

REPUBLIC OF MOLDOVA

**MINISTRY OF ENVIRONMENT
AND NATURAL RESOURCES**

**UNITED NATIONS ENVIRONMENT
PROGRAM/GLOBAL ENVIRONMENTAL
FACILITY**

**CONVENTION ON BIOLOGICAL DIVERSITY
THE CARTAGENA PROTOCOL ON BIOSAFETY**

NATIONAL BIOSAFETY FRAMEWORK

**Produced within the UNEP/GEF Project GF/2716-02-4520
„Development of the National Biosafety Framework
for the Republic of Moldova”**

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PROJECT BACKGROUND

UNEP/GEF PROJECT: DEVELOPMENT OF THE NATIONAL BIOSAFETY FRAMEWORK FOR THE REPUBLIC OF MOLDOVA

The UNEP/GEF Project Paper “Development of the National Biosafety Framework for the *Republic of Moldova*” was signed by the UNEP Representative Mr. E. F. Ortega and the Minister of Finance of the Republic of Moldova Mrs. Zinaida Greceanii in November 2002. The official project approval date was **11 November 2002** and the expected project completion date has been set as **13 May 2004**. Project implementation started in January 2003. Subsequently the Project lifetime extended by 4 months and the project ended on **11 September 2004**.

The National Executing Agency for the above UNEP/GEF project
Ministry of Ecology and Natural Resources
Dr. hab. Constantin Mihailescu, Minister
str. Cosmonauților, 9
MD-2005 mun. Chișinău
Phone: +(373 22) 20-45-07, Phone/Fax: +(373 22) 22-68-58
E-mail: egreta@mediu.moldova.md

The National Project Coordinator
Dr. Angela Lozan.
str. Cosmonauților, 9
MD-2005 mun. Chișinău
Phone/Fax +(373 22) 22-68-74
E-mail: alozan@biosafety.md

The National Coordinating Committee consisted *of* 7 members, which represent the following institutions and organizations: **Ministry of Ecology and Natural Resources, Ministry of Economy, Ministry of Agriculture and Food Industry, Institute of Genetics of the Academy of Sciences of Moldova, Biodiversity Project, NGO “Biotica”**.

INTRODUCTION

The issue of biodiversity is one of the principal problems facing the mankind in the third millennium. The problem consists in the fact that continuous technological progress and intensive use of natural resources have resulted, among other things, in significant human-generated impact upon biological diversity, diminishing considerably the number of species and varieties of living organisms, which inhabit our Earth. Every day one species of mammals, birds or plants disappears from the globe as the result of human activities. This situation has put on guard the international community and civil societies in many countries. *The Convention on Biological Diversity* was developed as the result of summit discussions and opened for signature at the UN Conference for Environment and Development in Rio de Janeiro on 5 June 1992, coming into effect on 29 December 1993. The Convention's principal objective is protection, conservation and sustainable use of biological diversity.

Biosafety is one of the issues covered by the Convention. Biosafety system should protect human health and environment from possible adverse effects caused by use of modern biotechnologies. At present it is well known and has been acknowledged that modern biotechnologies have a considerable potential for improvement of human life quality, in particular regarding satisfaction of critical needs in the sphere of food security, agriculture and human health. The Conventions has acknowledged openly those aspects of modern biotechnology.

The development of scientific research in the field of biotechnologies started in the 60-ies of the 20th century, although their practical application began as late as in the 80-ies with cultivation of genetically modified plants. From that time the discussion has never stopped in scientific circles and in civil society regarding potential benefits and possible risks for the environment and human health connected with use of genetically modified organisms (GMOs).

Thus, *the Cartagena Protocol on Biosafety* was adopted on 22 January 2000 at the first extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity held in Montreal, Canada. 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 safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity, taking into account risks to human health and specifically focusing on transboundary movements. Signing of the Protocol is believed to be a very significant step because it establishes international regulatory framework for reconciliation of the relevant commercial needs and environment protection in the biotechnological industry. Thus, the Protocol creates favorable environment for ecologically feasible modern biotechnology application, making possible to find the balance between use of the benefits from the potential offered by biotechnology and minimizing the risks for the environment and human health at the same time.

The Republic of Moldova ratified *the Convention on biological diversity* in 1995 and *the Cartagena Protocol on Biosafety* in 2002. According to the commitments made under the above documents, the Ministry of Ecology and Natural Resources has taken numerous steps to ensure compliance with provisions of the above international documents. In particular, the documents, which have been developed and approved include: *The First National Biological Diversity Report, the National Strategy and Action Plan in the field of Biological Diversity, and the Law on Biosafety*. At present the Republic of Moldova is making practical steps to strengthen its capacity in the field of biosafety through development of the national biosafety framework and contributes to the process of raising public awareness of the relevant issues.

With the aim to ensure compliance with the provisions of the Cartagena Protocol, the United Nations Environment Programme (UNEP) and Global Environmental Facility (GEF) are providing technical assistance to the Government of the Republic of Moldova to consolidate efforts towards establishment of the national biosafety system.

The UNEP/GEF Project „Development of the National Biosafety Framework in the Republic of Moldova” forms part of the Global Project for Development of National Biosafety Frameworks in more than 100 countries. This Project has been designed to contribute to the implementation of the Cartagena Protocol on national level, especially in developing national policy, regulatory system, administrative procedures for handling notification including risk assessment, procedures for public participation in decision making process and enforcement and monitoring of the activities connected with production, transportation, imports and exports and distribution of GMOs and products made with use of such organism. New Concept for the *National Biosafety Framework (NBF)* of the Republic of Moldova was developed to that end and with the project’s support as the guidance specifying priority directions in the development of a national system for GMO regulation, control and monitoring to comply with the requirements of the Cartagena Protocol.

To support these efforts, the UK Embassy in Chisinau, Moldova, has contributed to the above initiatives by financing of the co-project *„Support for the Development of the National Biosafety Framework in the Republic of Moldova”*. The activities planned within the framework of that co-project were focused on training of professionals in the relevant spheres, facilitation of the processes of awareness-raising and dissemination of information among the broad public and civil society of Moldova regarding knowledge of the Cartagena Protocol provisions and current practices of the European countries regarding regulation of GMO use.

The Government of the Republic of Moldova established the *National Biosafety Committee* with the power and function to make decisions and authorize activities connected with GMO use. *The Regulations on authorization of activities connected with production, testing, use and distribution of GMOs* were approved as the guidelines for application of the *Law on Biosafety*. The above Law and Regulations specify rules for contained use, deliberate release in the environment, placing to the market release as well as imports and exports of GMOs.

The National Biosafety Testing Center was established by joint decision of the Ministry of Ecology and Natural Resources and the Ministry of Education to provide detection of GMOs, additional safety assessment trails if necessary and to assess potential risks of GMOs for the environment and for human health.

The National Biosafety Framework is a combination of policies and legal, administrative and technical tools, which has to be developed to ensure an adequate level of protection in the field of safe transfer, handling manipulation and use of GMOs resulting from modern biotechnologies, which may have adverse effect impact upon conservation and sustainable use of biological diversity, and to prevent risks for human health.

The National Biosafety Framework includes the following components:

- Government policy in the field of biosafety;
- Regulatory biosafety framework;
- Administrative system for handling notification and authorization system which also includes Risk assessment for the environment and human health;
- Enforcement and control;
- Institutional framework and notification and authorization system;
- The system of decision-making, monitoring and assessment of risks for the environment and human health;
- Mechanisms for public participation in the decision-making process, awareness raising and education.

The purpose of description of the NBF is twofold:

1. To provide an overview of current situation in the country that was assessed during the lifetime of the NBF Development Project and what is currently in place in this country (i.e. legislation, administrative systems, etc.) (*Chapter I*);

2. To identify what still needs to be done in order to complete the NBF (the missing legislation, which still needs to be drafted/adopted, gaps in the administrative or enforcement systems, etc.) (*Chapter II*).

This NBF describes the current legislative and regulatory framework, the institutional capacity of the national and local public administration authorities, and the institutions with R&D functions. Based on the analysis of goals and deficiencies identified in the current legislative and institutional system, priorities and actions were determined, which are required to strengthen the national capacity in the field of biosafety and to bring it in compliance with the requirements of the Cartagena Protocol. In particular, the needs were identified regarding amendments and modifications to branch laws in the sphere of agriculture, feed, food imports and exports, customs procedures, licensing of activities, R&D, intellectual property rights, protection of consumer rights, etc.

The developed new concept of NBF described in Chapter II provides for the establishment of a number of Technical Committees and/or appointment of technical officers in the relevant specialized national authorities, which would have the function to ensure implementation of risk assessment mechanisms in the relevant sector/industry. Special attention should be given to activities connected with awareness-raising and consultations with broad public, NGOs, private businesses and civil society during the period preparatory to making a decision making process, and monitoring of its implementation.

We would like to express our gratitude to the UNEP Biosafety Office in Geneva, Biodiversity Office in Nairobi as well as the Global Environmental Facility for the kind collaboration, advice and financial support provided to the Republic of Moldova in order to develop the National Biosafety Framework.

THE LIST OF USED ABBREVIATIONS

BS	– Biological Safety;
BCH	– Biosafety Clearing House;
CBD	– Convention on Biological Diversity;
DNA	– Desoxyribonucleic Acid;
FAO	– Food and Agriculture Organization;
GEF	– Global Environmental Facility;
GMO	– Genetically Modified Organism;
LC	– Licensing Chamber;
MAFI	– Ministry of Agriculture and Food Industry;
MENR	– Ministry of Environment and Natural Resources;
MH	– Ministry of Health;
NAIPR	– National Agency for Intellectual Property Rights
NBC	– National Biosafety Committee;
NBF	– National Biosafety Framework;
NCAC	– National Codex Alimentarius Committee;
NCPV	– National Committee for Plant Varieties;
NRM	– National Register of Medicines;
NSRCPHC	– National Scientific Research Center for Preventive Health Care;
PCA	– Partnership and Cooperation Agreement;
RPV	– Register of Plant Varieties;
SCPV	– State Council for Plant Varieties;
SCTPV	– State Commission for Testing of Plant Varieties;
SIPPA	– State Industrial Property Protection Agency;
SPQI	– State Phytosanitary Quarantine Inspectorate;
SPPI	– State Plant Protection Inspectorate;
SSI	– State Seed Inspectorate;
SVI	– State Veterinary Inspectorate;
TRAC	– Testing and Risk Assessment Center;
UPOV	– Convention on Protection of Plant Varieties;
UNEP	– United Nations Environment Programme;
WTO	– World Trade Organization.

CHAPTER I

THE CURRENT SITUATION REGARDING MODERN BIOTECHNOLOGIES AND BIOSAFETY IN THE REPUBLIC OF MOLDOVA

1. POLICY AND STRATEGIES

1.1. INTERNATIONAL BIOSAFETY FRAMEWORK

Convention on Biological Diversity (Rio de Janeiro, 1992)

At present the problem of biological diversity conservation has grown outside the limits of a purely scientific problem and rates as one of the urgent objectives facing countries and international organizations, designed to ensure favorable living conditions for the population via sustainable use of natural resources and protection of the environment. An important global-level document regulating this activity is *the Convention on Biological Diversity (CBD) (Rio de Janeiro, 1992)*. The Convention requires from the parties of CBD to attach high importance to activities directed at conservation of biological diversity in natural habitats (wildlife), rational use of biological resources, strict control over biotechnological processes, etc. Biosafety is one of the issues covered by the Convention. Biosafety system should protect human health and environment from possible adverse effects caused by use of GMOs

The Republic of Moldova ratified the Convention on 16 May 1995 (by Parliamentary Decision no. 457-XIII). To implement the commitments made by Moldova as a signatory party to the Convention on biological diversity, the Government developed and approved *National Strategy and Action Plan in the field of biological diversity conservation and the First National Report on Biological Diversity*.

National Strategy and Action Plan in the field of biological diversity conservation (approved by Parliamentary Decision no. 112-XV of 27 April 2001) provides for development of an integrated plan of urgent actions required to ensure biosafety in Moldova:

- Regulation of imports and exports of transgenic organisms;
- Creation of the relevant legislative and institutional framework;
- Capacity building via staff training;
- Establishment of a testing laboratory to exercise control over GMOs; and
- Development of special public information programs to raise awareness of the consequences of GMO use.

The National Strategy and Action Plan attaches special importance to transparency and preventive actions in use of GMOs. A comprehensive package of immediate measures has been provided for to ensure biosafety in Moldova.

The Cartagena Protocol on Biosafety of the Convention on Biological Diversity

The Cartagena Protocol on Biosafety 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 and special emphasis on transboundary movement of LMOs. The Protocol establishes the standards and procedures, which enable the importing countries to control imports/exports of living genetically modified organisms and their derivatives produced using modern biotechnology methods. The term “Genetically Modified

Organisms” (“GMOs”) is considered as a synonym of “ Living Modified Organisms” (“LMOs”) and used more frequent in our country. In continuation we will use “GMOs” in the text.

The Concept Paper on the National Biosafety Framework was developed in conformity with the Protocol provisions, comprising 5 principal components:

- Political framework;
- Legislative framework;
- Institutional framework;
- Risk assessment and decision-making system;
- Public awareness raising and education.

1.2. NATIONAL ENVIRONMENTAL AND BRANCH POLICIES AND STRATEGIES

Environmental policy and the European integration

The new *Concept of Environmental Policy of the Republic of Moldova* was adopted in November 2001 by the Parliament. It provides for a radical change in the attitude towards environment and use of natural resources and highlights the need to integrate environmental concerns into socio-economic development of the country. The policy implementation is to become the basis for all environmental activities at local and national levels of the Republic of Moldova.

In this respect, the newly developed *Concept of the Environmental Policy of the Republic of Moldova* adjusted the major environmental objectives to the social and economic changes in the country as well as the regional and global programs focusing on environment protection. The environmental policy’s main objectives are: (i) prevention and mitigation of adverse impact of economic activities upon the environment, natural resources and public health in the context of sustainable national development; and (ii) ensuring of a safe environment for the country.

The environmental priorities are set in the policy paper as following:

- a) Capacity building and cross-industry collaboration;
- b) Control of environmental impacts, pollution prevention and rehabilitation of the environment;
- c) Ensuring of financing for environmental activities;
- d) Public participation in the environmental decision-making process;
- e) Integration of requirements for environmental protection;
- f) Protection and use of natural resources;
- g) Implementation of mechanisms for environmental protection;
- h) Provision of technical assistance and sustainable environmental investment projects;
- i) International collaboration in the field of environment.

The policy of the Republic of Moldova in the field of environment protection is an urgent necessity; it is required to consolidate the country’s course towards sustainable development and European integration, towards intensification of international collaboration in that sphere. As of today, the Republic of Moldova has ratified 18 International Environmental Conventions, and compliance with their provisions requires a detailed review of the legislative and regulatory framework and its harmonization with the relevant EU Directives. The documents approved to achieve that goal include:

- *Partnership and Cooperation Agreement (PCA) between the Republic of Moldova and the European Union* signed in 1998. Article 50 of this agreement states that the Republic of Moldova undertakes to bring its legislation in conformity with the EU legislation step by step;
- *Parliamentary Decision no. 1267-XV of 19.07.2002 regarding the results of control over implementation of Law no. 851-XIII of 29 May 1996 On ecological expertise and assessment of impact on the environment*. Article 3 states that the Ministry of Ecology and Natural Resources shall harmonize the environmental legislation of the Republic of Moldova with the international law in that sphere;
- *Decree of the President of the Republic of Moldova no. 957-III of 13 November 2002 On establishment of the National Committee for European Integration*;

- *Comments and suggestions to the European Integration Strategy of the Republic of Moldova* developed within the framework of TACIS Project „Assistance in implementation of the Partnership and Cooperation Agreement between the Republic of Moldova and the European Union”.

The documents being currently developed jointly with stakeholder ministries and institutions include: *New Neighborhood Policy Paper and Action Plan „Republic of Moldova – European Union”*; they are developed with the aim to make use of the opportunities offered by the new EU policy in respect of its future neighbors. This Action Plan covers the period of 2004-2006. The Ministry of Ecology and Natural Resources has participated in the development of this Action Plan and proposed measures to harmonize environmental legislation, including the legislation regarding biosafety issues.

Branch policy and strategies

The general agricultural policy of the Republic of Moldova includes securing of the country’s food safety and raw materials for the processing industry by encouraging agricultural production. At present the agriculture of the Republic of Moldova is in the process of reform and restructuring as a result of implementation of the *New agricultural policy and Concept of agricultural reform and social-economic development of the countryside*, approved in 1991. Unfortunately, certain negative phenomena have become manifest as the result of dramatic social-economic transformations in agriculture during the last 10-12 years. The most important ones include the twofold decrease of agricultural production in comparison with the 1990 level and the decrease of 3-4 times in processing of the agricultural raw materials.

Considering the importance of agriculture and agribusiness for Moldova’s national economy and in view of the objective to enter the international market of agricultural products, the Government has approved *the National Concept for natural farming, production and distribution of environmentally clean and non-GMO food* (Government Resolution no. 863 of 21.08.2000). The document declares that use of gene engineering is considered inadmissible for the purposes of ecological agricultural production.

In order to overcome this difficult situation, measures are taken at different levels of the agricultural sector management, including the Government of the Republic of Moldova. The policies and strategies of the Government for the agrarian sector have been included in the following strategies and action plans:

- *Activity Program of the Government of the Republic of Moldova for the years 2001-2005* (Government Decision no. 854 of 16.08.2001, MO no. 100-101/887 of 18.08.2001);
- *Strategy for economic development of the Republic of Moldova for mid-term (till 2005)*, (Government Decision no. 1415 of 19.12.2001, MO no. 5-8/35 of 10.01.2002);
- *National Strategy for Sustainable Development (for the period 2000-2020)* (UNDP, Chisinau, 2000);
- *Strategy for the Development of the Agricultural and Food Sector (for the period 2000-2010)*;
- *Strategy for Economic Growth and Poverty Reduction (2004-2006)* as well as a number of other Government decisions.

The necessity of application of new technologies in agriculture as a precondition for entrance to the European market has been confirmed by credible scientific research. The Parliament of the Republic of Moldova has approved the following strategic priorities for the period 2004-2010 as governmental programs for research and development in the field of agriculture:

- *Advanced biotechnology with intended application in agriculture, food industry and medicine*;
- *Development of modern technologies based on the use of agricultural biodiversity gene pools in the field of phytotechnology and animal breeding*;
- *New technologies for production of food products and ensuring their safety*;

- *Development of safe environmental systems for integrated protection of plants and achievement of high quality, natural-farming based and competitive agricultural production;*
- *Quality assessment of soil resources, development of a system for soil fertility improvement;*
- *Molecular genetic control of differentiated expression of plants genes;*
- *Development of economic standards and state-of-the-art information database for the agribusiness sector;*
- *Development and implementation of advanced technologies and modern equipment in production and processing of essential volatile oils and medicinal raw materials;*
- *Implementation of valuable medicinal herbs and obtaining of the necessary biologically active substances for the production of medicinal substances of vegetable origin;*
- *Theoretical basis for economic doctrines regarding marketing tools at the current stage.*

The necessity of ensuring a sustainable economic growth as the main condition for poverty eradication and solving of food security problems can be ensured only based on scientific research, technological development and modern innovation activities, simultaneously satisfying the requirement for rational use of natural resources, environmental protection and biodiversity conservation. The *Strategy for Economic Growth and Poverty Reduction (2004-2006)* was approved by Governmental Decision No. 617 of 04.06.2004.

According to the *Strategy of Social-Economic Development of the Republic of Moldova* (Government Decision no. 1415 of 19 December 2001), the future development of the Moldovan economy will be innovational, based on the use of scientific research findings and advanced technologies.

The agrarian reform in the Republic of Moldova was carried out at the beginning of the 1990s with the help of the *National Program "Pamintul" ("Land")*. It made possible distribution of titles of ownership to land and restructuring of 90% of collective farms and state-owned farms; it solved the problem of historical debts of collective farms. As the result new agricultural producers and agribusiness emerged in a number of legal statuses (joint-stock companies - SA, farmer associations, individual (peasant) farms, sole proprietorships, agribusinesses farming rented land, etc.).

The Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters was ratified by the Republic of Moldova at 1999 (Law nr. 346-XIV of 7.04.99). The objective of the Convention is to contribute to the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being, each Party shall guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters in accordance with the provisions of this Convention. In this concern the following documents have been elaborated and approved by the Republic of Moldova:

- *Regulation on public access to the decision-making in the field of the environment* (Governmental Decision nr. 72 of 25.01.2000). The Regulation is prepared in accordance with the Aarhus Convention, as well as the Chapter III of the *Law on ecological expertise and impact assessment to the environment* nr. 1515-XII of 16/06.93.
- *Law on public access to the information* nr.982-XIV of 11.05.2000 has as objectives the followings:
 - a) Establishment of the general regulation framework of public access to the information;
 - b) Efficiency of the process of public information and the public control over public authorities and public institutions;
 - c) Stimulating the formation of public opinion and participation to the decision-making in democratic spirit.

As regards the basic principles of *the 1991 Act of the International Union for Protection of New Plant Varieties (UPOV)*, Moldova ratified the UPOV by Parliament Decision no. 1355-XIII of 22.10.1997. Moldova is responsible to secure intellectual property rights for the respective plant varieties during 10 years from the date of its accession to UPOV.

2. REGULATORY REGIME

2.1. LEGISLATIVE BIOSAFETY FRAMEWORK

According to the requirements of the Convention on Biological Diversity and the Cartagena Protocol regarding biosafety, a package of laws was developed in the Republic of Moldova, which is designed to establish the legal framework in that sphere.

To fulfill the requirements of the *Law on ratification of the Cartagena Protocol on Biosafety*, the Government has appointed the Ministry of Ecology and Natural Resources as the national authority responsible for liaison with the Secretariat of the Convention on Biological Diversity and for coordination of actions towards implementation of its provisions in the Republic of Moldova (*Government Resolution no. 197 of 25.02.2003*) (*Appendix 1*).

The National Biosafety Law

The Ministry of Ecology and Natural Resources drafted the *Law on Biosafety* (no. 755-XV of 21.12.2001, MO no. 75 of 13.06.2002). This Law has been harmonized with the EU Directive 2001/18/EC on deliberate release of GMOs in the environment and regulation of activities connected with creation, testing, production, use and distribution of GMOs using modern biotechnology methods.

Provisions of the above Law cover the following activities:

- (a) creation, multiplication, testing and use in contained conditions, for various purposes, of the microorganisms, plants and animals modified genetically using modern biotechnology methods;
- (b) deliberate release in the environment and market release of the organisms modified genetically using modern biotechnology methods, including any living structure capable to reproduce organisms, such as seeds, bulbs, layers, pollen, spores, etc.;
- (c) unintentional release of GMOs in the environment;
- (d) deliberate release in the environment and market release of the processed products containing GMOs and/or living components of the living GMOs – whether processed or unprocessed;
- (e) any and all research of GMOs, including laboratory, clinical or field research as well as production experiments;
- (f) deliberate imports/exports operations with GMOs and products obtained from such organisms;
- (g) deliberate transboundary movement of GMOs;
- (h) storage, burial or disposal of GMOs and/or products obtained from such organisms, utilization of waste produced from use modern biotechnology methods.

To assess potential danger for human health and environment generated by activities regulated by the above law, the following risk classes were specified for isolated systems for 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.

The Biosafety Law identifies the National Biosafety Committee (NBC) as the inter-governmental body empowered with the decision making duties regarding issuing (or refusing) authorizations approved for various activities connected with GMOs (Art. 5, 6).

The Biosafety Law identifies four types of activities, which require different authorization procedures within the Committee: (1) contained use of GMOs; (2) deliberate release of GMOs; (3) placing of GMOs and products thereof on the market; and (4) imports/exports of GMOs and products thereof.

The first three procedures require of the notifier to submit a notification to the NBC. The applicant shall conduct the risk assessment of the proposed activity and suggest what class of risk that activity in contained use should be assigned to. The Committee verifies whether the application is in conformity with the *Law on Biosafety*, the risk assessment content, measures of protection, actions in case of an eventual accident and measures on waste management are adequate. The NBC may request the applicant to provide additional information. It may also set limits to validity of the authorization and establish additional requirements in the authorization (Art. 10, 12, 14, 19, 20, 23-1).

The Law provides for the mandatory requirement to obtain Opinion Papers from the national authorities on agriculture, food industry, health and consumer protection. The NBC has a right to refuse an authorization for any of the procedures (contained use of GMOs (1), deliberate release of GMOs (2), or placing of GMOs and products thereof on the market (3)). Furthermore, the request for Opinion Papers from the national authorities on agriculture, food industry, health and consumer protection is a requirement for the above three processes (contained use, deliberate release and the placing of GMOs and products thereof on the market) - Art. 12(1), 14(2)(c), 20(1)(b), 20(2), 23(1).

The Law does not require the NBC to inform and consult with the public in the case of contained use (1), which is, however, mandatory in the second and the third procedure (deliberate release of GMOs (2), and placing of GMOs and products thereof on the market (3)) – Art. 20(1)(a), 23(1).

Labeling of products to be placed on the market shall be determined in advance. The marking “This product contains genetically modified organisms” is obligatory for the label. The Law requires such labeling where GMO content exceeds 1% of the total product weight or 0.3% of seed weight. The marking “This product contains genetically modified organisms” shall occupy not less than 10% of the packaging or accompanying documentation – Art. 23(3), 24 (1) (c).

The imports/exports procedure provided by the BSL is mostly similar to the basic provisions of the Cartagena Protocol on Biosafety, including the advance informed agreement procedure, the notification, acknowledgement of receipt, and the decision procedure.

Risk assessment is required in all procedures and shall be based on two principles: scientifically sound character and transparency. Risk assessment is performed by public authorities or scientific institutions chosen by the Committee and paid for by the notifier – Art. 34. Unfortunately, the mechanism for payment has not been elaborated as yet.

The authorization issued by the Committee shall stipulate the conditions of use. The authorization for deliberate release of GMOs into the environment shall stipulate the size of the genetically safety zone (GM free zone). That zone shall not be less than 3 km for nature protection territories – Art. 20 (4).

The Law determines the risk assessment as estimation of direct and indirect immediate and long-term consequences of the release into the environment of GMOs or their components for environment and human health of the release into the environment of GMOs or their components. Furthermore, it defines risk management as development and application of the comprehensive measures to monitor risks and emergency measures to be taken in case of an accident. The Law provides for simplification of procedures where GMO is permitted for use in the EU. The Art 19 (7) of the Law foresees that in order to facilitate decision making for deliberative release of GMOs that have already been notified and/or, by case, approved by the member states of the EU and the Organization for Economical Cooperation and Development, notifier should submit to the NBC the copies of notification and approving document from the EU to be eligible for simplification procedures.

To ensure transparency of the NBC activities, a special procedure on consultations with the public has been provided for in the Biosafety law. Upon receipt of a notification for deliberate release of

GMOs into the environment and/or for release of GMOs and products thereof into the market, the Committee has to inform the public within 10 days. Comments should be sent to the Committee within 30 days. The Committee should take into consideration the comments received from the public. Public hearings may be organized depending on the comments. The Commission shall be guided by the national law and international agreements to ensure public participation – Art.39. This includes undoubtedly the *Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters*.

The Committee may treat certain information as confidential with respect to protection of the confidential business information. The general description of GMOs, name and address of the applicant, purpose and site for use of GMOs, class of risk, risk assessment conclusions, monitoring methods and plans, and emergency measures may not be confidential (Art. 11).

Regulations on the National Biosafety Committee

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 use;
- 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.

Regulation on authorization of activities connected with production, testing, use and distribution of GMOs

The Regulation on authorization of activities connected with production, testing, use and distribution of GMOs (Government Resolution no. 1153 of 25.09.2003) has been drafted in line with the provisions of the Law on Biosafety and harmonized with *the EU Directive 2001/18/EC on deliberate release of GMOs in the environment, Directive 90/219/EEC on contained use of GMOs and Directive 98/81/EEC on contained use of GMOs*.

The Regulations provide for authorization of GMO-related activities via issuance of licenses confirming the holder's right to perform certain activities subject to compliance with the license (authorization) terms and conditions.

The National Biosafety Committee is the authority with the function of licensing of the activities connected with production, use and distribution of such organisms. The Regulations require authorization of the following activities:

- contained use of GMOs;
- deliberate release of GMOs in the environment;
- deliberate market release of GMOs and products made thereof;
- imports/exports of GMOs and/or products made thereof.

To apply for an authorisation, the notifier must submit the following documentation to the NBC:

a) Application to include the following information:

- for a legal entity: its full name and legal status, registered office (registered address) and a Company State Registration Number;
- for an individual: first name and family name, ID data (series, number, permanent residence address) and a Company State Registration Number;
- the exact activities for which the authorisation is solicited;

b) A separate notification for each activity to include:

- general information, including the list of the relevant staff and information regarding staff training;
- information on the relevant GMO(s);
- information regarding the impact of the relevant GMO(s) on human health and the environment;
- a monitoring plan to identify the impact of the relevant GMO(s) on human health and the environment;
- information regarding control, recycling, waste disposal and emergency action plans;

c) environmental risk assessment survey complete with bibliographical references and indication of the methods used;

d) summary file.

Some of the information, which the notifier must include in his notification, may be considered confidential. The NBC decides as to what information should be treated as confidential after consultations with the notifier and informs the notifier accordingly.

The following information may not be considered confidential:

- 1 General characteristics of the relevant GMO(s), the notifier's name and address, the goal and place of use;
- 2 Risk category for contained use and containment measures;
- 3 Conclusions of the risk assessment survey regarding inherent risks for human health and the environment; and
- 4 Monitoring methods and plans as well as emergency measures in case of an accident.

Receiving the notification, the NBC shall:

- 1 inform and consult the public regarding the notification received;
- 2 request opinions from the national authorities for the environment, economy, agriculture and food industry, public health and consumer protection;
- 3 inform the public about the notification within 10 days upon its receipt. The NBC should keep the evidence of addressing the public with the request to make comments;
- 4 at the same time place the documents regarding the notification on the relevant web page of the web site of the National Environmental Authority;
- 5 comments received from the public shall be treated as consultative. They may be submitted within 30 days after the public information day and the NBC takes them into consideration in decision-making regarding the notified activity. Public hearings may be organized in respect of any aspects of the problem under examination depending on the received comments.

The NBC should give an answer to the notifier within not more than 90 days upon receipt of the notification. Its answer may include the following:

- 1 Statement to the effect that the notification received is in compliance with the applicable law;
- 2 Request to the notifier to submit additional information (if any);
- 3 Statement to the effect that the notified activity is not in compliance with the applicable biosafety law and NBF regulations and therefore the application is rejected; or
- 4 Statement to the effect that the notified activity does not fall within the scope of the applicable biosafety law and NBF regulations.

The above 90-day period does not include the period during which the NBC:

- 1 Waits for additional information requested from the notifier;
- 2 Waits for opinions from the approving expert authorities;
- 3 Survey of public opinion or consults other organizations and/or the public.

Market release of a product requires that its label and/or accompanying documents provide at least the following information: the name of the product and the GMO contained in it, country of origin, the manufacturer's, the packager's, the exporter's or the importer's name and address, net weight, nutritive value, storage conditions, date of manufacture and shelf life, reference to the standards or regulations governing manufacture and identification (marking) of the product, specifications including conditions of use, type of use, and the relevant genetic modification type. The label and/or the accompanying documents must indicate clearly the presence of GMO(s) via mandatory use of the wording: „**This product contains genetically modified organisms**”.

The Regulations include provisions regarding the necessary information on GMOs in terms of monitoring, control, treatment of waste and emergency actions in case of emergency. The notifier may start the notified activities solely upon receipt of an authorization issued by the NBC and solely in compliance with the authorization (license) terms and conditions. A failure on the part of the NBC to confirm duly the receipt of the notification shall not mean and may not be interpreted as a tacit agreement on its part.

The NBC may withdraw authorizations issued earlier in the following cases:

- 1 Where it is found that the information submitted in the application for the authorization was not true;
- 2 Where the notifier (legal entity or individual) is found in non-compliance with the applicable law or authorization terms and conditions;
- 3 Where there was a grave accident, for which the license holder (legal entity or individual) is responsible.

The NBC withdraws the authorization based on the notice received from the controlling authorities stating the reason underlying such decision.

A copy of the decision to withdraw the license is given to the license holder (legal entity or individual).

Upon remedy of the reasons resulting in withdrawal of the license the relevant legal entity or individual should inform the NBC accordingly and submit a request to issue a new license.

Regulation on the National Biosafety Testing Center

The National Biosafety Testing Center was established by joint Order of the Minister of Ecology and Natural Resources and Minister of Education no. 19 of 10.02.2004 and based on the decision of the Senate of State University of Moldova. The Center's task is to perform tests and control plants, seeds and foodstuffs to identify GMO presence and content therein. The Center will also perform assessment of potential risks such organisms might present for the environment and human health; and assessment conclusions will be used as the basis for decision-making in this sphere.

2.2. BILATERAL AND MULTILATERAL AGREEMENTS

At present the Republic of Moldova is a party to the following international agreements in the field of environment protection, which have indirect relation to the problems of biological diversity conservation, scientific research development, information sharing and overcoming of negative effects of natural calamities and adverse anthropogenic factors (*Appendix 2*):

1. *Protocol on collaboration between the Ministry for Environment Protection of Ukraine and State Department for Environment Protection and Natural Resources of the Republic of Moldova* signed in Kiev (Ukraine) on 19 November 1993. This Protocol specifies principal directions for collaboration in the sphere of flora and fauna protection, environmental monitoring, prompt dissemination of information regarding transboundary pollution, mutual provision of assistance in liquidation of aftereffects in case of industrial accidents or natural calamities;
2. *Agreement between State Department for Environment Protection of the Republic of Moldova and the Ministry for Natural Resources and Environment Protection of the Republic of Belarus on collaboration in the environmental sphere* signed in Chisinau on 23 December 1994 and effective since 14 April 1997. The Agreement specifies principal directions for collaboration in the sphere of improvement of methodology, regulatory, guidance and legislative framework on the use of natural resources, environmental monitoring and availability of information, activities regarding protected areas, and protection of gene pool for rare plant and animal species;
3. *Agreement on collaboration between State Ecologic Inspectorate of the Republic of Moldova and between State Ecologic Inspectorate and Fishery Inspectorate of the Vinnitsa Province of Ukraine* concluded on 13 June 1996 in the city of Vinnitsa (Ukraine), which provides for guaranteed environmental information sharing, experience sharing and implementation of certain joint programs;
4. *Agreement on collaboration between the State Department for Environment Protection of the Republic of Moldova and the Ministry of Waters, Forests and Environment Protection of Romania in the sphere of environment and sustainable utilization of natural resources* signed on 18 March 1997. The agreement provides for improvement of methodology, regulatory, guidance and legislative framework on environment protection and use of natural resources, harmonization of legislation, regulations and technical norms in the field of environment protection;
5. *Convention between the Government of the Republic of Moldova and the Government of Romania on cooperation in the sphere of quarantine and plant protection* signed in Bucharest on 15 May 1997 and effective since 21 November 1997. The Convention specifies modalities for exports of plants or vegetable origin products and regulations designed to prevent penetration of organisms subject to quarantine;
6. *Agreement between the Ministry of Environment and Territory Protection of the Republic of Italy and the Ministry for Environment, Construction and Territory Development of the Republic of Moldova on collaboration in the sphere of environment protection and utilization of natural resources* signed in Chisinau on 10 June 2002. The Agreement specifies directions for collaboration in the sphere of environmental legislation and regulations, environmental monitoring, scientific research on environmental protection and traditional use of natural resources, protected areas, gene pool protection and environmental education.

It should be mentioned, however, that the above agreements and conventions have no specific clauses regarding collaboration or partnership projects with the sub-region countries to ensure biosafety.

We believe it would be useful to introduce amendments and modifications to the above bilateral intergovernmental agreements to bring them in compliance with the Cartagena Protocol and Law on Biosafety. This would promote the harmonization of biosafety systems in the region as well as regional cooperation and support.

2.3. BRANCH REGULATORY FRAMEWORK

The national legislation includes a number of laws, which regulate the spheres indirectly connected with the issues of biosafety and food safety and which can influence decision-making to a certain extent, although they do not have provisions directly relating to the above issues.

These laws include: Laws on animal breeding, horticulture, plant protection, medicines, and other (12 laws on the total). Furthermore, the category of legislation acts indirectly related to the issues of biosafety includes a number of Parliamentary Resolutions and Government Decisions (*Appendix 3*).

Special importance should be attached to correct application of modern biotechnologies in the various sectors of agriculture in view of the necessity to minimize the risks connected with biosafety.

In view of the necessity to take urgent measures towards improvement of the situation with foreign trade and integration of Moldova's economy in the global trade system, the Government has approved a list of actions required to fulfill commitments made by the Republic of Moldova to the World Trade Organization (WTO) (Government Resolution no. 1035 of 16.10.2000).

The Ministry of Economy was appointed the authority in charge of coordination of actions by ministries and departments in the process of WTO accession. In February 2001 the agreements were finalized regarding accession of the Republic of Moldova to the WTO (Government Resolution no. 173 of 28.02.2001) and that year Moldova became a full WTO member. At the same time, in conformity with the relevant international commitments Moldova adopted the *Law on certification* (no. 652-XIV of 28.10.1999), which establishes the legislative framework for certification, including provisions for creation of conditions for business operation of merchants at the market.

In the context of Moldova's commitments to WTO, Moldova established legislative framework for removal of technical barriers to trade in the process of development, adoption and application of technical regulations, standards and quality assessment procedures (*Law on technical barriers to trade* no. 866-XIV of 10.03.2000). According to that document, technical regulations must not be more restrictive for trade than it is necessary to ensure national security and protection of health and safety for humans, flora and fauna and the environment.

In 1997 Moldova ratified the *Statutes of the Codex Alimentarius Commission* (by Parliamentary Decision no. 1342–XIII of 8.10.1997). By becoming a member of the above Commission, the Republic of Moldova undertook to ensure protection of consumer health, to promote international trade and to harmonize the national requirements regarding food with the international requirements provided for in *Codex Alimentarius*. Those actions rated among the priority actions to facilitate accession of the Republic of Moldova to WTO.

For the purpose of collaboration with *the Codex Alimentarius Commission*, the Government has established *the National Codex Alimentarius Committee* (NCAC) with the status of an advisory body (by Government Decision no. 866 of 21.09.1999).

The Regulations for NCAC (Government Decision no. 419 of 03.05.2000) set as one of the Committee's principal objectives protection of consumer health in the field of foodstuffs, simplification of international trade via removal of barriers and implementation of partnership relations in trade.

To prevent spreading and imports of plant pests and unsafe food and to implement the relevant control measures, the Republic of Moldova has joined *the Convention on Plant Protection* (Law no. 926-XIV of 13.04.2000). *The Law on ratification of the Convention on Plant Protection* provides for establishment of state phytosanitary quarantine inspectorate and ensures representation of Moldova's interests in the Convention on Plant Protection of the Global Food and Agriculture Organization (FAO).

Prevalence of imports in Moldova's foreign trade balance and the high portion of imported foodstuffs has forced the Government to take comprehensive measures towards protection of consumers from eventual negative consequences of consumption of food produced using of GMOs.

Consumer rights protection

The legislation worth mention in that context includes *the Law on Protection of Consumer Rights* (no. 105-XV of 13.03.2003), effective since 27.10.2003 and substituting a similar law preceding it (no. 1453-XII of 25.05.1993).

According to that law, products and services categorized as inoffensive are those products and services, which do not present risks for consumer life, health, heredity or property, or for the environment. The law prohibits production, storage, market release and distribution of products and provision of services, which do not comply with obligatory requirements specified in the relevant regulatory documents, or which might present risks for consumer life, health, heredity or safety in the process of their intended use.

For the purposes of correct application of the above law, the Government adopted *the Decision on Intensification of consumer protection actions* (no. 1297 of 27.11.2001). That document says that import contracts for products intended for distribution at the domestic market must include obligatory requirements to the respective product regarding its quality and safety, or reference to national sanitary and technical standards and regulations specifying obligatory requirements for particular products. Although this Decision does not have provisions directly relating to GMOs, its provisions make it possible to establish controls over use of GMOs or products obtained with use thereof.

To that end the Government approved *the Decision on establishment of the national network for monitoring and laboratory control over pollution of the environment with bacterial (biological) substances* (no. 477 of 19.05.2000). The basic function of the control network would consist in identification of pollution with bacterial substances, laboratory controls, expertise of food and primary materials for its production, feed and water, and issuance of opinions regarding the possibility of their use and consumption.

To extend the range of measures directed at consumer protection, including in case of GMO use, the Government instructed the Ministry of Health (MH) to develop and to approve sanitary regulations for adequate labeling of GM food (Government Decision no. 996 of 20.08.2003).

Phytosanitary sector

To ensure biosafety in the Republic of Moldova, it is very important to establish clear rules for seed production and control over their use. *The Law on Seeds* (no. 659-XIV of 29.10.1999) establishes the underlying legislative, economic and administrative framework for seed production, quality control, distribution and use in respect of agricultural plants and regulates legal relationships between the relevant state authorities on the one part and seed producers and consumers on the other part.

According to that law, *the Ministry of Agriculture and Food Industry* (MAFI) and *the State Committee for Testing of Plant Varieties* (SCTPV) operating by the above ministry, *State Seed Inspectorate* (SSI) and other relevant governmental authorities and institutions are in charge of implementation of state policies and state regulation regarding seeds.

The Law allows seed production, distribution, use and imports solely in case the relevant plant variety has been duly entered in *the Register of Plant Varieties* (RPV). It is prohibited to use (to seed) seed materials and to distribute seeds, whose quality has not been duly tested or certified according to the established procedures.

All the relations emerging in the process of creation, use or legal protection of plant varieties are regulated by *the Law on Protection of Plant Varieties* (no. 915-XIII of 11.07.1996). The authorities in charge of implementation of state policies in the sphere of legal protection and use of plant varieties in the Republic of Moldova are: *State Committee for Testing of Plant Varieties* (SCTPV) and *State Intellectual Property Protection Agency* (SIPPA).

General and specific terms and conditions for production and use of reproductive material and seedlings of horticultural crops are regulated by the *Law on Horticulture* (no. 728-XIII of 06.02.1996). MAFI is the authority in charge of regulation.

A license must be obtained for operations in the above area. SSI is the authority in charge of control and certification of seedlings. Imports of seedlings are allowed solely subject to existence of the relevant phytosanitary certificate issued by the national authorities of the exporting country in charge of phytosanitary quarantine and authorization by MAFI and *State Phytosanitary Quarantine Inspectorate* (SPQI).

State Phytosanitary Quarantine Inspectorate (SPQI) established by the Government (Government Decision no. 697 of 10.10.1995) for the purpose of implementation of *the Law on Phytosanitary Quarantine* (no. 506-XIII of 22.06.1995) has the function to ensure adequate control with the aim to prevent unauthorized penetration of GMOs to the Republic of Moldova. The system of governmental measures in the area of external and domestic phytosanitary quarantine has been designed, in particular, to protect the territory of Moldova from penetration or introduction from other countries of weeds and pests, which are able to cause considerable damage to national economy and biodiversity.

Within the framework of consumer health protection measures as well as for the purpose of establishing a system of state controls over procurement by way of imports, testing and use of biological pesticides, herbicides, weed killers and plant growth stimulators, the Government established the *Interdepartmental Council for Approval of Phytosanitary Products and Fertilizers* (Government Decision no. 897 of 08.12.1994). At the same time *the State Center for Certification and Homologation of Phytosanitary Products and Fertilizers* was established to operate by the Ministry of Agriculture and Food Industry.

The Law on Plant Protection (no. 612-XIV of 1.10.1999) establishes the legislative, economic and administrative framework for plant protection in the Republic of Moldova. All the activities in the sphere of plant protection are organized and coordinated by *the State Plant Protection Inspectorate* (SPPI), *State Center for Certification and Homologation of Phytosanitary Products and Fertilizers* and the *Interdepartmental Council for Approval of Phytosanitary Products and Fertilizers* with the purpose to ensure implementation of consumer health protection measures and state controls over procurement, imports, testing and use of biological products designed to control pests, plant diseases and weeds.

Animal breeding

According to the *Law on Animal Breeding* (no. 412-XIV of 27.05.1999), biotechnology development and application in animal breeding may be performed by scientific research institutions; but their application is subject to control exercised by specialized institutions solely upon issuance of the relevant approvals and licenses.

Coordination of activities in the field of animal breed improvements is one of MAFI's functions. Specialized agencies have been established to improve genetic potential and regional productivity of animal breeds. Imported material may be used for reproduction purposes solely upon its approval by the relevant scientific institutions and regional agencies existing in the Republic of Moldova. State control in animal breeding is in duty of the State Veterinary Inspectorate (SVI).

Pharmaceutics

One more risk source in biosafety is presented by active biological substances produced with use of biotechnologies and used in production and preparation of medicines. Such substances are covered by the *Law on Medicines* (no. 1409-XIII of 17.12.1997). Although this law has no mention of food additives or nutrients added to animal feed, MH has the power to apply provisions of this law where such additives contain biologically active components or demonstrate manifest after-effects for humans.

MH's functions include medicine expertise, approval and registration, publication and upgrading of the National Register of Medicines (NRM), and control and monitoring in respect of quality and aftereffects of medicines. The service studying manifest after-effects of medicines forms an integral part of the state control system maintained by the MH.

Sanitary epidemiological sector

Adequate sanitary and epidemiological surroundings for the population mean such a level of public health and living conditions development where no activities harmful or hostile for human health and life are performed and where favorable living conditions are ensured. *The Law on Public Sanitary and Epidemiological Security* (no. 1513-XII of 16.06.1993) establishes the legislative framework for activities connected with prevention, identification and control of infringements and violations in the sphere of ensuring adequate public sanitary and epidemiological surroundings.

To that end the Law permits use of biologic plant protection preparations and plant or animal growth stimulants solely after their toxicological and hygienic assessment and upon their approval by *National Scientific Research Center for Preventive Health Care* (NSRCPHC). The sanitary epidemiological opinion or hygienic certificate is required for the purposes of production, use and distribution of food or food additives, application of production techniques. Based on the order issued by the local public administration authorities, scientific research institutions or other institutions acting within their powers and functions provide expert opinion and specialized advice regarding assessment of the effects particular conditions might have on human health.

For the first time all biological substances in use and preparations made thereof as well as bacteriological diagnostics systems presenting potential danger for human life and health are subject to obligatory state registration. Sanitary epidemiological control is the function of NSRCPHC operating by MH.

Adequate sanitary and epidemiological surroundings form part of the human right to health protection guaranteed by the Constitution. According to *the Law on Health Care* (no. 411-XIII of 28.03.1995), the human right to health protection is ensured through conservation of the country's gene pool, prevention of diseases and support of the adequate environmental situation, fundamental and applied research of the problems connected with gene pool situation depending on the environmental situation.

Food safety

Protection of state and consumer interests implemented via actions designed to ensure product and service quality, their non-offensiveness for human life and health as well as the environment is the subject matter covered by the *Law on Standardization* (no. 590-XIII of 22.09.1995).

At the same time that actions taken to achieve the above goals are required not to violate the rights of other countries in the sphere of international trade.

State Sanitary Epidemiological Service (SSES) is the authority in charge of state control and supervision over compliance with the regulations regarding standardization. Within that framework it is very important to ensure control uniformity. The relations emerging in that sphere are regulated by the *Law on metrology* (no. 647-XIII of 17.11.1995). Metrological state control and supervision is performed in many areas, including health care, medicines, food and environment protection.

To ensure efficient implementation of the Food Security Program of the European Commission in Moldova, the Government established a special *Committee for monitoring and assessment of that Program* (Government Decision no. 657 of 27.05.2002). The Committee has the functions to submit suggestions to the European Commission regarding allocation of finance and control over use of financial allocations, to perform supervision and to identify spheres and sectors where technical assistance should be directed, and to assess reform implementation progress according to the terms and conditions specified in the bilateral memorandum of understanding.

Considering the vital importance of agriculture and food industry for Moldova's economy and for the purpose of securing a place at the international agro-industrial market, the Government approved *the National Concept of natural farming, production and distribution of environmentally clean food not modified genetically* (Government Decision no. 863 of 21.08.2000). In particular, that documents requires excluding the application of gene engineering in production of agricultural products.

Imports/exports regulations. World Trade Organization (WTO)

In view of the necessity to take urgent measures for improvement of the situation in foreign trade and Moldova's economic integration in the global trade system, the Government approved *the List of actions to fulfill the commitments of the Republic of Moldova made to the World Trade Organization (WTO)* (Government Decision no. 1035 of 16.10.2000). The Ministry of Economy was appointed the authority in charge of coordination of actions to be performed by various ministries and state departments in connection with Moldova's accession to WTO. The negotiations preparatory to Moldova's accession to WTO were finalized in February 2001 (Government Decision no. 173 of 28.02.2001), and Moldova became a WTO member in May of that year.

At the same time, according to relevant commitments Moldova adopted *the Law on Certification* (no. 652-XIV of 28.10.1999), which establishes legal framework for certification of products, equipment, processes, production methods, computer software and application packages, quality systems and services.

Certification is required to create legal environment for operation of market participants in the Republic of Moldova and to promote their integration in the global trade system, to ensure national security, protection of consumer life, health and property as well as environment protection, to confirm quality of the products distributed at the market.

According to its commitments to the WTO, Moldova established legal framework for removal of technical barriers to trade and in the process of development, adoption and application of technical regulations, standards and quality assessment procedures (*Law on technical barriers to trade* no. 866-XIV of 10.03.2000). Technical barriers in trade shall mean either specific requirements at the national level, which differ from common international practices, including technical regulations, standards and conformity assessment procedures, or ignorance of such international practices resulting in additional costs as compared to ordinary trade procedures for distribution of products at the national or international market.

Technical regulations for trade purposes may not be more severe than it is strictly necessary to ensure national security as well as protection of human health and safety, flora and fauna or the environment.

To a certain extent the above laws contain regulations covering indirect consequences of agricultural and other activities for the environment and human health, which may result in decreased national biosafety and thus in deterioration of the environmental situation and living conditions of the population.

Licensing

The licensing function is performed by the *Licensing Chamber of Moldova*. The *Law on Licensing of Certain Activities* No. 451-XV of 30.07.2001 (MO No. 108-109 of 06.09.2001) has identified 57 activities subject to licensing, including:

- Production and/or wholesale distribution of seeds and seedlings;
- Breeding of pedigree livestock, production of biological materials of horses, cattle, pigs, sheep, poultry and fish;
- Veterinarian and pharmaceutical activities (excepting State Veterinary Service);
- Imports and/or distribution of chemicals and biological plant protection preparations as well as growth stimulators;
- Pharmaceuticals, including psychotropic substances and narcotics; imports and/or production of perfumes and cosmetics;
- Activities in the sphere of genetics and microbiology.

The notifier intending to practice activities in contained use classified into Risk Category III or IV may obtain an authorization to perform such activities solely where they have a relevant license issued by the National Licensing Chamber according to the Law on biosafety and the Law on licencing.

3. THE SYSTEM FOR HANDLING OF NOTIFICATIONS

3.1. THE NATIONAL SYSTEM OF NOTIFICATION AND AUTHORISATION OF THE ACTIVITIES CONNECTED WITH USE OF GENETICALLY MODIFIED ORGANISMS

Activities

The system for regulation and monitoring of the GMO-related activities is specified in the *Law on Biosafety and Regulations for authorization of activities connected with production, testing, use and distribution of GMOs*.

Authorization is required for the activities connected with:

- a) obtaining, multiplication, testing and use in contained conditions, for various purposes, of microorganisms, plants or animals modified genetically using modern biotechnology methods;
- b) deliberate release in the environment or market release of organisms modified genetically using modern biotechnology methods, including any living structures capable of reproducing an organism, such as seeds, bulbs, sprigs, pollen, spores, etc.;
- c) unintentional release of GMOs in the environment;
- d) deliberate release in the environment or market release of processed products containing GMOs and/or non-living components of living GMOs in unprocessed or processed state;
- e) any and all GMO research, including laboratory, clinical, field or industrial production tests;
- f) deliberate imports/exports of GMOs or products obtained therefrom;
- g) storage, deposition or disposal of GMOs or products obtained therefrom;
- h) utilization of waste resulting from use of modern biotechnology methods.

Authorization procedures

To obtain an authorization to perform activities connected with contained use, deliberate release in the environment or market release, the notifier must submit the following documents to the National Committee:

- a) application specifying the merchant's name and legal status, registered office (actual location) and a Company State Registration Number or the individual's first name and family name, passport or ID number and issue date and personal State Registration Number as well as the activities for which authorization is requested;
- b) special notification for each activity;
- c) environmental risk assessment report for the environment and human health accompanied with the relevant bibliography and indication of the used methods; and
- d) short notification information format.

Upon registration of the notification, the National Committee informs the public and starts public consultations, requests opinions from the national authorities for the environment, economy, agriculture and food industry, health care and protection of consumer rights. At the same time it transfers the summary file to a competent research institution for the purposes of risk assessment. Based on the accumulated information, the National Commission decides to issue the authorization or to reject the application, giving the applicant the substantiating argumentation.

Within 90 days upon issuance of the confirmation for being in receipt of the notification the National Committee must make one of the following decisions:

- To issue an authorization for the notified activities;
- To prohibit practice of the notified activities;
- To request additional information; or
- To extend the period required for decision-making for the time required to assess additional information.

3.2. INSTITUTIONAL FRAMEWORK RELATED TO BIOSAFETY

Biosafety Institutional Framework

According to the provisions of the Cartagena Protocol and the Law on Biosafety, the Ministry of Ecology and Natural Resources was appointed the national authority in charge of their implementation.

The relevant institutional framework was established at the national level to ensure implementation of the Law on Biosafety, comprised of:

- National Biosafety Committee;
- National Focal Point for the Cartagena Protocol on Biosafety;
- Relevant scientific research institutions;
- Units/directorates and professionals operating within the framework of the Ministry of Ecology and Natural Resources, the Ministry of Agriculture and Food Industry, the Ministry of Health, state departments, agencies and other governmental authorities with functions in the sphere covered by the above law.

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 Focal Point for the Cartagena Protocol is the national environmental authority, which has the function to ensure fulfillment at the national level of the responsibilities resulting from provisions of the international legal acts regarding implementation of biosafety measures regarding GMO use.

The National Biosafety Testing Center has been established for the purpose of assessment of risks for public health and the environment, testing of GMOs and products obtained therefrom, and monitoring of the relevant activities.

National public administration authorities

The national public administration system of the Republic of Moldova is described in the country's Constitution adopted on 29 July 1994 and in the Law of the Republic of Moldova on the Government no. 64-XII of 31.05.1990.

The Parliament of the Republic of Moldova adopts laws and ensures uniformity of the legal and regulatory framework in all the country, approves principal directions for the country's domestic and foreign policies, including those in the sphere of biosafety, facilitates and directs the activities of the National Committee for Ecology and Territorial Development. The Parliament exercises control over activities of executive authorities, ratifies international agreements and treaties signed by the Republic of Moldova, approves state budget and controls its implementation, organizes examination and audit of all the problems in the spheres of national interest. The legislation vests the right to legislative initiative with the Parliament Members, President of the Republic of Moldova, the Government and the National Council of Gagauz-Yeri Autonomous Area.

President of the Republic of Moldova, as head of state, is the guarantor of its sovereignty, national independence and territorial unity of the country; he signs international treaties and agreements on behalf of the Republic of Moldova and makes annual presentations to the Parliament regarding issues of national interest, including biosafety. The President promulgates national laws after their approval by the Parliament.

The Government of the Republic of Moldova ensures promotion of the domestic and foreign state policies and directs operations of the public administration authorities. To be able to fulfill its functions, the Government develops Action Programs to be approved by the Parliament. The Government has the following functions in the sphere of environmental safety and public health:

- To facilitate state policies and measures for protection and rational use of natural resources, maintenance of biological balance and ensured renewal of all biological systems, exercising state control in the relevant areas;
- To facilitate state policies in the issues of public health protection and measures to secure the country's population with food, medicines and primary services, to ensure protection of consumer rights;
- To facilitate state policies in the sphere of standardization, metrology, product expertise and certification, state control over their quality;
- To facilitate development and implementation of national concepts, strategies and programs, technical requirements and other regulations regarding standardization, to facilitate and coordinate state control and supervision over standardization regulations;
- To ensure observance and fulfillment of laws, Parliamentary Resolutions, Decrees of the President of Moldova, and international agreements to which the Republic of Moldova is a party.

National branch authorities in the relevant fields

The national authorities in charge of particular areas are the ministries. Moldova has currently 15 ministries. They implement the Government policies according to the law and ensure policy implementation in the areas administrated by them as the authorities responsible for the relevant spheres of activities. In addition, the Parliament may establish state departments within the Government upon the Prime Minister's suggestion to direct and control the activities, which do not fall under the authority of the existing ministries. Moldova has currently 15 state departments. To control compliance with laws, decisions, resolutions and other regulations issued by the Parliament, Government and President, the Government may establish state services and inspectorates. Acting within their powers and functions, state departments, services and inspectorates develop regulations for the relevant areas.

The Government may set up permanent or provisional committees and councils to examine particular issues and develop decisions for various situations in the process of Moldova's social and economic development, including biosafety issues.

The Ministry of Ecology and Natural Resources (MENR) is the national environmental and national resources authority responsible for:

1. Development and implementation of policies and strategies regarding environment and natural resources;
2. Development of draft laws and regulations, standards, requirements, other regulatory documents;
3. Implementation of environmental management and management of natural resources at the national and local level, monitoring and control;
4. Development of biodiversity protection strategies and actions jointly with other stakeholders;
5. Establishment of guidance and control actions to ensure Moldova's environmental safety and biosafety;
6. Environmental inspections;
7. Production of reports regarding environment quality and situation with various environmental aspects;
8. International collaboration and fulfillment of international commitments in the environmental sphere.

- The Ministry of Health* (MH) is the national authority in charge of public health, responsible for:
2. Ensuring of adequate public health quality and provision of a comprehensive range of medical services;
 3. Development of policies and programs, draft laws and regulations, standards regarding human health and sanitary-epidemiological situation;
 4. Management of public health care and sanitary-epidemiological activities, sanitary control and monitoring.

The Ministry of Agriculture and Food Industry (MAFI) is the national governmental authority for agriculture and food industry, responsible for:

1. Industry monitoring and control over compliance with laws and standards regarding use and management of pesticides and chemical fertilizers;
2. Testing of chemical and biological products and issuance of approvals for imports/exports of pesticides and fertilizers as well as maintenance of their National Register;
3. Quality testing and control in respect of pesticides and fertilizers and their monitoring in soil, feed and agricultural products, ensuring of public food security regarding quality, amounts and availability of agricultural products;
4. Supervision over compliance of certified agricultural products in agriculture and food industry with the requirements of applicable laws and regulations;
5. Control over observance of ecological restrictions in agriculture and agroindustry.

The Licensing Chamber (LC) was established within the Government as the national authority in charge of state regulation in the sphere of licensing. Acting within its powers and jointly with other relevant national authorities, it specifies conditions for issuance of licenses to perform activities subject to licensing; decides in the issues of issuance or refusal to issue a license; controls jointly with the other relevant authorities compliance with license terms and conditions on the part of license holders.

Local public administration authorities

The local public administration authorities operate according to the following underlying principles: local autonomy, decentralization of social services, election of the local public administration authorities and public consultations in the issues of local interest. The principle of autonomy applies both to operation and structure of the local public administration authorities and to management of issues presenting local interest. Application of the above principles does not affect state unity.

The local public administration authorities have the following responsibilities in the sphere of environment protection and management of natural resources:

- (1) Facilitation of control over compliance with the standards and laws applied at the local level;
- (2) Coordination with the MENR of local quotas for use of natural resources;
- (3) Development of local programs for environment protection and management of natural resources; and
- (4) Facilitation of transparency and dissemination of timely and true information to the public regarding quality of the environment and environmental situation.

3.3. INTELLECTUAL PROPERTY RIGHTS

Protection of intellectual property in the field of production, use and distribution of seeds and seedlings

The authorities in charge of implementing state policies in the sphere of legal protection and use of plant varieties in the Republic of Moldova include: *State Council for Plant Varieties (SCPV)*, *State Commission for Testing of Plant Varieties (SCTPV)* and *State Intellectual Property Protection Agency (SIPPA)*.

The State Council is the principal authority establishing state policies in the sphere of new variety homology. The Council's decisions are used as the basis for approval of varieties for use in the Republic of Moldova. The State Commission is the Council's permanently functioning body and the Agency's expert body, performing tests of new varieties to assess their economic feasibility and eligibility for patenting. The State Commission maintains *the Register of Plant Varieties*. The State Commission tests each new variety for distinctiveness, homogeneity and stability based on the requirements for variety testing and within its various variety testing facilities, such as research stations and institutions, specialized laboratories and services, according to internationally accepted methodology and standards. A variety may be used industrially solely where all the relevant legal provisions are complied with and subject to issuance by the State Commission of a certificate based on the results of state variety testing and registration of the new variety in the National Register of Plant Varieties. All varieties, hybrids, and lines of agricultural crops and other plants obtained by selection locally or abroad are subject to obligatory state testing in Moldova. The State Commission for Testing of Plant Varieties is the authority in charge of performing variety tests.

The State Commission operates to ensure implementation of the *Law on Protection of Plant Varieties* and according to the methodology approved by *the Convention on Protection of Plant Varieties* (UPOV).

State Council for Plant Varieties is the authority promoting governmental policies in the sphere of assessment and establishment of the plant range, which authorizes use and ensures protection of plant varieties irrespective of their origin. To decide on issues connected with its day-to-day activities, the Council has a permanently operating body – SCTPV – and collaborates with State Agency and Moldova's State Seed Inspectorate.

The State Intellectual Property Protection Agency (SIPPA) is another authority performing tests of new plant varieties with the aim to assess their economic feasibility and eligibility for patenting according to *the Law on Protection of Plant Varieties*.

The merchants licensed to produce and distribute seeds must be entered in *the National Register of seed producers* and are required to:

1. comply with the requirements regarding technologies of seed production and procession, packaging, storage, transportation and distribution according to the applicable technical norms and guidelines;
2. keep records regarding seed application and seed production, procession, storage and distribution;
3. distribute only the seeds complying with the applicable standards regarding variety and crop characteristics.

The merchants licensed to produce and distribute seeds are held responsible for seed quality and authenticity according to the applicable law and obliged to cover eventual damage to stakeholders.

Protection of consumer rights in the field of food safety

State Inspectorate for Cereals and Bakery Products is the authority in charge of control over quality of cereals, their derivative products, seeds of oil-producing crops and legumes, raw materials for production of feed and mixed feed, cereals forming part of state provisions and funds, quality of bread, bakery products and pasta products in all companies, enterprises and organizations, irrespective of their industrial subordination, legal status or ownership type; the above Inspectorate operates within the framework of the Ministry of Agriculture and Food Industry.

4. MONITORING AND INSPECTION

Monitoring

Monitoring of GMO-related activities is the task of the National Biosafety Committee. The national legislation does not specify the exact control authorities with the function of performing inspection and control of GMO-related activities. Monitoring objectives, general rules and procedures for development of a monitoring plan are specified in Appendix 5 (2) to *Regulations on authorization of activities connected with production, testing, use and distribution of GMOs*.

Although not a single application has been registered as yet regarding authorization of GMO-related activities, the relevant Moldovan authorities take certain actions by way of monitoring. The Ministry of Agriculture and Food Industry developed *Regulations regarding imports and exports of seeds and seedlings* approved by Government Decision no. 360 of 27.03.02. There is an urgent need to complete the existing legislation framework and enforcement system and to specify responsibilities and duties of the governmental inspection bodies with the GMOs monitoring and inspection functions.

Authorities with authorization, control and inspection functions

A number of inter-ministerial authorities were established next to the national authorities to ensure fulfillment of the principal functions and control over activities directly or indirectly connected with GMO issues.

The National Biosafety Committee (NBC) operating by the Ministry of Ecology and Natural Resources is the national authority with the functions to promote state biosafety policy and to perform authorization and monitoring in that sphere. MENR performs the function of the Committee's secretariat.

The National Council for Plant Varieties (NCPV) is the authority ensuring implementation of state policies regarding assessment and specification of plant varieties, authorizing their use and ensuring variety protection. NCPV coordinates its actions with MAFI. *State Committee for Testing of Plant Varieties* and *State Seed Inspectorate* were established to decide on the issues covered by the respective areas. To be able to perform its functions, NCPV has the power to require from the above authorities as well as other services established within MAFI the documentation necessary for decision-making on the problems falling within its sphere of expertise.

The tasks of *the National Interdepartmental Council for approval of phytosanitary products and preparations designed to improve soil fertility* are: to accumulate a range of new and efficient plant protection methods, to ensure state control over import procurements, testing and use of chemicals and biological products designed to control pests, crop diseases and weeds as well as plant growth stimulators. The Council makes preliminary decisions regarding approval or rejection of new plant protection methods and prohibits use of the products found not in compliance with toxic or hygienic requirements and therefore presenting danger for humans, animals and the environment.

The National Codex Alimentarius Committee (NCAC) has the status of a consultative body in the issues regarding uniformity of requirements to food quality and security and propagation of healthy nutrition according to recommendations of the *Codex Alimentarius* Commission.

The State Seed Inspectorate (SSI) is the authority operating within MAFI and empowered to control seeds and seedlings and to certify seeds.

The National Scientific Research Center for Preventive Health Care (NSRCPHC) established within the MH framework is the authority in charge of sanitary epidemiological control and continuous information of the population about sanitary-epidemiological and hygiene situation.

The State Phytosanitary Quarantine Inspectorate (SPQI) is the authority in charge of implementation of domestic and external phytosanitary quarantine actions, facilitation of identification, localization and control of pests and plant disease hotbeds, and state phytosanitary control.

The State Center for certification and Homologation of phytosanitary products and Fertilizers has the function to facilitate testing and approval of new products and preparations falling in the above category. It operates within MAFI framework.

5. BIOTECHNOLOGY RESEARCH AND DEVELOPMENT (R&D) POTENTIAL

Biotechnology R&D institutional capacity

The principal institutions performing research in the area of genetics and biotechnologies in the Republic of Moldova are the following scientific research institutes operating within the framework of the *Academy of Sciences of Moldova (Appendix 5)*:

- Genetics Research Institute;
- Plant Physiology Research Institute;
- Microbiological Research Institute;
- Botanical Research Institute;
- *Zoological Research Institute*; and
- Plant Protection Research Institute.

Furthermore, a number of universities perform scientific research in the above areas, including:

- State University of Moldova;
- *State Medical and Pharmacological University „Nicolae Testemitanu”*; and
- *State Agricultural University of Moldova*

The biotechnology research directions developing most intensively in the above institutions include:

1. Non-traditional plant improvement methods and techniques:
 - Tissue cultures;
 - Genetic material transmission methods using protoplasm or recombinant DNA fusion techniques;
 - Vegetative plant regeneration;
2. Products used as gene engineering tools:
 - vectors (plasma derivatives);
 - genes or gene fragments isolated from plants, viruses, bacteria or animals;
 - promoters, activators, operators and specific function DNA sequences;
 - crop cell lines (inbred cell lines);
 - plant parts (multiplication materials).

Extensive research in the sphere of molecular biology and gene engineering is conducted in the laboratories of the *Genetics Research Institute of the Academy of Sciences*. The laboratory for molecular genome structure and gene formulation identified, isolated and cloned regulating sequences for certain reproductive system gene promoters of several superior plants (tomatoes, corn, melandrium), established the primary structure for those sequences, identified the homology of the regulatory element nucleotide successions with genes of other organisms.

It was the first to establish the presence certain successions, demonstrating high homology with the mobile genetic element En in corn, in the genome of the *Fabacea* family plants. An artificial chimerical gene was synthesized, producing green fluorescent protein as gene marker in zygotic and somatic plant embryogenesis.

The laboratory for genome instability and genetic engineering created plasmidic vectors produce transgenic potato plants and oligonucleotide primers for molecular identification of hepatitis HBV and hepatitis TTV DNA.

A number of laboratories and research units, whose activities have indirect relevance to new biotechnologies, operate within the framework of research institutes, including:

1. In the Academy of Sciences of Moldova:
 - *Genetic Research Institute*: Laboratory for molecular genome structure and gene formulation; Laboratory for genome instability and genetic engineering; Laboratory for non-traditional amelioration technologies; Laboratory for ontogenetics and cell engineering; Laboratory for induced genetic variability;
 - *Microbiology Research Institute*: Laboratory of enzymology; Laboratory for microbial products;
 - *Botanical Gardens (Research Institute)*: Laboratory for embryology and biotechnology;
 - *Plant Physiology Research Institute*: Laboratory of ontogenesis biochemistry; Laboratory for cell structure and ultrastructure;
2. In the universities:
 - *State University of Moldova*: Chair of vegetal biology;
 - *State Agricultural University of Moldova*: Chair of genetics and plant improvement;
3. In Ministries and State Departments:
 - *Department of Standardization and Metrology*: Genetic expertise laboratory;
 - *National Grapes and Wine Institute*: Laboratory of sparkling wines;
 - *Scientific Research Institute for Corn and Sorghum*: Laboratory of biochemistry, physiology and biotechnology;
 - *Northern Station for Project Implementation and Chemical Research*: Research laboratory;
 - Horticulture Research Institute.

A number of private companies are licensed to provide certification services in respect of food, soil and water samples, mineral fertilizers, seeds, agricultural products; or diagnostics services in respect of viral and microbial infections; certain biotechnology components may be present in their work. Such companies include:

- *Center for standardization and quality assessment of canned products* (Chisinau);
- *Joint Moldovan-Romanian Venture „Immunotechnomed”* (Chisinau);
- *Scientific Research and Production Association „SPM Group”* (Chisinau);
- *„Romanta Plus” S.R.L.* (Chisinau).

According to Law no. 567-XIV of 29 July 1999 *On the state policy in the research and development sphere*, the *Supreme Council for Science and Technological Development* has been instituted as the central public administration authority in the field of research and development. The Consultative Expertise Council, formed of expert committees, activates beside the Council.

The scientific research in the agricultural and food sector is carried out by a network of institutions subordinated to the *Ministry of Agriculture and Food Industry*, including 11 research institutes and 3 branches, 2 scientific research and production centers, 2 scientific research stations, and State Agrarian University of Moldova. Those institutions carry out research within the framework of technical and scientific research programs with co-participation of certain subdivisions within the Moldovan Academy of Sciences. Activities of state institutions in the field of agricultural research and development are coordinated by the respective subdivision within the Ministry of Agriculture and Food Industry. The following branch research institutes should be mentioned in connection with biotechnology research and agricultural plant selection: *National Institute of Corn and Sorghum*, *National Fruit and Grape Research Institute*, *National Institute of Crop Science*, *National Institute of Viticulture and Wine* within the Ministry of Agriculture and Food Industry.

In the last 15 years scientific research in the field of agriculture developed in the following directions: soil and water resources, cereals, feed and proteins, technical crops, sunflower, tobacco, essential volatile oil-bearing plants and medicinal herbs, vegetables, fruit, viticulture and wine, animal breeding, procession of agricultural raw materials, plant protection, agribusiness mechanization and automation and energy systems, agribusiness economy and dissemination of information.

Education and professional training

The principal higher education institutions providing university training in the relevant biosafety spheres include:

- *State University of Moldova;*
- *State Agricultural University of Moldova;*
- *State Medical and Pharmacological University of Moldova „N. Testemitanu”;*
- *University of Ecology and Socio-Humanitarian Sciences.*

Professional post-graduation training in that sphere takes place mostly in the research institutes within the Moldovan Academy of Sciences and Industrial Research Institutes. Such institutions offer professional training according to master or doctor degree training programs.

The specialisms offered for training in the relevant areas include mainly:

- *Ecology and environment protection;*
- *Industrial biotechnologies;*
- *Animal breeding;*
- *Veterinary medicine;*
- *Biology;*
- *Variety improvement and genetics;*
- *Plant protection;*
- *Forestry and public gardens;*
- *Agricultural biotechnologies; and*
- *Environmental law*

6. PUBLIC INFORMATION AND PUBLIC INVOLVEMENT IN DECISION-MAKING PROCESS

Public awareness and involvement in decision making

Regulatory framework has been established in the Republic of Moldova to implement the principles of public participation in decision-making in the field of biosafety (Article 23 of the Cartagena Protocol). The Ministry of Ecology and Natural Resources drafted the *Law on Biosafety*. (no. 755-XV of 21.12.2001). To ensure transparency of the NBC activities, a special procedure on consultations with the public has been included in the Biosafety law. The National Biosafety Committee should take into consideration the comments received from the public. Public hearings may be organized depending on the comments.

The Commission shall be guided by national legislation and international agreements to ensure public participation – Art. 39. This includes doubtless the *Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters*. Based on the information in the submitted notification, the National Committee, acting in conformity with Government Decision no. 1153 of 25.09.2003, Paragraph 29 and 30, must inform the public about the information provided in the notification within 10 days upon its receipt and start consultations; consider the received comments and questions and place the notification documentation within the same time on the official web page of the National Environmental Authority. In decision-making regarding the notified activity, the Committee must consider comments in the nature of advisory received from the public within 30 days after the day of information dissemination. Depending on the received comments, the Committee may organize public hearings regarding any aspect of the issues being considered.

To ensure detailed implementation of the above provisions, the Minister of Ecology and Natural Resources issued Order 19 of 10.02.2004 *on Regulations on Information and Public Consultations on Genetically Modified Organisms* establishing procedures for regulation of public access to information regarding GMOs and mechanisms for influencing the discussion and drafting of decisions.

The Ministry of Ecology and Natural Resources must establish and maintain *the Register of interested parties* where any legal entity or individual may be included upon request. The list of interested parties approved by Order of the Minister for Ecology and Natural Resources should include, in particular:

- Environmental NGOs;
- Consumers and their associations;
- Medics and their associations
- Mass media;
- Scientific community;
- Farmers and their associations;
- Seed importers;
- Local public administration authorities;
- Local communities;
- Professional associations.

The National Committee should inform interested parties via Internet or otherwise about the following:

- Proposed activities and notification providing the basis for decision making, with the respective summary files;
- The type of decision to be made (issuance of an authorization for GMO imports, deliberate release in the environment or market release, use and location);
- The proposed procedures for examination, dissemination of information to the public, as well as address, procedures and deadlines for submission of comments and questions.

Local communities are considered an interested party where GMO use is proposed on the territory of the community or on the neighboring territory; they must be kept informed via local press, announcements placed on the board in or near the offices of the local administration authorities, public hearings or other methods within the timeframe established for information of interested parties.

Draft opinion of the National Committee with comments received and their assessment by the Committee must be placed on the official web page of the Ministry of Ecology and Natural Resources, and representatives of the interested parties, which have made proposals in respect of the published information, are entitled to an argued answer from the National Committee regarding acceptance or rejection of public proposals. The National Committee must make a final decision within 20 days after it places draft opinion on the web page in the Internet.

The National Committee maintains and publishes the *National Register of GMOs and products made with use thereof*, Authorizations regarding their use and the *Register of decisions regarding authorization of the relevant activities* together with non-confidential materials submitted by the applicant and expert opinions issued by the relevant research institutions.

CHAPTER II

CONCEPT FOR THE FUTURE DEVELOPMENT OF THE NATIONAL BIOSAFETY FRAMEWORK OF THE REPUBLIC OF MOLDOVA

INTRODUCTION TO THE NEW NBF CONCEPT AND THE BIOSAFETY CAPACITY-BUILDING NEEDS

The detailed survey of the existing legislative and institutional framework in the sphere of biosafety and in adjacent spheres has resulted in identification of a number of goals and deficiencies. Their analysis made it possible to determine the needs and priorities in the development of the National Biosafety Framework.

Certain regulations as well as institutional framework exists currently in the Republic of Moldova, covering only in part the needs of an integrated Biosafety framework, as determined by the Cartagena Protocol on Biosafety to the Convention on Biodiversity.

As a result of examination of the current situation, discussions with stakeholders and civil society and in view of the necessity to adapt this situation to the requirements of the Cartagena Protocol, certain amendments are proposed to the legislative framework with the aim to make it meet in full the objectives specified in the Protocol.

Currently the Biosafety law put the decision making to the National Biosafety Committee, but in accordance to the new concept of the National Biosafety Framework (*fig. 1*), the National Biosafety Committee should be the supreme coordinating authority in the Republic of Moldova in the field of Biosafety, and the Ministry of Ecology and Natural Resources should be the decision-making authority with the right to issue authorizations for the activities connected with uses of the GMOs.

According to this Concept, every notifier planning activities connected with obtaining, management or marketing of genetically modified organisms or products containing components obtained from such organisms is obliged to obtain an authorization for such activities from the National Biosafety Committee. As the national authority composed of specialists from the various public, private and non-governmental institutions and operating in the status of a public organization, the Committee will have a Technical Group. Thus, the notifier will address the National Biosafety Committee through its Technical Group, which should operate permanently. The Technical Group will perform assessment of every application. This assessment will be performed with the aim to check the extent of compliance of the submitted application with technical requirements for such documents. Then the Technical Group should include examination of this application in the agenda of the National Biosafety Committee Meeting and request convening of such meeting. It is planned to complete the Regulation on NBC with the provisions regarding the Technical Group.

The National Biosafety Committee examines the notification from the notifier and decides on case-by case basis, which should be the procedure for its examination. Therefore the National Biosafety Committee will proceed, if appropriate, in one of the two possible ways.

The first way provides for a simplified examination method. In such a situation the National Biosafety Committee, acting through its Technical Group, forwards the notifier's documentation for examination and issuance of an opinion to technical Biosafety committees in the relevant Ministries, to scientific councils in the relevant research institutions and to NGOs accredited as experts in the sphere of the notified activities. The National Committee should determine the list of such organizations on case-by case basis depending on the type of the notified activities.

The institutions included in the list must issue an opinion recommending the National Committee to approve or not to approve the activity requested by the notifier. Simultaneously with the issuance of opinions by technical committees, scientific councils and NGOs included in the list made by the National Committee, an additional opinion in respect of each individual application may be issued

by any other governmental, non-governmental or private institution, researcher as well as by general public. The implementation of this mechanism should be ensured via mandatory placement of each application upon its receipt on web page of the Biosafety Clearing House and Public Relations Office operating by the Ministry of Ecology and Natural Resources. This office's task will be to develop and maintain the National Registry of GMOs. The National Committee will be obliged to consider every opinion received before the beginning of the discussion regarding the submitted application, regardless of the way in which they have arrived or by whom they have been expressed.

The second way provides for a detailed examination method. This mandatory examination includes all the procedures required in the case of a simplified examination and additionally the procedure of risk assessment regarding possible risks connected with obtaining, management and use of GMOs. In this case an opinion will be requested from the National Testing and Risk Assessment Center in addition to assessments performed by Biosafety technical committees of the relevant Ministries, scientific councils of research institutions and NGOs accredited as experts on the notifier's type of activity. This opinion must assess possible risks for human health and the environment presented by the notified activity in respect of GMOs.

All the opinions issued in either case must reflect and assess the risks for human health and the environment presented by the activities with GMOs or products obtained therefrom. The conclusions must be supported with findings of earlier scientific research or survey on similar activities already practiced. Additional research may be performed by the National Testing and Risk Assessment Center solely where more detailed examination is required in respect of certain opinions regarding the requested activity.

Upon receipt of all opinions on every separate activity requested by the notifier, which opinions should be collected and systematized by the Technical Committee of the National Biosafety Committee, the latter discusses each activity separately at one of its ordinary meetings. The National Committee must issue an opinion indicating whether the activity with GMOs proposed by the notifier should be approved or rejected. This opinion is submitted for approval to the National Environmental Authority of the Republic of Moldova (which is currently the Ministry of Ecology and Natural Resources). The approval of the opinion issued by the National Biosafety Committee should be formalized by an order issued by the National Environmental Authority. Based on this order, the National Biosafety Committee, acting on behalf of the National Environmental Authority, issues an authorization for the activity requested by the merchant. The merchant may start planned activities solely upon receipt of the respective authorization. Legal responsibility for the consequences of the approved or rejected activities lies with the Government of the Republic of Moldova acting via the National Environmental Authority.

Having obtained the authorization, the notifier may start the procedure for implementation of the planned activities. During this period the National Biosafety Framework provides for a system for monitoring, control and inspection of authorized activities for the purpose of monitoring compliance by the notifier with the terms and conditions of the authorization. The State Ecological Inspectorate of the National Environmental Authority, Phytosanitary Inspectorate and Seed Quality Control Inspectorate of the Ministry of Agriculture and Food Industry, sanitary inspectorates of the Ministry of Health, the Customs Control Department, the Department for Emergency Situations and the Department of Standardization and Metrology acting within their powers should be involved in this process. These institutions will have the functions of control, inspection and monitoring.

Where non-compliance with the authorization terms and conditions is identified, the authorities with control functions may apply penalties provided for in the applicable laws and regulations or submit a special request to the National Committee in exceptional cases, demanding to withdraw the authorization for the relevant activity. The National Environmental Authority may withdraw the authorization on the request of the National Biosafety Committee. Disputes relating to concentration or presence in food or feed of components derived from GMOs, or to categorization of an organism with GMOs should be settled solely on the basis of the results of tests performed and presented by the National Testing and Risk Assessment Center or by an international institution with the functions of testing and identification of such products and organisms.

1. NBF: FUTURE PLANS FOR THE BIOSAFETY POLICY

Biosafety policy

The most important gaps of current political framework have been identified:

- Political framework and strategies in the biosafety sphere are not very clearly determined or detailed sufficiently clearly;
- There is no integration of biosafety to other related strategies or policies.

As mentioned in the above, the principal document, which currently determines the policies and strategy in the field of Biosafety in the Republic of Moldova, is the National Strategy and Action Plan in the field of Biodiversity Conservation. Annual action plans are developed based on this document. In this context it is necessary to include the activities making possible completion of an integral National Biosafety Plan in the action plans for the next 2-3 years.

As the Republic of Moldova has chosen the strategic course towards integration into the European Union, the future policies and strategies in the field of biosafety will be determined by the relevant legislative and institutional framework for the EU.

Regional collaboration

Currently the Republic of Moldova has agreements regarding environment protection at the regional level with Ukraine, Belarus, Romania, Italy, Poland and the Russian Federation. For the future it would be necessary to review bilateral intergovernmental agreements with the aim to bring them in compliance with the requirements of the Cartagena Protocol. The priority activities in this context would be:

- harmonization of customs procedures;
- information sharing regarding transboundary movements of organisms or products containing components obtained from GMOs, including emergency exchange of information in case of accidents or illegal transboundary movements;
- scientific collaboration in the field of biosafety;
- emergency exchange of information in case of accidents or illegal transboundary movements;
- joint activities to prevent and control the consequences caused by GMOs to the environment and human health;
- an agreement on acceptance of simplified imports/exports/transit procedures.

2. FUTURE PLANS FOR THE REGULATORY FRAMEWORK

The most important gaps of current legislative framework have been identified:

- The current laws in that area have predominantly the horizontal application character,
- The legal framework is not sufficiently detailed and requires integration in the branch legislation to ensure efficient implementation of the decisions;
- The regulatory framework for application of biosafety legislation is not sufficiently developed in order to ensure monitoring and inspection, mechanisms for payment, clearing house activities etc.

The law currently in effect does not provide sufficient details regarding the powers for inspection and monitoring of compliance with the requirements in respect of GMOs or enforcement of laws and regulations. Insufficiently clear or detailed provisions regarding the mechanisms for inspection and monitoring and, where appropriate, for enforcement of the law results in the decreased efficiency of the law as such.

Legislative framework and enforcement system

In this context, the Law on Biosafety should be amended to bring it in compliance with the National Biosafety Framework described earlier. Currently the Republic of Moldova has a single basic

law – the Law on Biosafety and a number of additional regulations covering the issue of regulation of the activities connected with production, use and marketing of GMOs and products containing such organisms.

To these regulatory needs it would be necessary to introduce certain amendments to the Biosafety legislative framework regarding the following:

- Segregation of powers and functions of state authorities regarding: a) the process of examination and decision making; b) involvement of new institutional components – technical biosafety committees of the relevant ministries and departments, and development of their statutes;
- procedures and methodologies for monitoring, inspection and control of the authorized GMO-related activities;
- introduction of a new chapter regarding the Biosafety Clearing House and Biosafety Register;
- development of procedures and methodologies for testing and risk assessment/ management of biotechnology risks.

It would be necessary to amend and harmonize branch laws with the provisions of the Cartagena Protocol and the National Biosafety Framework.

Furthermore, it would be necessary to amend the following laws and regulations with provisions regarding contained use, deliberate release into the environment, placing on the market, imports/ exports, transport, labeling, packaging and customs procedures:

Within the system of the Ministry of Agriculture and Food Industry:

- Government Decision no. 863 of 21.08.2000 *On approval of the National Concept for ecological farming, production and distribution of environmentally clean food not modified genetically;*
- *Law on Seeds* (no. 659-XIV of 29.10.1999);
- *Law on Protection of Plant Varieties* (no. 915-XIII of 11.07.1996);
- *Law on Horticulture* (no. 728-XIII of 06.02.1996);
- Government Decision no. 697 of 10.10.1995 *on establishment of the State Phytosanitary Quarantine Service;*
- *Law on Phytosanitary Quarantine* (no. 506-XIII of 22.06.1995);
- *Law on Animal Breeding* (no. 412-XIV of 27.05.1999).

Within the system of the Ministry of Health:

- *Law on Medicines* (no. 1409-XIII of 17.12.1997);
- *Law on Public Sanitary Epidemiological Security* (no. 1513-XII of 16.06.1993);
- *Law on Health Care* (no. 411-XIII of 28.03.1995);
- *Law on Protection of Consumer Rights* (no. 105-XV of 13.03.2003);
- Government Decision no. 1297 of 27.11.2001 *On intensification of Consumer Protection Actions;*
- Government Decision no. 477 of 19.05.2000 *On establishment of the national network for laboratory control and monitoring of the bacterial (biological) environment pollution;*
- Government Decision no. 996 of 20.08.2003 *On approval of Requirements to labeling of food and Requirements to labeling of household chemicals;*

Within the system of the Standardization and Metrology Department:

Law on Standardization (no. 590-XIII of 22.09.1995);

Law on Metrology (no. 647-XIII of 17.11.1995).

For efficient application of the Biosafety Law it would be necessary to develop a package of new regulations, which would ensure enforcement and implementation of this law. An Action Plan for amending branch regulations will be elaborated. To this end it would be necessary to develop detailed regulations, guidelines and manuals covering the following:

- procedures and internal documentation for the Testing Laboratory;
- procedures and methodologies for risk assessment in situations of contained use;
- procedures and methodologies for risk assessment in situations of deliberate release into the environment;
- procedures and methodologies for risk assessment in situations of placing on the market;
- operation of technical committees within the relevant ministries and institutions and Technical Committee of the National Biosafety Committee;
- guidelines and checklist for examination of notifications and risks assessment;
- procedures and methodologies and requirements for packaging, labeling, storage and transportation;
- monitoring of the GMO activities;
- establishment of the state GMO inspection system (guidelines for relevant branches inspectorates);
- education and training in the field of GMOs for public servants;
- contents and maintenance of the National GMO Register including providing information to the BCH;
- methodology of calculation of costs and charges in the GMO regulation system;
- information and management of consequences in case of emergency, accident or unintentional release;
- adjustments of the Regulation on authorization of activities related to obtaining, testing, use, release into the environment and placing on the market of genetically modified organisms and products containing such organisms to relevant requirements for the comprehensive National Biosafety Framework;
- approximation of customs procedures to the international requirements regarding GMO transboundary movement;
- examination of possibilities to simplify GMO imports/exports customs procedures with the neighboring countries and in the region;
- regulations regarding confidential information.

3. FUTURE PLANS FOR THE SYSTEM OF HANDLING AND INSTITUTIONAL FRAMEWORK

The most important gaps of current institutional framework have been identified:

- The relevant ministries have not appointed expert units/teams to ensure examination of notifications or risk assessment;
- The institutions in charge of monitoring, control and inspection, their functions and powers have not been clearly determined;
- There is no system of information storage and public information
- Guidelines and methodologies for testing and risk assessment have not been developed to ensure efficient operation of the National Biosafety Center;
- The National Biosafety Center has not been properly accredited at the national or international level, contrary to the requirements;
- There are no regulations for maintenance of the National Register of GMOs and products obtained using GMOs, which are allowed for use, the Register of decisions on authorizations of the respective activities and the Register on public participation in decision making and monitoring.

The National Environmental Authority and Branch Authorities

According to the new concept of the Biosafety Framework for the Republic of Moldova, the National Biosafety Committee will be the advisory body in this area, and the National Environmental Authority will be in charge of decision-making.

As Moldova's authority responsible for liaison with the Convention Secretariat, the National Environmental Authority must have the following additional functions in order to:

- develop the national policy in the field of biosafety;
- make decisions taking into account the National Committee's recommendations regarding activities connected with GMOs use and issue authorizations;
- administrative procedures to ensure coordination at the national level of activities provided for in the Cartagena Protocol;
- establish and maintain the National GMO Register;
- finance and coordinate the activities of the Biosafety Clearing House and Public Relations Office;
- develop the legislative and regulations

Currently the national branch authorities of the Republic of Moldova with the functions connected with implementation of the National Biosafety Framework include: the Ministry of Agriculture and Food Industry, the Ministry of Health, and the Academy of Sciences of Moldova. Those authorities will participate in the process of issuance of authorizations, acting via their own technical committees on biosafety. The Ministry of Education will participate in the process of education and professional training of specialists in the field of biosafety.

The *State Ecological Inspectorate*, the inspectorates of the *Ministry of Agriculture and Food Industry (State Phytosanitary Quarantine Inspectorate, State Seed Inspectorate, State Veterinary Inspectorate)*, the *National Scientific Research Center for Preventive Health Care of the Ministry of Health*, the *Customs Control Department*, the *Department for Emergency Situations*, and the *Department of Standardization and Metrology* will be involved in the process of monitoring, inspection and control of activities connected with GMOs.

In order to fulfill these tasks, the above authorities will have additional functions in the following areas:

- establishment of technical committees for examination of notifications and issuance of the respective opinions;
- development of regulations regarding operation of technical committees;
- development of regulations and procedures for GMO monitoring, inspection and control;
- education and training of specialists in the field of biosafety;
- introduction of amendments to the Regulations for the State Ecological Inspectorate regarding the function to control activities connected with genetically modified organisms;
- introduction of amendments to the Regulations for agro-industrial inspectorates regarding the function to control activities connected with GMO use in the phytosanitary, animal breeding and veterinary sphere;
- introduction of amendments to the Regulations for the preventive health care system regarding the function to control activities connected with GMO use in food and placing on the market; traceability of placing on the market of genetically modified organisms and/or products deriving from such organisms.

The National Biosafety Committee and Ministerial Technical Committees

The National Biosafety Committee will have advisory functions in the process of decision making in the field of biosafety. To achieve these objectives, it will have the tasks to:

- develop opinions in the nature of recommendations regarding approval or rejection of GMO-related activities requested by the notifier;
- submit the respective opinion to the National Environmental Authority for approval;
- coordinate its actions with technical committees on biosafety in the relevant authorities and institutions and with units in charge of monitoring, inspection and control functions;

- coordinate the operation of the National Testing and Risk Assessment Center;
- develop concepts regarding state strategies and policies in the field of biosafety and GMO;
- coordinate authorization issuance and authorization withdrawal procedures; and
- monitor the process of information and public consultations.

To ensure efficient examination of notifications and risk assessment, it is proposed to establish technical committees for biosafety within national authorities in the field of agriculture and food industry, health care and the Academy of Sciences of Moldova.

Such technical committees will have the tasks to:

- assess the notifier's activities and the degree of risk these activities might present for the environment and human health;
- issue the respective opinion and submit it to the National Committee.

Biosafety Clearing House, Public Relations Office and the GMO Register

To comply with the requirements of the Cartagena Protocol, the National Biosafety Clearing House and Public Relations Office will be established within the National Environmental Authority. This Office will have the functions to:

- gather information and develop databases on GMO-related activities;
- establish and maintain of an interactive system for public consultation to ensure public involvement in the decision making;
- ensure information sharing at the national and international levels;
- ensure information sharing in emergency situations; and
- develop and maintain the GMO Register;
- establish the national BCH;
- ensure procedures for accurate and timely information flow to the BCH ;
- establish procedures for controlling completeness and accuracy of the information on the BCH.

Testing and Risk Assessment Center

The Center for Testing and Risk Assessment will have the following functions:

- testing of living genetically modified organisms to identify if they belong with the GMO category;
- testing of products to identify if they belong with the category of products obtained from genetically modified organisms or containing ingredients obtained from genetically modified organisms;
- assessment of risks presented by production, use and management of GMOs in contained use and deliberative release;
- assessment of risks presented by placing on the market of products obtained from GMOs.

To comply with the requirements of the Convention and the Protocol, the following activities would be carried out to facilitate testing and risk assessment:

- Provision of the National Testing and Risk Assessment Center (TRAC) with the required analytical laboratory equipment;
- Facilitation of TRAC national and international accreditation;
- Training of TRAC specialists in the field of testing and assessment of risks presented by GMO-related activities;
- Development of GMO sample databanks and access to reference material;
- Development and approval of methodologies for testing and assessment of risks for the environment and human health;
- Development of procedures for provision of testing and risk assessment services and for calculation of their costs.

4. FUTURE PLANS FOR MONITORING, INSPECTION AND CONTROL

Monitoring, inspection and control

To ensure monitoring, inspection and control, the institutions with the relevant functions will have the obligation to:

- Perform monitoring, inspection and control of GMOs in situations of contained use, release to the environment and placing on the market;
- Control the notifier's compliance with technical requirements and standards specified in the authorization;
- Impose penalties according to the applicable laws in case of non-compliance with applicable standards;
- Initiate the procedure for authorization withdrawal in exceptional situations.

Transportation, labeling and packaging

For transportation of GMOs or products derived from such organisms, especially in transboundary or transit movement, it is necessary to develop regulations specifying requirements for transportation, labeling and packaging and to harmonize them at the regional level and to the EU requirements.

The national authorities in the field of the environment, standards and metrology, and health care would have the task to develop methodologies for transportation, labeling and packaging of GMOs. The following actions will be taken to ensure fulfillment of these tasks:

- State Ecological Inspectorate (border-crossing offices) and the Customs Control Department will have the functions of border monitoring, inspection and control over compliance with the requirements for transportation, labeling and packaging of GMOs;
- Inside the country the functions of monitoring, inspection and control over transportation, labeling and packaging will be exercised by inspectorates within the Ministry of Health, Department of Standardization and Metrology, and State Ecological Inspectorate.

Customs procedures

The following actions are suggested to ensure control over GMO imports/exports/transit:

- To vest the function to perform customs procedures in respect of GMOs with the customs offices at border-crossing points;
- To establish inspection, control and monitoring services within the customs office to ensure control over imports/exports/transit of GMOs;
- To include a special section in the customs declaration for the transported goods for the purpose of declaration of presence or absence of GMOs;
- To ensure prompt information of the national and international biosafety institutions about transboundary movement of GMOs.

5. FUTURE PLANS FOR THE DECISION-MAKING SYSTEM

According to the concept of the National Biosafety Framework, the decision-making system will be facilitated by a number of the national governmental authorities, depending on the intended use of GMOs.

The following regulations for internal use, guidelines and procedures will be developed to ensure implementation of the National Biosafety Framework:

- Procedure for submission of notifications to the National Committee;
- Procedure for preliminary examination of the submitted application for compliance with the requirements of the applicable legislation;
- Procedure for forwarding of the notification to branch technical committees;

- Procedure for forwarding of the notification to the National Testing and Risk Assessment Center, if necessary, for assessment of potential risks for the environment and human health;
- Procedure for placement of information on the web site of the National Biosafety Authority;
- Procedure for examination by the National Biosafety Committee of opinions issued by technical committees and the National Testing and Risk Assessment Center and consideration of the public opinion;
- Procedure for issuance of the opinion of the National Biosafety Committee;
- Procedure for forwarding the application documentation package and the Opinion of the National Biosafety Committee to the National Environmental Authority for approval;
- Procedure for issuance of authorization by the National Biosafety Committee;
- Procedure for public consultation and public hearings.

The decision-making methods and procedures are supposed to be similar for situations of contained use, deliberate release into the environment and placing on the market of genetically modified organisms and products derived from GMOs.

6. FUTURE PLANS FOR RISK ASSESSMENT

It is proposed to perform optional assessment of risks presented by activities connected with genetically modified organisms in the Republic of Moldova. The National Biosafety Committee will decide on case-by-case basis regarding the necessity to perform additional tests for the purpose of risk assessment in Moldova's conditions. The notifier would have to submit an application to the National Biosafety Committee to obtain an authorization for activities connected with genetically modified organisms.

Together with the application, the notifier would have to submit a set of documents presenting the findings of prior scientific research or survey of prior practices, which is designed to demonstrate the low or reasonable risks in planned activities connected with genetically modified organisms. If such documents are satisfactory and convincing for the National Committee, the procedure for issuance of the authorization will not involve additional risk assessment tests. If the National Committee finds the argumentation presented in such documents unsatisfactory or insufficient, it initiates the procedure of risk assessment via additional tests to be performed by the National Testing and Risk Assessment Center.

Taking into account a limited experiences of the biosafety risk assessment procedures in Moldova, it is an urgent need to ensure training of decision makers, experts and researchers in risk assessment methodologies.

7. FUTURE PLANS FOR PUBLIC INFORMATION, EDUCATION AND PARTICIPATION MECHANISMS

To implement the standards ensuring public participation in the field of biosafety, regarding the issue of risks connected with use of GMOs, the National Biosafety Committee must:

- ensure public access to decision making process;
- ensure public awareness via mass media, seminars, books, brochures, etc.;
- create a web page, inform the public about it and ensure its regular updates;
- establish permanent contacts and collaboration with the relevant accredited NGOs and other stakeholders with the purpose of involving them into the decision making process and into the process of adequate public information;
- develop capacities for implement traceability and transparency;
- inform the public regarding the problems and risks associated with use of GMOs via mass media, workshops, publications, etc.;
- create a specialized web page, inform the public about it and ensure its regular updates;

The awareness of general public of the term “genetically modified” is quite high, but the level of knowledge is low and mostly formed by fright of the unknown due to the following: for the most part adversely presented/ scandalous information on GMOs is disseminated via mass media and enhanced by the lack of understanding regarding basic facts behind modern biotechnology products. However, it was felt that the importance of the issue for the general public is moderate and influenced by other aspects, such as food price.

The following activities could be recommended to raise public awareness and knowledge:

- 1 dissemination by mass media of information regarding basic facts underlying modern biotechnology – with assistance of popular science writers; it would be recommended to use publications in specialized magazines (health, agriculture) and daily newspapers;
- 2 raising awareness via qualified intermediaries, such as science teachers at schools;
- 3 public participation in decision-making processes (facilitated via involvement of local governments).

Information sharing and consultations

Public information and consultations can be ensured via identification of the interested parties and development of their Register with due consideration of the fact that this category may include any party accredited in this field. Provisions of Government Decision no. 1153 of 2003 and Order of the Ministry of Ecology and Natural Resources no. 19 of 2004 must be implemented to this end. The process of information and consultation should be performed with assistance of the relevant nongovernmental sector.

Education and professional training: Future needs and priorities

The following is required to ensure education in the field of biosafety:

- at pre-university (secondary school) level: analysis and study of the school curriculum and introduction of amendments (new modules or subjects) jointly with the Ministry of Education;
- at university level: ensured training on biosafety issues, with due consideration of specifics with each specialist, for the following specialists: ecology and environment protection; industrial biotechnology; animal breeding; veterinary care; biology; plant improvement and genetics; plant protection; forestry and public gardens; agricultural biotechnologies; environmental law;
- at post-graduate level: review of training and advanced training programs in view of the latest developments in the field of gene engineering and its applications, national and international law;
- at professional level (teachers, physicians, farmers, agricultural specialists): use of potential offered by the relevant industry or sector in the field of biosafety.

For training of specialists the Biosafety Clearing House and Public Relations Office will be established at the national level and developed, using the infrastructure available with the educational establishments and of private sector.

NGOs and public participation in the monitoring

Special attention must be paid to education of specialists in the nongovernmental sector to make possible public monitoring of law enforcement in the field of biosafety at the national and local level. To this end the relevant national authorities must make the results of their activities publicly known, organize public hearings on regular basis, facilitate dialogues with the interested parties, and seek public assistance regarding control over implementation of the laws and regulations.

USE OF TERMS

“*Contained use*” means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

“*Exports*” means intentional transboundary movement from one Party to another Party;

“*Exporter*” means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

“*Imports*” means intentional transboundary movement into one Party from another Party;

“*Importer*” means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

“*Living modified organism*” (LMO) or “Genetically modified organisms” (GMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

“*Living organism*” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

“*Modern biotechnology*” means the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

“*Transboundary movement*” means the movement of a living modified organism from one Party to another Party

Laws and Resolutions in the field of Biosafety

1. ***The Convention on Biological Diversity (Rio de Janeiro, 1992)*** ratified by Parliamentary Decision 457-XIII of 16.05.1995 published in „Monitorul Oficial” Official Gazette no. 33 of 15.06.1995;
2. ***The Cartagena Protocol on Biosafety to the Convention on Biological Diversity*** signed at New York on 14.02.2001, ratified by Law 1381-XV of 11.10. 2002 published in „Monitorul Oficial” Official Gazette no. 149-150 of 07.11.2002;
3. ***National Strategy and Action Plan in the field of biodiversity conservation*** approved by Parliamentary Decision 112-XV of 27.04. 2001 published in „Monitorul Oficial” Official Gazette no. 90-91 of 02.08.01;
4. ***Government Resolution on appointment of the national authority responsible for liaison with the Secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity*** no. 197 of 25.02.2003 published in „Monitorul Oficial” Official Gazette no. 27-29 of 28.02.2003;
5. ***Law of the Republic of Moldova on Biosafety*** no. 755-XV of 21.12.2001, published in „Monitorul Oficial” Official Gazette no. 75 of 13.06.2002;
6. ***Government Resolution on the National Biosafety Committee*** no. 603 of 20.05.2003 published in „Monitorul Oficial” Official Gazette no. 91-96 of 30.05.2003;
7. ***Government Resolution on approval of the Regulation regarding authorization of activities connected with trials, production, use and distribution of GMOs*** no. 1153 of 25.09.03 published in „Monitorul Oficial” Official Gazette no. 211-214 of 10.10.03;
8. ***Government Resolution on approval of Regulations regarding labeling of food and Regulations regarding labeling of household chemicals*** no. 996 of 20.08.2003 published in „Monitorul Oficial” Official Gazette no. 189-190 of 29.08.03;
9. ***Government Resolution on approval of the National concept regarding natural and environmentally friendly farming, production and distribution of natural and non-GMO food*** no. 863 of 21.08.2000 published in „Monitorul Oficial” Official Gazette no. 109-111 of 31.08.2000;
10. ***Order of the Ministry for Environment, Construction and Territory Development on Regulations regarding information sharing and public consultations in connection with GMO Issues*** no. 19 of 10.02.04;
11. ***Order of the Ministry for Environment, Construction and Territory Development and Ministry of Health on establishment of the Biosafety Testing Center*** no. 28/61 of 18.02.04.

Bilateral and multilateral agreements

1. *Protocol on collaboration between the Ministry for Environment Protection of Ukraine and State Department for Environment Protection and Natural Resources of the Republic of Moldova* signed in Kiev (Ukraine) on 19 November 1993;
2. *Agreement between State Department for Environment Protection of the Republic of Moldova and the Ministry for Natural Resources and Environment Protection of the Republic of Belarus on collaboration in the environmental sphere* signed in Chisinau on 23 December 1994 and effective since 14 April 1997;
3. *Agreement on collaboration between State Ecologic Inspectorate of the Republic of Moldova and between State Ecologic Inspectorate and Fishery Inspectorate of the Vinnitsa Province of Ukraine* concluded on 13 June 1996 in the city of Vinnitsa (Ukraine);
4. *Agreement on collaboration between the State Department for Environment Protection of the Republic of Moldova and the Ministry of Waters, Forests and Environment Protection of Romania in the sphere of environment and sustainable utilization of natural resources* signed on 18 March 1997;
5. *Convention between the Government of the Republic of Moldova and the Government of Romania on cooperation in the sphere of quarantine and plant protection* signed in Bucharest on 15 May 1997 and effective since 21 November 1997;
6. *Agreement between the Ministry of Environment and Territory Protection of the Republic of Italy and the Ministry for Environment, Construction and Territory Development of the Republic of Moldova on collaboration in the sphere of environment protection and utilization of natural resources* signed in Chisinau on 10 June 2002.

Branch legislation and resolutions

1. *Law on protection of consumer rights* (no. 105-XV of 13.03.2003);
2. *Decision on intensification of actions to protect consumer rights* (no. 1297 of 27.11.2001);
3. *Decision on establishment of the national laboratory network for monitoring and control of environment pollution with bacterial (biological) substances* (no. 477 of 19.05.2000);
4. *Government Resolution on approval of Regulations regarding labeling of food and Regulations regarding labeling of household chemicals* (no. 996 of 20.08.2003, „Monitorul Oficial” Official Gazette no. 189-190 of 29.08.03);
5. *Law on seeds* (no. 659-XIV of 29.10.1999);
6. *Law on protection of plant varieties* (no. 915-XIII of 11.07.1996);
7. *Law on horticulture* (no. 728-XIII of 06.02.1996);
8. *Law on phytosanitary quarantine* (no. 506-XIII of 22.06.1995);
9. *Law on plant protection* (no. 612-XIV of 1.10.1999);
10. *Law on animal breeding* (no. 412-XIV of 27.05.1999);
11. *Law on medicines* (no. 1409-XIII of 17.12.1997);
12. *Law on public sanitary epidemiological security* (no. 1513-XII of 16.06.1993);
13. *Law on health care* (no. 411-XIII of 28.03.1995);
14. *Law on standardization* (no. 590-XIII of 22.09.1995);
15. *Law on metrology* (no. 647-XIII of 17.11.1995);
16. *Government Resolution on approval of the National Concept for natural farming, production and distribution of environmentally clean and non-GMO food* (no. 863 of 21.08.2000);
17. *Government Resolution on approval of measures to fulfill commitments made by the Republic of Moldova to the World Trade Organization (WTO)* (no. 1035 of 16.10.2000);
18. *Law on certification* (no. 652-XIV of 28.10.1999);
19. *Law on technical barriers to trade* (no. 866-XIV of 10.03.2000);
20. *Government Resolution on accession to the Charter of Codex Alimentarius Commission* (no. 1342–XIII of 8.10.1997);
21. *Government Resolution on establishment of the National Codex Alimentarius Committee (NCAC)* (no. 866 of 21.09.1999);
22. *Law on ratification of the Convention on plant protection* (no. 926-XIV of 13.04.2000);
23. *Law on the State Policy in the sphere of Research and Development* (nr.567-XIV 11.07. 1999);
24. *Government Resolution on the Concept of Agrarian Reform and the Nation’s Social-Economic Development* (no. 510 of 19.02.91);
25. *Government Resolution on Strategic Priorities for the Research and Development for 2004-2010* (no. 566-XV of 25 December 2003);

26. *Government Resolution on the Measures for Implementation of the Program of Activities of the Government of the Republic of Moldova for 2001-2005 "Revival of the Economy is the Revival of the Nation" (no. 854 of 16.08.2001);*
27. *Government Resolution on Approving of the Strategy for Mid-Term Social-Economic Development of the Republic of Moldova (till 2005) (no. 1415 of 19.12.2001);*
28. *The National Strategy for Sustainable Development (for the period 2000-2020), The Supreme Economic Council by the President of the Republic of Moldova, UNDP, Chişinău 2000;*
29. *Government Resolution on the Strategy for Economic Growth and Poverty Reduction (2004-2006) (no. 617 of 4.06.2004);*
30. *Law on ratification of the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (nr. 346-XIV of 7.04.1999);*
31. *Governmental Resolution on Approving the Regulation on Public access to the decision-making in the field of the environment (nr. 72 of 25.01.2000);*
32. *Law on public access to the information (nr. 982-XIV of 11.05.2000);*
33. *Parliament Decision on the ratification of the International Union for Protection of New Plant Varieties (UPOV), (no.1355-XIII of 22.10.1997).*

UNEP/GEF PROJECT „DEVELOPMENT OF THE NATIONAL BIOSAFETY FRAMEWORK FOR THE REPUBLIC OF MOLDOVA”

PROJECT OUTCOMES

The following important outcomes have been achieved during the lifetime of the project:

Phase 1: Survey of the current biosafety framework

The aim of Phase 1 was to survey the current situation regarding Biosafety Framework in Moldova and to identify key stakeholders. Therefore the following surveys were made during Phase 1: survey and analysis of the goals, gaps and weaknesses in the national legislative and institutional framework; research and development; risk assessment/ risk management; international, regional and sub-regional cooperation; biotechnology uses and production; development of the list of biosafety experts and the list of experts to support risk assessment.

The final output of the Project's Phase 1 was creation of a web page on the National Biosafety Framework for Moldova, where the most important information on biosafety was made publicly available (www.biosafety.md).

Phase 2: Analysis and Consultations

During this phase workshops were organized to review the findings of the survey phase, to identify gaps, needs and priorities for Moldova's NBF. A series of workshops was targeted at different GMO regulation administrative levels and stakeholders (inspectors, risk assessment experts, ministries, researchers, farmers, business, NGOs, mass-media, etc.).

Phase 3: Preparation of the draft National Biosafety Framework for Moldova

The output of Phase 3 is this document, which was discussed by the stakeholders identified in the previous Project phases and approved by the NCC.

Best practice examples

Within the scope of the project, the following mechanisms for promoting and facilitating public awareness, education and participation were employed: organization of workshops, seminars, round tables, press conference, publications, press releases, interviews (Radio and TV); development of biosafety website; preparation and distribution of informative materials.

Promotion and facilitation of public awareness, education and participation:

In order to facilitate public awareness of GMO-related issues, the following activities were undertaken: 30 training workshops, round table discussions and seminars organized at the national, local (district) and community levels (some of these in collaboration with the British Embassy project), publication of 5 information brochures, development of the Biosafety website, and a number of actions with mass media involvement.

To raise public awareness and to facilitate public and stakeholder participation in the decision-making processes regarding environment-related issues, including GMO use, thirteen workshops and seminars were held in the city of Chisinau and seventeen workshops and seminars in a number of Moldova's areas and regions (the Northern, the Central and the Southern zones) and two more - in large villages. The target audience of these meetings included representatives of local governments, farmers, local authorities, researchers, business, regional nature protection agencies, NGOs as well as other interested parties.

Publications:

The information brochures published to raise public awareness and to educate included:

- 1 “*Biosafety in the Republic of Moldova: Legislative and Institutional Aspects*” in Romanian and Russian, targeted at decision-makers and the broad public;
- 2 “*Genetically Modified Organisms: Benefits and Risks*” in Romanian, intended for the broad public,
- 3 “*Authorization of Activities related to Genetically Modified Organisms (GMOs): A Practical Guide*” in Romanian, targeted at decision makers, farmers and business;
- 4 “*The Cartagena Protocol on Biosafety (Compendium)*” in Romanian, intended for decision makers and the broad public;
- 5 “*Genetically Modified Organisms: Opinions and Suggestions*” in Romanian, intended for farmers and other interested parties.

Two books were published to support university-level education and training:

- 1 “*Modern Biotechnologies in Phytotechnology and the Biosafety*” in Romanian, for university teachers and students, researchers, specialists and other interested parties;
- 2 “*Genetics and Biosafety Glossary*” in Romanian.

Publications regarding the current GMO-related issues, including answers to specific related questions, were prepared for readers of the dailies “Moldova Suverana” (“Independent Moldova”), “Fermierul Moldovei” (“The Moldovan Farmer”), “Nezavisimaia Moldova” (“Independent Moldova”, Russian Edition), the weeklies “Ora Satului” (“The Village Hour”), “Jurnal de Chisinau” (“The Chisinau Magazine”), “Kishinyovskoe Obozrenie” (“The Chisinau Review”), “Trud” (“Labour”, “Office”, “Capitala” (“The Capital City”), “Novoe Vremea” (“New Times”), “Natura” (“Nature”). The monthly “NOI” (“US”) for children and teenagers published a number of articles on GMO uses, biotechnology and biosafety in its three issues.

Interviews on the national radio and TV:

The representatives of the Ministry of Ecology and Natural Resources, the National Biosafety Committee, the NCC, researchers and project experts, NGOs, the National Farmer Federation, etc. gave interviews on GMO-related issues and answered questions for the *Moldovan Radio* (the National Governmental radio station). The number of special radio and TV programs dedicated to biosafety issues was about 20.

Press conferences:

Press conferences were organized on 12 March 2004 (“*Genetically Modified Organisms: the current situation and the future*”) and on 15 April 2004 (“*The Cartagena Protocol: regulations regarding Genetically Modified Organisms*”).

Press releases:

Within the scope of the Project, the Moldovan Ministry of Ecology and Natural Resources distributed five *press releases* - on 25.06.03, 07.10.03, 12.03.04, 15.04.04, and 17.06.04.

Website:

The Moldovan Biosafety website www.biosafety.md was developed and launched providing the information on GMO-related issues in Moldova and reviews regarding the current situation in the field of biotechnology and biosafety in Moldova in Romanian and in English, targeted at general public.

Distribution of information materials

Brochures, informational leaflets and fliers bearing logos of the UNEP Biosafety project and Biosafety website were handed out to participants of the workshops and seminars. The copies of the above brochures and books were distributed to libraries, universities and schools.

List of Biotechnology Research Institutions in Moldova

Institution	Contact	Programme details, strengths and weaknesses
Academy of Sciences of Moldova, Section for Biological and Chemical Sciences, Institute of Genetics	Anatol Jacota 20, Padurii Str. MD 2002 Chisinau Tel.: 37322 770447 Fax.: 37322 556180 Email: igcanc@mail.md	Sixty-eight researchers working in 11 laboratories. Research on genetic and molecular control of important crop traits for breeding applications. Collaborative research with France, Romania and Ukraine.
Institute of Genetics, Laboratory of Molecular Organization of Genome and Genome Expression	Nicolae Barbarac 20, Padurii Str. MD 2002 Chisinau Tel.: 37322 556119 Fax.: 37322556180 Email: barbarac@hotmail.com	Molecular mapping in tomato and maize. Well-equipped molecular genetics laboratory.
Institute of Genetics, Laboratory of Instability of Genome and Gene Instability	Lidia Tumanova 20, Padurii Str. MD 2002 Chisinau Tel.: 37322 780434 Fax.: 37322 556180 Email: lturmanova@hotmail.com	<i>In vitro</i> and protoplast cultures for several crops. Somatic hybridization and genetic transformation of potato, tomato and tobacco using Bt genes (work since ceased). Study of genome structure of entomopathogenic bacteria. Maize transposon studies and marker-assisted selection. Well-equipped laboratory.
Institute of Genetics, Laboratory for Natural Bioregulators	Pavel Kintia 20, Padurii Str. MD 2002 Chisinau Tel.: 37322 555259 Fax.: 37322 556180 Email: pkintia@hotmail.com	Studies on steroidal glycosides for use as crop growth stimulators and food additives (world leader). Numerous (>165) patents held. Laboratory equipped for mass and NMR spectroscopy.
Institute of Genetics, Centre for Plant Genetic Resources of Moldova	Anatol Ganea 20, Padurii Str. MD 2002 Chisinau Tel.: 37322 550249 373 22 569361 Fax.: 37322 556180 Email: a_ganea@hotmail.com	Study and conservation of rare species. Micropropagation laboratory planned.

Institution	Contact	Programme details, strengths and weaknesses
Academy of Sciences of Moldova, Section for Biological and Chemical Sciences, Institute of Plant Physiology	Simeon Toma 22, Padurilor Str. MD 2002 Chisinau Tel.: 37322 555514 Fax.: 37322 550026 Email: radu@conf.usm.md	Research on the physiological basis of adaptation in various crop plants. <i>In vitro</i> facilities and associated equipment.
Institute of Plant Physiology, Biochemistry and Biotechnology Laboratory	Alexandru Dascaluc Tel.: 37322 555514 Fax.: 37322 550026 Email: adascal@iatp.md	Isolation of biologically active substances. Tissue culture of ginseng, micropropagation of walnut. Collaboration with France, Greece, the UK and the USA. Plans for creating a private enterprise Centre for Advanced Biotechnology with support from the USA.
Academy of Sciences of Moldova, Section for Biological and Chemical Sciences, Botanical Garden (Institute) Laboratory of Embryology and Biotechnology	Alexander Cibotaru 18 Padurii Str. MD 2002 Chisinau Tel.: 373 22 55 04 43 Fax.: 373 22 52 38 98	Carries out plant breeding. Micropropagation of several species. Meristem culture of virus-free ornamentals.
Academy of Sciences of Moldova, Section for Biological and Chemical Sciences, Institute of Microbiology	Valeriu Rudic 1, Academiei Str. MD 2028 Chisinau Tel.: 37322 739878	Main research on systematics, ecology, microbial metabolism. Production of microbial enzymes and biopesticides.
Academy of Sciences of Moldova, Section for Agricultural Sciences, Institute of Biological Protection	Leonid Voloshchuc 58, Dacia Bld. MD 2060 Chisinau Tel.: 37322 779636 Fax.: 37322 779641 Email: slibbp@cc.acad.md	Biological control, pheromone identification. International cooperation with France, Germany and Sweden. Poorly equipped laboratories.
Ministry of Agriculture and Food Industry, Institute of Maize and Sorghum	Vasile Micu Criuleni, Pascani Tel.: 37322 245574/1	In vitro work and ELISA certification of virus-free potato.

Institution	Contact	Programme details, strengths and weaknesses
Ministry of Agriculture and Food Industry, Institute of Crops Sciences	Boris Boincean 1, Calea Iesilor Str. Balti Tel.: 373 231 30 127 Tel.: 373 231 331 54 Mob.tel.: 069159388 selectia@beltsy.md	In vitro production of eggplant and pepper.
Ministry of Agriculture and Food Industry, Institute of Fruit and Grapes Sciences	Mihai Rapcea 14, Cotujeni Str. MD 2019 Chisinau Tel.: 37322 764427 Fax.: 37322774936	In vitro production of apple and cherry.
Ministry of Agriculture and Food Industry, National Institute of Viticulture and Wine	Nicolae Ciutac 128 Grenoble Str. MD2028 Chisinau Tel.: 37322 761622, Fax.: 37322 775841	In vitro production of grapevine.
Ministry of Education, State University of Moldova, Department of Vegetal Biology	Maria Duca 60 Mateevici Str. MD2009 Chisinau Tel.373 22 577527 Mduca2000@yahoo.com	Biochemical analysis of crops varieties.
Ministry of Agriculture and Food Industry, State Agrarian University, Department of Crops Melioration, Genetics and Biotechnology	Andrei Palii 44 Mircesti Str. MD2049 Chisinau tel.: 373 22 294966	In vitro production of crops varieties.