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Ukraine

Biotechnology

Agricultural Biotechnology Report

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Report Highlights:

The government of Ukraine (GOU) achieved a major success with the adoption of "the Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms". However, the law lacks implementing regulations and fails to provide a clear mechanism for product testing, transport and usage. Also, the law does not designate institutional authority. GOU is expected to address these issues through sub-legislative decrees and orders.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Kyiv [UP1]
[UP]

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Executive Summary

On May 31, 2007, the Ukrainian parliament (Rada) voted on and adopted the "Law of the State System of Biosafety 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 membership which is expected in 2008.

There are some in the government of Ukraine that see the benefits biotech products can deliver to Ukrainian agriculture. These officials and scientists have been instrumental in persuading key policy officials into approving the legislation on agricultural biotechnology. However, there continues to be many dissenters and biotechnology remains a very sensitive issue in Ukraine.

Imports of food and agricultural products to Ukraine totaled $2.6 billion (CIF value) in 2005 and $3.2 billion in 2006. United States captured 4% ($107 million) in 2005 and 5% ($167 million) in 2006 of the import market. Major U.S. food and agricultural products exported to Ukraine were poultry meat, fish, tobacco, planting seeds, soybean meal, pet food, proteins derived from soybeans and tree nuts. According to FAS-Kyiv estimates, the value of U.S. soybean meal, soy proteins and isolates, corn products, planting seeds and other products that faced, or could have encountered trade restrictions, because of unclear biotechnology regulations ranged from $1.1 million (2003) to $20 million (2006). As long as Ukraine has no functioning system for biotech products, issues of market access for products of agricultural biotechnology are expected to become more critical as Ukraine continues to increase its oilseed processing capacity.

Section II. Biotechnology Trade and Production.

Production

Ukraine has not approved a single biotechnology crop for commercial production despite having received five applications in 1997-1999. Therefore, authorities claim that Ukraine's agriculture remains GMO-free. A weak regulatory system, the lack of field surveillance programs and laboratory capacities, however, leave doubt to Ukraine's GMO free status. In fact, it is estimated that half of Ukraine's soybean production, or 375,000 tons, are Round-up Ready Soybeans. Other plantings of biotech crops are also suspected (i.e.: corn, sugar beats).

Ukrainian researchers in cooperation with a Russian scientist reportedly developed potatoes resistant to the X-virus 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 --

α-interferon and somatropine (human growth hormone). However, this technology has not yet been commercialized.

Trade

Below is a summary of Ukraine's import data for major products that might contain biotech corn or soybean events: Corn Flour (HS 110220); Corn Meal or Groat (HS 110313); Worked 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.

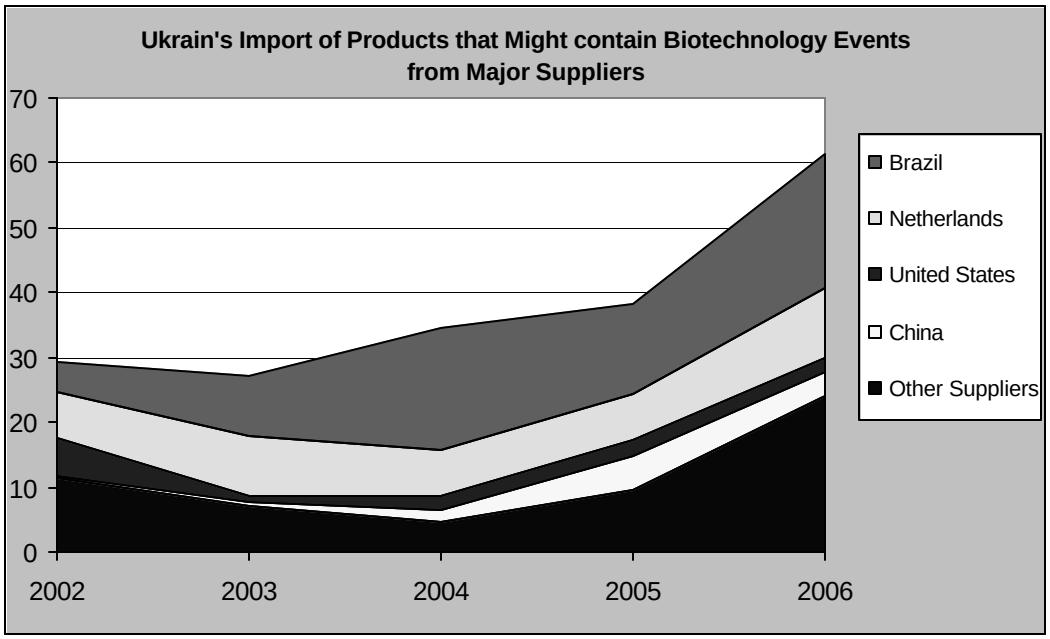
Ukraine imported products valued at $39 million in 2005 that could contain GMOs. For 2006, these products increased by 59% and totaled almost $62 million.

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

	2005		2006	
	Value $ million	Share %	Value $ million	Share %
Corn Flour (HS 110220);	0.382	1%	0.107	0%
Corn Meal or Groat (HS 110313);	0.033	0%	0.008	0%
Worked Corn (HS 110423);	0.001	0%	0	0%
Soybeans (HS 120100);	0.05	0%	0.727	1%
Soy Sauce (HS 210310);	0.325	1%	0.433	1%
Protein Concentrates (HS 210610);	3.346	9%	6.188	10%
Corn Gluten (HS 230310);	0.118	0%	0.069	0%
Soybean Meal (HS 230400);	25.476	66%	47.299	77%
Protein Isolates (HS 350400)	9.061	23%	6.571	11%
Total Value, $ million	**38.792**	**100%**	**61.402**	**100%**

Data source: State Statistics Committee of Ukraine

The United States is the third largest supplier of these products after Brazil and Netherlands (please refer to the graph below).



Data source: Prepared by FAS-Kyiv based on Ukraine's official trade data for the following HS Codes: 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 Code	Description	2003		2004		2005		2006	
		Value $ mln	Share %	Value $ mln	Share %	Value $ mln	Share %	Value $ mln	Share %
230400	SOYBEAN MEAL	0.24	21%	1.18	51%	0.17	7%	0.1144	5%
350400	PEPTONE, PROTEIN ISOLATES	0.43	37%	1.04	45%	1.75	71%	1.39326	58%
210610	PROTEIN CONCENTRATE	0.01	1%	0.05	2%	0.48	19%	0.40451	17%
120100	SOYBEANS	0.06	6%	0.04	2%	0.03	1%	0.3656	15%
210310	SOY SAUCE	0.01	1%	0.01	1%	0.02	1%	0.10876	5%
230310	CORN GLUTEN	0.40	35%	0.00	0%	0.00	0%	0	0%
110423	WORKED CORN	0.00	0%	0.00	0%	0.00	0%	0	0%
Total		**1.15**	**100%**	**2.34**	**100%**	**2.46**	**100%**	**2.39**	**100%**

Data source: State Statistics Committee of Ukraine

The future impact of biotech policy on agricultural trade, however, is not only guided by the information provided in the table above. One new crushing plant capable of crushing soybeans is scheduled to begin operations in the Port of Illichivsk (near Odesa) in MY 2007/2008. Although, currently there are no plans to import soybeans for crushing, it is probable that soybeans will be imported in the future assuming favorable crushing margins and the existence of clear regulations governing imports of GM soybeans. Imports of 50,000 metric tons of soybeans could increase the value of trade by $13 million.

Issues related to the presence of biotech products in food assistance programs are not expected to have any significant importance in the future. The Ukrainian government and non-government organizations received agricultural products under various U.S. food assistance programs in 1995-2000. Since then, the country has not faced problems with commercial food imports, hard currency shortages or foreign exchange. Ukraine is by far a net food exporter and will not likely require any food assistance in the future.

Section III. Biotechnology Policy

Currently, Ukraine has no functioning biotech approval and regulatory system despite adoption of the new biotech law on June 21, 2007. As GOU continues to work on creating and implementing a new system that will approve and regulate products of agricultural biotechnology, Ukraine will continue to operate without a functioning system to regulate, test, and approve biotech products.

The current regulatory process for approval of biotech crops in Ukraine is very cumbersome and is based on mandatory registration procedures designed for conventional plant varieties. A biotech plant variety is required to go through a more rigid and lengthy registration process than a variety using conventional plant breeding. However, no biotech variety has ever been approved or registered for cultivation in Ukraine.

Field Trails of Biotech Varieties in Ukraine

In 1998, 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

A New Bio-safety Law was Adopted in Ukraine

The following is a translation of the new “Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms” that was adopted on June 21, 2007:

The “Law of the State System of Bio-safety in Creating, Testing, Transporting and Using Genetically-Modified Organisms” must regulate relations between 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.

Enforcement of this Law will be ensured by central executive bodies within the scope of their authority and in accordance with the procedure stipulated by law. Responsibilities of the authorities are stipulated by the law but are not distributed to the institutions (Ministry of Health, Ministry of Environment and Nature Protection, Ministry of Science and Education).

Supplementary documents must regulate the mechanism and system of:

1. Areas of activity subject to regulation in the course of GMO handling;
2. Powers of the central executive authority on agricultural policy;
3. Regulating genetic engineering activities at institutions, organizations and enterprises;
4. State registration of GMOs and establishing restrictions on their use;
5. Use, transportation, storage and recycling of GMOs.

[Comment: The newly adopted law does not establish a system or mechanisms for the creation, testing, transport and use of biotech products. The law only creates a framework for biotech products and will be followed by supplementary documents to this law that will provide the next steps and implementing regulations. The Biosafety Commission will be responsible for drafting the supplementary regulations that will govern the approval and use of GMO products in Ukraine. More specific details and a timeline are not yet available.]

Labeling

The new Biosafety Law that was adopted on June 21 (but yet to be implemented) does not contain any requirements for labeling and does not regulate food products that contain GMOs. Therefore, labeling requirements remain unchanged from the last annual Biotech Report.

Ukraine's Current Labeling System

Under the current and yet unchanged system, there are no labeling requirements applicable to biotech feeds. However, Ukraine's current GMO labeling rules represent one of the major uncertainties for food importers. Food products that contain GMOs were not regulated prior to October 24, 2002, the date when the Parliament of Ukraine incorporated changes into the Law of Ukraine On Food Safety. The legislation included food products that contain "genetically modified components" to the category of new food products along with newly developed foods, products that have not been imported before, products that contain new components/ingredients and products that were produced using new technology. A separate line on the presence of GMOs in food products was included to the list of mandatory information to be provided on the label. It appears that any quantity of GMOs must be labeled according to the Law.

This legislation was adopted to reflect the consumers' "right to know" because the GOU does not conduct food safety risk assessments for GMOs at this point. The current labeling legislation is unclear on label language, placement or threshold. The implementing regulations entitled "On Approving Rules of Retail Trade in Food Products" adapted by the Ministry of Economy of Ukraine on July 23, 2003 did not clarify these issues. The regulations simply prohibited the sale of domestically produced and imported consumer packaged food products that do not have an "easy to comprehend" label. Unofficial tests of consumer–ready products conducted by Ukrainian labs capable of identifying selected GM components revealed possible presence of GM components in some products that are readily offered for sale in Ukraine. So far, the domestic food industry and food importers are not labeling GM products due to the lack of clarity in the requirements. Ukrainian state agencies also chose

to ignore labeling requirements due to limited lab facilities, illicit testing techniques, lack of maximum residue level threshold, as well as legislative ambiguities.

Section IV. Marketing Issues

There are no studies on potential market acceptance related to the sale of biotechnology products in Ukraine. As consumer incomes in Ukraine rise, the country is expected to increase imports of processed and consumer ready food products from the United States and other countries. Enforcement of GMO labeling requirements or possible adoption of EU labeling and tracebility regulations would have a major negative impact on both domestic and imported food sales. Consumers in Ukraine tend to carefully analyze the contents on the label. There is a widespread belief that products that contain food additives are not healthy. Therefore, consumers would exercise great caution in purchasing products with the "contains GM components" mark on the label.

Although enforcement of GM labeling of food products is not expected to occur due to the adoption of the new law on biosafety, if labeling were required, it would likely harm U.S. exports of soy-based ingredients used by local meat processors and other food producers. Feed producers, however, are not going to change their purchasing decisions as these will likely continue to be determined by price level and not what's on the label. As part of Ukraine's commitments under the Cartagena Protocol (Ukraine ratified the Protocol on Biosafety to the Convention on Biological Diversity on September 12, 2002), documentation requirements for custom clearance of soybeans or other bulk commodities are expected to have a greater impact on oilseed processors and feed producers than food labeling requirements.

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 imports regulations and standards by downloading the following report prepared by FAS-Kyiv http://www.fas.usda.gov/gainfiles/200508/146130466.pdf

Section V. 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 2006 the Black Sea Biotechnology Association with financial support from the Ukrainian Academies of Science, the Foreign Agricultural Service and other organizations held an international symposium in Yalta from May 10 – 14, 2006, on agricultural biotechnology research, regulatory policies, and public perception. A broad range of speakers discussed topics including basic science research, global biotech crop adoption, global regulatory policies, international organizations working on biotechnology capacity building, and the biotech's economic impact on countries in the region. The conference audience comprised scientists and others with an interest in biotechnology. Government officials from some of the Black Sea countries, especially Ukraine and Russia, were also present but they mostly held advisory positions rather than being key policy decision-makers. Symposium materials were posted on the All-Ukrainian Association of Plant Biologists web site http://www.auapb.org/eng/indexeng.htm.

FAS-Kyiv facilitated an International Seminar on Biosafety in November 2003. Two professors from UC Davis traveled to Ukraine to make presentations on the U.S. regulatory system and, vertical and horizontal gene flow. Scientists from Great Britain and Switzerland

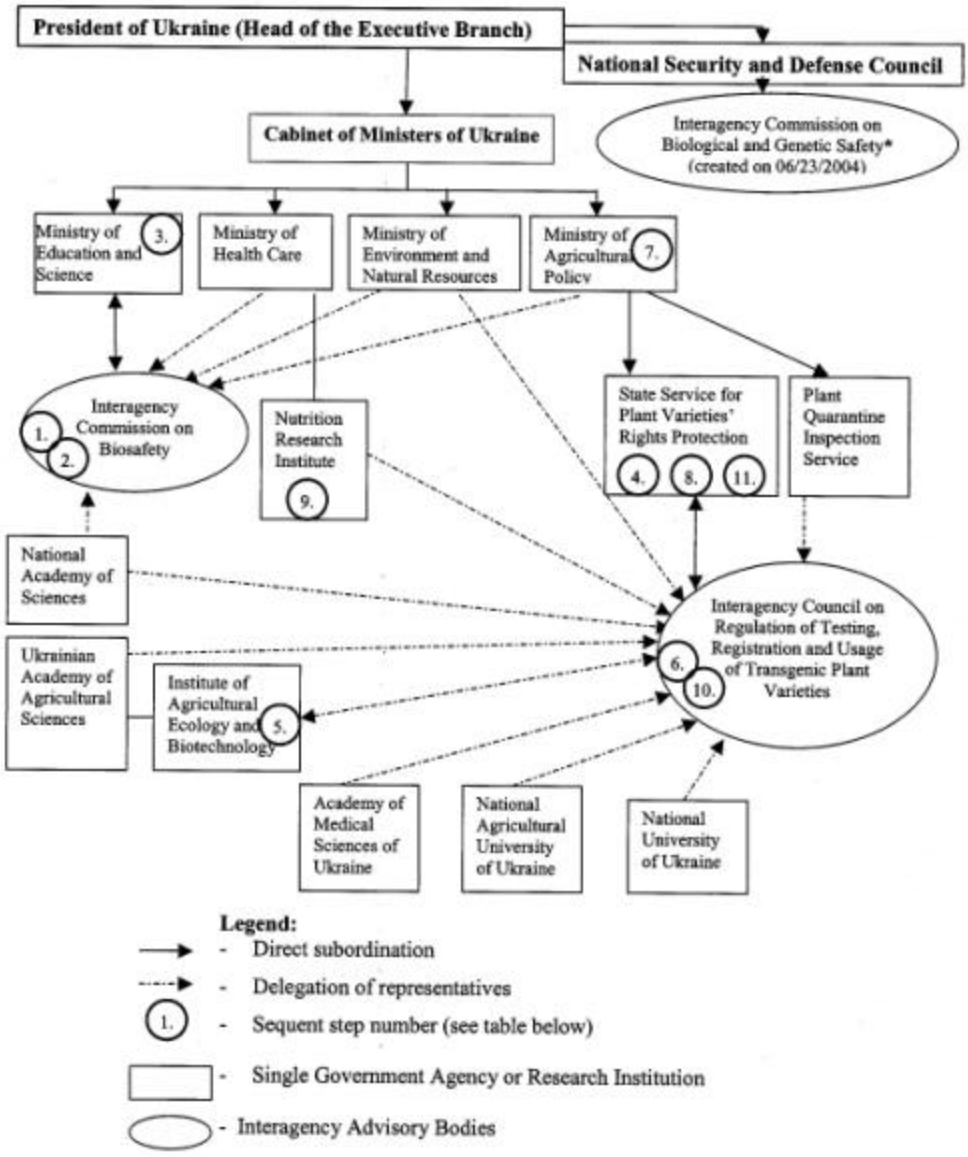
made presentations on public debates over GM foods and genomics. Approximately 50 scientists, graduate students and regulators from various Ukrainian research institutes and regulatory agencies representing 20 of the 25 Ukrainian oblasts were present, providing excellent regional coverage. All presentations 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 biosafety 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.

Appendices

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



Prepared by FAS-Kyiv based on available Ukrainian Regulations and interviews with industry experts.

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

Phase	Step	Description	Responsible Agency	Required time
State Registration of the GMO.	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); identifiability)	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)	
	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	**270 days**
Import Permit for Testing	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**
Testing	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**
Final permit	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**
Estimated minimum time required				**3-4 years**

* Presidential Degree established Interagency Commission on Biological and Genetic Safety under the National Security Council of Ukraine on 06/23/2004. It is yet another advisory body responsible for biosafety issues. It is expected, however, that this Commission will pay more attention to bioterrorism-related problems.

Appendix C. Agency Responsibilities As Prescribed by the New Ukrainian "Law of the State System of Biosafety for Creating, Testing, Transporting and Usage of Genetically Modified Organisms" (not yet implemented).

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.