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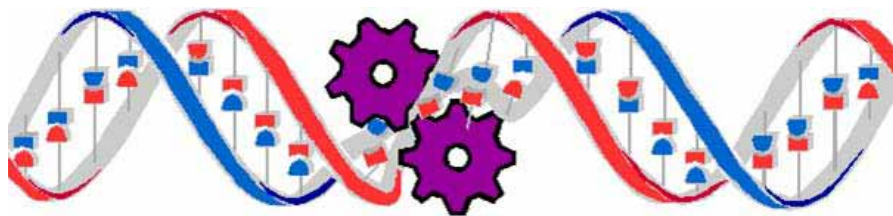
UNEP/GEF Project “Development of National Biosafety Framework”



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# DRAFT NATIONAL BIOSAFETY FRAMEWORK FOR REPUBLIC OF MACEDONIA



Skopje, February 2005

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## **INTRODUCTION TO THE NATIONAL BIOSAFETY FRAMEWORK**

UNEP/GEF Project on Development of National Biosafety Frameworks in the Republic of Macedonia started on April 1, 2003 and lasted until February 28, 2005.

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**FOREWORD**

Techniques of modern biotechnology are viewed by many scientists as a new and promising tool for crop improvement and novel uses of plants, animals, and microorganisms. Concerns about the safety of GMO's to human health and the environment, however, moderate the rate of GMO product development and deployment. National biosafety systems are intended to serve as mechanisms for ensuring the safe use of biotechnology products without imposing unacceptable risk to human health or the environment, or unintended constraints to technology transfer. However, establishing a system for biosafety review has many facets and associated challenges, and, apart from defining national guidelines, will require investments in people responsible for implementing and managing the system. The need to build national systems for risk assessment and national biosafety frameworks is one of the priorities emerging from the Convention on Biological Diversity. The strive to apply biotechnology safely has led countries to agree on measures that ensure the safe handling and use of living modified organisms (LMO's). Measures designed to prevent adverse effects of LMO's on human health and biodiversity are laid out in a supplementary agreement to the Convention on Biological Diversity. This agreement, known as the Cartagena Protocol on Biosafety, includes articles stating that parties should cooperate in developing and strengthening human resources and institutional capacity in biosafety.

The Protocol sets out a comprehensive regulatory system for ensuring the safe transfer, handling and use of GMO's subject to transboundary movement, in which way it seeks to meet the consumers need, the industry and the environment for many decades to come. With purpose to promote the biosafety, the Protocol reflects a fundamental concept known as the precautionary approach.

In respect of the above, the support in form of the UNEP/GEF project "Development of National Biosafety Framework for the Republic of Macedonia" was extremely valuable for producing an initial document that reflects the current status of biotechnology, as well, as the strategy for establishment of the biosafety system in our country.

As such, this document will serve as a basic guide for the implementation of the regulatory biosafety system. The involvement of different ministries and several stakeholders in the preparation of this document ensures that different views were taken into account when developing effective and efficient system to enable safe use of GMO's in the Republic of Macedonia.

**Zoran Shapurik**  
**Minister of Environment and Physical Planning**

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**MEANING OF ABBREVIATIONS**

<b>BCH</b>	Biosafety Clearing House
<b>CDS</b>	Catalogue of Data Sources
<b>GDP</b>	Gross Domestic Product
<b>GEF</b>	Global Environment Facility
<b>GMO</b>	Genetically Modified Organism
<b>GTZ</b>	German Technical Cooperation / GTZ, Deutsche Gesellschaft fur Technische Zusammenarbeit, GmbH
<b>EU</b>	European Union
<b>EPPO</b>	European Plant Protection Organization
<b>FAO</b>	UN Food and Agriculture Organization
<b>HACCP</b>	Hazard Analysis and Critical Control Points in Production
<b>ISTA</b>	International Seed Testing Association
<b>ICGEB-MASA</b>	Research Center of Genetic Engineering and Biotechnology-Macedonian Academy of Sciences and Arts
<b>IAEA</b>	International Atomic Energy Agency
<b>IPGRI</b>	International Plant Genetic Resources Institute
<b>IPPC</b>	International Plant Protection Convention
<b>JICA</b>	Japanese International Cooperation Agency
<b>LMO</b>	Living Modified Organisms
<b>MAFWE</b>	Ministry of Agriculture, Forestry and Water Economy
<b>NBF</b>	National Biosafety Framework
<b>NCC</b>	National Coordinating Committee
<b>NEAP II</b>	National Environmental Action Plan II
<b>NGO</b>	Non Governmental Organization
<b>OSTS</b>	Official Seed Testing Station
<b>REReP</b>	Regional Environmental Reconstruction Program for Southeastern Europe
<b>SPS</b>	Sanitary and Phyto-sanitary Agreement
<b>SAA</b>	Stabilization and Association Agreement (between Macedonia and EU)
<b>SIDA</b>	Sweden International Development Agency
<b>TBT</b>	Technical Barriers to Trade Agreement
<b>UNEP</b>	United Nations Environment Program
<b>WTO</b>	World Trade Organization
<b>WHO</b>	World Health Organization

## **1. INTRODUCTION TO BIOSAFETY**

Genetically modified crops represent an important new technology which ought to have the potential to do much good in the world provided that proper safeguards are maintained or introduced. All those who are involved in developing the new technology, whether they are researchers in the public sector, in agrochemical or agricultural businesses or farmers, or food manufacturers and retailers need to recognise and accept a very broad responsibility to the public. They need to ensure that ethical concerns are taken account of, that their new technologies and products are safe for human consumption and avoid further harm to the environment, that the potential of GM technology is harnessed to meet the most urgent food needs of as well as commercial benefit, that impartial information is made widely available to the public and that consumer choice is fully respected.

The rapid development of the biotechnology over the past few decades has initiated a development of relevant legal biosafety frameworks. On the one hand the National Biosafety Framework is to ensure an adequate level of protection of human health and the environment from possible adverse effects resulting from the products of modern biotechnology, and on the other hand to provide a basis for public confidence and for legal certainty for research organizations and industry.

Biosafety Protocol constitutes an important treaty by providing a regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing biotechnology industry. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol contains reference to a precautionary approach and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a Biosafety Clearing-House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol. The range from ethical considerations to potential risks to human health and the environment, and encompass also a number of socio-economic issues. A vigorous debate is taking place addressed on potential risks and benefits of genetic modification. In the field such as the safe transfer, handling and use of genetically modified organisms in the environment and in foodstuffs, it is obligatory to take a rational precautionary approach. The release of GM plants into the environment and of GM material into the human food chain should be the subject to regulatory regimes, so that products and releases are carefully assessed before consents are given.

In regard to all this issues the form of a national biosafety framework is enforcing the principle of a precautionary response. Precautionary response should be based on the public opinion, which explains an actual understanding of the ethical considerations that underpin the welfare of society, combined with science and technology based knowledge and internationally approved risk assessment procedures. Therefore a framework must include access to and exchange of information at international and national levels.

Acknowledging the significance of the modern biotechnology and biosafety, the Republic of Macedonia has signed the Cartagena Protocol on Biosafety in 2000, and the process of its ratification is underway.

Introduction of a biosafety regulations in the Republic of Macedonia are essential to public trust. As concerns about the safety of biotechnology and its products continue to be raised worldwide, it becomes increasingly important that the Macedonian public feel confident in the effectiveness of their national biosafety regulations.

In future the Republic of Macedonia should be more aware of the importance of public education and should raise public awareness of the biotechnology benefits and risks and how the biosafety system operates to ensure the safe use of GMO's.

## **2. BIOSAFETY POLICY**

### **2.1. Review of the current situation regarding the biosafety**

The space setting and humanization, the environment and nature protection and promotion are the basic values for the Republic of Macedonia defined by the Constitution. The Constitution, adopted by the Parliament at the end of 1991, places the environment protection and promotion among the fundamental values.

The Republic of Macedonia has not defined a policy on GMO management so far. There is no particular legal act to regulate the biosafety issues. The National Biosafety vision is in an initial phase, presenting only a segment of other strategies, such as: environment protection, biodiversity conservation, and food safety.

*The policy on environment protection* is based on the Law on Environment and Nature Protection and Promotion (see item 2.1 of the Regulatory System). The Ministry of Environment and Physical Planning, in the efforts to develop and implement efficient policy on environment, is lead by "driving forces" that may be grouped in two categories:

- The Republic of Macedonia is actively included in the ministerial process "Environment for Europe". As part of this process, the Government has prepared and adopted the National Environmental Action Plan (NEAP), as a main strategy for environment protection. Having in mind the undergoing systematic changes - the process of decentralization and approximation to the EU, the NEAP shall be revised and harmonized with the current situation;
- The Republic of Macedonia and the European Community signed an Association and Stabilization Agreement on 12 April 2001, which obliges the country to harmonize the environmental legislation with the EU normatives. In that direction, the Government of the Republic of Macedonia has adopted a Programme on approximation of the national legislation to the EU legislation. Chapter 22 of the Programme (Environment) envisages adoption of a special Law on Genetically Modified Organisms until 2007. (see the Chapter Regulatory Regime – Future Plans).

The Republic of Macedonia has accessed the *Convention on Biodiversity* with the adoption of the Law on Ratification (Official Gazette of RM no. 54/97). The Law entered into force on 2 March 1998. The Ministry of Environment and Physical Planning, in cooperation with the other competent bodies in the country, is the responsible body for implementation of the Convention in the Republic of Macedonia. The Republic of Macedonia signed the Cartagena Protocol on 26 July 2000, and started the procedure on its ratification. *The National Strategy and Action Plan on biodiversity conservation and sustainable use* (NBSAP) was adopted in January 2004. The main objective of this document is to protect the biodiversity and provide for its sustainable use. The chapter on legislation within the frames of the Action Plan (general objective 9, strategic principle 12) envisages adoption of a special Law on GMO and ratification of the Cartagena Protocol on Biosafety by the Parliament of the Republic of Macedonia.

Irrespective to the adoption of the Law on Food (Law on Safety of Food and Products and Materials getting in contact with the Food - Official Gazette of RM no. 54/2002), there is still no system on *food safety* in the country regarding the presence of GMO. A Direction on Food was established in accordance with this Law. Currently, the system on control of the food is based on the existing inspection services and laboratories, which are not accredited. The State Health Administration in Skopje and the Veterinary Institute, in cooperation with the inspection services, monitor the safety of the food imported in the Republic of Macedonia, but do not carry out analysis on the presence of genetically modified organisms.

The membership in WTO is preconditioned by the harmonization of the sanitary and phytosanitary measures with the international standards. This prescribes supplementing and amending of the respective laws and procedures on harmonization with the international conventions applied in the

field of veterinary protection (OIE - Office International des'Epizooties), phytosanitary systems (International Convention on Plant Protection) and safety of food (the Alimentarius Codex).

Currently, the Strategy of the Aarhus Convention Implementation in the Republic of Macedonia is under preparation. It is considered that the public awareness on the biotechnology and biosafety in the Republic of Macedonia is on a very low level. The public shall be accurately informed on the use and trade of products containing genetically modified organisms and the possible risks occurring as a result of it. A Programme on public participation in the process of decision-making on biosafety needs to be adopted.

There are several documents that define particular aspects of the strategic environmental development:

- The Parliament of the Republic of Macedonia adopted the Spatial Plan of the Republic of Macedonia in 2004. The Spatial Plan presents the basis for organization, setting, use and protection of the space of the Republic of Macedonia, with a time frame of 20 years;

- The Republic of Macedonia is in a phase of preparation of a National Strategy on Sustainable Development with an Action Plan as one of the priorities of the Government, in accordance with the National Strategy on Integration of the Republic of Macedonia in the EU.

## 2.2. Future needs and priorities

Republic of Macedonia is recognizing biosafety as an important area, which is also proven by the commitment of ratifying Cartagena, and setting up the national regulatory framework as well.

The integration on biosafety system into other (non-environmental) sectors such as: health, agriculture, food and feed, R&D and industry, is of great importance for development of functional mechanism for operation on the biosafety legislation. For that purpose the establishment of the interministerial Working Group for harmonization of the legislation in accordance to the EU Directives, is the first step to achieve the integration of biosafety issues in all significant sectors.

The development of National Biosafety Frameworks is of great significance for the Republic of Macedonia, since it shall enable setting of the basis of the biosafety system.

The Republic of Macedonia is in a starting phase of establishing legal and administrative system on biosafety, which shall set the mechanism of making decisions on safe transfer, handling and use of genetically modified organisms (GMO).

The main elements of the National Biosafety Framework (NBF) shall be:

- regulatory system
- administrative system
- decision-making system, which shall include risk assessment and risk management
- mechanism of public participation and informing, which shall include public consultations during the process of decision making on GMO.

The development of intersectoral cooperation for practical implementation of the legislation to regulate the biotechnology and biosafety in the future is of particular interest for the Republic of Macedonia. In that direction, the stress is put on the process of strengthening the institutional capacities through a programme supported by the EU. The support of the UNEP/GEF through the Project on Development of National Biosafety Frameworks is of great significance for the Republic of Macedonia, which shall enable starting a process of creation of national biosafety system. The strives for biosafety system functionality are also a hope for support of the next phase of the National Biosafety Framework implementation, in order to meet the needs of the country.

The priority needs of infrastructure development include development of national research institutions and provision of finances for operational functioning of the scientific Committees, industry, legal entities and other relevant stakeholders in the biosafety system. Steps shall be undertaken in the future for enriching the programme for the scientific personnel through appropriate educational programmes and scientific-research projects, and continuous staff education as well.

### **3. REGULATORY SYSTEM**

#### **3.1. Current Situation of the Biosafety Regulatory System in Macedonia**

The Republic of Macedonia has still not created a regulatory system for implementing procedures for genetically modified organisms (GMO's) yet. There is no specific law regulating issues concerning import, export, marketing, usage and production of GMO's and GMO products.

According to the Book of Regulations of the Working Committee on European Integration, and the Decision on establishing working groups on harmonization of the RM legislation with the *acquis communautaire* (adopted on 31 March 2004), the Government of the Republic of Macedonia has made a Decision on establishing working groups, part of which is the Working Group on Environment. A *sub-group on chemicals and genetically modified organisms - 22G* is established in the frames of the Working Group on Environment. According to the plan for work, the objective of this working sub-group is to prepare a Law on Genetically Modified Organisms in compliance with the EU Directives in the period until 2007. The members of WG's are appointed in a manner that provides optimal balance of all the parties concerned. The members of the WG's were nominated upon an official request by the MOEPP, based on a proposal of the other concerned ministries, government institutions, the local self-government units, high-educational institutions, NGO, business sector and the Chamber of Commerce of the Republic of Macedonia and other organizations.

Within the frames of the UNEP/GEF Project on Development of National Biosafety Frameworks, a need was ascertained for preparation of Law on GMO, which is at the moment in a form of Draft Version. The Draft Version is enclosed in Annex 1 of this document.

Several Laws in the Republic of Macedonia regulate the GMO issues, in a direct or indirect manner.

##### **3.1.1. LAWS IN ENVIRONMENT PROTECTION AREA**

###### ***Law on Environment and Nature Protection and Promotion***

**Status:** (Official Gazette of RM No. 69/96, 13/99, 51/00, 45/02 and 13/03) (clear text)

**Summary:** The Law shall regulate the rights and obligations of the Republic of Macedonia and the legal entities and physical persons, in providing conditions for environment and nature protection and promotion, with an objective of implementing the citizens' right to a healthy environment.

**Relation to GMO's:** There are no specific Articles in the Law concerning the genetically modified organisms. Nevertheless, Article 7 defines that the data on the environment and nature quality and cases of endangering shall be public. Accordingly, the Ministry shall inform, in accordance with the consumers' right to information, on the impact of the products and services on the environment and human health by means of instruction given with the product, underlined on the wrappings or in other appropriate manner.

**Competent authority:** Ministry of Environment and Physical Planning

###### ***Law on Environment***

**Status:** (The Law is in parliamentary procedure and is expected to be adopted by the end of 2004)

**Summary:** The Law on Environment is a General Act covering common issues regulated by the particular laws on certain media of the environment and waste management.

**Relation to GMO's:** The Chapter on Access to Environmental Information provides that: "*every person, without proving his/her interest, has the right to access to information on the environment in written, visual, audio, electronic or any other accessible form, regarding the media conditions and environment areas such as the air and atmosphere, water, soil, biological and regional diversity including genetically modified organisms as well as mutual interaction of these elements*".

**Competent authority:** Ministry of Environment and Physical Planning

***Law on Nature Protection*****Status:** (Official Gazette of RM No. 67/04)**Summary:** The Law shall regulate the nature protection through protection of the biological and regional diversity and protection of the biological heritage in the protected areas.**Relation to GMO's:** Measures and activities envisaged by Law shall be undertaken to prevent the negative impact of the genetically modified organisms on conservation and sustainable use of the biologic diversity, human health and the environment, respectively all issues shall be regulated with a special law on GMO's.**Competent authority:** Ministry of Environment and Physical Planning**3.1.2. LAWS IN THE AGRICULTURAL SECTOR*****Law on Plant Protection*****Status:** (Official Gazette of RM No. 25/98-1446, 6/00-225)**Summary:** The Law shall regulate the plant protection against diseases, pests and weeds; the health control of plants in internal and transboundary trade; the production, trade and use of resources for plant protection; the equipment and measures for preventing the harmful impact of the use of plant protection resources on the human health and animals; and the environment and nature protection.**Relation to GMO's:** There are no specific regulations in the Law concerning the genetically modified organisms. Nevertheless, it shall regulate the regular monitoring of their occurrence and distribution, keeping records, taking protection measures, preventing and eliminating diseases, pests and weeds, exchange of information and informing the relevant international and regional institutions. The Law shall also regulate the health control of plants in internal trade and transboundary trade in respect of providing conditions for control and implementation of the standard principles of control of plants and plant products packages. The Law shall also regulate the trade and use of resources for plant protection, the equipment and measures for preventing the harmful impact of their use on the human health and animals, and environment and nature protection. There is a special regulation on conditions of approving resources for plant protection concerning efficiency for certain purpose, phyto-toxicity, toxic and eco-toxic impacts, containments, labeling, their proper application, storage and destruction of the resources and wrappings used.**Competent authority:** Ministry of Agriculture, Forestry and Water Economy***Law on Stockbreeding*****Status:** (Official Gazette of RM No. 61/97)**Summary:** The Law shall regulate the breeding and trade of oxes, sheep, goats, pigs, horses, poultry, martens and other livestock of economic importance, obtaining livestock products, obtaining and trade in seeds and embryos, production of and trade in fodder and other issues related to the stockbreeding.**Relation to GMO's:** The Conservation on genetic values of autochthonous stock breeds and their preservation in native forms shall be a responsibility of the institution selected by the Minister of Agriculture, Forestry and Water Economy, meeting the following conditions: creating new breeds and hybrids of domestic animals by applying recognized and adopted scientific methods. The Minister of Agriculture, Forestry and Water Economy shall carry out recognition of new breeds and hybrids of domestic animals, under suggestion by relevant Commission and based on the results from previous researches. The Minister of Agriculture, Forestry and Water Economy shall issue a Permit on importing heads of breeding stock of new species, breeds and hybrids in the Republic of Macedonia.**Competent authority:** Ministry of Agriculture, Forestry and Water Economy***Law on Veterinary Health*****Status:** (Official Gazette of RM No. 28/98)**Summary:** The Law shall regulate the animal health protection against diseases, protection against contagious diseases being transmitted from animals to humans, veterinary-sanitary examination and control, veterinary protection and improvement of the environment and nature, minimal obligatory

scope of animal health protection against diseases, reimbursements and costs for animal health protection, organizing and implementing veterinary-health practice and other issues in the area of veterinary health. During the import, export and transit, the shipments shall have regulated international veterinary certificate, confirming: the origin, shipment identity, destination, registry number of the transport vehicle and shipment health condition (good condition) unless otherwise regulated by international agreement. The import of products of animal origin, which are not produced in export facilities registered by the competent authority of the export country, shall be prohibited.

**Competent authority:** Ministry of Agriculture, Forestry and Water Economy

#### ***Law on Hunting***

**Status:** (Official Gazette of RM No. 20/96-613, 26/96-841, 34/97-1405)

**Summary:** The Law shall regulate the raising, breeding, protection, hunting and use of game (hunting). Entering new non-autochthonous game species in the hunting ground shall be possible on an approval of the Ministry of Agriculture, Forestry and Water Economy, upon prior delivery of expert documentation from a scientific institution, selected by the Minister of Agriculture, Forestry and Water Economy.

**Competent authority:** Ministry of Agriculture, Forestry and Water Economy

#### ***Law on Forests***

**Status:** (Official Gazette of RM No. 47/97, 7/00)

**Summary:** The Law shall regulate the cultivation, use and protection of forests. The Government of the Republic of Macedonia shall specify the forests for special purposes, except for the national parks which are specified by Law. The forests for special purposes shall be specified upon a request of the interested subjects on the basis of expert-technical documentation on the purpose, need and justification of its determination. An Article of the Act on Specifying Forest for Special Purposes shall define the purpose, regime of cultivation, protection of forests, and legal entities to cultivate and protect the forests for special purposes. The entities operating with forests shall undertake measures for forest protection against fires, elementary disasters, plant diseases, harmful pests, illegal utilization and other damages.

**Competent authority:** Ministry of Agriculture, Forestry and Water Economy

#### ***Law on Seed Material, Planting Material and Material for Breeding, Recognizing, Approving and Protecting of Varieties***

**Status:** (Official Gazette of RM No. 41/00)

**Summary:** The Law shall regulate the production, finishing, trade, export and import of seed material, planting material and breeding material of plant origin; and the recognizing, approving and protecting sorts except for reproduction material or seeds for the forestry activities.

**Relation to GMO's:** According to Article 24 of this Law, for the purpose of protection of the consumers during the trade, import and export of reproduction material or seeds for the forestry activities, a Certificate shall be issued on:

- 1) the quality in accordance with the conditions defined by the International Seed Testing Association (ISTA);
- 2) the identity in accordance with the conditions defined by the Organization for economic co-operation and development (OECD), and
- 3) the health suitability in accordance with the conditions defined by the International Plant Protection Convention (IPPC).

**Competent authority:** Ministry of Agriculture, Forestry and Water Economy

#### ***Law on Organic Agricultural Production***

**Status:** (Official Gazette of RM No. 16/04) (Secondary legislation in procedure)

**Summary:** The Law shall regulate the production, marketing, labeling and control of organic agricultural products for which methods of organic production were applied. The provisions of this Law shall also be applied for food products and products intended for stock feeding by application of methods of organic production.

**Relation to GMO's:** The secondary legislation resulting from the Law is in a procedure of preparation.

**Competent authority:** Ministry of Agriculture, Forestry and Water Economy

### 3.1.3. LAWS IN MEDICINE AND HUMAN HEALTH CARE AREA

#### ***Law on Food Safety and Safety of Products and Materials in Contact with Food***

**Status:** (Official Gazette of RM No. 54/02)

**Summary:** The Law shall regulate the conditions on providing safety of food and products and materials coming in contact with food, production and trade, the rights and obligations of physical persons and legal entities producing or trading, in order to protect the human health, protect the consumers from mislead and enable free trade on the internal and foreign markets.

**Relation to GMO's:** The Law on Food Safety and Safety of Products and Materials in Contact with Food specifies that the food which contains or consists of genetically modified organisms produced by genetically modified organisms, is called food produced by innovative technologies not yet available for public use. The Law shall specify the plant food and plant food products with seed material genetically intervened on as unsafe food, and shall prohibit the production of and trade in unsafe food.

**Competent authority:** Ministry of Health

**Note:** Currently this law is given for amendments to the Government of Republic of Macedonia, and the issue of genetically modified food will be adopted in accordance to the EU legislation.

### 3.1.4. LAWS IN THE ECONOMY AREA

#### ***Law on Consumer Protection***

**Status:** (Official Gazette of RM No. 38/04)

**Summary:** The Law shall regulate the protection of consumers' rights, conditions and methods of consumers' protection, terms of trade important for protection of consumers' rights, rights and obligations of consumers associations, and competencies of the administrative authorities in relation to the consumers' protection.

The Ministry of Economy shall supervise the legal implementation of this Law. The State Market Inspectorate, the State Sanitary and Health Inspectorate and State Environment Inspectorate shall carry out inspection supervision, in accordance with the competences defined by law.

**Relation to GMO's:** The Law shall define the meaning of the term safe product, i.e. the trader shall sell safe products in accordance with the regulations on environment and human health protection. *Safe product* shall mean any product that present no risk under normal conditions or reasonable anticipated terms of use, including the time of expiration, or the risk is minimal and appropriate for use of the product, taking into consideration: product traits including its content, package, instruction for composing, use and maintenance; effects on other products if they are logically used together; product presentation, labeling, instruction for use, discarding and any other indications or information on the product and consumer categories, particularly children and elder, exposed to risk during its use. *A harmful product* shall mean every product that does not meet the criteria for safe product.

**Competent authority:** Ministry of Economy

#### ***Law on Industrial Property***

**Status:** (Official Gazette of RM No. 47/02)

**Summary:** The Law shall regulate the acquisition, implementation and protection of industrial property rights. The industrial property rights shall mean: patent, industrial design, trademark, indication of origin and geographic indication.

**Competent authority:** Protection on Industrial Property Office, an operating authority as legal entity within the Ministry of Economy.

### 3.1.5. LAWS IN THE FINANCE AREA

#### *Customs Law*

**Status:** (Official Gazette of RM No. 21/98, 26/98, 63/98, 86/99, 25/2000, 109/2000, 31/2001, 4/2002, 5/2002 and 42/2003)

**Summary:** The Law shall regulate the customs procedure, rights and obligations of the participants in the customs procedure and the scope of operation, method of work and organization of the competent authority in the customs affairs.

**Relation to GMO's:** The Customs Office shall carry out control of the export, import and transit of goods regulated by special measures of interest for preserving the health and life of people, animals and plants, environment protection and other measures regulated by Law. The Government of the Republic of Macedonia shall prohibit or limit some customs goods under special conditions, in order to provide protection of the human health and life, animals, plants and the environment. The customs authority shall allow goods if there are not any kinds of limitations or prohibitions preventing implementation of the selected customs procedure. In respect of the law, the prohibition shall be introduced for goods with specially regulated import, if the importer does not meet the specified terms, and for goods harmful and hazardous for human living and working environment.

**Competent authority:** Ministry of Finance - Customs Office of the Republic of Macedonia

### 3.1.6. LAWS IN THE PHARMACY AREA

#### *Law on Pharmaceutical Drugs, Supplementary Treatment Substances and Medical Assistive Devices*

**Status:** (Official Gazette of RM No. 21/98)

**Summary:** The Law shall regulate the conditions of market authorization, production and trade, tests of quality, safety and efficiency, and supervision of the production, market authorization, trade and quality control of pharmaceutical drugs, supplementary treatment substances and medical assistive devices, as issues of public interest.

**Relation to GMO's:** The Law also concerns the pharmaceutical drugs containing or produced with genetically modified organisms. The external wrappings and labels of pharmaceutical drugs containing genetically modified organisms shall have appropriate instructions for use and warnings on the level of exposure of the medical workers and other people being in contact with them, and shall thereof be in accordance with the warnings for environment protection. The pharmaceutical drugs containing genetically modified organisms shall be packed in external and contact wrappings that provide safe storage, and shall particularly provide safety after their opening or reconstruction under aseptic conditions.

Ministry of Health supervises implementation of this law.

**Competent authority:** Ministry of Health

### 3.1.7. LAWS IN TRANSPORT AND COMMUNICATIONS AREA

#### *Law on Road Transport*

**Status:** (Official Gazette of RM No. 63/95, 29/98, 7/99)

**Summary:** The Law shall regulate the conditions and methods of transport of passengers and goods in the internal and international road transport. The international transport shall be carried out in accordance with the regulations of this Law and the international agreements signed or joined by the Republic of Macedonia. In case there is no signed international agreement with certain countries, transport between these countries and the Republic of Macedonia is carried out in accordance with the regulations of this Law and other international agreements that oblige the Republic of Macedonia under the terms of reciprocity. Foreign transport provider of a country with which the Republic of Macedonia has signed an agreement for international transport of goods, shall carry out international transport of goods on the territory of the Republic of Macedonia on the basis of a Permit issued by the Ministry of Transport and Communications. The Ministry of Transport and Communications shall transfer the Permits for international transport of goods to the competent authority in the country of the foreign transport provider.

**Competent authority:** Ministry of Transport and Communications

### 3.1.8. SIGNED AND RATIFIED INTERNATIONAL AGREEMENTS

The Republic of Macedonia has ratified 14 Conventions with a special Law on Ratification. By their publishing in the Official Gazette, they shall become part of the domestic right and can not be applied or supplemented in accordance with Article 118 of the Constitution. They shall be implemented by supplements of the existing national laws, or by new laws.

#### **1. Convention on Biological Diversity (Rio, 1992)**

**Status:** Ratified (Official Gazette of RM No. 54/97)

**Summary:** The main goals of this Convention, to be realized in accordance with its relevant regulations, shall be: protection of the biological diversity, acceptable use of its components and fair and justified distribution of gains obtained as the result of the use of genetic resources, including access to the genetic resources and transfer of the relevant technologies while taking into account all rights over those resources and technologies, and establishing appropriate funds. The Republic of Macedonia ratified the Convention in 1997.

**Relation to GMO:** The concept refers to the need to protect the human health and environment from the possible negative impact of the modern biotechnology products. On one hand, it shall provide access to and transfer of technologies, including biotechnologies that are relevant to the conservation and sustainable use of biological diversity (Article 16). On the other hand (Articles 8 and 19), it shall ensure the development of appropriate procedures to enhance the safety of biotechnology in the context of the Convention overall goal for reducing all potential threats to the biological diversity, taking also into account the risk to human health. Article 8 deals with measures that Parties should take at national level, while Article 19 sets the stage for the development of an international legally binding instrument to address the issue of biosafety.

**Competent authority:** Ministry of Environment and Physical Planning

#### **2. Cartagena Protocol on Biosafety of the Convention on Biological Diversity signed by RM**

**Status:** Signed on 26 July 2000; process of ratification under way

**Summary:** The objective aim of the Protocol is to provide appropriate level of protection in the area of safe transfer, handling and use of GMO's which are products of modern biotechnology and may have negative impacts on the preservation and continuous use of biological diversity while taking care of human health risks with particular focus on transboundary movement.

**Competent authority:** Ministry of Environment and Physical Planning

### ***3. Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention)***

**Status:** Ratified in 1999 (Official Gazette of RM No. 40/99)

**Summary:** In order to contribute towards the protection of the right of every individual of present and future generations to live in a healthy environment suitable for his health and welfare, each Party shall guarantee the rights to access to information, participation of the public in the decision-making and access to justice for issues related to the environment protection, in accordance with the regulations of this Convention.

**Relation to GMO's:** The Convention imposes an obligation for the public authorities, within the frames of the national legislation, to allow access of the concerned public to all available information relevant in the procedures of decision making on whether the deliberate release of GMO's into the environment should be allowed to a viable and suitable degree. Each Party shall also develop mechanisms that would provide available information on the products to the public. The obligation of making information available, irrespective whether by the state, producers or traders, shall be carried out in a manner that shall enable the consumers to be informed on the environmental aspect. The convention also ensures public participation in decision making procedure as well as access to justice.

**Competent authority:** Ministry of Environment and Physical Planning

### ***4. Law on Ratification of the Protocol on Accessing the World Trade Organization by the Republic of Macedonia***

**Status:** (Official Gazette of RM No. 7/03)

**Summary:**

Sanitary and Phytosanitary Agreement - SPS

This Agreement shall enable the WTO members to temporarily block the trade on behalf of the public health protection. Such Decisions shall certainly be based on scientific principles, international procedures and risk assessment.

When there is not enough scientific evidence for determining the risk resulting from the import of certain goods, the WTO members shall adopt measures based on accessible information. Additional information on the support of the original decision shall be presented within specified period of time.

The Agreement shall not allow the members to discriminate certain countries-exporters with same or similar conditions, unless there is enough scientific support on that.

Technical Barriers to Trade Agreement - TBT

The Agreement obliges the WTO members to ensure that their national regulations do not unnecessarily limit the international trade. The Agreement shall consist of three components: 1. the members are encouraged to accept standard equivalence, meaning that other countries' standards are commonly accepted through clear agreements; 2. the agreement shall promote the application of internationally based standards; 3. the agreement shall request the WTO members to inform each other on the significant changes. It shall mean that the members should establish centers for collection of all the information concerning the production standards and trade regulations. These Centers shall answer all questions raised by other countries and consult the trade partners in order to discuss important trade needs.

General Agreement on Tariff and Trade (GATT)

The Agreement concerns the rules of trade exchange of agricultural-food products and higher liberalization of the global market. Negotiations on its signing are underway.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP's)

The Agreement concerns protection of patents for innovations, protection of geographic indicators.

**Competent authority:** Ministry of Economy

### ***5. Convention on Conservation of Wildlife and Natural Habitats in Europe (Bern, 1979)***

**Status:** Ratified in 1997

**6. *Basel Convention on the Control of Cross-border Movement of Hazard Waste Pollutants and Their Disposal (Basel, 1995)***

**Status:** Ratified in 1997

**7. *Convention to Combat Desertification in Countries Experiencing Serious Droughts and/or Desertification, Particularly in Africa (UN, 2000)***

**Status:** Ratified in 2002

**8. *UN Framework Convention on Climate Changes (New York, 1992)***

**Status:** Ratified in 1997

**9. *Decision for approachment of the Republic of Macedonia to the EU Agreement on International Transport of Hazardous Substances in the Traffic (ADR 8/94, 1957)***

### **3.2. Future needs and priorities**

According to the plan for work, the objective of the working sub-group on chemicals and genetically modified organisms is to prepare a Law on Genetically Modified Organisms in compliance with the EU Directives in the period until 2007. The Republic of Macedonia shall prepare secondary legislation for implementation of the Law on GMO one year after its entering into force

Taking into consideration the fact that the Republic of Macedonia has no legislation in the field of biosafety until the aforementioned period (2007), the preparation of draft version of the Law on Genetically Modified Organisms was initiated in the frames of the UNEP/GEF Project on Development of National Biosafety Frameworks. The draft version (enclosed as Annex 1 of NBF) shall present the basis for work of the Working sub-group on chemicals and genetically modified organisms. One of the conclusions of the development of National Biosafety Frameworks is to change the time period envisaged for the preparation of the Law on Genetically Modified Organisms until 2007, and develop a new plan for work. According to it, the Law on Genetically Modified Organisms shall be prepared and adopted in the period until 2006.

There shall be a need of consultations with team of experts and close cooperation with the non-governmental sector during the preparation of the Law on Genetically Modified Organisms. The general public shall have access to information on the activities carried out by the working sub-group, and a possibility for active participation through the web-site *www.biosafety.org.mk*, developed in the frames of the UNEP/GEF Project on Development of National Biosafety Frameworks.

#### **3.2.1. Operationalization of the Draft Law on GMO's**

The Draft Law on GMO shall regulate the contained use of GMO's, the deliberate release into the environment and placing a product on the market, import and export of GMO's or products containing GMO's or consisting GMO's or their combinations. This Draft Law shall include provisions of the Directive 90/219/EEC and 98/81/EC, Directive 2001/18/EC and some provisions from the Cartagena Protocol on Biosafety, whose ratification is underway.

#### **Commission on GMO management**

The Government of the Republic of Macedonia shall establish a Commission on GMO management for monitoring of the conditions and development in the area of GMO management. The Commission shall consist of 17 members appointed by the Government. The Commission shall include officials of:

- The Macedonian Academy of Sciences and Arts,

- Social sciences and humanities,
- Natural and biotechnical sciences,
- Medical, veterinary and pharmaceutical sciences,
- Scientific committees,
- Non-governmental organizations (area of: environment and nature protection, consumers' protection and health care),
- Economic Chamber of the Republic of Macedonia.

The responsibilities of the Commission shall be as follows:

1. Monitoring the conditions and development in the area of using genetic technologies and GMO management,
2. Taking positions and providing opinions and initiatives in relation to using genetic technologies and GMO management, as well as social, ethic, technical and technological, scientific and other aspects of the GMO management,
3. Advising the Government in relation to using genetic technology and GMO management,

### **Scientific Committees**

In order to provide professional assistance to the institutions responsible for making decisions in relation to the GMO management, the Government shall establish:

- Scientific Committee for working with GMOs for contained use and
- Scientific Committee for intentional release of GMOs into the environment and placing products on the market.

The Committees shall have responsibilities as follows:

- Providing experts opinions on GMO management,
- Providing opinions and suggestions in the preparation of regulative on GMO management,
- Providing opinions and suggestions on other issues related to the GMO management upon request by the competent ministries,
- Defining means of implementation (elements and scope) of risk assessment on the methodology of creating GMO's, contained use and intentional release and placing GMO's on the market

The members of the Committees shall be proposed by the Minister of Education and Science, and appointed by the Government.

*The Committee on contained use* shall consist of experts in the area of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacy, biotechnology and protection on work.

*The Committee on deliberate release and placing GMO's on the market* shall consist of experts in the area of biology, microbiology, genetics, agriculture, forestry, veterinary science, biochemistry, molecular biology and medicine.

The Ministry of Environment and Physical Planning shall provide the tools for work of the Committees, such as the technical and administrative support.

### **Contained use of GMO's**

Contained use of GMO's shall mean any action implying genetic modifications of organisms or cultures, storage, transport, destroying or making waste or any other activity including GMO's, with application of protection measures such as: closed facility, measures and other physical barriers for efficient prevention of contacts of GMO's with the people or the environment.

Secondary legislation shall be adopted for regulation of the:

- Criteria for classification of each contained use of GMO into specific class, containment and other safety measures, the rules of management and other conditions for individual class shall be precisely defined by special secondary legislation
- Contents of the following issues shall be precisely defined:
  - Notification on premises for contained use and
  - Notification of contained use
- Specifying the elements and scope of the risk assessment of contained use of GMO's and methodology for production of GMO's.

- Detailed contents and the scope of the Emergency Plan in relation to the class of work, the methodology of its preparation, examining and supplementing and the manner and scope of informing and warning competent bodies, services and the general population in the event of an accident.

#### **Deliberate release into the environment**

Deliberate release of GMO's into the environment means any activity for deliberate release of GMO's into the environment without any restrictions concerning the ban on contacts of GMO's with people or the environment.

Detailed regulation of the deliberate release into the environment requests preparation of secondary legislation that shall precisely define:

- Methodology, elements and scope of the risk assessment of the deliberate release of GMO's into the environment,
- Notification on the deliberate release into the environment, and
- Scope and contents of the report on the deliberate release.

#### **Placing GMO's on the market**

Placing GMO's on the market means deliberate release of GMO product into the environment, including delivery or providing accessibility to a third party with or without payment.

Secondary legislation shall be prepared to regulate the following issues:

- Principles, scope and methodology of risk assessment of placing a product on the market and the methodology of its production
- Specifying the contents of the notification for placing a product on the market and data that shall not be a part of the notification, shall be specified in the secondary legislation in agreement with the Minister for Agriculture, forestry and water economy,
- Specifying the extent and elements of the assessment report shall be specified in the secondary legislation
- Specifying the content and extent of the Programme of monitoring and the manner and extent of reporting shall be specified in the secondary legislation in agreement with the Minister of Health and Minister of agriculture, forestry and water economy
- Specifying the content and extent of data on the packaging or in the declaration of the product and requirements for packaging the product shall be specified in the secondary legislation in agreement with the Minister of Health and Minister of agriculture, forestry and water economy
- The labeling shall be covered in accordance to the EU Directive 1830/2003/EC. The packaging shall not be considered as separately but under requirements for transport and packaging, which is covered by ADR agreement. Any special requirements for packaging may be part of the approval conditions.

#### **Transboundary movement of GMO's**

The import, export and transit of GMO products shall be regulated according to the provisions of the Cartagena Protocol and the EU Regulation (No.1946/2003) for transboundary movement

#### **GMO Register**

The secondary legislation shall prescribe the form, means of entering data and their updates by the competent institutions, according to the Cartagena Protocol and the Law on GMO in accordance with the provisions of the Commission Decision on laying down detailed arrangements for operation of the registers for recording information on genetic modifications in GMO's provided for in the Directive 2001/18/EC of the European Parliament and of the Council. (23 February 2004).

#### **Transport, packaging and identification**

It is necessary to define recommendations on safe transport and packaging of GMO's or products containing GMO's that should respect during transboundary movement transport and transit, complying with the Article 18 of the Cartagena Protocol.

**Labeling**

Placing on the market can be done only with products that have data declaration on their package citing it contains or that it consists of GMO's, as well as other data regarding the product and its use. The label on the package or declaration of the product shall also have an easily visible note indicating: \*This product contains genetically modified organisms\*. The scope of data on the package or declaration of the product and rules of packaging of the product shall be defined with a special regulation in agreement with the Ministry of Health and Ministry of Agriculture, Forestry and Water Economy. GMO's available to third parties for contained use or deliberate release in the environment shall also be labeled.

The threshold of GMO (not higher than 0,9%), shall be presented by a secondary legislation act in accordance with the Regulation (EC No.1829/2003 of the European Parliament and of the Council) of 22 September 2003 and on genetically modified food and feed.

**Customs**

An agreement on cooperation between the Ministry of Environment and Physical Planning on one side and the Ministry of Finance-Customs Office on the other shall be signed, which shall, among other things, regulate the cooperation in relation to GMO's;

The Customs Office of the Republic of Macedonia needs clear and simple instructions on:

Adaptation of cross-border procedures on import/export of GMO's for Customs and control/inspection services;

Procedures and documents imposed by the Cartagena Protocol on export and import of GMO's and their clear transposing in national legislation;

Certain border crossings shall be indicated for export and import of GMO's. Only border crossings with control/inspection services shall be suitable;

Contact persons for connection with the Ministry of Environment and Physical Planning shall be appointed, who shall follow and contribute to correct implementation of the regulations in this area;

Contact persons from the Ministry of Environment and Physical Planning shall be appointed for connection with the customs terminals in the Customs Office, for appropriate coordination of the possible activities of the customs authorities - border and internal customs terminals.

## **4. ADMINISTRATIVE SYSTEM - SYSTEM TO HANDLE NOTIFICATION**

### **4.1. Current situation in the biosafety administrative system in Macedonia**

The Republic of Macedonia has not created a system for implementing procedures of genetically modified organisms (GMO's) yet. There is no special law regulating issues concerning the import, export, cross-border movement, production and use of GMO's and products containing GMO's.

### **4.2. Future needs and priorities**

The part below describes the defined activities for implementation of the administrative procedures in accordance with the Draft Version of the Law on Genetically Modified Organisms (prepared in the frames of the UNEP/GEF Project on Development of National Biosafety Frameworks).

#### **4.2.1. Contained use of GMO's**

The GMO's in contained use shall be categorized according to the draft Law on GMO's in one of the following four classes:

- class 1, in case of insignificant risk,
- class 2, in case of low risk,
- class 3, in case of moderate risk,
- class 4, in case of high risk.

The classified contained use of GMO shall be treated in accordance with the defined/required containment and other safety measures. Criteria for classification of each contained use of GMO in the specific classes, containment and other safety measures, rules of management and other conditions for the specific class shall be defined.

The contained use of GMO's shall be in accordance with the requested containment measures upon classification, other measures of security and regulations. Criteria for classification, limiting and other measures of security, as well as rules of management for every class should be regulated with special regulations.

The contained use of GMO shall/may only be carried out in premises which fulfill the required conditions on the class into which the intended work is carried out.

The notifier shall submit a notification to the Ministry prior to the starting of the use of the premises for contained use. The notification shall contain data on the notifier, the premises and the class of the intended contained use.

The competent Ministry shall check if the notification meets the necessary regulations, and upon an expert opinion from the Committee on contained use, the Ministry shall issue approval and enter data on the premises in the GMO's register and issue confirmation for registering the notifier.

The notifier shall, prior to commencing the contained use, provide estimation of risks related to the work. In the risk assessment, the possible negative impact, risk levels and necessary containment, and other security measures shall be specified on the basis of the analysis of GMO characteristics and the planned work and the environment to be exposed to the risk. Measures for waste management and its disposal shall be specified. The notifier shall, on the basis of the risk assessment, categorize the contained use in one of the classes.

The notifier shall, prior to commencing the contained use, provide an Emergency Plan in case of accident.

The notifier shall retain the risk assessment and all administrative information on the projects for a period of at least five years.

The Ministry shall verify the compliance of the notification no later than 45 days of the submission of the notification if classes 3 and 4 of the contained/limited use for which a Permit has been issued have already been carried out, and all the required conditions were fulfilled during the contained use.

The Ministry shall, on the basis of a written opinion given by the Committee on contained use, issue decision on the notification within a period of 90 days of its submission.

The notifier may ask for extension of the Permit prior to its expiration should all the required conditions be fulfilled.

#### **4.2.2 Deliberate release of GMO's into the environment**

The notifier shall obtain a Permit by the Ministry of Environment and Physical Planning for deliberate release of GMO's into the environment. The Ministry shall issue such Permits in agreement with the Ministry of Agriculture, Forestry and Water Economy.

The deliberate release of GMO into the environment shall take place in accordance with the provisions and conditions specified in the Permit. The material produced by GMO's as the subject of deliberate release of GMO's into the environment can be placed on the market only upon prior issuing of a Permit for placing on the market. The notifier shall, prior to the submission of the notification on issuing Permit on deliberate release of GMO's into the environment, provide risk assessment of the intended deliberate release.

In the risk assessment, on the basis of the GMO analysis and characteristics and their deliberate release into the associated environment and the environment which could be exposed to risk, the harmful impact and the possible consequences of it, the level of risk and measures required for their control shall be defined and assessed.

The Committee on deliberate release of GMO(s) shall submit the opinion within a period of 45 days of the reception of the Notification; otherwise the opinion shall be considered negative.

#### **4.2.3. Placing GMO's on the market**

The Ministry of Environment and Physical Planning shall, upon a prior agreement with the Ministry of Health and the Ministry of Agriculture, Forestry and Water Economy, issue a Permit for release of products for trade.

The Permit shall be issued for products which are for the first time placed on the market.

The notifier shall, prior to submitting the notification for obtaining a Permit on placing products on the market, provide risk assessment on the intended d release of products for trade.

In the risk assessment, on the basis of the analysis and characteristics of GMO, products containing GMO and their use, and the environment in which the GMO and products containing GMO shall be used, the negative impact and the possible consequences on the human health and the environment, the level of risk and measures required for their control shall be defined and assessed.

The secondary legislation acts of the Law on GMO shall specify form and content of the notification and the submission procedure as well as monitoring, RA, Labeling.

#### **4.2.4. Capacity building**

The Republic of Macedonia has a potential of laboratory capacities, both on university level and within the public institutions and commercial laboratories. There are no available statistic data on the deliberate release of GMO, and no controls on transboundary movement of GMO have been carried out. Thus, the knowledge on import of certain agriculture cultures (soybeans, wheat and corn) which are not ascertained as genetically modified may be taken into consideration

The emphasis on the expert experiences strengthening, the development of appropriate mechanisms on collection and exchange of information are all in order to implement the provisions of the national biosafety system.

## **5. MONITORING AND INSPECTION**

### **5.1. Review of the current situation**

The Republic of Macedonia has no Law on regulating issues of monitoring and inspection of GMO's and products containing GMO's. The inspection services have no regulation on monitoring and inspection of GMO's use, during contained use of GMO's, deliberate release of GMO's and placing GMO's on the market.

#### **5.1.1. Inspection Services**

##### **Ministry of Environment and Physical Planning**

The State Inspectorate of Environment, an operating authority within the Ministry competent for environment matters shall provide inspection supervision on the application of technical-technological measures for air and waters protection against pollution, specific protected natural resources, soil protection against degradation and pollution, protection against noise and waste materials and ionized and non-ionized radiations.

In providing supervision on application of the protection measures for the specific protected natural resources and bio resources, the Inspectorate shall confirm whether:

1. The Protection of plant and animal species and specific protected natural resources is carried out under terms and manners defined by law;
2. The Cadastre of specific protected natural resources is run under stipulated methodology and if the cadastre data are submitted to the competent authority;
3. Programme on protection and development of specific protected natural resources and annual plans for their implementation are prepared and carried out;
4. The protected moveable natural resources are exported or taken abroad by regulated approval and if there is evidence for the issued approvals, and
5. It confirms other situations within its competence/jurisdiction.

##### **Ministry of Agriculture, Forestry and Water Economy**

The State Inspectorate of Agriculture, the State Inspectorate of Forestry, the Veterinary Medicine/Veterinary Inspection Administration and the Plant Protection Administration shall operate in the agricultural section with counselors on plant protection and regional reporters, in accordance with the Law on Organization and Function of the State Administration Authorities.

According to the Law on Plant Protection, inspectors on plant protection and inspectors on plant protection on border crossings shall operate within the Inspectorate of Agriculture.

The work and activities of the State Inspectorate of Agriculture shall be directed by authorizations, rights and obligations arising from the Law on Organization and Function of the State Administration Authorities, Law on Agricultural Inspection as a basic law, laws in the agricultural area, activities in the current obligations being directly imposed by the work in the Ministry of Agriculture, Forestry and Water Economy, as well as activities under the Programme of the Inspectorate of Agriculture and Programme of the Ministry.

The inspection supervision shall be carried out for the agricultural stock companies, agricultural cooperatives, legal entities in production of and trade in raw materials, concessionaires managing fishing areas and fishing compounds, agricultural institutes and experts services authorized in expert and health control for the production of seeds and planting material, citizens' associations, legal entities for finishing seeds material, natural persons etc.

##### **Ministry of Health**

###### *State Sanitary and Health Inspectorate - Law on Food Safety*

The Ministry of Health has within its structure the State Sanitary and Health Inspectorate whose authorizations are defined in the Law on Sanitary and Health Inspection. During the supervision on the

enforcement of the laws and regulations in sanitary-hygienic and epidemiological protection area, the Inspectorate shall supervise among other things the health condition of food products and subjects for general use in production and trade.

By the Law on Food Safety, the Inspectorate shall prohibit the production of and trade in unsafe food. Article 6 of the Law states that plant food and plant food products with seed material genetically intervened shall be considered as unsafe food.

### **Ministry of Economy**

#### *State Market Inspectorate*

The general regulations of the Law on Trade (Official Gazette of RM No. 16/04) specify that the law shall regulate the terms and manners of trade on the internal and foreign market, measures of limiting the trade and measures of protection.

Article 2 defines that trade in respect of this law shall mean buying and selling goods and carrying out trade services, which can be done by legal entities and natural persons registered for carrying out relevant activities. The State Market Inspectorate Regarding shall carry out the inspection supervision on implementing the provisions of this Law.

### **5.1.2. Customs**

Cooperation shall be established with the other competent institutions (the State Veterinary Inspectorate and the Plant Protection Administration) which control, together with the Customs Office, entering of goods on the border crossings in the Republic of Macedonia, and institutions (State Market Inspectorate and State Sanitary Inspectorate) which control the import of goods on the internal customs terminals in the Republic of Macedonia.

### **5.1.3. Other infrastructure relevant to biosafety**

There are laboratories in the Republic of Macedonia that apply methods in biotechnology and genetic engineering area, but none has worked on detection of GMO's yet. Laboratories within the following institutions currently have the equipment, staff and possibilities to work on certain techniques for DNA manipulation:

- Research Center of Genetic Engineering and Biotechnology - MASA
- Laboratory of biochemistry and molecular biology at the Faculty of Agricultural Sciences and Food,
- Laboratory of molecular biology within the Faculty of Natural Sciences and Mathematics,
- Laboratories at the Faculty of Medicine,
- Laboratory at the RIHP,
- Laboratories at the Faculty on Veterinary Medicine
- Laboratory at the Faculty on Pharmacy

None of the aforementioned laboratories is accredited by the Institute of Accreditation in the Republic of Macedonia for detection of GMO's in products.

None of the laboratories is appointed by the Macedonian Government as a reference laboratory for: detection of GMO's in products, following permanent use of GMO's and following production and release of GMO's.

None of the above mentioned laboratories is member of the European Network of Laboratories for GMO's detection.

## 5.2. Future needs and priorities

### 5.2.1. Inspection

Having in mind the fact that the informing of the inspection services of GMO is on a very low level, a Review of the inspection system shall be prepared to define the required capacities for inspection supervision of the genetically modified organisms. In that regard, the following activities shall take place:

- organize more trainings, in order to approach the overall administrative procedure to the inspection system, thus enable the inspection services to elaborate the manner of inspection;
- prepare Handbooks on all types of GMO inspection;
- prepare all forms for implementation of the GMO inspection (ex. informing on prohibition, reporting on the research, etc.)
- ensure the access to the relevant information (BCH, national biosafety information system)

#### *Responsible inspection offices*

The Draft Version of the Law on Genetically Modified Organisms prepared in the frames of the UNEP/GEF Project on Development of National Biosafety Frameworks specifies that the inspection supervision for implementation of the provisions of this Law shall be carried out by 5 competent bodies:

- the State Environmental Inspectorate within the Ministry of Environment and Physical Planning
- the Direction for Food within the Ministry of Health
- the State Inspectorate on Agriculture, the State Inspectorate on Forestry, the Veterinary Administration/Veterinary Inspection and the Administration on Plant Protection within the Ministry of Agriculture, Forestry and Water Economy
- the State Market Inspectorate of the Republic of Macedonia within the Ministry of Economy,
- the State Labor Inspectorate within the Ministry of Labor and Social Policy, each in accordance with its competences.

The responsible bodies shall carry out:

1. supervision of the implementation of the contained use,
2. supervision of the implementation of the deliberate release of GMO into the environment,
3. supervision of the placing products on the market,
4. supervision of the implementation of the provisions or measures for preventing the possible negative impacts and the prohibitions ordered in that regard.

### 5.2.2. Monitoring

The Monitoring Plan shall be part of the Notification, in accordance with Article 54 of the Draft version of the Law on Genetically Modified Organisms (prepared within the frames of the UNEP/GEF Project on Development of National Biosafety Frameworks) on monitoring of the placing GMO products on the market. The monitoring shall present ongoing process, dependent of the results from the risk assessment. The notifier placing product on the market shall provide monitoring of the impact of the product and its use on the environment and human health in accordance with the monitoring Programme for the product, and shall regularly inform the responsible bodies on the monitoring results.

Therefore, Guidelines shall be provided for the scientific committees and the notifier on the different approach to the monitoring.

### **5.2.3. Customs**

An agreement on cooperation between the Ministry of Environment and Physical Planning on one side and the Ministry of Finance-Customs Office on the other shall be signed;

An appropriate training for certain number of customs workers and preparation of booklets and manuals on practical shall be carried out;

Agreements shall be signed on cooperation with the other competent institutions (the State Veterinary Inspectorate and the Plant Protection Administration) which control, together with the Customs Office, entering of goods on the border crossings in the Republic of Macedonia. These services and other institutions shall participate in the coordination of the procedures on the border in regard to defining procedures and exchanging information's;

Examination shall be carried out of the available infrastructure on border crossings with the aim of defining necessities for efficient cross-border inspection control.

Ensure the access to the relevant information (BCH, national biosafety information system)

### **5.2.4. Other infrastructure relevant to biosafety**

#### *Significance of the laboratories for GMO detection*

Consideration of the great importance of laboratories for GMO detection in the Republic of Macedonia, support to infrastructure i.e. apparatus in certain laboratories working in biotechnology and genetic engineering area shall be provided. The introduction and development of modern methods of GMO detection and education of eligible staff shall also be supported. In the view of accession to EU, the country shall apply the validated methods approved by the EU reference laboratory (JRC – Ispra).

The existing laboratories in RM shall start a procedure on accreditation on a national level, and their inclusion in the European network of GMO laboratories which detect GMO's and products containing GMO's.

## **6. MECHANISM FOR PUBLIC PARTICIPATION AND INFORMATION**

### **6.1. Current situation**

Informing about the environment is essential for the work of MOEPP and presents particularly important base in preparing plans and strategies in the environment aspect.

Public Relations Office is established within the Information Center of the MOEPP. The basic principle of work is two-way communication with the public or giving to and receiving information from the public. This office is a link between the Information Center and the public.

The absence of appropriate legislation currently makes the public access to information on GMO's difficult; therefore mechanisms of public participation shall be established, taking into consideration the cultural, social and political conditions in the country.

#### **Principle of public participation**

One of the provisions in the Law on GMO's shall regulate the public right that defines: The public has a right to access to information on the GMO's, right to timely informing on suffered damages and undertaken activities for elimination of the damages, and a right to participate in the decision making process related to the GMO's management.

This principle shall be included in the Law by various means and provisions.

### **6.2. Future needs and priorities**

#### **6.2.1. Consultations and public informing - Contained uses of GMO's and deliberate release of GMO's in the environment**

The notifier shall/may, in the Notification, specify the business rights and the rights to intellectual property that are to be protected as confidential in the procedure, on which verified justification shall be submitted.

The Ministry shall, in the procedure for issuing Permit on contained use class 3 and 4 as well as to deliberate release of GMO's into the environment, provide a copy of the notification on risk assessment, provide transparency of the Notification for the public, the opinion of the Committee on release of GMO(s). The Ministry shall release in the public media information on the time and location of maintaining the transparency, and the manner of providing opinions and comments.

#### **New information**

Should the notifier obtain new information on the contained use carried out or change the contained use, thus significantly impacts the level of risk or classification of contained use, new notification or new request shall be submitted. The public shall again participate in the new notification.

In case of new information on deliberate release of GMO's into the environment the Ministry shall inform the public on the new information and changes made after the Permit issuing, and the Decision made in that regard.

#### **Emergency Plan in case of accidents**

The notifier shall, prior to the contained use or deliberate release, provide an Emergency Plan in case of accidents. In addition to other demands it shall imply means and continuation in providing information and warnings to the competent authorities, services and whole population in case of emergency or unintentional release.

#### **Emergencies and unintentional release of GMO**

The Ministry shall prepare Report on emergency or unintentional release, undertaken measures and their efficiency that the Government shall accept and inform the public on it without delay.

## **6.2.2. Consultations and public informing - placing GMO's on the market**

### **Public consultations**

The Ministry shall, in the procedure for issuing Permit on release of product for trade or its extension, whenever it is evident from the Assessment Report that the product is suitable for release for trade, provide transparency of the Notification for the public, the opinion of the Committee on release of GMO(s) and the Assessment Report.

Public notice with a statement on the place and time of the evidence and the manner of providing opinions and comments shall be published in public media. The time period in which the Ministry shall provide the transparent and possibility of giving opinions and comments shall be defined in the Law on GMO. The Ministry shall, in the procedure of Permit issuing, take into consideration the public opinion and comments referred to in the previous paragraph.

### **Public informing**

The Ministry shall immediately inform the public through the ministry responsible for protection of consumers' rights on the issuing of Permit on placing product on the market, or its extension, or refusal to extend the issued Permit, with an explanation.

The information on issuing or extending the Permit shall contain data on the type of GMO(s) or their combination of which the product is composed and intended use of the product.

### **New information**

In case of new information regarding risk that could be caused by the product, the procedure on issuing permission or their eliminating shall be applied with necessary participation of the public.

### **Monitoring**

The notifier placing product on the market shall provide monitoring of the impact of the product and its use on the environment and human health in accordance with the monitoring Programme for the product, and shall regularly inform the responsible bodies on the monitoring results.

Report data on the monitoring results shall be available open for the public according to the regulation on environment protection.

## **6.2.3. GMO Register**

The GMO Register shall consist of documents on the premises, the contained use, deliberate release of GMO(s) into the environment and the release of products for trade. This Register shall include recordings of location, contained use, deliberate release of GMO's into the environment and placing of GMO products on the market.

An integral part of the register shall be the offers and Permits issued for the premises, contained use, deliberate release into the environment and placing of GMO products on the market.

The Ministry of Environment and Physical Planning shall keep the GMO Register as a public document. Other competent ministries shall also run relevant registers with data which should be delivered to the central GMO Register of MOEPP, according to the specific rules and regulations.

Anyone shall have the right to peruse the data from the GMO Register, and right to obtain data from the Register in a manner and under conditions defined in accordance with the Law on Environment, contrary to paying costs that should be no more than material costs of communication.

The Register shall be part of the Macedonian Biosafety Server and accessible on Internet. The Register shall be prepared after the adoption of the Law on GMO's.

#### **6.2.4. Review of the public participation by cooperation with non-governmental organizations**

The representatives of non-governmental have actively contributed the past work related to biosafety activities. One of the non-governmental organizations is OPM, as NCC member in the project.

The representatives of the non-governmental sector may take part in both governmental (ministerial) authorities - Commission on GMO's management and Scientific Committee providing support in the process of decision-making related to the deliberate release, contained use of GMO's and placing on the market.

Other non-governmental organizations shall take part in the process of detailed public presentation, contributing in decision making related to all GMO activities.

##### **Future needs and priorities**

- To provide undisturbed flow of information related to GMO's for all concerned parties, as defined in the Cartagena Protocol and the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention)
- The public awareness rising on biosafety shall be directed toward specific target groups by appropriate forms (booklets, flyers, discussions, workshops, web page...)
- Special attention shall be paid on media relations by specific publications, leaflets, workshops...
- Better presentation of the gains and risks of the modern biotechnology to the public, booklets with worked out details on Cartagena Protocol and Acts related to GMO's shall be prepared for publishing.

#### **6.2.5. Macedonian Biosafety Clearing House**

Macedonian Biosafety Clearing House (MBCH) shall be an integral part of the Biosafety Clearing House (BCH) mechanism established according to the Cartagena Protocol (Article 20), in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experiences with, living modified organisms, and to assist parties to implement the Protocol.

BCH system is designed as decentralized system with components of national BCH's organized by parties in this Protocol and the central port (managed by the Secretariat of the Convention on Biological Diversity) as a support in organizing information flow from the national BCH's. (according to the principles of the CBD Secretariat)

Considering the great interest in Macedonia for developing a system for electronic information exchange, the accessibility to governmental services by electronic means shall be of great importance in the future.

In the process of establishing MBCH ([www.biosafety.org.mk](http://www.biosafety.org.mk)) during project activities one must take into consideration that there is no other web page in the Republic of Macedonia handling information on biosafety on a national level. In order to have fair and transparent access for the public, MBCH shall offer information estimated as significant in addition to the necessary information requested from the central port.

Taking into consideration the fact that Macedonia is in a process of preparing legislation, or to be more precise - in period of starting the ratification of the Cartagena Protocol, the National biosafety Clearing House, although in the form of a web-site, is not directly or inter-operationally connected to the central port yet. With the adoption of the Law, ratification of the Cartagena Protocol and creation of GMO Register on a national level, all necessary information and data shall be available and globally connected via the central port.

In order to have uniformity in delivering data to the central port in the future, MBCH shall be conceived in the form of a menu. It shall enable easy access for all information users of the Macedonian biosafety clearing house to the central port and opposite.

### **6.2.6. Future challenges to the Macedonian Clearing House**

#### *Accessibility of the Macedonian Biosafety Clearing House*

Broad public as a key actor in the process of making decisions in the national biosafety system should be informed about the possibility of getting information as well as giving opinions and comments regarding some themes in the biosafety area. For that purpose MBCH was presented by educational promoting material distributed within the project. Besides connecting this web page to large global searching pages, major task will be publication of increasing number of pages related to biotechnology and biosafety.

#### *Connecting to the inter-operational side of the central port*

The main purpose in the future as it is already mentioned in the previous paragraphs shall be connecting the Macedonian Biosafety Clearing House to the central port.

## **7. UNEP- GEF PROJECT "DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORK IN MACEDONIA"**

The National Biosafety Frameworks of the Republic of Macedonia shall be developed in the frames of the UNEP/GEF (UNEP-GEF) Project on Development of National Biosafety Frameworks in the Republic of Macedonia. It presents part of the global UNEP/GEF project, aimed at assisting the countries (119 countries included at the moment) in the implementation of the Cartagena Protocol on Biosafety through development and implementation of the National Biosafety Framework.

### **Phases of the National Project in Macedonia**

#### **PHASE 1. Development of National Biosafety Review**

The main objective of the first phase of the national project is data collection and Development of National Biosafety Review on a national level. The objective of this Review is to present the current situation in relation to the biosafety in Macedonia, and identify the key stakeholders in the biosafety system. During this phase, a review was made of the following:

- modern biotechnology,
- list of biosafety experts,
- review of the legislation and of the competent bodies in the country,
- review of the international legislation,
- review of the projects on capacity building,
- web-sites

The first phase resulted in preparation of the Internet-site of the UNEP/GEF (UNEP-GEF) Project on Development of National Biosafety Frameworks in the Republic of Macedonia.

All segments of the National Biosafety Review in the Republic of Macedonia are available at the web-site [www.biosafety.org.mk](http://www.biosafety.org.mk).

#### **PHASE 2. Phase of analyses and consultations**

During the second phase of the national project, Workshops were organized to present the biosafety system, gap analysis and key priorities in the biosafety system, risk assessment and mechanism for public informing, public awareness raising and inclusion of the public in the decision making process.

Workshops:

- Introduction in the System on Biosafety (September, 2003)
- National Review on Biosafety and identification of the priorities in the biosafety system (February, 2004)
- Risk assessment and Risk management (April, 2004)
- Informing the public and public participation (June, 2004)
- Identification of the key components of the NBR (September, 2004)

The presentations are available in electronic version at the Macedonian Biosafety Clearing House web-site ([www.biosafety.org.mk](http://www.biosafety.org.mk)):

#### **PHASE 3. Development of National Biosafety Frameworks**

The Workshop organized with active participation of the NCC and the other stakeholders of the biosafety system in the Republic of Macedonia, has presented the basis of the National Biosafety Frameworks. During the development of the NBF, the need of preparation of Draft version of the Law on GMO for the Republic of Macedonia was identified (Annex 1). In that direction, a Working Group was established (Decision no. 02-4690/1), composed of 5 experts nominated by relevant institutions. They have prepared, within a specified period of time, the Draft version of the Law on GMO, applying some of the provisions of the Cartagena Protocol, the EU Directives (2001/18/EC; 90/219/EEC and 98/81/EC), and experiences of the countries which have biosafety systems that are closest to the institutional infrastructure of the Republic of Macedonia.

In order to initiate improvement of the mechanism for public participation, statistic analysis was made of the current level of public awareness on in relation to the biosafety and GMO (Annex 2).

### **Educative - promotional material**

According to the assessed level of public awareness in the Republic of Macedonia, the following printed educative-promotional material was prepared and distributed in the frames of the National Project, available also in electronic version at the Macedonian Biosafety Clearing House web-site ([www.biosafety.org.mk](http://www.biosafety.org.mk)):

- What is biosafety? (Brochure aimed for all the active participants in the system of biosafety)
- What are GMO? (Brochure aimed for the advisors in the agriculture production)
- Poster for the agriculture producers
- Strip brochure - What are GMO? (aimed for the schools)
- Poster for the schools
- Inserter for the daily press

### **Media coverage of the National Project**

- Interview in the daily newspaper "Utrinski Vesnik" with Pance Nikolov, Ministry of Agriculture, Forestry and Water Economy, member of NCC within the UNEP/GEF Project on Development of National Biosafety Frameworks, on topic "The genetically modified food shall be regulated legally" (2 February 2004)
- Summary of the UNEP/GEF Project on Development of National Biosafety Frameworks as part of the presentation of the activities of the Ministry of Environment and Physical Planning in the monthly issue of the magazine "Revija Ekologija" (April 2004)
- Interview on radio "RAVEL" - Show "Green Umbrella" with Jasmina Ginovska - NPC and D-r Liljana Simjanovska, MANU (Macedonian Academy of Sciences and Arts) - member of NCC within the UNEP/GEF Project on Development of National Biosafety Frameworks, on topic "Genetically Modified Organisms" (July 2004)
- Interview in the daily newspaper "Utrinski Vesnik" with D-r Liljana Simjanovska, MANU (Macedonian Academy of Sciences and Arts) - member of NCC within the UNEP/GEF Project on Development of National Biosafety Frameworks, on topic "Dillema of the humankind - for or against the genetically modified food" (17-18 July 2004)
- Distribution of inserter "What are GMO?" in the two outstanding daily newspapers "Dnevnik" and "Utrinski Vesnik" (27 October 2004), with 73 000 copies on a national level
- Distribution of inserter "What are GMO?" in the outstanding daily newspaper in Albanian language "Fljaka" (27 October 2004), with 15 000 copies on a national level.
- Interview in the monthly magazine "KAPITAL" with Marija Dirlevska Caloska, on topic: *Macedonia has to regulate the use of genetically modified food urgently*

### **Project activities organized on international, regional and sub-regional level**

- Stojanco Gugusovski - NPC, Marija Dirlevska Caloska - Head of NCC and 2 members of NCC took part at the Regional Workshop on Risk Assessment and Risk Management, Public Awareness Raising, Public Informing and Participation, organized by UNEP/GEF, Vilnius, Lithuania (27-30 May 2003)
- Jasmina Ginovska - NPC, presented the current setting of the mechanism on Public Awareness Raising, Public Informing and Participation at the Workshop on Public Awareness Raising, Public Informing and Participation, Republic of Slovenia (September 2003)
- Jasmina Ginovska - NPC, Marija Dirlevska Caloska - Head of NCC and Doc. Dr. Vlatko Andonovski - expert coordinator of NCC, took part at the Workshop on Genetical Engineering and the Role of the Mass-Media in the Process of Public

- Informing and Education (Sofia - Plovdiv, Republic of Bulgaria, 25 - 29 November 2003)
- Representatives of the UNEP/GEF Project on Implementation of National Biosafety Frameworks took part at the Workshop on Introduction of the Biosafety System, Republic of Bulgaria (September 2003)
  - Jasmina Ginovska - NPC, Marija Dirlevska Caloska - Head of NCC and 2 members of NCC, took part at the Regional Workshop on Administrative and Regulatory Systems on Biosafety, organized by UNEP in Antalia, Turkey (December 2003)
  - Representatives of the UNEP/GEF Project on Implementation of National Biosafety Frameworks took part at the Workshop on Risk Assessment and Risk Management, and the organized roundtable, Republic of Bulgaria (22-23 April 2004)
  - Representatives from Slovenia and Austria took part at the Workshop on Public Awareness Raising, Public Informing and Participation, and the organized round table, (28-29 June 2004)
  - Jasmina Ginovska - NPC and Marija Dirlevska Caloska - National contact person on the Cartagena Protocol, held working meetings on exchange of experiences and subregional coordination during the development of national systems on biosafety in both countries, in the frames of the UNEP/GEF Project on Development of National Biosafety Frameworks, Belgrade, Republic Serbia and Montenegro (4-6 November 2004)
  - Jasmina Ginovska - NPC and Marija Dirlevska Caloska - National contact person on the Cartagena Protocol, held working meetings at which support was given to the Republic of Macedonia for the development of National Biosafety Framework and preparation of the Draft Version of the Law on GMO, Ljubljana, Republic of Slovenia (16-19 November 2004)
  - Marija Dirlevska Caloska - National contact person on the Cartagena Protocol, took part at a Workshop on GMO- Evaluation of the NBF in Croatia, Zagreb, Republic of Croatia (16-17 December 2004)

## **8. CONCLUSION**

All the project activities during the UNEP/GEF Project on Development of National Biosafety Frameworks have been carried out in accordance with the developed Project Plan.

In general as most successful output of the project is that all stakeholders in the NBF have identified their roles and will initiate the coordination of their activities among themselves. In regard to our activities we were also very pleased by the responses from the stakeholders and by establishing the main links we have initiated the possibility for extended cooperation. In the addition to the above mention, the continuity of this scope of activities that facilitated the building of NBF might result in some problems in the future, since within the national biosafety system all stakeholders have to apply for the resources in the national budget every year. Due to the limited resources in the country the support in form of the UNEP-GEF project 'Development of National Biosafety Framework (NBF) for Macedonia and other projects financed form abroad was extremely valuable in the development of the national biosafety system and have foster many of the activities towards establishment of the functional and efficient NBF.

We sincerely hope that Macedonia will also be part of the Implementation of National Biosafety Framework Project, in order to follow the continuance in the already started activities, connections and mechanisms among most of the stakeholders in the biosafety area on different levels.

## **9. ACKNOWLEDGMENT**

We would like to thank to all contributors to the National Project for their support and evaluation during the development of the National Biosafety Framework for Republic of Macedonia. A special thanks is given to the Ministry of Environment and Physical Planning as well as to all Macedonian authorities and institutions for their support. The enthusiastic collaboration by the National Coordination Committee helped to prepare valuable survey on the biosafety sector in the country, organize workshops and working groups, all in manner to develop the most efficient biosafety framework for Macedonia. We would like to express our gratitude for their support to all other individuals, organizations, and collaborating experts from Slovenia, Bulgaria, Austria, Croatia, Serbia and Montenegro, research institutions and universities, non-governmental organizations, with special thanks to Dr. Darja Stanich Racman for the great support as adviser during the development of the Macedonian NBF. And on behalf of the National Project team and the Ministry for Environment and Physical Planning in Republic of Macedonia, a great appreciation and thanks to the UNEP/GEF for the valuable financial, administrative and expert assistance and support, with special thanks to the UNEP/GEF team in Geneva, Liina Eek, Christopher Briggs and Andrea Gondova for their quick and efficient consultation.

**ANNEX 1**  
**Draft Version**

**LAW ON GENETICALLY MODIFIED ORGANISMS**

**Chapter I**  
**GENERAL PROVISIONS**

**Article 1**  
**Subject of the Law**

(1) This Law shall regulate the rights and responsibilities of the Republic of Macedonia and the legal entities and natural persons regarding the management of the genetically modified organisms and their products, measures for preventing and reducing the possible adverse effects on the environment and of human health, as a result of the contained use of genetically modified organisms (hereinafter: GMO), deliberate release of GMO in the environment or placing on the market of GMO or products containing or consisting of GMO or their combinations, and the import, export and transboundary movement of GMO and their products.

(2) The procedures defined by this Law shall be regulated by the Law on General Management Procedure, unless defined otherwise by this Law.

**Article 2**  
**Application of the Law**

(1) The Provisions of this Law referring to the contained use shall not apply for the following procedures of modifying the genetic material:

- mutagenesis,
- cell or protoplast fusion (combining) of cells of procariotic species with a possibility to create organisms by traditional breeding techniques/methods;
- cell or protoplast fusion (combining) of cells of procariotic species, including obtaining of hybridomas and plant cell fusion (combining);
- self-cloning, including the removal of nucleic acid (NA) sequences from cells or part of the NA or syntetic equivalent, with or without reinsertion of all or part of that NA or syntetic equivalent, with or without prior enzymatic or mechanical treatment, into cells of the same or phylogenetically related species. The self-cloning may also include use of recombinant vectors with a verified safe use in the particular micro-organisms, provided that they do not include the use of molecules of the recombinant nucleic acids or other GMO except for those created with the use of these procedures;

(2) The Provisions of this Law referring to the deliberate release of GMO into the environment and placing on the market of GMO or products containing or consisting of GMO or their combinations, shall not apply for the following procedures of modifying the genetic material:

- mutagenesis
- cell or protoplast fusion (combining) of plant cells if it is possible to obtain organisms thus created with ordinary techniques of culture, provided that they do

not include the use of molecules of the recombinant nucleic acids or other GMO except for those created with the use of these procedures;

(3) The provisions of this Law shall not apply to the transport of genetically modified organisms by railway, road, internal waterways or air

(4) The provisions of this Law shall not apply to the placing on the market of GMO, import and export of GMO and their products shall not apply for:

- pharmaceutical products used in the human and veterinary medicine, containing or consisting of GMO or their combinations, and
- food and food products used for production, treatment, processing and preparation of food aimed for human use, containing or consisting of GMO or their combinations, placing on the market, import and export of GMO that are to be regulated by specific provisions for food.

### **Article 3 Objectives of the Law**

(1) The objectives of this Law shall be:

1. High level of environment and human health protection when managing GMO and their products;
2. Monitor the developments and use of GMO and their products;
3. Preserve the biological diversity and control the risk by deliberate release of GMO and their products into the environment;
4. Guarantee proper level of protection in the field of safe transport, handling and use of GMO, particularly in the transboundary transport;

### **Article 4 Definitions**

1. ***Organism*** shall mean any biological entity capable of replication or of transferring the genetic material, including the sterile organisms, viruses and viroids;
2. ***Micro-organism*** shall mean any cellular or non-cellular microbiological entity, capable of replication or of transferring the genetic material, including viruses, viroids, and cultures of animal and plant cells;
3. ***Genetically modified organism (GMO)*** shall mean organism in which the genetic material has been altered in a manner that does not occur naturally by the processes of mating and/or natural recombination, including micro-organisms, with the exception of human beings;
4. ***Deliberate release of GMO into the environment*** shall mean any deliberate release of GMO or combination of GMOs into the environment, on which no special containment measures are used to limitate the contact of GMO with the environment, thus provide the human population and the environment high level of safety;
5. ***Placing GMO on the market*** shall mean making GMO available for third parties, in return for payment or free of charge;
6. ***GMO product*** shall mean a preparation/product consisting of or containing GMO or combination of GMO, that is placed on the market;

7. **Contained use of GMO** shall mean activity carried out in a premise, installation or other physical structure, in which the organisms are genetically modified or in which such genetically modified organisms are cultivated, stored, transported, destroyed, distributed or in any other way used, in order to limit the contact of GMO and provide high level of safety for the population or the environment;

8. **Accident** shall mean any incident that includes significant and unintended release of GMO(s) during contained use, which could present immediate or delayed hazard to the human life and health or the environment;

9. **Immediate effects** shall mean the effects on the human health or the environment occurring after the release of GMO into the environment, or their placing on the market. The immediate effects may be direct and indirect;

10. **Cumulative long-term effects** shall generally mean accumulated effects from the contained use of GMO(s), or deliberate release of GMO(s) into the environment, on the human health, including the *inter alia* flora, fauna, soil fertility, disintegration of organic matters in the soil, food chain, biological diversity, animal health;

11. **Level of containment** shall mean complex of safety measures for protection of the human health or the environment, aimed at reducing to the lowest level the contact between the premisses, people and environment on one, and the GMO(s) on the other hand, during the contained use;

12. **Modern biotechnology** shall mean application of:

a. *in-vitro techniques of nucleic acid*, including the recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid in the na organel cells, or

b. **Fusion of cells** that do not belong to the taxonomy family, exceeding the natural physiological and reproductive barriers, and not techniques applied in the traditional breeding and selection;

13. **Notification** shall mean submission of documents containing the information required by the authorities in the country;

14. **Notifier** shall mean legal entity or individual that intends to or carries out activities with GMO(s) during the contained use, intends to deliberately release GMO into the environment, or intends to release or places products on the market;

15. **Environmental risk assessment** shall mean assessment of the risks on the human health or the environment - direct or indirect, current or delayed, that could cause deliberate placing on the market;

16. **Transboundary movement** shall mean movement of the genetically modified organism from one to the other country/ies;

17. **Import** shall mean any entry of the product in the customs area of the Republic of Macedonia, regardless to the use or notification of the product;

18. The following activities shall not be considered genetic modification:

1. *in vitro insemination*;

2. *natural processes, such as: conjugation, transduction and transformation*;

3. *polyploid induction*;

4. *culture of tissue*.

**Article 5**  
**Principles**

**Principle of Integration**

(1) The bases and objectives of the policy of GMO management, and the measures for preventing the harmful effects on the environment and human life shall be integrated in all the strategic plan and programme documents in the field of finances, education, research work and developments, adopted by the authorities of the Republic of Macedonia.

**Article 6**  
**Principle of Precaution**

(1) Should there be any justified doubt of possible harmful effects on the environment and human life and health caused by the use of GMO, all necessary measures and activities for protection shall be undertaken prior to obtaining the credible scientific evidence on the occurrence of such harmful effects.

**Article 7**  
**Principle of Bio-ethics**

(1) During the GMO management, the welfare of people and the welfare of all living organisms and the environment shall be taken into consideration.

**Article 8**  
**Principle “Case by Case”**

(1) The contained use, deliberate release of GMO(s) into the environment and placing products on the market shall be carried out upon a prior assessment of the risks and possible harmful effects on the environment and human health, differing from case to case, taking into account the possible cumulative effects from the mutual impact with the other GMOs and/or the environment.

**Article 9**  
**Principle Step by Step**

(1) The introduction of GMO into the environment shall be carried out based on the gradual reduction of the control of GMO, and gradual increase of the scope of release of GMO, “step by step”, but only if the assessment of the prior steps regarding the human health and environment protection indicate that the next step can be undertaken.

**Article 10**  
**Causer pays Principle**

(1) The entity carrying out activities of contained use of GMO, deliberate release of GMO(s) into the environment and placing on the market, shall cover all the costs for elimination of the danger, costs for sanation of the consequences of the harmful effects from the GMO management.

**Article 11**  
**Principle of Responsibility**

(1) The entity carrying out activities with contained use of GMO, deliberate release of GMO into the environment, and placing on the market, shall reimburse the costs for the damage occurred during the GMO management.

**Article 12**  
**Obligatory/compulsory measures**

(1) The Republic of Macedonia shall undertake all the measures required for reducing or preventing the consequences of the harmful effects from the contained use of GMO, deliberate release of GMO into the environment, and release into trade, if the entity carrying out these activities can not be identified.. If the entity is additionally identified, the entity shall reimburse the costs occurred for elimination or prevention of the consequences.

**Article 13**  
**Principle of Public Participation and access to information**

(1) The state authority bodies shall provide all the necessary measures for exercising the right to access to information on the state of GMO, the occurred damages and undertaken activities for elimination of the damages, and a right of public participation in the process of decision making on the GMO management.

## **Chapter II Commission and Technical Committees**

### **Article 14 Commission on GMO management**

(1) The Government of the Republic of Macedonia shall, for the purpose of addressing the GMO issues, management of GMO and monitoring of the conditions and developments in the field of GMO management, upon a proposal of the Ministry of Environment and Physical Planning, establish a Commission on GMO Management (hereinafter: Commission).

(2) The Commission referred to in Paragraph 1 of this Article shall consist of fifteen members, with a mandate of four years.

(3) The Commission shall consist of:

- a representative of the Macedonian Academy of Sciences and Arts,
- two representatives of the social sciences,
- four representatives of the natural and biotechnical sciences,
- three representatives of the medical, veterinary and pharmaceutic sciences,
- two representatives of the scientific Committees,
- two representatives of the citizens associations in the field of environment and nature protection, consumer protection and health protection), and
- representative of the Chamber of Commerce of the Republic of Macedonia.

(4) The Minister of Environment and Physical Planning shall specify the conditions and procedure for nomination and appointment of the members of the Commission referred to in Paragraph 1 of this Article

(5) The Commission shall issue Rules of Procedure for its work.

(6) The Commission shall be independent and sovereign in its work.

(7) The work of the Commission shall be public.

(8) The Ministry of Environment and Physical Planning shall provide the expert and administrative-technical activities required for the work of the Commission.

(9) The members of the Commission shall be entitled to a fee.

(10) The Government of the Republic of Macedonia shall specify the amount of the fee referred to in Paragraph 9 of this Article.

### **Article 15 Responsibilities of the Commission**

(1) The responsibilities of the Commission shall be:

1. monitoring the conditions and developments in the field of use of the genetic technologies and GMO management,
2. taking positions and giving opinions and proposals on the use of of the genetic technologies and GMO management in relation to the social, ethical, technical and technological, scientific and other aspects of GMO management,
3. advising the Government of the Republic of Macedonia in relation to the use of the genetic technologies and GMO management,
4. informing the public on its work, especially in relation to the conditions and developments in the field of use of the genetic technologies and GMO management, exchanging experiences and data and cooperating with related institutions, and similar.

### **Article 16**

## **Scientific Committees**

(1) In order to address the issues in the field of GMO and provide professional assistance in giving opinions and proposals, the Government shall, as advisory bodies, establish:

- Scientific Committee on work with GMO(s) in contained use (hereinafter: Scientific Committee on contained use), and
- Scientific Committee on deliberate release of GMO(s) into the environment and placing products on the market (hereinafter: Scientific Committee on GMO release) .

(2) The Scientific Committee on contained use shall consist of seven members – prominent experts and individuals with technical knowledge on an expert level in the field of microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, biotechnology and safety at work.

(3) The Scientific Committee on deliberate release of GMO(s) shall consist of seven members - prominent experts and individuals with technical knowledge on an expert level in the field of microbiology, genetics, biology, agriculture, forestry, veterinary science, biochemistry and molecular biology, microbiology and medicine.

(4) The Minister of Education and Science shall specify the conditions and procedure for nomination and appointment of the members of the Committees referred to in Paragraph 1 of this Article and their deputies. The members of the Committees referred to in Paragraph 1 of this Article shall be appointed for a period of 4 years.

(5) The Committees may, in relation to the nature of notification on which an expert opinion is given, include/invite other experts from fields relevant for the discussion.

(6) The Government shall define in detail the scope and manner of work of the Committees in detail.

(7) The Ministry of Education and Science shall provide the expert and administrative-technical activities required for the work of the Committees.

(8) The members of the Committees shall be entitled to a fee.

(9) The Government of the Republic of Macedonia shall specify the amount of the fee.

## **Article 17**

### **Scope of the Scientific Committees**

(1) The Scientific Committees referred to in Paragraph 1, Article 16 of this Law shall address and give opinions and proposals in relation to:

- providing expert opinions on the GMO management,
- providing opinions and proposals in the drafting of the regulative and other legal acts on GMO management,
- providing opinions and proposals on other issues related to the GMO management on a request of the relevant ministries,
- defining the manner of implementation (elements and scope) of the risk assessment from the methodology of generation of GMO, contained use, deliberate release of GMO into the environment, and release into trade,.

(2) The Committees referred to in Paragraph 1, Article 16 of this Law shall submit an annual Report on their work to the Government of the Republic of Macedonia until 31 January in the ongoing year, and shall publish the Reports.

## **Article 18**

### **(Exclusion of interests and data protection)**

(1) The members of the Committees referred to in Paragraph 1, Article 16 of this Law and their Deputies can not be related, or have business or financial relations with the notifiers on whose Notifications the Committees shall adopt an expert opinion in accordance with the provisions of this Law.

(2) The members of the Committees and their Deputies referred to in Paragraph 1 of this Article shall, during their mandate in the Committee and after its expiry, protect the data which are defined as confidential in accordance with this Law.

(3) The outside experts who participate in the work of the Committees referred to in Paragraph 1, Article 16 of this Law shall protect the confidential data in accordance with the provisions of this Law.

### **Article 19 (Informing the public)**

(1) The data on contained use, deliberate release of GMO into the environment, and release of products into trade shall be public, in manner and conditions defined by law.

### **Article 20 (Additional responsibilities)**

(1) The Ministry of Environment and Physical Planning shall undertake all measures required for reduction or elimination of the consequences of the contained use, deliberate release of GMO into the environment, and release of products into trade.

(2) The Ministry of Environment and Physical Planning shall immediately inform the public on the possible consequences and undertaken measures referred to in Paragraph 1 of this Article.

(3) The Ministry of Environment and Physical Planning shall, through the Ministry of Foreign Affairs, initiate a procedure to inform the competent authorities of the neighboring countries on the measures undertaken in case in which the undertaken measures have negative impact on the environment and human health in the neighboring countries.

## **Chapter III CONTAINED USE**

### **Article 21 (Classes)**

(1) Depending on the level of risk it poses upon the human life and health and the environment, the contained use shall be classified in one of the following four classes:

- Class 1, in case of insignificant risk,
- Class 2, in case of low risk,
- Class 3, in case of moderate risk,
- Class 4, in case of high risk,

(2) The classification referred to in Paragraph 1 of this Article shall be carried out in accordance with the containment and other safety measures specified by this Law.

(3) The Government of the Republic of Macedonia shall define the criteria for classification referred to in Paragraph 1 of this Article, and the criteria for defining the safety measures, rules of management and other conditions for the specific class.

(4) The Minister of Environment and Physical Planning shall, in cooperation with the Minister of Agriculture, Forestry and Water Economy, based on the criteria referred to in Paragraph 3 of this Article, define in details the contained use of GMO in the specific classes,

the particular safety measures, rules of management and other conditions for the specific class.

## **Article 22** **Notifications on the premises**

(1) The contained use of GMO may only be carried out in premises which fulfill the required conditions on the class into which the intended work is carried out, in accordance with the provisions referred to in Article 21 of this Law.

(2) The notifier shall, prior to the starting of the use of the premises for contained use, submit a Notification to the Ministry of Environment and Physical Planning.

(3) The notification shall in particular contain data on the notifier, the premises and the class of the intended contained use.

(4) The Ministry of Environment and Physical Planning shall, within a period of 60 days from receiving the notification, issue a **Receipt** for enrolling the premises in the Registry of GMO(s).

(5) The Ministry of Environment and Physical Planning shall issue a Receipt referred to in Paragraph 4 of this Article upon obtaining a prior expert opinion by the Committee on contained use.

(6) The Committee shall submit the opinion within a period of 30 days of the reception of the Notification; otherwise the opinion shall be considered negative.

(7) The Minister of Environment and Physical Planning shall define in details the content of the Notification referred to in Paragraph 3 of this Article and the procedure after the Notification.

## **Article 23** **(Class 1 of contained use of GMO)**

(1) Class 1 of contained use of GMO may start without notification to the Ministry of Environment and Physical Planning should it be carried out in premises for which a Receipt is issued in accordance with Article 22 of this Law.

(2) The notifier shall, at a request of Ministry of Environment and Physical Planning, submit the risk assessment on the planned work.

## **Article 24** **(Class 2 of contained use of GMO)**

(1) The Notification on class 2 of contained use of GMO which shall be carried out in premises for which a Permit is issued in accordance with Article 22 of this Law, shall be submitted to the Ministry of Environment and Physical Planning.

(2) The notification referred to in paragraph 1 of this Article shall include in particular data on the premises, type and characteristics of GMO, duration, manner and purpose of the work with them, safety measures, including the measures on waste management, and envisaged measures in case of accident. A summary of the risk assessment on the intended work with GMO shall be part of the notification.

(3) The notifier may commence the work 45 days after the submission of the notification, or prior - at own request and with permission of the Ministry of Environment and Physical Planning.

(4) The Ministry of Environment and Physical Planning may, within a period of 45 days, require the notifier that the contained use of GMO does not commence.

(5) The notifier may, after the submission of the notification, commence the work, should somebody else has previously carried out work in the same premises with GMO of second or higher class on which all the required conditions are fulfilled.

(6) The Ministry of Environment and Physical Planning shall decide on the request referred to in paragraph 5 of this Article, within 45 days of the submission of the notification, upon a prior obtained written opinion by the Committee on contained use of GMO.

(7) The Committee on contained use of GMO shall, within a period of 21 days from the day of the reception of the notification, send/submit a written opinion to the Ministry of Environment and Physical Planning; otherwise the opinion shall be considered negative.

(8) The Minister of Environment and Physical Planning shall define in details the detailed content of the notification on Class 2 of contained use of GMO, and the conditions, manner and procedure for Permit issuing.

#### **Article 25** **(Classes 3 and 4 of contained use of GMO)**

(1) The notifier shall obtain a Permit from the Ministry of Environment and Physical Planning, on Classes 3 and 4 of contained use of GMO which shall be carried out in premises for which a Receipt is issued in accordance with Article 22 of this Law.

(2) The notification shall in particular contain:

- data on the work carried out by the notifier,
- description of the equipment in the premises,
- brief description of the notification,
- content on the risk assessment of the intended work with GMO, and
- plan in the event of accident.

(3) The Ministry of Environment and Physical Planning shall, on the basis of the opinion given by the Committee on contained use, verify the compliance of the notification.

(4) The Ministry of Environment and Physical Planning shall verify the compliance of the notification no later than 45 days of the submission of the notification if classes 3 and 4 of the contained use for which a Permit has been issued have already been carried out, and all the required conditions were fulfilled during the contained use.

(5) The Ministry of Environment and Physical Planning shall, in cases not referred to in Paragraph 4 of this Article, on the basis of a written consent given by the Committee on contained use, verify the compliance of the notification within a period of 90 days of its submission.

(6) The Committee on contained use of GMO shall, within a period of 21 days of the reception of the notification copy in the cases referred to in Paragraph 3 of this Article, and within a period of 45 days of the reception of the notification copy in the cases referred to in paragraph 4 of this Article, submit a written opinion to the Ministry of Environment and Physical Planning; otherwise the opinion shall be considered negative.

(7) The Permit on classes 3 and 4 of contained use shall be issued for the period requested by the notifier. The notifier may, prior to the expiry of the Permit validity, request for its extension, should all required conditions be fulfilled.

(8) The Minister of Environment and Physical Planning shall define in details the detailed content of the notification.

#### **Article 26** **(Risk assesment)**

(1) The notifier shall, prior to commencing the contained use, make a risk assessment related to the work.

(2) In the risk assesment, on the basis of the analysis of GMO characteristics, intended work and the environment to be exposed to the risk, the possible negative impact, level of risk and required containment, safety measures and waste management measures shall be defined. The measures of waste management and its release shall also be defined.

(3) The notifier shall, on the basis of the risk assessment, classify the contained use on one of the classes referred to in Article 21 of this Law.

(4) In case the notifier is not certain about the class in which the contained use should be included, the contained use shall be classified in the class with more strict containment measures, or in the class with less strict containment measures only upon a prior consent by the Ministry of Environment and Physical Planning.

(5) The notifier shall make the risk assessment until the completion of the work with GMO.

(6) During the application of the contained use, the notifier shall, at least once a year, make revision of the risk assessment, supplement it if required, in relation to the suitability of the containment and other measures related to the class and other scientific achievements, inform the Ministry of Environment and Physical Planning on each supplement related to the work with GMO of second, third and fourth class.

(7) The Minister of Environment and Physical Planning shall define in details the elements and scope of the risk assessment and the methodology of carrying out contained use.

### **Article 27 (Emergency Plan)**

(1) The notifier shall, prior to commencing the contained use, prepare an Emergency Plan in case of accident.

(2) The Emergency Plan shall consist of:

- Risk assessment on the of possible threats to the environment and human health in case of accident,
- Statement on the measures on risk elimination and the immediate and delayed consequences from the accident,
- Statement on the persons and competent bodies to be included in the implementation of the expected measures,
- The manner and scope of providing information and warning the responsible bodies, services and population in case of accident.

(3) The notifier shall, prior to commencing the contained use, submit the Emergency Plan to the Ministry of Environment and Physical Planning, the Ministry of Defence, the municipality on whose territory the contained use is carried out, which shall use the Emergency Plan during making the risk assessment and the plan on protection and rescue in accordance with law.

(4) The notifier shall, at least once a year, verify the suitability of the Emergency Plan. The notifier shall, if considered necessary, supplement the Plan and inform the competent bodies on this.

(5) The Minister of Environment and Physical Planning shall in detail define the content and scope of the Emergency Plan regarding the class of work, methodology of preparation, examination and ammendment, the manner and scope of informing and warning the competent bodies, services and population in case of accident.

### **Article 28 (Data confidentiality)**

(1) The notifier may, in the notification referred to in Articles 22, 24 and 25 of this Law, specify the business and intelectual property rights which should be protected as confidential in the procedure, on which a verifiable justification should be given.

(2) The notifier may not specify as confidential the following data:

1. the name, surname, company name, address and registered office of the notifier,
2. the site for carrying out the contained use,
3. any data required for risk assessment,
4. the class of contained use,
5. the containment measures, and

6. data on possible harmful and other impacts on the environment and human health.

(3) The Ministry of Environment and Physical Planning shall, within a period of 15 days from the day of the reception of the Notification, specify the data which should be protected as confidential in the procedure.

(4) The data which are specified as confidential in accordance with the provisions of this Article shall remain protected in the event of the notifier withdrawing the notification.

### **Article 29 (Additional requirements)**

(1) Should the Ministry of Environment and Physical Planning consider that, in the procedure for Receipt issuing referred to in Article 22 of this Law, or Permit issuing referred to in Article 24 or 25 of this Law, additional information for the environment and human health protection, or change of the conditions for intended work or the classification in specific class are required, it may request the notifier to supplement the notification within a specified time period.

(2) The Ministry of Environment and Physical Planning shall, if the notifier does not supplement the notification within the specified time period, by decision terminate the procedure for Permit issuing.

(3) Should the Ministry of Environment and Physical Planning consider that, on the basis of class 2 of contained use, change of the conditions for intended work or the classification in specific class are required for the environment and human health protection, it may request the notifier to make the required changes within a specified time period, during which the work with contained use is temporarily suspended, until approved again with a new notification.

(4) Should the Ministry of Environment and Physical Planning consider that change of the conditions for carrying out class 1 of the contained use is required for the environment and human health protection, it may request the notifier to introduce/implement the required changes within a specified time period, during which the work is temporarily suspended.

(5) The time period for supplementing the notification referred to in Paragraph 1 of this Article shall not be taken into consideration within this time period when issuing the Receipt referred to in Article 23 of this Law, or when issuing the Permit referred to in Article 24 or 25 of this Law.

### **Article 30 (New information)**

(1) Should the notifier obtain new information on the contained use carried out or change the contained use, thus significantly impacts the level of risk or classification of contained use, the notifier shall submit the new information to the Ministry of Environment and Physical Planning if the information refers to class 2 of contained use, or shall require a Permit if the information refers to class 3 and 4 of contained use.

(2) Should the Ministry of Environment and Physical Planning itself obtain new information on the contained use carried out or on change of the contained use, thus significantly impacts the level of risk or classification of contained use, the Ministry shall start a procedure of requesting the notifier to change the conditions of contained use, in a manner that shall be in accordance with the new requests.

(3) The Ministry of Environment and Physical Planning may, in the cases referred to the Paragraphs above, request the notifier to temporarily suspend the contained use for a

specified period, until a decision is made on the compliance of the new notification with the requirements.

(4) Should the Ministry of Environment and Physical Planning, on the basis of the new information on the contained use or the changes in the work that may significantly impact the level of risk, conclude that the contained use can not be carried out any longer, the Ministry shall by Decision prohibit it.

### **Article 31 (Accidents)**

(1) The notifier shall undertake measures in case of accident in accordance with the Emergency Plan, and immediately inform the Ministry of Environment and Physical Planning on:

1. the circumstances of the accident,
2. type and quantities of GMO which have entered the environment from the contained use,
3. measures required and undertaken,
4. other data relevant to the assessment of the accident impact on the environment and human health,

(2) The Ministry of Environment and Physical Planning shall, through the Ministry of Foreign Affairs, inform the competent bodies of the neighboring countries, if the accident may significantly increase the risk on the environment and human health in these countries.

(3) The Ministry of Environment and Physical Planning shall prepare a Report on the accident, measures undertaken and their efficiency, no later than three months after the notification referred to in Paragraph 1 of this Article,

(4) The Government of the Republic of Macedonia shall adopt the Report referred to in Paragraph 3 of this Article and inform the public of it with no delay.

**Chapter IV**  
**DELIBERATE RELEASE OF GMO INTO THE ENVIRONMENT**

**Article 32**  
**(Deliberate release of GMO)**

(1) The Ministry of Environment and Physical Planning shall, in cooperation with the Ministry of Agriculture, Forestry and Water Economy, issue a Permit on deliberate release of GMO into the environment.

(2) The deliberate release of GMO into the environment shall take place in accordance with the provisions and conditions specified in the Permit.

(3) The material obtained from GMO which is the subject of deliberate release of GMO into the environment may be placed on the market only on the basis of prior obtained Permit for placing products on the market.

**Article 33**  
**(Risk Assessment)**

(1) The notifier shall, prior to submitting the notification for obtaining a Permit on the deliberate release of GMO into the environment, provide risk assessment on the intended deliberate release.

(2) In the risk assessment, on the basis of the GMO analysis and characteristics and their deliberate release into the associated environment and the environment which could be exposed to risk, the harmful impact and the possible consequences of it, the level of risk and measures required for their control shall be defined and assessed.

(3) The Minister of Environment and Physical Planning shall, in cooperation with the Minister of Agriculture, Forestry and Water Economy, define in details the elements for the scope/the scope of the risk assessment on the deliberate release of GMO into the environment and the methodology,.

**Article 34**  
**Emergency Plan in case of unintended release**

(1) The notifier shall, prior to the commencing of the deliberate release of GMO into the environment, provide an Emergency Plan in case of unanticipated spread of GMO into the environment.

- (2) The Emergency Plan shall in particular consist of:
1. methods for control of GMO in case of unintended release into the environment,
  2. assessment of the possible consequences and threats to the environment and human health,
  3. measures required at the site of deliberate release of GMO, and
  4. measures required for prevention of the further spread and removal from the exposed environment.

(3) The notifier shall periodically verify the suitability of the Plan referred to in Paragraph 2 of this Article, the notifier shall, if considered necessary, supplement the Plan and inform the Ministry of Environment and Physical Planning on this.

**Article 35**  
**(Data confidentiality in case of deliberate release of GMO)**

(1) The notifier may, in the Notification referred to in Article 36 of this Law, specify the business and intellectual property rights which should be protected as confidential in the procedure, on which a verifiable justification should be given.

(2) The notifier may not specify as confidential the following data in the Notification:

1. the name, surname, company name, address and registered office of the notifier,
2. other data required for the risk assessment,
3. the purpose of the deliberate release and intended use,
4. the location of the deliberate release,
5. programme on monitoring of the Emergency Plan in case of unintended release of GMO into the environment,
6. data on the risk assessment of the intended work.

(3) The Ministry of Environment and Physical Planning shall, within a period of 15 days of the reception of the Notification, by a conclusion specify the data which should be protected as confidential in the procedure.

(4) The data which are specified as confidential in accordance with the provisions of this Article shall remain protected in the event of the notifier withdrawing the Notification.

### **Article 36 (Notification)**

(1) The Notification on Permit issuing on deliberate release of GMO into the environment shall contain:

1. The technical documentation shall consist of:

- data on the Notification, including data on the qualifications of the personnel,
- data on the GMO,
- data on the conditions of the deliberate release and the receiving environment,
- data on the interaction of the GMO and the environment,
- programme on monitoring for establishing and monitoring of the impact on the environment and the human health,
- data on the methods of control of the release of GMO into the environment, waste management and Emergency Plan in case of unintended release of GMO into the environment, and
- summary of the technical documentation;

2. risk assessment on the deliberate release of GMO, and

3. other data the notifier considers important.

(2) The notifier may, in the Notification, refer to the data or results of the deliberate release of GMO into the environment, which another notifier has submitted to the Ministry of Environment and Physical Planning at any time prior to his Notification, only if such data are not protected as confidential in accordance with the provisions of this Law, upon an obtained written consent on their use by the previous notifier.

(3) The notifier may, in the Notification request a uniform Permit on deliberate release of GMO or combination of GMO(s) in various locations, for the same purpose within a specified time.

(4) The Minister of Environment and Physical Planning shall, in cooperation with the Minister of Agriculture, Forestry and Water Economy, define the detailed content of the Notification.

### **Article 37 (Permit issuing)**

(1) The Ministry of Environment and Physical Planning shall, within a period of 90 days from the day of the reception of the Notification, in agreement with the Ministry of Agriculture, Forestry and Water Economy and upon a prior obtained opinion of the Committee on release of GMO(s), issue a Permit on deliberate release of GMO into the environment.

(2) The Committee on release of GMO(s) shall, within a period of 45 days of the reception of the Notification, submit a written opinion; otherwise the opinion shall be considered negative.

(3) The Permit on deliberate release of GMO into the environment shall be issued for the period requested by the notifier.

(4) The notifier may, prior to the expiry of the Permit validity, request for its extension, should all required conditions be fulfilled. The notifier shall submit the request for Permit extension within a period of 30 days prior to the expiration of the Permit validity.

### **Article 38 (Additional requirements)**

(1) Should the competent bodies consider that, in the procedure for Permit issuing referred to in Article 37 of this Law, additional information are required, the Ministry of Environment and Physical Planning may request the notifier to supplement the notification within a specified time period. The Ministry shall, in the request, specify the reasons for requiring additional data.

(2) The Ministry of Environment and Physical Planning shall, if the notifier does not supplement the notification within the specified time period, by decision terminate the procedure for Permit issuing.

(3) The time period referred to in Paragraph 1 of this Article shall not be counted within the time period required for the Permit issuing referred to in Article 37 of this Law.

### **Article 39 Consulting and informing the public**

(1) The Ministry of Environment and Physical Planning shall, during the procedure on Permit issuing, provide the public perusal to the technical documentation, risk assessment referred to in Paragraph 1 of Article 37, opinion of the Committee on release of GMO(s) on the deliberate release, and a public hearing on the intended release.

(2) The place and date of the public hearing referred to in Paragraph 1 of this Article, the manner of giving opinions and comments, shall be published in the public media.

(3) The time period in which the Ministry of Environment and Physical Planning shall provide perusal to the information and possibility of giving opinions and comments shall be at least 15 days, and at most 30 days, which shall not be counted within the time period required for the Permit issuing referred to in Article 37 of this Law.

(4) The Ministry of Environment and Physical Planning shall, in the procedure of Permit issuing, take into consideration the public opinion and comments.

(5) The costs of the public hearing shall be borne by the notifier.

### **Article 40 New information**

(1) Should the notifier, after the submission of the Notification referred to in Paragraph 1, Article 36 of this Law, obtain new information on the deliberate release of GMO into the environment, which significantly impact the level of risk, the notifier shall, without

delay, submit the new information to the Ministry of Environment and Physical Planning, and submit a new Notification.

(2) Should the notifier, after the issuing of the Permit on deliberate release of GMO into the environment, obtain new information referred to in Paragraph 1 of this Article, or if during the carrying out of the deliberate release unexpected changes occur, which significantly impact the level of risk, the notifier shall, without delay:

1. undertake all the required measures for environment and human health protection,
2. inform the Ministry of Environment and Physical Planning on the planned or unexpected changes of the new data, and
3. submit a new Notification

(3) Should the competent bodies referred to in Paragraph 1, Article 32 of this Law, after the Permit issuing on deliberate release of GMO into the environment, obtain new information on the changes referred to in Paragraph 2 of this Article, the Ministry of Environment and Physical Planning shall request the notifier to change the conditions on deliberate release of GMO into the environment.

(4) The Ministry of Environment and Physical Planning shall, in agreement with the Ministry of Agriculture, Forestry and Water Economy and the Ministry of Health, in the cases referred to in Paragraphs 2 and 3 of this Article, request the notifier to temporarily suspend the deliberate release of GMO into the environment, until a Permit is issued on the compliance of the new notification with the requirements.

(5) Should the competent bodies, on the basis of the new information or the changes referred to in Paragraphs 2 and 3 of this Article, conclude that the deliberate release of GMO into the environment can not be carried out any longer, the Ministry of Environment and Physical Planning shall, in agreement with the Ministry of Agriculture, Forestry and Water Economy and the Ministry of Health, prohibit it.

(6) The Ministry of Environment and Physical Planning shall inform the public on the new data or changes occurred after the issuing of the Permit on deliberate release of GMO into the environment.

#### **Article 41**

##### **Report**

(1) The notifier shall, no longer than 60 days after the expiry of the period for which the Ministry of Environment and Physical Planning has issued a Permit on deliberate release of GMO into the environment, or within the period specified in the Permit referred to in Article 37 of this Law, submit a Report to the Ministry, on the results of the deliberate release of GMO into the environment.

(2) The notifier shall, in the Report, state the intention to release the product or any other material obtained from GMO placing on the market, or any subject of deliberate release into the environment referred to in Paragraph 1 of this Article.

(3) The Minister of Environment and Physical Planning shall, in agreement with the Minister of Agriculture, Forestry and Water Economy, define in details the scope and content of the Report.

#### **Article 42**

##### **Unintended release na GMO**

(1) The notifier shall, in case of unintended release of GMO into the environment, undertake measures in agreement with the Emergency Plan referred to in Article 34 of this Law, and shall immediately inform the Ministry of Environment and Physical Planning on:

1. the extent of consequences from the scope of unintended release of GMO into the environment and the threat on the environment and human health,

2. measures undertaken and additional measures to be undertaken for environment and human health protection,
3. measures undertaken and additional measures to be undertaken for reduction or elimination of the consequences, elimination of the GMO from the unintended release into the exposed environment, and
4. other data relevant to the assessment of the effects on the environment and human health, caused by the unintended release of GMO into the environment.

(2) The Ministry of Environment and Physical Planning shall, on the basis of the Notification referred to in Paragraph 1 of this Article, in cooperation with the competent Ministries, prepare a Programme on remediation of the consequences of the uncontrolled spread of GMO into the environment.

(3) The Programme shall define the competent bodies, conditions and measures for remediation of the consequences or prevention of the further uncontrolled spread of GMO, the deadlines for their preparation and implementation, the manner of covering the expenses/costs and required restrictions or prohibitions in relation to the further deliberate release of GMO, the import, trade or use of GMO.

(4) The Government of the Republic of Macedonia shall adopt the Programme on remediation of the consequences of the uncontrolled spread of GMO into the environment.

(5) The Ministry of Environment and Physical Planning shall prepare a Report for the cases referred to in Paragraph 1 of this Article, on the preparation and implementation of the Programme referred to in Paragraph 2 of this Article, which the Government shall adopt, and inform the public on it without delay.

(6) Should the Ministry of Environment and Physical Planning conclude that the undertaken activities may have negative impact on the human life and health and on the environment at the territory of another country, it shall immediately inform the competent bodies of the other country.

## **Chapter V**

### **PLACING PRODUCTS ON THE MARKET**

#### **Article 43**

##### **Placing products on the market**

(1) The Ministry of Environment and Physical Planning shall, upon a prior obtained consent by the Ministry of Health and the Ministry of Agriculture, Forestry and Water Economy, issue a Permit for placing products on the market.

(2) The Permit shall be issued for products which are for the first time placed on the market.

#### **Article 44**

##### **Risk assessment**

(1) The notifier shall, prior to submitting the notification for obtaining a Permit on placing products on the market, provide risk assessment on the intended placing products on the market.

(2) In the risk assessment, on the basis of the analysis and characteristics of GMO, products containing GMO and their use, and the environment in which the GMO and products containing GMO shall be used, the negative impact and the possible consequences on the human health and the environment, the level of risk and measures required for their control shall be defined and assessed.

(3) The Minister of Environment and Physical Planning shall, in cooperation with the Minister of Health and the Minister of Agriculture, Forestry and Water Economy, closely define the methodology, the elements and the scope of risk assessment on the placing products on the market, and the methodology for its preparation.

#### **Article 45**

##### **Notification**

(1) The Notification on issuing of Permit for placing products on the market shall in particular contain the following:

1. The technical documentation shall consist the data referred to in item 1, Paragraph 1, Article 36 of this Law, and data on:
  - the proposed trade name of the product,
  - information on the producer, importer and distributor responsible for placing products on the market,
  - the institutions to carry out control of the samples and their submission to the competent bodies,
  - the intended use of the product,
2. Risk assessment and intended placing products on the market,
3. Data on the conditions for placing products on the market, including the conditions for use and management of the products,
4. Programme on monitoring of the impact of the product and its use on the environment and human health, including the proposed period for their implementation,
5. Proposal on the period for which the Permit shall be issued,
6. Proposal on the product labeling regarding the GMO content,
7. Proposal on the product packaging,

8. Brief description of the content of the Notification, and
9. Additional information

(2) Should the notifier, on the basis of the results from the prior deliberate release of a GMO into the environment in accordance with the provisions of this Law, or on the basis of other scientific facts, conclude that the placing of the product on the market and its use do not present a risk, the notifier may propose to the Ministry of Environment and Physical Planning a specification of a lesser scope of the Notification than the one referred to in Paragraph 1 of this Article.

(3) The notifier may, in the Notification, include data on the deliberate release into the environment of the same GMO or combination of GMO(s) as in the product, which has been notified or used in the country and abroad.

(4) The notifier may refer to the data or results of the prior submitted Notification to the Ministry of Environment and Physical Planning, providing evidence that they are not protected as confidential, or upon an obtained written consent on their use.

(5) A special Notification for placing products on the market shall be obtained for the GMO and products containing GMO to be used for purposes different than the ones referred to in the first Notification, a Permit for which has already been issued.

(6) The Minister of Agriculture, Forestry and Water Economy shall, in cooperation with the Minister of Health, closely define the content of the Notification for release of GMO and products containing GMO to be placed on the market and the data which are not part of that Notification, for the cases not referred to in Paragraph 2 of this Article.

#### **Article 46**

##### **Data confidentiality**

(1) The notifier may, in the Notification referred to in Articles 46 and 49 of this Law, specify the business and intellectual property rights which should be protected as confidential in the procedure, on which a verifiable justification should be given.

(2) The notifier may not specify as confidential the following data:

1. the name, surname, company name, address and registered office of the notifier,
2. the intended method for the product use and the location of the placing of the product on the market and its use,
3. any data required for the risk assessment,
4. programme on monitoring in case of placing of the product on the market and its use, and measures in case of unanticipated risks during the placing of the product on the market and its use, and Emergency Plan, and
5. risk assessment.

(3) The Ministry of Environment and Physical Planning shall, within a period of 15 days of the reception of the Notification, by decision specify the data which should be protected as confidential in the procedure.

(4) The data which are specified as confidential shall remain protected in the event of the notifier withdrawing the Notification.

#### **Article 47**

##### **Assessment Report on the product**

(1) The Ministry of Environment and Physical Planning shall, on the basis of a prior obtained opinion on the release of GMO(s), in cooperation with the Ministries referred to in Article 48 of this Law, prepare an Assessment Report on the product to be placed on the market and its use (hereinafter: Assessment Report), which shall indicate that the product is:

- suitable for placing on the market,

- suitable for placing on the market under specified additional conditions, or
- unsuitable for placing on the market.

(2) The scientific Committee on deliberate release of GMO(s) into the environment and placing products on the market shall, within a period of 45 days from the day of reception of the Notification, submit a written opinion to the Ministry of Environment and Physical Planning; otherwise the opinion shall be considered negative.

(3) The Ministry of Environment and Physical Planning shall submit the Assessment Report on the product to the notifier within a period of 60 days of the reception of the Notification.

(4) The notifier may, within a period of 7 days from the reception of the Assessment Report, withdraw the Notification on issuing a Permit on placing products on the market, or shall inform the Ministry of Environment and Physical Planning in writing on the intention to supplement the Notification, should the Report state that the product is suitable for placing on the market under specified additional conditions.

(5) If the notifier does not inform the Ministry of Environment and Physical Planning in writing on the intention to supplement the Notification resulting from the Report, the Notification shall be considered withdrawn.

(6) The Ministry of Environment and Physical Planning shall, if the notifier withdraws the Notification or acts in accordance with the provisions of Paragraph 5 of this Article within the time period specified in Paragraph 4 of this Article, by decision terminate the procedure.

(7) There shall be no appeal against the resolution referred to in Paragraph (6) of this Article.

(8) If the notifier inform the Ministry of Environment and Physical Planning in writing within the specified time period on the intention to supplement the Notification, the Ministry shall specify a time period for supplementing the Notification. The time period for supplementing of the Notification shall not be included within the time period specified for obtaining the Permit referred to in Article 48 of this Law.

(9) The Minister of Environment and Physical Planning shall define in details the scope and elements of the Assessment Report.

#### **Article 48**

##### **Permit on placing products on the market**

(1) The Ministry of Environment and Physical Planning shall, in agreement with the Ministry of Health and the Ministry of Agriculture, Forestry and Water Economy, within a period of 105 days from the day of the reception of the Notification, issue a Permit on placing products on the market.

(2) The notifier may place products on the market, in accordance with the conditions specified in the Permit.

(3) The Permit on placing products on the market may be issued for a period of 10 years, with a possibility for its extension in accordance with the provisions of this Law.

(4) If the products are reproduction material or seeds for the forestry activities, the Permit referred Paragraph 1 of this Article shall be issued for a period of 10 years from the day of inclusion in the National Register of species, in accordance with the provisions.

#### **Article 49**

##### **Extending the Permit**

(1) The Permit on placing products on the market may be extended should the notifier, within a period of 9 months prior to the expiry of the Permit validity, submit to the Ministry of Environment and Physical Planning a Notification on extending the Permit, which shall contain:

1. copy of the Permit on placing products on the market for which the extension is requested,
2. report on the monitoring referred to in Article 54 of this Law,
3. new information on the risks that may occur from the use of the product, if such there are such information,
4. proposal on amending and supplementing the conditions specified in the original Permit, related to the placing products on the market, in particular related to the monitoring and time limitations of the Permit validity, should these be relevant.

(2) The provisions referred to in Article 47 of this Law shall be used in the decision making procedure on extending the Permit on placing products on the market.

(3) The Ministry of Environment and Physical Planning shall, in agreement with the Ministries referred to in Article 48 of this Law, within a period of 90 days of the reception of the Notification, for cases not referred to in Paragraph 6, Article 47 of this Law, decide to extend the Permit on placing products on the market.

(4) The Permit may be extended once or more times should all conditions be fulfilled, each time for a maximum period of 10 years.

#### **Article 50** **Content of the Permit**

(1) The Permit on placing products on the market shall contain:

1. the purpose and scope on which the Permit is issued, including the data and marks for identification of the product and GMO(s) in it, and its characteristics,
2. the validity period of the Permit,
3. the conditions for placing products on the market, including the special conditions for use, handling and packing of the product, conditions for protection of the specific ecosystems, parts of the environment or geographic zones,
4. responsibilities of the notifier for preserving the control samples of the product sending the control samples to accredited institutions for analysis,
5. responsibilities for labeling the product on the content of GMO,
6. responsibilities for monitoring, including specification of the period for their application and responsibility of the notifier to inform the Ministry of Environment and Physical Planning on the results of the monitoring, and
7. possible other responsibilities of the persons selling or using the product.

(2) The Permits, except for the data protected as confidential in accordance with this Law, and the risk assessment referred to in Article 44 of this Law, shall be available for the public, in accordance with the law

#### **Article 51** **Consultation with the public**

(1) The Ministry of Environment and Physical Planning shall, in the procedure for issuing Permit on placing products on the market or its extension, whenever it is evident from the Assessment Report that the product is suitable for placing on the market, provide access for the public to the Notification, the opinion of the Committee on release of GMO(s) and the Assessment Report.

(2) The Ministry of Environment and Physical Planning shall release in the public media information on the time and location of maintaining the transparency referred to in Paragraph 1 of this Article, and the manner of providing opinions and comments.

(3) The time period in which the Ministry of Environment and Physical Planning shall provide the transparency and possibility of giving opinions and comments shall be at least 15 days, and at most 30 days, which shall not be counted within the time period required for the Permit issuing referred to in Article 48 of this Law, or for extending the Permit referred to in Article 49 of this Law.

(4) The Ministry of Environment and Physical Planning shall, in the procedure of Permit issuing, take into consideration the public opinion and comments.

## **Article 52**

### **Informing the public**

(1) The Ministry of Environment and Physical Planning shall inform the public on the issuing of Permit on placing products on the market, or its extension, or refusal to extend the issued Permit, with an explanation.

(2) The information on issuing or extending the Permit shall contain data on the type of GMO or products containing or consisting of GMO or their combinations GMO, and intended use of the product.

## **Article 53**

### **New information**

(1) Should the notifier, after the submission of the Notification referred to in Articles 45 or 49 of this Law, prior to the Permit issuing, obtain new information on the possible risk from the placing products on the market, the notifier shall, without delay, inform the Ministry of Environment and Physical Planning, and submit a new Notification.

(2) Should the notifier, after the issuing of the Permit on placing products on the market, obtain new information from the users or in any other manner, the notifier shall, without delay:

- undertake all the required measures for environment and human health protection,
- inform the Ministry of Environment and Physical Planning on the new information and changed conditions, and
- submit a new Notification

3) Should the Ministry of Environment and Physical Planning, prior to the issuing of the Permit on placing products on the market, obtain new information related to the placing products on the market or the risk from using the product, the Ministry shall take them into consideration when making the decision on Permit issuing.

(4) Should the Ministry of Environment and Physical Planning, after the issuing of the Permit on placing products on the market, obtain new information, it shall immediately start a procedure to change the conditions for placing products on the market, in accordance with the new requirements.

(5) The Ministry of Environment and Physical Planning shall, in agreement with the Ministries referred to in Article 48 of this Law, issue a Permit on placing products on the market, within a period of 90 days from the day of the reception of the Notification on the changed conditions in accordance with the new requests, which supplement the existing ones, or shall annul the Permit validity, if the product can no longer be placed on the market due to the changed conditions.

(6) During the procedure of issuing or annulling of the Permit referred to in Paragraph 5 of this Article, the provisions referred to in Articles 47, 51 and 52 of this Law shall be applied.

## **Article 54**

### **Monitoring**

(1) The notifier placing products on the market shall provide monitoring of the impact of the product and its use on the environment and human health in accordance with the monitoring Programme for the product, and shall regularly inform the competent bodies on the monitoring results of, in accordance with the Permit referred to in Article 50 of this Law.

(2) The Ministry of Environment and Physical Planning may, on the basis of the data from the first report on the monitoring results, request the notifier to amend or supplement the monitoring Programme referred to in the Permit.

(3) The data from the monitoring Report shall, in accordance with the Law on Environment, be public.

(4) The Minister of Environment and Physical Planning shall, in cooperation with the Minister of Health and the Minister of Agriculture, Forestry and Water Economy, define in details the content and scope of the monitoring Programme and submission of the data from the monitoring, and the manner and scope of informing referred to in Paragraph 1 of this Article.

### **Article 55** **Labeling the products**

(1) The notifier may place on the market only a product the packaging or declaration of which includes information that the product is containing or consisting of GMO and other information related to the product and its use.

(2) In all phases of placing on the market of GMO as such or inside the products, indicates the following words at a visible place:

\*This product contains genetically modified organisms\*.

(3) The Minister of Environment and Physical Planning shall, in agreement with the other competent ministries, define in details the labeling and packaging of the product.

(4) The Minister of Environment and Physical Planning shall, in cooperation with the Minister of Health and the Minister of Agriculture, Forestry and Water Economy, define in details the scope of information indicated on the packaging or declaration of the product, and the regulations for packing the product.

### **Article 56** **Labeling the GMO(s)**

(1) GMO(s) available to third persons for contained use or deliberate release into the environment shall be labeled in the manner defined in Article 55 of this Law, but it shall not be considered placing product on the market in accordance with Item 5, Article 4 of this Law.

**Chapter VI**  
**IMPORT AND EXPORT OF GMO(s) AND THEIR PRODUCTS**

**Article 57**  
**Import of GMO(s)**

(1) The import of GMO(s) or their products may be carried out upon a prior issuing of a Permit on contained use, Permit on deliberate release into the environment or Permit for placing product on the market, for GMO(s), in accordance with the provisions of this Law.

(2) The import of GMO for contained use, classified in classes 1 or 2 shall only be permitted if, prior to the import, a Permit has been obtained on inclusion of the premisses in the GMO register, in accordance with Article 22 of this Law.

(3) The Minister of Environment and Physical Planning shall define in details the compulsory management and other conditions in relation to the import of GMO(s) or their products.

**Article 58**  
**Export of GMO and their products**

(1) The Minister of Environment and Physical Planning shall define in details the compulsory management and other conditions in relation to the export of GMO(s) or their products.

## **Chapter VII GMO REGISTER**

### **Article 59 GMO Register**

(1) The GMO Register shall consist of documents on the premisses, the contained use, deliberate release of GMO(s) into the environment and placing products on the market.

(2) The documents referred to in Paragraph 1 of this Article shall contain the following data:

1. names of the companies and address of the notifiers for:
  - contained use,
  - deliberate release of GMO(s) into the environment, or
  - placing products on the market
2. addresses and characteristics of the premisses,
3. contained use and its classification,
4. deliberate release of GMO(s) into the environment, including including description of the location of the release, i
5. products and their placing on the market, including description of the location of the placing product on the market.

(3) The Receipts on the premisses, and the issued Permits on contained use, deliberate release of GMO(s) into the environment and the placing products on the market shall be an integral part of the Register.

(4) The Ministry of Environment and Physical Planning shall maintain and keep the GMO register. he Register shall be a public document.

(5) Anyone shall have the right to perusal to the data from the GMO Register, and right to obtain data from the Register in a manner and under conditions defined by law.

(6) The data protected as confidential shall not be included in the documents referred to in Paragraph 1 of this Article.

(7) The Minister of Environment and Physical Planning shall define the form, content, methodology and manner of keeping the Register, and the specification of the material costs for data provision.

## **Chapter VIII SUPERVISION**

### **Article 60 Inspection supervision**

(1) The inspection supervision for implementation of the provisions of this Law shall be carried out by:

- the State Environmental Inspectorate within the Ministry of Environment and Physical Planning
- the Food Directorate within the Ministry of Health
- the State Inspectorate on Agriculture, the State Inspectorate on Forestry, the Veterinary Administration/Veterinary Inspection and the Plant Protection Unit within the Ministry of Agriculture, Forestry and Water Economy
- the State Trade Inspectorate of the Republic of Macedonia within the Ministry of Economy,
- the State Labour Inspectorate within the Ministry of Labour and Social Policy, each in accordance with its competences.

(2) The competent bodies shall carry out:

1. supervision of the implementation of the contained use,
2. supervision of the implementation of the deliberate release of GMO into the environment,
3. supervision of the placing products on the market,
4. supervision of the implementation of the provisions or measures for preventing the possible negative impacts and the prohibitions ordered in that regard.

### **Article 61 Measures to be undertaken by the competent inspectorates**

(1) Should the inspector, during carrying out of his work, or on the basis of the Notification, establish that due to the unfulfilled required conditions and requirements defined by the provisions of this Law, the environment and human health are at risk because of the possible negative impact, the inspector may order the following measures:

1. prohibit the contained use, the deliberate release of GMO into the environment, the placing products on the market;
2. order temporary suspension of the contained use, the deliberate release of GMO into the environment, the placing products on the market;
3. order rectifying of the established irregularities within a time period specified by the Inspector himself; and
4. order improvement and other measures on rectifying and reducing the consequences from the harmful impacts occurred during the GMO management.

## **Chapter IX PENALTY PROVISIONS**

### **Article 62 (Offences)**

(1) A fine of 50.000 denars to 300.000 denars shall be levied upon the legal entity for the offences, if it:

1. during the contained use, do not apply the measures of containment and other safety measures, and do not act in accordance with the required provisions on classification (Article 21),
2. operates in premises without a Receipt of the Ministry of Environment and Physical Planning on inclusion of the premise in the GMO Register (Article 22).
3. does not retain risk assessment during the work with GMO, or does not inform the Ministry of Environment and Physical Planning on an additional assessment should it concern the work in class 2, 3 or 4 (Article 26, Paragraph 5 and 6).
4. has not prepared an Emergency Plan in case of accident, or does not inform the competent Ministries and services within the local self-government units on it (Article 27)
5. carries out work with GMO on contained use of class 1, without a Receipt of the Ministry of Environment and Physical Planning on inclusion of the premise in the GMO Register (Article 23, Paragraph 1),
6. does not inform the Ministry of Environment and Physical Planning on the risk assessment on contained use at its request (Article 23, Paragraph 2),
7. carries out work with GMO on contained use of class 2, without a Notification, or starts to implement it prior to the expiry of the specified legal time period with or without Permit of the Ministry of Environment and Physical Planning, or is in conflict with the decision on prohibition of the work (Article 24, Paragraphs 1, 3 and 4),
8. carries out work with GMO on contained use of class 3 and 4, without a Receipt of the Ministry of Environment and Physical Planning or in conflict with the conditions specified in the Permit (Article 25, Paragraph 1),
9. acts in conflict with the provisions of Article 29 of this Law,
10. acts in conflict with the provisions of Article 30 of this Law,
11. in case of accident does not undertake measures in accordance with the Emergency Plan, or does not immediately inform the Ministry of Environment and Physical Planning on the accident (Article 31)
12. deliberately release GMO into the environment without prior obtaining of Permit, or in conflict with the conditions specified in the Permit (Article 32, Paragraphs 1 and 3)
13. does not prepare an Emergency Plan in case of unintended release of GMO into the environment (Article 34)
14. acts in conflict with the provisions of Article 40 of this Law,
15. does not submit a Report on the results of the deliberate release of GMO into the environment to the Ministry of Environment and Physical Planning within the specified time period (Article 41, Paragraph 1),
16. in case of unintended release of GMO into the environment, does not undertake measures in accordance with the Emergency Plan, or does not immediately inform the Ministry of Environment and Physical Planning on the case (Article 42),

17. place products on the market without prior obtaining of Permit, or in conflict with the conditions specified in the Permit (Article 43, and Article 48, Paragraph 2),
18. does not submit a Notification on extending the Permit on placing products on the market within the specified time period (Article 49, Paragraph 1)
19. acts in conflict with the provisions of Article 53 of this Law,
20. does not carry out monitoring on the impact of the product and its use on the environment and human health, or does not inform the Ministry of Environment and Physical Planning on the monitor results (Article 54, Paragraph 1)
21. place on the market product which is not labeled or packed in the requested manner (Articles 55 and 56),
22. provide GMO on contained use or deliberate release to third person in conflict with the provisions of Article 56 of this Law, and
23. imports GMO or product in conflict with the provisions of Article 57, Paragraphs 1 and 2 of this Law.
24. A fine of 10.000 to 300.000 denars shall be levied upon the natural person in relation to the independent carrying out of activities referred to in Paragraph 23 of this Article.

(2) A fine of 1.000 denars to 50.000 denars shall be levied upon the natural person - member of the scientific Committee, who shall not protect the data specified as confidential in accordance with the provisions of this Law. (Article 28 Paragraph 2).

**Chapter X**  
**TRANSITIONAL AND FINAL PROVISIONS**

**Article 63**  
**Government provisions**

The Government of the Republic of Macedonia shall, within a period of nine months from the day of the entering into force of this Law, provide:

1. establishment of a Commission on GMO management (Article 14) and scientific Committees (Article 16)
2. define the criteria for classification and criteria for defining the safety measures, rules of management and other conditions for the specific class. (Article 21)
3. compulsory management and other conditions related to the import of GMO or their products (Article 57)
4. compulsory management and other conditions related to the export of GMO or their products (Article 58)

**Article 64**  
**Food products**

(1) Irrespective to the provisions of Paragraph 4, Article 2 of this Law, prior to the entering into force of the regulations for the specific requests for placing on the market of new food products, the provisions of this Law referring to the placing products on the market and import and export of GMO(s) and their products shall also be used for the food products, which are GMO (s) or products containing or consisting of GMO or their combinations.

(2) The Ministry of Health shall, in cooperation with the Ministry of Agriculture, Forestry and Water Economy, in the cases referred to in Paragraph 1 of this Article, make decisions on the Permit issuing in accordance with Articles 48 and 49 of this Law.

**Article 65**  
**Regulations on the implementation of the Law**

(1) The specific regulation on the implementation of this Law shall be issued within a period of one year from the day of entering of this Law into force.

**Article 66**  
**Entering into force**

This Law shall enter into force on the eight day of its publishing in the Official Gazette of the Republic of Macedonia.

## **ANNEX 2**

**POLL CARRIED OUT WITH THE CONSUMERS  
IN THE REPUBLIC OF MACEDONIA  
IN RELATION TO BIOSAFETY AND GMO**

**CONSUMERS ORGANIZATION OF MACEDONIA**

Skopje, December 2004

Project manager: **Marijana Loncar-Velkovska**

Author: **Lidija Petrusevska-Tozi**

Analyst and researcher: **Stevan Tomovski**

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Participants: **Tatjana Gegoska**

**Natasa Loparska**

## **1. PROPOSED APPROACH METHODOLOGY**

### **Subject of the poll**

The research of the consumers regarding their familiarity with the Genetic Modified Organisms is the subject of this poll. This research has been carried out in the frames of the Project "National Frame for Biosafety" within the Ministry of Environment and Physical Planning.

### **Territorial distribution**

The City of Skopje was covered by this research with 600 polled.

### **Defining the structure of citizens incorporated in the poll**

During the polling of the citizens, efforts were made to include consumers of different sex, age, education, employment status and nationality.

### **Organization of the poll**

A Questionnaire was created for this poll, enclosed in Attachment 1.

The Questionnaire for the consumers consists of 21 (twenty one) questions and 4 (four) identification questions. 600 Questionnaires were printed, 580 out of which were filled in, and 563 were selected as conscientious/proper ones.

Twenty pollsters took part in the poll: one responsible for coding the data, two responsible for entering the data, one analyst and one project manager.

The poll was carried out in the period from 25 October to 5 November 2004.

### **Manner of data collection**

The terrain research was carried out during a period of one week, after which the Questionnaires were submitted. A visual control was carried out after the submission, thus the Questionnaires were coded and incorporated in the programme pack for statistic processing.

The Questionnaires are classified according to settlements prior to their inclusion.

### **Data processing**

After the inclusion in the programme pack, the **input** of the Questionnaires is transferred into the applicative *SW MS EXCEL*, which is, as an **output**, processed in tables and diagrams - as shown in this Report.

## 2. DYNAMICS OF THE RESEARCH ACTIVITY

Year	2004					
Month	10		11		12	
Activity						
1. Establishing working groups						
2. Training the pollsters						
3. Polling the consumers						
4. Control						
5. Code system						
6. Data entering						
7. Final Report						

### Groups of questions on the Questionnaire

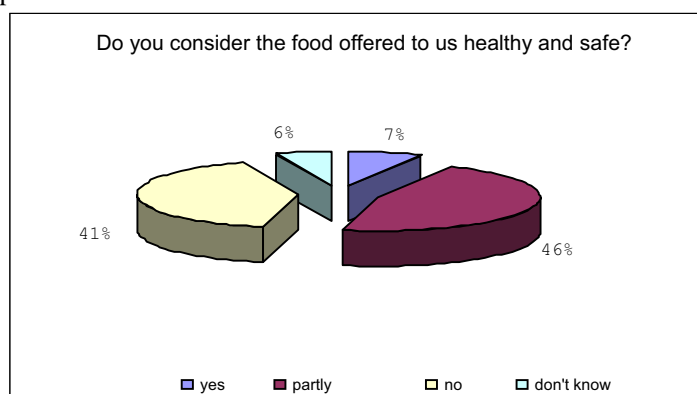
The question in the Questionnaire were grouped in 5 groups:

1. Questions regarding the GMO and the environment
2. Questions regarding the biotechnology and biosafety
3. GMO and the drugs and food
4. Legislation and GMO
5. Informing the consumers and their rights

## 3. ENVIRONMENT

The issues related to the environment are given in the first three questions from the Questionnaire: "Do you consider the environment in which we live healthy"? "Do you consider the food offered to us healthy and safe?" and "Do you consider the drugs offered to us healthy and safe?".

Only 5,86 % of the polled consider the environment in which we live healthy, 38,37 % - partly healthy, and 52,40% consider it not healthy. This is a large percentage of people that consider the environment in which we live not healthy for living. The Graphic review shows the position of 563 polled in percents:

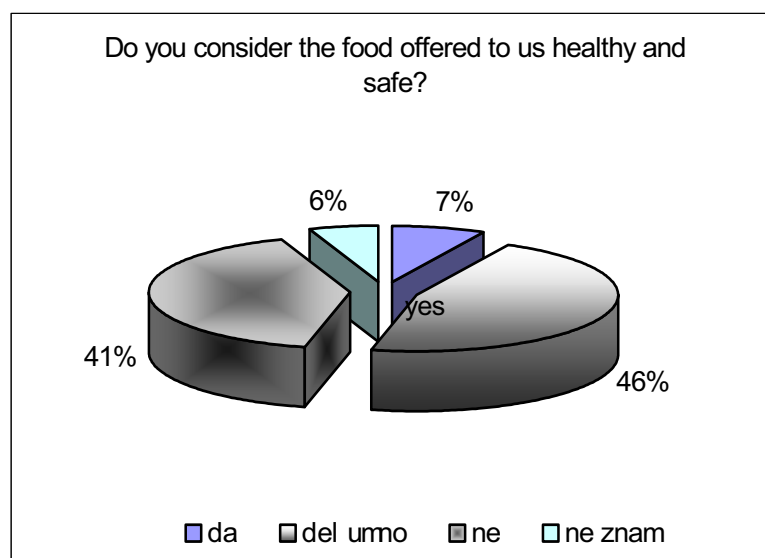


Graphic no.1

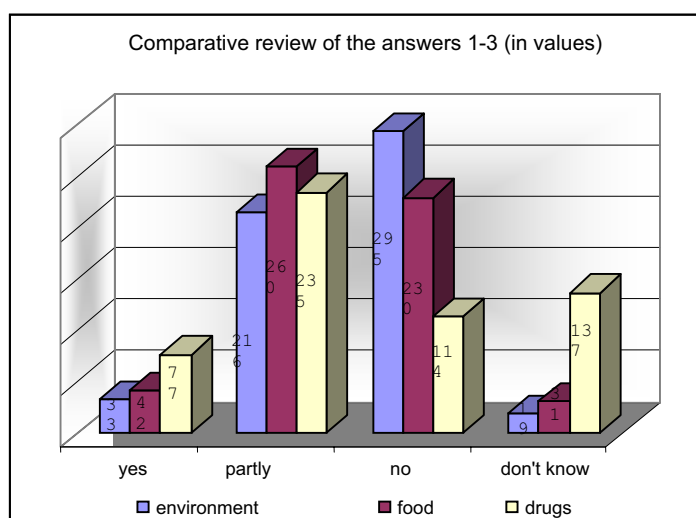
Even 56 % of the young people at the age of 20-39 consider the environment not healthy for living. 48,7% of the polled at the age of 40-59 have the same opinion. The Table below shows the answers of the polled according to their age structure (in values):

	yes	partly	no	don't know
under 19	1	9	9	0
20 - 39		81	128	8
40 - 59	13	101	116	8
60 - 74	5	23	36	3
75 and over	1	2	6	0

Regarding the healthy food, the position is the same - the food offered to us is not healthy.  
Graphic no. 2



The question "Do you consider the drugs offered to us healthy and safe?" was answered positively by 13,68% of the polled; 41,74 % - consider the drugs offered partly healthy, while 40,85% - not healthy and safe.



Graphic no. 3

#### 4. BIOTECHNOLOGY

The biotechnology is a modern science in which genetically modified organisms are used for preparation of different products for specific purposes. The Questionnaire incorporated six (6) questions from this area (questions 4,5,6,7,8 and 9).

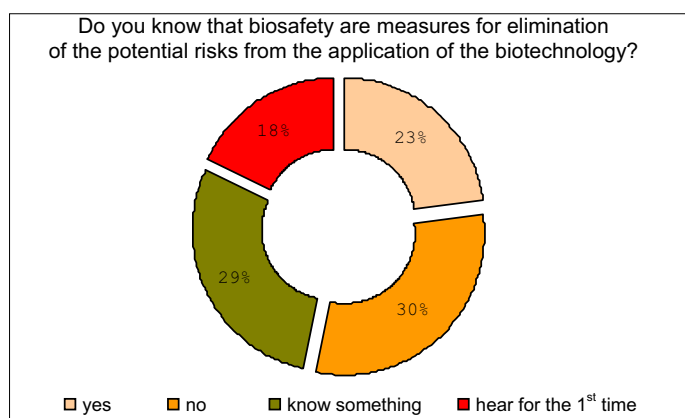
The high level of informing of the citizens on this modern science is surprising. Even 46% of the polled know something about the **biotechnology**, 18% have not heard anything, 27% have heard something, and only 8% hear about it for the first time. The high level of informing of the citizens should not be such a surprise, since the poll was carried out only in urban areas with great number of highly educated population, thus not present a representative specimen of the Republic of Macedonia. The poll was carried out immediately after the release of a flyer in the daily newspaper "Dnevnik". The Table below shows the results in correlation to the education.

	yes	no	know something	hear for the first time
primary	4	12	2	9
secondary	137	68	115	30
university	117	21	38	7

Compared to the age structure of regarding the citizens' informing on the biotechnology, the young people are better informed, which is to be expected, due to their education during the education process. Since the biotechnology is a modern, relatively young science, there is a smaller percentage of polled at the age over 59 which are familiar with it. The Table gives a detailed review of the answers according to the age:

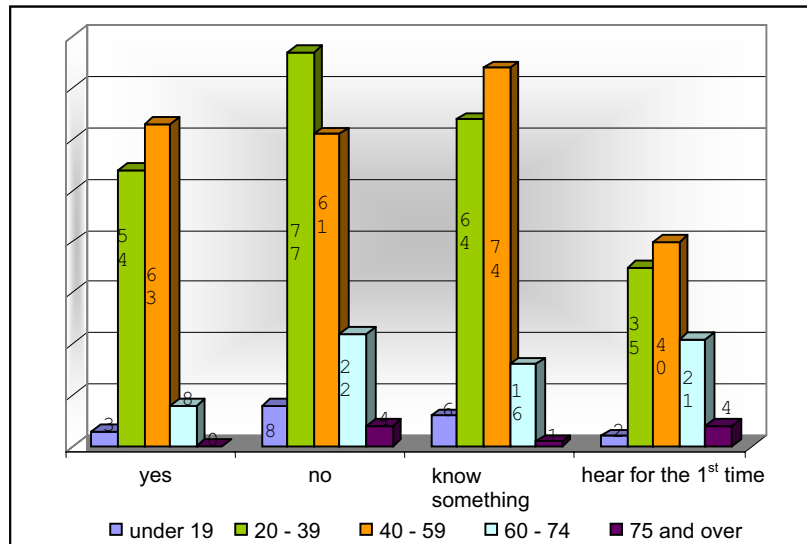
	yes	no	know something	hear for the first time
under 19	9	7	2	1
20 - 39	134	27	57	12
40 - 59	97	42	79	20
60 - 74	20	19	18	10
75 and over	0	6	0	3

Regarding the question "Do you know that biosafety are measures for elimination of the potential risks from the application of the biotechnology?" the percentage of informing is smaller compared to the previous question (see Graphic 3 - 4,5,6,7 histograms). There are 22,74% citizens that are informed about this, 30,55% don't know, 28,6% know something, 18 % hear for the first time. The answers to this question are shown in Graphic no. 4.



Graphic no. 4

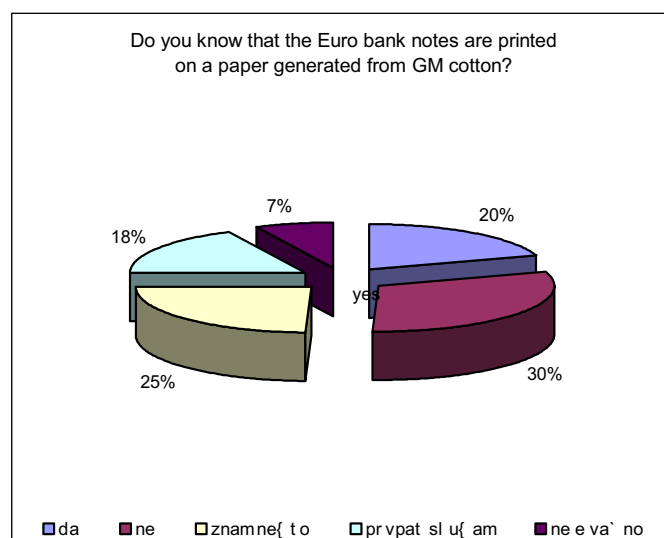
Analysing the data obtained from this question, it occurs that there is a need of carrying out additional analysis of the answers in accordance with the age structure of the polled. A conclusion can be drawn up that the percentage of young people that answered the previous question positively, is not the same for this question. The polled at the age over 40 are well informed that the biosafety are measures for elimination of the potential risks from the application of the biotechnology. The graphic review shows the informing of the polled on the biosafety measures according to the age group.



Graphic no. 5

The second group in the Questionnaire includes the question of GMO as organisms that possess new genetic material. 35,88% of the polled are informed on this, 27,35% are not informed, 26,60% are partly informed, and 10,48% hear for the first time.

One of the more attractive is the question on the Euro bank notes printed on a paper generated from GM cotton. Out of 563 polled, only 112 know this information, which is 19,89%; 138 polled or 24,51 % know something; 30,73 % don't know anything; 17,76 hear for the first time; 7,10 % do not consider it important.

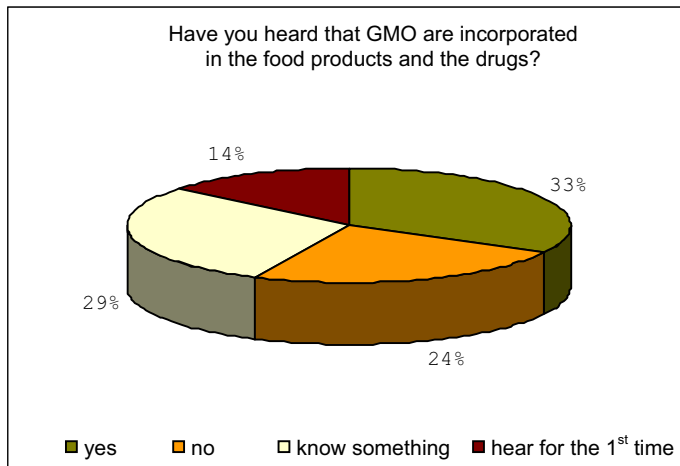


Graphic no. 6

The opinion of the polled regarding the question on the greatest part of the insuline in the world being produced with the biotechnology, is as follows:

excellent	16,16 %
assistance for the sick people	48,67 %
Don't know	20.25 %
Shall see the consequences	14,92 %

There are a big percentage of citizens (32.68%) that know GMO are incorporated in the food products; 24.33% don't know; 29,13% know something; 13,85% hear for the first time. The graphic review of the data is given below:



Graphic no. 7

## 5. GENETICALLY MODIFIED ORGANISMS INCORPORATED IN THE DRUGS

The genetically modified organisms (GMO) incorporated in the drugs have showed advantages, ex. edible vaccines to avoid the (needle)pricking, simpler production and more active substances, aimed for healing solely.

The answers of the polled to the question "Do you consider the use of GMO in the medicine good - justified?" are as follows:

	number	%
yes	95	16,87
no	40	7,10
know something	199	35,35
perhaps, sometimes	229	40,67
Total	563	100

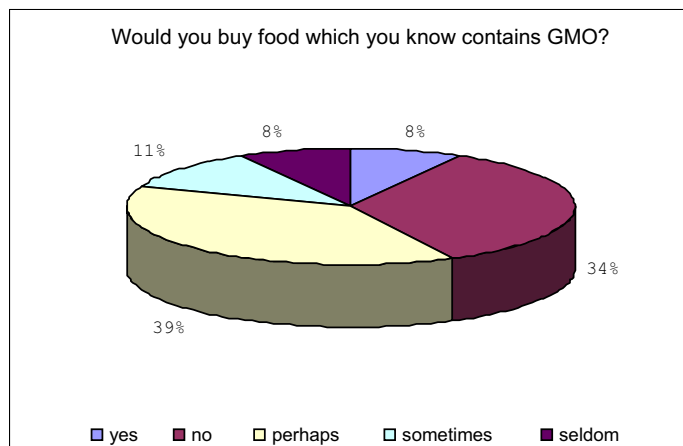
## 6. GENETICALLY MODIFIED ORGANISMS INCORPORATED IN THE FOOD

The genetically modified organisms (GMO) incorporated in the food contribute towards bigger returns - more food for everyone, food that is more resistant to the external impacts and is nutritive richer, but there are still no data on the effect on the human health.

The group of questions 11 to 14 refers to the opinion of the citizens regarding the GMO incorporated in the food.

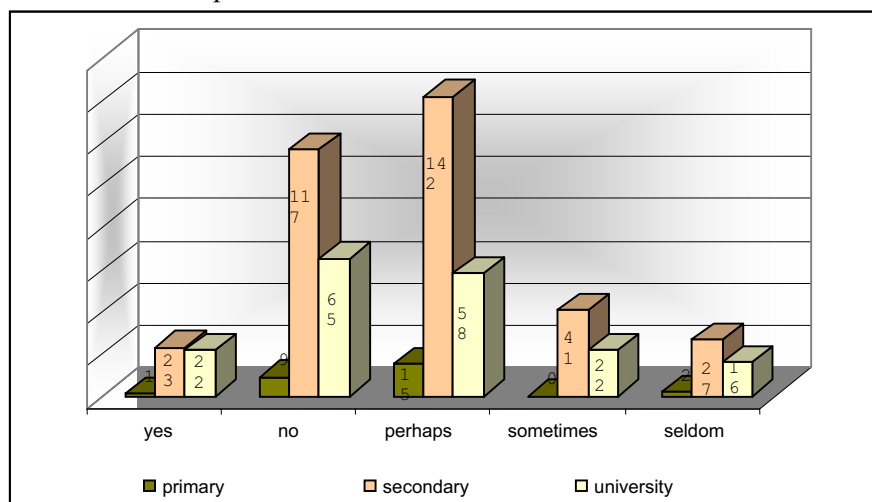
46 polled answered positively to the question "Would you buy food which you know contains GMO?" The answers of 216 polled that might buy, or 63 that would sometimes buy food which contains GMO

should not be neglected. 193 of the polled have negative position, respectively 45, which would seldom decide to buy this kind of food. The percentage review of the answers is given in the Graphic below:



Graphic no. 8

By connection the answers to this question to the education of the polled, the analysis have given the data shown in the Graphic below:



Graphic no. 9

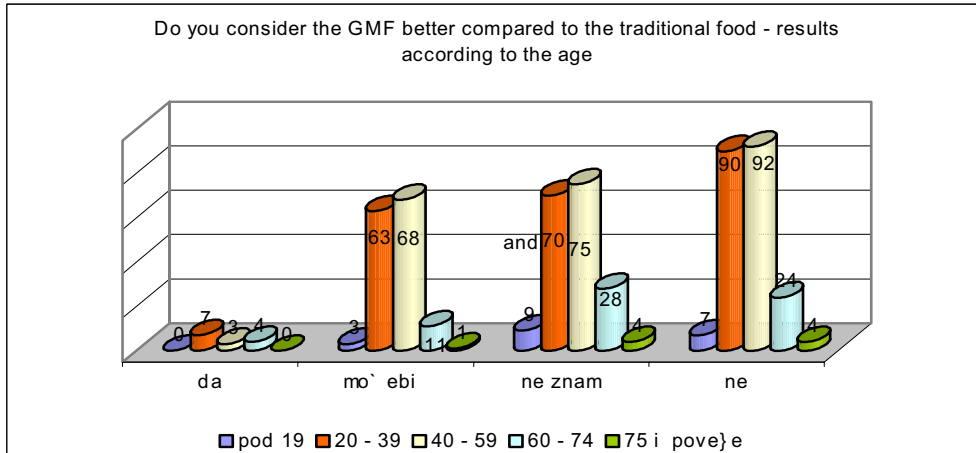
Besides the opinion of the polled that they would or might decide to buy food which contains GMO, an analysis should be made of the answers to the question whether the GM food is healthy and safe. Only 6% of the consumers responded positively; 15,63% consider the GM food partly safe, 19,72% - not safe; 28,95% - perhaps; 29,66% don't know. These data indicate that the distrust of the polled towards the GM food might be a result of the insufficient informing on the contents of GMF or the habit of buying traditional food. It is practically continuation of the answers to the question on comparison/choosing the traditional over the GM food.

Compared to the traditional food 2,49% of the polled consider the GM food better, 25,93% responded it might be better, 33% don't know, and 38,54% consider it is not better. The position of the polled regarding the GMF is shown in the table - in correlation with the age group they belong to:

	yes	perhaps	don't know	no
under 19	0	3	9	7
20 - 39	7	63	70	90
40 - 59	3	68	75	92
60 - 74	4	11	28	24

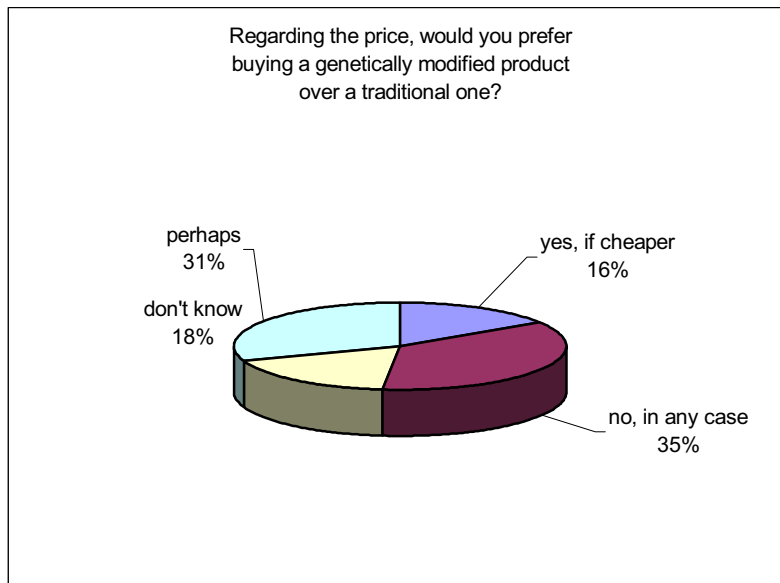
75 and over	0	1	4	4
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Besides the table review, this information is also shown in Graphic no.10:



Graphic no. 10

The price is a significant factor in the food procurement. 15.81% of the polled would buy GMF should it be cheaper than the traditional one, 35,88% would not buy in any case, 17,76 % don't know, and even 30,55 % hesitate.

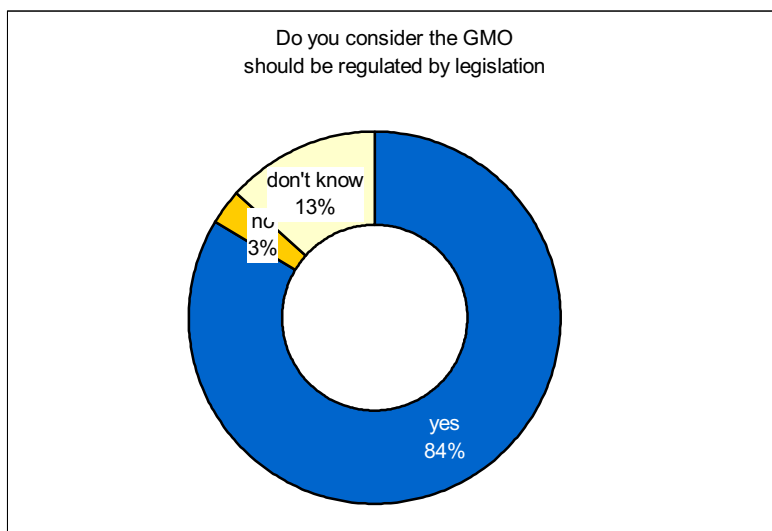


Graphic no. 11

## 7. REGULATING THE GMO USE

The opinion of the citizens regarding the regulation of the issue of GMO use is related to the issues of legislation, application and use.

83.66% of the citizens are at the opinion that the use of GMO has to be regulated by law, 3% think it is not necessary, 13 % don't know.



Graphic no. 12

9,59 % are informed that there is a procedure for adopting a legislation on the application and use of GMO ongoing at the moment, while 45.83% are not informed. The other 44.58% don't know that about this procedure for adopting a legislation on the application and use of GMO.

	number	%
yes	54	9.59
no	258	45.83
don't know	251	44.58
Total	563	100

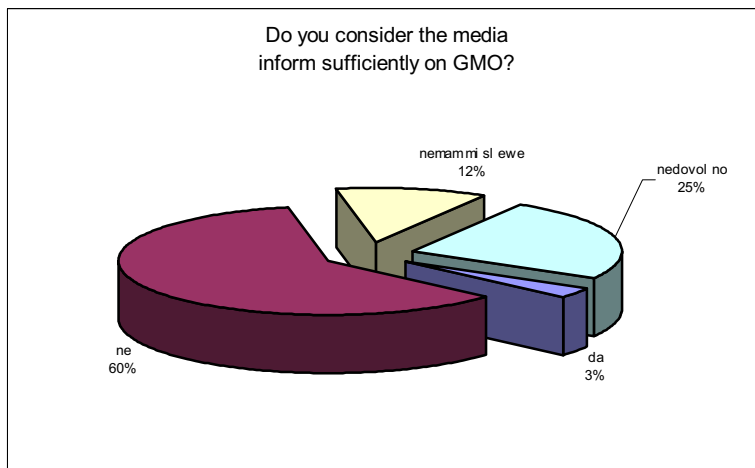
## 8. INFORMING THE CONSUMERS

The rights adopted by the United Nations Organization and the World Health Organization induce the need for the consumers to have right to a healthy and safe environment, right to a choice and right to be informed. The manners of informing differ. The electronic media and product labels are some of them.

The analysis of this research gives an insight into the level of informing of the citizens and their opinion.

Regarding the question "Do you consider the media inform sufficiently on GMO?" only 3,02% of the polled answered positively. There is a high percentage that considers the media do not inform sufficiently on GMO. The Table shows the position of the polled - in figures and percents:

	number	%
yes	17	3,02
no	341	60,57
have no opinion	66	11,72
not sufficiently	139	24,69
Total	563	100

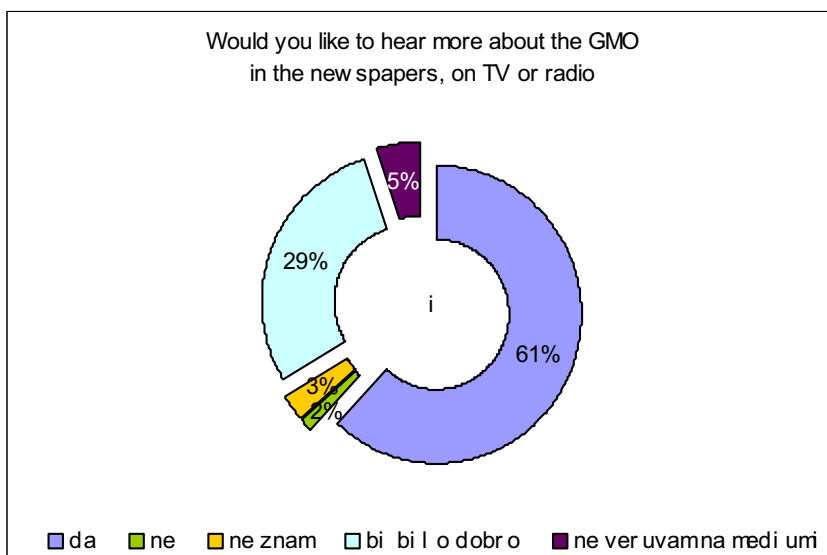


Graphic no. 13 shows the results from this question:

Graphic no. 13

The answers indicate that the percentage on the information on GMO in the electronic media is very low. In that direction, there is a need of educational and scientific programs and articles in the daily newspapers and weekly magazines.

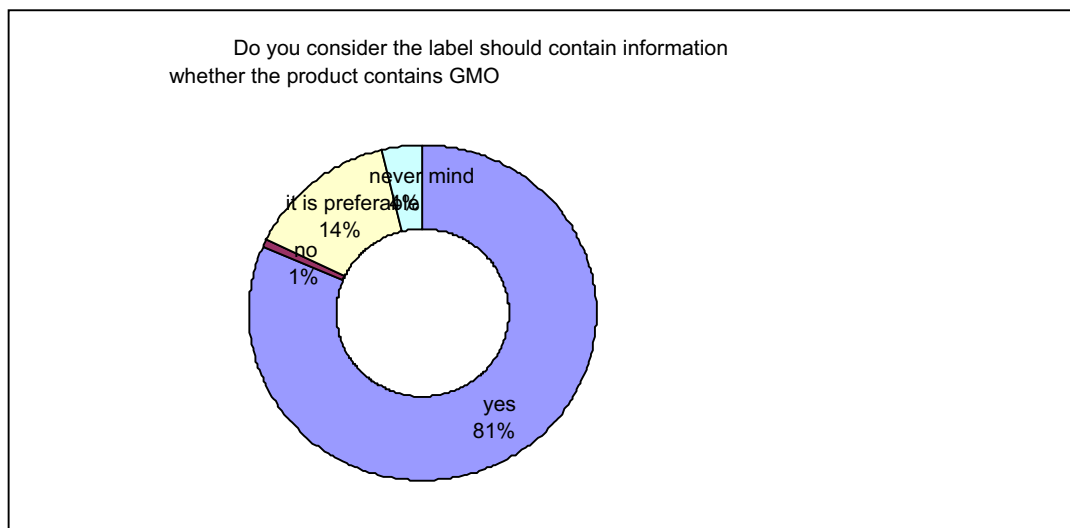
The total percentage (90,76%) of consumers that would like to hear more information on GMO in the media is high, 61,81 % of which prefer the TV or radio, and 28,95% do not define the source of information. They simply consider it would be good to know something more on GMO. Only 4,8 % do not trust the media, and 4,44 % don' know. Regardless to the sex, age category and the employment/working status, the polled would like to be informed more on GMO.



Graphic no. 14

The question whether they have seen the leaflet - addition to the daily newspaper Dnevnik was responded positively by 23 % of the polled, and 77 % answered they have not seen the leaflet.

When buying a product for the first time, 44% of the consumer's check the contents of the goods, 3,6 % don't check since they know the contents, 5,86 % never check, 25,58% often check, and only 20,78% seldom check the label. 81,53% consider the label should give information whether the product contains GMO, 13,85% prefer to read an information, 0,71% do not consider it important, and 3,91% do not care what kind of information the label contains.



Graphic no.15

## 9. CONCLUSION

According to the Report, the results are:

- The consumers are not very familiar with the biotechnology, biosafety and genetically modified organisms;
- Most of the consumers consider the environment and food not healthy;
- There is a high percentage of consumers that would not accept the genetically modified food;
- There is a need for adoption of a national legislation on GMO;
- There is a need for implementation of ongoing campaigns, tribunes or other forms of informing (newspapers, TV) for transmitting the information to the consumers.

We certainly hope that the data presented in the report are going to serve as a stimulus for organizing further activities in the frames of the national system on biosafety.

## **ANNEX 3**

### **LIST OF EXPERTS IN THE FIELD OF BIOSAFETY**

<b>No.</b>	<b>Name and Surname</b>	<b>Institution / Organization</b>
1. Doc.Dr	Andonovski Vlatko	Faculty of forestry
2. Dr.	Bosevska Golubinka	Republic institution for health protection
3. Prof. Dr	Danev Mihail	Faculty for veterinary medicine
4. Prof. Dr	Dimevska Gordana	Faculty for mathematics and natural sciences/ Institute for biology
5. MSc	Dimitrievska Blagica	Faculty for agricultural sciences and food
6. Doc. Dr.	Dimitrovski Koco	Faculty for medicine/ Institute for transfuziology
7. Prof. Dr.	Dimovski Aleksandar	Faculty for Pharmacy
8. Doc. Dr.	Efremov Dimitar	Faculty for medicine/ Clinic for hematology
9. Prof. Dr.	Efremov Gjorgji	Research Center for Genetic Engineering and Biotechnology
10. Prof. Dr.	Zafirovska Roganovic Danica	Faculty for mathematics and natural sciences/Institute for biology
11. Prof Dr.	Ivanovska Sonja	Faculty for agricultural sciences and food
12. Dr.	Karanfilska Plaseska Dijana	Research Center for Genetic Engineering and Biotechnology
13. Prof. Dr.	Lazarevska Stanislava	Faculty for agricultural sciences and food
14. Dr.	Mitrev Sasha	Institute for south crops
15. BSc.	Nakova Roza	Ministry of Agriculture, Forestry and Water Economy/ Plant Protection Unit
16. Prof. Dr.	Nikolov Nikola	Faculty of forestry
17. BSc.	Nikolov Pance	Ministry of Agriculture, Forestry and Water Economy/ Department for organic production
18. Dr.	Panov Saso	Faculty for mathematics and natural sciences/Institute for biology
19. BSc.	Petrovska Mirjana	Ministry for foreign affairs
20. Dr.	Pop Simonova Gordana	Institution for agriculture
21. Doc.Dr	Popovski Zoran	Faculty for agricultural sciences and food
22. Prof. Dr.	Prodanov Risto	Faculty for Veterinary medicine
23. Dr.	Ristovska Gordana	Republic institution for health protection
24. BSc.	Runtevski Dejan	Ministry of Finance
25.Dr.	Simjanovska Liljana	Research Center for Genetic Engineering and Biotechnology

- |               |                              |   |
|---------------|------------------------------|---|
| 26. Dr        | Stefanovska Sukarova Emilija | Research Center for Genetic Engineering and Biotechnology |
| 27. Prof.Dr.  | Stojkovski Cane              | Faculty for agricultural sciences and food                |
| 28. Doc.Dr.   | Stojceva Taneva Olivera      | Faculty for medicine/ Clinic for nephrology               |
| 29. Prof.Dr.  | Tozi Petrussevska Lidija     | Faculty of Pharmacy                                       |
| 30. Prof. d-r | Hristovski Miso              | Faculty for Veterinary medicine                           |
| 31. BSc.      | Caloska Dirlevska Marija     | Ministry of environment end spatial planning              |

**ANNEX 4**

**RESEARCH INSTITUTIONS IN THE FIELD OF BIOTECHNOLOGY, GENETICS  
AND MOLECULAR BIOLOGY**

**UNIVERSITY in SKOPJE**  
**„St. Kiril i Metodij“**

**Faculty for agricultural sciences and food**

- Lecturing desk for genetics and selection
  - Laboratory for plant biotechnology
- Lecturing desk for livestock production
  - Laboratory for biochemistry and molecular biology
- Lecturing desk for plant protection

**Faculty for Veterinary medicine**

- Institute for veterinary
- Institute for food
- Institute for biomedicine
- Institute for reproduction and biotechnology

**Faculty of forestry**

- Lecturing desk for genetic of forests and forest species
  - Laboratory for genetic of forests
- Lecturing desk for protection of forest and wood

**Faculty for mathematics and natural sciences**

- Institute for biology
  - Laboratory for molecular biology
  - Laboratory for genetics

**Faculty for medicine-Skopje**

- Lecturing desk for transfuziology
  - Laboratory for serological analyses
- Lecturing desk for internal medicine
  - Clinic for hematology
  - Clinic for nephrology

**Faculty for Pharmacy**

- Institute for pharmaceutical chemistry
  - Department for molecular biology and genetics
  - Department for immunology and immunochemistry

**Institute for agriculture, Skopje**

- Department for farming and vegetable growing
- Department for lineage growing
- Department for fruit growing

**Institute for livestock breeding-Skopje**

**Institute for south crops-Strumica**

- Department for agrotechnics
- Department for biotechnology of plants
- Department for genetics and selection of plants
- Department for production and controlling of seeds

**UNIVERSITY in BITOLA**  
**“St. Kliment Ohridski”**

**Institute for tobacco-Prilep**

**Hidrobiology institution, Ohrid**

**PUBLIC INSTITUTIONS FOR BIOTECHNOLOGY**

**Research Center for Genetic Engineering and Biotechnology**

- Laboratory of DNA Analyses
- Laboratory of Protein Analyses

**Republic institution for health protection**

- Department for epidemiology and microbiology
- Department for hygiene and protection of living space
- Department for social medicine
- Department for control and researches of medicaments

**INDUSTRY**  
**(COMERCIAL LABORATORIES)**

**SBW Romero Vitro– Vinica**

- Laboratory for implementation of the Project on Use of tissue culture in the horticulture production

**A.D. Replek, Skopje - pharmaceutical biotechnology**

- Replek Farm
- Laboratory for control of medicine

**Center for livestock production - Holstein Friesians (HF) – Bogdanci**

**A.D. Alkaloid, Skopje - pharmaceutical biotechnology**

- Department for pharmacy
- Laboratory for control of medicine

**A.D. Jaka Radovis - pharmaceutical biotechnology**

- Department for pharmacy
- Laboratory for control of medicine

Above mention data's are in relation only to the relevant departments that works directly in the field of biotechnology and biochemistry. More detailed information for these institutions is given on the internet site: [www.biosafety.org.mk](http://www.biosafety.org.mk)