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## 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 to shape its policy in-line with European Union standards. Debates over agricultural biotechnology presence are active in the country. The value of imported agricultural and food products that potentially contain genetically engineered events is hampered by the deteriorated economic situation, growing domestic agricultural production, and a build-up of the food industry in Ukraine.

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**Executive Summary:**

Ukraine's attitude towards biotechnology has largely remained unchanged, while the country has committed to shape 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 financial outcome. Both of these opinions are reflected in the draft legislation developed and pending consideration by the Ukrainian Parliament.

In late 2014, national legislation was amended in order to eliminate duplicative control functions of various governmental authorities over 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 biosafety legislation.

Despite the new national legislation establishing biotech registries, the Government of Ukraine (GoU) has not approved any GE products for cultivation due to the lack of sub-legislation containing the actual procedures and requirements for those events to be listed. Only one GE event (Roundup Ready MON 40-3-2) in the form of soybean meal, for animal feed use is legal for distribution in Ukraine. No other GE events are currently legal for import, production, or sale in Ukraine.

As the national economy is gradually recovering from political and economic shocks experienced in 2013 through 2015, the value of imported goods that potentially contain GE events (processed food products) reached \$19.8 million in calendar year 2016, a 4-percent increase compared to the previous year. Exports of products that may contain GE events (mainly corn and soybeans) decreased to \$3.9 billion in calendar year 2015, a 3.8-percent decrease compared to the previous year.

**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.

**b. Commercial Production:**

There is no legal commercial production of GE products in Ukraine. However, positive test results for corn and soybeans at export facilities imply there is GE crop production. Reports indicate that some food products in Ukraine occasionally test positive for GE presence, thus 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 60-70 percent of soybeans and 3-5 percent of corn produced for export is genetically engineered.

Over the last few years the share of production of GE soybeans is believed to have remained stable as seeds can be produced on-farm as part of cost cutting strategies practiced by small and medium sized producers. Some farmers indicate that GE soybeans are less costly in terms of inputs and provide a better financial outcome compared to conventional production.

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

**c. Exports:**

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

However, there have been documented cases when exported commodities 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 have been stimulated by 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 the isolated case mentioned above, most grains and oilseeds exported from Ukraine are delivered to destinations that do not require strict biotech 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 values of exports from Ukraine that potentially contain GE events are shown in Table 1 below. The total trade in these goods decreased to \$3.9 billion in calendar year 2016, around 4-percent below the previous year mainly due to lower volume of corn exports.

Table 1. Major Exports from Ukraine Subject to Biotechnology Regulation

Product HS Code	Product Description	2014		2015		2016		% Change
		Value (\$)	Share %	Value (\$)	Share %	Value (\$)	Share %	2016/2015
100590	Whole corn	3,323,288,898	78.9	2,992,955,878	74.2	2,639,431,481	68.0	-11.8
110220	Maize (Corn) Flour	580,517	0.0	279,442	0.0	377,688	0.0	35.2
110313	Maize (Corn) Meal and Groats	7,141,292	0.2	5,283,535	0.1	6,463,195	0.2	22.3
110423	Processed Maize (Corn)	7,407,641	0.2	682,937	0.0	352,277	0.0	-48.4
120190	Soybeans (non-seed)	701,020,599	16.6	805,361,300	20.0	985,484,428	25.4	22.4
120810	Soybean meals and flours	55,804	0.0	-	0.0	464	0.0	-
150710	Soybean Oil (non-refined)	94,714,303	2.2	106,831,474	2.6	111,357,806	2.9	4.2
150790	Soybean Oil (refined)	832,402	0.0	39,615	0.0	51,472	0.0	29.9
210310	Soya Sauce	206,214	0.0	190,282	0.0	247,821	0.0	30.2
210610	Protein Concentrates	20,842	0.0	11,821	0.0	29,240	0.0	147.4
230310	Maize (Corn) Gluten	15,563,097	0.4	14,276,630	0.4	14,170,643	0.4	-0.7
230330	Distillers' Dried Grains	3,884,599	0.1	2,326,033	0.1	3,111,604	0.1	33.8
230400	Soybean Meal	55,598,666	1.3	102,988,909	2.6	116,421,005	3.0	13.0
350400	Protein Isolates	3,754,735	0.1	2,699,182	0.1	1,723,768	0.0	-36.1
<b>Total</b>		<b>4,214,069,609</b>	<b>100.0</b>	<b>4,033,927,038</b>	<b>100.0</b>	<b>3,879,222,892</b>	<b>100.0</b>	<b>-3.8</b>

Source of Data: State Fiscal Service of Ukraine

Corn is a major export item for Ukraine, while the EU and China are among its largest buyers of corn. Both customers have established import procedures for biotech products (see [GAIN Report 14032](#) and [GAIN Report FR1624](#) for further details) which allow imports of GE-positive cargo if the shipment is declared accordingly and contains only approved GE events.

Soybeans are predominantly exported to Iran, Turkey, and Egypt, which accept GE cargo (see [GAIN Report](#) and [GAIN Report TR6054](#) for further details).

#### d. Imports:

In the second half of 2013, a GE soybean variety (Roundup Ready MON 40-3-2), in the form of meal, was reinstated in the official registry of approved feeds that contain GE events until July 22, 2018. This feed is included in the approved list and published on the official website of the SFSCPS in the “Registry of Feeds and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms” ([in Ukrainian](#)).

Overall imports of products to Ukraine that potentially contain GE events are shown in Table 2 below. The total trade in these goods reached \$19.8 million in calendar year 2016, a 4-percent increase compared to the previous year. The major driver for this growth was a 32-percent increase in value of soybean imports compared to the previous year. It has been suggested by contacts that this is an indication that farmers are “refreshing” their seeds to get better yields. Although the particular commodity identified by import data (HS Code 120190) would suggest that these seeds are not intended to use for planting, industry sources suggest that this commodity position likely captures imports of product that are planted as unregistered seeds. Soybean seeds intended for planting (HS Code 120110) are subject to rigorous verification/testing by Ukrainian state authorities. The majority of soybean seeds for planting were imported from neighboring Belarus under HS Code 120190.

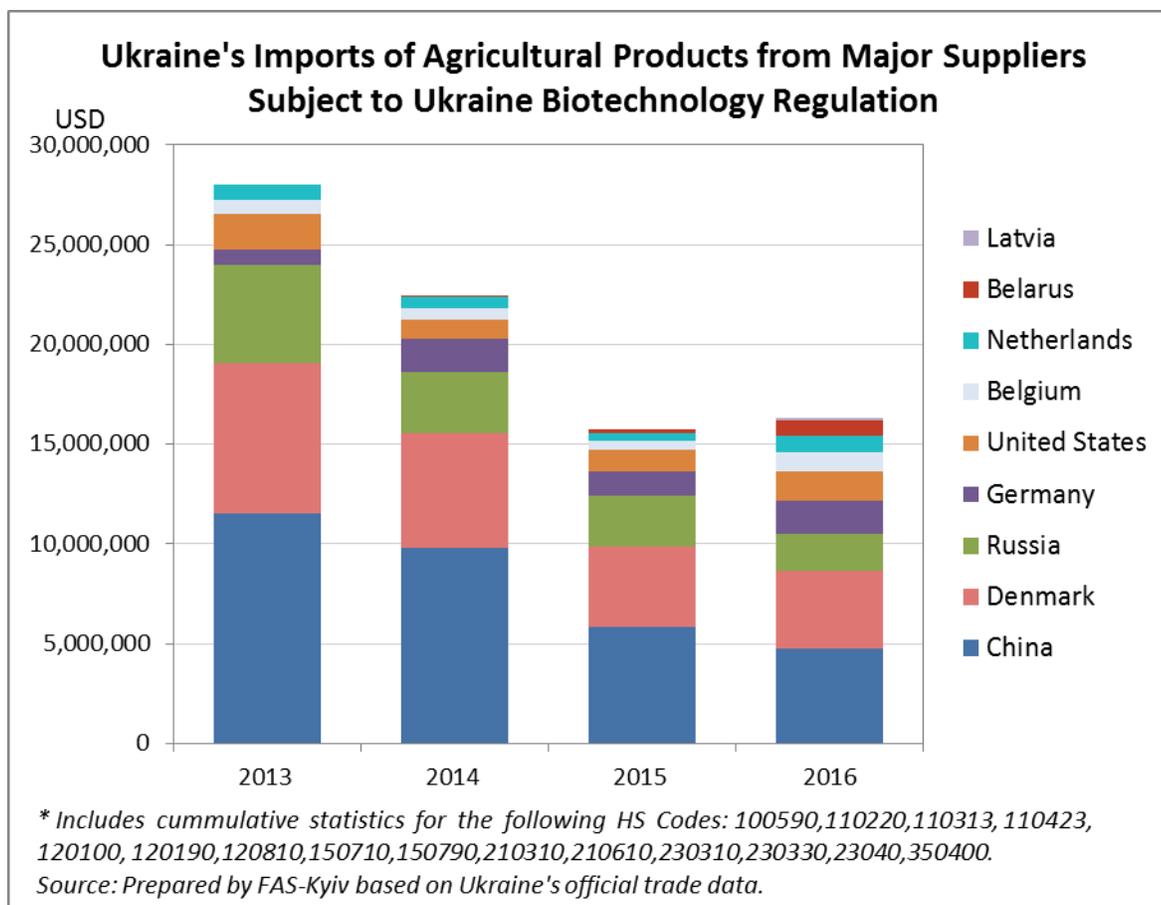
Table 2. Major Imports to Ukraine Subject to Biotechnology Regulation

Product HS Code	Product Description	2014		2015		2016		% Change
		Value (\$)	Share %	Value (\$)	Share %	Value (\$)	Share %	2016/2015
100590	Whole corn	528,622	1.9	494,240	2.6	576,814	2.9	16.7
110220	Maize (Corn) Flour	-	0.0	5,067	0.0	4,146	0.0	-18.2
110313	Maize (Corn) Meal and Groats	85,733	0.3	11,757	0.1	13,556	0.1	15.3
110423	Processed Maize (Corn)	37,369	0.1	-	0.0	-	0.0	-
120190	Soybeans (non-seed)	520,494	1.9	1,056,913	5.6	1,391,237	7.0	31.6
120810	Soybean meals and flours	67,948	0.2	62,669	0.3	69,312	0.4	10.6
150710	Soybean Oil (non-refined)	55,593	0.2	2,919	0.0	37,603	0.2	1188.2
150790	Soybean Oil (refined)	91,530	0.3	43,254	0.2	14,138	0.1	-67.3
210310	Soya Sauce	3,342,968	12.2	1,910,481	10.1	2,298,515	11.6	20.3
210610	Protein Concentrates	4,108,982	15.0	3,023,145	15.9	3,218,506	16.3	6.5
230310	Maize (Corn) Gluten	83,626	0.3	62,126	0.3	135,094	0.7	117.5
230330	Distillers' Dried Grains	22,075	0.1	17,383	0.1	32,175	0.2	85.1
230400	Soybean Meal	1,716,916	6.3	1,061,208	5.6	1,577,956	8.0	48.7
350400	Protein Isolates	16,780,356	61.1	11,256,801	59.2	10,390,802	52.6	-7.7
<b>Total</b>		<b>27,442,212</b>	<b>100.0</b>	<b>19,007,963</b>	<b>100.0</b>	<b>19,759,854</b>	<b>100.0</b>	<b>4.0</b>

Source of Data: State Fiscal Service of Ukraine

The growth in imports of soybeans and corn for processing is, in part, attributed to the stabilization and small growth of the local economy, which positively influenced consumer spending and created higher demand for processed products.

In 2016, China, Denmark, Russia, Germany and the United States remained the largest suppliers of products to Ukraine that potentially contain GE events (see graph and Table 3 below).



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

Partner Country	United States Dollars				% Share			
	2013	2014	2015	2016	2013	2014	2015	2016
<b>World</b>	<b>42,498,572</b>	<b>27,442,211</b>	<b>19,007,964</b>	<b>19,759,855</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>
China	11,547,106	9,820,911	5,840,235	4,750,230	27.2	35.8	30.7	24.0
Denmark	7,509,844	5,758,348	4,044,690	3,930,174	17.7	21.0	21.3	19.9
Russia	4,932,359	3,032,576	2,515,376	1,821,572	11.6	11.1	13.2	9.2
Germany	765,615	1,650,830	1,230,610	1,637,921	1.8	6.0	6.5	8.3
United States	1,821,964	952,581	1,080,162	1,506,633	4.3	3.5	5.7	7.6
Belgium	678,851	572,100	438,230	963,878	1.6	2.1	2.3	4.9
Netherlands	731,883	585,140	410,538	835,413	1.7	2.1	2.2	4.2
Belarus	0	2,622	185,281	748,961	0.0	0.0	1.0	3.8
Other	14,510,952	5,067,103	3,262,840	3,565,072	34.1	18.5	17.2	18.0

Source of Data: State Fiscal Service of Ukraine

**e. Food Aid:**

Ukraine is not normally a food aid recipient country. However, starting in November 2014, the [United Nations World Food Program](#) (WFP) began providing food aid to conflict-affected areas of Eastern Ukraine. The food aid does not contain GE products. According to official notification: “The WFP food basket includes buckwheat, macaroni, sunflower oil, sugar, salt, rice, wheat flour and peas...”. 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 (cultivation for commercialization) are not complete and have not moved 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 mainly on redistribution of responsibilities between various government agencies, including:

- Cabinet of Ministers: oversight and control over various Governmental agencies implementing the Biosafety Law as well as approval of regulations for GE turnover (cultivation, processing and marketing);
- Ministry of Education and Science: support of GE product research and development (R&D); development and enforcement of safety criteria for GE product R&D in a closed system (field trials);
- State Agency for Intellectual Property Rights (IPR): protection of national and international patents safeguarding IPR for GE product R&D;
- State Environmental Inspection: state examination of genetic engineered products intended to be released into the open system; state registration of plant protection products made using genetic engineering; issuing permits for GE product release into the open system; biosafety and genetic control for biological objects in the environment during the development, testing, and commercial use of GE products in the open system;
- Ministry of Environment and Natural Resources: development of criteria for evaluation of potential risks for GE product impact to the environment;
- Ministry of 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;

- State Sanitary and Epidemiological Service: ensuring supervision and control over GE product safety for human health during development, testing, and use in open systems; conducting state examination of GE product safety for human health;
- Ministry of Agricultural Policy and Food of Ukraine: development of regulations for ensuring biosafety of GE products during development, testing, and use of in open systems; conducting state testing and registration of GE plants, animals, and microbes used in agriculture;
- SFSCPS: state registration of GE traits used in foodstuffs, feeds, feed additives and veterinary medicines; approving methods for GE event identification and detection; monitoring of GE-derived feeds, feed additives, and veterinary medicines to verify presence of GE events; ensuring biosafety of GE plants during development, testing, and use of GE plants 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 [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 regime governing the production and circulation of GE crops and products, including:

- Draft Law #2977 ([in Ukrainian](#)) envisages increased 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 agencies supervising agricultural biotechnology as well as introducing 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 a moratorium for commercial production of GE plants and market circulation of GE products while allowing GE imports for R&D purposes. However, Draft Law # 4968 proposes a temporary moratorium until the year 2023, while Draft Law # 3446 intends to set a permanent ban.
- Draft Law #7186 ([in Ukrainian](#)) envisages a revision of the existing agricultural biotechnology

control system in order to boost its efficiency as well as harmonize national legislation with that of the EU (namely Directives 2001/18/EC and 2008/27/EC, Regulations (EC) No 1829/2003, No 1830/2003, No 1946/2003). The draft identifies powers of different state agencies governing the distribution of GE products, including placement on the market, production, processing, and usage as food and feed; identifies GE product registration procedures, labeling, and traceability requirements. It directly prohibits distribution of unregistered GE products on the market.

- Draft Law #7210 ([in Ukrainian](#)) envisages a revision of the existing agricultural biotechnology control system in order to boost its efficiency as well as harmonize national legislation with that of the EU (namely Regulation (EC) No 1830/2003, Directives 2001/18/EC and 90/220/EC). The draft establishes traceability requirements and amends the labeling procedures for GE products. It empowers SFSCPS to govern distribution of GE products.

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) 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.

Post believes that the pace of implementation of the abovementioned Action Plan will depend on the GoU’s administrative capacity and the specific priorities of various governmental authorities involved in this process, as well as the general political and economic climate in Ukraine.

Please also refer to Annex 1 at the end of this report, depicting the regulatory framework governing GE product 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 was introduced, replacing the previous system of registration of individual products containing GE material

Resolution #919 ([in Ukrainian](#)) incorporates procedures for state registration of GE events in foodstuffs, feeds, feed additives and veterinary medicines. SFSCPS is tasked with conducting registrations. Applicants submit a dossier containing information about the developer; information about the GE event(s); and conclusions of GE testing. SFSCPS then makes a decision about registration within 10 working days from submission of the dossier. State registration is free of charge and is valid for 5 years after the GE event is included into the relevant state registry. State registration could be denied based on scientifically proven information that the GE product has a negative impact on human or animal health, or adverse impacts on the environment. A new round of testing could be initiated if new facts about potential adverse impacts of an already registered GE product become available after it is placed on the market.

Resolution #808 ([in Ukrainian](#)) incorporates procedures for state testing and approval of GE plant material for use in open systems (meaning commercial cultivation). The owner of a GE plant variety must submit 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 of the GE plant variety;
- conclusions of state authorities indicating compliance of the GE plant variety with bio- and genetic safety requirements;
- data confirming that GE plant variety is safe to use;
- report by the accredited institution that conducted the testing.

The Authority has 120 days to consider dossier and can grant state registration of a GE plant variety for a five-year period.

The Ukrainian approval system for products of agricultural biotechnology remains underdeveloped and is not functional 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 that monitor or test for GE presence. So far, no registration criteria have been clearly identified and/or written into law that could lead to approvals or rejections.

Only one agricultural plant product that contains GE content has been officially registered and approved for feed use in Ukraine. This product is Monsanto’s Roundup-Ready soybean variety MON 40-3-2 (please refer to section “Imports” above more information). It was temporarily allowed for use in Ukraine in July 2013, and has been gradually extended through July 2018.

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

No specific approval process for stacked events has been defined.

**d. Field Testing:**

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

In accordance with Resolution # 308 “On Approval of Procedures for Issuing Permits 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 plants or plant products.

**e. Innovative Biotechnologies:**

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

**f. Coexistence:**

Since Ukrainian regulations for GE product cultivation are undeveloped, the country does not have a coexistence policy.

**g. Labeling:**

Food product labeling legislation requires 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), if a product contains GE materials, and that ingredient exceeds 0.9 percent of the food product, the seller must label it as “Containing GMO.”

The GoU has discontinued the “GMO-free” compulsory labeling for products that do not contain GE traits. However, producers/exporters may choose to use a “GMO-free” label. In this case, absence of GE material must be confirmed as stipulated by existing regulations. Lack of information about presence of GE traits from ingredients suppliers may serve as sufficient reason for such labeling.



Retail packaging of various commodities: sunflower oil, corn porridge, soft drink (from left to right) bearing various designs of “GMO-free” label, indicated by red arrows.

#### h. Monitoring and Testing:

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

For the purpose of monitoring for presence of unregistered GE content in food products derived from genetic engineering, the Ministry of Health of Ukraine approved Order #971 ([in Ukrainian](#)). This Order contains a list of GE crops and/or products that are the subject to testing:

- Soybeans;
- Corn;
- Tomatoes;
- Squash;

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

The GoU inspects all imported food products upon arrival at the border. All products are required to have the appropriate certificates showing GE product test results, and the seller must label the product 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 Grain Products, which was approved by the GoU Resolution #848 ([in Ukrainian](#)). However, according to industry sources, 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 at a premium. Another rationale is compliance with the Biosafety Law's requirement to exercise controls over GE events.

There is a requirement to indicate GE presence in the cargo's accompanying documentation. Imports might be tested for GE presence upon arrival at the Ukrainian border by SFSCPS. Samples are taken from shipments that arrive at the border by SFSCPS's inspector in case discrepancy in accompanying paperwork is found and are sent to the testing lab while the cargo stays at the customs warehouse awaiting the results. Designated state testing labs in Ukraine test for GE presence.

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

Ukraine does not have a defined LLP policy. From Post'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 Resolution #919 in "Approvals" section for more details). The state registration could be revised and subsequently revoked in cases when 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 which entered into force in the country in 2003.

#### **m. International Treaties/Forums:**

In the past, Ukraine promoted 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 [signed the Danube Soya Declaration](#) in June 2015. This step did not have an immediate effect on the market; however, it can be seen as an indication that Ukraine might follow in the footsteps of the EU in providing governmental regions to "opt-out" from cultivation for non-scientific reasons.

#### **n. Related Issues:**

Ukraine has a 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).

### **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 biotech commercialization or use in the country. The biotechnology topic, in general, was not given much attention in Ukraine from 2015 to early 2017 because of the country's internal reform efforts and the broader geo-political and economic issues that took priority.

The Ukrainian public lacks awareness of science-based facts about biotechnology and GE products.

Industry discussions indicate that the Ukrainian 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 [GAIN Report UP1544](#). This creates opportunities for the development of streamlined and comprehensive regulatory procedures for implementation of the legislation in force.

The leadership of the SFSCPS has indicated its commitment to enforce biosafety legislation (please refer to section “Regulatory Framework” for more details) to prevent inflow of smuggled GE seeds (predominantly soybeans) that might subsequently force farmers to stop production of unregistered GE plants in Ukraine.

#### **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 testing regimes for GE products, 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, soybeans, sugar beets, and corn for Ukrainian agriculture. They indicated that commercialization of GE crops leads to increased incomes for farmers. More independent and in-depth research in Ukraine could raise awareness and favorable attitudes of the population, and encourage decision makers to increasingly base the regulatory framework on scientific facts.

## **Chapter 2: Animal Biotechnology**

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal biotechnologies such as genetic engineering and is 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 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 Development:**

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 make this regulation declarative and dependent on exporters' voluntary statements. Unlike enacted EU legislation, Ukraine has taken no direct action 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 September 2015, after the DCFTA with Ukraine was signed. Ukraine's reaction is yet to be determined, but Post does not expect 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 prevents them from entering the domestic 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 engineered term covers animal and fish species. 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, macro injections and micro encapsulations;

- cell fusion (including protoplasm fusion) or hybridization methods when live cells with a new combination of genetic materials are formed through two or more cells fusing in a way that does not occur in nature.

Ukrainian legislation does not currently use the term “cloning” or “cloned organisms” except for the Law of Ukraine #2231-IV “On Prohibition of Human Cloning” ([in Ukrainian](#)). This Law is not applicable to cloning of other living organisms.

Enforcement of these regulations is difficult in Ukraine due to the absence of adequate scientific expertise of the competent authorities and lack of legislative/regulatory norms governing cloning/biotechnology. Voluntary declaration of the importer/exporter is likely the only tool that will allow competent authorities to monitor export/import operations for cloned or GE animals. Given the ban on circulation of non-registered GE organisms, Post is unaware of any biotech declarations.

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

**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. 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 traits, but does provide some protection for registered plant varieties and breeds. Please refer to the discussion on IPR for plants in Chapter 1, Part B of the report.

**e. International Treaties/Forums:**

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. Ukraine is the member of [Codex Alimentarius](#) as well as the [World Organization for Animal Health](#). FAS-Kyiv is unaware of any Ukrainian position on cloning or GE animals.

**f. 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 primary focus of the public and private sectors on GE plant materials, it is difficult to gauge public and private opinion on animal biotechnology. However, it is believed that the majority public opinion would not be favorable based

on the Ukrainian public's lack of scientific knowledge and understanding about biotechnology.

**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.

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 of GE agricultural plants for their further use in open system

**GoU Resolution #308**  
  
Procedures for issuing permits for GE field testing

**GoU Resolution #919**  
  
Procedures for state registration of GE sources for foodstuffs, feeds, feed additives and veterinary medicines

Tier 3 – Ministry-level Sub-Legislation

**Registry**  
  
Ukraine’s register 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