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COUNCIL OF PRODUCTIVE FORCES STUDY OF UKRAINE**

**DRAFT NATIONAL BIOSAFETY FRAMEWORK OF UKRAINE**

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## INTRODUCTION

To build up the international biosafety system and assist certain countries, in November 2000, the Global Environmental Facility Council approved a joint project of the UN Environment Programme and Global Environment Facility at its 16<sup>th</sup> conference. The project was launched in June 2001, and more than 120 countries have participated in it. Since April 2003, the UNEP-GEF project “Development of the National Biosafety Framework of Ukraine” has been implemented by the Ministry of Environmental Protection of Ukraine (MEPU). The key objective of this project is to develop the national biosafety framework in accordance with the regulations of the Cartagena Protocol on Biosafety. The framework includes regulatory, administrative, decision-making, risk assessment and management systems and proposals on raising public awareness and information dissemination. The document “National Biosafety Framework of Ukraine” was developed by the Council of Productive Forces Study of Ukraine (CPFSU) under the National Academy of Sciences of Ukraine (NASU) with the assistance of engaged experts upon the request of the MEPU in 2006.

**Genetically modified organisms** (GMOs) include “any living organism that contains a new combination of genetic material derived using modern biotechnologies” (*Article 3 of the Cartagena Protocol on Biosafety of the Convention on Biological Diversity*).

According to Article 1 of the *Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”*, **a genetically modified organism, a living modified organism (GMO/LMO)** is “any organism with genetic material modified using artificial methods of transgenesis, which is absent under natural conditions”.

First GMOs as commercial products appeared in the world market a decade ago and gradually started being used in agriculture. Over the recent years, the market of LMOs (microorganisms, plants or animals) that contain GMOs, has gained momentum.

In 2002, genetically modified organisms were officially grown in 16 countries. The official status of these organisms means that they were registered in public agricultural plant registers, underwent testing and were allowed for commercial distribution. Approximately 1.7 million hectares were under transgenic crops in the world in 1996, 52.6 million hectares - in 2002, and 91.2 million hectares - in 2005. Food industry uses GM soya (70%), GM corn (25%), as well as GM potatoes, rice, rape, tomatoes, and sugar beet.

The key producers of GMO-containing products are USA (68%); Argentina (12%); Canada (6%) and China (3%). In the EU countries, the greatest number of registered notifications about GMOs’ use belongs to France (28 % of the total number for EU countries), Italy (15 %), Spain (14 %) and Great Britain (12 %), as well as the Netherlands, Germany, Belgium, and Portugal.

GMOs’ use allows increasing the crop capacity of cultivated plants and avoiding losses in their storage, improving vegetable food quality (increasing vitamins, proteins and other useful substances content) and, at the same time, reducing the use of herbicides, pesticides, fertilizers and other agricultural chemicals. However, for today, there are no reliable methods to determine effects of GMOs’ and GMO-derived products’ distribution to the environment and human health.

Specialists believe that GMOs’ introduction must be carefully considered. On the one hand, it is necessary to take into account the advantages of their industrial use, on the other hand, the

society requires guarantees that these technologies will not harm human health and the environment. Despite the economic advantages of using such organisms, this turns public attention to solving the problem of prevention or, if necessary, elimination of any possible negative consequences of their use for human health and the environment.

In order to develop the national biosafety system, and in accordance with the Law of Ukraine “On joining the Cartagena Protocol”, on May 31, 2007 the Verkhovna Rada (Parliament) of Ukraine approved the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”. It is planned to develop in Ukraine the regulatory background for risk assessment and GMOs’ management to prevent their potential negative impact on the environment and human health. This process will include the development of methods and procedures to guarantee safety in GMOs’ generating, testing, transportation and use, GMOs’ registration review and labeling.

Proposals on generating and development of the national biosafety system were prepared in accordance with national laws and regulations of the Cartagena Protocol on Biosafety, WHO/FAO and WHO regulatory documents, OECD recommendations, the AAarhus Convention and EU directives. This document was prepared in the framework of UNEP/GEF project “Development of the National Biosafety Framework of Ukraine”. The project was launched in April 2003 and will be completed in February 2009, after some delays in project execution between 2005-2008.

## LIST OF USED ABBREVIATIONS

BS – Biological Safety (Biosafety)  
BCH – Biosafety Clearing House  
CBD – Convention on Biological Diversity  
CIS  
FAO  
GEF – Global Environment Facility  
GMO – Genetically Modified Organism  
LMO – Living Modified Organism  
NBC – National Coordination Biosafety Council  
NBF – National Biosafety Framework  
UNEP – United Nations Environment Programme  
NASU – National Academy of Science of Ukraine  
UAAS – Ukrainian Academy of Agricultural Science  
WHO  
WTO – World Trade Organization  
GCEC—Governmental Commission for Export Control

**Comment [biosafety1]:** Carta gena refers only to LMO – need to decide on a standard use of LMO/GMO?

## I. INTERNATIONAL, BILATERAL AND MULTILATERAL TREATIES ON GMOs

### 1.1. International bilateral and multilateral treaties on GMOs

The global community pays great attention to the development of scientifically proven approaches to the assessment of potential risk of GMOs' use, which would provide for the proper protection of human health and the environment. Leading countries of the world have developed their systems of scientific research and analysis regarding biosafety and biotechnology development prospects, as well as well-regulated national legislations on GMOs' use. Appropriate laws and enactments are in force in the USA, Canada, Australia, EU countries, Russian Federation and many other countries of the world.

The key international documents regulating biosafety issues include as follows:

#### **Agenda 21: Agenda for the 21st Century**

*Agenda for the 21<sup>st</sup> Century* adopted by the *World Summit on Sustainable Development* in June 1992 in Rio-de-Janeiro states that biotechnology can make significant contribution to the development of the sustainable growth of humankind and mentions the necessity to observe the requirements of "... ecologically safe regulation of biotechnologies..." or biological safety.

**Biosafety** is a new term that has recently appeared in our life. It defines efforts aimed at reduction or prevention of potential risks of biotechnology and its products.

**Comment [biosafety2]:** Biosafety has other meanings of course but even the use for modern biotechnology dates back to 1980s.

#### **Convention on Biological Diversity (Rio de Janeiro, 1992)**

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

The Convention on Biological Diversity, ratified by the Verkhovna Rada of Ukraine (the Law of Ukraine "On ratification of the Convention on Biological Diversity Protection" №257/94-BP of 29.11.94), admits that a biotechnology developed and used with adequate measures of safety for the environment and human health can facilitate achieving the goals of the convention, namely "...preservation of biological diversity, sustainable use of its components and sharing equitably benefits arising from the use of genetic resources." Article 19(3) of the Convention commits the parties to "consider the need for and modalities of a protocol ... in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology..."

#### **The Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

In execution of Article 19 of the Convention on Biological Diversity and in accordance with the decision II/5 of the Second Conference of the Parties to the Convention (Jakarta, November 1995), in 1996, the Working Group of international experts initiated the development of the Protocol on Biosafety. It was planned to

approve the protocol in winter of 1999 in the city of Cartagena, Columbia, but the Parties didn't reach the agreement, and the work on the document continued for another year. On January 29, 2000, the Protocol was approved at the second sitting of the Extraordinary Conference of the Parties to the Convention on Biological Diversity (the city of Montreal, Canada). The Intergovernmental Committee for the Cartagena Protocol on Biosafety was formed to develop its implementation mechanisms.

On September 11, 2003, the Protocol officially entered into force, 90 days after it had been ratified by the 50th country. The Verkhovna Rada of Ukraine approved the Law of Ukraine "On Ukraine's joining the Cartagena Protocol on Biosafety to the Convention on Biological Diversity" №152-IV on September 12, 2002, and Ukraine currently is a full-fledged Party to the Protocol, together with over 150 other countries.

Comment [biosafety3]: 153  
as of 5th May 2009

The Cartagena Protocol on Biosafety to the UN Convention on Biological Diversity is the first international document that regulates relations between countries in terms of GMOs' handling and use. Its key objective is to establish international rules for the countries that ratified it concerning safe transfer, handling and use of GMOs "that may have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account risks to human health." The document is specifically focused on the regulation of GMOs' transboundary transfer.

The Protocol, in particular, envisages compulsory notification of an importing country about GMOs' importation into its territory (provided that the importing country has permitted this), with such notification stating the purpose of import of such organisms, e.g. for laboratories or food shops (Article 18). Each country that ratified the Protocol should have an appropriate national competent authority to control GMOs' transportation over a country's territory, GMOs-related export and import operations etc. The Protocol has to assist in the provision of a proper level of protection in safe transfer, handling and use of living modified organisms resulting from modern biotechnologies that may have adverse environmental impacts on the conservation and sustainable use of biological diversity. The Protocol envisages compulsory risk assessment and an advanced informed agreement procedure before GMOs' importation.

This document pays most attention to living modified organisms intended for release into the environment. If a party plans to export such GMOs, it has to inform an importing country about that beforehand in accordance with the "advanced informed agreement" procedure. If the importing country agrees to accept such GMOs, the shipment shall be marked as "living modified organisms" imported in accordance with the Cartagena Protocol requirements.

A country decides whether to import GMOs for their release into the environment independently after assessing risks according to the general principles outlined in the document. The protocol allows countries to make a negative decision about GMOs' import in case of ambiguous scientific conclusions. Such approach is based on a precautionary principle of the Declaration on Environment and Development approved at the UN Conference in Rio-de-Janeiro in 1992. This principle is formulated as follows: "In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. In cases when there is a risk of material or inevitable damage, lack of complete scientifically proved assurance shall not give grounds to put off any preventive environmental measures, which are efficient in terms of costs".

GMOs intended for use as food or feed, or for processing, constitute another category in the Protocol. A less strict system of advanced information is applied to them by means of the Biosafety Clearing House. However, an importing country has the right to conduct risk

assessment and make its independent decision about the importation of such GMOs. It has to be stated in export documents that a shipment may contain GMOs. Article 18 of the Cartagena Protocol stipulates that any accompanying documents for any GMOs regulated by the Protocol, including GMOs intended for use as food or feed, or for processing, shall clearly state that a shipment contains (as for the latter case – “may contain”) GMOs.

The Protocol does not regulate the transboundary transfer of pharmaceutical preparations resulting from genetic engineering and products manufactured out of living modified organisms, with any matters related to it being regulated by other respective international agreements or organizations.

Apart from the above international regulations, the issue of environmental protection on GMOs' release is regulated by the following laws:

- *Codex Alimentarius*, which is a collection of standards, guidelines, practices and recommendations (developed by FAO and WHO) on food safety, in particular, safety of food produced based on biotechnologies, its labeling, risk analysis and assessment. As for today, there have been adopted up to 300 standards, some of which were modified and amended in the course of time to make them topical and compliant with progressive developments in science and practice. Among them, we could specify standards on food and biosafety, in particular, the following: General Standard for the Labeling of Prepackaged Foods dated 1985 (as amended in 2008); General Principles of Food Hygiene dated 1969 (as amended in 2003); Code of Ethics for International Trade in Food dated 1979 (as amended in 1985); Principles for Food Import and Export Certification and Inspection dated 1995; Principles and Guidelines for the Conduct of Microbiological Risk Assessment dated 1999; Principles for the Risk Analysis of Foods Derived from Modern Biotechnology dated 2003 (as amended in 2008); Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2003, 2008), -GM microorganisms (2003), - GM animals (2008); Guidelines for Food Import Control Systems dated 2003 (as amended in 2006); Principles and Guidelines for the Conduct of Microbiological Risk Management dated 2007 (as amended in 2008); Guideline for the Validation of Food Safety Control Measures dated 2008<sup>1</sup>; *International Plant Protection Convention (Rome, 1951, updated edition of 1997.)*, (the Decree of the President of Ukraine on joining the Convention dated January 31, 2006 № 81/2006) regulating international cooperation to prevent the introduction and dissemination of plant and plant food pests in fauna and flora, and promotion of respective measures to control them. The Convention is famous for its set of phytosanitary standards and guidelines on GMOs and biosafety;
- *UN Voluntary Code of Industrial Development Conduct for GMOs' Release into the Environment (1992)* regulating the operations of subjects that participate in releasing of GMOs or GMO-derived products into the environment, as well as assistance in the development of national regulations on GMOs' handling;
- *UNEP International Technical Guidelines for Safety in Biotechnology (1995)* containing technical guidelines for assessing biosafety, defining measures to manage forecasted risks, and facilitating monitoring, investigation and information exchange processes;

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<sup>1</sup> The list and texts of current standards could be find at:  
[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en#](http://www.codexalimentarius.net/web/standard_list.do?lang=en#)

- *The Pan-European Biological and Landscape Diversity Strategy (Sofia, 1995)*, among Strategic Principles for the period of 1996- 2016, one should pay attention to the “Threat prevention principle: introduction of respective procedures requiring environmental expertise of projects, which may have a substantial negative impact on biological and landscape diversity to prevent such impact, and if required, ensure public participation in such procedures. This will be applied to projects of the introduction into the environment of exotic sorts and genetically modified organisms”;
- *Model Law on Safety of Activity Related to GMOs* (adopted at the 27<sup>th</sup> plenary session of the Interparliamentary Assembly of CIS countries (Resolution № 27-9 dated 16 November 2006)). The Law “regulates operations related to receipt, testing, production, use and sale of GMOs using modern biotechnology. The stipulated mode of the above operations regulation, authorization and management is aimed at ensuring the implementation of such operations under biosafety conditions, which allows preventing, eliminating or reducing any risks related to GMOs’ negative impact on human health, biodiversity, ecological balance and environmental quality”;
- *Framework Convention on the Protection and Sustainable Development of the Carpathians (Kyiv, May 22, 2003)* (ratified by the Law of Ukraine dated April 7, 2004), according to which “The Parties shall conduct the policies aimed at the prevention of import of non-indigenous species and distribution of genetically modified organisms that present danger to ecosystems, environment or species, and at their control or elimination (par. 3, art. 4);
- *The Black Sea Biodiversity and Landscapes Conservation Protocol to the Convention on the Protection of the Black Sea Against Pollution (Sofia, June 14, 2002)* (ratified by the Law of Ukraine dated February 22, 2007) stating in Article 3 that all Parties shall take any appropriate measures to regulate the intentional introduction and prevent the accidental introduction of non-indigenous species or genetically modified organisms, and in Article 5 stating that all contracting parties shall take “all appropriate measures to regulate the intentional introduction and prevent the accidental introduction of non-indigenous species or genetically modified organisms to the wild flora and fauna, and prohibit those that may have harmful impacts on ecosystems, habitats or species in the area to which this Protocol applies”; *The Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters (Aarhus, June 25, 1998)* (ratified by the Law of Ukraine dated July 6, 1999). In 2003, the Guidelines on Access to Information, Public Participation and Access to Justice in GMO Matters were adopted under the Convention in Kyiv. The Guidelines’ objectives include further development of the national legal framework and facilitation of the practical application of the Aarhus Convention provisions to GMOs. The guidelines define key elements of public participation in decision making on GMOs’ use in closed systems. Although the Guidelines are of recommendation nature, the Parties to the Convention shall systematically report on their use experience at the national level.

At the 2<sup>nd</sup> Meeting of the Parties (Alma-Ata, 2005), the Parties adopted the Amendment to the Aarhus Convention with the decision II/1, which disseminates key elements and principles of public participation in decision making related to environmental matters and GMOs, stipulated by Article 6 of the Convention. The amendment modifies the provisions of Paragraph 11 of Article 6 of the Convention and introduces Appendix 1 containing a list and description of key elements of public participation in GMO-related decision making. Such key elements include the following:

- Ensuring public participation in decision making at its early stages, that is during the period when public has all the possibilities to influence decisions effectively;
- Necessity to provide public with an access to any information concerning both the description of decision-making procedures, and the essence of any issue that is a subject of a decision, except for confidential information;
- Ensuring sufficient time for providing any public comments and remarks pertaining to the essence of any proposed decision. Such comments shall be considered while taking final decisions by competent authorities, and such decisions together with their grounds shall be promulgated.

The amendment should be ratified by all the Parties to the Convention, and most EU members, as well as Norway and Moldova, have already ratified it in contrast to Ukraine.

In view of Ukraine's initiatives for integration with EU and its entry into the World Trade Organization (WTO), there was adopted a set of legal acts and regulatory documents pertaining to biosafety, exactly the following:

- The Resolution of the Cabinet of Ministers of Ukraine dated 11 June 2008 № 821-p *“On the approval of an action plan on implementing in 2008 the State Program of Adapting Ukrainian Laws to the EU Legislation”* (par. 6, 7, and 14) outlines the necessity to adapt Ukrainian laws on human health, animal and plant protection, and legal regulations on products general safety, environmental protection and ensuring intellectual property rights through making amendments to current statutory acts and adopting new ones.
- *The Program of the President of Ukraine “The Program of EU Integration” dated 14 September 2000* includes the following provisions:
  - Developing an informational database on biological features of genetically modified organisms that undergo public testing in Ukraine, and their impact on the preservation and sustainable use of biological diversity;
  - Completing the development of the draft Law of Ukraine on Bioethics and its submission for the review by the Verkhovna Rada of Ukraine in 2000;
  - Preparing a textbook on bioethics;
  - Ensuring the passing of the Law of Ukraine on state regulatory policy in genetic engineering in 2001;
  - Generating EU-adapted bylaws to the Law of Ukraine on state regulatory policy in genetic engineering;
  - Elaborating EU-adapted criteria, regulations and standards for the assessment of possible GMOs' impact on the conservation and sustainable use of biodiversity;
  - Expanding and improving the database of biological features and impact of genetically modified organisms, that are released into the environment, on the conservation and sustainable use of biological diversity in Ukraine and Europe;
  - Appointing a national coordinator (CPB National Focal Point) responsible for any communications with the Protocol Secretariat and a national authority dealing with administrative functions.

The Decree of the President of Ukraine dated 13 December 2003 № 1433/2003 *“On State European and Euroatlantic Integration Programs of Ukraine for 2004-2007”* was passed to ensure the execution of the above listed tasks.

The EU legislation on GMOs has been in existence at least since 1990. In its GMO-related activities, the EU seeks to protect human health and the environment while observing the regulations of the common market. There are laws on GMOs' use, dissemination, sale and detection in products. Prior to reaching the EU market, genetically modified products are thoroughly tested. Such testing is performed in laboratories that belong to the European network of the EU Joint Research Centre. In addition, the EU legislation clearly regulates the principles of GMO-containing products' labeling.

A complete list of the EU normative acts relevant to the regulation of GMOs and biosafety is provided in Annex 1.<sup>2</sup>

The following EU Directives establish a regulatory framework concerning GMOs and biosafety in the EU. The requirements of these directives have been implemented in national laws of EU members.

**1. Directive 2001/18/EC dated March 12, 2001 of the European Parliament and Council** on the deliberate release into the environment of genetically modified organisms that repeals the Council Directive 90/220/EEC. All the activities of EU countries related to GMOs' generating and use are regulated by the Directive 2001/18/EC on the deliberate GMOs' release into the environment. The objective of this Directive is to approximate laws, regulations and administrative provisions of the Member States and protect human health and the environment while:

- Carrying out the deliberate release into the environment of genetically modified organisms for any purposes other than placing on the market within the Community; and
- Placing GMOs as or in products in the market within the Community.

All issues that are not regulated by other laws fall under the scope of this Directive. GMOs' types whose distribution is regulated by other laws are also subject to environmental risk assessment. New higher safety standards aimed at environmental and human health protection are established in accordance with this Directive. This document provides a wider approach to risk assessment procedures and contains new monitoring concepts for the determination of product sources. This may assist in determining and eliminating GMOs' adverse effects at earlier stages. On the other hand, the reviewed version lacks the prohibition of the use of antibiotic-resistant marker genes and does not solve the problem of legal responsibility and permitted levels of genetically polluted components content.

**2. Council Directive 98/81/EC dated October 26, 1998** amending the Directive 90/219/EEC on the contained use of genetically modified micro-organisms. The Directive lays down common measures for the contained use of genetically modified micro-organisms with a view to protect human health and the environment. In accordance with the Directive, Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment that might arise from the contained use of GMOs.

The following are the key directly applicable EU legislative acts concerning GMOs and biosafety.

1. **Regulation (EC) No 1946/2003** dated July 15, 2003 of the European Parliament and Council on transboundary movements of genetically modified organisms.

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<sup>2</sup> Full texts of the EU legal acts can be found on <http://europa.eu.int/eur-lex/en/search/index.html>

The Regulation:

- Establishes a common system of notification about transboundary movements of GMOs; and
- Ensures the coherent implementation of the Cartagena Protocol provisions on behalf of the Community in order to facilitate ensuring of an adequate level of protection in safe transfer, handling and use of the GMOs that might have adverse effects on the conservation and sustainable use of biological diversity, taking into account any risks to human health.

The Regulation establishes the procedures that are compliant with the Cartagena Protocol regarding GMOs' exportation to third countries (which are not EU members). There are different procedures for:

- GMOs intended for the deliberate release into the environment; and
- GMOs intended for the direct use as food and feed, or for processing.

2. **Regulation (EC) 1829/2003** dated September 22, 2003 of the European Parliament and Council on genetically modified food and feed. In accordance with the general principles laid down in the Regulation (EC) No 178/2002 (see below), this Regulation:

- Provides the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;
- Lays down the Community procedures for the authorization and supervision of genetically modified food and feed;
- Lays down detailed provisions for the labeling of genetically modified food and feed.

In particular, the Regulation requires the labeling of food and feed that should be directly delivered to end consumers and:

- (a) contains or consists of GMOs; or
- (b) is produced from or contains ingredients produced from GMOs.

The Regulation also states that the labeling of foods containing a material which contains, consists of or is produced from GMOs, is not required in the case when the GMOs' proportion is up to 0.9% of total ingredients of any food product, which are considered individually, or for food consisting of a single ingredient, provided that such GMOs' presence is adventitious or technically unavoidable.

3. **Commission Regulation 641/2004 dated April 6, 2004** establishes detailed rules for the implementation of the Regulation (EC) No 1829/2003 of the European Parliament and Council regarding applications for the authorization of new genetically modified food and feed, and notifications about existing products.

4. **Regulation (EC) No 178/2002** dated January 28, 2002 of the European Parliament and Council laying down general principles and requirements of food laws, establishing the European Food Safety Authority and laying down procedures on food safety. The Regulation lays down general principles and responsibility, efficient organizational mechanisms and procedures to make decisions on food and feed safety.

5. **Regulation (EC) No 1830/2003** dated September 22, 2003 of the European Parliament concerning the traceability and labeling of genetically modified organisms and food and feed products produced from genetically modified organisms and amending the Directive 2001/18/EC. The Regulation provides a framework for the traceability of products consisting of or containing GMOs, and food and feed produced from GMOs, with the objectives of facilitating the accurate labeling, monitoring environmental and health effects and the

implementation of appropriate risk management measures, including, if necessary, the withdrawal of products from circulation. The Regulation is applied to products consisting of or containing GMOs and food and feed produced out of GMOs at all stages of a product placement on the market.

Other directly applicable EU legislation acts concerning GMOs and biosafety are listed in Annex 1.

### **World Trade Organization**

Several laws related to trade issues regulation have been passed in connection with Ukraine's entry into the World Trade Organization. Only over the period of July 2005 – May 2007, while preparing to the WTO's entry, there were made amendments to forty nine laws and bylaws of Ukraine. In particular, on May 31, 2007, there was passed the Law of Ukraine ““On the national biosafety system in generating, testing, transportation and use of genetically modified organisms””.

The following three agreements among WTO's treaties are considered to be directly relevant to biosafety and GMO export-import operations:

- General Agreement on Tariffs and Trade (GATT);
- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); and
- Agreement on Technical Barriers to Trade (TBT).

In accordance with WTO's requirements, Ukraine has established its legal framework for the removal of technical barriers and the facilitation of the development, adoption and application of technical regulations, standards and quality assessment procedures. Technical barriers in trade shall mean specific requirements at the national level, which differ from common international practices, including technical regulations, standards and conformity assessment procedures.

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

### **Conclusions and Recommendations**

The key reason for not sufficiently effective implementation of respective international regulations is lack of systematized and consistent national laws and developed subordinated regulations rather than their contradictions with national legislation. International laws are considered as regulations of direct action, since they directly regulate interactions between entities and exactly international regulations shall prevail in cases when Ukrainian laws and subordinate regulations are not compliant with international ones.

That is why, it is necessary to adapt national laws, in particular, the Law of Ukraine ““On the national biosafety system in generating, testing, transportation and use of genetically modified organisms””, to the Convention on Biodiversity and the Cartagena Protocol. In particular, the Law should be supplemented with the following provisions:

- Biosafety Clearing House;
- Advanced informed agreement;
- GMOs identification and labeling;

- Regulation mechanisms, measures and strategies; and
- Risk assessment and risk management.

There should be defined a body authorized to act as a National Focal Point ensuring constant information exchange with the Secretariat of CBD.

In order to execute the decision of the 3<sup>rd</sup> Meeting of the Parties to the Aarhus Convention, it is recommended to expedite the ratification of the Alma-Ata Amendment to the Aarhus Convention and adapt Ukrainian laws to its provisions. Thus, the Action Plan to execute the decision of the Parties to the Aarhus Convention III/6f on the implementation of the Aarhus Convention in Ukraine, which is developed by the MEPU in the section “Legislative Initiatives”, states the necessity “...to elaborate a draft law, according to which amendment regarding GMOs to the Convention should be ratified”, with the execution deadline being December 2008. In spite of the fact that the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms” outlines an access to information on GMOs’ handling, currently, public participation in decision making is not regulated by respective subordinate laws. The ratification of the Alma-Ata Amendment is the other possibility.

While developing laws and bylaws on biosafety and GMOs’ handling, the provisions of Codex Alimentarius, the UN Voluntary Code of Industrial Development Conduct for GMO Release into the Environment, UNEP International Technical Guidelines for Safety in Biotechnology, Pan-European Biological and Landscape Diversity Strategy, Model Law on Safety of Activity Related to GMO, Guidelines on Access to Information, Public Participation and Access to Justice in GMO Matters, respective WTO agreements, in particular, General Agreement on Tariffs and Trade; Agreement on the Application of Sanitary and Phytosanitary Measures; Agreement on Technical Barriers to Trade, and other international regulations and standards shall be considered and implemented in practice.

It is recommended to consider respective EU Directives and regulations in the process of the national biosafety framework build-up and implementation. It is also recommended to approve relevant bylaws for the effective implementation of the above listed international treaties.

## **II. NATIONAL BIOSAFETY FRAMEWORK AND RECOMMENDATIONS ON ITS IMPROVEMENT**

### **2.1. NATIONAL BIOSAFETY LEGISLATION**

#### **2.1.1. Analysis of the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”**

On May 31, 2007, the Verkhovna Rada of Ukraine adopted the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”. The draft law was submitted as early as in 2002 and adopted in the first reading. The passing of the law was declined by three convocations of the Verkhovna Rada of Ukraine. The draft’s consideration was finally abated on May 31, 2007. A new draft Law providing background for the development of the national biosafety system was adopted instead.

The Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms” regulates relations between executive authorities, producers, sellers (suppliers), developers, researchers, scientists and consumers of genetically modified organisms and products generated according to technologies that involve their development, generating, testing, research, transportation, import, export, market placement, release into the environment and use within Ukraine (hereinafter referred to as GMOs’ handling) to ensure biological and genetic safety.

The key principles of the public policy on genetic engineering and GMOs’ handling are as follows:

- Priority of human health protection and environmental conservation as opposed to economic advantages of GMOs’ use;
- Guarantee of biological and genetic safety of GMOs’ generating, research and practical use with economic purposes;
- Control over GMOs and GMO-derived products importation into Ukraine’s customs territory, their registration, and circulation;
- General availability of information on potential risks of GMOs’ use in open systems and measures to ensure biological and genetic safety;
- Public support of genetic engineering researches and scientific and practical developments on biological and genetic safety of GMOs’ generating, research and practical use with economic purposes.

The objectives of this Law are as follows:

- Human health and environmental protection in genetic engineering and GMOs’ handling;
- Ensuring civil rights to safe GMOs’ use;
- Providing conditions for GMOs’ safe practical use for economic purposes;
- Defining rights and duties of subjects of regulation in GMOs’ handling and the ascertainment of their responsibility for law infringements;
- Protecting citizens in case of damages to their health resulted from GMOs’ consumption;
- Establishing the legal framework of international cooperation in genetic engineering and GMOs’ handling.

The Law regulates relations in the area of genetic engineering, defines the basis for the use of genetically modified organisms in Ukraine and determines responsibilities of central executive authorities. (Article 3. Basic principles of the public policy in GMOs' handling and the Law's objectives).

In accordance with Article 5, the following activities are subject to regulation in GMOs' handling:

- Genetic engineering in closed systems;
- Genetic engineering in open systems;
- State registration of GMOs and GMO-derived products;
- Placing GMOs and GMO-derived products on the market;
- GMOs' export, import and transit.

According to Article 9 of the Constitution of Ukraine, international treaties to which Ukraine is signatory represent a part of the Ukrainian national legislation. Based on the above, the Cartagena Protocol requirements shall be considered as a part of Ukrainian national legislation. At the same time, the Protocol allows any Party providing a higher level of protection than that stated in it. But, first of all, the provisions of the Protocol are related to the transboundary movement of any living modified organism (LMO) resulting from modern biotechnology that may have adverse environmental impacts on the conservation and sustainable use of biological diversity by the mean of introducing an appropriate procedures of the advanced informed agreement. Therefore, such procedures have to be specified in the Ukrainian legislation. The use of terminology in the Cartagena Protocol and the Law of Ukraine "On the national biosafety system in generating, testing, transportation and use of genetically modified organisms" has to be harmonized, in particular:

A) "a living modified organism" – shall be considered in the Law of Ukraine as a synonym to the term "genetically modified organism";

B) "advanced informed agreement procedure" – the term is not presented in the Law of Ukraine.

The following national authorities are listed in the Law of Ukraine as those responsible for GMOs' management:

1. The Cabinet of Ministers of Ukraine;
2. The Ministry for Environmental Protection;
3. The Ministry of Health Protection;
4. The Ministry of Agrarian Policy; and
5. The Ministry of Education and Science.

The Law does not regulate the procedure of interaction of respective executive authorities – the matter concerns only general coordination of their operations. The procedure of GMOs' and GMO-derived products public registration is approved by the Cabinet of Ministers of Ukraine (Article 7 of the Law). Ministries are responsible for development of respective draft procedures. Thus, in particular, the Action Plan of the Ministry of Environmental Protection concerning the preparation of draft regulatory acts for 2008 (the Order of the Ministry for Environmental Protection of 26 December 2007 # 657) stipulates the elaboration of respective draft Resolutions of the Cabinet of Ministers of Ukraine (Items 23 and 24).

As for the transfer of GMOs intended for scientific research or public approbation

(testing):

- It is permitted to import them into the customs territory of Ukraine prior to their public registration, provided that the authorization for this is obtained;
- Permits for the importation of unregistered GMOs are issued by the central executive authority responsible for science and education. At the same time, this responsibility is not determined among those defined in Article 8;
- Permits are issued taking into account results of a public ecological and sanitary-and-epidemiological expertise on GMOs' biological and genetic safety to be conducted in accordance with recognized international standards. The issue of competence required for such expert examinations remains unregulated. The laws of Ukraine that regulate the procedure of such expertise do not cover expertise on GMOs' biological and genetic safety. Therefore, it is needed to modify such laws or approve by-laws regulating procedures of expertise on GMOs' biological and genetic safety.

All the above provides ground for a need to modify Articles 7-11 of the Law.

In accordance with the Law, there were defined more strict rules for the importation into Ukraine's customs territory of food products, cosmetics, medicines, feed supplements and veterinary preparations that contain GMOs or are derived from GMOs for their proper use, in particular the following:

- Their importation into Ukraine's customs territory is possible only subject to public registration of appropriate GMO sources and products listed above;
- The procedure of such importation is established by the Cabinet of Ministers of Ukraine, which is provided for by Article 7 of the Law. However, such procedure is absent today. At the same time, it shall include the procedure of public registration of GMO sources, or the latter shall be included into the procedure of public registration of the product types listed above;
- Authorities responsible for public registration of these products are as follows: 1) the central executive authority dealing with health protection (GMO sources of food products, food products themselves, cosmetics, medicines that contain GMOs or are derived from GMOs); 2) the central executive authority dealing with agricultural policy (GMO feed sources, feed supplements and veterinary preparations that contain GMOs or are derived from GMOs).

It is necessary to ensure the development of appropriate procedures by corresponding central executive authorities for the Government.

## **Conclusions and Recommendations**

In order to improve the national biosafety legislation it is proposed to:

- 1) Analyze the Law "On the national biosafety system in generating, testing, transportation and use of genetically modified organisms" for compliance with the regulations of the Cartagena Protocol and EU Directives;
- 2) Prepare a list of other legal acts that require modifications or additions;

3) In order to ensure more complete legalization of GMO-related activities, it is necessary to prepare a list of regulatory acts recommended for the improvement and prepare procedures and methods for the following:

- GMOs' and GMO-derived products' public registration and limitations of their use;
- Risk assessment and issuing permits for the import and transit of GMO food and feed sources and GMO-derived food and feed;
- Systems of the packaging, storage, transportation and labeling of products that come into the market;
- GMOs' contained use and disposal;
- Risk assessment for living modified organisms intended for immediate use as food products or feed, or for processing;
- Requirements for GMOs and the procedure of their release into the environment for approbation (testing);
- Monitoring and controlling GMO-related activities;
- Maintenance of registers/(national biosafety database) and information exchange by means of the Biosafety Clearing House;
- Cost calculation of risk assessment and expert examination procedures;
- Systems of information and actions in case of emergency situations;
- Licensing of genetic engineering in closed and open systems;
- Regulating information confidentiality;
- The procedure of GMOs' public approbation (testing) in open systems and authorization of such testing;
- Criteria for safety of GMOs' handling in closed systems;
- Approval of the form of public statistical reporting "Report on the formation and testing of non-pathogenic GMOs";
- Including information on biological risks to compliance certificates in GMOs' transboundary transfers;
- The Ministry of Health Protection of Ukraine and the State Committee of Ukraine for Technical Regulation and Consumer Policy should develop and approve standards regarding GMOs' detection methods.

### **2.1.2. Analysis of the existing national legislation concerning GMOs**

The Ukrainian civil legislation states that the highest social value among intangible benefits that are objects of civil law rights is human life and health, honor and dignity, inviolability and safety (par. 2, art. 201 of the Civil Code of Ukraine). The Ukrainian Constitution states in Article 50 that "Everyone shall have the right to the environment that is safe for life and health, and to compensation for damages inflicted through the violation of this right. Everyone is guaranteed the right of a free access to information about the environmental situation, the quality of food and consumer goods, as well as the right to disseminate such information. No one shall make such information secret." This regulation is an important element of a system of constitutional guarantees of citizens' personal safety.

The legal basis in this field consists of the Law of Ukraine "On Protection of Population and Territories from Emergency Situations Caused by Technological Activities of People or by Natural Causes" dated June 8, 2000; the Law of Ukraine "On Consumer Rights Protection" dated May 12, 1991; the Law of Ukraine "On Quality and Safety of Food Products and Food Raw Materials" dated December 23, 1997 (the Law is drafted in a new version by the Law of Ukraine dated September 6, 2005); the Law of Ukraine "On Withdrawal from Circulation,

Processing, Recycling, Destruction, or Further Use of Low-Quality and Dangerous Products” dated January 14, 2000. In accordance with Article 1 of the Law of Ukraine “On Quality and Safety of Food Products and Food Raw Materials”, the safety of food is the lack of danger of food, food raw materials and accompanying materials adverse impact on a human organism, and food products safety indices are scientifically proven indices of contents (maximum allowed effect limits) of harmful components or substances of chemical, biological, radiation or any other origin in the products, the exceedance of which causes a detrimental impact on human health. Low-quality food products are those whose quality indices and consumption properties fail to comply with those indicated in a declaration of conformity, normative documents or legal acts, and unsafe food products are those whose safety indices fail to meet those established in the Ukrainian legislation for such products or indicated in a declaration of conformity, normative documents and legal normative acts, as well as food raw materials whose consumption (use) is associated with a high risk for human health and life. Article 20 of the same Law states that it shall be prohibited to produce, import, sell, use in wholesale or retail trade, or in public catering any low-quality, dangerous for human health and life, or counterfeit food products, food raw materials or accompanying materials.

Prior to the adoption of the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”, the following normative and regulatory documents of Ukraine regulated individual GMO-related issues:

**The Law of Ukraine “On Baby Food” dated 14.09.2006 (laws could be in chronological order)**

Article 8. Requirements to raw materials intended for manufacturing of baby food products. Raw materials used in manufacturing of baby food products shall not contain any hormone preparations or genetically modified organisms. I fear that this is in contradiction with EU and WTO rules. GMOs as such cannot be prohibited unless they have any adverse effect (in that sense, art 10 is completely OK).

Article 9. Key requirements to manufacturing of baby food products. It is prohibited to use any raw materials that consist of or contain genetically modified organisms in manufacturing of baby food products.

Article 10. Key requirements to the circulation of baby food products. The circulation of baby food products is prohibited if they, in particular, fail to comply with established quality and safety requirements and/or contain any genetically modified organisms;

**The Law of Ukraine “On Customer Rights Protection” dated 12.05.1991**

Article 15. Consumer right to product information.

1. A consumer has the right to access any essential, reliable, available and timely product information that provides the possibility of conscious and competent product selection. The information shall be made available to a consumer prior to product purchase or work (services) ordering. Product information shall not be considered as advertisement.

Product information shall include:

- a label on the presence of any genetically modified components;

2. Information defined in the first part of this article shall be made available to consumers by a manufacturer (executor, seller) in the accompanying documentation supplied with a product, on its label, via labeling, or in another way (in an accessible visible form) that is accepted for certain types of products or in certain kinds of service;

### **The Law of Ukraine “On Ensuring the Sanitary and Epidemiological Well-Being of the Population” dated 24.02.1994**

Article 1. Defining key terms and concepts.

The following terms and concepts shall have the following meanings in this Law: environmental factors – any biological (viral, prionic, bacterial, parasitic, genetically modified organisms, biotechnology products etc.), chemical (organic and non-organic, natural and synthetic), physical (noise, vibration, ultrasound, infrasound, thermal, ionizing, non-ionizing and other types of radiation), social (nutrition, water supply, conditions of life, labor, rest, study, upbringing, etc.), and any other factors that have impact or may have impact on human health, or health of future generations;

### **The Law of Ukraine “On Priority Innovative Activities in Ukraine” dated 16.01.2003**

This law establishes a legislative base for the concentration of national resources in priority research and science activities in order to modernize industry and services.

Article 8. Medium-term priority innovative activities:

- Improvement of chemical technologies, new materials, development of biotechnologies;
- Development of genetic engineering technologies, genetically modified cultures and organisms;

### **The Law of Ukraine “On National Security Fundamentals of Ukraine” dated 19.06.2003**

Article 7. Threats to the national interests and security of Ukraine.

At present, the key real and potential threats to Ukraine’s national security in the environmental field are as follows:

- Uncontrolled importation to Ukraine of environmentally dangerous technologies, substances, materials and transgenic crops, agents of diseases that are dangerous to people, animals, plants and organisms, environmentally unjustified use of genetically modified plants, organisms, substances and their derivatives;
- Reinforced influence of harmful genetic effects within populations of living organisms, in particular, genetically modified organisms, and biotechnologies;

### **The Law of Ukraine “On Population Protection from Infectious Diseases” dated 06.04.2000**

Article 14. Generating of new and genetically modified microorganisms and biological active substances.

Enterprises, institutions, organizations regardless of their form of ownership, their organization departments (laboratories) dealing with researches on generating any new and genetically modified microorganisms, or biological active substances, are subject to compulsory registration at a special executive authority responsible for health protection in order to exercise state control over such researches.

### **The Law of Ukraine “On the Animal World” dated 13.12.2001**

Article 51. Protection of the animal world from adverse impacts of biotechnology products.

Generating of new microorganism cultures, biological active substances, cultivation of GMOs’ breeding, and production of other biotechnology products shall be conducted only in accordance with the established procedure, provided that there are positive results of state environmental expert examination. It is prohibited to use the above organisms and substances

without such results.

**The Law of Ukraine “On Fundamentals of Public Supervision (Control) in Business Operations” dated April 5, 2007.**

The Law, in particular, states that “the public supervision (control) means operations of authorized central executive authorities, their territorial bodies, bodies of local government, and other bodies (hereinafter – public supervision (control) authorities) within their competence stipulated by respective laws related to detecting and preventing law infringements by business entities and ensuring public concern, in particular, an adequate quality of products, activities and services, the level of danger acceptable to the population and environment”; a risk means a quantitative degree of danger that covers the possibility of negative effects of any business operations and possible scope of related costs; as well as defines general principles and requirements of public supervision (control).

Apart from the Laws listed above, several subordinate normative legal acts were approved by the Cabinet of Ministers of Ukraine, Ministry of Education, Ministry of Health, Ministry of Agricultural Policy, Ministry of Environment and Natural Resources. However, their activities are unrelated, and there is no accurate interaction. Key bylaws regulating GMO-related activities are listed below:

**Temporary procedure of import, state testing, registration and use of transgenic plant varieties in Ukraine approved by the Decree of the Cabinet of Ministers of Ukraine dated 17.08.1998 №1304**

It defines the mechanism of import, state testing, registration and use in Ukraine of genetically modified (transgenic) plant varieties in order to establish conditions for use of biotechnology developments, in particular, transgenic plant varieties, in agriculture, and to observe biosafety regulations.

On August 20, 2008, the Cabinet of Ministers of Ukraine adopted **the Resolution № 734 “On Approving the Authorization Procedures on Import of Non-Registered Genetically Modified Organisms to Ukraine’s Customs Zone for Research Purposes and Public Testing”**. The Resolution is valid since January 1, 2009. According to Paragraph 2 of the Procedures, authorizations shall be issued to legal entities and individuals for every GMO free of charge based on a conclusion of public scientific and technical expertise and considering recommendations from the **Interagency Commission for Biosafety founded by MOH**. An authorization shall be valid within the period of research activities or public testing, but not more than five years.

**The Resolution of the Cabinet of Ministers of Ukraine dated October 16, 2008 № 922 “On approval of temporary safety criteria for GMOs’ handling and genetic engineering operations in closed systems”**. The above temporary criteria define risks for genetic engineering operations in closed systems, with GMOs being used in such operations. The Resolution defines four risk levels and criteria to assess danger degrees according to the extent of GMOs’ potential negative impact:

**First** – GMO-related genetic engineering operations, with outcomes not having an adverse effect on human health and the environment;

**Second** - GMO-related genetic engineering operations, with outcomes having a potential minor reversible adverse effect on human health and the environment;

**Third** - GMO-related genetic engineering operations, with outcomes having a potential reversible adverse effect on human health and the environment;

**Fourth** - GMO-related genetic engineering operations, with outcomes having a potential irreversible adverse effect on human health and the environment, as well as GMO-related genetic engineering operations, with an effect on human health and the environment being not sufficiently researched.

Assessment of a danger degree depends on the following:

*Biological peculiarities of donors and recipients* – information on reproductive cycles, nature of pathogenicity, virulence, toxicity and disease transmission vectors; information on availability of medicine resistance genes, etc.;

*MO behavior* – description of MO derivation methods, the structure and number of a vector's or donor's DNA, being preserved in final construction, the level of a new genetic material expression;

*Peculiarities of a MO's human health impact* – toxicity and allergenicity of MO and their metabolites, pathogenicity parameters; environmental effect – factors effecting GMOs' survival and reproduction in the environment, possible cumulative effects.

**The Resolution of the Cabinet of Ministers of Ukraine dated December 19, 2006 № 1757 “On approval of the Regulation on the Ministry of Education and Science of Ukraine”.** In Paragraph 4-40, the Regulation is replenished with the Ministry's powers related to functions defined by the Law of Ukraine ““On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”.

**Concept of balanced (sustainable) development of agricultural ecosystems in Ukraine for the period until 2025 approved by the Order of the Ministry of Agricultural Policy of Ukraine dated 20.08.2003.**

It defines that in order to ensure agricultural activity compliance with biosafety requirements, it is necessary to:

- 1) Develop an efficient system of state control over the import and distribution of GMOs and GMO-derived products;
- 2) Conduct genetic monitoring that includes: a) assessing potential danger from the modification of genetic diversity of animal breeds and plant varieties; b) assessing GMOs' impact on agricultural ecosystems formation.

**Concept for the improvement of food provision and nutrition quality for the population approved by the Decree of the Cabinet of Ministers of Ukraine dated May 26, 2004, N332**

It considers the legal regulation of production and circulation of food raw materials generate using biotechnologies, including genetically modified raw materials, food products and animal feed made of such materials, as well as functioning of an efficient system of control and supervision over the quality and safety of food products and food raw materials at all stages of their production and circulation (Item 4-3). It is aimed at strengthening and preservation of human health, and prevention of malnutrition-related diseases.

The key objectives of the concept are:

- 1) To increase the extent of high quality food raw materials usage in Ukrainian food industry;
- 2) To minimize the use of genetically modified raw materials for this purpose.

**Practical policies “Medical and biological assessment of non-traditional food raw materials and new food products” approved by the Order of the Ministry of Health of Ukraine dated 09.07.97, N204**

The purpose of the document is to create a common methodical approach to prevent an adverse impact of non-traditional food raw materials and new food products of Ukrainian and foreign origin on human health.

The policies solve the problems of:

- 1) Determination of the nutrition value of a product and its valuation as a source of the most important nutrients;
- 2) Determination of the safety of the traditional consumption of food raw materials and food products;
- 3) Regulation of quality and safety indices;
- 4) Development of recommendations on production, storage, sale and consumption of food products;
- 5) Delivering scientifically proven conclusions on the nutrition value and safety of non-traditional food raw materials and food products.

**Regulations on food products retail trade approved by the Order of the Ministry of Economy and European Integration of Ukraine dated 11.07.2003, №185**

This document regulates the procedure of reception, storage, presale preparation and sale of food products in retail trade network, and specifies requirements to consumer rights protection concerning the quality and safety of products and standards of retail services; It prohibits the sale of packaged Ukrainian and imported foods without labels in Ukrainian state language. Such labels shall, in particular, contain readable information on the contents of genetically modified raw materials in a product.

**The Decree of the President of Ukraine dated December 28, 2005, N 1867/2005 “On the decision of the National Security and Defense Council of Ukraine dated December 9, 2005 “On the situation in agricultural industry and actions for ensuring the food security in Ukraine”**

According to this Decree, the Cabinet of Ministers of Ukraine has been given the task to ensure legal support for the draft Law “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms” (registration N 2017) at the Verkhovna Rada of Ukraine;

**The Resolution of the Cabinet of Ministers of Ukraine №14 dated 10.01.2002 “On approving the Interagency Integrated Program “Health of the Nation” for the period of 2002-2011.” As I said in my previous comment, then the system of all those decrees, orders, decisions etc remains unclear to me. Why are there so many overlapping regulations regulation food labeling?**

Compulsory labeling of food products that contain genetically modified ingredients shall be introduced in order to reduce a human health impact of low-quality and polluted food products, and optimize nutrient budgets.

**The Decision of the Cabinet of Ministers of Ukraine №132/292 dated 28.11.2002 “On approving the municipal cross-sectoral integrated program “Health of Kyivans” for the period of 2003-2011.”**

Compulsory labeling of food products that contain genetically modified ingredients shall be introduced.

**In accordance with the above, the Kyiv Municipal State Administration issued the Bylaw №1825 dated 30.09.2003 “On approving the actions concerning the implementation of the municipal cross-sectoral integrated program “Health of Kyivans” for the period of 2003-2011.”**

Compulsory labeling of food products that contain genetically modified ingredients shall be introduced.

**The Bylaw of the Kyiv Oblast State Administration №247 dated 06.05.2003 “On approving the Kyiv oblast integrated program “Health of the Nation” for the period of 2003-2011.”**

Compulsory labeling of food products that contain genetically modified ingredients shall be introduced.

**The Letter of the State Customs Service of Ukraine №11/1-9763 dated 15.10.1997 “On the list of goods imported or transited by the permission of GCEC.”**

Any genetically modified microorganisms or genetic elements that contain fragments of nucleic acid that encode pathogenic factors and are derived from microorganisms shall be included into the list of goods imported or transited through the Ukrainian territory by the permission of the Governmental Commission for Export Control.

**The Letter of the State Customs Service of Ukraine N 11/4-10-2326-EII dated 17.02.2003 “Public regulation of food products’ and raw materials’ import into Ukraine’s customs territory.”**

It is prohibited to sell and use Ukrainian food products or to import foreign food products without labels in the Ukrainian state language that contain readable information on the following:

- the presence of components made of genetically modified raw materials in a food product (in cases when the use of such components is ensured by respective regulatory documents);

In accordance with this temporary procedure, only transgenic plant varieties that are recognized as biologically safe, officially registered and permitted for use in any member state of the International Union for the Protection of New Plant Varieties, shall be allowed to be imported in Ukraine.

Transgenic plant varieties are imported in Ukraine by the permission of the Ministry of Agricultural Policy.

Transgenic plant varieties may be imported into Ukraine provided that the packaging (boxes, packages, parceling) is marked as “TG” and inner labels contain information about plant species, name of a variety, its mass, name and address of a sender.

**The Letter from the Ministry of Education and Science №1/9-326 dated 16.06.2005 “On methodic recommendations for studying basic disciplines in 2005/2006 academic year.”**

A teacher should turn pupils’ attention to the important role of plants in the nature and human life, describe at the conceptual level, taking into account age peculiarities of pupils, directions of up-to-date biological studies in crop production: raising new varieties, genetically modified plants, etc.

**The Order of the Ministry of Agricultural Policy of Ukraine, Ukrainian Academy of Agricultural Science №318/92 dated of 24.10.2001 “On approving the “Agricultural Biotechnology 2001-2005” program**

A system of control over the distribution of transgenic plants and environmental expert examination shall be developed.

**The Resolution of the Presidium of the National Academy of Science of Ukraine №107 dated 29.03.99 “On enhancing the role of NAS of Ukraine in intensifying the market**

### **reforms and forming a strategy of Ukraine’s economic development.”**

The Resolution provides for the development of a regulatory legal basis and a state system of biosafety control of work with genetically modified organisms, as well as a system of registering new producer transgenic organisms.

**The Draft Law of Ukraine “On making amendments to the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms” (regarding the improvement of certain provisions).**

The Draft Law was introduced to the Verkhovna Rada by People’s Deputy of Ukraine Karmazin Yu. A.

The draft law contains the following key provisions:

- Founding a special authority dealing with safety of genetic engineering operations under the Cabinet of Ministers of Ukraine, its composition and competence;
- Powers of central executive authorities in charge of technical regulation and consumption policy;
- Risk levels;
- Control system requirements;
- Food labeling.

### **Conclusions and Recommendations**

The above list of bylaws affirms that the Regulation “Temporary procedure of import, state testing, registration and use of transgenic plant varieties in Ukraine” practically has not functioned, since it has not provided for the distribution of responsibility between key Ministries within the framework of the state control over GMOs in Ukraine.

In 1999, the Ministry of Agricultural Policy elaborated the program “Agricultural Biotechnology for 2001-2005.” Its improved and extended version was issued in 2003 as the concept of improving the food provision and nutrition quality for the population. This concept, in turn, was approved by the Cabinet of Ministers of Ukraine in 2004 as the concept of improving the food provision and nutrition quality for the population. All these three documents point at the necessity of state control and legal regulation of production and circulation of food raw materials produced with the use of biotechnology, including GMOs.

The program of the EU integration developed in 2000 and approved by the Decree of the President of Ukraine was aimed at the adaptation of the Ukrainian biosafety regulation to EU requirements. No clause of this program has been executed, except for the signing of the Protocol on Biosafety and approval of the cross-sectoral integrated program “Health of the Nation.” This program was developed and approved by the resolution of the Cabinet of Ministers of Ukraine. Later, in accordance with this program, the municipal program “Health of Kyivans” was developed and approved by the Kyiv Municipal Council and Kyiv Municipal State Administration, and Kyiv oblast integrated program “Health of the Nation” was developed as well. The essence of GMO-related issues comes to the introduction of compulsory labeling of food products that contain genetically modified organisms.

Among the departmental bylaws regulating GMO issues in particular sectors, one should note letters of the State Customs Service. The first of them states that GMOs’ import and transit is executed by the permission of GCEC, and the second one prohibits the sale and use of Ukrainian food products and import of foreign food products without labeling that informs about GMOs’ contents. However, these enactments practically do not function, since they are based on the temporary import procedure that, in turn, practically does not function. Special attention should be paid to the Regulations on food products retail trade that prohibit the sale

of packaged Ukrainian and imported food products without GMOs' labeling. There is also the Resolution of the NAS of Ukraine on the development of a regulatory basis and generating a state system of biosafety control of work with genetically modified organisms.

The Resolution of the Cabinet of Ministers of Ukraine dated October 16, 2008 № 922 “On approving temporary safety criteria for GMOs’ handling and genetic engineering operations in closed systems”, which defines criteria for danger and risk assessment, is important for the development of the national biosafety framework.

However, according to analyzed material, in spite of numerous laws and subordinate regulations, our legislation does not have any regulatory mechanisms pertaining to their implementation procedures. Also, national laws do not outline the responsibility of food producers or sellers for regulatory infringements. According to the above, Ukraine does not have adjusted laws related to GMOs’ derivation, testing, transportation and use. There is no authority (one or several) defined to control GMOs’ transportation within the country, GMO-related export-import operations, etc.

If we analyze the Law of Ukraine “On Quality and Safety of Food Products and Food Raw Materials,” we can see that it only states that the procedure of production and putting into circulation of GMO-derived food products has to be regulated by special legislation, which currently does not exist. This means that today the law on quality and safety of food products does not regulate any issues related to safety and quality of GMO-derived products and their circulation. However, Article 38 contains the regulation that states that any new food product or new technology putted into circulation in Ukraine has to undergo expert examination in the State Sanitary and Epidemiological Service of Ukraine.

The regulations on GMOs’ use are clearly stated in the Laws of Ukraine “On National Security Fundamentals of Ukraine,” “On Population Protection from Infectious Diseases,” and “On the Animal World.” They say that the intensified impact of harmful genetic effects within populations of living organisms, in particular genetically modified organisms, and biotechnologies, constitutes a threat to the national security, and, therefore, GMOs are subject to compulsory registration at the central executive authorities dealing with health protection, and generating of new strains of microorganisms, biological active substances, breeding of genetically modified organisms and production of other biotechnology products may be performed only in accordance with the established procedure and is subject to state environmental expert examination.

The Law of Ukraine “On Baby Food” completely prohibits using raw materials that consist of or contain genetically modified organisms at any stage of production of raw materials intended for baby food production, the production itself and circulation of baby food products.

Analyzing the **Draft Law of Ukraine “On making amendments to the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”** (regarding the improvement of certain provisions), the following could be stated:

- A specialized authority dealing with safety of genetic engineering operations under the Cabinet of Ministers of Ukraine may duplicate particular functions of the Interagency Commission for Biological and Genetic Safety under the National Security and Defense Council, as well as undertake powers of the central executive authorities, which are defined by the Law “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”. Moreover, the draft Law

does not stipulate informing the Parties to the Protocol through the Biosafety Clearing House about respective decisions made.

At the same time, the draft law contains a set of provisions that are rather topical. This concerns the following:

1. Regulating the operations of the central executive authority dealing with technical regulation and consumer policy. The authority is expected to:

- Organize, coordinate and perform operations regarding the development of national standards and take measures to make national standards on GMOs' control compliant with respective international (regional) regulations;
- Coordinate activities in accordance with international practice regarding professional testing of research laboratories to prove their competence;
- Ensure the attestation of methods regarding qualitative and quantitative measurement of GMOs in GMO-derived food, cosmetics, medicines and feed or those containing GMOs;
- Provide public (market) supervision and control of observance of GMO-containing food labeling requirements by producers, suppliers and sellers.

2. Requirements to the control system:

- Control of food and feed that is produced, composed of or contains GMOs shall be ensured through obligatory submission by producers, suppliers and importers of written information (declaration) on GMOs' content in products at all stages of their placement on the market in production and circulation;
- The control system shall be able (technical control measures) to identify food and feed that is supplied by a producer (supplier) to end users.

3. Requirements to food labeling:

- Food that contains over 0.9 % of GMOs shall be obligatory labeled;
- Food and feed that contains up to 0.9% of GMOs shall not be labeled;
- Food containing over 0.9 % of GMOs shall be labeled by producers, suppliers and sellers as follows:
  - in the list of ingredients after the name of a GMO-derived ingredient(s) the following inscription shall be made: "made of genetically (name of an organism)", or such inscription shall be made in the form of a note to an ingredient list, with the name of a GMO-derived ingredient(s) being marked with (\*), and such inscription shall be made in the same print as the ingredient list;
  - for products containing one ingredient, the inscription: " made of genetically (name of an organism)" shall be made after a general name of a product in the same print as the ingredient's name.

Food that does not contain GMOs but is made of agricultural products, with GMOs amounting to over 0.9 %, shall be labeled similar to GMO containing products. The labeling shall be made on every consumer container, label, counter-label, tag, any other information carrier.

Food that is sold without consumer packaging or with the largest area of consumer packaging being less than 10 cm<sup>2</sup> shall be labeled by sellers on a price-list based on information specified by producers or suppliers on transit packs or in accompanying documents in a perceivable and readable print. Any food or feed that does not meet labeling requirements specified in the Law shall be retired.

## **2.2. INSTITUTIONAL STRUCTURE**

### **2.2.1. Competent national authorities**

In accordance with the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms” (Articles 6-11), GMOs’ handling operations are ensured by the following executive authorities within their competence.

#### **The Cabinet of Ministers of Ukraine shall:**

- Provide state regulation and control in GMOs’ handling and genetic engineering;
- Ensure the implementation of measures related to state support of genetic engineering;
- Direct and coordinate activities of central and other executive authorities in GMOs’ handling and genetic engineering;
- Organize international cooperation in order to provide safe GMOs’ handling and development of scientific knowledge in this field;
- Approve the procedure of public registration of GMOs and GMO-derived products;
- Approve the procedure of importation of GMO food and feed sources and GMO-derived food and feed;
- Approve the procedure of authorization of GMOs’ transit through the territory of Ukraine;
- Approve the procedure of licensing genetic engineering activities in closed and open systems;
- Approve the procedure of state approbation (testing) of GMOs in an open system and authorization of such testing;
- Approve the criteria of safe GMOs’ handling in closed systems.

#### **The Ministry of Education and Science shall:**

- Provide for the development of scientific and technical potential in genetic engineering;
- Provide for the protection of international and national patents and other types of intellectual property in GMOs’ handling and genetic engineering;
- Develop criteria for safe GMOs’ handling and genetic engineering in closed systems;
- Develop and improve a system of controlling the observance of genetic engineering safety regulations;
- Conduct licensing of genetic engineering in closed systems;
- Issue permits for the importation of unregistered GMOs, if they are to be used exclusively for research purposes in closed and open systems, and public testing purposes, taking into consideration the results of state ecological and sanitary-and-epidemiological expert examination of GMOs’ biological and genetic safety that is conducted in accordance with international treaties of Ukraine.

#### **The Ministry for Environmental Protection shall:**

- Conduct state ecological expertise of GMOs intended for use in an open system;
- Develop criteria for risk assessment of a potential GMOs’ impact on the environment based on scientific principles and international experience;
- Conduct state registration of GMO-derived plant protection products;

- Conduct state supervision and control over the observance of biological and genetic safety measures concerning environmental biological subjects in GMOs' generating, research and practical use in an open system;
- Issue authorizations for GMOs' release in an open system.

**The Ministry of Health Protection shall:**

- Develop criteria for risk assessment of a human health potential impact of GMOs and GMO-derived products, including food, based on scientific principles and international experience;
- Conduct state sanitary-and-epidemiological expertise of GMOs that are used in open systems to prove conclusions on their biological and genetic safety for human health in order to perform their public registration;
- Conduct state supervision and control over the observance of biological and genetic safety measures concerning human health in GMOs' generating, research and practical use in an open system;
- Conduct state sanitary-and-epidemiological expert examination of GMO-derived products to prove conclusions on their safety for human health and life;
- Conduct public registration of GMO food sources and food, cosmetics, medicines that contain GMOs or are derived from GMOs;
- Approve a list of food products that are monitored for GMOs' contents, and a list of appropriate methods for GMOs' detection and identification;
- Monitor GMO-derived food products for the presence of registered GMO sources.

**The Ministry of Agrarian Policy shall:**

- Provide for the state approbation (testing) and state registration of GMO-derived agricultural plant varieties, animal breeds, microbiological agricultural and veterinary preparations;
- Conduct state supervision and control over the observance of biological and genetic safety measures concerning agricultural plants and animals in GMOs' generating, research and practical use in open systems at agro-industry enterprises, institutions and organizations, regardless of their subordination and form of ownership;
- Conduct state registration of GMO feed sources and state registration of feed supplements and veterinary preparations that contain GMOs or are derived from GMOs;
- Approve a list of feeds that are monitored for GMOs' contents, and a list of appropriate methods for GMOs' detection and identification;
- Monitor GMO-derived feeds for the presence of registered GMO sources.

**Interagency Commission for Biological and Genetic Safety under the National Security and Defense Council**

The Interagency Commission for Biological and Genetic Safety under the National Security and Defense Council was founded to implement the Decree of the President of Ukraine "On particular issues of the Interagency Commission for Biological and Genetic Safety under the National Security and Defense Council" dated September 20, 2007, № 905/2007, which establishes the commission's composition. The Commission is composed of representatives of the Ministry for Environmental Protection, Ministry of Health, Security Service of Ukraine, scientists from top research institutions. The Head of the Interagency Commission is a member of the National Academy of Science of Ukraine and the Academy of Medical Science of Ukraine Komisarenko S.V. The key functions of the commission include defining

the national interests of Ukraine in terms of new biotechnologies and genetic engineering, improving the legal support system on biological and genetic safety of Ukraine, and improving efficient information support to the President of Ukraine.

A regular meeting of the Interagency Commission for Biological and Genetic Safety under the National Security and Defense Council with the agenda: “Ukrainian biosafety laws and proposals on amendments to the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms” took place on October 24, 2008. The meeting involved the consideration and support of proposals on making amendments to the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”. It was also proposed to consider the criteria for labeling of GMO containing products while considering the issue “Healthy nutrition and food safety as an integral part of national food safety”. It was also proposed to discuss the support of the development of national research activities focused on creating modern high-end and safe biotechnologies at one of the meetings of the Commission. The Commission adopted the recommendations to the State Television and Broadcasting Committee of Ukraine to arrange public explanation of truthful and impartial information on GMO use and human health impact via mass media by top biosafety specialists.

#### **Scientific institutions that deal with GMO issues: what does it mean – deal with GMO issues?**

1. Institute of Botany named after M. G. Kholodny, Kyiv, Tereshchenkivska st., 2
2. Institute of Zoology named after I. I. Shmalgausen, Kyiv, Bohdana Khmelnytskoho st., 15
3. Institute of Plant Physiology and Genetics, Kyiv, Vasylykivska st., 31/2
4. Institute of Cytobiology and Genetic Engineering, Kyiv, Akademika Zabolotnoho st., 148
5. International Institute of Cytobiology, Kyiv, Akademika Zabolotnoho st., 148
6. Institute of Southern Ocean Biology named after O. O. Kovalevsky, Sevastopol, Rakhimova av., 2
7. Institute of Food Chemistry and Technology, Kyiv, Osypovskoho st., 2A

#### **Educational institutions that study and research GMOs**

##### ***National Agricultural University***

Research and Education Institute of Environmental Protection and Biotechnology  
Research and Education Institute of Agricultural Ecology, Standardization and Certification of Objects and Territories

Areas of education: 0929 — “Biotechnology”, with speciality “Ecological biotechnology”, and 0708 — “Ecology”, with speciality “Ecology and Environmental Protection.”

##### *Scientific activities:*

1. Assessment of GMOs’ safety for people and the environment.
2. Study of biological methods of environmental protection (biosafety of use of GMOs and recombinant DNA of various purposes using biofilms, active sludge, selection of hydrobionts and forming of lagoons, and of GMOs’ generating).

##### ***National University of Food Technologies***

Since 1999, the university has been teaching specialists under the speciality “Ecology and Environmental Protection,” specialization “Ecology of Food Industry.” Training is conducted at the department of biochemistry and ecology of food production. Educational institutions dealing with biology provide training on GMO-related issues at courses of General Genetics and Ecology.

### ***State Enterprise All-Ukrainian Center of Standardization, Metrology, Certification and Consumer Rights Protection***

In order to provide control of products for GMOs' contents, a laboratory of molecular and genetic research was founded under the State Enterprise All-Ukrainian Center of Standardization, Metrology, Certification and Consumer Rights Protection (Ukrmetrteststandart). The laboratory was founded in accordance with requirements to molecular and genetic laboratories. The laboratory is outfitted with modern analytic equipment. The laboratory staff includes specialists that have been trained at the laboratory of molecular and genetic analysis of LLC "Test-Pushchino" (Pushchino, Russian Federation), as well as "Bio Rad Laboratories" (France).

The laboratory performs the following testing of food products and food raw materials:

- Testing food products and food raw materials for GMOs' presence – detection of regulatory sequences of a promoter (35S) and a terminator (NOS);
- Detecting soya and corn DNA in food products and food raw materials;
- Identifying and detecting the quantity of genetically modified lines of soya - CTS 40-3-2, and corn - MON 810;T25; Bt11; MON860;

Testing of food products and food raw materials for GMOs' contents is performed in accordance with requirements of the international standard ISO 21570:2005 Foodstuffs – Methods of analysis for the detection of genetically modified organism and derived products – Quantitative nucleic acid based methods, ISO 21571:2005 Foodstuffs – Methods of analysis for the detection of genetically modified organism and derived products – Nucleic acid extraction. In order to control the quality of testing results, the laboratory uses certified standard samples ("FAPAS," Great Britain) with attributed values of GMOs' contents in food products and food raw materials. The laboratory of molecular and genetic research started its work on January 15, 2007.

#### **2.2.2. Recommendations on the development of the national biosafety institutional structure**

not needed in this place

With the adoption of the Law of Ukraine "**On the national biosafety system in generating, testing, transportation and use of genetically modified organisms**", and in accordance with Article 19 of the Cartagena Protocol on Biosafety, Ukraine has determined that the Cabinet of Ministers of Ukraine is the responsible authority that directs and manages activities of central executive authorities and other executive bodies in GMOs' handling and genetic engineering. Currently, analyzing other countries' approaches to the operations of coordination centers, whose activities are defined by Article 19 of the Cartagena Protocol, it could be proposed to appoint the **Interagency Commission for Biological and Genetic Safety under the National Security and Defense Council** to perform the functions of the **Coordination Biosafety Council**. The Commission would include representatives of competent authorities defined by Articles 7-10 of the Law of Ukraine "On the national biosafety system in generating, testing, transportation and use of genetically modified organisms," and other interested parties, namely:

- The Cabinet of Ministers of Ukraine, including a representative of the National Focal Point (2)
  - The Ministry of Education and Science (1)
  - The Ministry for Environmental Protection (1)
  - The Ministry of Health Protection (1)
  - The Ministry of Agrarian Policy (1)
  - The National Academy of Science of Ukraine (1)
- For further consideration of particular issues, it is proposed to engage as follows:
- Representatives selected from the register of scientists of respective description (2)
  - Scientific research institutions (by agreement)
  - Standardization and Metrology Committee (1)
  - Representatives of public organizations and businessmen associations (2) (by agreement)

The competence of the **Coordination Biosafety Council** is proposed to include taking its final decision on internal use (including market sale) of a living modified organism, which may be a subject of transboundary transportation for its direct use as food or feed.

It is proposed to appoint/found under the **Interagency Commission for Biological and Genetic Safety under the National Security and Defense Council** a working body: **the National Focal Point/ National Coordination Center** to act as a secretariat and be charged with communications with the CBD Secretariat on behalf of Ukraine. **The National Focal Point** shall perform administrative functions. **The National Focal Point** is proposed to involve a representative of the Ministry for Environmental Protection, who will act as **BCH Focal Point** according to the Cartagena Protocol. The representative shall ensure the collection of information on biosafety issues from ministries and departments, and its submission to the Secretariat of the Cartagena Protocol. The competence of **the National Focal Point** is proposed to involve:

- Generating a register of biosafety experts and ensuring the operations of the Expert Council for Biosafety;
- Transferring documents for their preliminary assessment to the Expert Council for Biosafety;
- Familiarizing respective competent authorities with the Expert Council's opinions, provide examinations and take respective decisions;
- Informing the Parties to the Protocol by the National Focal Point through the Biosafety Clearing House about decisions on internal use, including market sale of living modified organisms that can be the subjects of transboundary transfer for direct use as food or feed, or for processing;
- Ensuring public access to biosafety information;
- Processing and summarizing information that is included in registers of specific competent authorities.

We propose to approve the Regulations on founding the Coordination Biosafety Council and the National Focal Point by the Decree of the President of Ukraine. The Decree shall regulate powers of the aforementioned bodies (**Coordination Biosafety Council** and **the National Focal Point**) and their competence. After passing the decree, the National Focal Point should inform the Secretariat of the Cartagena Protocol about its powers, realm of competence and contact addresses of all stakeholders.

While assessing risks, any respective information is proposed to be submitted to **the Expert Council for Biosafety** founded under **the Coordination Biosafety Council** and announced to competent executive authorities with the assistance of **the National Focal Point**.

In future, in order to ensure more comprehensive risk assessment, it is proposed to develop regulations on the functioning of laboratories accredited for testing and assessment of products for GMOs' contents that could be involved for the performance of laboratory studies. Specially accredited laboratories may be formed as part of the Ministry of Health Protection of Ukraine, Ministry of the Agricultural Policy of Ukraine, and other bodies that according to current Ukrainian laws are obligated to control the quality of corresponding products.

The powers of **central executive authorities** should include:

- Ensuring the procedures for review of notifications about activities related to GMOs' generating, testing, transportation and use;
- Examining (environmental and hygiene and sanitary) information obtained to implement notification review procedures.

It is proposed to form specialized subdivisions as parts of competent authorities, or appoint persons responsible for effective making of decisions on notifications about GMOs' generating, testing, transportation and use.

The key difference from the proposed system in the Draft National Biosafety Framework is that all the powers pertaining to making decisions, issuing authorizations and implementing regulatory policy shall be delivered to **the National Biosafety Commission under the Cabinet of Ministers of Ukraine**.

## **2.3. MONITORING, INSPECTION AND CONTROL**

### **2.3.1. The existing system of monitoring, inspection and control**

In accordance with Articles 8-11 of the Law of Ukraine *“On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”*, state supervision and control over the observance of biological and genetic safety measures is vested on the central executive authorities dealing with environmental issues and natural resources (concerning environmental biological subjects in GMOs' generating, research and practical use in open systems), central executive authorities dealing with science and education (develops and improves a system of controlling the observance of genetic engineering safety regulations), central executive authorities dealing with health protection (conducts state supervision and control over the observance of biological and genetic safety measures concerning human health in GMOs' generating, research and practical use in open systems), central executive authorities dealing with agricultural policy (conducts state supervision and control over the observance of biological and genetic safety measures concerning agricultural plants and animals in GMOs' generating, research and practical use in open systems at agro-industry enterprises, institutions and organizations, regardless of their subordination and the form of ownership).

Currently, several departments, regional and local subdivisions function as parts of the aforementioned central executive authorities and perform functions of state supervision and control over the observance of biological and genetic safety measures:

**State Ecological Inspection** is a governmental body of state administration that acts as part of the Ministry of Ecology and Natural Resources and is subordinated to it. The Regulation on the State Ecological Inspection was approved by the resolution of the Cabinet of Ministers of Ukraine dated November 17, 2001, N1520. In accordance with this regulation, the State Ecological Inspection is responsible for state control over:

- The observance of legal requirements to environmental protection;
- The observance of environmental safety requirements: 1) in scientific, research and development activities, introduction of discoveries, inventions, imported systems and technologies into production; 2) at border crossing points and in the area of operations of customs offices at destination and exit points; 3) in transportation, storage, use, disposal, destruction and detoxification of pesticides and agricultural chemical preparations;
- The observance of requirements of the state environmental expert examination results in the use, reproduction and protection of natural resources, the observance of issued authorizations, limits and quotas for the special use of natural resources, transboundary transfer of animals and plants.

The State Ecological Inspection submits its proposals to the Ministry of Ecology and Natural Resources on the following:

- Improvement of the system of registration, reporting and state statistics on issues within its competence, approval and reconciliation of regulations, norms and standards on environmental protection, use of natural resources and ecological safety in accordance with the established procedure;
- Issuing, suspension or annulment of authorizations for the special use of natural resources, emissions and discharges of pollutants into the environment, handling of dangerous chemicals, transboundary transfer of animals and plants in accordance with the established procedure;
- Planning and execution of preventive actions regarding emergencies of man-caused and natural origin.

The State Ecological Inspection interacts with mass media on the coverage of urgent problems on state control in environmental protection, informs state administration, local self-government and population about environmental status of territories and subjects, cases and reasons of extreme environmental pollution.

**The State Sanitary Epidemiological Service of Ukraine (SES)** is a system of bodies, institutions, departments, sections and subdivisions that constitute a part of the Ministry of Health Protection of Ukraine. Their activity is aimed at the prevention of infectious, work-related and mass non-infectious diseases (poisonings), prevention of an adverse impact of environmental factors on human health and life, execution of state sanitary epidemiological supervision over products and environmental safety for human health and life. The “Regulation on the State Sanitary Epidemiological Service” was approved by the Resolution of the Cabinet of Ministers of Ukraine dated August 19, 2002, N 1218.

The State Sanitary Epidemiological Service of Ukraine performs the following:

- Executes state sanitary epidemiological supervision and control over the observance of sanitary legislative requirements by executive authorities, local self-government, enterprises, institutions, organizations, and citizens;
- Performs analysis and assessment of risk for human health and life, argumentation of actions on risk management, state sanitary epidemiological expert examination, inspection, investigation, laboratory and instrumental examination and testing, and sanitary, hygienic, toxicological, epidemiological and other assessments of the environment, subjects of economical and other activities, production, works, services,

- project documentation, and delivers conclusions about their compliance with sanitary regulations;
- Performs analysis of factors of danger to human health and conducts state sanitary epidemiological supervision at all stages of the production and sale of food products, approves safety systems for food production;
  - Studies, assesses and predicts population health indices depending on environmental condition, determines factors that adversely affect human health.

The SES submits proposals on actions to ensure sanitary and epidemiological well-being of the population, introduction of quarantine procedures, ensures protection of the Ukrainian territory from bringing and spreading of highly dangerous diseases (including quarantine diseases) and dangerous infectious diseases, performs state sanitary epidemiological supervision and control at state border crossing points; approves sanitary and anti-epidemic (prevention) measures developed by executive authorities, local self-government, enterprises, institutions, organizations, and controls their execution; issues compulsory resolutions, orders, instructions on the elimination or limitation of a harmful impact of environmental factors on human health and life; submits proposals on the limitation or prohibition of export, import, or transit of shipments and goods from countries or regions of epidemiological concern in accordance with the established procedure.

***The Central State Plant Quarantine Inspection*** of the Ministry of Agricultural Policy of Ukraine is a special executive authority dealing with plant protection. It heads the state plant protection service that includes state plant quarantine inspections of the Autonomous Republic of Crimea, oblasts and districts of Ukraine, and a network of specialized laboratories.

The realm of competence of the Central State Plant Quarantine Inspection includes phytosanitary diagnostics and supervision of the development, spreading and injuriousness of harmful organisms, introduction of integrated plant protection systems, determination of assortment and amount of production of plant protection products by Ukrainian industry, coordination of the purchase of imported plant protection products; organization and execution of state control over timely performance of plant protection, observance of storage, transportation and use regulations for plant protection products, approval of the assortment of plant protection products, technical conditions of their production and use, a plan of state testing and registration of plant protection products, a list of pesticides allowed for use in Ukraine, assortment of pesticides that are imported in Ukraine, and licensing of activities related to their production, storage, transportation and sale; organizing the implementation of scientific and technical achievements and methods and actions for plant protection that are safe for the environment and human health.

***The State Veterinary Medicine Department*** is a governmental authority acting as subordinated part of the Ministry of Agricultural Policy. The Regulation on the State Veterinary Medicine Department was approved by the Resolution of the Cabinet of Ministers of Ukraine dated June 8, 2001, N 641.

The key tasks of the State Veterinary Medicine Department include: state veterinary sanitary control and supervision of the quality and safety of raw materials, food raw materials, products and food products of animal origin, quality of veterinary medications and preparations, feed, feed supplements, and protection of the territory of Ukraine from bringing of causal organisms of infectious animal diseases from the territory of other countries or from quarantine zones, veterinary sanitary expert examination of products of animal and (at markets) of vegetable origin intended for feeding of people, further processing, feed, feed

supplements, issues compulsory orders, directions, instructions on actions for the prevention and liquidation of infectious animal diseases, disinfection, etc.; organizes actions for the prevention, diagnostics, liquidation of infectious, invasive, and non-contagious animal diseases and their treatment. The State Veterinary Medicine Department conducts state control and supervision over the observance of standards, pharmaceutical norms and regulations, technical specifications, instructions, technological regulations, and veterinary sanitary rules in the development, generating, testing, storage, transportation, sale and use of veterinary medications and preparations, feed and feed supplements; issues one-time authorizations for the import of veterinary medications and preparations, feed and feed supplements that are not registered in Ukraine; together with the Ministry of Health Protection organizes the protection of population from diseases that are common in humans and animals, and exchanges appropriate information; organizes laboratory and clinical virological, bacteriological, chemical and toxicological, patho-anatomical, histological, parasitological, radiological and other studies to diagnose animal diseases, assess the quality of products of animal origin, feed and water; together with the state sanitary epidemiological service participates in investigations of outbreaks of diseases that are common in humans and animals; coordinates, controls and executes state veterinary sanitary supervision over activities related to measures aimed at the prevention and treatment of animal diseases, improvement of the quality of products of animal origin, prevention and control of diseases that are common in humans and animals; executes state veterinary sanitary control and supervision over public veterinary medicine institutions' selection of samples of products of animal, vegetable and biotechnological origin for appropriate studies.

### **2.3.2. Recommendations on the optimization of monitoring, inspection and control operations**

The activity of controlling executive authorities is regulated by several current regulatory documents. In order to ensure these activities in the context of the development of biosafety system in Ukraine, it is necessary to introduce appropriate changes and additions to several regulatory documents.

Despite of the functioning system of controlling bodies, to develop the biosafety system in Ukraine it is necessary to enhance the competence of officials of the departments dealing with monitoring, inspection and control of biosafety. To achieve this, it is proposed to organize special seminars and trainings on GMOs' impact monitoring and GMOs' use control.

Significant attention should be paid to the development of appropriate methodical guidelines on monitoring and control. It is necessary to develop procedures and methods for the determination and assessment/management of risks related to GMOs' use.

It is necessary to work on changes and corrections to the current legislation determining responsibility for the infringement of biosafety laws.

It is necessary to develop a system of monitoring of environmental and human health impacts.

In order to expand the system of laboratory and scientific researches, cooperation should be established with similar EU institutions like ENGL.

### **2.3.3. Approaches to risk assessment and risk management**

In accordance with Article 15 of the Cartagena Protocol, risk assessment is conducted by scientifically proven methods according to Appendix III, taking into consideration recognized methods of risk assessment. Such risk assessments have to be based at least on information given in accordance with Article 8 and other available scientific information in order to determine and assess a possible harmful impact of living modified organisms on the conservation and sustainable use of biological diversity, while taking into consideration risks for human health. An importing party shall ensure that risk assessment is performed for decision making according to Article 10. It may demand from an exporter to perform risk assessment. The importer shall bear risk assessment costs if an importer demands this.

In accordance with Article 16 of the Cartagena Protocol, Ukraine has committed to develop and support appropriate mechanisms, actions and strategies for the regulation, management and control of risks related to the use, processing and transboundary transfer of living modified organisms.

Actions based on risk assessment results should be taken to the extent necessary to prevent an adverse impact of living modified organisms on the conservation and sustainable use of biological diversity, while taking into consideration risks for human health. Ukraine has to ensure that any living modified organism imported or created within the country is observed for a sufficient period corresponding to its living cycle prior to beginning of its planned use.

#### **Safety requirements to the regulation of genetic engineering in closed systems**

Genetic engineering in closed systems is regulated in accordance with Article 12 of the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms.” Genetic engineering in closed systems is subject to licensing. Licenses for such activity are issued based on risk assessment of GMO’s handling in a closed system. Enterprises, institutions and organizations dealing with genetic engineering (hereinafter referred to as institutions) form the Commission for Biological and Genetic Safety in Genetic Engineering (hereinafter referred to as the Commission) as a part of an institution. The task of the Commission is to perform preliminary risk assessment in planning and preparation of genetic engineering. In cases when genetic engineering is performed by natural persons, or the number of personnel at an institution does not allow formation of a Commission as a part of the institution, such persons or institutions shall be attached to an existing commission with the approval of the central executive authority dealing with science and education.

#### **Safety requirements to GMOs’ release into the environment for approbation (testing)**

It is proposed to prohibit the release of opportunistic and pathogenic genetically modified organisms into the environment for testing. The release of non-pathogenic genetically modified organisms into the environment for testing shall be performed only with the authorization issued by the Ministry for Environmental Protection of Ukraine. The authorization is issued if conclusions of state environmental expert examinations on GMOs’ safety are positive. The authorization issued for the first release of non-pathogenic GMOs shall be valid for subsequent releases of genetically modified organisms of this genotype into the environment. It is proposed to test non-pathogenic genetically modified organisms at their first release into the environment on experimental fields and other objects that are specially equipped for the prevention of a possible adverse impact of these organisms on the environment and comply with safety requirements established by the Ministry for Environmental Protection of Ukraine.

#### **Safety requirements to GMOs’ testing with economic purposes in an open system**

It is recommended to prohibit the use of opportunistic and pathogenic GMOs with economic purposes. The use of non-pathogenic GMOs in the form of genetically modified plant varieties, genetically modified animal breeds and genetically modified non-pathogenic microorganism strains with economic purposes is allowed after their public registration by the Ministry of Agricultural Policy of Ukraine. Public registration is performed provided that conclusions of state expert examination on GMO's safety and results of GMOs' testing by means of their release into the environment are positive. Information about registration of genetically modified plant varieties, genetically modified animal breeds and genetically modified non-pathogenic microorganism strains is entered into the state register of genetically modified plant varieties, genetically modified animal breeds and genetically modified non-pathogenic microorganism strains. The proof of the public registration of genetically modified plant varieties, genetically modified animal breeds and genetically modified non-pathogenic microorganism strains shall be a certificate of their public certification.

### **Safety requirements to GMOs' transportation**

Means of transportation of non-pathogenic genetically modified organisms shall be equipped with devices that rule out the possibility of unapproved release of genetically modified organisms into the environment. Transportation of opportunistic and pathogenic genetically modified organisms shall be carried out in accordance with the legislation on transportation of dangerous shipments and safety requirements for transportation of such organisms approved by the Ministry of Transportation of Ukraine.

### **Safety requirements to GMOs' import to Ukraine, export from Ukraine, and transit through the territory of Ukraine**

GMOs' import to Ukraine and transit through the territory of Ukraine shall be authorized provided that an exporting country (the country that performs transit operations) is a party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Import to Ukraine of non-pathogenic genetically modified organisms intended for the release into the environment for testing shall be allowed provided that there is an authorization for the release of non-pathogenic genetically modified organisms into the environment for testing. Import to Ukraine of non-pathogenic GMOs intended for economic purposes shall be allowed provided that there is a certificate of public registration of genetically modified plant varieties, genetically modified animal breeds or genetically modified non-pathogenic GMO strains. Import to Ukraine of opportunistic and pathogenic genetically modified organisms shall be allowed provided that there is an authorization for their import issued by the Ministry of Health Protection of Ukraine in accordance with the established procedure approved by the Cabinet of Ministers of Ukraine and is performed for scientific studies only. In case of an unapproved import of genetically modified organisms, a person performing import operations shall remove them from the territory of Ukraine at its own expense in accordance with the procedure established by the legislation. Transit of non-pathogenic genetically modified organisms through the territory of Ukraine shall be allowed after a carrier notifies the Ministry for Environmental Protection of Ukraine in accordance with the procedure approved by this Ministry (most of the counteies in the world do not regulate transit. Reconsider the need for that. If this is non-pathogenic and if it would not be shipped in your territory, then most of the countries have found that there is no need for administrative burden for regulating it.). Transit of opportunistic and pathogenic genetically modified organisms through the territory of Ukraine shall be allowed provided that there is an authorization for transit issued by the Ministry of Health Protection of Ukraine in accordance with the procedure approved by the Cabinet of Ministers of Ukraine. Export of non-pathogenic genetically modified

organisms from Ukraine shall be allowed provided that there is an authorization for their import issued by competent authorities (organization) of a destination country. Export of opportunistic and pathogenic genetically modified organisms from Ukraine shall be allowed provided that there is an authorization for their import issued by competent authorities (organization) of a destination country, and an authorization for their export issued by the Ministry of Health Protection of Ukraine in accordance with the procedure approved by the Cabinet of Ministers of Ukraine.

### **Safety requirements to GMOs' deactivation**

The deactivation of GMOs shall be performed in accordance with the legislation on waste products. Any GMOs attributed in accordance with the legislation on waste products, GMOs that were released into the environment for testing without any proper authorization issued in accordance with the established procedure, GMOs' used by legal persons and individual entrepreneurs with economic purposes without a certificate of state registration of genetically modified plant varieties, genetically modified animal breeds or genetically modified non-pathogenic microorganism strains shall be deactivated. The deactivation of opportunistic and pathogenic genetically modified organisms shall be performed in accordance with requirements of regulatory documents approved (issued) by the Ministry of Health Protection of Ukraine and technical regulations.

### **Risk assessment of GMOs' possible adverse impact on human health**

A system of safety assessment of GMOs and new GMO-derived food products shall be based on a principle of substantial equivalence. The concept of "substantial equivalence" is legally formalized in the special EU Regulation [EU, 1997 Regulation EC 258/97, 1997], which states that any new food products placed on the market have to be equivalent to existing traditional food products in terms of their composition, nutrition value, metabolism, nature of use and level of undesirable substances content.

In accordance with the substantial equivalence principle, the procedure of risk assessment shall include the comparative analysis of new food products and their traditional analogues focused on their similarities and differences. If there are found any new risk factors or if there are changed any factors that have been available earlier, a risk associated with them should be adequately evaluated.

Such comparative approach implies that:

- Traditional products are not absolutely safe;
- In case that GMO-derived food products or their ingredients are substantially equivalent to traditional food products or ingredients, they may be used in the same way without expecting any additional adverse impact on human health.

### **State ecological and sanitary epidemiological expert examination of GMOs' safety**

The regulation on state ecological and sanitary epidemiological expert examination of GMOs' safety shall be included into the existing Law of Ukraine "On state ecological expert examination" and into the Order of the Ministry of Health Protection of Ukraine № 120 dated 14.03.2006 "The procedure of state sanitary epidemiological expert examination." It is proposed to mention that ecological and sanitary epidemiological expert examination of GMOs is performed in order to determine the possibility of their release into the environment for testing or their use with economic purposes based on the GMOs' identification and studying risk assessment materials on a possible adverse impact of GMOs on human health and the environment.

State ecological and sanitary epidemiological expert examination of GMOs' safety shall be used for GMOs at their first release into the environment for testing and at state registration of genetically modified plant varieties, genetically modified animal breeds or genetically modified non-pathogenic microorganism strains intended for use with economic purposes. The subjects of state ecological and sanitary epidemiological expert examinations are the following:

- GMO samples;
- Materials containing information about risk assessment of a possible adverse impact of GMOs on human health and the environment, and about measures of such risks prevention.

The responsibility for infringement of any GMOs' handling laws is regulated in accordance with Article 18 of the Law "On the national biosafety system in generating, testing, transportation and use of genetically modified organisms."

The responsibility is incurred by persons guilty of the following:

- Concealment or misrepresentation of any information, which may have caused or has caused any danger to human health and life or the environment;
- Inobservance or violation of any standards, rules, public health regulations on GMOs' use, transportation, storage, or realization;
- Use of unregistered GMOs or GMO derived products (except for cases specified in Article 18 of the Law);
- Violation of GMO disposal and destruction rules;
- Inobservance of legal requirements of state officials dealing with state supervision and control.

The responsibility for other types of violation of the Ukrainian legislation in genetic engineering may also be established by the law.

If in GMOs' use, any competent authorities receive information that can lead to discovering of a potential risk of GMOs' adverse impact on human health and the environment, a producer of such product shall remove it from the environment and liquidate the pollution under the control from public authorities dealing with ecological control (at the expense of a producer).

In case of any accident resulting in uncontrolled GMOs' release into the environment and/or arising out of potential risks for human health and the environment, the liquidation of accident consequences is performed by the central executive authorities dealing with emergency situations and the protection of population from the consequences of the Chernobyl disaster, environmental issues and natural resources, science and education, other enterprises, institutions and organizations that are involved in the liquidation of accident consequences, or by a GMO owner, independently or with the assistance of appropriate organizations.

The efficiency of the liquidation of accident consequences shall be assessed by a commission consisting of representatives of the central executive authorities dealing with environmental issues and natural resources, health protection, and other authorities at the expense of a producer of pollutant products.

## 2.4. DECISION-MAKING SYSTEM

### Regulation of genetic engineering in closed systems

#### 1<sup>st</sup> stage

In accordance with Article 12 “Regulation of genetic engineering at institutions, organizations, and enterprises” of the Law of Ukraine “On the national biosafety system in generating, testing, transportation and use of genetically modified organisms”, genetic engineering in closed systems is subject to licensing. The procedure of such licensing is established by the Cabinet of Ministers of Ukraine based on an application from the central executive authorities dealing with science and education. Enterprises, institutions and organizations dealing with genetic engineering (hereinafter referred to as institutions) form the Commission for biological and genetic safety of genetic engineering (hereinafter referred to as the Commission) as a part of an institution. The task of the Commission is to perform preliminary risk assessment for planning and preparation of genetic engineering. In GMOs’ generating in a closed system, a researcher must provide the assessment of their safety.

#### 2<sup>nd</sup> stage

Survey results regarding GMOs’ safety for human health and the environment shall be reflected in appropriate documents (dossier). These materials shall be submitted for their expert examination to the **Expert Council for Biosafety** under the **National Focal Point**. At the same time, the information (GMOs’ open dossier, except for confidential information) that undergoes the authorization procedure shall be made available on the **National Focal Point’s** web site for public comments resulting from public hearings and discussions. This is not appropriate. NO other country in the world uses such a system for closed systems. This is a system for marketing and field tests. If you would do it for all bacteria etc, then you would kill your scientists! Such conclusions shall be mentioned in a GMO risk assessment protocol; however, experts may not take them into consideration if there is no sufficient argumentation.

#### 3<sup>rd</sup> stage

Expert conclusions shall be drawn on the results of examination of the submitted information and submitted to the Ministry for Environmental Protection of Ukraine for the authorization of GMOs’ release on experimental grounds release? I understood that this part is about closed systems?. At the same time, an applicant shall be informed about the possibility of submission of documents for registration to appropriate executive authorities for the authorization of the first GMOs’ release on experimental grounds.

#### 4<sup>th</sup> stage

It is proposed to test GMOs for their first release into the environment on experimental fields and other objects that are specially equipped to prevent any possible adverse impact of these organisms on the environment, and comply with safety requirements that shall be established by the Ministry for Environmental Protection of Ukraine. I am lost – is this story about closed systems or release or marketing? What does those steps mean? Please, make it more clear – licensing for closed systems, licencing for releases and marketing etc. The term of GMOs’ testing on experimental fields may vary from 1 to 3 years. Inspectors from the Ministry for Environmental Protection of Ukraine shall execute control over the observance of the aforementioned requirements. GMOs that can be used for economic purposes as food raw materials shall be submitted to the Ministry of Health Protection for their laboratory examination at specially accredited laboratories.

#### 5<sup>th</sup> stage

The results of testing shall be properly documented and submitted to the Ministry for Environmental Protection of Ukraine and the Ministry of Health Protection of Ukraine for their appropriate expert examination (sanitary epidemiological and ecological).

#### **6<sup>th</sup> stage**

The results of expert examination shall be submitted to the **Coordination Biosafety Council** to take a decision on the possibility of GMO's release. The decision might be one of the following:

1. GMOs' release into the environment is safe for the environment and will not cause any adverse effect on human health.
2. GMOs' release into the environment is safe for the environment and human health provided that any additional requirements stated in the conclusion are met.
3. GMOs' release into the environment is potentially dangerous for the environment and human health and will cause adverse effects to the status and development of an ecosystem.

GMOs that obtain the first or second conclusion shall be entered into GMO registers of appropriate central executive authorities and into the general register of the **National Focal Point**. GMOs that obtain the third conclusion are considered as those that fail the registration and shall not be entered into GMO registers. An access to information contained in registers shall be provided for by appropriate central executive authorities and the National Focal Point on Biosafety.

#### **7<sup>th</sup> stage**

Appropriate executive authorities shall issue an authorization for GMOs' use with economic purposes to an applicant. The authorization shall include measures of prevention of GMOs' spreading in the environment.

Within 15 days after making a decision on the internal use, including sale on the market of GMOs that may become subjects of transboundary transfer for direct use as food or feed, or for processing, the **National Focal Point** shall inform about that the Parties to the Protocol by means of the Biosafety Clearing House. Such information shall contain the data mentioned in Appendix II to the Cartagena Protocol.

Conclusions on the safety of GMOs' release into the environment may be reviewed in case of any infringement of the Ukrainian biosafety legislation by legal or physical persons, and if a subject enforcing the Law receives scientifically proven information that may lead to the reassessment of a risk of GMOs' adverse impact on human health and the environment in terms of its increase. At the same time, monitoring of prolonged GMOs' use may result in changing its status to unregulated, if it is scientifically proven that the risk of an adverse impact of this organism on human health and the environment is absolutely negligible.

#### **Regulation of public registration of GMO varieties for import into the territory of Ukraine**

It is proposed to authorize the use of imported GMO varieties with economic purposes only after they are entered into GMO registers of appropriate executive authorities and into the general register of the National Focal Point. We proposed to establish the procedure for the entry of GMO varieties into appropriate registers similar to the **Regulation of genetic engineering in closed systems** with the exception of the **1<sup>st</sup> stage** that concerns GMOs' generating in a closed system.

## **Regulation of import of GMO-derived products as food or feed, or for processing purposes**

The procedure concerning GMOs intended for direct use as food or feed, or for processing is regulated by Article 11 of the Cartagena Protocol. GMOs' import is entitled by the fact of GMOs' registration in a country of origin. A country of GMOs' origin shall submit comprehensive information on GMOs' safety to the **National Focal Point** in accordance with Appendix II of the Cartagena Protocol. **The National Focal Point / National Coordination Center** shall deliver this information to competent executive authorities. In addition, the **National Focal Point** shall have the right to make an inquiry and obtain additional information on safety of the GMOs proposed for import or determine additional biosafety measures within the limits of the national legislation. It is proposed to include information on determination of GMOs' nature into the procedure of customs clearance of products. Information about import of GMO-derived products and their presence on the Ukrainian market should be covered by mass media and made available on the web site of the **National Focal Point**. It is recommended to develop upon public request and with the assistance of the National Focal Point the regulations on selective control of GMO-derived products intended for direct use as food. An exporter of products shall bear any costs for the additional control of the products. It is proposed to amend the regulations on compulsory labeling of GMO-derived products that are sold in the Ukrainian retail network in accordance with the national legislation and EU Directives.

Since, in accordance with Article 11 of the Cartagena Protocol, "The lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity with an importing Party, taking into account any risks to human health, shall not prevent such Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects," Ukraine has to develop scientific and technical potential to control GMOs intended for direct use as food or feed, or for processing.

In cases of unlawful transboundary GMOs' transfer, Ukraine shall demand from an origin country to remove such GMOs at its expense by means of the repatriation or destruction, as the case may be. What if the importer is Ukrainian and country of origin has done everything correct?

### **III. PUBLIC INFORMATION AND PARTICIPATION IN BIOSAFETY ASSESSMENT AND AUTHORIZATION OF GENERATING, TESTING, TRANSPORTATION AND USE OF GENETICALLY MODIFIED ORGANISMS**

At present, the procedure of public information on issues related to generating, testing, transportation and use of genetically modified organisms is regulated by the following normative acts: the Constitution of Ukraine, the Law of Ukraine “On Information” dated October 2, 1992, the Law of Ukraine “On Public Appeals” dated October 2, 1996, the Law of Ukraine “On Environmental Protection” dated June 25, 1991, the Law of Ukraine “On Ecological Expert Examination” dated February 9, 1995, the Law of Ukraine “On Consumer Rights Protection” dated December 1, 2005, the Resolution of the Verkhovna Rada of Ukraine “On Public Information on Environmental Issues” dated November 4, 2004, international treaties, with Ukraine being a party. The key international regulations regarding the above issues are the following: the Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters; the Alma-Ata Amendment to the Convention, which regulates public participation in decision making on GMOs’ deliberate release into the environment and placement on the market; Guidelines on Access to Information, Public Participation and Access to Justice in GMO Matters; as well as respective provisions of the CBD and the Cartagena Protocol.

#### **Public risk assessment and GMO discussions**

To meet Ukraine’s internal and international commitments, in particular, Articles 3-9 of the Aarhus Convention, Articles 13 and 17 of the Convention on Biodiversity, Article 23 of the Cartagena Protocol to the Convention on Biodiversity, it is recommended to:

- Inform the public about activities related to generating, testing, transportation and use of genetically modified organisms by making this information available on the official web site of the **National Focal Point** and in its annual and quarterly progress reports;
- Prepare and publish a register of applications for the import into Ukraine, release into the environment and use with economic purposes of genetically modified organisms and products derived from them, and a register of denied applications with explanations of reasons for denying the import or use;
- Make GMO open dossiers under authorization procedures available on the web site of the **National Focal Point** and send appropriate information letters about discussion subjects to industrial groups, non-governmental organizations, and other interested parties;
- Provide information in reply to inquiries and appeals from citizens regarding issued authorizations for generating, testing, transportation and use of GMOs in accordance with the Aarhus Convention and the Law of Ukraine “On Public Appeals”;
- Obtain and submit for further expert examination conclusions of public hearings. Such conclusions shall be mentioned in a GMO risk assessment protocol.

It is recommended to define the following limitations in providing information and conducting public GMO hearings:

- Information defined as confidential by the **National Focal Point** in accordance with Article 23 of the Cartagena Protocol and the Laws of Ukraine “On Information” and “On Consumer Rights Protection” shall not be made available to public.
- The period for submission of public responses to the **National Focal Point** shall be limited to 30 days after publication of a GMO open dossier on the web site of the **National Focal Point**.

- The **National Focal Point** together with central executive authorities shall work to increase public awareness and education regarding the safety of GMOs' use for the conservation and sustainable use of biological diversity, taking into account risks for human health. Information about new GMOs to be used within Ukraine shall be made available for mass media.

### **Public participation in GMO decision making**

Public participation in GMO decision making shall include the following integral elements:

- All decision-making procedures regarding GMOs' release into the environment, placement on the market or use in closed systems (not appropriate for closed systems, even Aarhus does not require it), as well as GMOs' import authorizations, shall ensure efficient information provision and public participation, including optimal terms, in order to provide public with adequate possibilities to express its opinions regarding proposed decisions.

- At the earliest possible stage of decision-making procedures, a competent central executive authority shall provide public with a summary of an obtained application for the authorization of GMOs' release into the environment, placement on the market or use in closed systems. The authority shall also provide its opinion on risk assessment, except for confidential information. It should be noted that any information on general description of respective GMOs, name and address of an applicant, expected use and, if required, place of release, methods and plans on respective GMOs' monitoring, emergency elimination measures, and environmental risk assessment shall not be considered confidential.

- Decision-making procedures shall be transparent, that is competent executive authorities shall make respective procedural information accessible to public. Such information, in particular, covers the following: the nature of possible decisions; indication of a public authority responsible for decision making; description of methods of public participation in the above decision making; indication of a public authority, where one can get respective information; indication of a public authority, to which one should address its notes and comments and their submission deadlines.

- Public may deliver any notes, information, comments, analysis outcomes or opinions, which it considers to be necessary.

- Public participation outcomes shall be considered by a respective competent executive authority while taking its final decision.

- The text of a decision taken, together with reasons and grounds, shall be made public. Before also public dossiers were mentioned – what about those?

### **Confidentiality of information**

Information on GMOs' handling is open and accessible to everyone, except for the information referred to in the Ukrainian legislation as confidential and secret. While submitting GMO information, an applicant may also submit a grounded proposal to make some information confidential, including cases pursuant to the legislation on intellectual property. The **National Focal Point** shall decide which information should be treated as confidential and inform the applicant and specially authorized executive bodies about its decision. If the **National Focal Point** decides that information considered by the applicant as confidential cannot be treated as such, then the applicant shall be informed about this decision prior to making information available, and reasons for the decision shall be explained on demand, to make possible further consultations and internal review of the decision prior to its announcement. [Comment: Perhaps say something about application withdrawal/cancellation if applicant does not wish information to be released ?]

The **National Focal Point** shall not treat any information as confidential regarding the following:

- Biological particularities of GMOs;
- Methods of GMOs' monitoring and emergency action plans;
- Potential GMOs' impact on human health and the environment.

### **Labeling of products that contain GMOs**

Ensuring of the right to food safety lies in a person's possibility to make decisions freely and at its own discretion on the possibility of consumption of certain products. Thus, provided that a person is informed about low quality or danger (including possible), or about the absence of information on safety or danger, the person has the right to make its independent decision about consumption of such food products. The issue of the execution of the right to food safety is fundamentally related to the issue of information. A person shall have a free access to information on the nature of used feed supplements, as some of them can cause allergy or addiction.

In accordance with EU Directives, producers shall place information about GMOs' contents on a label, if they constitute at least 0.9% of in a product. In Ukraine, the issue of a percentage limit of genetically modified ingredients has not been regulated yet at all.

On 1 August 2007, the Cabinet of Ministers of Ukraine adopted the Resolution № 985 "On circulation of food containing GMOs and/or microorganisms" stating that "the import and sale of food containing GMOs and/or microorganisms of over 0.9% shall be performed with respective labeling available and specification of a qualitative composition of such products. It is prohibited to import, produce and sell any baby food containing GMOs and/or microorganisms". In 20 days, on 21 November 2007, the Cabinet of Ministers of Ukraine adopted another Resolution - № 1330 "On labeling agricultural goods produced using GMOs", which repeals the above regulation. The latter Resolution was appealed in a court, and on 11 February 2008, the District Administrative Court in Kyiv declared the respective paragraph of the Resolution to be unlawful and resolved on its revocation. Thus, the Resolution of the Cabinet of Ministers of Ukraine № 985 on obligatory labeling of food containing GMOs shall be valid and shall be applied, although it is not implemented in practice.

It is recommended to take into consideration and apply the regulations of the Directive №2001/18 of the European Union and the Regulations on genetically modified organisms' handling of the European Parliament №1829/2003, and №1830/2003 that regulate the issue of labeling of genetically modified organisms and products that are derived from them, in particular:

- The responsibility for delivering comprehensive and accurate information on GMOs' contents in food and light industry products and animal feed shall be undertaken by producers and sellers of such products;
- Notifications about GMOs shall be placed on a product packaging; if there is no packaging, such notification shall be included into accompanying documents of a product and/or be placed on product price tickets in retail trade;
- The notification shall include information about GMOs' contents in food or light industry products, GMOs' name and its percentage in a product, warning about contraindications of consumption and use, possible risk for health, allergenic capacity of a product or its ingredients.

Requirements to labeling of GMOs and GMO-derived products could include the following provisions:

At all stages of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators have to ensure that the following information is transmitted in writing to the operator receiving the product:

- (a) That a product contains or consists of GMOs;
- (b) The unique identifier(s) assigned to those GMOs.

For products consisting of or containing GMOs, operators have to ensure that:

(a) For pre-packaged products consisting of, or containing GMOs, the wording “This product contains genetically modified organisms” or “This product contains genetically modified [name of an organism(s)]” shall appear on a label;

(b) For non-pre-packaged products offered to a final consumer, the wording “This product contains genetically modified organisms” or “This product contains genetically modified [name of an organism(s)]” shall appear on, or in connection with, a display case with the product.

[comment: isn't the language used “ may contain”?]

As for GMO-derived food and feed, the labeling could include the following information in writing:

- (a) The indication of each food ingredient produced from GMOs;
- (b) The indication of each feed material or additive produced from GMOs;
- (c) If there is no ingredient list - the indication that the product is produced from GMOs.

The Law “On Consumer Rights Protection,” Article 15, p. 1, states that a consumer has the right to obtain reliable, available, accurate and timely information about products (works or services). Information about product shall include the indication of the presence of genetically modified ingredients. Part 2 of this article states that the information mentioned in Part 1 of the article shall be made available to consumers by a producer (executor, seller) in accompanying documents that are supplied with a product, on a product label, on its labeling, or in any other way. Therefore, producer’s defiance of these requirements is the rude infringement of the legislation, which is punishable by fines.

In order to inform public about the presence of genetically modified organisms in products of animal and vegetable origin, in accordance with Article 116 of the Constitution of Ukraine, Articles 16, 17 of the Law of Ukraine “On Environmental Protection,” and in the execution of Article 50 of the Constitution of Ukraine, Article 18 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 15 of the Law of Ukraine “On Consumer Rights Protection,” it is necessary to develop and introduce appropriate labeling of products that contain GMOs. It is proposed to introduce the labeling of GMOs’ presence in food, if GMOs’ content exceeds 0%. (A similar approach was introduced in the Republic of Belarus).

**List of EU legal acts regulating GMOs and biosafety**

**1. EU directives and relevant decisions:**

2001/18/EC Directive of the European Parliament and Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

2002/623/EC: Commission Decision of 24 July 2002 establishing guidance notes supplementing Annex II (*Principles for the environmental risk assessment*) to Directive 2001/18/EC of the European Parliament and Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

2002/811/EC: Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII (*Monitoring plan*) to Directive 2001/18/EC of the European Parliament and Council on the deliberate release into the environment of genetically modified organisms and repealing the Council Directive 90/220/EEC.

2002/812/EC: Council Decision of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and Council the summary information format relating to the placing on the market of genetically modified organisms as or in products.

2002/813/EC: Council Decision of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market.

2003/701/EC: Commission Decision of 29 September 2003 establishing pursuant to Directive 2001/18/EC of the European Parliament and Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market.

2004/204/EC: Commission Decision of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in the Directive 2001/18/EC of the European Parliament and Council.

Commission Decision 94/730/EC of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC.

Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms

Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

96/134/EC: Commission Decision of 16 January 1996 amending Decision 91/448/EEC concerning guidelines for classification referred to in Article 4 of Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

2000/608/EC: Commission Decision of 27 September 2000 concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

2001/204/EC: Council Decision of 8 March 2001 supplementing Directive 90/219/EEC as regards the criteria for establishing the safety, for human health and the environment, of types of genetically modified micro-organisms (Text with EEA relevance).

## **2. EU Regulations:**

Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

2002/628/EC: Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety.

Regulation (EC) 1829/2003 of the European Parliament and Council of 22 September 2003 on genetically modified food and feed.

Commission Regulation 641/2004 of 6 April 2004 that establishes detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Commission regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

### **2.1. Recommendations:**

Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (notified under document number C(2003) 2624).

### **White Paper:**

White Paper on Food Safety, Commission of the European Communities, Brussels, 12 January 2000, COM (1999) 719 final.

**THE LAW OF UKRAINE**

On the national biosafety system in creation, testing, transportation and use of genetically modified organisms

This Law regulates relations between bodies of executive power, producers, sellers (suppliers), developers, researchers, scientists and consumers of genetically modified organisms and production manufactured according to technologies that involve their development, creation, testing, research, transportation, import, export, market placement, release into the environment and use in Ukraine (hereinafter referred to as GMO handling) to ensure biological and genetic safety.

This Law does not apply to human beings, tissues and separate cells that are parts of a human body.

**Chapter I  
GENERAL PROVISIONS**

**Article 1. Terms and definitions**

The following terms shall have the following meanings in this Law:

Biological safety – conditions of human vital activity environment under which the negative impact of its factors (biological, chemical, physical) on biologic structure and function of human beings in present and future generations is absent, and the irreversible negative impact on environmental biologic objects (biosphere) and agricultural plants and animals is also absent;

Genetic safety – conditions of human vital activity environment under which any unnatural impact on human genome is absent, any unnatural impact on genomes of biosphere objects is absent, and uncontrolled impact on genomes of agricultural plants and animals, industrial microorganisms, that causes appearance of negative or unwanted characteristics, is also absent;

Organism, living organism – any form of biological existence (including sterile organisms, viruses and viroids) that is able to reproduce itself or transmit hereditary factors;

Genetically modified organism, living modified organism (GMO) – any organism whose genetic material was modified by artificial methods of gene transfer that do not happen under natural conditions, namely:

Recombinant methods that involve forming of new combinations of genetic material by inclusion of nucleic molecule (produced in any way outside the organism) into any virus, bacterial plasmid, or any other vector system and their inclusion into host organism in which they are not normally found but are able for prolonged reproduction;

Methods that involve direct introduction of hereditary material prepared outside the organism into the organism including microinjections, macroinjections, and microencapsulations;

Cell fusion (including protoplasm fusion) or hybridization methods, when living cells with new genetic material combinations are formed by fusion of two or more cells in a way that is not realized under natural conditions;

GMO-derived products – products, including food products and fodder, that are produced using GMO at any stage;

Genetic engineering activity – a practical field of activity related to GMO creation, testing and putting into circulation;

GMO release into the environment – an action (act or omission) that results in GMO introduction into the environment;

Closed system – the system of genetic engineering activity in which genetic modifications are made to an organism or GMO, cultivated, processed, stored, used, transported, destroyed or buried in circumstances where protection systems exist that prevent their contact with population and environment;

Open system – the system of genetic engineering activity that involves GMO contact with population at their planned release into the environment, use in agricultural practice, industry, medicine, nature conservation purposes, technology transfer and other areas of GMO circulation;

Risk – possibility of occurrence and possible scale of results of negative impact on human health and environment during genetic engineering activity and GMO handling in the course of certain time period;

Risk analysis – the process that consists of three interconnected components: GMO risk assessment, risk management, and risk notification;

Risk assessment – scientifically grounded process that consists of GMO danger identification, danger description, impact assessment, and risk description;

Risk management – the process of choosing among alternative decisions based on GMO risk assessment results and, if necessary, selection and introduction of appropriate management (control) methods including regulatory actions;

Risk notification – mutual exchange of information about GMO risks between risk assessment specialists, persons that perform risk management, interested trade partners and other interested parties;

GMO state registration – GMO registration subject to risk assessment of their impact on human health and environmental conditions in order to receive authorization for GMO practical use in Ukraine according to their economic purposes;

GMO state register – specialized list of registered GMO that includes their economic purposes;

GMO food and fodder sources state register – specialized list of GMO that are considered suitable to use as food and/or fodder, and/or their sources, based on international regulations and criteria of assessment of their safety to human and animal health;

Circulation – relocation (transportation) or storage and any actions that involve transfer of ownership or possession, including sale, exchange, or donation.

**Article 2.** Ukrainian legislation in the field of genetic engineering activity and GMO handling

Ukrainian legislation in the sphere of genetic engineering activity and GMO handling consists of this Law, other Ukrainian legislative acts that are issued in accordance to it, and appropriate international treaties that are agreed to be binding by the Verkhovna Rada of Ukraine.

**Article 3.** Basic principles of the state policy in the field of GMO handling and tasks of this Law

Basis principles of the state policy in the field of genetic engineering activity and GMO handling are as follows:

priority of human health protection and environment conservation as opposed to economic advantages of GMO use;  
guarantee of biological and genetic safety of GMO creation, research and practical use with economic purposes;  
control over GMO and GMO-derived products importing into Ukraine customs territory, registration, and circulation;  
general availability of information about potential risks of GMO use in an open system and measures to ensure biological and genetic safety;  
state support of genetic engineering researches and scientific and practical developments in the field of biological and genetic safety of GMO creation, research and practical use with economic purposes;

Tasks of this Law are as follows:

human health and environmental protection in genetic engineering activity and GMO handling;  
ensuring the civil rights to safe GMO use;  
creating conditions for safe practical GMO use for economic purposes;  
definition of rights and duties of subjects of regulation in GMO handling and ascertainment of their responsibility for law infringement;  
protection of citizens in case of damage to their health resulted from GMO consumption;  
establishment of legal framework of international cooperation in the field of genetic engineering activity and GMO handling.

**Article 4.** Subjects of regulation

Regulations of this Law are applied in the territory of Ukraine to legal and natural persons that conduct business related to GMO handling. Legal and natural persons of Ukraine and other states and stateless persons are equal in their rights and duties defined by this Law.

If a international treaty of Ukraine indicated in article 2 of this Law provides other regulations than those established in this Law, then regulations of the international treaty shall apply.

**Article 5.** Fields of activity that are subject to regulation during GMO handling

The following field of activity are subject to regulation by this Law:  
genetic engineering activity conducted in a closed system;

genetic engineering activity conducted in an open system;  
state registration of GMO and GMO-derived products;  
putting into circulation of GMO and GMO-derived products;  
GMO export, import, and transit.

## **Chapter II** **LAW ENFORCEMENT**

**Article 6.** Subjects that enforce this Law

This Law is enforced by central bodies of executive power within their powers and according to the procedure established by Ukrainian legislation.

**Article 7.** Authorities of the Cabinet of Ministers of Ukraine

The Cabinet of Ministers of Ukraine shall:

provide state regulation and control in the field of GMO handling and genetic engineering activity;  
provide implementation of measures related to state support of genetic engineering activity;  
direct and coordinate activities of central bodies of executive power and other bodies of executive power in the field of GMO handling and genetic engineering activity;  
organize international cooperation in order to provide safe GMO handling and development of scientific knowledge in this field;  
approve the procedure of state registration of GMO and GMO-derived products;  
approve the procedure of import of GMO food and fodder sources and GMO-derived food and fodder;  
approve the procedure of authorization of GMO transit through the territory of Ukraine;  
approve the procedure of licensing of genetic engineering activities in closed and open systems;  
approve the procedure of state approbation (testing) of GMO in an open system and authorization of such testing;  
approve the criteria of safe GMO handling in a closed system;

**Article 8.** Authorities of the central body of executive power responsible for science and education

The central body of executive power responsible for science and education shall:  
provide for development of scientific and technical potential in the field of genetic engineering activity;  
provide for protection of international and national patents and other types of intellectual property in the field of GMO handling, genetic engineering and genetic engineering activity;  
create criteria of safe GMO handling and genetic engineering activity in closed systems;  
create and improves the system of control of observance of genetic engineering activity safety regulations;  
conduct licensing of genetic engineering activity in closed systems;  
taking into consideration the results of state ecological and sanitary-and-epidemiological expert examination of GMO biological and genetic safety conducted in accordance to international treaties of Ukraine, gives authorization for import of unregistered GMO if they are to be used exclusively for research purposes in closed and open systems, and for their state testing.

**Article 9.** Authorities of the central body of executive power responsible for environmental issues and natural resources

The central body of executive power responsible for environmental issues and natural resources shall:

conduct state ecological expert examination of GMO intended for use in an open system;  
create the criteria of risk assessment of potential GMO impact on environment based on scientific principles and international experience;  
conduct state registration of GMO-derived plant protection products;  
conduct state supervision and control over observance of biological and genetic safety measures concerning environmental biological objects in GMO creation, research and practical use in an open system;  
issue authorizations for GMO release in an open system.

**Article 10.** Authorities of the central body of executive power responsible for health protection

The central body of executive power responsible for health protection shall:

create the criteria of risk assessment of potential impact on human health of GMO and GMO-derived products including food based on scientific principles and international experience;  
conduct state sanitary-and-epidemiological expert examination of GMO that are used in open systems to prove the conclusions on their biological and genetic safety to human health in order to perform their state registration;  
conduct state supervision and control over observance of biological and genetic safety measures concerning human health in GMO creation, research and practical use in an open system;  
conducts state sanitary-and-epidemiological expert examination of GMO-derived products to prove the conclusions on their safety for human health and life;  
conduct state registration of GMO food sources and state registration of food, cosmetics, medicines that contain GMO or are derived from GMO;  
approve the list of food products that are monitored for GMO contents and the list of appropriate methods of GMO detection and identification;  
monitor GMO-derived food products for the presence of registered GMO sources only.

**Article 11.** Authorities of the central body of executive power responsible for the agricultural policy

The central body of executive power responsible for the agricultural policy shall:  
provide for state approbation (testing) and state registration of GMO-derived agricultural plants varieties, animal breeds, microbiological agricultural and veterinary preparations;  
conduct state supervision and control over observance of biological and genetic safety measures concerning agricultural plants and animals in GMO creation, research and practical use in open systems in agro-industry enterprises, institutions and organizations regardless of their subordination and form of ownership;  
conduct state registration of GMO fodder sources and state registration of feed supplements and veterinary preparations that contain GMO or are derived from GMO;  
approve the list of fodders that are monitored for GMO contents and the list of appropriate methods of GMO detection and identification;  
monitor GMO-derived fodders for the presence of registered GMO sources only.

**Chapter III**  
**REGULATION OF GMO HANDLING AND GENETIC ENGINEERING ACTIVITY**  
**IN A CLOSED SYSTEM**

**Article 12.** Regulation of genetic engineering activity in institutions, organizations, and enterprises

Genetic engineering activity in a closed system is subject to licensing.

Licenses for such activity are issued based on risk assessment of GMO handling in a closed system.

The procedure of such licensing is established by the Cabinet of Ministers of Ukraine upon submission of the central body of executive power responsible for science and education.

Enterprises, institutions and organizations that conduct genetic engineering activity (hereinafter referred to as institutions) form the Commission for biological and genetic safety of performance of genetic engineering work (hereinafter referred to as Commission) as a part of the institution. The task of the Commission is to perform preliminary risk assessment for planning and preparation of genetic engineering work.

The central body of executive power responsible for science and education approves the standard Regulation on the Commission for biological and genetic safety of performance of genetic engineering work.

In cases when genetic engineering activity is performed by natural persons or the number of personnel in the institution prevents from forming the Commission as a part of the institution, such persons or institutions are attached to an existing Commission on approval by the central body of executive power responsible for science and education.

**Chapter IV**  
**REGULATION OF GENETIC ENGINEERING ACTIVITY IN AN OPEN SYSTEM**  
**AND GMO STATE REGISTRATION**

**Article 13.** Requirements to GMO and the procedure of their release into the environment for approbation (testing)

Genetically modified organisms that are used in an open system have to comply with requirements of biological and genetic safety provided the intended technology of their use is observed.

The necessary requirement of GMO use in an open system is the availability of methods and techniques of their identification created in accordance with international standards and approved in accordance to the established procedure in Ukraine.

It is prohibited to release GMO into the environment prior to their state registration.

GMO release into the environment prior to state registration is possible only with the purpose of state approbation (testing). GMO state approbation (testing) in an open system is performed only by authorization issued by the central body of executive power responsible for environmental issues and natural resources. The authorization is valid for one occasion only of specific GMO state approbation (testing).

The procedure of issuing of such authorization and its form are approved by the Cabinet of Ministers of Ukraine upon submission of the central body of executive power responsible for environmental issues and natural resources. The authorization states specific conditions and terms of GMO state approbation (testing).

The authorization for GMO state approbation (testing) in an open system may be revoked in case when there is scientifically proven information that can cause reassessment of risk of the GMO impact on human health and environment towards its increase, or when there is an infringement of the authorization conditions.

**Article 14.** GMO state registration and limitations of use

GMO and GMO-derived products state registration is performed by the central bodies of executive power according to their authorities stated in articles 8-11 of this Law.

The central bodies of executive power keep State registers of GMO and GMO-derived products, make them available on their official web sites and regularly publish in the mass media.

The following products shall be registered in GMO State Registers:

agricultural plant varieties and animal breeds based on GMO;

GMO-derived plant protection products;

GMO food sources and food, cosmetics, medicines that contain GMO or are derived from GMO;

GMO fodder sources and feed supplements and veterinary preparations that contain GMO or are derived from GMO;

State registration is free of charge and is valid for five years. Re-registration is performed in accordance to the same procedure as registration.

Time for consideration of registration documents cannot exceed 120 days since the day of submission including time for appropriate expert examination.

Tariffs for expert examinations that form the grounds for GMO and GMO-derived products state registration are approved by the Cabinet of Ministers of Ukraine upon submission of the appropriate central body of executive power.

GMO and GMO-derived products state registration may be denied if scientifically proven information on danger of their proper use for human health or environment is obtained.

Limitations may be imposed on cultivation of genetically modified agricultural plant varieties on lands that are defined by the central body of executive power responsible for environmental issues and natural resources.

**Chapter V**  
**GMO USE, TRANSPORTATION, STORAGE AND DISPOSAL**

**Article 15.** GMO use

Industrial manufacturing and putting into circulation of GMO and GMO-derived products prior to their state registration is prohibited.

**Article 16.** GMO import and transit

GMO and GMO-derived products import into the customs territory of Ukraine prior to their state registration is prohibited, except for those that are intended for scientific research or state approbation (testing).

The authorization for import of GMO intended for scientific research or state approbation (testing) is issued by the central body of executive power responsible for science and education in accordance with the procedure established by the Cabinet of Ministers of Ukraine.

The authorization for import of GMO-derived products intended for scientific research is issued by the central bodies of executive power according to their authorities stated in articles 8-11 of this Law in accordance to the procedure established by the Cabinet of Ministers of Ukraine.

Import of food, cosmetics, medicines, feed supplements and veterinary preparations that contain GMO or are derived from GMO, for their proper use is possible only subject to state registration of appropriate GMO sources and products listed in this paragraph.

The procedure of such import is established by the Cabinet of Ministers of Ukraine.

The authorization for transit of GMO that are not registered in Ukraine is issued by the central body of executive power responsible for environmental issues and natural resources in accordance with the procedure established by the Cabinet of Ministers of Ukraine.

**Article 17.** GMO transportation, storage and disposal

GMO transportation and storage has to involve a package of measures that prevent uncontrolled GMO release into the environment.

Accountable GMO material obtained during testing, unusable or forbidden to use GMO and their packages have to be disposed of, destroyed and neutralized in accordance to the procedure established by the central body of executive power responsible for science and education and by the central body of executive power responsible for environmental issues and natural resources.

Regulations of this article do not apply to GMO food and fodder registered in accordance with the requirements of article 14 of this Law.

**Chapter VI**  
**FINAL PROVISIONS**

**Article 18.** Responsibility for infringement of the legislation in the field of GMO handling

Breach of requirements of this Law and regulatory legal acts adopted on its basis entails civil, administrative, disciplinary or criminal responsibility in accordance with the legislation.

Responsibility is incurred by persons guilty of the following:

concealment or misrepresentation of information that may have caused or has caused danger to human health and life or environment;  
inobservance or violation of requirements of standards, rules, public health regulations of GMO use, transportation, storage, and realization;  
use of unregistered GMO or GMO derived products (except for scientific research purposes);  
violation of GMO disposal and destruction rules;  
inobservance of legal requirements of state officials that perform state supervision and control.

The responsibility for other types of violation of Ukrainian legislation in the field of genetic engineering activity may also be established by the law.

**Article 19.** Main requirements for the authorization system on GMO handling in the field of economic activity

Authorization for import of unregistered GMO for scientific research purposes in closed and open systems, and for their state approbation (testing); for import of GMO-derived products intended for scientific research purposes; for transit of GMO that are unregistered in Ukraine; for GMO release in an open system are issued free of charge by the central bodies of executive power according to their authorities stated in articles 8-11 of this Law in accordance with the procedure established by the Cabinet of Ministers of Ukraine.

Authorization may be denied if scientifically proven information on danger of their proper use for human health or environment is obtained.

Time for consideration of authorization documents cannot exceed 45 days since the day of submission including time for appropriate expert examination.

Tariffs for expert examinations that form the grounds for issuing of the said documents are approved by the Cabinet of Ministers of Ukraine upon submission of the appropriate central body of executive power.

**Article 20.** Access to information on GMO handling

Information on GMO handling is open and accessible to everyone except for the information referred in Ukrainian legislation as confidential and secret.

Information on potential GMO impact on human health and environment should not be considered confidential and secret.

**Article 21.** International cooperation

Ukraine concludes international treaties, participates in international information exchange in order to develop and strengthen international cooperation in the field of biological and genetic

safety of genetic engineering activity and GMO handling in accordance with the current legislation.

**Article 22.** Closing regulations

This Law comes into force on the day of its promulgation.

The Cabinet of Ministers of Ukraine shall:

prepare and submit for consideration of the Verkhovna Rada of Ukraine its proposals concerning changes to the laws of Ukraine in connection with adoption of this Law;  
bring its regulatory and legal acts in line with this Law;  
provide for revision and cancellation by ministries and other central bodies of executive power of their regulatory and legal acts that contradict this Law.

The President of Ukraine

V. YUSHCHENKO

City of Kyiv, May 31st 2007  
N 1103-V