Ministry of Nature Protection of the Republic of Armenia

NATIONAL BIOSAFETY FRAMEWORK

FOR ARMENIA

YEREVAN 2004

Ministry of Nature Protection of the Republic of Armenia

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Foreword

Development of modern biotechnologies and integration to the international market economy emphasizes different types of urgent and significant issues, such as protecting environment from newly emerged and unknown living organisms and ensuring the safety of their use.

The biosafety issues are highlighted in the Cartagena Protocol of the Convention on the Biological Diversity (CBD) and are based on the concept of necessity of protecting environment, biodiversity and human health from the possible adverse effects caused by living modified organisms (LMOs) obtained through the application of modern biotechnologies.

Until the behavior and features of LMOs in various environments are completely investigated and revealed, the unpredictable threats to the biodiversity and human health exist. This mainly relates not only to living modified organisms, but also to food, foodstuff and drugs obtained from LMOs processing and development. Another issue of concern is related to the modern biotechnologies gradual transformation to the high industrial branch of economy. The products of this sphere comprise a significant part of the worldwide trade and the market is hardly manageable in regard to biological safety, due to poor regulatory framework and improper mechanisms for control. The Cartagena Protocol on Biosafety internationally regulates the obtaining, use and transfer of LMOs (or their constitute components) resulted from the application of modern biotechnologies. A special attention is paid to their transboundary movements.

The Protocol offers to the signatory Parties exact mechanisms to ensure obtaining, processing transferring and deliberate releasing to the environment of any LMO by reducing or minimizing its adverse effects on environment and risks for human health.

The National Assembly of the Republic of Armenia has ratified the Cartagena Protocol of CBD on March 16, 2004. This can be considered the first significant step towards ensuring the active participation of Armenia in international cooperation in the framework of the Protocol.

We hope that the present National Biosafety Framework will promote effective implementation of the provisions of the Protocol and will support addressing biosafety-related issues in Armenia.

V. Ayvazyan
Minister of Nature Protection of the Republic of Armenia

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List of Abbreviations

AIAP	Advanced Informed Agreement Procedure
BCH	Biosafety Clearing-House
CBD	Convention on Biological Diversity
COP	Conference of Parties
CPB	Cartagena Protocol on Biosafety
EEP	European Economic Partnership
GEF	Global Environment Facility
GMO	Genetically Modified Organism
HEI	Higher Educational Institution
ICARDA	International Center for Agricultural Research in the Dry Areas
ISTC	International Scientific Technical Center
LMO	Living Modified Organism
MB	Modern Biotechnology
MNP	Ministry of Nature Protection
NAS RA	National Academy of Sciences of the Republic of Armenia
SNCO	State Non-Commercial Organization
SRI	Scientific Research Institute
UN	United Nations
UNESCO	United Nations Educational Scientific and Cultural Organization
UNEP	United Nations Environment Program
WTO	World Trade Organization
YSU	Yerevan State University

INTRODUCTION

The Republic of Armenia is distinguished by the certain scientific and technological potential in the field of biotechnologies, which is an important prerequisite for the country to enhance this scientific-industrial branch of the economy. Concerns about the safety of GMOs to human health and the environment, however, moderate the rate of GMO product development. National biosafety system is intended to serve as a mechanism for ensuring the safe use of biotechnology products without imposing unacceptable risk to human health or the environment, or unintended constraints to technology transfer.

The current report provides a review of the present status of the biosafety system in Armenia and is aimed at:

- Assessing the efficiency of biosafety policies and procedures associated with the introduction of biotechnology products in Armenia;
- developing recommendations for enhancing the operation of Armenia`s biosafety system and minimizing potential constraints to technology transfer;
- identification of areas where further national and international assistance should be necessary.

The biosafety processes in Armenia are considered to be country driven, as Armenia is a country with a rather well developed biotechnology, scientific and technological capacity. The national and worldwide importance of biosafety in Armenia is conditioned by a number of factors, e.g. RA territory is the origin for a number of flora and fauna species, Armenia is located on the cross-road of migration routs for a number of animal and bird species, as well as is a habitat for some of them, the nature-climatic conditions fluctuate in the altitudes 375-4095 meters above sea level, etc.

In 2003 the national biosafety framework was initiated, which has revealed a number of gaps and some necessary steps have been undertaken for capacity development, public awareness and monitoring.

The objectives of the National Biosafety Framework in Armenia are to:

- Integrate the country into the international cooperation in the framework of Cartagena Protocol to prevent and regulate the uncontrolled LMO distribution in Armenia;
- Prevent any LMO-related activity that is prohibited in Armenia;
- Develop technical and procedural norms for conservation of biodiversity, protection of environment and human health, taking into consideration the risks related to LMOs' use;
- Develop administrative, institutional and scientific capacities to control and manage the import, export, obtaining and use of LMOs;
- Provide opportunities for land owners and biotechnological industries to decide between application of modern biotechnologies and traditional production techniques (including organic farming);
- Provide consumers with a choice between the products obtained by application of modern biotechnologies and those of traditional production techniques;
- Create equal opportunities for public to participate in LMO-related decision-making process;
- Establish appropriate administrative and legislative framework to ensure proper implementation of the Cartagena Protocol.

The priorities are set as follows:

- To regulate national processes on GMOs in the spheres of science, production and trade;
- Prevent non licensed transfer and import of goods of unknown origin, improve custom and tax inspection;
- Involve Armenia into bilateral and multilateral regional and international cooperation, taking into consideration efficiency of joint efforts. In this context and in the line with other issues Armenia initiates rehabilitation of the former technological (including agrobiotechnology) capacity, considering the new opportunities.

To attain the above-mentioned objectives a number of stakeholder organizations of the field were identified and involved in the project implementation (for the list of stakeholders please refer to Annex 3).

1. National Biosafety Policy

Biosafety related activities started in 1993 when the National Assembly of RA ratified the Convention on Biological Diversity. During the recent years RA has gained a good experience. The «First National Report on Biodiversity of Armenia» and «Biodiversity Strategy and Action Plan» developed under UNDP/GEF project (1999) state the general issues and gaps for developing biodiversity and biosafety framework and public awareness. Based on the above mentioned strategic documents, as well as two national Laws "On Flora" and "On Fauna" and "Assessment of Capacity Needs for Biodiversity Conservation" were developed in 2002 (with UNDP/GEF support). Capacity analysis revealed the achievements and constraints.

To implement country policy on conservation and sustainable use of biological diversity, Armenia has ratified the following Conventions:

- Convention on Biological Diversity (1993)
- Convention on Environmental Impact Assessment in a Transboundary Context (1996)
- Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Basel, 1992)
- UNECE Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters (Aarhus, 2001)

Since Armenia has ratified the UN Convention on Biological Diversity in 1993 it has undertaken commitment to conserve and sustainable use of biodiversity. In this context and as a part of RA National Policy on sustainable development the biosafety issues are considered as national priorities in the scope of global environmental policy. As an initial consideration for biosafety state policy the Republic of Armenia currently undertakes all possible measures to join the European Economic Partnership. Therefore nowadays harmonization of the policies and legislation of the Republic of Armenia with European criteria is underway.

Armenia has participated in negotiations on Cartagena Protocol formulation. The Cartagena Protocol directly originates from the Convention on Biological Diversity signed in Nairobi in 1992 and ratified by 185 states. The main objectives of the Convention are: conservation and sustainable use of biodiversity as well as equitable sharing of the benefits from the utilization of genetic recourses. As one can notice from the depth of the objectives of the Convention, they are rather comprehensive and include social and economic aspects as well. The later covers also the issues related to the use of biotechnologies.

Cartagena Protocol was ratified by RA National Assembly in March 2004 and has entered into force on July 29, 2004.

The main prerequisite for implementation of provisions of the Cartagena Protocol is ensuring environmental protection, including human health, without constraining technology development and following principles of caution, transparency and awareness.

In May 2003 the Fifth Ministerial Conference "Environment for Europe" adopted a declaration of 51 environmental ministers, including Armenia. The declaration identified the commitment of parties to enhance cooperation in environmental protection between the countries of Europe, North America, Caucasus and Central Asia.

Since Armenia has not yet developed a special policy on LMO and as a part of the country`s global policy on nature protection, Armenia will particularly follow the Declaration on discretion in use of LMOs, until the possible risks for environment and human health is not identified.

2. Regulatory system

Primary source of information for the study was a review of documents pertaining to biosafety. Environmental legislation along with a number of international conventions is intended for regulation of human/nature interrelations.

General provisions of the convention on biodiversity prioritize developing legislative basis for regulating the use of genetic resources and ensuring biosafety in the convention member-states, including Armenia.

Current Status

The analysis of existing environmental legislation of Armenia revealed lack of any relevant law to regulate access to genetic resources and benefit sharing. Although some preconditions for regulation of legal issues in this sphere do exist in many normative documents.

The main law of the Republic of Armenia – the ***RA Constitution***, states the obligations of the country in the field of protection and rehabilitation of the environment and reasonable use of natural resources (Annex 1, Art. 10) and declares the right of citizens to live in sound environment (Annex 1, Art. 8).

The Law of the Republic of Armenia on "***Principles of Legislation on Nature Protection of RA"*** (09.07.1991) specifies principles of environmental policy of the country.

Proceeding from the necessity of conserving the natural gene pool and rehabilitating animal and plant resources, the law permits use of natural resources only with ensuring its conservation and rehabilitation.
The RA Government, environmental and healthcare authorities are entitled to restrict the transboundary permitted norms for harmful impact caused to environment and human health.

Law "***On Flora***" (23.11.1999) and Law ***"On Fauna***" (16.03.2000) state the national policy on scientifically justified conservation, protection and sustainable use of flora and fauna.

These laws give the definition of the concepts *"Genetically Modified Organism"* and *"Biological Technology"* and directly discuss the issues pertaining to genetically modified organisms (GMO). Definition of GMO coincides with that of the Cartagena Protocol.

Certain articles of the mentioned laws prohibit illegal import and export of animals and plants for acclimatization and selection purposes (Annex 3 Article 15/18·, Annex 4 Article 19³), unwarranted use of biotechnologically developed living GMOs, (Annex 3 Article.18¹, Annex 4 Article.19·),
However, these Laws don't regulate issues of access to genetic resources and benefit sharing. Hence it is necessary to amend and supplement the laws in accordance with the Convention on Biodiversity.

The ***"Law on Selection Achievements"*** (23.11.1999) also refers to the issues of plant conservation and use. The law regulates legal issues in the sphere of protection and use of plant selection achievements. It specifies the criteria for legal protection of selection achievements to be novelty, distinctive, homogeny and sustainable.
It is considered to be expedient to include "genetic modification" among these criteria as well.

The procedure of providing precise data on import and export of commercial products, requirements and norms on main commodity features of products, consumers' rights, safety and liability for the damage to human health are regulated by the laws of RA on ***"Consumers' Rights Protection"*** (26.06.2001; Annex 5, Art.11, 15), "***On Standardization"*** and "***On Conformity Assessment***" (06.19.2004), as well as by a number of by-laws acts.

RA Government resolution No15 on ***"Obligatory certification of products and services in RA"*** (12.05.2000) specifies the list of products and services subject to obligatory certification in Armenia and the procedure of import of these products into customs area of Armenia. Moreover, the RA Government resolution No 595 on ***"Establishment of principal rules of wholesale trade***" (19.12.1997) prohibits sale of products subject to obligatory certification without corresponding certificates. The RA Government resolution No 238 "***On Accreditation of certification bodies and testing laboratories"*** (12.05.2000) requires to establish an Accreditation Board for authorities granting certificates and laboratories. The overall supervision lays on the Ministry of Trade and Economic Development as a state authorized body for standardization, metrology and certification.
Issues of LMO certification are not included in its scope of responsibilities.

Article 10 of the ***Law "On Licensing"*** focuses on gene engineering issues and Government resolution No 1922 (28.11.2002) specifies gene engineering activities in Armenia.
However, the abovementioned law does not focus on main principles of gene engineering management and liability issues.

The Law ***"On Environmental Impact Expertise"*** (20.11.1995) is intended to prevent possible harmful impact of concepts and planned activities on the environment, human health and sustainable economic and social development of Armenia.
The issues of development and use of GMOs are in some intend included in the scope of the law, though they are not clearly defined.

The issues of GMOs use are being regulated by ***RA Criminal Code*** enforced in 2003. (Chapter "Environmental safety transgretions" Articles 282, 284, 285). Some penalties are envisaged for imprudence and deliberation.

There are also other normative acts in the legislative field of Armenia concerning biosafety issues, as for instance, the ***laws "On Advertisement", "On Transport", "On Population Protection at Emergency Situations", "On State and Administrative Secret"*** and others.

Presently there are following resolutions in the field of safe use of biotechnologies:

(a) Resolution of RA Prime-Minister, No 91 (08.03.2000) on "***Ratification of the Agreement Between the Ministry of Agriculture and International Center for Agricultural Research in the Dry Arias*** (ICARDA)" on collaboration in the field of agriculture. The inter-institutional agreement on ***"Cooperation between the Ministry of Agriculture and International Center of Agricultural Research in the spheres of Dry-zones and Agricultural Science (ICARDA)"*** signed in Aleppo was

ratified on 16 September 1999. According to the latter the exchange and research of drought-resistant plant seeds of cultivated plants for dry zones is permitted. The agreement doesn't make any reference about import and export of living GMOs.

(b) Government resolution No 621 (25.05.2002) on ***"Approving the regulation on VAT-free import of Potato, Barley and Spelt Seeds into Armenia".***
According to this resolution the goods imported into RA can be considered as seeds, when they are supported by Certificate of quality, given by a competent organization of the exporter country or by other international recognized competent organization.
The resolution does not cover the issues on GMOs.

(c) In 2002 the Ministry of Agriculture submitted to the National Assembly of the Republic of Armenia a Draft Law ***"On Seed-Growing***" aimed at regulating import and export of seeds. The Draft Law presumed certain restrictions on import of seeds not circulated in the country.
However, the National Assembly has not approved the draft law yet.
The issues of environmental information and awareness are to some intend referred in the RA Law on ***"Environmental education"***. Although any special provision for GMOs do not exist.

Currently the most important tool for regulating public information and public participation is the ***Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention).***

Public awareness and public participation is also explicitly mentioned in ***Article 23 of the Protocol*** stating that parties should promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Relevant provisions of the draft Law ***"On Living Modified Organisms"*** refers to the right of the public to be informed about GMO management, and to be involved in the procedure of issuing permission in different manners and provisions.

(For the list of biosafety related laws see Annex 2)

In conclusion it is worthy to mention that Armenia still lacks a comprehensive biosafety legislative framework that will regulate the LMO use, their deliberate release to the environment, placing on the market, export and import of LMOs and GMO contained products. Developing a Law on biological safety and mechanisms and tools for its enforcement are in the priorities of MoNP.

Analyzing an international experience we found out that foundation of any biosafety regulatory system is authority. Authority refers to the enabling legislation (acts, laws, decrees, and government orders) governing biosafety. At the national level, this is the authority to promulgate regulations, facilitate trade or domestic movement, and implement enforcement agencies.

In some countries the regulatory oversight of LMOs generally began with nonbinding, voluntary guidelines. The designated authorities developed information guidelines and technology developers abided by these. The benefits of voluntary guidelines include the speed by which they can be put in place and the flexibility they allow to adopt revisions incorporating new information requirements without delay.

According to above mentioned, the project has developed an informational guideline to address the biosafety issues to stakeholders, technology developers, government officials, general public. The guideline has been widely discussed during the national seminar.

The next step in improving the regulatory system of Armenia`s biosafety was developing a draft concept of RA Law ***"On Living Modified Organisms"***, based on the provisions of Cartagena Protocol on Biosafety and aimed at regulating the harmless impact of the LMOs in the country.
The concept is aimed at identification of the approaches and principles, developed through discussing the Law with stakeholders, relevant specialists, state governing bodies and officials. From other hand the experience of above mentioned specialists will significantly contribute to formulate a comprehensive law.
Any living organism obtained in or imported to Armenia, which is derived by application of modern biotechnologies, is subject for legislative regulation at the stages of obtaining, maintaining, importing, exporting, transferring and eliminating. Taking into account the socio-economic benefits of LMO use and aiming at preventing or minimizing potential harmful effects on environment, biodiversity and human health, the Law establishes legal grounds for environmentally sound management of the biosafety field, LMOs application and information management.

The Law will also regulate the legal relationships among stakeholders in the sphere of biosafety and will be aimed at the constitutional right of the citizens of the Republic of Armenia for proper environment. The Law will define the main objectives and tasks for biosafety in Armenia, the rights and obligations of bodies involved in the sphere, the limitations and requirements for their operation, etc. The draft Law is based on the following key concepts:

- The prevalence of the safety of biodiversity and human health care upon the economic effectiveness of LMO application;
- The scientific justification of the biosafety provisions during LMO application;
- The synergism between potential risks of LMO application and the effectiveness (usefulness) of the process;
- The participation of the stakeholder legal and physical entities at the development of draft laws or other legislative acts on biotechnologies;
- The openness of the decision-making process on LMO application;
- The right of legal and physical entities to receive any relevant information on LMO obtaining, importing and activities related to their application.

The Law clarifies and defines:

- System of State competent authorities responsible for biosafety of LMO obtaining, testing, reproduction, conservation, transfer, use and eliminating, their relationships, rights and obligations;
- Requirements, conditions, limitations and peculiarities of biosafety activities related to LMO obtaining, testing, reproduction, conservation, transfer, use and eliminating;
- Development and maintenance of a database on LMO-related information;
- Requirements of LMO risk assessment and risk management;
- Requirement for mandatory notification on consistency for food and feed derived from GMOs;
- Requirement for mandatory state expertise for LMOs impacts on environment, biodiversity and human health;

- Procedures on awareness raising and public informing activities on biosafety, ensuring the requirements of state secrets.

The draft Law is currently under development stage and we expect to submit it to the RA Government for approval in early 2005.

To further strengthen the draft Law RA should seek assistance of developed countries and international organizations.

Some additional regulations complementing the Law should be drafted, particularly:

- Regulation on Intellectual Rights Protection;
- Regulations on Issuing Licenses and Permits;
- Regulations on Contained Use and Disposal of LMOs;
- Regulation to Identify Content of the Notification for Placing a Product on the Market;
- Regulation on the Packaging or Declaration of the Product;
- Regulation on developing indicators and Content of Monitoring Programme;
- Regulation for Releasing Genetically Modified Organisms into Environment.

3. System for handling notifications or requests for permits

The system is envisaged by draft Law in general, but some regulations are still needed to precisely define these procedures.

Currently the responsible institution for ensuring biosafety (preventing invasion of modified organism) is the RA Ministry of Nature Protection. According to the charter of the Ministry of Nature Protection, it is the responsible body for formulation of state policy and management in the field of protection of environment and prevention of harmfull impacts on it. The MNP "....organizes activities to ensure the safety of biodiversity from invasive plant and animal species and modified organisms". (RA Government Decree N 1237 –N, August, 2002 on " Establishing "Ministry of Nature Protection" state enterprise and approving the regulation and staff chart).

Bioresources Management Agency of the MNP issues licenses for import and export of biological resources, including invasive plant and animal species. In the scope of activities of the Agency is envisaged to implement the measures for GMO use, import and export.

According to one of the provisions of the Charter of the Ministry of Agriculture, the latter is responsible for ensuring state control upon food safety. However, there is no function aimed at ensuring control upon obtaining and use of GMOs, including ones obtained by application of modern biotechnologies.

The Charter of the Ministry of Health considers the "... organization of the examination of the environmental factors impacting human health". However, again there are no references to the organization of activities for investigation of the GMOs' and modern biotechnologies impact on the human health.

Currently only two entities are actually involved in deriving GMOs through modern biotechnological applications and related research. They are (1) Scientific Research Institute of Biotechnology under the Ministry of Trade and Economic Development and (2) Faculty of Biology of Yerevan State University.

Biotechnological research is being implemented at a number of scientific-research and educational institutes under RA Ministries of Education and Science, Trade and Economical Development, as well as National Academy of Science namely the Institute of Molecular Biology, Institute of Fine Organic Chemistry, Center for Medical Genetics, Institute of Radiophysics and Electronics, Institute of Zoology, and Research Institute on Physics.

Among the institutions under the competency of the Ministry of Health of Armenia, it is worthy to mention the following institutions: Scientific Research Institute for Oncology, particularly its Laboratory of Cancerogenesis and National Dispanser for Tuberculosis (Abovyan city). The organizations under the Ministry of Agriculture of Armenia, particularly Center for Applied Zoology and Botany (Yeghvard, Kotayk province), are also involved in development of modern biotechnologies and research on GMOs using modern biotechnologies.

The biological safety of those institutions is regulated by the mentioned structures. Although developing and use of LMO is not being regulated.

There is a lack on coordination of the activities of Armenian NGOs as well regarding the issues on GMOs. Nevertheless a number of organizations (such as "Association for Sustainable Development" NGO, "Environmental Protection Advocacy Center" NGO) consider these issues during the implementation of environmental impact assessment.

Currently the MB products are not exported from Armenia. Any appropriate supervision on import of MB products or LMOs do not exist. Although we are aware that a great number of food, feed, seeds are imported into Armenia from USA, Canada, Brasil, Russia, Turkey in commercial purposes. As the process is not controlled and data on products origin is unknown the product can be MB product or LMO.

In February 2003 an agreement was signed between RA and CIS on the free transboundary transfer of goods. The agreement contradicts some provisions of Cartagena Protocol. In this context developing a relevant legislative framework should regulate import procedures for LMO containing products.

According to the provisions of the Protocol, each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements (CP, Art. 25).

In this context a guideline on handling, transport, packaging and identification of LMO (under Article 18), as well as guideline on liability and redress for damage resulting from transboudary movements of LMO (Art.27) should be developed.

The relevant services of RA State Custom Service need to formulate exact management principles and mechanisms to control illegal transboundary transfer of LMOs. A strong cooperation with the above structures is required.

The new draft Law on Living Modified Organisms should contain provisions on LMO developing, handling, testing, replication, transfer, contained use and disposal, as well risk assessment.

Risk Assessment

The objective of risk assessment in the frameworks of the Cartagena Protocol is to identify and evaluate the potential adverse effects of modified organisms on the human health and environment. Competent authorities use risk assessment to make informed decisions regarding modified organisms.

Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advise of, and guidelines developed by, relevant international organizations. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

To fulfil its objective, risk assessment entails, as appropriate, the following steps:

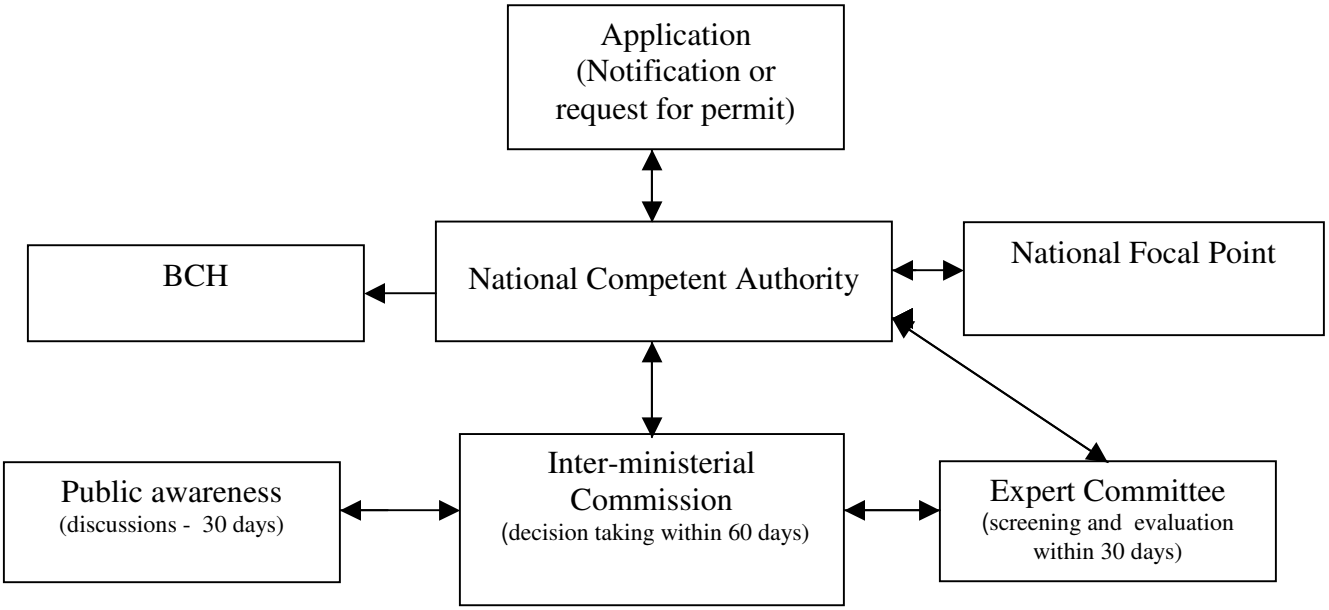
- An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
- An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organisms;
- An evaluation of the consequences should these adverse effects be realized;
- An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified effects being realized;
- A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identifications of strategies to manage these risks; and
- Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Risk assessment should be implemented by Expert Committee. The results can be assessed by "Environmental expertise" SNCO under RA MoNP. The public awareness on the results is implemented by Information-Analytical Centre, as well as mass-media (newspapers, TV, radio, announcements, internet, etc.)

The final conclusion on LMOs environmental impact assessment, mainly in the case of LMOs import/export is given by Expert Committee, the final decision is made by MoNP based on conclusions of "Environmental expertise" SNCO and public hearings. Implementation of expert committee recommendations, approved by MoNP are monitored by State Environmental Inspection. The state Environmental expertise implements the periodical inspections if envisaged by the current activity.
The following steps are proposed for decision making by the Ministry of
Nature Protection for biosafety on GMO related matters:

- Application to the National Competent Authority is delivered.
- Information to the applicant on receiving of the proposal for evaluation
- Screening and evaluation of the proposal by Expert Committee (within 30 days)
- Discussions with stakeholders and general public(within 30 days)
- Competent Authority takes the decision (not late than in 60 days after submission of application).

Scheme of the System for Handling Notifications or Requests for Permits



To ensure risk assessment some activities proved by relevant Articles of Cartagena Protocol (e.g. advanced informed agreement procedure, contained use, intentional introduction into environment) should be undertaken, particularly the following regulations have to be prepared:

- Regulation aimed at clarification of elements and the extent of the risk assessment when placing a product on the market;
- Regulation to identify contents of the notification for placing a product on the market;
- Regulation on contents and extent of monitoring programme;
- Regulation on the packaging or declaration of the product;
- Approximation of the EU Regulation on transboundary movements of Genetically Modified Organisms.

State Regulatory Bodies, their Rights and Obligations

In general, the central issues around the implementation of biosafety framework involve the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication, while managing within existing financial, technical, and human resource constraints. So the creation of a regulatory structure that allows separation of the scientific risk assessment and regulatory decision-making processes will be helpful.

In this regard and according to the requirements of Articles 17 and 19 of the Protocol each party should nominate a National Focal Point, National Authorities and Contact Point for unintentional transboundary movements and emergency measures. RA government is likely to apply a simplified system for receiving notifications, considering the centralized management structures. The responsibility for receiving notifications should be managed by National Focal Point, National

Competent Authority, Expert Committee and Inter-ministerial Commission. The state regulatory bodies for Armenia are envisaged as follows:

- Inter-ministerial Commission
- National Competent Authority
- National Focal Point
- Expert Committee

Inter-ministerial Commission is a permanent and responsible body, with inter-institutional composition and is responsible for final decision making.

National Competent Authority
The activities of the Competent Authority are set up by RA Government. The Competent Authority is authorized to implement activities set up by RA legislation and/or international agreements signed on behalf of RA Government.

National Competent Aauthority/furthermore Competent Authority / The objectives and goals of the Competent Authority

- Provide expertise (risk assessment) of LMOs intended for use and transit on the territory of Armenia and decision making on export and import.
- Ensure biosafety of living modified organisms that are intended for direct use as food or feed, or for processing, introduction into the environment, avoiding adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
- Take necessary measures to require that living modified organisms that are subject to intentional transboundary movement are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.
- Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.

The Competent Authority is liable to:

- Ensure biosafety expertise and release into environment, testing and contained use;
- Licensing (permits) on LMO developing, testing, release, transfer, import, export and disposal;
- Submit regulation on risk assessment to RA government approval;
- Monitor implementation of requirements of Law on biosafety and other relevant by-laws;
- Based on the conclusion of national focal point proceed licenses;
- Supervise and coordinate activities of national focal point and expert committee;

- Represent RA in the relevant international organizations.

The Competent Authority is responsible for:

- Implementation of risk assessment monitoring;
- Monitoring of biosafety requirements set uo by law and other legal documents;
- Ensuring information dissemination on risk assessment, expertise.

National Focal Point is a contact person to Secretariat and is designated by the decree of Minister of Nature Protection. The same time the National focal point shoul perform function of contact point for unintentional transboundary movements and emergency measures.

According to requirements of Protocol the National Focal Point shall inform the BCH on:

1. Existing laws and by-laws, regulating LMO related activities;
2. Summary of activities on risk assessment;
3. Copies of agreements on LMOs imported in purposes of use or handling within 15 days from the day of decision taking;
4. Final decision and reports on LMO import or release in 270 days after receiving notification;
5. On all illegal transboundary movements and changes in the above mentioned activities.

National Focal Point is liable to:

- Develop and maintain data base on modern biotechnologies, LMOs (receiving, testing, disposal, import, export), stakeholders dealing in the field;
- Ensure information exchange with relevant international organizations.

National Focal Point is responsible for:

- Appropriate maintenance of data base;
- Appropriate information exchange with relevant international organizations.

Expert Committee carries out biosafety expertise and risk assessment.

Expert Committee is responsible for:

- Accuracy of biosafety expertise and risk assessment results;
- Timeliness of implementation of biosafety principles, regulations, norms and deadlines;
- Maintaining documents and materials.

Expert Committee comprise of experts from:

- RA Ministry of Nature Protection
- Armenian Agricultural Academy
- Institute of Zoology, National Academy of Science
- Institute of Botany, National Academy of Science
- Institute of Microbiology, National Academy of Science

- Scientific Research Institute of Biotechnologies
- Yerevan State University

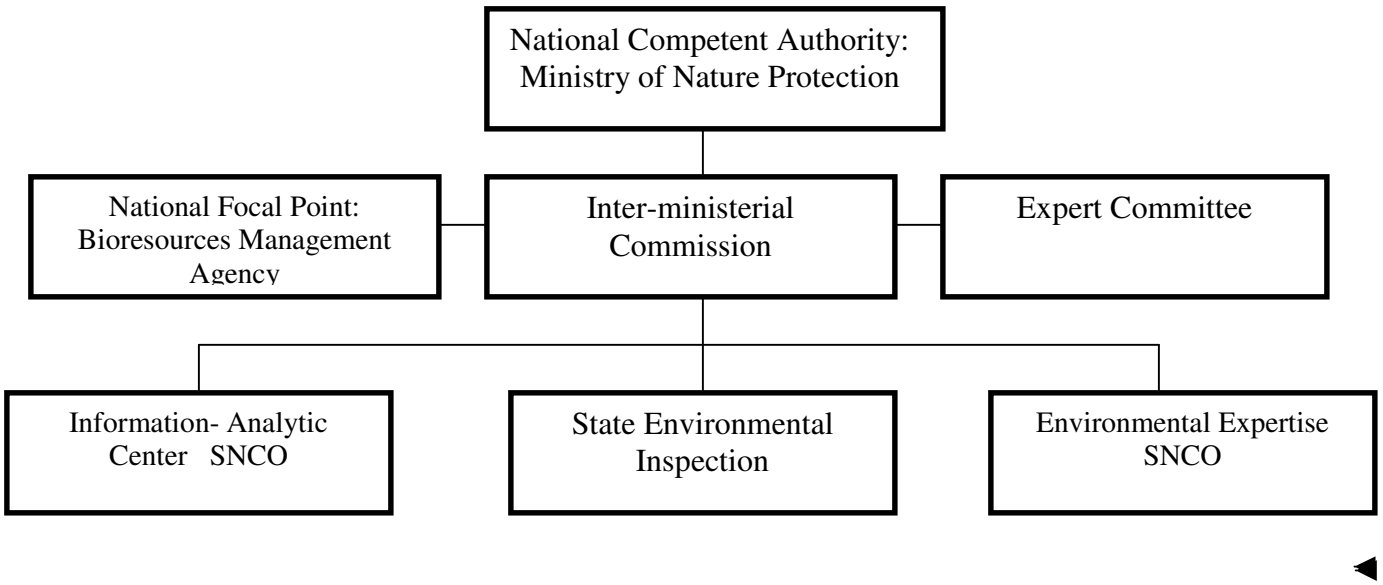
Decisions on LMOs intentional introduction into environment on the territory of RA are taken and the permits granted by RA Ministry of Nature Protection (Inter-ministerial Commission)

Licensing for LMO domestic use (local market) is issued by RA Ministry of Nature Protection (National Competent Authority) based on the conclusion of Expert Committee.

The draft composition of Inter-ministerial Commission is submitted to Government for approval. (see Annex 4).

The composition and regulations of Expert Committee is stated by an authorized body.

The Structure of National Regulatory Bodies



4. Monitoring and enforcement

Monitoring is perhaps particularly required in cases, such as this Protocol, where most of the obligations are not self-executing, and thus require national measures, of a legislative, regulatory and institutional character, to enable their implementation.

According to one of obligations towards the Cartagena Protocol for ensuring biosafety in Armenia, the country is required to develop a National Strategy and Action Plan on Biosafety Monitoring.

The role and importance of MB monitoring in Armenia is vital for ensuring biosafety in the country. The volume of experimental research on MB development and GMO use in scientific-research institutes and scientific-technological centers of Armenia is currently considerable. Some applications are already developed and are currently at the experimental and setting-up stages. Because of the lack of commercialization experience and absence of appropriate material-technical base and financial means, the biotechnologically obtained products are not being exported to international market. At the same time there is no proper control on the import of MB products and GMOs to Armenia as well. The genetic origin of the imported plants, animals, seeds, seedlings is not mentioned in corresponding certificates. The food products, including foodstuff and their supplements are not being labeled properly.

Any imported product of plant and animal origin, regardless whether it is labeled as a product of gene engineering, needs to be tested additionally for biosafety purposes. From this point the role and significance of monitoring of MB/GMOs, as well as the establishment of a relevant monitoring system is of priority need for Armenia.

Currently environmental monitoring is implemented through the SNCOs under MoNP, however they do not directly include monitoring on MB and LMOs.

Monitoring activities on LMO release and their possible adverse effects are also implemented by "Environmental Monitoring Center" SNCO and "HayPetHydroMet" SNCO. Some supervision responsibilities lay on the Water Resources Management Agency and Bioresources Management Agency, as well as on National Parks («Sevan» and «Dilijan»), reserves(Shikahogh, Khosrov) and Reserve-Park Complex SNCO (set up by their charters).

However, the supporting documentation is not fully developed yet and some necessary points are missing, e.g. genetic origin of the product. The imported food and feed products are not appropriately labeled. A testing system for imported product is lacked.

The current monitoring system is insufficient and needs to be further developed. A special attention should be paid to monitoring of the possible harmful impact of LMOs on human health. Currently only data on environmental monitoring is available.

The GMO/LMO monitoring system gaps:

- System for MB/GMOs monitoring has not been established yet
- The appropriate legislative framework is absent
- There is no structural body responsible for implementation of MB/GMOs monitoring

Some measures for improving the biosafety monitoring are required:

- Final development and adoption of the Law on LMOs.
- Establishing a system for LMO monitoring.
- Ensuring transparency of administrative as well as industrial activities (information accessibility on food, pharmaseuticals).

- Import/ export agreements between MoNP and Custom services.
- Improvement of existing monitoring services(sanitary service, veterinary service, etc.) and clarification of their responsibilities.
- Establishing laboratories for identification and investigation of MB/LMO products.

To ensure implementation of provisions of Cartagena Protocol a comprehensive monotoring system should be developed.

5. Public participation, education, awareness raising and information

Currently, there is a lot of information on modern biotechnologies, LMO and food products and feed derived from them. It includes scientific, popular-scientific, advertising and legal publications, videotapes and electronic information.

At present, information dissemination concerning modern biotechnologies and biosafety (including GMOs) is spontaneous and unstructured. Occasionally, some issues are arisen in the newspapers by concerned specialists and public organizations on the point. However, they are designed without participation of governmental officials and public sector. It proves that legislative framework for information dissemination in the field of biotechnology and biosafety is not sufficient.

According to the "Law on Mechanisms for Discussion of Public Suggestions, Applications and Complaints" of Armenia, local or public authorities are obliged to inform public of the taken measures within one month after request or within 15 days in case it needs no additional consideration. Neglecting of these provisions brings to administrative responsibility. This timeline can be extended only in case of vast constraints arisen during the consideration of the application.

According to the Aarhus Convention, the public requirements should be taken under the control and decision on requirements must be provided within two years after application.

The *Aarhus Convention*, the *Cartagena Protocol and two European Union Directives (90/219/EEC and 2001/18/EC)* as well as the documentation on GMO application of the *Codex Alimentary Commission* Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology were discussed by Committee on Environmental Policy of United Nations Economic Commission for Europe. As a result the various GMO applications were specified in details on the basis of different international documents.

Objectives of the Public Awareness and Participation Promoting

- Raise the awareness of specialists and public in the field of biosafety issues.
- Establish biosafety related information system in Armenia, that will ensure effective stakeholders and public involvement and participation in the Cartagena Protocol implementation
- Ensure the trust of the public towards the safety of application of the modern biotechnologies.

Public Awareness Mechanism

Establishment of LMO-related public awareness mechanism in Armenia is in consistence with the rights of the citizens of the country stated in the Constitution, as well as provisions of the Convention on Biological Diversity, Cartagena Protocol, Aarhus Convention and a number of international agreements ratified by the Parliament of Armenia.

The ratification of the Convention on Biological Diversity in 1993 has an objective to ensure the constitutionally stated public right to live and work in safe environment. By the ratification of the Aarhus Convention the constitutional right to be informed for any physical and legal entity has been

certified. The ratification of the Cartagena Protocol emphasized the public right not only on awareness but also on involvement within the LMO-related processes. The Parties of the protocol are obliged to:

- Support and promote public awareness, education and participation in LMOs' safe transfer, processing and use by ensuring access to relevant information.
- Consult the public on the LMO-related decision-making in the framework of existing national legislation.
- Inform the public on the mechanisms of access to biosafety information system.

To address the above-mentioned rights, the Republic of Armenia has initiated the establishment of Mechanisms for promoting and facilitating public awareness, education and participation. A public awareness mechanism based on the concept of trust is being developed within the national biosafety framework. The applicants and responsible bodies on one side and the public (including stakeholders, non-governmental organizations and individuals) on the other should attain a mutual agreement to promote such LMO-related activities that are rather safe for environment and human health. The main objective of the Public Awareness Mechanism is to ensure the full access to information on LMO-related activities for all stakeholders and public.

The Public Awareness Mechanism operates via passive and active components. The passive awareness component creates an information field to be used by stakeholder organizations and individuals. Meanwhile the active awareness component provides the information to stakeholders in mandatory manner and ensures the follow up and backward link. The means for passive awareness include but are not limited to: internet portal, LMO register, and national component of awareness mechanism, awareness raising brochures, leaflets, newspapers and magazines. The following means of active awareness are chosen: seminars, workshops, professional discussions, and educational courses, training for public servants, appropriate courses in secondary schools and higher educational institutions and publication of educational manuals.

Current Status of Public Awareness and Participation

Prior to the RA "Law on Living Modified Organisms" and RA Government Resolution on "Approving the composition and regulation of National Responsible Body for LMO-related activities" come into the force, the public awareness and participation issues are regulated by the subdivisions of the Ministry of Nature Protection.

The environmental issues of the sphere, including the public awareness on LMO release into the environment are addressed by the Agency for Bioresources Conservation of the Ministry of Nature Protection and the subdivision under its competency (the appropriate provisions exist in their operational statutes).

The public awareness and participation, including on LMO importing issues are also addressed by the "Environmental Expertise" SNCO operated under the umbrella of the Ministry of Nature Protection. The mentioned organization implements public awareness activities through mass media and promotes public participation through organization of public hearings. Some public awareness activities are conducted also by the secretary on mass media of the MNP.

The "Environmental Monitoring Center" SNCO has the awareness raising function as well. It regularly publishes periodicals and brochures on the results of monitoring. The "Information Analytical Center" SNCO of the Ministry of Nature Protection disseminates information on environment and MNP activities mainly through the Internet.

It is intended to create a permanently updateable home page, which will integrate all relevant information on LMOs and will serve as the main information dissemination mean in the sphere. The home page will constitute an integral part of Biosafety Clearing House national component and is in the process of construction. However the main works are still ahead. After the completion this system should provide the public with any new LMO-related information, excluding the information of state

secret nature. The LMO register is another source of information for stakeholders. It is in the process of development as well and will constitute a component of an overall information system.

Biosafety Clearing-House (BCH)

The Armenian Biosafety Clearing-House (BCH) is in the process of establishment. As the initial steps, the mechanisms for information maintenance and management have been identified for further setting up of the information within the BCH Internet site in order to ensure easy access for the public.
Currently the biosafety web-page is developed and placed on the web-site of the MoNP (http://www.mnpiac.am/biosafety).

The establishment of a national database on biosafety has been chosen as the primary information framework for future BCH national site. The database includes data on Armenian stakeholder organizations and individual experts working in the field of biotechnologies, biosafety, GMOs, risk assessment and risk management.

The upper level of the database is comprised of four sections, which are interlinked among each other. Each of the sections possesses a number of links to the lower level of information with contact data on institutions and professionals involved in the sphere. Contact data on the National Focal Point in the field of biosafety is presented in the first section of the database. The second section incorporates the contact data and related information on Inter-ministerial Committee and National Competent Authority. The third section represents roster of specialists and organizations dealing with biotechnologies and biosafety issues in Armenia. For each institution the following data is presented: contact information, scientific research topics related to the field, technical capacities possessed, contacts of specialists of the institution involved in the biotechnology-related activities. The fourth section describes the existing legislative framework of the country. Here one can find the quotes and links to the Laws and Government Resolutions related to the issues of biosafety and biotechnologies. The fifth section presents publications produced within the current Project. In future the database is subject to permanent revising and updating.

Labeling

A special issue is the packaging and labeling of the GMO containing products. As it is stated in the Protocol any living modified organisms that are intended for direct use as food or feed, or for processing, should be labeled and clearly identify that they "may contain" living modified organisms or their products. In this context recently are made suggestions to the Ministry of Agriculture to amend Art. 9 of RA Law “On food safety” with the following words “food obtained from the genetically modified sources which may contain more than 1% of GMOs should be labeled as “GM food” or “food obtained from GM sources”.

LMO Register

Any LMO-related activity is being recorded in the LMO register, which is considered a public document, is maintained at the Ministry of Nature Protection of Armenia and should be freely accessed for any applicant. The works towards development of the electronic version of the LMO register are currently underway. After the completion of the first version of the register its link will be submitted to biosafety clearing house through its national component.

All the LMO-related documents are recorded in the register. Along with other documents the protocols on LMO contained use and release to the environment should be included into the register containing the information on:

- Business names and registered offices on
    - contained use,
    - deliberate release into the environment, or

- placing a product on the market,

- Addresses and properties of the premise,
- Contained use and its classification,
- Deliberate releases into the environment, including an exact description of the location of release,
- Products and their placement on the market, including a description of the site in which the product is placed on the market.

The register should contain records for all the above-mentioned cases.
The form and manner of keeping the register and the manner of determining the material costs of communicating data should be specified in a separate regulation.

Mechanisms of Awareness in Emergency and Accidental Situations

- An emergency plan should be developed prior to dealing with LMOs. The information should be disseminated to the relevant structures (e.g. Sanitary, Veterinary services) and broader public.

When the emergency situation is occurred a relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism, information on the circumstances and estimated date of the release, any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures should be provided.

Existing human capacities and possibilities for education/training in the sphere

Fundamental to any national biosafety system is a strong base of scientific knowledge in support of the regulatory system and the development of core competencies in biotechnology product evaluation. The specialists of the following fields are needed in Armenia: biotechnology, including technologies of nucleic acid application; biochemistry and molecular biology; physiology; molecular genetics; genetics; taxonomy; bacteriology; immunology; allergology; ecology; virology; zoology; veterinary; entomology; botany; toxicology; forestry; standardization; risk assessment and information systems. Specialists of all the above-mentioned areas are currently available at the corresponding departments of Yerevan State University, Yerevan State Medical University after M. Heratsi, Armenian Engineering University and Armenian Agricultural Academy. Among the private higher education institutions it is worthy to mention Institute of Applied Biotechnologies and Yerevan State Medical University.

Teaching for the graduate (Masters) or post-graduate courses are conducted at the above-mentioned institutions as well as at the scientific research institutes of the National Academy of Sciences and scientific centres of the Ministries of Trade and Economic Development, Agriculture and Health. The number of specialists trained at international institutions is also high.

The main problem in this sphere is in absence of specialized training of biosafety specialists in Armenia. To overcome this problem it is necessary to complement the training of the existing specialists with teaching of younger generation. To achieve this, the support of international community, particularly the countries-Parties of Cartagena Protocol (such as Moldova, Belarus, etc.) will be beneficial.

It is also necessary to point out that specialized training course on biosafety need to be organized for all professionals on the above-mentioned specializations. This is important not only for capacity building in the field but also for strengthening cooperation among the stakeholder organizations of the field.

Existence of a roster of national experts and specialists is required for the complete resolution of the problems on biosafety in a given country.

RECOMMENDATIONS

Following the review of biosafety policies and procedures in Armenia, major recommendations of this report are summarized as follows:

1. Revise or re-issue the biosafety legislation;
2. Establish National Authorities for the NBF;
3. Institute mechanisms to disseminate information to the biotechnology community;
4. Develop a Proactive Plan for Building Public Acceptance and Education.

1. Revise or Re-issue the Biosafety Legislation

- To develop national standards taking into consideration internationally accepted norms in the sphere of biosafety and biotechnologies;
- To specify the procedure of conservation, use and safe transportation of living LMOs in governmental resolutions;
- To work out rules of import of commercial products developed from LMOs, including the issues of packing, labeling, exporting and sale. The rule should state the necessity for additional local testing procedure, for which the importer should provide product samples to relevant state bodies (inspectorates, laboratories);
- It is necessary to develop safety guidelines for application of modern biotechnologies and living LMOs intended for testing and research laboratories. The guidelines should focus on a complex of issues connected with safety measures in application of modern biotechnologies and its products. A special emphasis should be made on conditions of conservation and storage of biotechnology products, methods of waste processing and neutralization.
- The NBF should take the lead in revising the current Biosafety Regulations and legislation or in drafting NBF Guidelines, which would replace the existing document. New guidelines should describe the purpose and objectives of biosafety review and how it fits into the larger scheme of sustainable development. Procedural and facility requirements for laboratory, greenhouse, or field research should be either comprehensively described or, more practically, provided through reference to other documents.
- More detailed descriptions should be provided of the types of information to submit with applications; (instructions, sample application forms, and contact information should be provided).
- Careful decisions should be made on the new legislation, how to ensure compliance, and if deemed appropriate, what sanctions could be imposed on institutions not in compliance. Consideration should be given to formally informing the National Authorities prior to starting any genetic engineering research. All institutes, organizations, and private companies that are or are likely to work with agricultural GMOs should be informed about the biosafety system, its operations and approval procedures. A simple package of documents and ancillary information could be assembled for this purpose.

2. Establish National Authorities for the NBF

- The ***National Authorities*** should be instituted to manage administrative matters for the NBF. They would serve as an information resource to the members, individual scientists, and potential domestic and foreign stakeholders. It would establish a means to disseminate information and promote cooperation with other national or international biosafety organizations and initiatives. It would accept and process applications, coordinate reviews, keep written records, and maintain a database of applications received and their status. They would set up and maintain a Website that carries all relevant documents, forms and instructions in a downloadable format.
- All parties – academic and government scientific organizations, the local private sector, multinational companies – should be made aware of the NBF and its role in LMO research and product development, as well as requirements for compliance with the guidelines.

3. Institute Mechanisms to Disseminate Information to the Biotechnology Community

- Sound biosafety decision making, particularly regarding commercial releases of LMOs, can be seriously hampered by a lack of scientific knowledge. Priority areas for risk assessment studies targeted to Armenian conditions should be identified.
- To facilitate planning and procedural transparency, realistic time limitations for application review and decision making should be specified.
- National or private laboratories appropriate for certifying molecular and food and feed safety data should be identified. Qualified laboratory staff should have the capacity to work at the level of internationally accepted standards.

4. Develop a Proactive Plan for Building Public Awareness and Education

- The public holds the fate of biotechnology in its willingness or refusal to accept products produced through genetic engineering. Thus it is essential to organize a campaign to inform the public about all aspects of biotechnology. The communications effort should be based on recognition that the public is a full partner in deciding if, when, and how the technology is to be used. The first step is to develop a strategy for building public awareness and acceptance, preferably before misinformation from other sources takes root in public opinion.
- Science editors and TV broadcasters need to be educated. Editors not only transfer the ideas of scientists, but also act as filters of that information. It is essential that these communicators understand basic science and are educated about biotechnology. Although some efforts have been undertaken in 1999 with support from UNEP, these should be repeated periodically.
- Labeling of LMO-derived foods is gradually gaining wider acceptance worldwide, and is viewed by many as inevitable. Authorities should begin now to plan how labeling will be handled in Armenia.
- Development of core competencies for risk assessment within government departments and agencies.
- Concentrating the risk-assessment function within a single identifiable body, distributing this function among different government departments and ministries.

Annex 1

Members of National Coordinating Committee

N	Name	Position
1	Vardan Ayvazyan	Minister of Nature Protection of the RA, Chairman of NCC
2	Simon Papyan	First Deputy Minister of the Ministry of Nature Protection of the RA, Deputy Chairman of NCC
3	Artashes Ziroyan	Head of Bioresources Management Agency of the Ministry of Nature Protection of the RA, National Project Coordinator, Secretary of NCC
4	Tatyana Danielyan	Focal Point for CBD, Head of Biodiversity & Water Protection Division of the MoNP of the RA
5	Grigor Gyulkhandanyan	Scientific Research Institute of Biotechnology, Head of Laboratory of Enzymology
6	Aram Ter-Zakaryan	Ministry of Nature Protection of the RA, Head of International Cooperation Department
7	Amal Medany	UNDP, Deputy Resident Representative
8	Vardan Sahradyan	Ministry of Finances and Economy of the RA, Senior Specialist
9	Mikael Gyulkhasyan	Ministry of Science and Education, Armenian Agricultural Academy, Head of Plant Industry and Vegetable Growing Department
10	Ashot Khandanyan	Ministry of Trade and Economic Development of the RA, Head of Department
11	Levon Rukhkyan	Ministry of Agriculture of the RA, Deputy Minister
12	Ashot Charchoghlyan	Institute of Botany of the National Academy of Sciences of the RA, Director
13	Sergey Movsisyan	Institute of Zoology of the National Academy of Sciences of the RA, Director
14	Avetis Hayrapetyan	"Association of AgroEcologists of Armenia" NGO, Chairman
15	Lia Osipyan	Yerevan State University, Faculty of Biology, Chair of Botany, Chairperson
16	Kim Abelyan	Director of the Center of Cattle-Breeding and Veterinary
17	Volodya Abrahamyan	Armenian Agricultural Academy, Chair of Cattle-Breeding and Veterinary, Chairperson

RA Laws and Resolutions Related to Biosafety

	Name of Law	***In Force***
1.	Constitution of RA	July 5, 1995
2.	Principles of Legislation on Nature Protection of RA	July 29, 1991
3.	Law on Environmental Impact Assessment	April 3, 2000
4.	Law on Fauna	March 16, 2000
5.	Law on Flora	November 23, 1999
6.	Law on Protection and Quarantine of Plants	March 20, 1999
7.	Law on Environmental Education	November 20, 2001
8.	Law on Activities of State Agricultural Inspection	May 15, 1996
9.	Law on Protection of Population in Emergency Cases	December 29, 1998
10.	Law on Protection of Selection Achievements	November 23, 1999
11.	Law on Protection of Consumers' Rights	June 26, 2001
12.	Law on Advertisement	April 30,1996
13.	Law on Transport	February 3,1998
14.	RA Criminal Code	April 18, 2003
15.	Law on State and Administrative Secret	December 3,1996
16.	Law on Medical Help and Support to Population	March 4, 1996
17.	Law on Veterinary	October 26, 1999
18.	Law on Food Security	December 8, 1999
19.	Law on Standardization	June 19, 2004
20.	Law on Conformity Assessment	June 19, 2004
21.	Law on Licensing	June 27, 2001
22.	Law on Civil Service	December 12, 2001
23.	Agreement «On Implementing of Sanitary and Phytosanitary Measures»	February 5, 2003
24.	RA Government resolution No 15 on "Obligatory Certification of Products and Services in RA"	May 12, 2000
25.	RA Government resolution No 595 on "Establishment of principal rules of wholesale trade"	December 19, 1997
26.	RA Government resolution No 238 "On Accreditation of certification bodies and testing laboratories"	May 12, 2000
27.	Resolution of RA Prime-Minister, No 91 on "Ratification of the agreement between the Ministry of Agriculture and International Center for Agricultural Research in the Dry Arias (ICARDA)"	March 8, 2000
28.	Inter-institutional agreement on "Cooperation between the Ministry of Agriculture and International Center of Agricultural Research in the spheres of Dry-zones and Agricultural Science (ICARDA)"	September 16, 1999.
29.	RA Government resolution No 621 on "Approving the regulation on VAT-free import of Potato, Barley and Spelt Seeds into Armenia".	May 25, 2002
30.	Decree of the Minister of Agriculture No 389 on "Improvement of Import Procedure Measures of Agricultural Crop-Stuff, Plant and Plant Stuff".	December 17, 1998
31.	Draft Law "On Seed-Growing"	2002

Annex 3

Stakeholder Organizations

- Ministry of Nature Protection of RA
- Ministry of Agriculture of RA
- Ministry of Finance and Economy of RA
- Ministry of Health of RA
- Ministry of Trade and Economic Development of RA
- Ministry of Education and Science of RA
- National Security Service of RA
- State Customs Committee of RA
- National Academy of Science of RA
- NGOs
- Mass - Media
- Farmers households

Annex 4

Composition of Inter-ministerial Commission

1. Ministry of Nature Protection of RA (3 persons)
2. Ministry of Agriculture of RA (2 persons)
3. Ministry of Finance and Economy of RA (1 person)
4. Ministry of Health of RA (2 persons)
5. Ministry of Trade and Economic Development of RA (1 persons)
6. Ministry of Education and Science of RA (1 person)
7. National Security Service of RA (1 person)
8. State Customs Committee of RA (1 person)
9. National Academy of Science of RA (2 person)
10. NGOs (2 persons)
11. Armenian Apostolic Church (1 person)

Annex 5

Composition Of Expert Commitee

Ministry of Nature Protection of RA (1 person)

Armenian Agricultural Academy (1 person)

Ministry of Agriculture of RA (1 persons)

Institute of Zoology, NAS of RA (1 person)

Institute of Botany, NAS of RA (1 person)

Institute of Microbiology, NAS of RA (1 person)

Institute of Biotechnologies (1 person)

National Academy of Science of RA (1 person)

Yerevan State University (1 person)

Annex 6

Draft

Concept on RA Law

«On Living Modified Organisms»

Introduction

Developing the draft RA Law "On Living Modified Organisms" /furthermore Law/ is aimed at regulating the safe application of LMOs, such as processes of development, handling, transport, use, transfer, release and disposal.

Any living organism containing new genetic material obtained by the methods of gene engineering is a subject to legislative regulation in the cases of development, handling, contaminated use, import, export, transfer, release.

Considering the social-economic benefits of LMO application and aimed at minimization of possible adverse effects on human health, biodiversity conservation and sustainable use, the Law shall assign the regulatory framework for biosafety management, LMOs application and information provision.

Pursuant to provisions of RA legislation, particularly to RA Law «On Legal Acts» the draft Law shall state the subject, goals and objectives, spheres of activities, principles, rights, obligations and responsibilities of the state and local authorities, public and private sector, as well as other judicial and physical persons, dealing with LMO application, restrictions and requirements, avoiding dual character of Articles and provisions of the Law.

General principles

1. The procedures on living modified organisms' development, handling, contained use, transfer and disposal, as well as information provision should be aimed at ensuring implementation of requirements of RA legislation, including international agreements;
2. The Law should ensure simplicity, transparency, legality of the relations subject to regulation and their equal rights;
3. The requirements and restrictions stated by Law should be justified, clearly defined and applicable;
4. The Law should state efficient and flexible tools and mechanisms of biosafety state management, ensuring safety for environment and human health, biodiversity conservation and sustainable use;
5. The law should assign:
   - Requirement, conditions, restrictions and peculiarities of LMO developing, handling, contained use, transfer and disposal;
   - Special tools and conditions for LMO contained use;
   - Restrictions on illegal transboundary transfer and requirements for disposal;
   - Requirements on mandatory licensing and expertise for the gene engineering agents;

- Norms and regulations on introducing reporting systems for LMO developing, handling, contained use, transfer and disposal;
- Requirements on LMO registers maintenance;
- Mandatory conditions and requirements for LMO monitoring;
- Requirements on scientific testing;
- Mandatory requirement on quality conformance certificate for LMO products;
- Mandatory certification for agencies dealing with scientific testing of LMO;
- Mandatory requirement of state environmental expertise and environmental impact assessment of LMOs;
- Mandatory norms and mechanisms for public awareness and information provision;
- Requirements on establishing national focal point, national authorities and expert committee to ensure procedures of prior informed agreement;

6. The Law should assign principles of economical regulation of biosafety framework, as well as state financial and compensation mechanisms to regulate activities on LMOs (developing, handling, contained use, transfer, etc) ;
7. The Law should assign requirements and forms of penalties for infringement rules set up in biosafety purposes;
8. The Law should assign norms and rules for monitoring and supervision of implementation of legislation requirements.

II. The structure of the Law

1. Subject

The subject of the Law is to set up biosafety issues, requirements and rules on developing, handling, contained use, transfer or disposal of living modified organisms and their products for food, feed, to clarify the rights, obligations and relationship of the entities subject to regulation, as well as responsibilities for violation of biosafety requirements.

2. Use of terms

For the purposes of the Law the following terms should be described – biodiversity, biosafety, living organism, living modified organism, genetic resources, modern technology, etc.

3. Scope of Law

The Law shall apply to the state and local authorities, organizations, judicial and physical persons (including international), private and public sector

The Law shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations.

4. Legislation

The system of by-laws for enforcement of the current Law should be set in the Law.

5. Objectives, goals and principles of biosafety

5.1.Goals

Safe application of living organisms obtained by the methods of gene engineering – developing, handling, application, contained use, transfer (transport, disposal), with main emphasize on transboundary transfer, with possible harmful impact on biodiversity conservation and sustainable use, as well as negative impact to human health.

5.2. Objectives

- Application of safe mechanisms of LMOs application;
- Decision making on convenience of living modified organisms;
- Prohibiting application of any living modified organisms negatively impacting environment or human health;
- Implementing expertise and risk assessment on possible negative impact on environment and human health, based on investigation of LMOs information and/or testing;
- Application of relevant permits mechanisms for LMOs use, based on risk assessment;
- Ensuring the process of advance imformed agreement aimed at ensuring biosafety;
- Licensing for the gene engineering agents;
- Ensuring conditions for application of reporting systems, data bases and monitoring on living modified organisms;
- Ensuring activities of authorized institutions (labs) dealing with quality conformity and scientific testing for the products – result of LMO application;
- Ensuring state environmental inspection and impact assessment for LMO application;
- Ensuring public and customers awareness on biosafety, information provision and dissemination;
- Ensuring requirements and conditions for confidential information on LMO application;
- Ensuring monitoring and supervision of norms and requirements for LMO application;
- International cooperation.

5.3. Principles

The principles are set up as follows:

- Biodiversity conservation, given the benefits for current and future generations;
- Normative documents for restrictions and requirements of the LMO utilization;
- comprehensive and scientifically justified risk assessment for possible adverse effect on environment and human health, based on solid indicators for assessment;
- Participation of authorized scientific organizations and labs, expert scientists, national authorities and national focal point and general public in decision making process for living modified organisms;
- Objectivity, legality, transparency, publicity of decisions on utilization of living modified organisms (granting permits or prohibitions);
- Establishing responsibilities of all participants in decision making process on utilization of living modified organisms;
- The financial and material prerequisites for implementing measures on safe utilization of living modified organisms.

Precautionary principle should be applied and the measures should include:

- Sufficient scientific information and appropriate executive training of the specialists dealing with the organisms;
- Control measures that should be applied so that it could be possible to apply appropriate measures in the case of organism release followed by further unpredictable consequences;
- Released organisms and their genes flow control;
- Control of the entrance into the areas where organisms are released.

As regards the socio-economic considerations it will be very hard to control activities of small farmers, but surely they should be legally restricted if the LMO impact is assessed.

6. The rights, obligations and relationship of the entities subject to regulation

The responsibilities and obligations of the following structures will be assigned by Law:

- RA Government
- Inter-ministerial Commission
- National Competent Authority
- National Focal Point
- Expert Committee
- Local Authorities
- Other state management bodies
- Research and scientific institutions
- Judicial and physical persons and private sector
- Public sector

The Law will also assign liabilities of the state and local authorities in the fields of healthcare, agriculture, trade and economical development, spatial management and custom services, considering liabilities assigned by Laws and by-laws of RA.
The Expert Committee will be instituted to implement activities on LMOs risk assessment, testing, application of biotechnologies or introduction of new ones, providing expert recommendations.
The Law should also envisage articles and provisions to regulate relations between the national focal point, state and local authorities, national authorities, expert committee, scientific institutions, judicial and physical persons, public and private sectors.

7. Regulation of the biosafety framework

The Law should assign requirements, norms, rules and procedures for developing, handling, application, contained use, disposal, transfer (including transboundary), labeling, packaging and coding, as well as licensing of gene engineering activity, expertise, handling notifications and decision making, reporting, monitoring, maintenance of registers and data bases, public awareness and information provision.

8. Economic incentives and financing mechanisms

Should assign:

8.1. Principles of economic regulation of biosafety framework;

8.2. The Law should assign principles of economical regulation of biosafety framework, as well as state financial and compensation mechanisms to regulate government measures on LMOs (developing, handling, contained use, transfer, etc). The regulation should cover also establishing taxation system aimed at compensation of state allocations:

- Permits for developing, handling, application, transfer of living modified organisms;
- Licensing gene engineering activities;
- Provision of results of scientific investigations/ tests;
- Procedures for compensation of damages caused to state, civil society (including environment), judicial and physical persons, conditioned by LMO developing, handling, contained use, transfer, etc;
- Relevant financial mechanisms for damage rehabilitation (trade, environmental, insurance funds, etc.).

9. Monitoring and supervision

The chapter should state the authorities responsible for Monitoring and Supervision of implementation of the requirements of the Law, cases of administrative transgressions, forms of responsibilities and settling disputes.

10. Transitional provisions

Should assign the dates for enforcing some norms and provisions in transition, as well as requirements to changes and amendments in the Law, if any.

11. Final provisions

The Chapter should assign the provisions on adopting and regulating by-laws aimed at enforcing the Law.

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