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Biosafety Concerns in the Republic of Moldova: opportunities and challenges

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Introduction

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 Biological Diversity on 16 May 1995 (by Parliamentary Decision no. 457-XIII).

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.

Large import-export relations with Russia, Ukraine, and Romania, as well as lack of efficient mechanism for custom control for GMOs for economical agents and private persons create a fruitful base for the possible introduction of GMOs in Moldova as food and feed products, agriculture products, and seeds.

Thus, the Republic of Moldova is exposed to the introduction of GMOs in the country. 9 samples of soybean products collected in the market in Moldova have been sent to an independent laboratory in the UK at the end of 2004 for GMO testing. The quantitative and qualitative analyses have been provided in order to identify the presence of GMOs in the samples, and the quantity of the GMOs (in %). In 7 of samples the GMOs have been detected, and in 5 of the samples GMOs constitute more than 5%.

Being a *Party to the Convention on Biodiversity Conservation (CBD)* since 1995 (Parliament Decision No. 457-XIII of 16.05.1995), Moldova completed its *National Strategy and Action Plan in the field of Biodiversity Conservation (NSAPBC)*, adopted by the Resolution of the Moldovan Parliament no. 112-XV of 27 April 2001 (published in Moldova's official gazette *Monitorul oficial al Republicii Moldova* nos. 90-91 of 2 August 2001). Investigations of flora highlighted the possibility of using about 150 aromatic species, 200 medicinal plant species, 80 fodder plant species from spontaneous flora; about 43 species represent the forebears of agricultural plants in the country.

The conservation of genetic varieties as a component part of biodiversity is done in two ways: in-situ and ex-situ. Natural protected areas that covered the most representative natural ecosystems constitutes 66 467,3 ha or 1,96% of the territory. However, this not ensures the needed area for biodiversity conservation and protected areas are very sensitive one to the adverse impact provoked from the possible GMOs using in the environment. The process of autochthonous biodiversity conservation usually is very passive and some varieties are being lost. The use of biotechnologies and genetic engineering is at a very beginning of its way in the Republic of Moldova. Some biotechnological methods are used in agriculture, medicine and environmental protection (production of food and fodder proteins, vitamins, active biological substances, multiplication of endangerouse species etc.).

As provided for by the Convention, *National Strategy and Action Plan in the field of Biodiversity Conservation*, the Moldovan Government provides for the development of a comprehensive urgent actions package to ensure the national biodiversity and biosafety. It was considered necessary to improve the existing environmental legislation by adding elements of

ensuring the biological security of the country, regulating the GMOs uses respecting the Convention and the respective protocol. The package includes actions related to the biodiversity conservation :

- Protection of representative natural areas;
- Protection of natural habitats;
- Conservation of the natural heritage of unique natural objects, important zones for the reproduction of spontaneous flora and wild animal species;
- Regulation of biological resources use;
- Integration of the biodiversity conservation requirements onto the activities of the national economy sectors.

and to the biosafety needs:

- Regulation of imports and exports of organisms produced using transgenic methods;
- Establishment of an adequate legal and institutional framework;
- Training of experts and establishing of a laboratory to control GMOs;
- Development of special public awareness raising programs to disseminate information on the risks connected with use of GMOs.

Since the Moldovan Parliament ratifying the *Cartagena Protocol on Biosafety* the biosafety become a national priority in the field of the environmental protection actions. The new Concept of the environmental Protection, as well as the “Strategic Plan: Republic of Moldova- EU” consider important to promote harmonization the national legislation with the Cartagena protocol and the EU Directivs on the following aspects:

- contained use of genetically modified micro-organisms;
- GM food and feed regulates the placing on the market;
- traceability and labeling of GMOs;
- assistance for developing national strategies and best practices to ensure co-existence.

Moldova has already adopted the *National Law on Biosafety* no. 755-XV of 21 December 2002 (published in *Monitorul oficial al Republicii Moldova*

no. 75 of 13 June 2003) – the country’s main law in the field of biosafety, which regulates all activities regarding creation, testing, production, use and marketing of genetically modified organisms (GMOs). Any activities of that kind are subject to authorisation by the *National Biosafety Committee* (NBC). The National Biosafety Committee was set up by Government Resolution no. 603 of 20 May 2003 (published in *Monitorul oficial al Republicii Moldova* no. 91-96 of 30 May 2003). Additionally all activities involving high risks (III and IV class of risks) are subject to licensing in conformity with the Moldovan *Law on Licensing of Certain Activities* no. 451-XV of 30 July 2001, Section on licensing of certain activities in the sphere of genetics and microbiology. *Regulation on authorisation of the activities regarding of testing, production, use or marketing of GMOs* was approved by the Government Decision no. 1153 of 25 September 2003. Other related laws and regulations covering specific sectors or industries should be amended and harmonized with the provisions of the Cartagena Protocol, with consideration of Moldova’s current situation and specifics, peculiarities of its national economy, special activity requirements and suggestions submitted by stakeholders during follow-up on the work already performed in that direction.

The UNEP-GEF Project no. GF/2716-02-4520 “Development of the National Biosafety Framework (NBF) for the Republic of Moldova” has been implemented under the Moldovan Ministry of Ecology and Natural Resources during the 2002-2004. The *National Biosafety Framework (NBF)* for the Republic of Moldova was prepared thanks to the support given by the mentioned project.

The task of the national biosafety system is to provide for an indispensable level of biological security with respect to release and use of genetically modified organisms by:

- assessing possible negative effects during deliberate release into environment;
- establishing monitoring system;
- planning emergency actions to deal effectively with accidents;
- establishing systems to provide consent and certification on each stage of experiments and deliberate release into the environment;

- establishing a competent authority with the mandate to provide advice, decisions and control on registration, consent for GMO release and codes of practice;
- developing information system;
- establishing international co-operation;
- training personnel and public participation.

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.);
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.).

The 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.

The circumstances listed above had a negative impact on the national economy during a decade, generating serious problems, including economical decrease, degradation of natural resources, and the phenomenon of poverty. The identification and becoming aware of these problems is a condition of absolute need for the implementation of the *National Biosafety Framework in Moldova*, in order to develop an efficient and comprehensive policy, regulatory system, institutional and decision making appropriated to implement requirements of the Cartagena Protocol, to strengthen mechanisms for public awareness, training and involving into the decision-making.

The NBF provides a useful guide and aims at developing the appropriate level of biosafety with respect GMOs release and use, given both the risks associated with their use in food and feed and the possible negative ecological implications of the release of such organisms into the environment.

The sub-project “*Support for the Development of the National Biosafety Framework for the Republic of Moldova, co-financed by the British Embassy in Chisinau - the Global Opportunities Fund (Environment Fund)*” is to supplement the UNEP activities held under the project “*Development of the National Biosafety Framework for the Republic of Moldova*”. The two additional components covered from UK funds were: (a) work to harmonise Moldavian legislation with EU legislation; (b) training for Moldovan practitioners, including visits to the UK and study of the UK experience of biotechnologies (techniques and practices).

In addition, Moldova has also implemented the *UNEP-GEF project “Capacity Building for Effective Participation in the BCH”* by establishing their national node for the BCH and also by training decision-makers and stakeholders to use and benefit from the BCH.

The implementation of the National Biosafety Framework requires a substantial effort in capacity building. GEF support is therefore considered crucial in facing the following needs:

- The development of related Biosafety/Environment policy;
- Development of regulatory system. Special attention should be addressed to the sectorial regulation framework;
- Administrative arrangements. Risk assessment and risk management capacity building
- Enforcement mechanism and monitoring. Preparing of special regulations, guidelines, manuals etc.;
- Training of the stakeholders representatives, particularly in the areas of: risk assessment and risk management; strengthening the institutions serving as centers of excellence, expertise and reference laboratories for monitoring;
- Testing and monitoring;
- Increase in public awareness on issues relating to the use of GMOs, including providing information and answers for the media and NGOs;
- Development of information resources in the form of various databases (on experts, biosafety programs, research activities etc.).

The main purpose of the *UNEP-GEF project "Support for the Implementation of the draft National Biosafety Framework for the Republic of Moldova"* is to help Moldova to strengthen the existing institutional and technical structures and infrastructures needed to meet the obligations of the Protocol and have a National Biosafety Framework fully operational by:

- The implementation of the Moldova's legislative framework on the safe use of biotechnology through improvement of the Biosafety law, development of sectorial regulations, guidelines and manuals;
- The preparation of specific technical guidelines;
- The strengthening of appropriate institutional structures for risk assessment and decision making;
- The development and implementation of policies for biosafety;
- The training of decision makers, scientists, and administrative and technical staff on legal and technical matters;
- The reinforcement of the existing infrastructures (laboratories) to strengthen monitoring;
- The setting up of a mechanism for monitoring and enforcement;
- The strengthening of communication and information exchange relating to biosafety both at the national level as well as through the BCH
- Systems for strengthening public awareness, education and participation in decision making on GMOs.

The overall goal of the project is that by 2010 the Republic of Moldova has a workable and transparent national biosafety framework, in line with its national development priorities and international obligations by:

- Enforced a comprehensive National Biosafety policy as the basis for the development of the adequate national regulatory regime and institutional framework;
- Strengthened the national regulatory regime in line with Cartagena Protocol, NBF, and biosafety policy;
- Strengthened capacity building of the administrative system for adequate handling of notifications and authorization issuing complying with the Cartagena Protocol requirements;

- Enhanced national capacities for public awareness and participation into decision making process;
- Consolidated a fully functional system for monitoring and enforcement.

National Biosafety institutional arrangements:

According to the provisions of the Cartagena Protocol and the Law on Biosafety, the *Ministry of Ecology and Natural Resources* (MERN) 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:

- Ministry of Ecology and Natural Resources;
- The National Biosafety Committee;
- The National Focal Point for the Cartagena Protocol on Biosafety and the BCH (NFP CP and BCH)
- The National Task Force for Cartagena Protocol on Biosafety and the BCH

The National Biosafety Committee operates as the interdepartmental authority and consists of 14 members. *The National Authority on Biosafety - the Ministry of Ecology and Natural Resources* 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 Focal Point for the Cartagena Protocol on Biosafety* and the BCH – nominated person responsible for ensuring the relations with the Secretariat of the CCD and the CP, and to promote the requirement on Biosafety at national level. *The National Task Force for Cartagena Protocol on Biosafety* and the BCH – an CP implementation body composed from the 8 members from various governmental bodies, research and civil society, and is to help NFP for the CP implementation.

The National Biosafety Testing Center (NBTC) 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.

Policies and Strategies related to the Biosafety

The National Strategy and Action Plan in the field of biological diversity conservation (approved by Parliamentary Decision no. 112-XV of 27 April 2001) is to implement the commitments made by Moldova as a signatory party to the Convention on biological diversity, consequences of GMO use. The major goal of the Strategy on biodiversity conservation is the conservation, rehabilitation, reconstruction and efficient use of the biodiversity and landscape to ensure the sustainable social-economic development of the Republic of Moldova. The objectives of the Strategy can be achieved through consequent well-targeted actions, establishing deadlines and funding amount.

The new *Concept of Environmental Policy of the Republic of Moldova* (CEP) was adopted by the Parliament Decision nr 605-XV of 2 November 2001, and is 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, including the biological safety. The Environmental policy priorities for the Republic of Moldova focused on the Regulation on environmental impacts, pollution prevention and rehabilitation of the 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 *Action Plan "Republic of Moldova – European Union"* being currently signed in the framework of the VII-th Meeting of the Council for Cooperation: The Republic of Moldova- European Union in Brussels on 22.02.2005, and developed with the aim to

make use of the opportunities offered by the new EU policy in respect of its future neighbors.

The Strategy for Economic Growth and Poverty Reduction (2004-2006) adopted by the Law nr. 398-XV 02.12.2004, M.O. nr.5-12 of 14.01.2005, states the importance of biodiversity conservation as one of the main factors for poverty reduction and economic growth in the country. The EGPRSP recognizes the linkage between the quality of natural resources and the socio-economic welfare and stability, invoking the necessity to eliminate the contributing factors to natural resources degradation. The EGPRSP highlights the priorities for the period 2005-2008 and puts the emphasis on the implementation of the following objectives: (i) prevent and reduce the degradation of natural resources and increase efficiency of their use; (ii) maintain the quality of the environment as a factor that ensures health and quality of life; (iii) create an effective natural disaster monitoring, prevention and damage compensation system.

The major objective of the agricultural activities of the last 50 years was the property reform, the creation of the adequate institutional and economic conditions for the creation of the production and functioning structures of the economic entities in the agro-industrial sector, the diversification of the economic relations under the market economy conditions, restructuring of the services system, provision of information, advisory assistance and the improvement of knowledge of the new producers of the agro-industrial sector.

The main objectives of the agricultural and food policy in view of integration into the EU market are the considerable increase of the efficiency and productivity of labor in this economic sector and the adjustment of the requirements for the quality of food products to the European standards with the solution of the following problems:

- Ensure food security of the population
- Increase the efficiency of the labor force
- Increase the favorable conditions for the economic, social and ethnic-cultural development of the rural population
- Efficient use and conservation of natural resources and environment protection

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.

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.

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.

Biosafety Regulatory regime

The Law on Biosafety. 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.

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.

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.

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.

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 environ-

ment 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 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 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.

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.

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 Regulation provides 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 Regulation includes 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.

Law nr. 214-XV of 24.06.2004 on amendment and completion of the Law nr.451-XV of 30.07.2001 on licensing of some types of activities, stipulates in its art. 8, p.34: gene of activity "activity in the filed of genetics, microbiology" is completed with the following words "activities included in classes III and IV of risks, regarding use of genetically modified organisms"

Law nr.115-XVI of 09.06.2005 on ecological agro-food production, stipulates in the art.5: The basic methods and principles of the ecological agro-alimentary production, lit. d) “non-use of the genetically modified organisms and its derivatives, with the exception of products used for veterinary medicine”.

Governmental Resolution nr. 996 of 20.08.2003 on labeling of food products and the standards on labeling of housekeeping chemical products, in the p.5 of the resolution stipulates that the Ministry of Health Care have to elaborate in terms of 7 months from the entering into force of the Resolution, the Sanitary Standards for the labeling of food genetically modified products or products obtained from GMOs.

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.

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, stipulates that the Ministry of Ecology, Construction and Territorial Development is appointed as the National Authority responsible to ensure relations with the Secretariat of the Cartagena Protocol on Biosafety of the Convention on Biological Diversity, and for coordination of activities regarding the implementation of their stipulations in the Republic of Moldova.

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 Law on Biosafety* (no. 755-XV of 21.12.2001) stipulates provisions 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 Committee 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 is working to 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.

The Aarhus Convention on access to information, public participation and access to justice in environmental matters, signed in 1998, almost not

covered the GMO issue despite of evidence of importance of potential risks of this factor for environment and health, by Art. 6-11 referring to rights of each party to establish own regime of public participation in bio-safety issues. Civil society organizations, gathered at the Second Meeting of the Parties to the Aarhus Convention in Almaty, lobbied together with supporting national governments the amendment to the Convention giving the public the right to participate on decisions on GMO-related activities.

The GMO amendment came after four years of intense and polarized debate, with the EU and the biotech industry on one side, and civil society and the majority of EECCA countries on the other. Many states during negotiations referred to sufficiency to follow Art. 23 of Cartagena Protocol, but Moldova and NGOs insisted that public information and participation in UNECE region should be regulated more efficient. Significant compromises were eventually made by both sides. Despite the final amendment does not give the public the right to access to justice on GMO decisions, this is the first time that a pan-European obligation will provide the public with effective information and participation on decisions to authorize a GMO release for export and for commercial purposes. It is now the aim of Parties to ratify the amendment as soon as possible.

In present the Government of Moldova is in preparation of a bill to present amendment to the Parliament for ratification. In parallel, the GEF/ UNEP project prepared corresponding changes to national legislation to fully implement new-coming international duties.

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 as-

assessment conclusions will be used as the basis for decision-making in this sphere.

Biotechnology R&D institutional capacity

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

1. Within 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. Within the universities:

- *State University of Moldova*: Chair of vegetal biology;
- *State Agricultural University of Moldova*: Chair of genetics and plant improvement;

3. Within Ministries and State Departments:

- *Department of Standardization and Metrology*: Genetic expertise laboratory;
- *National Wine and Viticulture Research Institute*: Laboratory of sparkling wines;
- *Institute for Maize and Sorghum Research*: Laboratory of biochemistry, physiology and biotechnology;
- *Northern Station for Project Implementation and Chemical Research*: Research laboratory;

- *Institute of Fruit Trees Research*

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: *Institute of Maize and Sorghum Research, Institute of Fruit Trees Research, Institute of Crops Science, National Institute of Wine and Viticulture* within the Ministry of Agriculture and Food Industry.

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, Laboratories of the State Moldavian University, State Agrarian University*. 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.

The researches have resulted in the identification, cloning and characterization of the primary structure of the genes specific for reproductive processes in tomato and maize; identification and passportisation of spontaneous and cultivated forms of plants based on the molecular analysis of the genome; foundation of the library of molecular markers to test genotypes characterized by valuable economic indices; identification and localization of the genetic factors of plant resistance to thermal stress at the level of chromosomes and loci; elucidation of some regularities of the genetic control of quantitative indices in maize and tomato; production of the maize lines used as efficient haploid inducers; development of tech-

niques to yield tomato transgenic plants through the exogenic DNA using to interspecific hybridization and methods of pollen and haploid breeding of tomato and maize; development of the procedure of molecular diagnosis of some human viral diseases including hepatitis.

More than 1000 of new forms of tomato, maize, durum winter and soft wheat, triticales etc. have been obtained. Naturally occurring biological regulators belonging to the class of steroidal glycosides have been isolated from plant resources and studied both chemically and biologically. New 50 varieties and hybrids of maize, winter durum wheat, triticale, vegetable bean, peanut and gladiolus have been produced; 15 varieties have been registered in the Republic of Moldova.

Strengthen national infrastructure (reference laboratories) as needed for risk assessment and monitoring

Based on the Biosafety Law entered into force, the Ministry of Environment and Natural Resources in agreement with the Ministry of Education designated the reference laboratory of the State Moldavian University, as the *National Biosafety Testing Center* (NBTC). The laboratory should provide expertise with respect to those products, which are within their competence. The reference laboratory will also provide technical support to the biosafety system, risk assessment procedures and will be involved in the training activities.

Under this project, the reference laboratory, involved in research on GMO and equipped with basic instruments for DNA isolation, determination and electrophoresis, will be strengthened with additional equipment needed (Quantitative PCR) to meet the requirements of the Cartagena Protocol to carry out inspections on GMOs and related products as follows:

- GMOs involved in transboundary movement
- Living modified plants released to the environment
- GMOs used in containment,

- food products containing GMOs or where appropriate, products thereof (Article 20(3c), Annex I(i) and Annex III(5) of the Cartagena Protocol)

2006- Project Nr.1156 “The test of genetically modified products by PCR method”, 2006, financed by Ministry of Ecology and natural resources.

Biosafety Clearing-House

The UNEP/GEF BCH Capacity Building Project has the following objectives:

- a) Strengthen capacity in eligible countries through training of key stakeholders. The training will cover (i) data entry and management; (ii) identification and access to information required for decision-making under the Protocol and (iii) access to, and registration of, information in the BCH;
- b) Create an enabling environment for Parties to meet their obligations for implementation of the Protocol by providing participating countries with computer hardware and software for data storage and exchange (with the BCH) over the Internet and by other means;
- c) Support further capacity building through the development and dissemination of an interactive computer-based training package, which includes the BCH toolkit. The package will be developed at the global level in close collaboration with the CBD Secretariat to ensure that input from national BCH components is consistent with the BCH central portal.

The following main Project outcomes were achieved:

Outcome A. Establishing of the appropriate National BCH Center and Network;

Outcome B. Elaborating the structure and data content for National BCH Network and appropriate regulations and guidelines;

Outcome C. Assuring interoperability with BCH Central Portal;

Outcome D. Improving the national biosafety legal and institutional framework for National BCH Network;

Outcome E. Upgrading the key stakeholder workstations hardware and software;

Outcome F. Training stakeholders and key experts appropriately.

A. Implementation Alternatives

In accordance with the ‘Summary Outcomes of the Meeting of the Liaison Group of Technical Experts on the Biosafety Clearing-House’, prepared by Liaison Group of Technical Experts on the BCH during the Montreal meeting (10 to 11 April 2003), the following option can be considered as the basis for national BCH component:

Option 4. National interoperable biosafety clearing-house database:

- a. Develop and maintain interoperable database according to Biosafety Clearing-House interoperability protocols and meet minimum standards (national database/XML) – “push technology”.

B. National BCH Components in Moldova

Moldova NFP has to choose an option that meets better the local needs and the abilities depending upon the local Internet connectivity, personnel costs, security, hardware and software.

- a) National BCH Infrastructure
- b) Stakeholders Training
- c) National BCH Informational System

The information technology (IT) approach of the 1990s resulted in information systems that were cast in concrete and very difficult and costly to change, once deployed. Nowadays, the best of the modern systems are built around a concept of a so-called ‘model-driven architecture’ (MDA). Such approach is based on the assumption that change is constant and inevitable. As a result the best of modern software systems are process-oriented and user-centric. They do not require a lot of costly IT personnel, since the system interface can be easily customized by the business users via a visual, easy-to-use interface.

Two dominant, while competing platforms in the modern software development are *Microsoft.NET* pioneered by the Microsoft Corporation and *J2EE (Java for Enterprise Second Edition)* promoted by Sun Microsystems, Oracle, IBM and others. Both platforms are based on the same concept

of XML Web Services, a special set of network protocols for today's network-centric business applications and distributed computing. However, each competing camp offers its own unique mechanism for development and implementation of these Web Services. Although both provided free of charge, these so-called 'virtual machines' are proprietary and mutually exclusive.

Regardless the software development platforms, the system components, firstly, has to comply with open technical standards (e.g., TCP/IP for networking, XML and SQL for text and data management), to ensure interoperability and cross-system data interchange. Secondly, the Dublin Core Metadata Initiative (DCMI) has to be used as a methodology for data systematization. It will assure the conformance of data, stored at the national BCH Informational System level, with UNEP's "Biodiversity Clearing-House" data exchange format.

If to take into account Moldova ethnic and language best practice it can be recommended for National BCH Informational System to have three language - RO, RU and EN user interface, to support the publication of documents and it's classification in any of abovementioned language, but to use the EN language only for document metadata. The last one has the aim to warranty the UNEP's "Biodiversity Clearing-House" data exchange.

Speaking about the system development approach, it has to be mentioned a number of key assumptions and practical guideline demands. First of all, for quality assurance purposes development of the information system has to comply with internationally recognized standard software engineering processes such as ISO 9000-2, CMM (Capability Maturity Model) or RUP (Rational Unified Process) - one of the most popular best practices for software development.

Summing up the key abovementioned facts and the modern software technologies and development approaches, it appears that the Options 2, 3 or 4 are most convenient to implement the BCH Web-site in Moldova.

Thus, the National BCH Informational System will contain a public accessible national BCH Web-site, interacting with UNEP's "Biodiversity Clearing-House" Portal by data 'push' / 'poll' technology and a set of workstations,

placed on the key stakeholders (experts in LMOs, competent Ministries and Agencies, Government).

d) The System Functionality Overview

The National BCH Informational System has to enable all key participants of the discussion and decision process to work together toward quick and effective resolution of ecological disputes and studies. At a very high conceptual level (to be further detailed at the requirements analysis and design specification stages), the system is expected to accommodate the following groups of key stakeholders (also called 'system actors'): a) competent Ministries and Agencies; b) experts in LMOs, c) Government, and d) general public.

According to the common requirements the System, probably, will include as minimum the following functional modules: Document Center, News Center, Service Center, and Portal Management.

1. DOCUMENT CENTER

The **Document Center** will serve for managing and tracking non-structured, full-text documents and electronic files, covering a variety of functions including authoring, review and approval, publishing, organization, search, storage, archiving, etc.

User functionality: Document publication (national legislation, government decisions, scientific articles, expert opinions); Document classificatory (National BCH Infrastructure with elements, Responsibilities and Contacts, Risk evaluation, GMO register); document search.

Administrative functionality: Documents publication management (text and metadata); Classification management.

2. NEWS CENTER

The **News Center** will allow monitoring selected on-line news sources.

User functionality: Internet news sources; Documents annotation; Events announcement; New and events search.

Administrative functionality: News administration; Document annotation management; Events announcement.

3. SERVICE CENTER

The **Service Center** will incorporate a suite of applications for collaboration, including personalized message boards, instant messaging, file storage and exchange, personalized news channels and receive instant e-mail and text-to-cell-phone (CMS) alerts for new items of interest.

a) Workgroups:

User functionality: Chat rooms; Appeals to the experts. Administrative functionality: Workgroups administration.

b) Alert service:

User functionality: Event-driven instant messages to subscribers via email, fax, mobile phone or personal organizers (PDA); Subscriptions & notifications to instant email and text-to-cell-phone (CMS) alerts for new items of interest. Administrative functionality: Alert-er administration.

c) Opinion pool:

User functionality: Anonymous survey; Group poll / voting. Administrative functionality: Survey administration

4. WEB-SITE MANAGEMENT

- The management, in fact, will be necessary to manage the user roles and functionality and to configure the documents and news metadata interchange with UNEP's "Biodiversity Clearing-House" Portal.

C. Equipment

The data transmission equipment (ADSL/SDSL/HDSL/Wireless modems) has to be used for connecting to the Internet. The connection speed to the Internet for the server has to be about 512 Kbytes/sec (duplex).

Some Ethernet switch equipment (100 Mbit/s, full duplex, 16-port, preferably with a remote control capability) seems to be necessary in order to secure the data transfer between Informational System and the local network and a dedicated firewall (we recommend Firewall-IPFW) to ensure system security and attack defense.

The recommended configuration of stakeholder workstations includes one PC computer with Intel Pentium single processor, 256 MB RAM, and as minimum 80 GB HDD. The stable and relatively fast Internet access

being very important for the national BCH component network, it is necessary the 48 kbps DialUp or dedicated line modem and a qualitative Internet provider.

It is necessary to install equipment for backing up/restoring the Information System databases on magnetic tape.

D. Software

The software candidates are: (i) Free BSD 5.3 or later on the Information System server, (ii) PHP 5.0 with Apache Web-server as a front end, combined with MySQL DB as back end.

The MS Windows – 2000/XP and MS Office 2000-2003, combined with MS Internet Explorer 5.0 or later, and (i) Antivirus Kaspersky/Norton-Antivirus/McAfee Security Center, (ii) Fire Wall Zone Allarm/Agnitum Outpost/McAfee Firewall, (iii) Additional software as Arhivator (WinRor, Win Zip), and Adobe Acrobat Reader (all licencing). The Opera Web-browser can be the best suited software for the client workstations for administration purposes, remote access and content publication.

E. How the national information has to be related to BCH

The BCH was established as an international mechanism to inform all the Protocol Parties about the domestic use and placing on the market of GMOs, about transboundary movement for direct use as food or feed, or for processing; to facilitate the exchange of scientific, technical, environmental and legal information and experience with GMOs and to promote and facilitate public awareness, education and participation concerning the transfer, saving and use of GMOs.

The elements identified by the 'GEF Inter-Sessional Work Program Submission' document as required to implement the National BCH network were: i) a national portal, ii) and database(s); iii) Linkage of BCH central portal to national databases/nodes, and iv) common formats for information, which can incorporate linked information through appropriate search engines.

There are several types of information in the National databases have to be registered and stored in the plain text, Word or PDF format files:

- National Focal Points; competent Authorities, and Databases;

- National Laws, Regulations, and Guidelines; Bilateral, Regional & Multilateral Agreements, and Declarations under Art.11.6 of the Protocol;
- National decisions on GMOs under Advance Informed Agreement (AIA) procedure; and on GMO for food, for feed, or for processing under Art.11 of the Protocol; other Decisions & Declarations; Risk Assessments; Unique Identification (usually related to GMOs for food or feed, or for processing);
- National relevant web sites and Bibliographic Information.
- National Capacity-Building Opportunities, Projects, Needs and Priorities;
- Roster of National Experts Reports;

At the same time each of the above document type has to be pre-processed before to publish on National BCH Info System to have one of the recommended format: i) 'free text format' (FTF), when the users provide their own format of document words; ii) 'FTF with controlled vocabulary', when the user vocabulary is restricted by the optional answers, or by pre-defined check-box or by radio-button options list.

Taking into account Moldova's best practice, it is recommended for the National BCH Info System to support the following document language and user interface: RO, RU and EN. At the same time the aim to ensure data exchange with the BCH Central Portal implies to use the EN language only for document metadata.

Each document type will have a pre-defined structure. In addition, the Dublin Core Metadata Initiative (DCMI) will be used as an instrument for data systematization. It will assure the compliance of data, stored by the National BCH Info System, with BCH Central Portal data exchange format.

National BCH infrastructure sustainability strategy

At present there are good premises available to ensure the National BCH Component for long-lasting and sustainable activity and to continue its operation after the Project comes to an end.

A substantial national institutional and legislative base has to be developed in order to accomplish the Protocol obligations. A special regulation and guidelines approved and available will permit to ensure a workable BCH to the long term period. Moldova has also responsibility to sustain the BCH IT infrastructure, security of the system and regular upgrading of the operational systems. Databases of the BCH structure will be updated at a regular way. Created Biosafety Web-site will be maintained and updated with relevant news and information to ensure transparency and public information component. One of the important tasks is to involve qualified and trained during the project local IT personnel to implement the National BCH Network. A series of training workshop will be organized after the project end with the purpose to train technical skills to people which is in duty to run and manage database and web server. Special guidelines prepared and disseminated will be available to the personnel and the BCH operators.

To ensure the sustainability development of the National BCH, the following actions will be taken:

- The National BCH Center and Network will be established and equipped with appropriate hardware and software;
- The structure and content of the National Biosafety data and information will be elaborated;
- The interoperability and data exchange with BCH Central Portal will be ensured;
- The key stakeholders will be trained to ensure the operability of the National BCH;
- The national biosafety legal and institutional framework will be improved to ensure the National BCH functionality and to ensure its self-sustainability for long term.

The security aspects will be considered by the following:

The MS Windows – 2000/XP and MS Office 2000-2003, combined with MS Internet Explorer 5.0 or later, and (i) Antivirus Kaspersky/Norton-Antivirus/McAfee Security Center, (ii) Fire Wall Zone Allarm/Agnitum Outpost/McAfee Firewall, (iii) Additional software as Arhivator (WinRor, Win Zip), and Adobe Acrobat Reeder (all licencing).

The Ministry of Ecology and Natural Resources, and the affiliated to the BCH governmental agencies, as Ministry of Agriculture and Food Industry, Ministry of Health, State Phytosanitary Quarantine Inspectorate, State Committee for Testing of Plant Varieties, Institute of Genetics, institute of Crops research, Institute of Maize and Sorghum, State Seed Inspectorate will be responsible to ensure the operationability of the National BCH. The costs for the internet services, as well as technical personnel will be covered by the mentioned governmental bodies after the ending of the BCH project in order to ensure the sustainability of the BCH.

As the result, we identified the following categories of needs, which should be satisfied in order to build the national capacity for efficient participation in the International BCH:

- a. To improve the national legal and institutional framework in the relevant areas. The new national legal initiatives will have as their the main objective to provide the required legal basis to ensure the National BCH Network activity and to integrate it into the national biosafety framework;
- b. To assure the national information needs by creating the National BCH Center and Network. It will consist of a freely accessible National BCH Web-based Info Center and a set of stakeholder workstations. Presumably it would be necessary to provide the Info Center with the appropriate hardware and staff and to develop the necessary software tools;
- c. To develop the structure and content of the National Biosafety data and information. It is necessary to process the actual data content and to make the data structure uniform. In our opinion, it is essential also to take the measures required to ensure continuous maintenance and updates of the data content. The structure and content of the National Biosafety Data bases will take into consideration the international requirements and will be compatible with BCH;
- d. To assure interoperability and data exchange with the BCH Central Portal. The appropriate metadata and the DCMI standard will serve as the base to provide the BCH Central Portal the possibility to process the data stored by the National BCH Info Center;

- e. To increase the key stakeholder aptitudes to participate in the National BCH Network activities by upgrading their workstations' hardware and software and by training their staff appropriately. The training and workshops will cover mainly data management, identification of and access to information for decision-making process, etc.

Biosafety best practices

Republic of Moldova participated in the Global Project on “Development of National Biosafety Frameworks”. In order to design its *National Biosafety Framework*, Moldova carried out the following activities:

The survey of the current situation regarding Biosafety Framework in Moldova and to identify key stakeholders has been provided. Therefore the following surveys were made during the project: survey and analysis of existing national policy, legislative and institutional framework; branch policies and regulatory system related to the biosafety, system for handling of notifications and authorization procedures, international, regional and sub-regional cooperation; biotechnology uses and production; research and development, risk assessment/ risk management; monitoring, inspection and control; public information and educational capacities and public access to the decision making; main stakeholders and civil society. The final output of the Project's Phase 1 was creation of a Biosafety webpage, where the most important information on biosafety in Moldova, EU and CP CBD was made publicly available (www.biosafety.md).

Special workshops were organized to review the findings of the survey phase, to identify gaps, needs and priorities for Moldova's NBF. A survey and analysis of the gaps, lacks and weaknesses of the national legislative and institutional frameworks, research and development, risk assessment / risk management, international, regional and sub-regional cooperation, biotechnology use and production have been provided. Gaps and priorities in regulation and institutional frameworks have been identified. A survey on the current situation of information exchange and data bases infrastructure related to the Biosafety Clearing House (BCH) and identifications of building capacity needs has been provided. 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.).

Key components of the NBF Concept have been identified. The concept of the structure of the NBF final document has been elaborate. Draft of the “National Biosafety Framework for the Republic of Moldova “has been elaborated. The National Biosafety Framework for the Republic of Moldova was discussed with various stakeholders as central and local public administration, researchers, farmers, consumers associations, business and private sector, students, NGOs, representatives of mass-media and press, agricultural consultants and civil society during a series of workshops in Chisinau and in different districts of Moldova. A series of guidelines and drafts of legislations, brochures and books have been elaborated and published.

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 regarding the current GMO-related issues, including answers to specific related questions. 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 were organized and press releases

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.

Dissemination of information materials

Brochures, informational leaflets and fliers bearing logos of the UNEP Biosafety project and

Biosafety website was handed out to participants of the workshops and seminars. The copies of the above brochures and books were distributed to libraries, universities and schools.

Study Tour to the Great Britain, 16-22 November 2003 for 9 Moldavian experts in Biosafety

Study Tour Objectives:

- To familiarize Moldovan experts in biotechnology and Biosafety with the regulation Biosafety Framework of the United Kingdom, experiences and practices of the GMOs testing, certification, licensing and monitoring.
- Visits and meetings with the UK Governmental representatives

- Economists
- Agricultural specialists
- Experts in GMOs legislation and the EU legislation
- Risk assessment specialists
- Testing Centers specialists
- Farmer's Associations
- Public relation experts
- NGOs representatives
- Local Public Authorities
- Private Companies in the field of GMOs

Study Tour visits and meetings Program:

- The Department for Environment, Food and Rural Affairs (DEFRA)
- Vinopolis
- Food Standards Agency
- NFU - National Farmers Union
- DEFRA local agency, Cambridge
- NIAB – National Institute of Agricultural Botany, an independent organization working in the fields of food, farming, environment and research
- Monsanto
- The Central Science Laboratory, York
- Roundtable with the representatives of the NGOs

Study Tour in Brussels, European Union Commission - 25.07 – 30.07.2004:

Program of visits of the two Moldavian experts in Biosafety:

- European Commission, Environmental Directorate General
- Greenpeace
- EuroCoop European Community of Consumer Cooperatives
- Friends of the Earth Europe.

OGM soybean samples tested in a independent research laboratory:

Quantitative and Qualitative testing results of the gene modification of soybean (Glycine max):

Nr.d/o	Samples of soybean	Country of origin	Qualitative test	Quantitative test
1.	Soya Flour	SUA	Detected MG	> 5 %
2.	Soya Flour	Israel	Detected MG	> 5 %
3.	Soya Flour	Poland	Detected MG	> 5 %
4.	Soya protein	SUA	Detected MG	In limit of 0,1%
5.	Soya „Meat”	Ukraina	Detected MG	> 5 %
6.	Soya „Meat”	Holland	Not detected MG	--
7.	Soya groats	Romania	Detected MG	2,6 % +_ 3,3%
8.	Soya groats	Brasilia	Detected MG	> 5 %
9.	Soya groats	Moldova	Detected MG	Not detected MG

Public opinion pool survey regarding the genetically modified organisms

1100 persons were surveyed, with the age of 17 up to 80 years old.

The greatest weight of population that consider the use of products which contain GMO involves risks for human body is represented by persons with the age 56-80 years old (81%), persons who have secondary education (84%), pensioners (80%) and persons who have monthly income of 1000-3000 lei (80%). The lowest weight is represented by public servants (61%), persons who have university education and post-university education and persons from rural area (69%).

The greatest weight of persons, who consider that free production and sale of GMO and products which contain GMO in Moldova is opportune, but only after scientific test of the risks is represented by the persons with the age 36-55 years old (53%), persons who have university and post-university education (47%) and entrepreneurs (55%). The persons from rural area have also selected this variant of answer (47%).

The greatest weight of persons, who think the organic production is more suitable for Moldova is represented by the persons with age 23-35 years

old (58%), persons who have secondary education (59%), pensioners (76%) and farmers (65%).

The greatest weight of population, that consider the inclusion of this field in curriculum is opportune, is represented by the persons with the age 36-55 years old (63%), persons who have secondary education (62%), public servants (81%) and unemployed persons (74%). The lowest weight at this compartment is represented by persons with the age 56-80 years old (50%) and farmers (33%).

The greatest weight of population, that consider the consultation of public opinion in the process of taking decisions regarding GMO is opportune, is represented by the persons with the age 36-55 years old (75%), public servants and unemployed persons (84%), entrepreneurs (73%), pensioners (78%) and persons who have monthly income of more than 4000 lei (80%). The lowest weight at this compartment is represented by pensioners (15%), persons with the age 56-80 years old (12%) and farmers (44%).

Only a half of interviewed persons know about GMO. The most of interviewed persons have no clear idea about day-by-day use of GMO. The general opinion of the interviewed persons is that the consumption of products, which contain GMO, involves risks for human body. Most persons who participated at the survey consider that consumer has the right to know if the product contain or not GMO. 40% of interviewed persons consider that free production and sale of GMO and products which are obtained from GMO is opportune, but only after scientific tests of risks generated by their consumption, in the meantime, 54% of persons consider the organic agriculture is more suitable for Moldova.

Also, most of interviewed persons would like to be informed about benefits and risks related to GMO. TV, radio, Internet and written press are considered as most efficient ways of information. Only a half of interviewed persons consider that the inclusion of this subject in curriculum is opportune. A significant weight of interviewed persons (68%) considers the consultation of public opinion in the process of taking decisions regarding GMO is opportune.

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

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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.
12. *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);
13. *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);
14. *Government Resolution on the Strategy for Economic Growth and Poverty Reduction (20042006)* (no. 617 of 4.06.2004);
15. *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);
16. *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);
17. *Law on public access to the information* (nr. 982-XIV of 11.05.2000);
18. *“Biosafety in the Republic of Moldova: Legislative and Institutional Aspects”*, 2003, (in Romanian and Russian), Chisinau, (book).
19. A. Palii, G.Comarova, A. Lozan, V. Scorpan *“Biotechnologies in Phyto-technology and the Biosafety”*, 2004, Chisinau, (book)

20. V. Scorpan, A. Lozan *"Glossary of Genetically and Biotechnological Terms"* in Romanian, 2005, Chisinau, (book)
21. *"The Cartagena Protocol on Biosafety (Compendium)"*, 2004, Chisinau (brochure)
22. *"Authorization of Activities related to Genetically Modified Organisms (GMOs): A Practical Guide"*, 2004, Chisinau, (brochure)
23. *"Genetically Modified Organisms: Benefits and Risks"*, 2004, Chisinau, (brochure)
24. *"Genetically Modified Organisms: Opinions on Biosafety"*, 2004, Chisinau, (brochure)
25. *"Support for the development of the National Biosafety Framework of the Republic of Moldova"*, 2005 (brochure)

International framework for the NBF implementation project

- ▶ **Convention on Biological Diversity, Art. 19**
- ▶ **Cartagena Protocol on Biosafety Art.22**
- ▶ **COP/MOP Decision/capacity building (BS-I/5 and decision BS-II/3; MOP BS-III /3)**
 - ▶ **Action Plan for Building Cap acities for the Effective Implementation of the Cartagena Protocol on Biosafety**
- ▶ **GEF Initial Strategy for Assisting Countries to Prepare for the Entry Into Force of the Cartagena Protocol on Biosafety, October 17, 2000**
- ▶ **GEF -4 Focal Area Strategy for Biodiversity, October 18, 2006**
 - ▶ **Strategic Objective Three: Capacity Building for the Implementation of Cartagena Protocol on Biosafety**
- ▶ **UNEP-GEF Global projects - Development NBF/BCH/Implementation projects**

BIO SAFETY PRIORITIES IDENTIFIED for MOLDOVA

- ◆ **Enforce comprehensive National Biosafety Policy as the basis for the development of the adequate national regulations and institutional framework**
- ◆ **Establish responsive and fully functional national regulation framework in line with CP and national needs**
- ◆ **Enabling national system for handling request and decision-making as well as performing risk assessment and management associated to LMOs**
- ◆ **Encourage national system for “follow-up” activities, namely monitoring of environmental effects and legislation enforcement**
- ◆ **Enhance public awareness, education and participation to ensure access to information**

UNEP-GEF Projects: premises for implementation of the National Biosafety Framework for Moldova



1. Development of NBF
2002-2004

2. BCH Project
2005-2006

3. NBF Implementation Project

2006-2010

CURRENT ACTIONS/expected outcomes

Policy development

- Action Plan elaborated
- Domestic Biosafety Law improved
- Sectorial regulations strengthened with Biosafety requirements
- Secondary regulation and guides prepared

Capacity building for decision making

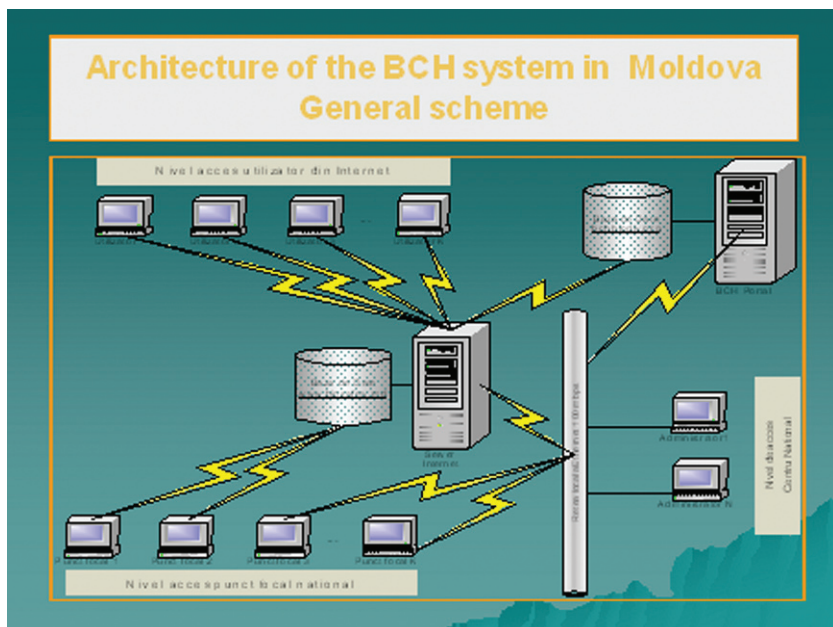
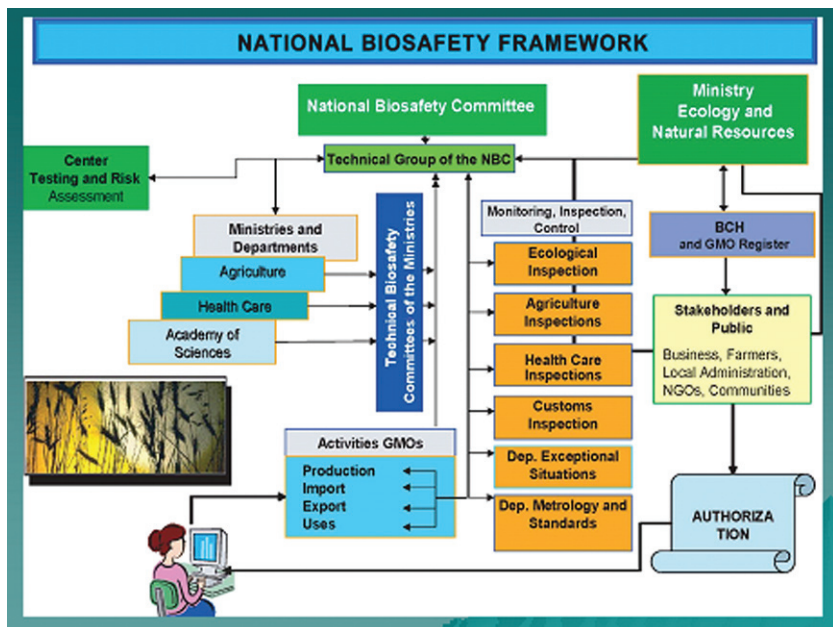
- Roles and responsibilities for handling of requests established
- Procedures for Notifications in place
- Risk assessment/management available

Enforcement & monitoring

- Procedures for monitoring and inspection in place
- GMO testing strengthened and available
- Emergency reply working
- Transportation, packaging & labeling respected

Public Participation

- Mechanism for public participation to decision making approved
- Trainings, workshops held
- Public awareness and education raised



BIOSECURITATEA ÎN MOLDOVA

Ministerul Ecologiei și Resurselor Naturale

- BIOSECURITATEA
- MANAGEMENT INFORMACIONAL
- CADRUL INSTITUTIONAL
- CADRUL LEGISLATIV
- CADRUL NORMATIV
- NOTIȚĂRI PRIVIND OMG
- INFORMĂȚII DE ILL
- F.A.Q.
- CUM ÎNĂLȚĂȚINE
- BAZA DE DATE OMG



Convention on Biological Diversity



Global Environment Facility



United Nations Environment Programme



Ministry of Ecology and Natural Resources

Evenimente

30.01.2007 / Conferința privind Diversitatea Biologică
 Conferința privind Diversitatea Biologică a fost convocată la Șantierul de la Flore de Ierocero din 1982, de către 150 de țări de guvern. Conferința este dedicată pentru promovarea dezvoltării. Fiind prezentată drept un instrument care transferă participă din Agenda 21 în realitate...

07.02.2008 / Planul de Acțiune privind Protecția Produselor de Biosecuritate a Republicii Moldova pentru perioada 2008-2010.

La 29 ianuarie 2008 la o întâlnire extraordinară a Conferinței Partilor la Convenția privind diversitatea biologică (Montreal, Canada), a fost adoptat [Protocolul de la Cartagena privind Biosecuritatea](#). Acest document la nivel global reglementează activitățile legate de asigurarea unui nivel adecvat de protecție pentru siguranța transferului, manipulații și utilizării organismelor modificate genetic rezultate din biotehnologii moderne și care pot avea efecte imprevizibile asupra biodiversității și utilizării durabile a diversității biologice. Într-o deosebită atenție este acordată riscurilor pentru sănătatea umană și concordanța sa în special asupra migrației transfrontaliere. Scopul Protocolului a fost să stabilească drept un pas semnificativ prin faptul că el asigură cadrul internațional de reglementare pentru reconcilierea necesităților respective de comerț și mediului în primă industrie biotehnologică. Astfel, Protocolul creează un mediu favorabil pentru aplicarea ecologică a biotehnologiei moderne, ceea ce permite utilizarea echilibrată a beneficiilor din potențialul științei biotehnologice, minimizând în același timp riscurile pentru mediu și sănătatea umană.

Mechanism de Schimb de Informații pentru Biosecuritate (BCH) a fost stabilit ca un mecanism internațional pentru informarea tuturor Partilor Protocolului despre utilizarea casnică și plasarea pe piață a OMG-ilor, de spre mișcarea transfrontalieră pentru uzul direct ca hrană sau sură, sau pentru producerea pentru facilitarea schimbului științific, tehnic, ecologic și legal și informării și implicării cu privire la OMG-ii și pentru promovarea și facilitarea capacităților, educației și participării publicului cu privire la transfer, păstrare și utilizare a OMG-ilor (art.20 al Protocolului de la Cartagena privind Biosecuritatea).

Republica Moldova a ratificat Convenția privind diversitatea biologică în 16 mai 1995 (*Hotărârea Parlamentului nr. 457-XIV*) și Protocolul de la Cartagena privind biosecuritatea la 11.10.2002 (Legea nr. 1394-XIV). În conformitate cu angajamentele luate, Ministerul Ecologiei și Resurselor Naturale întreprinde mai multe măsuri în vederea implementării prevederilor acestor documente internaționale. În special, s-a fost elaborată și aprobată Primul Raport Național privind diversitatea biologică, Strategia Națională și Planul de Acțiune în domeniul diversității biologice, Legea privind securitatea biologică (Nr. 755-XV din 21.12.2007). La momentul actual Republica Moldova întreprinde o serie de proiecte în vederea armonizării legislației naționale în domeniul diversității biologice și asigurării unui nivel adecvat de protecție pentru siguranța transferului, manipulațiilor și utilizării durabile a diversității biologice.

PROPOSALS & INITIATIVES

I. Sub-regional level

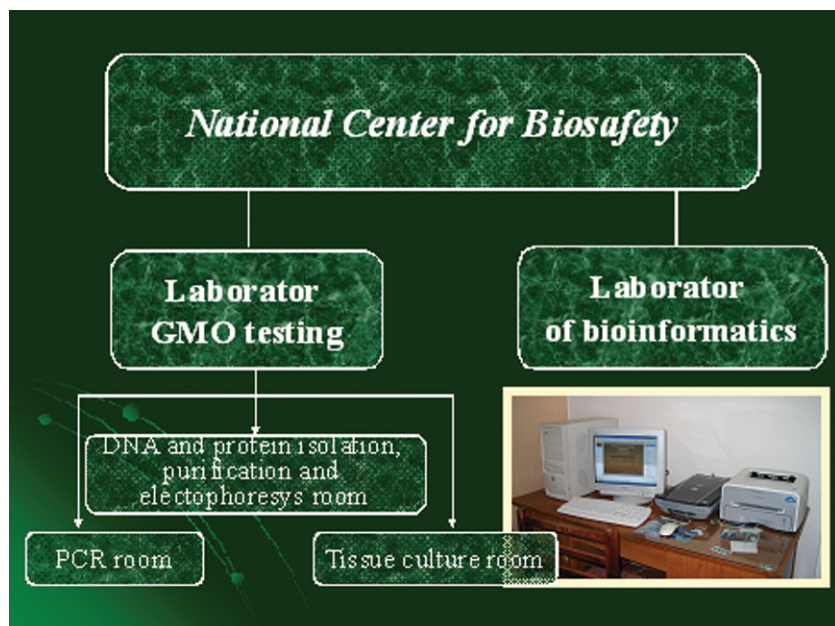
To enlarge the Sub-regional cooperation through:

- regulatory harmonization
- bilateral and multilateral agreements (art.14)
- agreement for Simplified procedures (art.13)
- monitoring over the Illegal transboundary movement (art. 25)
- strengthening joint capacities for Information exchange & Risk management (art.20 & art.16)
- agreement for Liability & redress (art. 27)
- cooperation in Biotech research and Risk assessment/detection (art. 15)

PROPOSALS & INITIATIVES

II. Domestic level

- ◆ To develop demonstrational pilot project as follow-up activities directed to:
 - ✦ arising awareness of farmers, crop producers and ecologists regarding the best practices for risk management (**art.16**) related to:
 - ✦ transboundary movement
 - ✦ Labelling and monitoring
 - ✦ direct use for FFP
 - ✦ crops production
 - ✦ coexistence of GM and non-GM crops in agriculture
 - ✦ protection of protected areas and natural landscapes
 - ✦ replication and dissemination of good practices via demonstrational actions and training



LABORATORY OF GMO TESTING

LARGE ROOM



LABORATORY OF GMO TESTING

PCR Laboratory



GMO detection methods in our laboratory

Phenotypic expression
of transgenes

Herbicide
Biotech
Basta

Protein detection
by SDS-PAGE

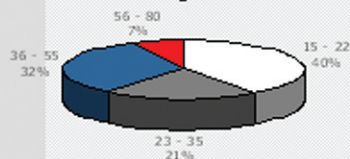
GFP,
27 kDa

PCR method for GMO
screening

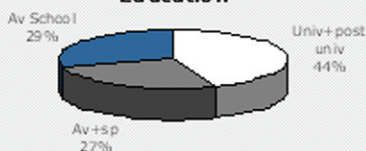
CaMV35S,
NOS-Terminator

Participants to the survey

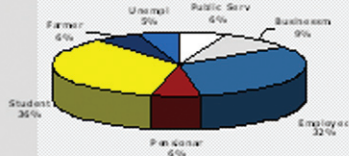
Age



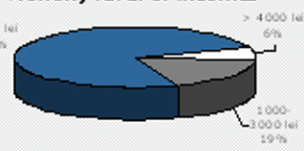
Education



Types of activity

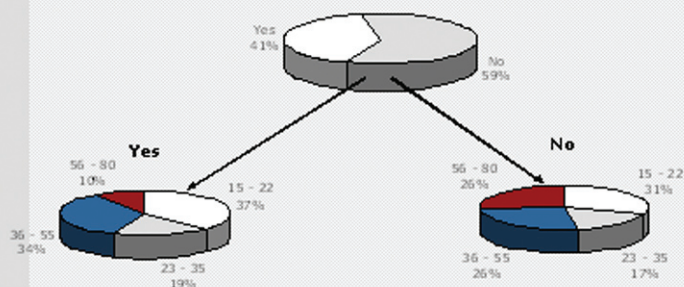


Monthly level of incomes



Degree of population awareness about the GMOs

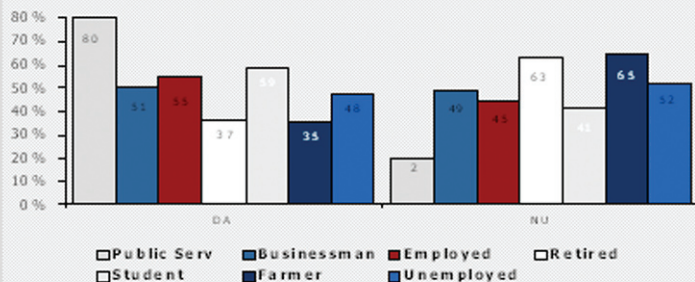
"Do You know anything about the application of GMOs?": Distribution of answers according to the age.



15

Degree of population awareness about the GMOs

"Do you know what are the GMOs?": - Distribution of answers according to type of activity.



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