action Plan for its implementation for the first period 2013-2016

Domestic Legislation

- Law on consumer protection adopted in 2003
- The Governmental Decision on approval of norms for labeling of food products and norms for labeling of chemical and household products approved in 2003
- The Law on public access to information adopted in 2000
- The draft Law on public access to environmental information of 2015
- The Regulation on information and public consultations on GMOs adopted in 2000.

2.1 Environmental protection sector

Political documents in field of environment

The main strategic documents on biological diversity and biosafety is the ***Strategy on Biological Diversity of the Republic of Moldova for 2015-2020 and the Action Plan***¹ that has the purpose to create conditions for quality improvement of biodiversity components through consolidation of the base for sustainable development of the country. The strategy establishes several actions in relation with GMOs that are described below.

The specific objective A – insurance of sustainable management and of an efficient institutional structure in field of biodiversity conservation till 2020 foresees to implement it through:

- A1. Development of normative framework in field of biodiversity conservation by development and promotion of normative documents regarding deliberate release of GMOs in the environment and on the market taking into consideration the provisions of *Directive 2001/18/CE of the European Parliament and of Council of 12 March 2001 on deliberate release in the environment of GMOs, Directive 90/219/CE of European Parliament and of Council of 6 May 2009 on*

¹The Strategy on Biological Diversity of the Republic of Moldova for 2015-2020 and the Action Plan was approved by Governmental Decree no. 274 of 18 May, 2015

contained use of genetically modified organisms. This activity is planned to be implemented by 2016 with involvement of relevant institutions as – Ministry of Environment, Academy of Science, Ministry of Economy, Ministry of Finance (Customs Service), Ministry of Agriculture and Food Industry, Ministry of Health.

- A2. Insurance of institutional framework efficient for sustainable use of biodiversity – through establishing by 2015, within the Ministry of Environment of the department on biodiversity, biosafety and protected areas
- A3. Insure integration of requirements of international agreements in national policies in field of biodiversity – by ratifying the *Nagoya-Kuala Lumpur Protocol on Liability and Redress under the Cartagena Protocol on Biosafety*, term being set as 2016, with involvement of Ministry of Environment, Ministry of Foreign Affairs and European Integration.

The specific objective B stipulates that by 2020, to reduce pressure on biodiversity through insurance of biosafety measures by developing of two procedures on risk evaluation on introduction of GMOs in the environment and establishing of a consultation centre. This specific objective B also foresees:

- Implementation of national biosafety framework in accordance with Cartagena Protocol provisions;
- Establishing the training and consultation centre in field of biosafety;
- Development of procedures and capacity building for risk evaluation/risk management as component part of authorization process for GMOs activities;
- Development of mechanism for liability and redress on biosafety;

These activities are planned to be implemented in the period 2016 – 2020 with involvement of Ministry of Environment, Academy of Science, Ministry of Economy, Ministry of Finance (Customs Service), Ministry of Agriculture and Food Industry, Ministry of Health.

Examples of mainstreaming of Biosafety through the NBSAP and other sectorial policies

Strategy on Environmental Protection for 2014-2023 and the Action Plan

Development of the Environmental protection Strategy² was dictated also by the political vector on European integration of our country, by actual requirements to align Moldova policies to the EU ones and by insurance of a sustainable development of our country through promoting green economy.

The main objective of the strategy is to establish an efficient system for environmental protection that will contribute to improvement of environmental quality and the health factor that will ensure the people right for a clean, healthy and sustainable environment.

The European integration process represents a big challenge for the environmental sector. The Environmental protection strategy is trying to facilitate these challenges and represent the key document for strategic planning of activities for the next 10 years period. The strategy vision has

²The Environmental protection Strategy for 2014-2023 and the Action Plan was approved by the Governmental Decree no. 301 of 24 April, 2014.

as permission the reform in the environmental sector that has to be made in a manner that will allow functioning of an institutional, administrative and management system that is aligned to European Union requirements and will ensure a sustainable environment and improvement of environmental factors.

The strategy scope is to guarantee to country population the right to a sustainable environment, non-pollutant and healthy that is in harmony with economic development and social prosperity. The objective of the strategy is to create an efficient environmental management system, which will contribute to quality improvement of environmental and health factors and which will insure the population right to a clean, healthy and sustainable natural environment.

The section 6 of the strategy – protection and conservation of natural resources, the **objective C** has information on state of biological resources and ways of their management. Thus, in the action plan to the strategy, there is foreseen by 2017 to develop the mechanism for implementation of the Biosafety Law, involving in this activity Ministry of Environment, Ministry of Agriculture and Food Industry, Ministry of Health, Academy of Science. Also, there are included activities on establishment, supply with necessary equipment and accreditation of the laboratory for identification and detection of genetically modified organisms. This activity is planned to be implemented by 2016 with involvement of Ministry of Environment, Ministry of Agriculture and Food Industry, Ministry of Health.

The Strategy for the sustainable development of the forestry in the Republic of Moldova of 2001 and the Action Plan for strategy implementation for the period 2003-2020

This strategy³ reflects the actual state of the forestry sector in Moldova, which put in evidence the fact that forests in our country are in continue degradation and the measures for forestry vegetation protection are insufficient to maintain the ecological balance so needed for sustainable development of the human society. Strategy foresees two fundamental directions for further development of the sector in order to improve the situation – to re-establish forests eco-protective potential and to extend the surface of the forest areas. The strategy has the following objectives – increase the Eco productive and bio productive potential of the national forests, conservation of the biological diversity of forests, extension of areas covered with forest vegetation, increase the secure activities for forestry fund, and increase the contribution of forest fund to solve socio-economic problems, conservation of natural rural landscape. This document does not contain some provisions on biosecurity

The draft Strategy on adaptation of forestry sector to climate change for the period 2016-2025 and the Action Plan for its implementation.

The draft strategy on adaptation of the forestry sector to climate change and the Action Plan for its implementation for the period 2016-2025 has the purpose to establish the vision, objectives, actions and measures to increase the forestry sector capacity to adapt to climate change and to contribute to diminishing the climate change effect per total and in other sectors of the national

³The Strategy for the sustainable development of the forestry in the Republic of Moldova of 2001 was approved by the Decision of the Parliament no. 350-XV of 12 June 2001

economy as agriculture or water management. At the same time the strategy seems to facilitate and contribute to increasing the green economy within the national economy.

The draft strategy scope is to contribute through the forestry sector and the forestry ecosystems to adaptation of the social and economic development of the Republic of Moldova to climate change impact and to fulfilment of the targets foreseen in Copenhagen Agreement on climate change.

The draft strategy looks to create conditions to increase the forest sector capacity to carbon sequestration with 25% comparing with the reference year of 1990 by rational use of land and forestry household. This draft strategy does not contain some provisions on biosafety.

The National Programme on Establishing the National Ecologic Network for 2011-2018

In order to establish the national ecological network, which represent an integrated part of the Pan-European Ecological Network, in 2001 the Government of the Republic of Moldova approved the National Programme⁴ on establishment of the national ecological network for the period 2011-2018, that refers to an integrated management of activities for establishing of the ecological network by conservation of natural genetic diversity, conservation of species of alive organisms included in natural ecosystems and complexes in order to ensure the optimal life conditions and sustainable development of territories adjacent to national ecological network. Implementation of regulatory framework for national ecological network foresees inter-sectorial coordination of activities in order to prevent and reduce the consequences of economic activities on environment, people health and life. The „Emerald” network will cover 18 sites that will include natural protected areas, other territories with valuable habitats with the area equivalent with 10% of the country territory. This programme does not contain some provisions on biosafety.

Legal documents in field of environment

Under this sub-chapter would be examined the main legal documents that are of main importance for biosafety provisions implementation at the national level, evaluation being referred to all examined sectors. In order to be more concise and clear we will use the comparative analysis approach using the main provisions of the Cartagena Protocol on Biosafety verso to national sectorial legislation.

Taking into consideration that actually there is in place the *Biosafety Law*, adopted in 2001, in 2015 started to be developed a new law on GMOs. The need for the new law was linked to the EU-RM Association Agreement provisions and also in the new law are clearly distributed the responsibilities of the administrative and regulatory competences of central public authorities in main sectors of the national economy. The new law on GMOs is in process to be adopted. Being realistic of process of adoption of the new laws, the consultant considered both legal documents – the existing Law on Biosafety and the draft Law on GMOs, when suggested recommendations on mainstreaming the biosafety issues in the sectorial policies and laws.

Table 1. Assessment of environmental protection legislation towards Cartagena protocol main provisions

⁴The National Programme on Establishing the National Ecologic Network for 2011-2018, approved by the Governmental Decree no. 593 of 1 August, 2011

Main provisions of Cartagena Protocol on Biosafety	National legislation provisions/sector	Recommendations
<p>Transit and use of GMOs in closed environment; Application of the Advance Informed Agreement Procedure, Notification for GMO introduction in the country, Traceability procedure for GMO intended to be used directly as food or feed or in processing activities, Risk evaluation and risk management, Manipulation, transport, labelling and GMO identification, The competent national authority – focal point, Exchange of information and prevention of biotechnological risks, Public information and public awareness.</p>	<p>Law of the Republic of Moldova on environmental protection no. 1515-XII of 16.06.93 – represent the main legal framework for development of the special normative documents and instructions in field of the environmental protection. This law does not contain some provisions on biosafety insurance as the Cartagena Protocol requires.</p>	<p>It is necessary to complete this law with provisions regarding the establishment and insurance of a security level of environmental protection in context of introduction in the country of, GMOs, use of GMOs, according the provisions of the Law on Biosafety of 2001, taking into consideration as well the provisions of the new Law on GMOs, especially provisions on risk evaluation, insurance of control, monitoring, of activities that involves GMOs insure public information and public participation in processes that refers to decision making on GMOs.</p>
	<p>Law on animal kingdom no. 439-XIII of 27.04.95 – represent the legal framework to ensure the efficient protection and rational use of animal kingdom. This law does not contain some provisions on biosafety.</p>	<p>It is necessary to complete this law with provisions on conditions for deliberate release in natural environment of the GMOs, use of GMOs in economic or scientifically purpose according the Law on Biosafety of 2001 taking into consideration also provisions of draft Law on GMOs on monitoring of animal resources that have/could have GMOs.</p>
	<p>Law on vegetal kingdom no. 239 of 08.11.2007 - regulates the objects of vegetal kingdom which grow in natural conditions as well as the objects of vegetal kingdom which are hold in cultural conditions with regeneration purpose and conservation of genetic fond. Also, this law sets the competences of the public authorities of all levels and of scientifically institutions in the field. This law does not contain provisions in context of biosafety.</p>	<p>It is necessary to compete the law with provisions on import/export /transit for the objectives of vegetal kingdom that are genetically modified, to include provisions on monitoring of these subjects according the provisions of the existing law on biosafety and/or of draft law on GMOs.</p>
	<p>Draft Law on GMOs - establish the general provisions on regulation of authorization of activities on introduction and use on the territory of RM of GMOs, establish the attributions of the authorities and central specialized bodies in context of GMOs, responsibilities of the National Commission on Biosafety in relation to GMOs</p>	

	<p>risk establishment, others.</p> <p>Draft law is partially transposing the Directive 2001/18/CE of the European Parliament and Council of 12 March 2001 on deliberate release in the environment of GMOs.</p> <p>The draft law contains the basic notions and main definitions in the field, administrative and regulatory competences, the authorization procedure, and risk evaluation, the mechanism of public information and participation in decision making process, the labelling procedure, confidentiality provisions, provisions on accidents and emergency situations with involvement of GMOs.</p>	
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Role / responsibilities of national bodies in the environmental protection sector that are part of the biosecurity process

The Ministry for Environment is the main authority in charge of the development and promotion of state policy in the field of environmental protection and the rational use of natural resources, waste management, bio-diversity conservation, geological exploration, the use and protection of subsoil, hydro-amelioration or land improvement, water resources management, water supply and sanitation, the regulation of nuclear and radiological activities, state ecological control, hydrometeorology and the monitoring of environmental quality.

The total number of staff positions in the Ministry is 65. The structure of the central body of the Ministry is presented in Annex 2. The functions of the institution are determined in the Regulations of the Ministry. Accordingly, the Ministry is responsible for an important range of functions as follows:

- 1) Developing the legislative and regulatory framework, ensuring compatibility with international treaties to which Moldova is a party and with EU legislation;
- 2) Determining priority directions of activity based on environmental assessment of the situation and identifying problems and risks;
- 3) Ensuring the integration of environmental requirements into the processes of economic reform and sectoral policies to ensure sustainable development and promoting non-pollutant and energy efficient technologies;
- 4) Carrying out state control over compliance with environmental legislation;
- 5) Authorizing activities on the use of natural resources and waste processing, importation, export / re-export of wild flora and fauna, importation, export, production and consumption of ozone depleting substances and other harmful products and substances, genetically modified organisms, hydro-meteorological observations and environmental impact studies;

- 6) Coordinating the national register of potentially toxic chemicals and the location of specialized platforms for neutralization and burial of production and household waste;
- 7) Participating in planning and implementing measures to avoid the occurrence of emergency situations, to reduce the extent of their consequences;
- 8) Ensuring the monitoring of environmental pollution, meteorological, hydrological, agrometeorological observations, to provide the population, economy, national defence and public authorities with hydro-meteorological information;
- 9) Participating in the coordination of scientific research on environmental protection;
- 10) Ensuring the study, evaluation, regulation, accounting and control, protection and realization of scientific and technical policy on the rational use of natural resources (soil, subsoil, water, forests, flora and fauna);
- 11) Managing the National Ecological Fund and coordinating the activities of the local environmental funds;
- 12) Cooperating with international organizations and similar bodies in other countries, promoting the signing, accession and ratification of international treaties;
- 13) Coordinating the implementation of relevant international treaties to which Moldova is a party;
- 14) Coordinating the preparation, training and performance evaluation of staff in its areas of activity;
- 15) Providing and creating management information systems and databases in its fields of competence;
- 16) Keeping statistics on the status and quality of surface water resources, surveying their use and discharges into them, keeping records of water resources and land improvement and ensuring the keeping of the State Water Cadastre;
- 17) Contributing to the information of the population about the benefits of environmental policy and raising awareness and environmental education through its communication strategy;
- 18) Collaborating with civil society.

Some functions and competences of the Ministry are performed also through its subordinated institutions: the Agency for Geology and Mineral Resources, the Apele Moldovei Agency (Water management), the National Agency for the Regulation of Nuclear and Radiological Activities, the State Ecological Inspectorate, the State Hydro-meteorological Service, the Fishery Service and the Institute of Geography and Ecology.

The National Commission on Biosafety (NCB), the Regulation of functionality of the NBC determines its power and the function to ensure governmental policies in the field of biosafety, acting in particular via issuance of authorizations, monitoring of the GMO-related activities, collaboration with governmental authorities and scientific institutions competent in the relevant sphere. NBC is nominated as a competent national authority that has a duty to exercise authorization attributes and control over for the following activities:

- GMO uses for contained us;
- Deliberative release in the environment;
- Accidental release in the environment;
- Placing on the market;
- Research activities;

- Import/export;
 - Transboundary accidental transportation;
 - Storage and destroy of GMOs.
- According to the Regulation, the NBC has the following functions:
- examination of notification documents;
 - elaboration of reports, synthesis and information for national and international uses;
 - public information;
 - cooperation with the competent research institutions;
 - maintaining and publishing the Register of the GMOs;
 - national and international participation.

The National Biosafety Committee operates as the inter-ministerial authority and consists of 14 members, including:

- 2 members from the national environmental authority, which have the functions of respectively the Chairman and the Secretary of the National Committee;
- 4 members from the Academy of Sciences of Moldova;
- 3 members from other scientific institutions and universities with biological or medical profile;
- 1 member from each of the following national authorities: for economy, agriculture and food industry, health care, standardization and metrology, and from environmental NGOs.

Other instrument in implementation of biosafety requirements at the national level is **Biosafety Office**. It is an independent non-commercial, non-profit structure, established by order of the Ministry of Ecology and Natural Resources. Office duties are to promote and strengthen national capacities to implement activities on the governmental sector, academic and in the civil society; also promoting studies and scientific research in the field of "climate change" and facilitate the implementation of the activities, programs and projects that contribute to the goals of the UN Convention on Climate Change at the local, regional and international levels.

a) logistic assistance of the Moldovan authorities and local institutions, organizations (institutions) non-governmental and academic activities implemented by Moldova and promoted by the Cartagena Protocol on Biosafety to the Convention on conservation of biological diversity;

b) projects and programs implementation regarding the activities:

- (i) designing and implementing of the national Biosafety Framework;
- (ii) risk assessment and socio effects on biological and economic components of the country;
- (iii) development and implementation of regulatory uses of GMOs;
- (iv) risks assessment of the technology and promoting the implementation of the biotechnologies which doesn't present risks for the environmental and health and contribute to the sustainable economic development of the country;
- (v) facilitating the creation of databases and information systems and monitoring the use of GMOs, participation at the Informational Exchange Mechanism on GMOs, including environmental cases of accidental seeping;
- (vi) strengthening national capacities to address biosafety issues related to the frame;
- (vii) promote and implement activities focused on sustainable use of biological resources;
- (viii) cooperation, promotion and implementation of activities, projects and programs under exchange mechanisms of information on GMOs, and other mechanisms and instruments provided by Cartagena Protocol on Biosafety, to which Moldova is party;
- (ix) development of project proposals, project concepts, documents, etc., presentation to funding

institutions and relevant international organizations;
(x) implementation and facilitation of awareness and information activities for civil society, relevant specialists and decision makers.

Conclusions of the desk study in environmental protection sector in context of improvement of implementation of Cartagena Protocol provisions.

After evaluation of the national political and legal documents in field of environmental protection, there have been identified the following conclusions on how to improve the integration of biosafety issues in the environmental protection sector, based on the requirements of the new draft Law on GMOs, as follows:

Institutional/administrative measures

- Development and adoption of the procedure on ecological risk assessment based on the provisions of the Directive 2001/18/CE on deliberate release of GMOs in the environment and the Cartagena protocol provisions;
- Development of measures and procedures on inspection, monitoring and control of LMOs released in the environment;
- Establishing the reference laboratories for GMOs and their accreditation.
- Establishing of the training and consulting Centre on biosafety;

Political measures

- Development of the Action Plan for Cartagena Protocol implementation at the national level;

Legal measures

- Development and approval by the Governmental decision of the notification model for the GMOs introduced in the country;
- Development and approval of authorization for GMOs introduced in context of scientifically researches;
- Development of measures for recovery in case of accidents / emergencies involving GMOs;
- Development and maintaining the Register on issued authorizations on introduction on the territory of the country of GMOs intended to be used in scientifically researches;
- Development of proposals to modify the Contravention Code in context of breaking legal provisions on biosafety;
- Development of a normative document on GMO transportation taking into consideration the CE Regulation no. 1946/2003 on trans boundary movement of GMOs;

2.2 Agricultural and food industry sector

Political documents in field of agriculture

Under this activity was planned to review and analyse the political and legal framework in agricultural and food industry sector and identify at what extent are transferred the provisions of Cartagena Protocol on biosafety in the agricultural sector.

Current policy framework that has an impact on development of the agricultural sector is guided by the *National Development Strategy "Moldova 2020"*, which main objective is the acceleration of the economic growth and reduction of poverty in the Republic of Moldova.

The National Strategy on Agriculture and Rural Development for years 2014-2020⁵, approved by the Governmental Decision no. 409 of June 4, 2014, is a framework for policy makers to identify the major problems and to help in identifying optimal solutions in agricultural and rural development sectors. The Strategy will be used as a tool to plan and programme all necessary measures and to secure financial support from Government of Moldova, international development partners, international financial institutions and donors for the implementation of the proposed agenda.

The Strategy on agriculture and rural development for the period 2014-2020, was developed based on a holistic approach and provide a guideline for development in economic, environmental and rural aspects. Also, the Strategy is planned to be used as a tool to plan and programme all necessary measures and to secure financial support from Government of Moldova, international development partners, international financial institutions and donors for the implementation of the proposed agenda.

As strategy is mentioning, crop production seems to be vulnerable to climate disasters: the years of severe droughts in Moldova (2003, 2007, 2009 and 2012) have had a disastrous effect on most of the crops. The high volatility of agricultural output is a reflection of underdeveloped weather - related risk mitigation instruments, including insufficient access to irrigation, low rate of adoption of modern agricultural technologies (such as drought –resistant varieties, anti-hail protection tools) and lack of innovative insurance schemes for agriculture, such as the index-based weather insurance program. Another reason behind slowing agricultural production is associated with the economic crises, bringing up input (e.g. fertilizer, fuel, and machinery) prices, causing hard times for agricultural producers.

The strategy mentions that the most popular imported products are relatively high value items as tabaco, off-season fresh fruits and vegetables and alcoholic beverages. Also, strategy specifies that the main partners in agri-food trade are the CSI countries and EU as well. If speaking about export of agri-food products, Moldova is exporting mainly to Russia, Belarus, Ukraine, Romania and Germany. Imports in the country are coming from Ukraine, Russia, Romania, Turkey and Germany and they make almost 60% of total afri-food imports (as for 2011).

The Republic of Moldova have signed and ratified the bilateral agreement RM-EU on Deep and Comprehensive Free Trade Agreement (DCFTA), that is influencing trade relations, expectations being that due to this agreement Moldova economy would have an increase of GDP of 5,4%.

⁵The National Strategy on Agriculture and Rural Development for years 2014-2020 was approved by the GD no. 409 of 04.06.2014.

Based on mentioned agreement Moldova exports are estimated to increase by 16%, while imports – 8%. Actually, Moldova does not export to EU meat or live animals, being accepted on the EU market only honey, caviar and powdered eggs. Since Moldova will align its sanitary system with the EU one, will be easier for agricultural and food products to access the EU market and vice versa. The Moldova agricultural sector is dominated by crop production that forms 60-70% of total agricultural production in period 2011-2012.

The strategy emphasizes that among weaknesses to have a developed agricultural sector are listed the following items – necessity to improve food safety and food quality for milk and meat processing sectors, insufficient public research, innovation, communication initiatives to serve processing sector.

The examination of argy-food sector, agricultural resources and issues related to regional development, lead to identification of the major problems in these areas that have been taken into consideration within the strategy. The strategy vision is to build a competitive, restructured and modernized argy-food business sector. The strategy has the scope to have a harmony between the agricultural activities and the natural environment mainstreaming the biodiversity, cultural and traditional values for the future generations. Also, the strategy intends to raise the competitiveness of the argy-food sector through restructuring and modernization of the sector and through improving the living and working conditions in rural areas whilst achieving the synergies between argy-food activities and the natural environment.

The strategy has three general objectives as:

1. Increase competitiveness of the argy-food sector through modernization of market integration;
2. Ensure sustainable management of natural resources in agriculture;
3. Improving living standards in rural areas.

Within the **general objective 1**, there are three specific objectives, among which the specific objective 1.2 – facilitate access to capital, inputs and output markets for farmers. This objective has the role to make accessible funds for formers, among it there is foreseen to reduce agricultural risks by mitigating risk and insuring against them. An open regime for the import of seeds and seeding, as well as for fertilizers and pesticides would improve farmer`s access to modern technology and contribute to be synchronized with the EU farmers. Unfortunately, this does not contain some other provisions for trade with GMOs, including seeds or seeding.

The **general objective 2**, here is a specific objective 2.1- support sustainable agricultural land and water management practices which foresee that one of the most efficient ways to ensure sustainable management of natural resources in agriculture is to use innovative land and water management practices through land consolidation and use of modern land cultivation practices including crop rotation and diversification of agricultural products. The specific objective 2.2 – support environmentally friendly production technologies, organic production and products ensuring biodiversity, specify that organic production should be supported especially taking into consideration the increasing demand for them on international markets. This strategy does not contain provisions on biosafety.

The Strategy on development of rural extension services for the period 2012-2022⁶ was approved in 2012. The provisions of this strategy refers at the development of rural extension services in the Republic of Moldova in order to contribute to development of rural economy and to increase productivity in agricultural sector, thus increasing the competitiveness of agri-food sector.

The general objectives of the strategy are:

- a) development of rural economy and increase of agricultural productivity;
- b) contribution to enhance the competitiveness of the agribusiness sector through providing rural extension services.

This strategy does not have some provisions in regard to biosafety.

Legal documents in field of agriculture and food industry

Following the review of the policy documents, there was examined the legal framework through comparing approach of the provisions of Cartagena protocol and main laws in the field and identified the level of compliance of legal provisions according the protocol requirements. Under this activity have been taken into consideration the following legal documents:

The Law on agro-food ecological production adopted in 2005⁷, establishes rules for activities on getting the ecological agro-food products without use of some synthetic chemicals, as well as marketing of vegetal and animal ecological products, as unprocessed primary products, processed products intended for human consumption, prepared from one or more ingredients of vegetal or animal origin, feed and raw materials.

The Law on principles and general legal rules for the food security adopted in 2012⁸ establishes the general principles toward the legislation which regulates the food products sector as well as the feed for animals and safety of these products, especially establish the National Agency for Food Security, establishes and define the its competencies and competencies of the Ministry of Health toward the food and feed safety. This law controls the legal and institutional framework for food and feed safety. It is important to mention that this Law is harmonized with chapters 1 and 2 of the Regulation 178/2002/CE of the European parliament and Council of 28 January 2002 on establishment of principles and general requirements for food legislation, on establishment of the European Authority for Food Security and of establishing of the procedures in field of food safety.

The Law on plant protection and phyto-sanitarian quarantine was adopted in 2004⁹, has the scope to consolidate the legal and institutional framework to create adequate legal and economic conditions for organization and carrying out the plant protection and phyto-sanitarian quarantine.

⁶The Strategy on development of rural extension services for the period 2012-2022 was approved by GD no. 486 of 4.07.2012.

⁷The Law on agro-food ecological production was adopted by GD no.115-XVI of 9.06.2005.

⁸ Law on principles and general legal rules for the food security was adopted by PD no. 113 of 18.05.2012.

⁹ Law on plant protection and phyto-sanitarian quarantine was adopted by GD no. 228 of 23.09.2010.

These activates intends to ensure the prevention of mass extension of dangerous organisms, to avoid harvest losses and to obtain a high agricultural production. Also, this law foresees measures on protection of the country territory from introduction, spreading, and migration of quarantine organisms.

The Law on food products¹⁰, adopted in 2004, establishes the legal framework for production, processing and distribution of food products, as well as regulates the basic conditions for circulation of these products, including insurance of inoffensiveness in order to protect human health and consumers interest in respect to food products.

The Law on seeds¹¹ **adopted in 2013** is establishing the legal framework for production, processing, control and quality certification, marketing of seeds and seedlings. Provisions of this law are not referring to activities of seeds production in individual households with the condition that seeds are not commercialized.

The Law on protection of plant varieties¹², adopted in 2008, regulates relations arising in the creation, legal protection and use of varieties that are part to all genres and species of plant.

The Law on sanitary-veterinary activity¹³ was adopted in 2007, establishes the main sanitary-veterinary norms and requirements in the Republic of Moldova, as well as the rights and obligations of state, physical and legal persons for the production, processing, storage, transport and marketing of live animals and animal products.

The Law on grape and wine¹⁴ adopted in 2006 establishes the legal, economic and social baseline in the nursery sector for vineyard, viticulture and winemaking, regulates relations arising in the production, processing and marketing of propagating and planting material, freight table grapes and wine, wines and other products based on wine and wine products of wine secondary products and products obtained by capitalizing wine secondary products.

The Law on tobacco and tobacco products¹⁵ adopted in 2007 establishes the legal, economic and social organization of the cultivation, for post-harvest and industrial tobacco processing, import, manufacture, storage and marketing of tobacco products, regulates relations arising in these activities and provides measures to prevent and combat the use of tobacco.

The Law on horticulture¹⁶ adopted in 1996 regulates the general and special conditions for production and marketing of fruits and berries, fruit tree seedlings, being oriented to preserving, developing and enhancing the productive potential of orchards and berry, regardless of the type of property and legal form of the household.

The summary of the results of legal framework evaluation in agricultural and food protection sector are shown in the table below:

¹⁰Law on food products was adopted by the PD no. 78-XV of 18.03.2004.

¹¹Law on seeds was adopted by PD no. 68 of 05.04.2013.

¹²Law on protection of plant varieties was adopted by PD no. 39 of 29.02.2008.

¹³Law on sanitary-veterinary activity was adopted by PD no. 221 of 19.10.2007.

¹⁴Law on grape and wine was adopted by PD no. 57 – XVI of 10.03. 2006.

¹⁵Law on tobacco and tobacco products was adopted by PD no. 278 of 14.12.2007.

¹⁶Law on horticulture was adopted in 1996 by PD no. 728-XIII of 06. 02. 1996.

Table 2 Assessment of agricultural and food industry legislation towards Cartagena protocol main provisions

Main provisions of Cartagena Protocol on Biosafety	National legislation provisions/sector	Recommendations
<p>Transit and use of GMOs in closed environment; Application of the Advance Informed Agreement Procedure, Notification for GMO introduction in the country, Traceability procedure for GMO intended to be used directly as food or feed or in processing activities, Risk evaluation and risk management, Manipulation, transport, labelling and GMO identification, The competent national authority – focal point, Exchange of information and prevention of biotechnological risks, Public information and public awareness.</p>	<p>The Law on agro-food ecological production adopted in 2005 has the notion on genetically modified organisms and their derivate. This law also introduces the notion of “Ecological Agriculture - Republic of Moldova”.</p>	<p>There is necessary to complete the law with provisions on not allowing use of GMOs, including on the products label information on GMOs free product.</p>
	<p>Law on protection of plant varieties adopted in 2008 has the notion on genetically modified organisms, also includes conditions on authorization of activities for introduction in the environment of genetically modified plants, and specifies conditions for patent creation for GM plants.</p>	<p>There is necessary to complete the law with provisions on regulating the import/export/transit for plant varieties GM, requirements on monitoring the plant varieties GM, requirements on labelling the GM plant varieties according the Law on biosafety of 2001/draft Law on GMOs.</p>
	<p>L The Law on seeds adopted in 2013 has provisions on production of GM seeds, their marketing, import, export, re-export, packaging and labeling, mentioning that this activity has to be authorized according the existing Law on Biosafety or draft Law on GMOs.</p>	
	<p>The Law on horticulture adopted in 1996 does not contain some provisions on biosafety.</p>	<p>It is necessary to complete this law with provisions regarding notification for introduction on the market or in the environment of planting material GM, risk evaluation, requirements on labelling GM fruit varieties, conditions on import, export and transit for planting material GM, monitoring of the planting material GM according the provisions of the existing Law on biosafety and/or draft Law on GMOs.</p>
	<p>The Law on grape and wine adopted in 2006 does not contain some provisions on biosafety.</p>	<p>It is necessary to complete this law with provisions on notification for introduction on the market or in the environment of grape planting material, grapes, wine that could be or are GM, authorization requirements, risk evaluation, include labelling requirements for grape varieties, wine</p>

		products GM, on monitoring of these products according the requirements of the existing Law on biosafety and/or draft Law on GMOs.
	Law on tobacco and tobacco products adopted in 2007 does not contain some provisions on biosafety.	It is necessary to complete this law with provisions on notification procedure for introduction on the market or in the environment of Tabaco planting material, Tabaco products that could be or are GM, conditions for authorization of these activities, risk evaluation, requirements on monitoring of GM Tabaco or Tabaco products, conditions for import, export or transit, according the requirements of the existing Law on biosafety or draft Law on GMOs.
	The Law on plant protection and phyto-sanitarian quarantine was adopted in 2004 does not contain some provisions on biosafety.	It is necessary to complete this law with provisions on notification on introduction in the market or the environment of plants/vegetal products that are or could be GM, on authorization of these activities, risk evaluation, labelling, the import, export and transit conditions, and monitoring process according the requirements of existing Law on biosafety and / or draft Law on GMOs.
	The Law on sanitary-veterinary activity adopted in 2007 has some provisions on biosafety, especially on control/presents of GMOs in animal products and feed, activity for what the Ministry of Agriculture and Food Industry, Ministry of Health and Ministry of Environment are responsible.	It is necessary to complete this law with provisions on notification E on introduction in the market or the environment of live animals, sanitary-veterinary products that are or could be GM, on authorization of these activities, risk evaluation, labelling, production conditions, the import, export and transit conditions and monitoring process according the requirements of existing Law on biosafety and / or draft Law on GMOs.
	The Law on food products adopted in 2004 has the notion of food products produces from GMOs, also it has provisions on labeling the GM food products.	It is necessary to complete this law with provisions on notification on introduction in the market of GM food products, on authorization of these activities, risk evaluation, specification of production procedure, labelling, import, export and transit conditions, insurance of human health security, and monitoring process according the requirements of existing Law on biosafety and / or draft Law on GMOs.

Description of role / responsibilities of national bodies in the agriculture and food industry sector that are part of the biosecurity process

The institutional set-up for the agricultural sector, currently, involves the following institutions that are implementing activities that contribute to the development of agriculture and rural areas, namely:

The Ministry of Agriculture and Food Industry (hereinafter - MAFI), together with its subordinate institutions, is responsible for developing and promoting the agricultural development policy, increase competitiveness and productivity of the sector and improve the quality of life and work in rural areas. For institutions subordinated to MAFI, which are supporting efforts of the Ministry in the implementation of agriculture and rural development policies, the following can be mentioned:

- *Interventions and Agriculture Payments Agency* (hereinafter - AIPA), which currently provides financial support for subsidies in agriculture and rural development, in accordance with the EU rules. Also, AIPA is currently acting as the implementing and payment agency for some donors, including the World Bank, providing support for agriculture and rural development measures;
- *Agricultural Information Centre*, created under the MAFI, responsible for coordination of the implementation of the e-Agriculture principle and for the integration and consolidation of agricultural information resources, such as Agricultural Producers Registry, Vineyard Registry, Agricultural Machinery Registry and other;
- *Consolidated Unit for Implementing and Monitoring the Wine Sector Restructuring Programme*, funded by the European Investment Bank, subordinated to MAFI, whose aim is to improve the competitiveness of the sector and to ensure the compliance with the quality requirements of the EU, thus conforming to the EU policies and instruments in the field of agriculture and rural development;
- *International Fund for Agricultural Development Programmes (hereinafter - IFAD) Consolidated Programmes Implementation Unit*, under MAFI, implementing measures on modernization and restructuring of agriculture and rural development in line with the EU policy on agriculture and rural development;
- *Consolidated Agricultural Projects Implementation Unit, funded by the World Bank (CAPMU)*, responsible for ensuring the efficient implementation of World Bank projects in agriculture and rural business development;
- *Implementation and Management Unit of the Food Production Increase Project (2KR)*, which contributes to the establishment of accessible and advantageous conditions of agricultural machinery purchasing by paying for it in instalments, with the view to renew and equipping the agricultural producers of the country with new machinery;

- *Implementation Unit of the project "Transition to a Competitive Agriculture"*, which manages activities that contribute to increasing rural incomes by stimulating growth in agriculture performance and catalyse investments in high value-added production.

The National Food Security Agency, which is responsible for implementing policies in the field of food safety, veterinary, plants protection and phyto-sanitary quarantine, seed control, quality of primary products, food products and fodder.

As mentioned earlier, beside the existing legal framework on biosafety, due to the aspirations of the Republic of Moldova to integrate the EU principles, taking into account signing and ratification of the RM-EU Association Agreement (Law no. 112 of 2 July 2014), now, under approximation process of legal framework are all environmental sectors including biosafety. Thus, was developed the new Law on biosafety which transpose in national legislation some of the EU directives in the sector, namely the Directive 2001/18/CE of the European Parliament and of Council of 12 march 2001 on deliberate release into environment of GMOs. This law now is under the approval procedure.

Thus, according with the new Law on Biosafety, the Ministry of Agriculture and Food Industry (MAFI) has the following responsibilities in context of biosafety measures:

- Development of the legal and normative framework on introduction and use of GMOs intended as food products or feed for animals, which contain or are prepared from GMOs or has ingredients that are prepared from GMOs, of food products of animal and non-animal origin which contain or are consisting of GMOs;
- Perform the administration function and act as national focal point in case of emergency situations related to identification of GMOs in agricultural and food products, seeding, forages, others that come up from the Rapid Alert System for Food and Feed (RASFF).

Also, the new law sets up the new responsibilities for the subordinated structures of the MAFI that are responsible for the implementation of state policy in field of regulation and control for food safety, sanitary - veterinary sector, for plant protection and phytosanitary quarantine, seeds control, quality of primary products, of food products and animal feed, as the following:

- Development in coordination with the central body in field of agriculture (MAFI), the authorization procedure for activities related to introduction, use of GMOs intended to be used as food products or feed for animals, which contain or are prepared from GMOs or has ingredients that are prepared from GMOs, of food products of animal and non-animal origin which contain or are consisting of GMOs;
- Development in coordination with the central body in field of agriculture (MAFI), the procedure on permits issuing for the simplified procedure for activities of introduction and use of GMO intended to be used as food and feed, of food products or feed products that contain or consist of GMOs and of food products that has ingredients prepared from GMOs, as well as of forages that contain GMOs;
- Ensure the state supervision and control regarding the introduction on the territory of the RM of GMOs intended to be used as food and feed products or of those that contain or consist of GMOs or has some ingredients produced from GMOs;

- Ensure supervision, inspection and control on presence of GMOs in food and feed products of animal or non-animal origin at the production, processing, transport, distribution and marketing stage;
- Ensure initiation in court of contravention actions in order to recuperate funds for accidents with involvement of GMOs;
- Ensure monitoring of food and feed products safety, of seeds, food products of animal, non-animal origin;
- Ensure stopping of illicit activities related to deliberate release into environment of GMOs and inform notify about the measures to be applied in order to remediate the adverse effects;
- Ensure reports writing on regarding identification of GMOs in food and feed products, seeds, products of animal and non-animal origin.

According the new law on biosafety, the central body in field of agriculture (MAFI) shell present to central body for environmental protection, annual reports on authorization of activities related to GMOs.

Conclusions on desk study review in agricultural and food industry sector in context of improvement of implementation of Cartagena Protocol provisions.

After evaluation of the national political and legal documents there have been identified the following conclusions on how to improve the integration of biosafety issues in agriculture and food industry sector, based on the requirements of the new draft Law on GMOs, as follows:

Institutional/administrative measures

- Development of procedure on permits issuing for the simplified procedure on introduction/use of GMOs intended to be used as food and feed products, food and feed products that consist or contain GMOs or contain ingredients GM, animal and non-animal products that contain or consist of GMOs;
- Development of annual reports on identification of GMOs;
- Undertake measures for accreditation of laboratory on detection of GMOs.

Political measures

- Review the political and legal framework in order to include provisions on biosafety according the requirements of the draft law on GMOs;

Legal measures

- Development and adoption of legal and normative documents in accordance with requirements of the Regulation 1829/2003 on genetically modified food and feed;
- Development of normative documents on ensuring state control for the activities on introduction on the territory of the RM of GMOs intended to be used as food and /or feed, of food and feed products that contain or consist of GMOs, or contain or consist of ingredients GM, animal and non-animal products that contain or consist of GMOs;

- Development of normative documents that insure supervision, inspection and control for GMOs presence in food, feed products, seeds, food products of animal origin, non-animal origin, at the stage of production, processing, transport, distribution and marketing;
- Development of normative documents on ceasing illicit activity of deliberate release in the environment of GMOs, specifying role of notified in this process;

2.3 Health care sector

Political documents in field of health care

Under this activity was reviewed and analysed the political and legal framework in healthcare sector and was identified at what extent are transferred the provisions of Cartagena Protocol on biosafety in health care sector.

*The national Strategy on public health for the period 2014-2020, approved in 2013*¹⁷, supports Government and society interactions for significant improvement of people health and prosperity, contributing to reduction of inequalities in health sector and consolidating the public health. The strategy is mentioning that actually there is a need to establish a National Inter-sectorial Committee for Biosecurity and Biosafety which will deal with identification, evaluation, monitoring and risk diminution of biological origin including activities related to prevention of bioterrorism acts. At the same time, in the strategy is mentioned that even there is established the NCB it has other purposes and role. Other provisions on biosafety were not identified in the text of strategy.

The draft sectorial Strategy on adaptation of health system to climate change is developed based on art. 6 of the *Law on state supervision of health adopted* in 2009 and also based on the provisions of the National Strategy on adaptation to climate change and it's Action Plan, which foresee that Ministry of Health shell develop the sectorial strategy on climate change and the action plan for its implementation. Through the draft sectorial strategy on adaptation of health system to climate change, is foreseen to apply an approach of complex actions that will comprise adequate measures for preparedness and response to risks for health caused by climate changes. By implementing this strategy, the RM will insure the people right for live, right for the highest standard of physical health, right to safe work and hygiene conditions.

Legal documents in field of health care

*The Law on state supervision of health adopted in 2009*¹⁸ regulates the organization of state supervision of public health, establishing general requirements for public health, the rights and obligations of physical and legal persons and the modality of organization of the state system of public health supervision. By this law the health in relation to environment is considered a priority issue for supervision of public health, but there is said nothing about biosafety.

¹⁷National Strategy on public health for the period 2014-2020 was adopted in 2013 by GD no. 1032 of 20.12.2013.

¹⁸Law on state supervision of health was adopted in 2009 by GD no. 10-XVI of 03.0.2009.

The Law on insurance the sanitary and epidemiological state of population adopted in 1993¹⁹ represent a complex of inter/intra departmental measures implemented at the state level, family and household level that have the purpose to maintain health, to prevent or combat the emergencies and spread of contagious, non-contagious and professional diseases, poisonings, dependence on harmful factors of the environment, sphere of production, habitat, education and human behavior. This law has no provisions related to biosafety.

The Law on drugs adopted in 1997²⁰ is applied to all spheres of activity that concern medicines: research, testing, approval, manufacturing, practical application, use, import, export, storage, distribution, sales and control. This law does not include provisions on biosafety.

The Law on pharmaceutical activity adopted in 1993²¹ regulates the activity of pharmaceutical products for humans and for pharmaceutical and para-pharmaceutical products for animals. This law does not include provisions on biosafety.

Draft Regulation on the contained use of genetically modified microorganisms that partially transpose the provisions of the Council Directive 2009/41/EC on the contained use of genetically modified micro-organisms²². The scope of the regulation is to insure the necessary legal framework for activities that imply GM micro-organisms on the territory of the RM, by respecting the precautionary principle, ethic principle in order to insure human health protection and the environment taking into consideration their impact on socio-economical interest of people and country. The draft regulation foresees responsibilities of the central bodies of public authorities in relation to GMOs activities, of NCB in context of risk assessment when introducing the genetically modified micro-organisms (GMM). Also it contains the main notions in the sector, provisions for notification procedure, public consultation and public participation mechanism in process of authorization of import and use of GMM.

The summary of the results of legal framework evaluation in health care sector are shown in the table below:

Table 3. Assessment of health care legislation towards Cartagena protocol main provisions

Main provisions of Cartagena Protocol on Biosafety	National legislation provisions/sector	Recommendations
Transit and use of GMOs in closed environment; Application of the Advance Informed Agreement Procedure, Notification for GMO introduction in the country, Traceability procedure for GMO intended to be used directly as food or feed or in processing	The Law on state supervision of health adopted in 2009 has no provisions in context of biosafety requirements.	There is necessary to complete the law with provisions on notification procedure when introducing on the market of food products GM, on risk evaluation of these products, production conditions, specify conditions for import, export and transit according the requirements of the existing law on biosafety and /or

¹⁹Law on insurance the sanitary and epidemiological state of population was adopted in 1993 by GD no. 1513 of 16.06.1993.

²⁰Law on drugs was adopted in 1997 by GD no. 1409 of 17.12.1997.

²¹Law on pharmaceutical activity was adopted in 1993 by GD no. 1456 of 25.05.1993.

²²OJ L117/1 of 8.05.1990.

activities, Risk evaluation and risk management, Manipulation, transport, labelling and GMO identification, The competent national authority – focal point, Exchange of information and prevention of biotechnological risks, Public information and public awareness.		the draft Law on GMOs.
	Law on insurance the sanitary and epidemiological state of population adopted in 1993 has no provisions on biosafety.	There is necessary to complete the law with provisions on notification and authorization procedure for introduction and use of food products GM, risk evaluation, stipulation of health protection measures during the production activity, requirements on import/export/transit according the Law on biosafety of 2001/draft Law on GMOs.
	The Law on drugs adopted in 1997 has no provisions on biosafety.	There is necessary to complete the law with provisions on notification and authorization procedure for introduction and use of drug products GM, risk evaluation for human health, stipulation of health protection measures during the production activity, requirements on import/export/transit according the Law on biosafety of 2001/draft Law on GMOs.
	The Law on pharmaceutical activity adopted in 1993 does not contain some provisions on biosafety.	There is necessary to complete the law with provisions on notification and authorization procedure for introduction and use of pharmaceutical and para-pharmaceutical products GM, risk evaluation for human health, stipulation of health protection measures during the production activity, labelling and packaging requirements for pharmaceutical products, requirements on import/export/transit according the Law on biosafety of 2001/draft Law on GMOs.

Roles / responsibilities of national bodies in the agriculture and food industry sector that are part of the biosecurity process

The **Ministry of HealthCare** activates according the Regulation on its organization and functioning adopted by GD no.397 of 31 may 2011. According this regulation, the MH has the following attributions:

- Develops and coordinates implementation of public policies on health development, health services adaptation to new needs by creating their proper infrastructure, development and coordination of public policies on the reduction of population inequality in health services;
- Organize the analysis and evaluation of population health indicators, the health system activity and performance of public healthcare institutions and ensure the dissemination of information pertaining to the public interest;

- Promote and realize cross-sector partnership to include results of analysis of the impact on public health in public policies of other sectors, as recommended by the European Commission 'Health in All Policies' (Health in All Policies) in order to maximize results in the field of health;
- Develops policies on organization and regulation of integrated care (primary care, secondary / tertiary rehabilitation) enhancing the role and authority and provides primary health care in the health system, with priority focus on prevention of diseases;
- Develops policies on the development of community care (home care, palliative nursing), provides and promotes strengthening intersectoral activities in this field;
- Prioritize, identify essential medical services needed by the population, respecting the principles of equitable provision of adequate population needs, giving priority attention to socially vulnerable groups;
- Develops and coordinates the implementation of public policies on state supervision of public health at national and local levels working with representatives of central and local public administration authorities, civil society and media in order to prevent illness, protection and health promotion.

The Ministry of Health has two central institutions:

National Centre on Health Management and National Centre on Public Health – these institutions are involved in process of data collection on state of population health. National Centre on Health Management is responsible for data collection, processing, evaluation of statistical data on population health issues, including morbidity, injuries, disabilities, etc., also, it is responsible of activity of medical bodies including their financing and financial supply.

The national Centre on Public Health is responsible for collection, processing and evaluation of data regarding transmissible disease, risks and urgencies in public health, as well as factors that determine the health – occupational, environmental and behaviourally. The National Centre on Public Health has similar centres in each rayon of the RM.

Conclusions on desk study review in health care sector in context of improvement of implementation of Cartagena Protocol provisions.

Based on comparative analysis there are a number of gaps and weaknesses identifies of non-compliance with the Cartagena Protocol provisions, as well as with the national Biosafety law (2001), National law on GMOs (draft, 2016), and the NBSAP (2015);

The identified conclusions relate to:

Institutional/administrative measures

- Develop the procedure on permits issue for the simplified procedure on introduction and use of GMOs intended to be used as medicines, pharmaceutical and para-pharmaceutical products;

- Develop annual reports on identification of GMOs in medicines and pharmaceutical and para-pharmaceutical products.

Political measures

- Review the political and legal framework in context of including of the biosafety provisions according requirements of the draft law on GMO, especially for activities related to introduction and use of medicines, pharmaceutical and para-pharmaceutical products that contain or consist of GMOs, taking into account the insurance of human health security;

Legal measures

- Development and adoption of the normative documents on authorization of activities on introduction and use of medicines, pharmaceutical and para-pharmaceutical products that contain or consist of GMOs, taking into account provisions of Cartagena Protocol requirements;
- Develop and approve the model on authorization for introduction and use of medicines, pharmaceutical and para-pharmaceutical products that contain or consist of GMOs;
- Develop the regulation document according provisions of Council Directive 2009/41/EC on the contained use of genetically modified micro-organisms, on activities of use in isolated conditions of GM micro-organisms that are part of activities of laboratory researching of biological, chemical, physical and radiological factors that can impact human health;
- Development of normative documents on ceasing the illicit activities on the territory of the RM with medicines, pharmaceutical and para-pharmaceutical products that contain or consist of GMOs;
- Development of normative documents on monitoring of medicines, pharmaceutical and para-pharmaceutical products that contain or consist of GMOs;

2.4 Trade and customs issues

Political documents in field of trade and customs issues

The National Strategy for Integrated Border Management for the period 2015-2017 and the Action Plan for its implementation adopted in 2014²³ is the main policy document that reflects the priorities and vision of the State in area of integrated border management to ensure border security, thus preventing and combating illegal migration and cross-border crime. Strategy contribute to achieving the strategic objective our country - EU accession, including reforms arising from the liberalization of the visa regime with the EU for Moldovan citizens (effective 28 April 2014) and of the Association Agreement with the EU (signed 27 June 2014). The strategy contains information on the competences of the authorities of integrated management system of the state border, which specifies the Ministry of Environment, through the State Ecological

²³National Strategy for Integrated Border Management for the period 2015-2017 and the Action Plan for its implementation was adopted in 2014 by a GD no. 1005 of 10.12.2014.

Inspectorate, Department of Fisheries, the National Agency for Regulation of Nuclear and Radiological Activities, State Hydro Meteorological Service, responsibilities In this context. Similarly, the strategy notes that there are numerically limited joint trainings for personnel with direct responsibilities to border authorities, and related authorities responsibilities of the thematic areas of mutual interest among which - risk analysis, border security, customs activity, risks phytosanitary and veterinary health, etc., This creates problems for integrated treatment of border issues. The strategy has no provisions on biosafety.

The domestic trade development Strategy for the years 2014 - 2020 and the Action Plan for the years 2014-2016 adopted in 2013²⁴ refers to development within the country of activities related to marketing of products and services that are regulated by the Law on trade of 2010. The purpose of the Strategy is to provide consumers with the necessary competitive products and services by creating an efficient marketing system throughout the country. Main objectives of the strategy aimed at increasing the efficiency of trade regulation inside the increased competitiveness of products / services placed on the market, improve trade infrastructure in the regions, especially in rural areas, modernization of forms of distribution and marketing of products / services, ensuring trade sector with qualified workforce. The strategy does not contain some provisions in the context of biosecurity.

Legal documents in field of trade and customs issues

The Law on approval of Combined Nomenclature of goods approved in 2014²⁵ is carrying out the classification of goods. This law facilitates tariff and non-tariff measures for regulation of foreign economic activity of the state, contribute to improving the statistical evidence and of exchange of information on the movement of goods abroad with their alignment with international standards. This law does not include provisions on biosafety.

The Law on internal trade approved in 2010²⁶ regulates the activity in the field of internal trade establishing the main requirements for implementation of these activities, stipulates forms of trade development, components of central specialized bodies and of LPA in field of trade. This law does not contain some provisions on biosafety.

The summary of the results of legal framework evaluation in trade and customs services sectors are shown in the table below:

Table 4. Assessment of trade and custom services legislation towards Cartagena protocol main provisions

Main provisions of Cartagena Protocol on Biosafety	National legislation provisions/sector	Recommendations
Transit and use of GMOs in closed environment; Application of the Advance Informed Agreement Procedure,	The Law on approval of Combined Nomenclature of goods approved in 2014 has no provisions in context of biosafety	There is necessary to complete the law with list of goods genetically modified included in the tariff codes based on which goods can be introduced to the

²⁴The domestic trade development Strategy for the years 2014 - 2020 and the Action Plan for the years 2014-2016 was adopted in 2013 by GD no. 48 of 25.11.2013.

²⁵The Law on approval of Combined Nomenclature of goods was approved in 2014 by GD no. 172 of 25.07.2014.

²⁶Law on internal trade was approved in 2010 by GD no. 231 of 23.09.2010.

<p>Notification for GMO introduction in the country, Traceability procedure for GMO intended to be used directly as food or feed or in processing activities, Risk evaluation and risk management, Manipulation, transport, labelling and GMO identification,</p>	<p>requirements.</p>	<p>country and could also be exported, provisions on notification procedure when introducing on the market of these goods GM, on risk evaluation of these goods, specify conditions for import, export and transit, monitoring according the requirements of the existing law on biosafety and /or the draft Law on GMOs.</p>
<p>The competent national authority – focal point, Exchange of information and prevention of biotechnological risks, Public information and public awareness.</p>	<p>The Law on internal trade approved in 2010 has no provisions on biosafety.</p>	<p>There is necessary to complete the law with provisions on notification and authorization procedure for introduction and use of products GM, risk evaluation, requirements on labelling and packaging of these products, requirements on import/export/transit according the Law on biosafety of 2001/draft Law on GMOs.</p>

Description of role / responsibilities of national bodies in the trade and custom services sectors that are part of the biosecurity process

According the *GD on approval of the staff limit and of Regulation on organization and functioning of the Custom Service*²⁷, the Custom service is the body of the public administration in suborder of the Ministry of Finance of the RM, that insures the state economic security, implement the custom policy and leads the custom activity on the territory of the RM. Customs Service of the Republic of Moldova is an institution of the law enforcement and state security system with the mission of ensuring the country's economic security through efficient collection of taxes, combating customs fraud, facilitate international trade and the protection of society, applying uniform and impartial customs legislation.

The main functions of the Custom Service consist of insurance of efficient custom operations, facilitation of trade and international transport services, regulates the exchange of goods on the territory of the RM, contribute to solving of political and trade problems on protection of internal market, stimulation of national economy development, and other objectives established by the government.

The Ministry of Economy is the central public institution that is responsible for trade regulation within the country. The activity of the ministry is stipulated in the Regulation on organization and functioning of the Ministry of Economy approved in 2009²⁸. According this document the ministry mission is to insure the increasing the national economy through optimization of regulation of entrepreneur activity, creating conditions for business development, technological development and insurance of competitiveness, creation an investing favourable environment, demonopolization of internal market and corruption liquidation, as well as development of international economic cooperation. Among the ministry functions is import to mention here those related to trade, especially – development and promotion of state policy on internal and external trade development, service providing based on priorities and state regulated sectors, development of regulations on undertaking the trade activities, monitoring of trade activities, others. Also, the ME has the responsibilities for elaboration of state programs and strategies on internal trade development, develop legal and normative documents in order to improve the legal framework in field of internal trade, develop and apply in cooperation with other governmental structures and civil society of a complex of stimulating measures for export of goods and services, create a favourable legal environment for undertaking the export measure, promotes the state image on the international arena, monitor the Trade Informational System through the local public authorities, etc..

Conclusions on desk study review in trade and custom service sector in context of improvement of implementation of Cartagena Protocol provisions.

²⁷GD on approval of the staff limit and of Regulation on organization and functioning of the Custom Service no. 4 of 02.01.2007.

²⁸Regulation on organization and functioning of the Ministry of Economy approved in 2009 by GD no. 690 of 13.11.2009.

Based on comparative analysis there are a number of gaps and weaknesses identifies of non-compliance with the Cartagena Protocol provisions, as well as with the national Biosafety law (2001), draft of National law on GMOs (draft, 2016), and the NBSAP (2015);

The identified conclusions relates to:

Institutional/administrative measures

- Insure within the custom service points of the country of procedure on import, export, transit for products that consist or contain the GMOs;
- Supply with actual information on transboundary movement of GMOs national and international structures for biological security.

Political measures

- Review the political and legal framework in trade and custom service sectors in context of including the biosafety provisions in sectorial legal framework, according the requirements of the draft law on GMOs, especially for activities related to introduction and use of food and feed products, products of animal and non-animal origin, seeds, planting material, medicines, pharmaceutical and non-pharmaceutical products that are GM, contain or consist of GMOs;

Legal measures

- Insurance of a normative framework on establishing the inspection, control and monitoring services for products that contain or consist of GMOs;

2.5 Public information and consumer protection

Political documents in field of public information and consumer protection issues

The Strategy on consumer protection for the period 2013-2020 and the Action Plan for its implementation for the first period 2013-2016²⁹, adopted in 2013 has the scope to insure consumers with necessary products and competitive services by establishing an efficient system for marketing of products on the whole territory of the country. The strategy has the following specific objectives:

- decreasing the risk on appearance of dangerous products and services;
- decrease the level of unfavourable transactions for consumers;
- increasing the decision taking capacity of consumers by training and information measures;
- make more efficient process for claiming of the rights and recovering of damages.

This strategy does not contain some provisions on biosafety.

Legal documents in field of public information and consumer protection issues

²⁹Strategy on consumer protection for the period 2013-2020 and the Action Plan for its implementation for the first period 2013-2016 was approved in 2013 by the GD no. 560 of 24.07.2013.

The Law on consumer protection adopted in 2003³⁰ defines the legal base for consumer and physical person protection. This is a framework law due to the fact that represent the general terms and protection forms for Moldova consumers. This law sets the consumer rights, as follows:

- Have his rights protected by the state; protection against the risk of purchasing a product, a service that might affect life, health, heredity or safety or to prejudice the legitimate rights and interests;
- free repair or replace, refund product, service or appropriate price reduction, repair damages including moral, caused by the product, improper service; full, fair and accurate information about products, training rights; organizing public associations for consumer protection;
- Addressing the public authorities and the representation of its interests; notification of consumer protection associations and public authorities on the rights and legitimate interests, as a consumer, and to make proposals on Improving over product quality, services.

This law does not contain some provisions on biosafety.

The Governmental Decision on approval of norms for labelling of food products and norms for labelling of chemical and household products approved in 2003³¹ contain provisions on technical and sanitary regulation for all food products and chemical products introduced on the market of Moldova and are obligatory for all producers form food industry sector and non-food sector as well, indifferent of type of property or legal organizational form. This GD is obliging the MH to elaborate and approve sanitary norms for labelling of nutritional products, food products with dietetic destination, labelling of food products genetically modified or obtained from genetically modified organisms, labelling of materials intended to be in contact with food products, labelling of games and toys, of cosmetic and perfume products.

The Law on public access to information adopted in 2000³² regulates the relations between information providers and the physical or legal person in process of insurance of the constitutional right to have access to information, sets the principles, conditions, ways of insuring the access to official information, stipulates the rights of information seekers, obligations of information providers during the process on accession of official information, modalities of protection the rights to access the information. This law sets the following objectives:

- Establishing a general framework on access to information;
- Making more efficient the process of population information and on control undertaken by citizens on activity of public authorities and of public institutions;
- Stimulation the process on opinion forming and active participation of population at the decision making process.

The draft Law on public access to environmental information is developed with the purpose to implement the provisions of Aarhus Convention ratified by PD no. 346-XIV of 7.04.1999, also

³⁰Law on consumer protection was adopted in 2003 by GD no. 105 of 13.03. 2003.

³¹The Governmental Decision on approval of norms for labeling of food products and norms for labeling of chemical and household products was approved in 2003 by GD no. 996 of 20.08.2003.

³²Law on public access to information was adopted in 2000 by GD no. 982 of 11.05.2000.

in context of implementation of the Association Agreement RM-EU for the years of 2014-2016. The draft law partially transposes the Directive 2003/4/CE of EP and of Council of 28 January 2003 on public access to environmental information. The main objective of this law is to insure public access to environmental information in order to actively involve community in environmental protection activities and in decision making process in the field.

*The Regulation on information and public consultations on GMOs adopted in 2000*³³ sets the information mode and public participation at decision making process in the field of GMOs use. This regulation was developed based on provisions of the Aarhus Convention on access to information, justice and public participation in decision making process in the field of environmental protection, Cartagena Protocol on biosafety, GD on composition of the National Commission on biosafety, etc..

The summary of the results of legal framework evaluation in public information and consumer protection sectors are shown in the table below:

Table 5. Assessment of public information and consumer protection legislation towards Cartagena protocol main provisions

Main provisions of Cartagena Protocol on Biosafety	National legislation provisions/sector	Recommendations
Transit and use of GMOs in closed environment; Application of the Advance Informed Agreement Procedure, Notification for GMO introduction in the country, Traceability procedure for GMO intended to be used directly as food or feed or in processing activities, Risk evaluation and risk management, Manipulation, transport, labelling and GMO identification, The competent national authority – focal point, Exchange of information and prevention of biotechnological risks, Public information and public awareness.	The Law on consumer protection adopted in 2003 has no provisions in context of biosafety requirements.	There is necessary to complete the law with provisions on access to information and participation in decision making process during the notification procedure when introducing on the market of GM products and goods, on risk evaluation of these goods, conditions for import, export and transit, labelling requirements for GM products and goods according the requirements of the existing law on biosafety and /or the draft Law on GMOs.
	The Governmental Decision on approval of norms for labelling of food products and norms for labelling of chemical and household products approved in 2003 has no provisions on biosafety.	There is necessary to complete the law with provisions on labelling and packaging of GM goods and products, according the Law on biosafety of 2001/draft Law on GMOs.
	The Law on public access to information adopted in 2000 has no provisions on biosafety.	There is necessary to review this law and include provisions on public information and participation in decision making process for activities that imply the introduction on the territory of the country of GMOs, according the requirements of the draft law on GMOs.

³³Regulation on information and public consultations on GMOs was adopted in 2000 by GD no.72 of 25.01.2000.

Roles / responsibilities of national bodies in the public information and consumer protection sectors that are part of the biosecurity process

As describe above in the trade and custom services subchapter, among many other functions, *the Ministry of Economy* is the central public authority that insures the issues of consumer protection. Also the Ministry of Economy is responsible for development of policy and promotion of draft of legal documents in field of consumer protection and insures the mechanism for their implementation, insures the coordination of control and supervision activities of market regarding the law enforcement , participate in development of technical regulations, national standards, other normative documents that establish requirements for products and services under the consumer protection issue, coordinates the activity of authorities of public administration that are responsible for consumer protection, coordinates the activities on information, training of citizens regarding their rights as consumers, hold the role of secretariat for the Coordination Council in the field of consumer protection .

Other institution that is authorized with responsibilities in field of consumer protection is the *Agency on consumer protection*³⁴ that is an administrative authority under the subordination of the Ministry of Economy of the RM. The Agency is responsible of implementing the policy in the field of consumer protection and of undertaking state control on law enforcement in the field as well as to implement state control on compliance of the products and /or services offered on the market to declared or written requirements, also it is undertaking the process of monitoring norms and rules of trade activities.

Conclusions on desk study review in public information and consumer protection sectors in context of improvement of implementation of Cartagena Protocol provisions.

Based on comparative analysis there are a number of gaps and weaknesses identifies of non-compliance with the Cartagena Protocol provisions, as well as with the national Biosafety law (2001), draft of National law on GMOs (draft, 2016), and the NBSAP (2015), there have been identified the following conclusions:

Institutional/administrative measures

- To facilitate the information flow via interconnection for sites of environmental conventions Clearing house mechanisms including BCH;
- Monitoring of respecting the consumer rights on introduction in the country and placing on the market the products GM or products that consist or contain the GMOs;
- Facilitate public participation in debates on introduction in the country and placing on the market of products that are GM;
- Facilitate training activities for specialist that work in this field from all sectors of the national economy in context of GMOs management;

Legal measures

³⁴The Agency on consumer protection was established by GD no. 936 of 09.12.2011.

- Revise and complete the legal framework in the evaluated sectors (environmental protection, agriculture and food industry, health care, trade and custom service, consumer protection) with provisions regarding the procedure of public information, public participation in decision making process for the issues related to biosafety, according the requirements of art.23 of the Cartagena protocol and of the draft Law on GMOs;
- To include the legal provisions in each evaluated sector regarding the public information via the BCH on the undertaken actions in the sector that involves or refers to GMOs taking into consideration provisions of draft Law on GMOs;
- To include the legal provisions on public access to the databases, the information systems that are relevant in context of GMOs;
- To include in text of label for products that contain or consist of GMOs the phrase ... more information on GMOs could be find on the BCH site;
- Development of national technical regulations taking in consideration provisions of Cartagena protocol on Biosafety and EU Directives in the sector, in order to integrate the biosafety objectives in sectorial legal framework;

3. Results of the round table meeting

According the TOR provisions, after undertaking the evaluation of the policy and legal framework in the selected sectors of the national economy – environmental protection, agriculture and food industry, health care, trade and custom services and public information and consumer protection, there have been organized a round able meeting in order to broadly discuss the results of the undertaken desk study.

At the 15 of June 2016, have been organized the round table meeting, with the title “Integration of biosafety issues in the sectorial policies”, that took place in the Ministry of Environment building. At this meeting have been invited representatives of Ministry of environment, State environmental Inspectorate, Academy of Science of the RM, Ministry of Agriculture and Food industry, National Agency for Food Security, Ministry of Economy, Agency for Consumer protection, Custom Service representatives, Ministry of Health, representatives of National Centre of Public Health, of Institute of Ecology and Geography, Institute of Metrology, Institute of Zoology, the Botanical Garden Institute, State Agricultural University of Moldova, State University of Moldova, representatives of NGOs, etc..

According the agenda for the meeting, there have been prepared several presentations that reflected the current situation on implementation of the National Strategy on Biodiversity for the period 2015-202 and it Action Plan, provisions of the Cartagena Protocol on Biosafety and state of integration of biosafety issues in sectorial policy and legal framework.

Thus, in the meeting have been presented information on:

- National Strategy on Biodiversity and the Action Plan for its implementation – results and perspectives;
- Integration of biosafety provisions in NSBAP and in national sectorial policies
- Comparative analysis of legal gaps in the sectorial policy in context of implementation of Cartagena Protocol on Biosafety

Also, at the meeting after presentations, participants have been asked to form 5 separate working groups to examine the identified by consultant gaps in legal framework and to express their opinion, to come with comments on the suggested issues. At the end, each group named a representative that presents the results of the group activity. After working in groups, have been identified some new proposals that have been reflected in this report, being included in conclusions for each sector.

For example, the group of agriculture and food industry mentioned that for improved implementation of the Cartagena Protocol it is important to have accreditation done for the laboratory of GMO detection that is organized within the National Agency on Food Security, under the MAFI subordination. Also they pointed out that is necessary to keep update the legal framework in this sector based on the new provisions that are imposed by the draft Law on GMOs.

The group that worked on public information and consumer protection issues submitted several good proposals, as follows – to interlink the Clearing Houses websites organized in all environmental conventions in order to facilitate the information flow and to make easier access of public to this information, other proposal in this sector was to include in the text of label for the GM products, the following information - ... more information on GMOs could be find at the website – BCH.

The participants of the environmental protection group, pointed out that it is also important to update the Contravention Code and to include provisions on case related to breaking the legal requirements for GMOs, mentioning the amount of penalties. They also mentioned that in context of developed new Law

on GMOs, all sectors have to review and accordingly update their sectorial legislation and to cooperate for implementation of the CP provisions in the national policy and legislation.

The round table meeting organization was reflected in the internet media, this information being placed on the web page of the Ministry of Environment - <http://www.mediu.gov.md/index.php/serviciul-de-presa/noutati/2481-integrarea-biosecuritatii-in-politicile-sectoriale>

The result of the round table has been considered by project consultant and included in the charter – next steps.

4. Next steps for improvement of integration of Cartagena Protocol provisions on biosafety in the sectorial policy and legal framework

After the evaluation process of the national sectorial policy and legal framework and based on the conclusions of the roundtable discussion held on 15 June 2016, were participated representatives of all evaluated sectors of national economy, have been identified the main recommendations for integrated implementation of the Cartagena protocol provisions as follows:

Policy measures

- Improvement of the sectorial political and legal framework with provisions of Cartagena Protocol on biosafety, taking into account as well the EU legislation provisions;

Legal measures

- Develop the regulations on activity of the sectorial technical Committees;
- Development of regulations and procedures for authorization of activities on GMOs, permits issuing for the simplified procedure of GMOs, risk assessment, monitoring, inspection and control activities related to GMOs, according the provisions of the new Law on GMOs and Cartagena Protocol;

Institutional/administrative measures

- Establish the sectorial technical Committees for examination of notifications on introduction in the country of GMOs;
- To review the institutional framework within sectors (environmental protection, agriculture and food industry, trade and custom services, public information and consumer protection) and improve the existing schemes with new responsibilities according the requirements mentioned in new draft Law on GMOs, especially for inspection and control of activities that involve GMOs;
- Insure the supervision of traceability for GMOs introduced in the country, application of requirements for labelling of GMOs/products;
- Development of adequate measures for the emergency situation that involve GMOs, for unintentional transboundary movement of GMOs and illicit deliberation to the environment of GMOs;

- Organization of trainings and capacity building activities for sectorial specialists that are dealing with law enforcement activities, research, control, authorization, monitoring, risk assessment, etc.;
- Insure adequate conditions for public information and participation in decision making process for all activities that involve GMOs.
- Insure necessary measures for establishing the identification and testing laboratories for GMOs insure their accreditation and functioning.

5. Mainstreaming of biosafety issues in political and legal frameworks within other sectors of national economy.

In context of describing process that lead to mainstreaming of biosafety in other sectors, we are bringing below some details and examples.

First of all, here is important to mention the *Law on transparency of decisional process nr. 239 – XVI of 13 November 2008* that deals with transparency of decisional process that is considered one of the main elements of good governance. According this law, new principles and procedures in activity of central and local public authorities have been introduced for informing people, civil society, stakeholders in an open and clear way about the activity of the authorities and to consult them during the elaboration and adoption process of the new political and legal framework. In this regard, when a new law is developed, there shall be followed several steps that allow public, institutions, civil society, stakeholders to be informed and participate in process of development of new legal framework in the sector.

The transparency of decisional process comprises several steps as:

- 1) publication of announcement of initiation of development of new law/by law,
- 2) announcement of initiation of public consultations for the new law,
- 3) the draft law/by law documents are made available for public discussions,
- 4) publication of list of adopted legislation.

Thus, when a new law is under development process it is **consulted with all interested parts**, including sector ministries and proposal for improvement are taken into consideration. Also, when the new law is adopted, the line ministries and agencies have obligation **to make modifications** in their sector legal framework according the provisions of the new adopted law, in order to insure implementation of the law.

For example, recently (9.09.2016) on the website of the Ministry of Health was posted for public consultation the draft Regulation on use in isolating conditions the GM microorganisms. The necessity to develop this regulation was done based on the provisions of *Law on biosafety of 2001*. This regulation also, is transposing provisions of the *Directive 2009/41/CE of 6 May 2009 on use in isolating conditions the GM microorganisms*. Also, the draft Governmental decision for approval of this normative act, foresees that regulation will enter to force **within 6 month** after its publication in Official Monitor of the RM. The GD on approval of this new regulation has the provision that control on implementation of regulation is put on responsibility of Ministry of Agriculture and Food Industry, Ministry of Health and Ministry of Environment. Thus, the cooperation/collaboration process shell continues.

If speaking about the agricultural sector, particularly the *Law on seeds of 2013 and Law on protection of plant varieties of 2008*, the provisions of biosafety have been included in these legal documents at the recommendation of the *Parliamentary Commission for public administration, regional development, environment and climate change*, when these laws were modified and presented for consultation in Parliamentary Commission. In case of the *Law on agro-food ecological production of 2005, Law on food products of 2004 and Law on sanitary-veterinary activity of 2007*, have been modified and incorporated provisions on biosafety under the implementation process of the *RM-EU Association Agreement*. Also, for better implementation of the agro-food ecological production, based on provisions of *Law on agro-food ecological production of 2005*, within Ministry of Agriculture and Food Industry was established a working group, part of which were is also an representative of the Ministry of Environment that comes from the Department of Natural Resources and Biodiversity, that is coordinating and promoting the activities related to biodiversity conservation, ecological production development and insurance of biosafety issues.

Other instrument that leads to mainstreaming of biosafety provisions in sectorial policies and legal framework can be considered the *National Strategy on Biodiversity for the period 2015-2020 and it's Action Plan*. According the AP of the Strategy, *for example*, the *Objective 1 – Development of the regulatory framework in field of biodiversity conservation*, foresee the *activity 4*, that says that there is need for development and promotion of regulatory documents on deliberate release into the environment and on the market of GMO, according the provisions of the *Directive 2001/18/CE* of March 12, 2001, as well as the *Directive 90/219/CE* of 6 March 2009. Term for implementation of this activity is 2016, responsible bodies for implementation of these provisions are the MoE, MAFI, ASM, Ministry of Finance with Custom Service, Ministry of Health. These activities are planned to be implemented within the available state budget, as well as with external funding sources.

Other activity included in the **NBSAP** is activity on implementation of the national framework on biosafety according the provisions of Cartagena Protocol on Biosafety. Term for implementation of this activity is 2020, responsible bodies are the MoE, MoH, MAFI, and ASM and there are plan to use state budget sources and external financial sources. This kind of strategic activities, are mobilizing and oblige all responsible bodies to introduce modifications in their sectorial legal framework and to bring it in accordance with NBSAP provisions.

Usually, the activities stipulated in the national strategy are transposed to the annual work plan of the institution (MoE, MAFI, MoH, etc). *For example*, in environmental protection sector (as in other sectors), each year is developed and approve by the minister a work plan. In the work plan there are specific actions for different objectives that have to be implemented during the year and for which are mentioned deadlines for approval, responsible department within the ministry. For example, for 2016, the WP of the Ministry of Environment foresee at the *Objective 5 – reestablishment, protection and conservation of biological diversity through extension by 15 % of wood area and of natural protected areas by 8%*, as well as insurance of efficient and sustainable management for natural ecosystems – there is planned for the II trimester of 2016, the activity of development and approval of the new Law on genetically modified organisms. Actually this Law is revised by Parliament Commissions. Since the new law will enter to force

its provisions shall be reflected in legal framework of other relevant ministries – example Ministry of agriculture and food industry, Ministry of health, other.

Other instrument that contributes to mainstreaming of the biosafety into legal framework of other sectors of national economy is the obligations that RM assumed after signing and ratification of the *RM-EU Association Agreement* that was ratified by the Parliament of the RM by Law no. 112 of 2 July 2014, the European Parliament ratified this agreement at 13 November 2014. At the national level, was developed an Action Plan for the period 2014-2016 that is focussed on implementation of Association Agreement provisions and which look for alignment of the national political and legal framework to the EU one.

Another instrument that can lead to mainstreaming of biosafety objectives in sectorial policy is the **right of the MoE to initiate a modification process in sectorial legal frameworks** of agriculture, health, custom services, etc., according the Cartagena Protocol provisions. This instrument was not applied yet.

Due to the fact that RM signed and ratified 18 environmental conventions, for their better implementation within the MoE are established the **Working Groups for each convention/agreement implementation** that are composed of representatives of different sectorial institutions, depending of the specific of the international treaty. Thus, the WG has regular meetings, representatives of the group are participating at thematic meetings organized within the convention/agreement and are informing other members about the result of the meeting when they came back. Due to the fact that members of the WG are form the institutions/ministries (*for example, WG for Cartagena Protocol is composed of representatives of MAFI, MoH, MoE, CS, ASM, NGO*) that has an important role in implementation of the convention/agreement provisions at the country level, through this group are also promoted in the institution/ministry which they represent the provisions of the international treaty, being included in the sectorial policy and legal framework.

Other instrument for mainstreaming the biosafety objectives into national political and legal framework is the *National Biosafety Committee*. The NBC is composed also from representatives of the ministry of environment, scientifically sector, member from each of the following national authorities: economy, agriculture and food industry, health care, standardization and metrology, and from environmental **NGOs**. This committee represents also a platform for mainstreaming the biosafety objectives into other sectors of national economy that are important in implementation of the Cartagena Protocol provisions.

As mentioned above, when a new law is developed it is consulted with line ministries and agencies and each institution is aware of the new provisions that should be introduced in sectorial legal framework once the new law will be adopted. This creates an opportunity for relevant institutions to start think already on how it would be possible to include in their sectorial policies these new provisions. Each adopted law has a provision regarding terms of entering into force, for example, for **new Law on GMO**, there is mentioned that it will **enter into force after 1 year** from its publication in the Official Monitor. Thus, the relevant ministries and agencies have sufficient time **to modify their legal framework according the new law provisions**.

Further, there will be given some information related to role of the **competent authorities which are involved in the mainstreaming process of biosafety issues**. First, it shall be mentioned the **Parliamentary Commission** for public administration, regional development, environment and climate change as responsible of functioning of central public authorities including for environmental protection, responsible for state policy in the environmental protection sector, of implementation of the environmental policy in the policies of other sectors, of protection of natural resources including biodiversity, control of central public authorities on implementation of the legal provisions, the **Ministry of Environment**, as the main responsible central public authority for ensuring the political and legal framework for biodiversity conservation and biosafety issues, the **National Committee on Biosafety**, as the national inter-ministerial responsible authority, the **Biosafety Office under the MoE**, as responsible for promotion and strengthen national capacities to implement activities related to biosafety on governmental and academic sectors and at civil society level.

Mainstreaming process cannot happen without financial support. Usually, activities that lead to mainstreaming of biosafety provisions into other sector policies and legal framework have been implemented based on the state budget, in available limits and based on the international funding under implementation of certain projects. More technical assistance is required to continue with this process.

An important role in mainstreaming process of biosafety, belong to **public and civil society**. They play an important role in the mainstreaming of biosafety provisions in the environmental sector as well as in other sectors on national economy. As more public and society is informed and have access to biosafety information, as more efficient is involved in monitoring of activities developed in this sector. According the actual legal framework regarding access to information, including the biosafety public is informed about what is happening in the sector – status of implementation, new plans for legal development and they can participate in these processes. Also, via **Biosafety Clearing-House** they can access the information regarding current status of implementation of the Cartagena protocol at the national level as well as at international level and benefit of the exchange of information with parties to the protocol and other international organisations that work in biosafety sector.

The successful mainstreaming of biosafety into national policy and legal framework is determined by the **political willingness of the leadership** of the line ministries, established **inter-sectorial cooperation framework**, available **financial resources**, on how well is informed and how active is the public and civil society at the country level. From the experience we gained till now in this process we can mention that all these elements (central public authorities, local public authorities, **inter-ministerial collaboration mechanisms, active civil society and public, financial resources**) are extremely important – cooperation and involvement of all relevant parts lead to successful implementation of the Cartagena protocol on biosafety.

An important role in mainstreaming process play the National Biosafety Committee.

The National Biosafety Committee operates as the inter-ministerial authority and consists of 14 members, including:

- 2 members from the national environmental authority, which have the functions of respectively the Chairman and the Secretary of the National Committee;

- 4 members from the Academy of Sciences of Moldova;
- 3 members from other scientific institutions and universities with biological or medical profile;
- 1 member from each of the following national authorities: for economy, agriculture and food industry, health care, standardization and metrology, and from environmental NGOs.

The National Biosafety Committee (NBC) was established by Government Resolution no. 603 of 20.05.2003 and operates as the national inter-ministerial responsible authority.

The Regulation of functionality of the NBC determines its power and the function to ensure governmental policies in the field of biosafety, acting in particular via issuance of authorizations, monitoring of the GMO-related activities, collaboration with governmental authorities and scientific institutions competent in the relevant sphere. NBC is nominated as a competent national authority that has a duty to exercise authorization attributes and control over for the following activities:

- a) GMO uses for contained us;
- b) Deliberative release in the environment;
- c) Accidental release in the environment;
- d) Placing on the market;
- e) Research activities;
- f) Import/export;
- g) Transboundary accidental transportation;
- h) Storage and destroy of GMOs.

According to the Regulation, the NBC has the following functions:

- a) examination of notification documents;
- b) elaboration of reports, synthesis and information for national and international uses;
- c) public information;
- d) cooperation with the competent research institutions;
- e) maintaining and publishing the Register of the GMOs;
- f) national and international participation.

The NBSAP identifies the establishment of ‘biosafety and protected areas’ as a tool for the achievement of its objectives. Actually, no progress is notified in regard to integration of biosafety into protected areas. The draft of the Law on GMO has a provision (art 25) that in the RM is forbidden the deliberate release into the natural environment (forest, aquatic, palustre and steppe ecosystems) and in agricultural one of the GMOs.

*Regulation on public participation in the development and adoption of environmental decisions, approved by Government Decision No. 72 from 25.01.2000 regulates public participation in the process of drafting of laws, programs and regulations, national projects and socio-economic development programs which involve the use of natural resources, a significant impact on the environment. The regulation also provides for public participation in decision-making process on the projects and types of planned activities at national level and in a transboundary context, according to the *Convention on Environmental Impact Assessment in a Transboundary Context*.*

The NBSAP has an activity in the Action Plan for its implementation that foresees implementation of the national framework on biosafety according the provisions of Cartagena protocol on Biosafety. Term for implementation of this activity is 2020, responsible bodies are the MoE, MoH, MAFI, and ASM and there is plan to use state budget sources and external financial sources for this purpose. This kind of strategic activities, are mobilizing and oblige all responsible bodies to introduce modifications in their sectorial legal framework and to bring it in accordance with NBSAP provisions.

Lessons learned and suggestions

In context of be successful in mainstreaming the biosafety in sectorial legal framework there is need to improve/faster the following measures:

- maintain/stimulate personal that works in this field for years, because they are well trained, skilled and know already what to do. Recently, was noted that fluctuation of personnel leads to decrease of level and quality of institutional expertise in biosafety;
- not sufficient prioritization of biosafety issues at ministries/institutional level;
- poor cooperation and synchronization of activities on biosafety between line ministries for mainstreaming biosafety in other sector policy and legal framework;
- not enough financial resources for implementation of activities related to biosafety as legislative, institutional, capacity building, awareness raising;
- insufficient activities related to exchange of experience with countries party at the Cartagena Protocol on Biosafety that are more advanced in implementation of protocol.

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