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Ukraine

Agricultural Biotechnology Annual

Agricultural Biotechnology Annual Report

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Report Highlights:

The biotech and regulatory system in Ukraine is still under development. The value of imports of goods that may potentially contain genetically engineered (GE) events in 2012 has decreased by 44 percent compared to 2011 figures. Domestic production of soybeans is projected to remain high in 2013 and is expected to continue to fuel the debate over GE presence in the country. The Minister is looking to modify the current regulations to allow experimental testing of GE products in the country.

Section I. Executive Summary:

There were some developments in Ukraine in the recent months that relate to the state of affairs for Genetically Engineered (GE) products in the country. According to the recent statement of the Minister of Agricultural Policy and Food, the Government of Ukraine (GOU) could conduct state experiments with GE crops, thus indicating an interest in the topic that could result in some movement towards finalizing the GE product registration and approval process that so far has some missing links.

A working group that was established to include several ministries as well as industry groups that has is expected to conduct more in-depth analysis of the legislation needs and propose viable solutions that would satisfy both the industry's interests and the State's needs.

Section II. Plant Biotechnology Trade and Production:

a. Product Development:

To the best of FAS-Kyiv 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:

On occasion, there are reports of some food products in Ukraine testing positive for GE presence which indicates there may be some sources present in the country. In addition, soybeans and corn grown in Ukraine are still considered the crops of concern. As in the previous years, the rumors remain around the industry that the majority of the soybeans grown in Ukraine are genetically engineered and that about a third of corn grown in Ukraine is also a biotech crop.

c. Exports:

Ukraine does not export any GE products due to the fact that no GE products have been officially registered and allowed for use and commercial sale in the country at present.

However, there were a handful of cases over the past several years when corn exported from Ukraine was tested GE-positive upon arrival at the final destination.. However, most grains and oilseeds exported from Ukraine are delivered to the destinations that do not require strict GE monitoring so the cargo is not usually scrutinized at the ports of unloading.

On the other hand, Ukraine has recently signed an agreement with China for a delivery of 4-5 million tons of corn a year for the next three years. In the phytosanitary norms China requires Ukrainian corn to be accompanied by GE-test results. 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:

Ukraine does not allow imports of GE products. On, occasion, some food products are tested positive for GE presence, which indicates there may be some sources present in the country or some GE presence may be leaking in with the imported goods.

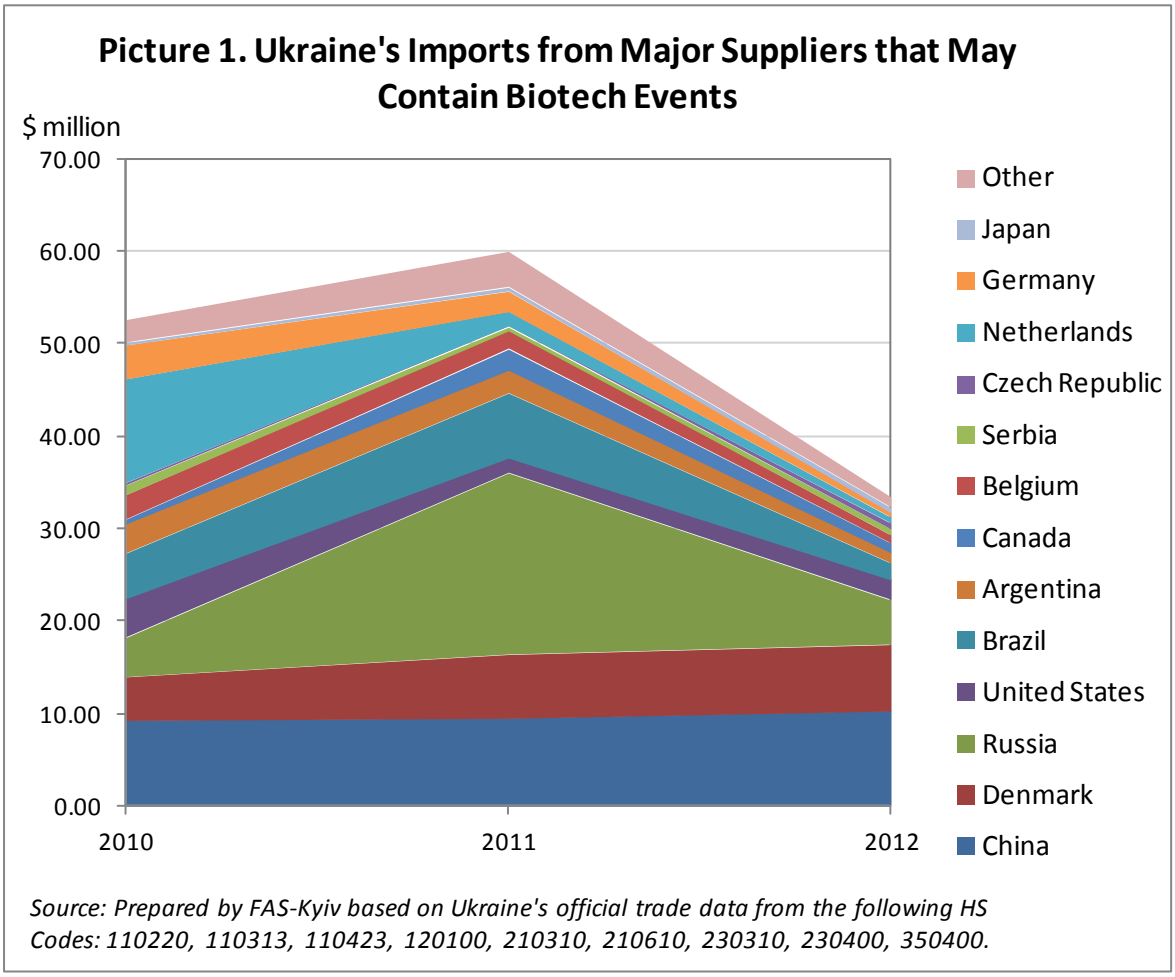
Imports of products to Ukraine that may potentially contain GE events are shown in Table 1 below. The overall quantity of trade in these goods has decrease in 2012 (calendar year) compared to that in 2011. A significant reduction in soybean and soybean product imports in Ukraine can be observed due to the increase in domestic soybean production in the recent years and thus greater availability of the products in the domestic market. In addition, corn production is on the rise in Ukraine, so corn product imports are becoming less in demand.

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

Product HS Code	Product Description	2010		2011		2012		% Change
		Value $ million	Share %	Value $ million	Share %	Value $ million	Share %	2012/ 2011
110220	Maize (Corn) Flour	0.01	0.0	0.00	0.0	0.01	0.0	1389.1
110313	Maize (Corn) Meal and Groats	0.27	0.5	0.24	0.4	0.17	0.5	-26.4
110423	Processed Maize (Corn)	0.00	0.0	0.09	0.2	0.00	0.0	-100.0
120100	Soya Beans	1.51	3.0	2.12	3.7	1.53	4.8	-27.7
210310	Soya Sauce	2.30	4.5	2.89	5.0	3.47	10.9	19.8
210610	Protein Concentrates	7.02	13.8	6.42	11.1	6.38	20.1	-0.6
230310	Maize (Corn) Gluten	0.06	0.1	0.15	0.3	0.11	0.3	-28.7
230400	Soya-Bean Meal	24.93	48.9	29.20	50.6	3.78	11.9	-87.1
350400	Protein Isolates	14.86	29.2	16.60	28.8	16.34	51.4	-1.6
Total		***50.96***	***100.0***	***57.71***	***100.0***	***31.79***	***100.0***	***-44.92***

Source of Dataa: State Statistics Committee of Ukraine

In 2012, China, Denmark, and Russia remained the largest suppliers of the products to Ukraine that may contain biotech events (see Picture 1).



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

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. This legislation was amended a number of times, please follow the link above to the most current version. The latest amendments took place in late 2012 and concentrate for the most part of the definition of the authority and detailed description of the responsibilities of the government agencies that monitor and control the environmental aspects of GE presence if any in the country. The Ministry of Science and Education was made responsible for issuance of the licenses for genetic engineering activities in the closed systems and also issues permits for importation of yet to be registered GE crops for testing (the samples ought to be used only for research purposes and for state trials).

There was 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. Even though GE products are yet to be allowed for registration in the country the legislators are working hard to prepare the system for such an event.

As a part of an effort initiated by agricultural businesses through their industry associations and the main ministries and educators in Ukraine, a public discussion on implementation of the state biosafety legislation and proposed amendments to related legislation took place in May 2013 in Ukraine. The industry groups as well as the government representatives indicate their awareness of the fact that some GE products may exist in Ukraine regardless of its legal status. A general recognition of the need to act upon the issue seems to have evolved into more formal conversations at this point. A working group on biosafety issues related to GE presence and its turnover in Ukraine was created in late 2012. The group has been working on proposals for the GOU's consideration that would allow a sorting out the major legislation issues and confusions related to biotech regulation in Ukraine.

According to this working group, the following is a list of major actions that the government needs to act upon to make any significant movement towards the readiness of the Ukrainian legislation for GE approval and accountability in the country.

1. Define the action of modification as a part of the registration process
2. Develop intellectual property protection regulation for GE events
3. Establish a minimum (technically impossible to omit) level of GE presence for imported products
4. Set registration expiration terms for GE events
5. Establish a single-point of contact for GE applications (the Ministry of Education and Science of Ukraine potentially may be charged with this function)
6. Allow to have a single application for multiple GE registration aspects
7. Allow for the biotech risk assessments done by recognized foreign entities to be accepted as legitimate
8. Develop and amend existing legislation to:
    a. Define and develop legislation to allow GE testing in Ukraine in the open systems
    b. Develop a process of and regulation of the veterinary and sanitary tests for GE presence in animal feed
    c. Establish rules for the state GMO testing labs placement and coordination of work with the state GE monitoring agency

In addition to the above mentioned initiative, the industry has also 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 may be in progress. FAS-Kyiv believes that such provision is desired by the industry to legalize the use of GE products that already exist in Ukraine while their official registration and approval have not yet been granted.

Also, in late spring 2013, the State Veterinary and Phytosanitary Service of Ukraine have formed a committee that will consider the issues of state registration of GE plants or products thereof. The state agency is working on developing the procedures for the State Registry of GE feeds, feed sources and veterinary drugs that contain GE traits or were made with GE events.

b. Approvals:

Over the last several years Ukraine has attempted to approach the issue of GE approvals in the country. However, the approvals system has not been developed yet. 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, no new GMO containing feeds were officially approved in Ukraine. In addition, Monsanto's Roundup-Ready soybeans MON 40-3-2 that were previously temporarily allowed for use in the country no longer are.

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 are registered and allowed for importation or commercial use in the country. The legislation and the framework for approval process is not complete and has not been consistently moving in that direction

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. Procedure can take years in different courts resulting in very week 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 of the world. 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 talks 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 industry is minor in the country mainly due to the lack of investment the feasibility of such development is dependent on the State support policy as well as on the State 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 result, 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. 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.

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. However, an overall positive tone about biotech use has been detected in the country in recent weeks.

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 sponsored 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 the fall of 2012 a seminar – Plant Biotechnology – was organized by the European Business Association that was sponsored by the industry groups and supported by FAS-Kyiv. Participants learned about the nature of genetic engineering in various life forms and some specifics about the technology. Also, the materials presented at the seminar highlighted the differences between the approaches in legislation and approval processes that are used in various regions in the word. Discussions that were raised as a result once again brought about the fact that general public usually has an opinion about biotechnology that is either based on emotional perceptions or on some misleading news stories that have nothing to do with scientific facts in regard to biotechnology. Also, several agricultural industry experts were sponsored to receive professional short course training on biotechnology in the major US public institutions.

b. Strategies and Needs:

The general public in Ukraine is still lacking awareness of the science-based facts about the biotechnology and

GE products. It would be good for interested parties to join the forces in make these facts known to the consumers to improve the generally negative public opinion and to show their support of the objective and facts-based decision making. Even though the process of changing the public perceptions may slow it is necessary for the technology to be received well by Ukrainians for it to have any feasible economic value created in the country.

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 in unaware of 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 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 future EU association agreement and possible EU membership in a long run.

Part G: Marketing

a. **Market Acceptance:**

Lack of clear government policy results 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 are no public studies related to animal biotechnology acceptance.

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.