



THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

**Date:** 10/11/2016

**GAIN Report Number:** UP1619

## **Ukraine**

### **Agricultural Biotechnology Annual**

### **Ukraine Biotechnology Annual**

**Approved By:**

Dwight Wilder, Agricultural Attaché

**Prepared By:**

Denys Sobolev, Agricultural Specialist

**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. The value of imports of agricultural and food products that may potentially contain genetically engineered events is constantly decreasing due to a combination of a deteriorated economic situation and the growing agricultural production and building up of food processing industry.

## REPORT OUTLINE

### Report Highlights:

Section I: Executive Summary	2
Section II: Plant and Animal Biotechnology	3
CHAPTER 1: PLANT BIOTECHNOLOGY	3
PART A: Production and Trade	3
PART B: Policy	7
PART C: Marketing	14
CHAPTER 2: ANIMAL BIOTECHNOLOGY	15
PART D: Production and Trade	15
PART E: Policy	16
PART F: Marketing	17
ANNEX I	18

### **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 general, public opinion about biotechnology in Ukraine is still negative. However, farmers indicate that genetically engineered (GE) crops are less costly in terms of input costs and provide a more stable outcome. Both of these opinions are reflected at the draft legislation developed and pending consideration by Ukrainian Parliament.

In the late 2014, national legislation was amended in order to eliminate duplicating control functions of various governmental authorities over the processed products containing GE components as well as their labelling. The leadership of the State Food Safety and Consumer Protection Service of Ukraine (SFSCPS) indicated its commitment to enforce the new biosafety legislation.

Despite the new national legislation establishing biotech registries, due to the lack of required sub-legislation only one biotech event (mentioned below) is legal for distribution in Ukraine for the purpose of animal feed. No other biotech events are currently legal for import, production, or sale in Ukraine.

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

In calendar year 2015, due to the turbulent political and economic environment, the value of imported goods that may potentially contain GE events (mainly processed food products) decreased to \$19 million, 30 percent below 2014 levels. Exports of the mentioned goods (mainly corn and soybeans) remained at a level of \$4 billion in 2015 calendar year, around four percent below compared to 2014.

## **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 (national) research institutions in Ukraine.

#### b. Commercial Production:

There is no legal commercial production of GE products in the Ukraine. However, testing of corn and soy implies there is GE production. Reports indicate that some food products in Ukraine occasionally test positive for GE presence, This indicating that there may be some sources of GE seed present in the country or brought in from abroad. Industry rumors in Ukraine suggest that of the products destined for export, that 60-70 percent of soybeans and about 5-10 percent of corn grown tested GE-positive.

Over the last few years the share of production of GE soybeans is believed to remain stable as they could be reproduced on-farm as part of cost cutting measures practiced by small and medium producers. Some farmers indicate that GE soybeans are less costly in terms of input costs and provide a more stable outcome.

At the same time, illicit production of GE corn is believed to be declining due to limited access to smuggled seeds by farmers in combination with significant improvement of productivity of conventional hybrids supplied by both multinationals and local seed producers.

#### c. Exports:

At the time of this report writing, 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.

However, there have been documented cases when exported corn from Ukraine tested GE-positive upon arrival at the buyer's port location. In August 2016, the Russian Federation filed WTO Notification [G/SPS/N/RUS/128](#) notifying temporary restrictions on the import of unregistered feed produced by Ukrainian enterprises due to repeated detection of GE components. This complaint might be stemming from recent legislative amendments prohibiting cultivation of GE plants and breeding of GE animals on the territory of the Russian Federation (for more details please refer to [GAIN Report RS1634](#)).

Despite this isolated case, most grains and oilseeds exported from Ukraine are delivered to destinations that do not require strict GE monitoring, thus, the cargo usually is not scrutinized at the point of unloading. Otherwise these commodities are dispatched to countries with established agricultural biotechnology regulations that authorize specific GE crops to be used for food and/or feed purposes.

Overall exports of products from Ukraine that may potentially contain GE events are shown in Table 1 below. The total trade in these goods remained at the level of \$4 billion in 2015 calendar year, around 4 percent below the previous year.

**Table 1. Major Exports from Ukraine Subject to Biotechnology Regulation**

Product HS Code	Product Description	2013		2014		2015		% Change
		Value (\$)	Share %	Value (\$)	Share %	Value (\$)	Share %	
100590	Whole corn	3,806,574,792	96.6	3,323,288,898	79.0	2,992,955,878	74.2	-9.9
110220	Maize (Corn) Flour	1,080,679	0.0	580,517	0.0	279,442	0.0	-51.9
110313	Maize (Corn) Meal and Groats	12,104,793	0.3	7,141,292	0.2	5,283,535	0.1	-26.0
110423	Processed Maize (Corn)	8,078,481	0.2	37,369	0.0	682,937	0.0	1727.5
120100	Soybeans (seed)	1,193,014	0.0	-	0.0	-	0.0	-
120190	Soybeans (non-seed)	-	0.0	701,020,599	16.7	805,361,300	20.0	14.9
120810	Soybean meals and flours	233,770	0.0	55,804	0.0	-	0.0	-100.0
150710	Soybean Oil (non-refined)	73,091,590	1.9	94,714,303	2.3	106,831,474	2.6	12.8
150790	Soybean Oil (refined)	1,271,707	0.0	832,402	0.0	39,615	0.0	-95.2
210310	Soya Sauce	170,359	0.0	206,214	0.0	190,282	0.0	-7.7
210610	Protein Concentrates	9,409	0.0	20,842	0.0	11,821	0.0	-43.3
230310	Maize (Corn) Gluten	17,236,221	0.4	15,563,097	0.4	14,276,630	0.4	-8.3
230330	Distillers' Dried Grains	3,962,455	0.1	3,884,599	0.1	2,326,033	0.1	-40.1
230400	Soybean Meal	11,888,761	0.3	55,598,666	1.3	102,988,909	2.6	85.2
350400	Protein Isolates	3,101,404	0.1	3,754,735	0.1	2,699,182	0.1	-28.1
<b>Total</b>		<b>3,939,997,435</b>	<b>100.0</b>	<b>4,206,699,337</b>	<b>100.0</b>	<b>4,033,927,038</b>	<b>100.0</b>	<b>-4.1</b>

Source of Data: State Fiscal Service of Ukraine

Corn is a major export item for Ukraine, and China is among its largest buyers of corn as the result of an agreement signed in 2013. 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, namely 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 of the SFSCPS 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 2 below. The total trade in these goods decreased to \$19 million in 2015 calendar year, over 30 percent below the previous year. The continuous decrease of imports is an indication that the national economy has not fully recovered from the 2013-14 crisis featuring significant fluctuations of the exchange rate which made imported products less competitive on the Ukrainian market.

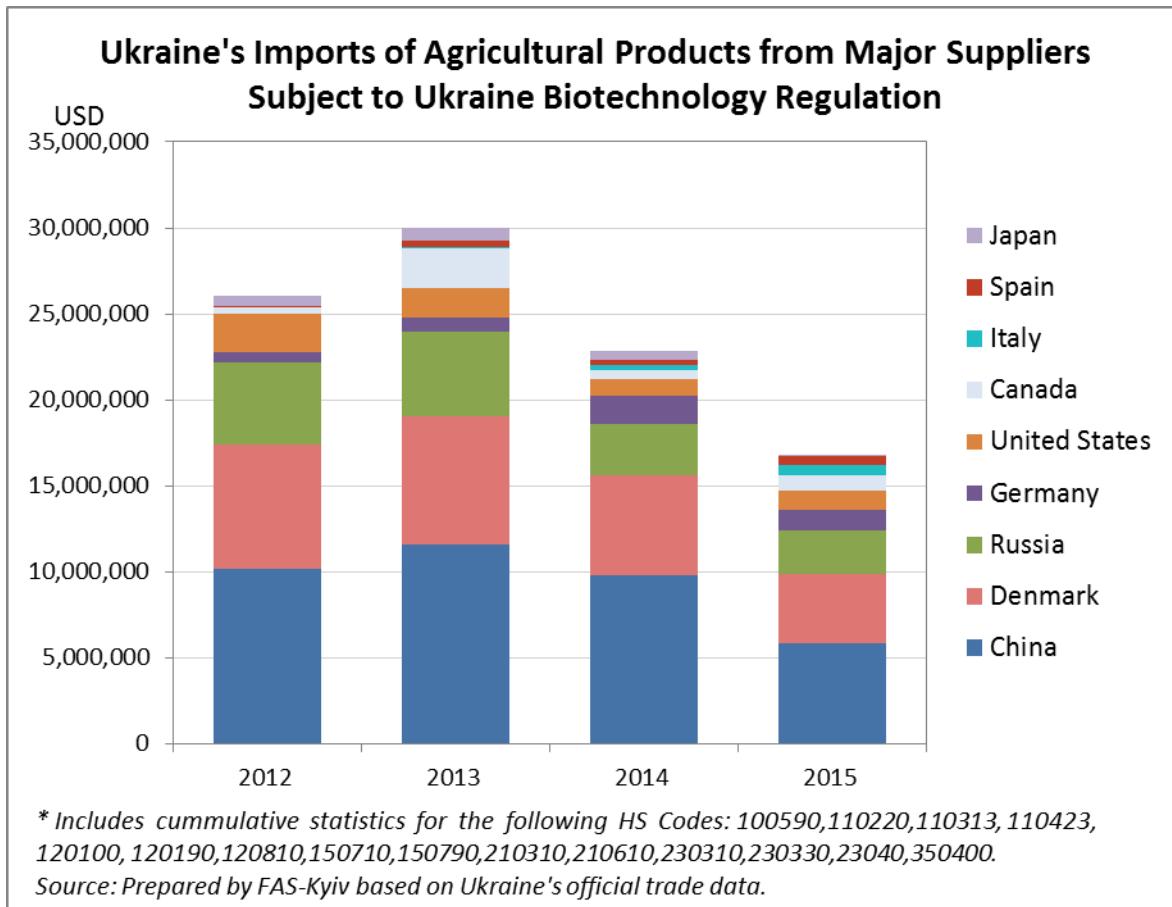
**Table 2. Major Imports to Ukraine Subject to Biotechnology Regulation**

Product HS Code	Product Description	2013		2014		2015		% Change
		Value (\$)	Share %	Value (\$)	Share %	Value (\$)	Share %	
100590	Whole corn	736,909	1.7	528,622	1.9	494,240	2.6	-6.5
110220	Maize (Corn) Flour	357	0.0	-	0.0	5,067	0.0	-
110313	Maize (Corn) Meal and Groats	169,778	0.4	85,733	0.3	11,757	0.1	-86.3
110423	Processed Maize (Corn)	-	0.0	37,369	0.1	-	0.0	-100.0
120100	Soybeans (seed)	3,631,858	8.6	-	0.0	-	0.0	-
120190	Soybeans (non-seed)	-	0.0	520,494	1.9	1,056,913	5.6	103.1
120810	Soybean meals and flours	52,978	0.1	67,948	0.2	62,669	0.3	-7.8
150710	Soybean Oil (non-refined)	36,714	0.1	55,593	0.2	2,919	0.0	-94.7
150790	Soybean Oil (refined)	86,099	0.2	91,530	0.3	43,254	0.2	-52.7
210310	Soya Sauce	4,244,114	10.1	3,342,968	12.2	1,910,481	10.1	-42.9
210610	Protein Concentrates	5,730,948	13.6	4,108,982	15.0	3,023,145	15.9	-26.4
230310	Maize (Corn) Gluten	153,262	0.4	83,626	0.3	62,126	0.3	-25.7
230330	Distillers' Dried Grains	100,388	0.2	22,075	0.1	17,383	0.1	-21.3
230400	Soybean Meal	6,057,702	14.3	1,716,916	6.3	1,061,208	5.6	-38.2
350400	Protein Isolates	21,227,958	50.3	16,780,356	61.1	11,256,801	59.2	-32.9
<b>Total</b>		<b>42,229,065</b>	<b>100.0</b>	<b>27,442,212</b>	<b>100.0</b>	<b>19,007,963</b>	<b>100.0</b>	<b>-30.7</b>

Source of Data: State Fiscal Service of Ukraine

A significant decrease of imports for soybeans, corn, and products of processing thereof to Ukraine could also be attributed to the increased volumes of production for these crops during recent years. Another factor in the declining imports is a buildup and upgrade of Ukraine's processing capacities for supplying a variety of processed products to the domestic market.

In 2015, China, Denmark, Russia, Germany and the United States remained the largest suppliers of products to Ukraine that may potentially contain GE events (see graph and Table 3 below).

**Table 3. Major Exporters of Products Subject to Ukraine Biotechnology Regulation, Calendar Year**

Partner Country	United States Dollars				% Share			
	2012	2013	2014	2015	2012	2013	2014	2015
<b>World</b>	<b>33,032,282</b>	<b>42,229,065</b>	<b>27,442,211</b>	<b>19,007,964</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>
China	10,142,472	11,547,106	9,820,911	5,840,235	30.7	27.3	35.8	30.7
Denmark	7,262,138	7,509,844	5,758,348	4,044,690	22.0	17.8	21.0	21.3
Russia	4,764,986	4,932,359	3,032,576	2,515,376	14.4	11.7	11.1	13.2
Germany	572,513	765,615	1,650,830	1,230,610	1.7	1.8	6.0	6.5
United States	2,251,662	1,768,376	952,581	1,080,162	6.8	4.2	3.5	5.7
Canada	398,291	2,319,536	506,313	890,174	1.2	5.5	1.8	4.7
Italy	13,900	19,920	268,723	611,786	0.0	0.0	1.0	3.2
Spain	34,986	385,999	306,203	511,271	0.1	0.9	1.1	2.7
Other	7,591,335	12,980,312	5,145,726	2,283,658	100.0	100.0	100.0	100.0

Source of Data: State Fiscal Service of Ukraine

**e. Food Aid:**

Ukraine is not normally a food aid recipient country. However, starting in January 2016, the United Nations World Food Program started providing food aid to conflict-affected areas of Eastern Ukraine. Ukraine does not provide food aid to other countries.

**f. Trade Barriers:**

The main trade barrier in Ukraine is that no GE events are allowed; except for Roundup-Ready Soybeans [MON 40-3-2] in the form of meal for the purpose of animal feed use (note that meal is a product, not a GE event). Despite establishing legal registries, the underlying legal framework for establishing an approval process for the release of GE crops in the open system are not complete and have not been consistently moving forward (please refer to section “Regulatory Framework” for more details).

**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 redistribution of responsibilities between various government agencies, including:

- The Cabinet of Ministers: oversight and control over various Governmental agencies implementing the Biosafety Law as well as approval of regulations in the GE field;
- Agency establishing state policy for science and education: support of GE research and development (R&D); development and enforcement of safety criteria for GE R&D in a closed system;
- Agency implementing state policy for intellectual property rights (IPR): protection of national and international patents safeguarding IPR for GE R&D;
- Agencies implementing state policy for environmental protection: state examination of GE intended to be released into the open system; state registration of plant protection means derived from GE; issuing permits for GE release into the open system; biosafety and genetic control for biological objects in environment during the development, testing and commercial use of GE in the open system;
- Agency developing state policy for environmental protection: development of criteria for evaluation of potential risks for GE impact to the environment;
- Agency developing state policy for public health: development of criteria for evaluation of potential risks from GE and GE-derived products to human health taking into consideration scientific information and international experience;

- Agency implementing state policy for public health: ensuring supervision and control over GE safety for human health during GE development, testing and use in open system; conducting state examination GE safety for human health;
- Agency establishing state policy for veterinary medicine and food safety: development of regulations for ensuring biosafety of GE during development, testing and use of GE in open system; conducting state testing and registration of GE plants, animals and microbes used in agriculture;
- Agency implementing state policy for food safety: state registration of GE sources for foodstuffs, feeds, feed additives and veterinary medicines; approving methods for GE identification and detection; monitoring of GE-derived feeds, feed additives and veterinary medicines to verify presence of GE sources;
- Agency implementing state policy for control in agricultural sector: ensuring biosafety of GE plants during development, testing and use of GE in open system.

On September 20, 2015, a new law became effective: the Law of Ukraine #1602-VII “On Amendments to Certain Legislative Acts of Ukraine regarding Foodstuffs” (Law #1602) ([in Ukrainian](#)). For more information about this law please refer to our [GAIN Report UP1538](#). This legislation introduced a number of amendments to the Biosafety Law. These were mainly 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 circulation 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 of biotechnology products;
- Draft Law #1844 ([in Ukrainian](#)) envisages implementation of simplified registration for GE plants and products that are 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 of 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.
- Draft Law # 3446 ([in Ukrainian](#)) and Draft Law # 4968 ([in Ukrainian](#)) both envisage moratorium for commercial production GE plants and market circulation of GE products while allowing in GE imports for R&D purposes. However, Draft Law # 4968 suggests temporal moratorium until year 2023, while Draft Law # 3446 intends to set the permanent ban.

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, including:

- 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 trans-boundary 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.

Please refer to Annex 1 at the end of this report depicting regulatory framework governing GE circulation in Ukraine.

**b. Approvals:**

In accordance with Law #1602-VII (please refer to section “Regulatory Framework” for more details) a

new state registration of GE events of food products, feeds and drugs has been introduced, replacing the previous system of registration of products containing GE. All related previous State Registers (that were never created with exception of the Register of Feeds) have been voided. The sanitary-epidemiological expertise of the products produced with GE use to justify its safety for human health has been voided. No registration has been required for foods, feeds, drugs, veterinary drugs and cosmetics that contain GEs or produced with GE use.

The GoU in its Resolution #808 ([in Ukrainian](#)) incorporates procedures for state testing and approval of GE agricultural plants for their further use in open systems (meaning cultivation). The owner of a GE plant variety submits a dossier to the Authority implementing state policy for control in the agricultural sector (Authority). The dossier should contain:

- information about the owner (individual or legal entity);
- detailed technical description GE plant variety;
- conclusions of state authorities indicating compliance of GE plant variety to bio- and genetic safety requirements;
- paper confirming that GE plant variety is safe to use;
- report by accredited institution that does actual testing.

The Authority has 120 days for consideration of the dossier and could grant state registration of a GE plant variety for five-year period.

Over the last several years Ukraine has attempted to approach the issue of GE approvals in the country. However, the approvals system remains underdeveloped at this time. In the Biosafety Law (please refer to section “Regulatory Framework” for more details) the legislation defines the roles and functions of the various government agencies as that monitor or test for GE presence. So far, no registration criteria that could lead to approvals or rejections have been clearly identified and/or written into law.

Ukraine has functional regulatory system that enables access of GE human drugs to the domestic market ([in Ukrainian](#)), as well as inclusion in the registry of approved drugs (e.g. insulin produced using recombinant DNA technology).

The only one agricultural product that contains approved GE content was officially registered and approved for feed use in Ukraine. This product is Monsanto’s Roundup-Ready soybeans MON 40-3-2 (please refer to section “Imports” above more information), temporarily allowed for use in Ukraine since July 2013 and gradually extended until July 2018.

Ukraine also approved the Antigen V-RG oral vaccine for carnivores “BrovaRabies V-RG” until October 2020, to be used for veterinary purposes.

**c. Stacked or Pyramided Events Approvals:**

No specific approval process for stacked events defined.

**d. Field Testing:**

Field testing is part of the official approval process in accordance with the Biosafety Law (please refer to section “Regulatory Framework” for more details).

In accordance with Resolution # 308 “On Approval of Procedures for Issuing Permit for State Testing (Approval) of ‘GMOs’ in Open System” ([in Ukrainian](#)) a permit for every field test of every single GE event should be issued by the authority establishing state policy for environmental protection.

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

**e. Innovative Biotechnologies:**

Ukraine has not determined a regulatory status for newly developed innovative biotechnologies.

**f. Coexistence:**

Since Ukraine regulations for GE cultivation are undeveloped, the country has not developed a 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 section), in case a product contains GE materials, and in case their share in product exceeds 0.9 percent in any of the ingredients of product, which includes, composed of, or made of GE materials, food product labeling must contain label “Containing GMO.”

“GMO-free” compulsory labeling for products that does not contain GE has been discontinued.

However, producers/exporters may choose to use a “GMO-free” label. In this case, absence of GE must be confirmed as stipulated by existing regulations. Lack of GE presence information from the ingredients suppliers may serve as sufficient reason for such labeling.

**h. 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 (including the plant itself and products of processing thereof):

- Soybeans;

- Corn;
- Tomatoes;
- Squashes;
- Melons;
- Papaya;
- Chicory;
- Sugar beets;
- Rapeseed;
- Flax oil;
- Cotton oil;
- Wheat;
- Rice;
- Infant formula and specialty food products that contain abovementioned plants and products of processing thereof;
- Yeast and leaven including products containing them.

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 the Grain Quality Certificate for Grain and Products of Processing thereof, which was approved by the GoU Resolution #848 ([in Ukrainian](#)). However, according to industry sources the commercial commodity batches are routinely express-tested for GE presence at inland silos and port transshipment terminals. This is primarily done to avoid having a low-level presence of a GE event in GE-free batches that are usually bought and sold with premiums attached. Another rationale is compliance with the Biosafety Law's requirements to exercise controls over GE events.

All planting seed imports are required to be tested for GE presence upon arrival at the Ukrainian border. Additionally, there is a requirement to test for GE presence prior to shipment with results reflected in the cargo's accompanying documentation. Genetically engineered presence tests for planting seeds are done by designated state testing labs in Ukraine. Samples are taken from seed shipments that arrive at the border and are sent to the testing lab while the cargo stays at the customs warehouse awaiting the results. The SFSCPS issues certificates that allow transportation and use of imported planting seeds in the country based on the cargo's accompanying documents.

i. **Low Level Presence (LLP) Policy:**

Ukraine does not have a defined LLP policy. From FAS-Kyiv's experience, agricultural products tested for GE presence with test results showing GE content above a zero level are prohibited from entering the market in Ukraine.

j. **Additional Regulatory Requirements:**

After expiration of the five-year period of registration, renewals can be attained by completing the registration procedure once again (please refer to "Approvals" section for more details). The state registration could be revised and subsequently revoked in cases where there are identifiable factors endangering human health and the environment due to the production of that GE plant variety in the

open system.

**k. Intellectual Property Rights (IPR):**

The Intellectual Property Rights protection policy for GE events has not yet been developed in Ukraine. Ukrainian legislation, at its current level of development, does not accommodate a registration process for GE events, but it does provide some protection for registered plant varieties and breeds. If a GE plant variety or animal breed could become registered in Ukraine (which has only been the case for one event, MON 40-3-2) the owner of the plant variety will have to rely on massive and cumbersome general legal procedures with all in-country partners in an attempt to secure their (owner's) rights. In most cases the owner would depend on the Ukrainian civil court system (which is not familiar with complicated IPR cases) to litigate cases. The burden of proof would be entirely on the petitioner, and overall legal and enforcement costs would likely be prohibitively high. Proceedings could take years in different courts, resulting in very weak protection. Due to the lack of registered GE plant varieties and animals and/or import procedures this IPR discussion is largely academic in nature, as there is limited legal precedence or experience.

**l. Cartagena Protocol Ratification:**

Ukraine is a member of the Cartagena Biosafety Protocol (CBP) which entered into force in the country in 2003.

**m. International Treaties/Fora:**

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

In order to promote the country's image as a non-GE soybean supplier, the representative of the Ministry of Agricultural Policy and Food of Ukraine (MAPF) [signed the Danube Soya Declaration](#) in June 2015. This step did not have an immediate effect on the market; however it could be seen as an indication that Ukraine might follow the footsteps of the EU in a gradual opting out from production of biotech crops in the long run.

**n. Related Issues:**

Recently, there have been some discussions in the agriculture industry about possible use of GE crops for biofuel production in Ukraine, which could open the doors for commercial production of GE events, but leave the human consumption issue aside. However, since the 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 subsidies. To date, no draft legislation has been proposed to allow GE crop production for biofuels feedstock.

## **Part C: Marketing**

**a. Public/Private Opinions:**

In general, individual large producers and grain and oilseed traders in Ukraine have not been very vocal to support the development of GE commercialization or use in the country. The biotechnology topic, in general, was not given much attention in Ukraine in 2015 – early 2016 because of the country's internal reform efforts and broader geo-political and economic issues took priority.

The Ukraine public lacks awareness of the science-based facts about biotechnology and GE products. Since our previous annual report, industry discussions indicate that the Ukraine public has a negative opinion about biotechnology that is either based on emotional perceptions or due to misleading news stories that are not based on sound science.

Even though the process of changing public perceptions may be slow, to create regulations that allow for GE cultivation and commercialization, it is necessary to have the technology supported by the Ukrainian public. In addition, to fostering positive regulatory developments, strong interest and support from local producers and potential users of the technology is crucial.

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 or even ban GE 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 “Regulatory Framework” section of this report for more information).

Currently a number of Governmental Agencies responsible for implementation of the Biosafety Law (referenced earlier), including the State Veterinary and Phytosanitary Service and the State Sanitary and Epidemiological Service have been merged into one single entity – the SFSCPS. For more information on this authority please refer to our latest [GAIN Report UP1544](#). This creates opportunity for development of streamlined and comprehensive regulatory procedures for implementation of legislation in force.

The leadership of the SFSCPS indicated its commitment to enforce biosafety legislation (please refer to section “Regulatory Framework” for more details) and for farmers to stop production of unregistered GE plants in Ukraine by 2017.

**b. Market Acceptance:**

Ukraine continues to be a challenging market for biotechnology promotion. The major factors causing this situation are the generally negative public opinions, the challenge of providing excessive required government paperwork, gaps in GE testing regimes, and gaps in the approval system.

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 oilseeds including rape, soya beans, sugar beets, and corn for Ukrainian agriculture. They have indicated that commercialization of GE crops leads to increased incomes for farmers. 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 decision makers.

## **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 D: Production and Trade:**

### **a. Product Developments:**

There is no known animal cloning or GE animal products under research or production in Ukraine at the time of publication of this report.

### **b. Commercial Production:**

There is no known animal cloning or GE animal products in commerce in Ukraine.

### **c. Exports:**

There are no known exports of animal clones or 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 a tracing process and testing capabilities makes this regulation declarative and dependent on exporters' voluntary statements. Unlike proposed EU legislation, Ukraine has taken no direct obligations to ban the cloning of all farm animals, the sale of cloned livestock and/or their offspring, and products derived from them. The EU proposed these types of policies in late 2015, after the DCFTA with Ukraine was signed. Ukraine's reaction is yet to be determined, but the Post does not expect any clarity on this issue in the near future.

### **e. Trade barriers:**

Lack of regulatory base governing access of GE products of animal origin on the market.

---

## **Part E: Policy**

### **a. Regulatory Framework:**

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 the term "cloning" or "cloned organisms," and at the same time the definition of genetic modification considers clones as biotechnology and respective regulations therefore cover cloned animals. The definition in the Biosafety Law (referenced earlier) states: a 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 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 a new combination of genetic materials are formed through two or more cell fusion in a way which does not occur in nature.

Since the 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, it is likely that products developed with use of molecular cloning (gene cloning) will fall under the existing definition of genetic engineering.

Enforcement of regulations is difficult, if even possible, due to the absence of adequate scientific expertise of competent authorities and the multiple aspects of the cloning process. Voluntary declaration of the importer/exporter is likely the only tool that will allow competent authorities to monitor export/import operations for cloned or genetically engineered 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. Innovative Technologies:**

There are no known regulations governing innovative technologies in animals, fish or insects.

**c. Labeling and Traceability:**

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

**d. Trade Barriers:**

There are no additional known trade barriers.

**e. Intellectual Property Rights (IPR):**

Similar to the 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.

**f. International Treaties/Fora:**

Ukraine is a Cartagena Protocol member and bases its internal legislation on this document. In the vast majority of cases, Ukraine follows the EU position due to the EU association agreement and its goal of EU membership in the future. FAS-Kyiv is unaware of any Ukrainian position on cloning or GE animals.

**g. Related Issues:**

There are no related issues.

**Part F: Marketing****a. Public/Private Opinions:**

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

**b. Market Acceptance/Studies:**

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

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

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

**Annex I****Regulatory Framework Governing GE Circulation in Ukraine****Tier 1 – Adopted by Parliament of Ukraine**

**Law of Ukraine #1103-V “On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms (“GMOs”)**

Framework legislation

**Law of Ukraine #1602-VII “On Amendments to Certain Legislative Acts of Ukraine regarding Foodstuffs”**

GE labelling in foodstuffs

**Law of Ukraine #152-IV**

Cartagena Protocol Ratification

**Tier 2 – Adopted by Government of Ukraine**

**GoU Resolution #808**

Procedures for state testing and approval GE agricultural plants for their further use in open system

**GoU Resolution #308**

Procedures for issuing permits for GE field testing

**Tier 3 – Ministry-level Sub-Legislation**

**Registry of Sources of Feed and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms**

**Ministry of Health Order #971**

List of products subject to GE testing