

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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Required Report - public distribution

Date: 6/22/2015

GAIN Report Number: UP1527

Ukraine

Agricultural Biotechnology Annual

Ukraine Biotechnology Annual

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Report Highlights:

The biotechnology regulatory system in Ukraine is still not fully developed, but the country has committed itself towards shaping its policy in line with European Union standards. Debates over agricultural biotechnology presence are active in the country.

REPORT OUTLINE

Report Highlights:

Section I: Executive Summary

Section II: Plant and Animal Biotechnology

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

PART B: Policy

PART C: Marketing

PART D: Capacity Building and Outreach

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: Production and Trade

PART F: Policy

PART G: Marketing

PART H: Capacity Building and Outreach

Section I. Executive Summary:

Ukraine’s attitude towards biotechnology has largely remained unchanged, while the country has committed itself towards shaping its biotechnology policy in line with European Union (EU) standards after signing the EU-Ukraine Association Agreement in 2014.

In the late 2014 national legislation was amended in order to eliminate duplicating control functions of various governmental authorities over the processed products containing genetically engineered (GE) components that would come into force in late September 2015. The effectiveness of these changes would depend on consistency of sub legislation as well as administrative capacity of the Government of Ukraine (GoU).

In calendar year 2014, due to turbulent political and economic events, the value of imports of goods that may potentially contain GE events decreased by 37 percent compared to 2013.

Roundup Ready MON 40-3-2, in the form of soybean meal, was reinstated in the official registry of approved feed sources that contain agricultural biotechnology for a term of five years from 2013-2018.

No GE animal products were registered or allowed for production, sale, or use in the country.

Section II. Plant and Animal Biotechnology

Chapter 1: Plant Biotechnology

Part A: Production and Trade :

a. Product Development:

At this time, it is not known if Ukraine is currently developing GE crops for commercial purposes. However, there are reports of some experiments with existing GE plants conducted at state research institutions in Ukraine.

b. Commercial Production:

Some food products in Ukraine occasionally test positive for GE presence. This indicates there may be some sources present in the country or brought in from abroad. Soybeans and corn grown in Ukraine are still considered the crops of concern. Industry rumors in Ukraine are that a large share of soybeans and about one-third of corn grown are GE.

c. Exports:

At the time of this report, Ukraine does not officially export any GE products due to the fact that none have been officially registered or allowed for production and commercial sale in the country.

Several years ago, there were a handful of cases when exported corn from Ukraine tested GE-positive upon arrival at the buyer's port location. However, most grains and oilseeds exported from Ukraine are delivered to the destinations that do not require strict GE monitoring, thus, the cargo usually is not scrutinized at the point of unloading. In case these commodities are dispatched to countries with established agricultural biotechnology regulation, such shipments might contain GE crops authorized to be used for food and/or feed purposes in the destination countries.

Ukraine continues trading corn with China per the agreement that was signed in 2013. So far, Ukraine has delivered over one million tons of corn in execution of this deal. China expects Ukraine to deliver up to five million tons of corn a year for the next several years. The official Protocol on phytosanitary and inspection requirements on corn export from Ukraine to China ([in Ukrainian](#)) does not contain direct references for testing GE presence in shipments, however the protocol allows exports of products compliant with China's phytosanitary legislation and standards. Technically such a framework might allow GE corn exports as China accepts GE-positive cargo, but only if the shipment is marked accordingly and contains only those GE events that are approved and allowed in China (see [Gain Report 14032](#) for further details).

d. Imports:

In the second half of 2013, genetically engineered soybeans, specifically Roundup Ready MON 40-3-2, in the form of meal, were reinstated in the official registry of approved feed sources that contain GE events. This source of feed is included in the approved list and published on the official website for Ministry of Agriculture in the "Registry of Sources of Feed and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms" ([in Ukrainian](#)).

Overall imports of products to Ukraine that may potentially contain GE events are shown in Table 1 below. The total trade in these goods decreased by about 35 percent in 2014 calendar year compared to the previous year due to significant deterioration of economic situation in Ukraine as well as fluctuations of exchange rates.

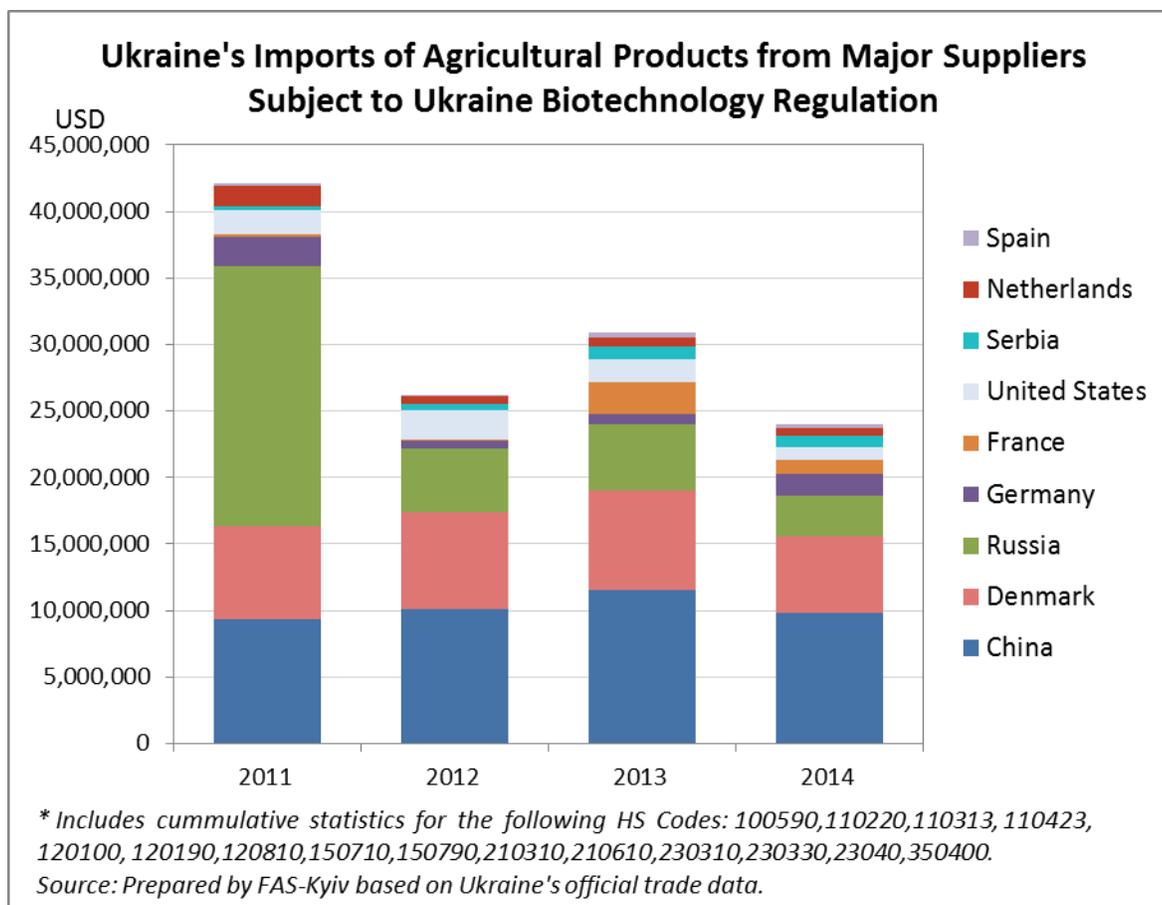
Table 1. Major Imports Subject to Ukraine Biotechnology Regulation

Product HS Code	Product Description	2012		2013		2014		% Change
		Value (\$)	Share %	Value (\$)	Share %	Value (\$)	Share %	2014/2013
100590	Whole corn	786,077	2.4	736,909	1.7	528,622	1.9	-28.3
110220	Maize (Corn) Flour	10,340	0.0	357	0.0	-	0.0	-100.0
110313	Maize (Corn) Meal and Groats	174,171	0.5	169,778	0.4	85,733	0.3	-49.5
110423	Processed Maize (Corn)	-	0.0	-	0.0	37,369	0.1	-
120100	Soybeans (seed)	1,407,383	4.3	3,631,858	8.6	-	0.0	-100.0
120190	Soybeans (non-seed)	-	0.0	-	0.0	520,494	1.9	-
120810	Soybean meals and flours	29,963	0.1	52,978	0.1	67,948	0.2	28.3
150710	Soybean Oil (non-refined)	458,402	1.4	36,714	0.1	55,593	0.2	51.4
150790	Soybean Oil (refined)	74,132	0.2	86,099	0.2	91,530	0.3	6.3
210310	Soya Sauce	3,465,123	10.5	4,244,114	10.1	3,342,968	12.2	-21.2
210610	Protein Concentrates	6,384,810	19.3	5,730,948	13.6	4,108,982	15.0	-28.3
230310	Maize (Corn) Gluten	108,354	0.3	153,262	0.4	83,626	0.3	-45.4
230330	Distillers' Dried Grains	21,114	0.1	100,388	0.2	22,075	0.1	-78.0
230400	Soybean Meal	3,777,367	11.4	6,057,702	14.3	1,716,916	6.3	-71.7
350400	Protein Isolates	16,335,045	49.5	21,227,958	50.3	16,780,356	61.1	-21.0
<i>Total</i>		<i>33,032,281</i>	<i>100.0</i>	<i>42,229,065</i>	<i>100.0</i>	<i>27,442,212</i>	<i>100.0</i>	<i>-35.0</i>

Source of Data: State Fiscal Service of Ukraine

A significant decrease of imports for soybeans, corn, and products of processing thereof to Ukraine could be also attributed to the increased volumes of production for these crops during the recent years as well as buildup and upgrade of processing capacities capable of supplying various processed products to domestic market.

In 2014, China, Denmark, and Russia remained the largest suppliers of the products to Ukraine that are subject to Ukraine biotechnology regulation (see graph and Table 2 below).



**Table 2. Major Imports Subject to Ukraine Biotechnology Regulation
by Country of Origin, Calendar Year**

Partner Country	United States Dollars				% Share			
	2011	2012	2013	2014	2011	2012	2013	2014
World	57677407	33032282	42229065	27442211	100	100	100	100
China	9327689	10142472	11547106	9820911	16.2	30.7	27.3	35.8
Denmark	6979625	7262138	7509844	5758348	12.1	22.0	17.8	21.0
Russia	19588624	4764986	4932359	3032576	34.0	14.4	11.7	11.1
Germany	2225043	572513	765615	1650830	3.9	1.7	1.8	6.0
France	160678	91102	2410629	1054146	0.3	0.3	5.7	3.8
United States	1862424	2251662	1768376	952581	3.2	6.8	4.2	3.5
Serbia	215267	412252	889891	852969	0.4	1.2	2.1	3.1
Netherlands	1599629	597929	731883	585140	2.8	1.8	1.7	2.1
Other	15,683,688	6,937,119	11,603,870	3,734,710	27.2	21.0	27.5	13.6

Source of Data: State Fiscal Service of Ukraine

e. **Food Aid Recipient Countries:**

Ukraine is not a food aid recipient country.

Part B: Policy

a. **Regulatory Framework:**

The principal legislation that governs GE events in Ukraine is the Law of Ukraine #1103-V_ “On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms (“GMOs”)” (Biosafety Law) ([in Ukrainian](#)), signed by the President of Ukraine and effective since June 21, 2007. The latest amendments to this law took place in April 2014 and concentrated for the most part on the definition of the authority and description of the responsibilities of various government agencies.

On September 20, 2015, a new law becomes effective: the Law of Ukraine #1602-VII “On Amendments to Certain Legislative Acts of Ukraine regarding Foodstuffs” ([in Ukrainian](#)). This legislation introduces a number of amendments to Biosafety Law intended to eliminate duplicative control functions of various governmental authorities over the processed products containing GE components.

Currently the Ukrainian Parliament is considering a number of legislative initiatives intended to change the regulatory field governing the production and turnover of GE crops and products, including:

- Draft Law #2977 ([in Ukrainian](#)) envisages increase of the level of financial sanctions for production and distribution of products of plant origin containing GE traits that have not been registered in Ukraine, introduces procedures for obligatory destruction of unregistered GE products, and redistributes the powers of governmental authorities supervising circulation biotechnology products;
- Draft Law #1844 ([in Ukrainian](#)) envisages implementation of simplified registration for GE plants and products that have already included in the [EU Register of authorized “GMOs”](#) in accordance to the procedure to be further approved by the Cabinet of Ministers of Ukraine;
- Draft Law #1708 ([in Ukrainian](#)) envisages redistribution the powers of governmental authorities supervising agricultural biotechnology as well as introducing some additional administrative procedures intended to tighten controls over GE products on the domestic market.

The GoU has adopted Resolution #847-p “On implementation of the [EU-Ukraine Association Agreement](#)” ([in Ukrainian](#)). It establishes the Action Plan for implementation of the Agreement for 2014-2017, to determine the terms of implementation of relevant EU legislation, to include:

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

- Regulation (EC) 641/2004 as of 06 April 2004 on detailed rules for the implementation of Regulation (EC) 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 favorable risk evaluation;
- Regulation (EC) 1830/2003 as of 22 September 2003 of the European Parliament and of the Council on 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;
- Directive 2001/18/EC of the European Parliament and of the Council as of 12 March 2001 on the deliberate release into the environment of genetically modified organisms – within 2 years of entry into force of the Agreement;
- Regulation (EC) 1946/2003 of the European Parliament and of the Council as of 15 July 2003 on transboundary movements of genetically modified organisms – within 2 years of entry into force of the Agreement;
- Directive 2009/41/EC of the European Parliament and of the Council as of 06 May 2009 on the contained use of genetically modified micro-organisms – within 3 years of entry into force of the Agreement;
- Commission Recommendation as of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic production (farming);
- Directive 2002/53/EC as of 13 June 2002 on the common catalogue of varieties of agricultural plant species.

FAS-Kyiv believes that pace of implementation of the abovementioned Action Plan would depend on the GoU's administrative capacity as well as specific priorities of various governmental authorities involved in this process as well general political and economic climate in Ukraine.

b. Approvals:

Over the last several years Ukraine has attempted to approach the issue of GE approvals in the country. However, the approvals system remains not fully developed at this time. In the Biosafety Law (referenced in the preceding section) the legislation defines the roles and functions of various government agencies as those monitoring or testing for GE presence. So far, no registration criteria that could lead to approvals or rejections were clearly identified and written into law.

Over the last year, one agricultural product that contains GEs was officially registered and approved for feed use in Ukraine. This product is Monsanto's Roundup-Ready soybeans MON 40-3-2 (see Imports section above more information), temporarily allowed for use in Ukraine since July 2013 and gradually extended until July 2018.

c. Field Testing:

No biotechnology field testing was officially reported by businesses or other non-government organizations.

d. Stacked Events Approvals:

There is no approval process for the stacked events.

e. Additional Requirements:

There are no additional requirements.

f. Coexistence:

Ukraine does not have any GE event coexistence policy.

g. Labeling:

Food product labeling legislation continues to require an indication of GE content presence in food products sold to Ukrainian consumers. In accordance with the provisions of the Law of Ukraine #1602-VII (referenced in Regulatory Framework chapter) the following labeling requirements were introduced as of September 20, 2014: If a product contains GE materials, and if their share in the product exceeds 0.9 percent of any of the ingredients of product (including ingredients composed of or made of GE materials), the food product's labeling must include the marking, "Containing GMO".

Before September 2014, the GE presence in a product was defined according to [GoU Resolution #468](#) "On Approval of Procedures for Labeling of Foodstuffs containing "GMO," produced using "GMO" and Introduced to Market" ([in Ukrainian](#)). Under the provisions of GoU Resolution #468, any food product that contains more than 0.9 percent GE content in a single package's total weight or was made with the use of GE products had to be labeled "Containing GMO."

Recognizing that Ukraine has not officially approved any GE events food purposes to date, it is not surprising that consumers do not encounter food products on the market with the "Containing GMO" marking included on the label.

h. Trade Barriers:

The main trade barrier in Ukraine is that no GE are registered and allowed for importation or commercial use in the country. Roundup-Ready Soybeans [MON 40-3-2] are allowed in the form of meal for feed use but only on the basis of a product approval, not approval of the GE event. The legislation and the framework underlying the approval process for release of GE crops in the open system are not complete and have not been consistently moving forward.

i. Intellectual Property Rights (IPR):

The Intellectual Property Rights protection policy for GE events has not yet been developed in Ukraine. Ukrainian legislation does not allow for registration of GE events, but does provide some protection for registered plant varieties and breeds. If a GE plant variety or animal breed gets registered in Ukraine (which has never been the case) the owner of the plant variety will have to rely on massive and cumbersome general contracting procedures with all in-country partners in an attempt to secure their (owner's) rights. In many cases the owner will depend on the Ukrainian civil court system which is not familiar with complicated IPR cases. The burden of proof will be entirely on the petitioner and overall enforcement cost can be prohibitively high. Procedures can take years in different courts resulting in very weak protection. Some companies that defend their conventional hybrids and varieties already had a chance to experience these IPR difficulties in the past. Due to the lack of registered GE plant varieties and animals and/or import procedures this IPR discussion is theoretic in nature.

j. Cartagena Protocol Ratification:

Ukraine is a member of the Cartagena Biosafety Protocol (CBP) which entered into force in the country in 2003. The legislation remains under development to bring the regulation in compliance with CBP.

k. International Treaties/Fora:

In the past, Ukraine was promoting itself as a GE-free region. However, in the recent years the State seems to have lessened strong opposition towards biotechnology, but they have not acted to support the technology, either.

l. Related Issues:

Recently, there were some discussions in the agriculture industry about possible use of GE crops for biofuel production in Ukraine, which could open the doors for the commercial production but leave the human consumption issue aside. However, since biofuels sector is very small in the country mainly because of the lack of investment, the feasibility of such development is dependent on the State support policy as well as on the subsidies.

m. Monitoring and Testing:

The presence of agricultural biotechnology materials is monitored in the food products that are imported and those produced in Ukraine as well as in the imports of agricultural products such as seeds for planting. In accordance to the provisions of the Biosafety Law (referenced in Regulatory Framework section), Ukraine has established a networks of accredited laboratories for GE testing, however FAS-Kyiv has no information about their operational capacities.

For the purpose of monitoring of presence of unregistered GE sources in food products derived from GE components the Ministry of Health of Ukraine has approved its Order #971 ([in Ukrainian](#)) containing the list of crops as well as products of processing thereof that are the subjects to GE presence testing.

All imported food products are inspected upon arrival at the border, are required to be accompanied by the appropriate certificates that show GE test results, and must be labeled for GE presence in accordance with the Food Labeling Law (referenced in Regulatory Framework section).

Ukraine no longer has a formal mechanism to check for GE presence in exported grains and oilseeds, since the abolishment of Grain Quality Certificate for Grain and Products of Processing thereof, which was approved by the GoU Resolution #848 ([in Ukrainian](#)). In September 2014, however the Biosafety Law retains requirements to exercise controls over exports of GE objects.

All planting seed imports are required to be tested for GE presence upon arrival at the Ukrainian border in addition to the requirement for the GE presence tests done prior to shipment and reflected in the cargo accompanying documentation. Genetically engineered presence tests for planting seeds are done by the designated state testing labs in Ukraine. Samples are taken from the seed shipments that arrived at the border and sent to the testing lab while cargo stays at the Customs Warehouse awaiting the results. The State Veterinary and Phytosanitary Service issues certificates that allow transportation and use of imported planting seeds in the country based on the cargo accompanying documents.

n. Low-Level Presence Policy:

Ukraine does not have a low-level presence policy defined. From FAS-Kyiv experience, agricultural products that were tested for GE presence (test results showed GE content of above zero level) were prohibited from entering the market in Ukraine.

Part C: Marketing

a. Market Acceptance:

Ukraine continues to be a challenging market for biotechnology promotion. The major factors that condition the situation are the generally negative public opinion and a bureaucracy along with gaps in GE testing and approval system in the country.

b. Public/Private Opinions:

In general, individual large producers and grain and oilseed traders in Ukraine have not been very vocal or public for that matter in their support of the GE use in the country. Biotechnology topic in general was not given much attention in Ukraine in 2014 – early 2015 because political and economic issues took priority.

c. Marketing Studies:

An economic study on the effects of using GE products for Ukrainian agriculture and the country's economy was published in 2012. This research was a joint effort by Dr. Blum (the Institute of Food Product Biotechnology and Genomics in Ukraine) and Dr. Brooks of the United Kingdom. The two scientists considered the environmental effects as well as direct economic benefits of the production of GE oilseed rape, soya beans, sugar beets, and corn for Ukrainian agriculture. More independent and in

depth research studies need to be conducted and published in Ukraine to raise the awareness of the population on the subject and to make the scientific facts available to the decision makers.

Part D: Capacity Building and Outreach

a. Activities:

None.

b. Strategies and Needs:

The general public in Ukraine is still lacking awareness of the science-based facts about biotechnology and GE products. It is recommended that interested parties join forces in making these facts known to the consumers to win over the generally negative public opinion and to show their support of the objective and facts-based decision making.

Industry discussions over the course of time since our previous annual report (July 2014) indicate that general public in Ukraine still has negative opinion about biotechnology that is either based on emotional perceptions or on some misleading news stories that are not based on sound science.

Currently in Ukraine there are polarized opinions regarding agricultural biotechnology. Some stakeholder groups intend to legitimize the current status-quo with production of GE crops through legislative amendments. Other groups are trying to tighten controls over their production in order to promote the image of Ukraine as a GE-free country. This split is visible from the legislative initiatives currently considered by the Parliament (please refer to Chapter 1, Part B of this report for more information).

Even though the process of changing public perceptions may be slow, it is necessary for the technology to be received well by Ukrainians for it to have any feasible economic value. In addition, strong interest and support from local producers and various potential users of the technology is crucial to keep the developments in the area going in a positive direction.

Currently a number of Governmental Agencies responsible for implementation of Biosafety Law (referenced earlier), including State Veterinary and Phytosanitary Service as well as State Sanitary and Epidemiological Service are being merged into one single entity under the framework GoU Resolution #442 ([in Ukrainian](#)). This creates opportunity for development of streamlined and comprehensive regulatory procedures for implementation of legislation in force as well as it might pose a risk for timely and efficient implementation of governmental functions in this field.

Chapter 2: Animal Biotechnology

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal

biotechnologies such as genetic engineering and therefore included in this report. Animal genetic engineering results in the modification of an animal's DNA to introduce new traits and change one or more characteristics of the animal. Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is therefore different from the genetic engineering of animals (both in the science and often in the regulation of the technology and/or products derived from it).

Part E: Production and Trade:

a. Product Developments:

There are no known GE animal products in research or production in Ukraine at the time of this report writing.

b. Commercial Production:

There are no known GE animal products in commerce in Ukraine.

c. Exports:

There are no known exports of animal GE products from Ukraine.

d. Imports:

It is not known if Ukraine imports animal GE products. Ukraine's ability to identify those products is limited if not absent completely. It is not known if there are imports of cloned animals, or genetics of cloned animals. Lack of tracing process and testing capabilities makes this regulation declarative and dependent on exporters' voluntary statements.

Part F: Policy

a. Regulation:

The official definition of GE organisms adopted in Ukrainian legislation is very broad. It does not distinguish between the species and covers all live forms capable of self-replication or transfer of inheritable factors (including sterile organisms, viruses and viroids). In this way the genetically engineering term covers animal and fish species. Ukrainian legislation at this point does not use term "cloning" or "cloned organisms" at the same time the definition of genetic modification allows to include clones into biotechnology and spreads respective regulations over to cloned animals. The definition in Biosafety Law (referenced earlier) states: genetically modified organism is any organism in which the genetic material was changed with the use of gene transfer techniques which are not found in the nature, specifically:

- recombinant methods;

- methods that envisage an introduction into the organism of inheritable material prepared outside of the organism including microinjections, macroinjections and microencapsulations;
- cell fusion (including protoplasm fusion) or hybridization methods when live cells with new combination of genetic materials are formed through the two or more cells fusion in a way which does not occur in nature.

Since term “Cloning” has multiple meanings and definitions that changed during the twentieth and twenty-first centuries, FAS/Kyiv identified this term is present only in Law of Ukraine #2231-IV “On Prohibition of Human Cloning” ([in Ukrainian](#)), which indicates “human cloning as ... process of transferring of nucleus of a body cell into gamete of female with pre-removed nucleus”. Taking into account that this Law is not applicable to cloning of other living organisms is a good chance that products developed with use of molecular cloning (gene cloning) will fall under the existing genetically engineering definition.

Enforcement of regulations is difficult if at all possible due to absence of adequate scientific expertise of competent authorities and multiple aspects of cloning process. Voluntary declaration of the importer/exporter probably is the only tool that allows the competent authorities to monitor export/import operations for cloned or genetically engineering animals. Given the ban for circulation of non-registered GE organisms it comes as no surprise that FAS/Kyiv is unaware of any GE declarations.

b. Labeling and Traceability:

Labeling of animal or fish GE products falls under the same set of regulations as other GE organisms in Ukraine.

c. Trade Barriers:

There are no additional known trade barriers.

d. Intellectual Property Rights (IPR):

Similar to explanations above, GE animals fall under the same rules as other GE species. Ukrainian legislation does not allow for registration of GE events, but does provide some protection for registered plant varieties and breeds. Please refer to the discussion on IPR in Chapter 1, Part B of the report.

e. International Treaties/Fora:

FAS-Kyiv is unaware of any Ukrainian position on cloning or GE animals. Ukraine is Cartagena Protocol member and is trying to base its internal legislation on this document. In the vast majority of cases, Ukraine follows the EU position on the issue explaining such stand by EU association agreement and possible EU membership in the future.

Part G: Marketing

a. Market Acceptance:

Lack of clear government policy and predominately negative press coverage of biotechnology results in low market acceptance of the GE products in general and of GE animal issues particularly.

b. Public/Private Opinions:

Due to the lack of information on animal biotechnology and focus of both public and private sectors on GE plants, it is difficult to gauge public and private opinion on the issue.

c. Market Studies:

There is no known public study or studies related to animal biotechnology acceptance in Ukraine.

Part H: Capacity Building and Outreach

a. Activities:

None.

b. Strategies and Needs:

Due to the shift of the GE discussion from the scientific circles into the mass media and considering the generally negative perception of biotechnology in the society, it is very difficult to develop a strategy for the sector. The strategy for GE animals should probably be similar to those for GE plants. Use of GE animals for medical or similar humanitarian purposes probably will be met with greater tolerance in Ukraine. Use of GE plants for animal feed may also be a better step toward more tolerant attitude in the country. Developments in the justice system may eventually facilitate some GE product legalization in Ukraine.