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Ukraine

Agricultural Biotechnology Annual

Annual Report

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Report Highlights:

The biotechnology regulatory system in Ukraine is still not fully developed, in part due to the focus on major political and economic issues in 2014. Domestic production of soybeans is projected to remain high in 2014 and is expected to continue to fuel the debate over GE presence in the country.

Section I. Executive Summary:

During the first part of 2014, priorities for Ukraine were driven by political and economic events, leaving biotechnology unchanged, even though some positive developments were made in late 2013 due to good communication and mutual understanding between the Government, scientists, and private agribusiness.

In calendar year 2013, the value of imports of goods that may potentially contain genetically engineered (GE) events increased by about 30 percent compared to 2012.

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

No Genetically Engineered (GE) animal products were registered and allowed for production, sale, or use in the country.

Section II. Plant Biotechnology Trade and Production:**a. Product Development:**

To the best of FAS-Kyiv's knowledge at present Ukraine does not have any GE crops under development for commercial purposes. Though, 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 are testing 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. There are rumors in the industry that in Ukraine, a larger share of soybeans and about one-third of corn grown are genetically engineered.

c. Exports:

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

However, there were a handful of cases several years ago when corn exported from Ukraine was 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 so the cargo usually is not scrutinized at the point of unloading.

Ukraine continues trading corn with China per the agreement that was signed in 2013. So far, Ukraine has delivered several hundred thousand tons of corn in execution of this deal. China expects Ukraine to be delivering up to five million tons of corn a year for the next several years. In the phytosanitary norms, China requires Ukrainian corn to be accompanied by test results for GE presence. China does import some GE products but accepts GE-positive cargo only if the shipment is marked accordingly and contains only those GE events that are approved and allowed in China as well as in the country of origin.

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 GMOs. This source of feed is included in the approved list and published on the official Ministry of Agriculture website in the Registry of Sources of Feed and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms. The following is the link to the official document (in Ukrainian): http://vet.gov.ua/sites/default/files/Reestr_GMO.doc

Overall imports of products to Ukraine that may potentially contain GE events are shown in Table 1 below. The total trade in these goods has increased by about 30 percent in 2013 calendar year compared to that in 2012.

Table 1. Imports of Products to Ukraine that Could Be Affected by Ukraine's Biotech Regulation

Product HS Code	Product Description	2011		2012		2013		% Change
		Value (\$)	Share %	Value (\$)	Share %	Value (\$)	Share %	2012/2011
110220	Maize (Corn) Flour	694	0.0	10,340	0.0	357	0.0	-96.5
110313	Maize (Corn) Meal and Groats	236,615	0.4	174,171	0.5	169,778	0.4	-2.5
110423	Processed Maize (Corn)	88,508	0.2	-	0.0	-	0.0	0.0
120100	Soya Beans	2,123,033	3.7	1,534,635	4.8	3,901,366	9.4	154.2
210310	Soya Sauce	2,891,554	5.0	3,465,123	10.9	4,244,114	10.2	22.5
210610	Protein Concentrates	6,423,089	11.1	6,384,810	20.1	5,730,948	13.8	-10.2
230310	Maize (Corn) Gluten	151,901	0.3	108,354	0.3	153,262	0.4	41.4
230400	Soya-Bean Meal	29,196,457	50.6	3,777,367	11.9	6,057,702	14.6	60.4
350400	Protein Isolates	16,599,169	28.8	16,335,045	51.4	21,227,958	51.2	30.0
<i>Total</i>		<i>57,711,020</i>	<i>100.0</i>	<i>31,789,845</i>	<i>100.0</i>	<i>41,485,485</i>	<i>100.0</i>	<i>30.5</i>

Source of Data: State Customs Committee of Ukraine

A significant increase in soybeans and soybean products imports in Ukraine can be observed due to an increase in domestic demand for animal feed. However, soybean production in Ukraine has been growing in recent years. Thus, greater availability of soybean products in the domestic market may lower the need for imports. In addition, corn production has been on the rise in Ukraine. As a result,

corn product imports are becoming less in demand.

In 2013, China, Denmark, and Russia remained the largest suppliers of the products to Ukraine that may contain biotech events (see graph and Table 2 below).

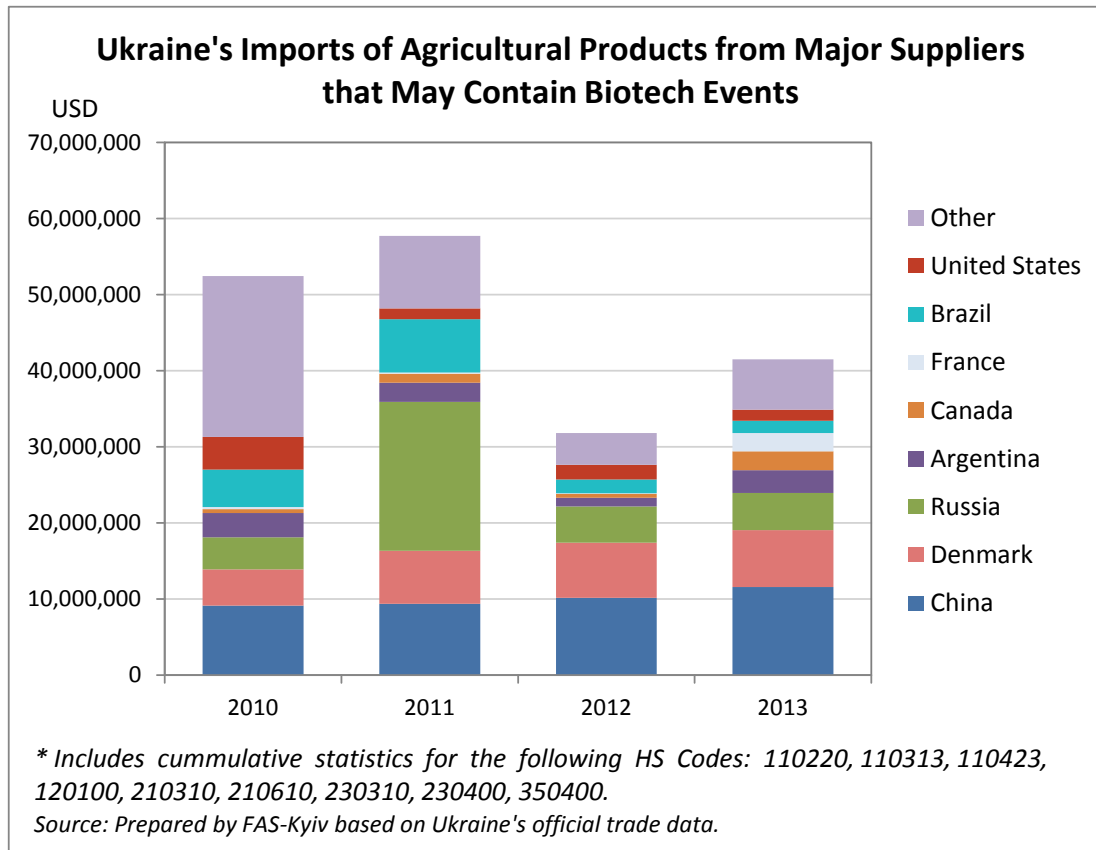


Table 2. Imports of Products to Ukraine that Could Be Affected by Ukraine's Biotech Regulation by Country of Origin, Calendar Year

Partner Country	United States Dollars				% Share			
	2010	2011	2012	2013	2010	2011	2012	2013
World	73624276	67250066	35952775	48092679	100	100	100	100
China	9120000	9339109	10144338	11546548	12.4	13.9	28.2	24.0
Denmark	4760000	6979625	7262138	7509845	6.5	10.4	20.2	15.6
Russia	4220000	19588624	4744510	4854125	5.7	29.1	13.2	10.1
Argentina	3190000	2532348	1152380	3003327	4.3	3.8	3.2	6.2
Canada	510000	1160053	520384	2504870	0.7	1.7	1.4	5.2
France	275662	147348	74134	2401196	0.4	0.2	0.2	5.0
Brazil	4920000	7008089	1810499	1591110	6.7	10.4	5.0	3.3
United States	4280000	1416776	1918538	1467268	5.8	2.1	5.3	3.1
Other	21174307	9539047	4162927	6607195	28.8	14.2	11.6	13.7

Source of Data: State Customs Committee of Ukraine

e. Food Aid Recipient Countries::

Ukraine is not a food aid recipient country.

Section III. Plant Biotechnology Policy:**a. Regulatory Framework:**

The main legislation that governs biotech events in Ukraine is the [Law of Ukraine #1103-16 \(Ukr\)](#) “On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms (GMOs)”, signed by the President of Ukraine and effective since June 21, 2007. The latest amendments to this law took place in April 2014 and concentrate for the most part of the definition of the authority and description of the responsibilities of various government agencies. No changes in regard to GE regulation were made recently. Please follow the link above to the most current version.

There were several draft laws developed and then abandoned in the recent year that were aimed at fortifying the nonfunctioning GE plant registration system in the country.

Initiatives in 2013, when the industry and the State representatives suggested establishment of a three year transition period for GE product registrations in Ukraine that would allow some use of GE crops/products while their registration and approval would have been in progress, seems to be put to hold. FAS-Kyiv believes that political and economic instability in Ukraine in 2014 would keep the Government of Ukraine occupied with priorities other than GE regulation issues.

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 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 GMOs 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) that was temporarily allowed for use in Ukraine in the past and then was taken off of the list for some time until recently.

c. Field Testing:

No GMO 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 GE content indicated on food products that are sold to Ukrainian consumers. The Government of Ukraine defines GE presence in a product according to the GOU [Resolution #661 \(Ukr\)](#). At present, 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, such food product has to be labeled "Contains GMO."

h. Trade Barriers:

The main trade barrier in Ukraine is that no GE events (Roundup-Ready Soybeans (MON 40-3-2) are allowed in a form of meal for feed use – note this is a product, not a GE event) are registered and allowed for importation or commercial use in the country. The legislation and the framework for approval process 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 been developed in Ukraine yet. 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 biotech-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:

GE presence 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 addition, grains and oilseeds that are exported from Ukraine also get checked for GE event presence. 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 above).

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. GE 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 GMO presence (test results showed GMO content of above zero level) had to be prohibited from entering the market in Ukraine.

Section IV. Plant Biotechnology Marketing Issues:

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 the first half of 2014 because political and economic issues took priority.

c. Marketing Studies:

An economic study on the effects that GMO use may have for Ukrainian agriculture and the country's economy in general 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 are needed 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.

Section V. Plant Biotechnology Capacity Building and Outreach:

a. Activities:

The U.S. Government has been sponsoring activities in Ukraine to educate the public on the topic of biotechnology and to promote science-based approach to the assessment and use of GE products. In 2013 FAS-Kyiv continued advocating for science based approach when dealing with GE events and agricultural products and emphasized it during various industry events. Post also engaged in experience sharing with the Working Group on Biotechnology established in 2012, it included representatives from various GoU ministries, legislators, scientists, and industry associations, had been quite active until economic and political situation in late 2013 took priority.

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 for the interested parties to 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 2013) indicate that general public in Ukraine still has an opinion about biotechnology that is either based on emotional perceptions or on some misleading news stories that are not based on sound science.

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.

Section VI. Animal Biotechnology:**Part E: Production and Trade:****a. Product Developments:**

To the best of FAS-Kyiv knowledge there are no GE animal products in research or production in Ukraine at the time of this report writing.

b. Commercial Production:

To the best of FAS-Kyiv knowledge there are no GE animal products in commerce in Ukraine.

c. Exports:

To the best of FAS-Kyiv knowledge Ukraine does not export animal GE products.

d. Imports:

To the best of FAS-Kyiv knowledge Ukraine does not import animal GE products. Ukraine's ability to identify those products is limited if not absent completely.

Part F: Policy

a. Regulation:

The official definition of GM 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 GMO 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 GMOs and spreads respective regulations over to cloned animals. The definition 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 is unaware whether or not cloning falls under the existing regulations. There is a good chance that products developed with use of molecular cloning (gene cloning) will fall under the existing GMO 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 animal GMOs. Given the ban for circulation of non-registered GMOs it comes as no surprise that FAS/Kyiv is unaware of a single voluntary GMO declaration.

b. Labeling and Traceability:

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

c. Trade:

To the best of FAS-Kyiv knowledge there is no trade in GE or cloned animals. Lack of tracing process and testing capabilities makes this regulation declarative and totally dependent on exporters’ voluntary statements.

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 the Chapter 1 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 long run.

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:

To the best of FAS-Kyiv knowledge, there are no public studies that relate to animal biotechnology acceptance conducted 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 not be very different from 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.