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## **Ukraine**

# **AGRICULTURAL BIOTECHNOLOGY ANNUAL**

## **Biotechnology**

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**Report Highlights:**

One year after WTO accession, Ukraine has made baby steps towards a biotech approval process, but the Government of Ukraine still needs to adopt a workable system. Biotech labeling requirements are proposed at levels more stringent than in EU legislation.

**Section I. Executive Summary:**

Some progress has been achieved in biotech legislation development in 2008-2009. However, the regulatory framework for biotech trade and production has not yet been finalized, which still makes it impossible to produce or sell products of biotechnology legally in Ukraine. Several regulations were adopted by the Government of Ukraine (GOU) to implement the “umbrella” bio-safety legislation – the Law of Ukraine “On State System of Bio-safety in Creating, Testing, Transporting and Using Genetically Modified Organisms”, which was passed on May 31, 2007. However, even with this new legislation adopted, a biotech system is not operational, sometimes lacking implementing rulings and actions at the Ministry level.

The GOU adopted a decision to introduce mandatory labeling of foods that contain genetically engineered substances

from July 1, 2009 with a GMO threshold set at 0.1%. However, the introduction of GMO labeling is likely to be postponed to January 1, 2010, as both private businesses and state authorities (including ones responsible for state laboratories) are reportedly not ready for its prompt implementation. The idea of widespread mandatory GMO labeling puts at question Ukraine's WTO obligations and is counterproductive to Ukraine's stated goal of encouraging the use of biotechnology in agriculture.

## Section II. Biotechnology Trade and Production:

### Production

Ukraine has not approved a single biotech plant variety for commercial production despite having received five applications during 1997-1999. Therefore, authorities claim that Ukraine's agriculture remains GMO-free. A weak regulatory system and lack of field surveillance programs, however, leave doubt to Ukraine's GMO free status. In fact, it is estimated that half of Ukraine's soybean production are Round-up Ready Soybeans. Other plantings of biotech crops are also suspected (i.e.: corn, sugar beets).

Ukrainian researchers in cooperation with a Russian scientist reportedly developed a virus-resistant potato in 1990. This was the first transgenic plant in the Former Soviet Union (FSU). Since then, research in this area has continued in the Institute of Cell Biology and Genetic Engineering (ICBGE) of the National Academy of Sciences of Ukraine, and Institutes of the Ukrainian Academy of Agricultural Sciences. According to available information, Ukrainian researchers developed transgenic sugar beets, potatoes, tobacco, rapeseeds, cabbage, alfalfa, soybeans, peas, flax, barley, buckwheat, and African millet. Most of these plants were developed for scientific purposes using non-patented technologies and utilized germplasm of the local varieties to gain insect resistance or herbicide tolerance.

Reportedly, scientists from the ICBGE developed transgenic soybeans, flax and African millet with *dinitranilin* resistant features (*Treflan* and other herbicides produced by DowAgro Sciences Co.). However, the technology has not yet been patented. All plants remain in the laboratory environment and have gone through the seed propagation stage. Ukrainian scientists also developed technology for plant recombinant proteins used in pharmacology --  $\alpha$ -interferon and somatropine (human growth hormone). However, this technology has not yet been commercialized.

In 1998, the GOU authorized field trials for biotech crops along with an environmental and food safety assessment. Insect resistant (Bt) potatoes and herbicide tolerant sugar beets, corn and rapeseed underwent full-scale field trials in 1998-2000. None have received final approval, however, due to the unwillingness of decision-making authority to take full responsibility for the approval of these products, especially since Ukraine has no established system for approving biotech varieties.

#### Field Trials of Genetically Modified Crops in Ukraine

Trait	Crop	Number of varieties	Applicant	Year of application	Status
BT (insect resistance)	Potatoes	3	Monsanto	1997	Pending
Glyphosinate tolerance (Liberty Link)	Sugar beets	1	Syngenta /Monsanto	1998	Pending
BT (insect resistance)	Corn	1	Syngenta	1998	Pending
Glyphosinate tolerance (Liberty Link)	Rapeseed	1	Bayer	1998	N/A
Glyphosate tolerance (Roundup)	Corn	1	Monsanto	1998	Pending

### Trade

Based on the biosafety legislation of Ukraine, it is prohibited to import any GMO and products produced using GM before they are registered by Ukrainian authorities in accordance with procedure adopted by the Government of

Ukraine. On February 18, 2009, the GOU adopted the procedure for state registration of genetically modified organisms of food source, food products and medicinal agents containing those organisms or derived therefrom, which came into force on June 1, 2009. According to the procedure, state registration of the products is carried out by the Ministry of Health. State registration should be carried out free of charge for a five-year period through the entry of the products in the State Register of Genetically Modified Organisms of Food Source, Food Products, Cosmetic and Medicinal Agents Containing Genetically Modified Organisms or Derived Therefrom. Data kept in the register must be available on the official website of the Ministry of Health, systematically published in mass media and provided free of charge upon requests from legal entities and individuals. However, the procedure still does not work, as the Ministry of Health's bylaws implementing the procedure have not been adopted nor are drafts available for public discussion. Therefore, it is still prohibited to import GMOs or products produced with GMOs to Ukraine.

Only GMOs for state trials may be imported to Ukraine without aforementioned registration, but the importation of GMOs for scientific purposes and state trials must be conducted with approval from the Ministry of Science and Education in accordance with the procedure adopted by the GOU. The procedure for the importation of GMOs for scientific purposes and state trials was adopted by the GOU on August 20, 2008 and came into force on January 1, 2009. The approval is granted to both legal entities and individuals for every GMO based on the results of state scientific and technical expertise taking into consideration the decision of Interagency Commission on Biosafety established by the Ministry of Science and Education. The approval is provided for the period of scientific research or state trials, but not more than for 5 years.

The procedure for the approval to conduct GMO state trials (approbations) was adopted by the GOU on April 2, 2009 and came into force on June 1, 2009. However, the procedures have not yet been put into practice.

In April 2009, the GOU adopted the procedure approving GMO transit. The approval for GMO transit is provided by the Ministry of Environment. The procedure came into effect on June 1, 2009. To get an approval for GMO transit, a legal entity or individual that conducts GMO transit has to fill in an application. If the Ministry considers that GMO transit is in line with set requirements (safe for environment and human health), the approval is granted in 45 days.

Therefore, the GOU continues developing prerequisites for trade in GM products, which is a positive step. As the system for GMO trade is not finally completed, based on official data there have not been any imports of GMOs or products produced with GMO technologies in recent years. However, considering the lack of a functioning system for biotech products, some products that enter Ukrainian market might contain GM.

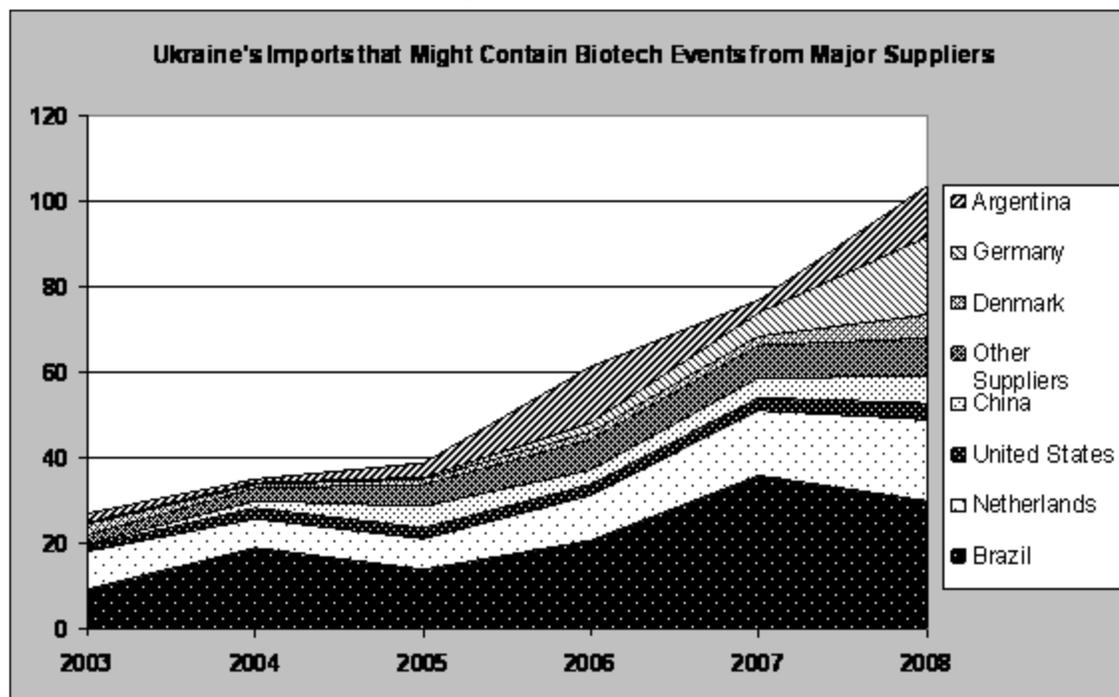
Below is a summary of Ukraine's import data for major products that might contain biotech corn or soybean GM events: Corn Flour (HS 110220); Corn Meal or Groat (HS 110313); Processed Corn (HS 110423); Soybeans (HS 120100); Soy Sauce (HS 210310); Protein Concentrates (HS 210610); Corn Gluten (HS 230310); Soybean Meal (HS 230400); Protein Isolates (HS 350400). Please note that prepared food products and feeds were not targeted in this research. Ukraine imported products that could contain GMOs valued at \$104 million in 2008, up from \$77 million in 2007.

#### Imports of Products that Could Be Affected by Ukraine's Biotech Regulations

Product	2006		2007		2008	
	Value \$ million	Share %	Value \$ million	Share %	Value \$ million	Share %
Corn Flour (HS 110220)	0.107	0%	0.072	0%	0.000	0%
Corn Meal or Groat (HS 110313)	0.008	0%	0.068	0%	0.115	0%
Processed Corn (HS 110423)	0	0%	0	0%	0.000	0%
Soybeans (HS 120100)	0.727	1%	0.489	1%	0.926	1%
Soy Sauce (HS 210310)	0.433	1%	0.714	1%	1.586	2%
Protein Concentrates (HS 210610)	6.188	10%	7.138	9%	10.119	10%
Corn Gluten (HS 230310)	0.069	0%	0.051	0%	0.042	0%
Soybean Meal (HS 230400)	47.299	77%	59.465	77%	76.681	74%
Protein Isolates (HS 350400)	6.571	11%	8.778	11%	14.143	14%
<b>Total Value, \$ million</b>	<b>61.402</b>	<b>100%</b>	<b>76.775</b>	<b>100%</b>	<b>103.61</b>	<b>100%</b>

Source: State Customs Committee of Ukraine

In 2008, the United States was the seventh largest supplier of these products after Brazil, China, the Netherlands and some other countries (please refer to the graph below).



Source: Prepared by FAS-Kyiv based on Ukraine's official trade data for the following HS Codes: 110220, 110313, 110423; 120100; 210310; 210610; 230310; 230400; 350400.

The following table illustrates U.S. exports of food and agricultural commodities that are affected, or might be affected, if Ukraine fails to complete implementation of an approval and regulatory system for products of biotechnology.

**Imports of U.S. Products that Could be Affected by the Lack of Biotech Regulations in Ukraine (CIF, \$ million)**

HS	Description	2004	2005	2006	2007	2008
210610	Protein Concentrates	0.05	0.48	0.40	0.32	1.33
230400	Soybean Meal	1.18	0.17	0.11	0.84	1.10
350400	Peptones, Other Proteins	1.04	1.75	1.39	1.47	0.64
210310	Soy Sauce	0.01	0.02	0.11	0.14	0.54
120100	Soybeans	0.04	0.03	0.37	0.07	0.18
	Total Value	2.34	2.46	2.39	2.84	3.79

Source: State Customs Committee of Ukraine

The future impact of Ukraine's biotech policy on agricultural trade, however, is not only guided by the information provided in the table above.

**Section IV. Biotechnology Policy:  
GM Production and Trade Legislation**

On May 31, 2007, the Parliament of Ukraine voted on and adopted the "Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms". The law was signed by the President on June 11, 2007 and published on June 21, 2007.

Ukraine committed to establishing a functioning approval and regulatory framework for biotech products prior to WTO accession, which occurred on May 16, 2008.

The “Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms” is said to regulate relations among executive authorities, manufacturers, suppliers, developers, researchers, scholars and consumers of genetically-modified organisms and products manufactured by technologies envisaging their development, creation, testing, study, transportation, import, export, marketing, discharge to the environment and use in Ukraine (hereinafter referred to as GMO handling) and ensuring biological and genetic safety.

In 2008-2009, several implementing regulations were adopted by the Government of Ukraine (GOU) to implement the “umbrella” bio-safety law. The new regulations include the following government resolutions:

- “On Approval of the Procedure of Issuing Permit on Importation of Unregistered Genetically Modified Organisms into the Customs Territory of Ukraine for Scientific Research or State Approval (Testing) Purposes” (#734, August 20, 2008),
- “On the Provisional Criteria for Handling the Genetically Modified Organisms and Realization of Genetic Engineering Activity in Enclosed Systems” (#922, October 16, 2008),
- “On Approval of the Procedure of State Registration of Genetically Modified Organisms, as well as Food Products, Cosmetics, Medicines that Were Obtained with Their Use” (#114, February 18, 2009),
- “On Approval of the Procedure of Issuing Permit for Conducting State Approbation (Trial) of Genetically Modified Organisms in Open Systems” (#308, April 2, 2009),
- “On Approval of the Procedure of Issuing Permit on Transit of Genetically Modified Organisms that Have Not Been Registered in Ukraine” (#423, April 28, 2009).

Even though Ukraine has made some progress in adopting implementing regulations, some additional work (adopting Ministry’s rulings, establishing commissions etc) must be accomplished at the Ministry level to make biotech market system operational. The task is difficult because there are 5 government state institutions (State Standards Committee, the Ministry of Education and Science, the Ministry of Agriculture, the Ministry of Health and the Ministry of Environment) involved and each has their own objectives.

### **GM Labeling Legislation**

In addition to the Government decisions, the President of Ukraine signed the Decision of the National Security and Defense Council “On Biological Safety of Ukraine” passed on February 27, 2009, which came into force on April 6, 2009. According to the Decision, the GOU should develop the Concept for a State Program on Biosafety and Biological Protection by October 1, as well as take different measures, including capacity building, to improve bio-safety in Ukraine. One of these measures was the introduction of mandatory GM labeling in Ukraine based on international standards.

The Government of Ukraine adopted Resolution #468 “On Approval of the Procedure for Labeling Food Products Containing Genetically Modified Organisms or Produced from Them and Put into Trade” on May 13, 2009, which should come into effect and introduce mandatory GMO labeling on July 1, 2009 (at the time this report was prepared). Government official recently said to put off the introduction of mandatory GMO labeling to at least January 1, 2010, as both private businesses and state authorities are reportedly not ready for its prompt implementation.

This procedure determines the requirements for labeling food products that contain genetically modified organisms or produced from them and put into trade in Ukraine. According to the resolution, a food product that contains more than 0.1 percent of genetically modified organisms or a food product that has ingredients containing more than 0.1 percent of genetically modified organisms, as well as a food product that does not contain genetically modified organisms, but was

wholly or partially produced with the use of agricultural products, the content of genetically modified organisms in which was over 0.1 percent, shall be labeled.

Labeling of food products containing genetically modified organisms or produced with their use, is done by a producer (supplier) through putting an appropriate label. In the list of ingredients, any food ingredient that contains genetically modified organisms or produced with their use shall be followed by the following phrase (in brackets): “genetically modified” or “contains genetically modified organism or was produced with their use” with the name of such organisms in the corresponding footnote. The phrase shall be printed in the same font as the list of ingredients.

Food products that have only one ingredient are marked as "genetically modified" or “contains genetically modified organisms or produced with their use" after the general name of the food product printed in the same font as the general name of the food product. Food products containing genetically modified organisms or produced with their use and put into trade in Ukraine that are not labeled in accordance with this procedure are subject to removal from trade.

It is not the first attempt to introduce mandatory GM labeling in Ukraine. On August 1, 2007, the GOU adopted Resolution #985, according to which all food products containing GM above 0.9 percent had to be labeled starting from November 1, 2007. On November 21, 2007, this government decision was canceled.

Unofficial tests of consumer products conducted by Ukrainian labs capable of identifying selected GM components revealed possible presence of GM components in some products that are sold in Ukraine. So far, the domestic food industry and food importers are not labeling GM products. In Ukraine only four labs are capable of identifying and measuring GM content, which makes countrywide implementation of mandatory GM testing and labeling cumbersome, expensive and hardly possible.

### **Section V. Marketing:**

Due to frequent regulatory changes in Ukraine, U.S. exporters are reminded to check with their importers on applicable regulations and documentation requirements prior to exporting to Ukraine. Interested exporters may learn more about food and agricultural import regulations and standards by downloading the following report prepared by FAS-Kyiv <http://www.fas.usda.gov/gainfiles/200807/146295315.pdf>

### **Section VI. Capacity Building and Outreach:**

U.S. government agencies have conducted a number of outreach activities that targeted the creation of an effective and transparent biotechnology regulatory framework.

In May 2009, the Public Affairs Section of the U.S. Embassy in Ukraine conducted a video conference with the University of Arkansas on legal regulation of bio-safety issues: national and international approaches. The conference was attended by representatives of the Parliament of Ukraine, National Academy of Sciences of Ukraine, educational and scientific institutions, private businesses, etc. Conference participants discussed GMO legal issues in both Ukraine and the United States, procedures for GMO importation, GMO labeling, Cartagena protocol implementation etc.

In April 2008, a U.S. biotech expert traveled to Ukraine to participate in a few outreach activities and a Ukrainian government sponsored conference. This is the first time the government of Ukraine presented a balanced approach to this issue and also encouraged fruitful dialogue. The expert was also able to have important discussions with relevant media.

In 2006, approximately 50 scientists, graduate students and regulators from various Ukrainian research institutes and regulatory agencies representing 20 of the 25 Ukrainian oblasts were present, providing excellent regional coverage. All presentations from this seminar were posted on <http://www.auapb.org/eng/pageseng/5.htm>.

In 2002, four Ukrainian scientists from the State Service on Plant Variety Rights Protection of the Ministry of Agricultural Policy, Institute of Ecohygiene and Toxicology of the Ministry of Health Care, Institute of Cell Biology and Genetic Engineering of the National Academy of Sciences and the Ukrainian Academy of Agricultural Sciences

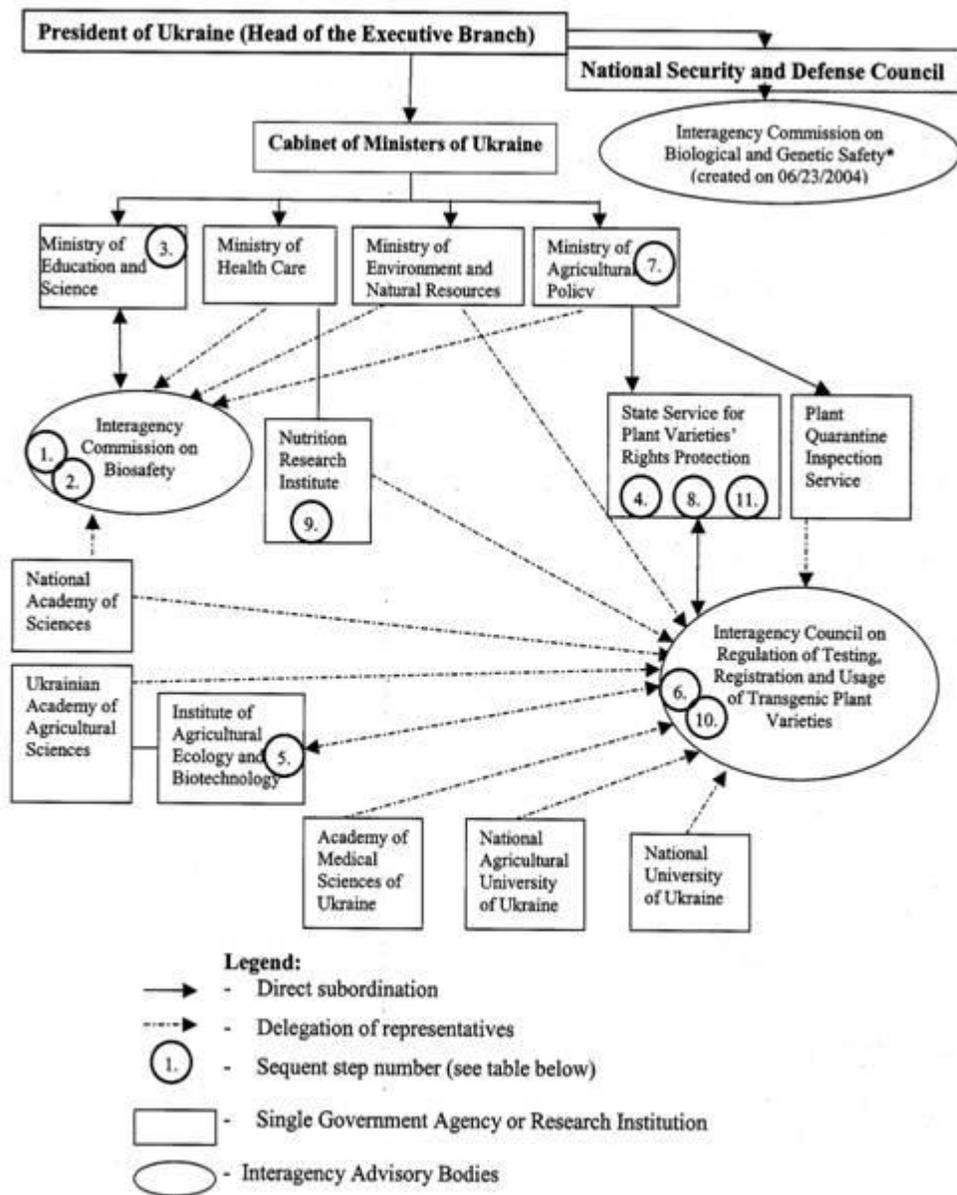
participated in a two-week training program under the Cochran Fellowship Program. The program helped to educate key Ukrainian researchers on the roles played by USDA, Food and Drug Administration and Environmental Protection Agency in the U.S. coordinated biotechnology regulatory framework as well as to provide more detailed information on APHIS biotech regulations.

The Department of State invited two Ukrainian scientists, two regulators and one journalist on the program entitled “Agricultural Biotechnology for Sustainable Development” in 2000 under the International Visitors Program. This was the first opportunity in Ukraine to study the U.S. biotechnology regulatory system. The trip helped in preparing the initial draft of Ukraine’s bio-safety law and provided an excellent opportunity to initiate a series of well-balanced articles on agricultural biotechnology (<http://www.zerkalo-nedeli.com/nn/show/419/36760/>; <http://www.zerkalo-nedeli.com/nn/show/317/28987/>; <http://www.zerkalo-nedeli.com/nn/show/372/33134/>). “Dzerkalo Tyzhnya” Weekly, one of the most reputable Ukrainian newspapers published articles and also hosted an electronic round table with participation of scientists from the U.S. Agency for International Development <http://www.zerkalo-nedeli.com/nn/show/317/28987/>. Articles and the transcript of the round table are available in Russian.

## **Section VII. Author Defined:**

### **Appendices**

#### **Appendix A. The Scheme of Ukraine’s Biotechnology Regulatory Process As It Currently Applies to Biotech Crops.**



Note: Prepared by FAS-Kyiv based on available Ukrainian regulations and interviews with industry experts. State Standards Committee, not on this diagram, has a role in GM technical regulation.

### Appendix B. Steps Necessary To Register a Biotech Crop in Ukraine

Step	Description	Responsible Agency	Required time
1	Application for GMO's environmental release and registration (The GMO must meet the two following criteria: absence of hazard for human health and the environment (if used as intended); identifiably)	Interagency Commission on Biosafety (ICB) (currently under the Ministry of Science and Education of Ukraine. According to the Draft Biosafety Law, ICB will report directly to the Cabinet of Ministers of Ukraine)	<b>270 days</b>

2	The ICB conducts environmental risk assessments and issues one of three possible verdicts: a. - release of the GMOs into the environment is safe; b. - release of the GMOs into the environment is safe subject to specific requirements; c. - release of the GMO into the environment is potentially unsafe	ICB	
3	The GMOs that received a or b-type verdicts (step #2) are to be included into the State Register of the GMOs*.	ICB, Ministry of Education and Science	
4	Application to import GMP plants for variety testing	State Service for Plant Varieties Rights Protection under the Ministry of Agricultural Policy of Ukraine (SSPVRP/MAPU)	Unknown
5	Application is forwarded for an examination	Institute of Agricultural Ecology and Biotechnology, Ukrainian Academy of Agricultural Sciences	Unknown
6	Supporting letter is sent to the Ministry of Agricultural Policy	Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties of the SSPVRP/MAPU	Unknown
7	Import permit for testing is issued	Ministry of Agricultural Policy of Ukraine	30
8	Usual State Plant Variety Testing Program under control of the Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties	SSPVRP/MAPU	2-3 years
9	GM samples are sent for a food safety assessment	Nutrition Research Institute under the Ministry of Health Care of Ukraine	Unknown
10	Approval of the GM variety subject to favorable test results (steps 9-10)	Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties of the SSPVRP/MAPU	Unknown
11	Entry of the GM plant variety into the State Register of Plant Varieties of Ukraine Note: Although, GM plant variety testing is to be conducted the same way as for conventional varieties, GM varieties have to be included into a separate section of the State Plant Varieties Register	SSPVRP/MAPU	Unknown

### Appendix C. Agency Responsibilities As Prescribed by the Law of Ukraine “On State System of Biosafety for Creating, Testing, Transporting and Usage of Genetically Modified Organisms”.

*The Cabinet of Ministers of Ukraine must:*

- ensure state regulation and control in the area of GMO handling and genetic engineering activities;
- ensure measures regarding state support of genetic engineering activities;
- direct and coordinate the work of central executive authorities and other executive bodies in the area of GMO handling and genetic engineering activities;
- organize international cooperation to ensure safe GMO handling and the development of scientific knowledge in this field;
- approve the procedures for the state registration of GMOs and products manufactured using GMOs;
- approve the procedures for importation of GMO sources of food products and feed manufactured from GMOs;
- approve the procedure for granting a permit for the transit of GMOs across the territory of Ukraine;
- approve the procedure for licensing genetic engineering activities in closed and open systems;
- approve the procedure for conducting state approbation (tests) of GMOs in the open system and obtaining a permit for conducting those;

- approve the safety criteria for GMO handling in closed systems.

#### Central Executive Authority on Education and Science must:

- ensure the development of scientific and scientific-and-technical potential in the field of genetic engineering activities;
- ensure protection of international and national patents and other types of intellectual property in the field of GMO handling, genetic engineering and genetic engineering activities;
- develop the safety criteria for GMO handling and the genetic engineering activity in closed systems;
- develop and improve the system of control over the observance of safety rules in genetic engineering activities;
- carry out licensing of genetic engineering activities in closed systems;
- issue permits for importation of unregistered GMOs, if they are used exclusively for science research purposes in closed systems and open systems and also for the purpose of state testing, with regard to the results of the state ecological and state sanitary and epidemiological inspections regarding the biological and genetic safety of GMOs that are carried out based on recognized international approaches,.

#### Central Executive Authority on Ecology and Natural Resources must:

- conduct state ecological inspections of GMOs intended for use in open systems;
- develop criteria which is based on scientific principles and international experience for assessing risk of the potential GMO impact on the natural environment;
- carry out state registration of plant protection means manufactured using GMOs;
- exercise state supervision and control over the observance of biological and genetic safety measures in respect to biological objects in the natural environment for creating, studying and practical use of GMOs in open systems;
- issue permits to discharge GMOs in open systems.

#### Central Executive Authority on Health Protection must:

- develop the criteria which is based on scientific principles and international experience for assessing the risk of GMOs and the potential impact on human health and products manufactured using GMOs, including food products;
  - carry out state sanitary and epidemiological inspections of GMOs that are used in open systems to determine their biological and genetic safety for humans and with the view towards gaining state registration;
  - carry out state supervision and control over observance of biological and genetic safety measures with respect to humans in creating, studying and practical use of GMOs in open systems;
  - carry out state sanitary and epidemiological inspections of products manufactured using GMOs to determine their safety for human health and life;
  - carry out state registration of GMO sources of food products as well as state registration of food products, cosmetics, and medicines containing GMOs or manufactured using GMOs;
- approve the list of food products, which contain GMO content and the list of relevant methodologies for detecting and identifying GMOs;
- monitor food products manufactured using GMOs to ensure only registered GMO sources are used.

#### Central Executive Authority on Agricultural Policy must:

- ensure state approbation (testing) and state registration of agricultural plant varieties, animal breeds, microbiological agricultural and veterinarian preparations created based on GMOs;
- carry out state supervision and control over biological and genetic safety measures with respect to agricultural plants and animals in creating, studying and practical use of GMOs in open systems at companies, institutions and organizations of agricultural and industrial complexes irrespective of their subordination and ownership;
- carry out state registration of GMO sources of feed as well as registration of feed additives and veterinarian preparations containing GMOs or manufactured with the use thereof;
- approve the list of feed in which control over the content of GMOs is carried out as well as the list of relevant methodologies for detecting and identifying GMOs;
- monitor feed manufactured using GMOs to ensure only registered GMO sources are used.