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Global Agricultural Information Network

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## Ukraine

### Agricultural Biotechnology Annual

### Report

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**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. Recently, regulatory steps were taken to enable a system for the registration of genetically engineered feed and veterinary drugs. Political debate over agricultural biotechnology is active in the country. Currently, there are no GE approved product registrations and therefore no GE products can legally be imported into Ukraine.

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**Executive Summary:**

The current law in Ukraine bans the cultivation of GE crops and requires the registration of any GE products that are imported into Ukraine. Currently, there are no GE approved product registrations and therefore no GE products can legally be imported into Ukraine.

Ukrainians' opinions toward biotechnology remain divided. The general public opinion toward genetically engineered (GE) products is negative. However, farmers indicate that GE crops are less costly in terms of input costs and provide a more stable financial outcome. Both of these opinions are reflected in several different pieces of draft legislation developed and pending consideration by the Ukrainian Parliament. Some drafts intend to impose a total ban on GE products (both imports and cultivation), while others propose permitting the cultivation of GE crops in commercial production.

Ukraine has committed to shape its biotechnology policy in-line with European Union (EU) standards after signing the EU-Ukraine Association Agreement (Association Agreement) in 2014. The Agreement contains specific milestones on approximation of Ukrainian legislation. These deadlines are contained in the text of this document as well as these are reflected in the action plan approved by the Government of Ukraine (GoU).

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 the labelling of such products. The leadership of the State Service of Ukraine on Food Safety and Consumer Protection (SSUFSCP) indicated its commitment to enforce biosafety legislation. In order to make this enforcement practical, in 2018, Ukrainian governmental agencies established procedures for the registration of GE events in foodstuff, feed, feed additives and veterinary medicines. This could potentially enable a wider variety of products to be included in the registry of approved GE products.

Previously, Ukraine had approved the registration of one GE event (Roundup Ready MON 40-3-2) in the form of soybean meal. However, this registration expired in mid-2018 and no request for renewal of the registration has been filed. Application for renewal requires completion of the same steps as required for the initial registration. Therefore, currently there are no GE events legally registered for

importation.

Regardless of the statutory restrictions on the cultivation and/or importation of GE products, industry sources have indicated to Post that some small farmers likely do cultivate some GE crops (mainly soybeans) in order to achieve economies on production costs and animal producers imported GE soybean meal. Based on these assumptions FAS/Kyiv estimates imports of GE events on the level of four million USD for 2017, please see table in Imports Section for more details.

## **Chapter 1: Plant Biotechnology**

### **Part A: Production and Trade:**

#### **a. Product Development:**

At this time, it is not known whether Ukraine is developing GE crops for commercial purposes. However, Post believes that there is currently no development in Ukraine for commercial purposes because cultivation is not allowed. According to the information available to Post, scientific institutions in Ukraine are conducting GE laboratory research, but it is mainly done to test in practice the scientific information that is already widely available. One of the institutions working on GE research is the Institute of Food Biotechnology and Genomics ([in Ukrainian](#)).

Post believes that the further research and development (R&D) in this field will likely be stalled until the GoU establishes clear and complete regulatory standards for the cultivation and importation of GE products. Without a clear understanding that a final GE product could not be commercialized in Ukraine (please refer to “Regulatory Framework” section for more details) there is no motivation to proceed with such research. Moreover, the Ukrainian scientific institute system is weak in providing linkages to the commercialization of scientific advancements. Until those linkages are better established, it is unlikely that Ukraine will make any scientific-to-commercial advances.

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

There is no legal commercial production of GE products in Ukraine. However, positive test results for corn, rapeseed and soybeans at export facilities indicate there is GE crop production. Industry rumors in Ukraine suggest that 60-70 percent of soybeans, 10-25 percent of rapeseed and 1-3 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. For soybeans, seed produced on-farm is used by small and medium sized producers as part of cost cutting strategies. Some farmers indicate that GE soybeans are less costly, in terms of inputs, and provide a better financial outcome compared with conventional production. The same rationale is applicable for growing GE rapeseed. Sources suggest that this rapeseed variety may be a Roundup Ready Canola variety. However, some rapeseed shipments may test false-positive for GE due to inadequate cleaning of vehicles used for transport. Industry sources indicate that the actual volume of GE rapeseed production may be closer to two to three percent.

On the other hand, large soybean producers are able to safeguard against cross-contamination of their soy products (oilseed, oil and meal) at all stages - including production, storage, in-land shipment, processing and export. Such producers prefer to specialize in non-GE varieties. This strategy enables such producers to obtain better prices for their exported crop as importers are willing to pay a premium for a non-GE product. According to some industry estimates, non-GE soy accounts for thirty percent of Ukraine's total soy production, by volume.

Illicit production of GE corn is believed to be declining, primarily due to limited access to smuggled seed. Additionally, significant productivity improvements in conventional hybrids, supplied by both multinational companies and local seed producers, have lessened the demand for GE corn seed.

Reports indicate that some food products in Ukraine occasionally test positive for GE presence, thus indicating that there some GE products in the Ukraine, however, it is not clear whether those products were domestically produced or imported.

#### **c. Exports:**

At the time of this report, Ukraine does not officially export any GE products since no GE products are currently, legally registered, or allowed for production and commercial sale in the country.

However, there have been documented cases of exported commodities from Ukraine testing 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 of temporary restrictions on the importation of feed produced by Ukrainian enterprises due to repeated detection of undeclared GE components. This complaint may have been stimulated by Russian 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](#)).

Russia import restriction remains to be an isolated case. Most Ukrainian grains and oilseeds exports that might contain GM events are delivered either to destinations that already have them approved for import or to destinations that already deregulated these specific events and allow their free circulation. This way, Ukraine's grain and oilseeds exports do not conflict with restrictions in the importing country.

Since Ukraine has no GE events in official production, FAS Kyiv cannot estimate volume of exports.

#### **d. Imports:**

In the second half of 2013, a GE soybean event (Roundup Ready MON 40-3-2), in the form of meal, was reinstated on the official Ukrainian registry of approved feed that contain GE events. This feed was included on the approved list and published on the official website of the SSUFSCP on the "Registry of Feed and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms" ([in Ukrainian](#)). Registration of this event expired in July of 2018 prior to submission this report. So far, no application had been filed for renewal of the registration. Although no public announcement of imports of GE soybean meal were made, some imports in 2013-18 might have legally contained GM

events. (See GE import estimate in the table below).

Another import product that may contain GE events is imported soybeans. Soybeans imported under HS Code 120190 are defined as commodity products not intended for planting. However, this Code most likely captures imports of some GE soybeans that are planted as unregistered seed. Soybean seeds for planting (HS Code 120110) are subject to rigorous verification/testing by Ukrainian authorities. To avoid long and costly registration procedure importers bring seeds (including possible GM seeds) as commodity product subject to less severe testing.

The trade estimates are included in the table below. Sources have indicated to FAS/Kyiv, that an increase in commodity soybean imports is an indication that farmers are “refreshing” their seed stock to obtain better yields. At the same time, the decrease in soybean meal imports is evidence of growth in domestic processing due to increased domestic crush capacity. For a more comprehensive outlook of the Ukrainian oilseeds market, please refer to our [Annual Oilseeds Report](#).

Major Imports to Ukraine Subject to Biotechnology Regulation							
Product HS Code	Product Description	2015		2016		2017	
		Value (\$)	Volume (MT)	Value (\$)	Volume (MT)	Value (\$)	Volume (MT)
230400	Soybean Meal	1,061,208	1,537	1,577,956	2,456	1,061,439	1,833
120190	Soybeans (non-seed)	1,056,913	1,500	1,391,237	3,192	3,264,345	8,393
	<b>Total</b>	<b>2,118,121</b>	<b>3,037</b>	<b>2,969,193</b>	<b>5,648</b>	<b>4,325,784</b>	<b>10,226</b>

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 is that no GE events are allowed into Ukraine since registration for Roundup-Ready Soybeans [MON 40-3-2], in the form of meal for the purpose of animal feed use, expired at the time of this report. Despite establishing a legal registry, the underlying regulatory approval process for the release of GE crops in the open system (cultivation for commercialization) is incomplete.

In 2018, the Ukrainian governmental agencies enabled procedures for the state registration of GE events in feed, feed additives and veterinary medicines. These procedures allow for a wider variety of products to be registered in Ukraine (please refer to Order #17 in Regulatory Framework Section for more details).

The incomplete regulatory framework clearly serves as a trade barrier for access of GE products to the Ukrainian market.

## **Part B: Policy**

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

Please also refer to Annex 1 at the end of this report, depicting the regulatory framework governing GE product circulation in place in Ukraine

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 were enacted in April 2014 and concentrated mainly on the redistribution of responsibilities between the various government agencies, including:

- Cabinet of Ministers: oversight and control over various Governmental agencies implementing the Biosafety Law, as well as the approval of regulations for GE turnover (cultivation, processing and marketing);
- Ministry of Education and Science: support of GE product 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 genetically engineered products intended to be released into the open system; state registration of plant protection products made using genetic engineering; issuance of 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 (MENR): development of the criteria for the evaluation of the potential risks for GE product impact to the environment;

- Ministry of Health (MoH): development of the criteria for the evaluation of the potential risks from GE and GE-derived products to human health, taking into consideration scientific information and international experience;
- State Sanitary and Epidemiological Service: ensure 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 (MAPF): development of regulations for ensuring biosafety of GE products during development, testing, and use of in open systems; conduct state testing and registration of GE plants, animals, and microbes used in agriculture;
- SSUFSCP: state registration of GE traits used in foodstuffs, feed, feed additives and veterinary medicines; approve methods for GE event identification and detection; monitoring GE-derived feed, feed additives, and veterinary medicines to verify the presence of GE events; ensure biosafety of GE plants during development, testing, and use of GE plants in open system.

On September 20, 2015, the Law of Ukraine #1602-VII “On Amendments to Certain Legislative Acts of Ukraine regarding Foodstuffs” (Law #1602) ([in Ukrainian](#)) was enacted. For more information about this law, please refer to [GAIN Report UP1538](#). This legislation introduced a number of amendments to the Biosafety Law. These amendments were mainly intended to eliminate duplicative control functions of various governmental authorities.

MAPF published Order #17 ([in Ukrainian](#)) establishing the requirements for state veterinary and sanitary examination of feed, feed additives and veterinary medicines containing GE organisms (Requirements). These MAPF requirements are the necessary key component (non-existent prior to Order #17) that will allow for the transparent requisites and procedures for state registration of GE events in foodstuffs, feed, feed additives and veterinary medicines. For more information about this regulation, please refer to [GAIN Report UP1806](#).

Interim safety criteria for the use of GE and bioengineered activity in a confined environment was approved by Resolution #922 ([in Ukrainian](#)) and remains valid at the time of the report writing. It differentiates bioengineering activities between four different categories depending on risk factors. The provision states that two low-risk categories do not require specific protective measures in place.



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 #1708 ([in Ukrainian](#)) envisages redistribution of the powers of governmental agencies supervising agricultural biotechnology. Additionally, it introduces administrative procedures intended to tighten controls over GE products in the domestic market.
- Draft Law #1844 ([in Ukrainian](#)) provides for a simplified registration for GE plants and products that are already included in the [EU Register of authorized “GMOs”](#) in accordance with procedures to be further approved by the Cabinet of Ministers of Ukraine;
- Draft Law #2977 ([in Ukrainian](#)) envisages an increase in the financial sanctions which can be levied for the production and distribution of products of plant origin containing GE traits that have not been registered in Ukraine. It also introduces procedures for obligatory destruction of unregistered GE products, and redistributes the powers of governmental authorities supervising the circulation of GE products;
- Draft Law # 3446 ([in Ukrainian](#)) and Draft Law # 4968 ([in Ukrainian](#)) calls for the implementation of a moratorium on the commercial production of GE plants and/or market circulation of GE products, while allowing GE imports for R&D purposes. While Draft Law #4968 proposes a temporary moratorium of commercial production until 2023, Draft Law #3446 provides for a permanent ban.
- Draft Law #7186 ([in Ukrainian](#)) would revise the existing agricultural biotechnology control system in order to boost its efficiency, as well as harmonize Ukrainian 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 commercialization, production, processing, and use as food and feed; identifies GE product registration procedures, labeling, and traceability requirements. It would directly prohibit the distribution of unregistered GE products on the market.
- Draft Law #7210 ([in Ukrainian](#)) would revise 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.

Two main political factors affecting legislative decisions regarding GE products are public opinion and Ukraine's international commitments on approximation of national legislation. Since the public opinion remains predominantly negative and the Association Agreement suggests EU-style model, Post does not currently expect legislative decisions that would liberalize the use GE agricultural products in Ukraine.

In accordance with Law #1602-VIIa new state registration of GE events of food products, feed and drugs was enacted, replacing the previous system of registration of individual products containing GE material. However, the supporting regulatory framework has not been enacted and no registration approvals have been processed.

Resolution #919 ([in Ukrainian](#)) incorporates procedures for state registration of GE events in foodstuffs, feed, feed additives and veterinary medicines. SFSCPS is tasked with conducting registration of GE products. 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. (For information of the process for Renewals of registration, please see the “Additional Requirements” section.)

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 MAPF. 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;
- a report by the accredited institution that conducted the testing.

The MAPF 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 GE agricultural products 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 of GE plant varieties intended for cultivation.

**b. Approvals:**

As of today, Ukraine does not have any GM events approved for food, feed consumption or in-country cultivation. Respectively, import or export of unregistered products is not allowed. Official list of such events is posted in SSUFSCP website and titled: [Register of Genetically Modified Sources of Feeds, Feed Additives and Veterinary Drugs That Either Contain Such Organisms or Derived of Them](#). The list contains only one veterinary drug.

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

No specific approval process for stacked events has been defined. According to the Post’s knowledge, there are no consideration of the regulatory treatment of multi-trait “stacked” or “pyramided” events in Ukraine.

**d. Field Testing:**

There are currently no field tests being conducted in Ukraine. Field testing is part of the official approval process in accordance with the Biosafety Law . The detailed field testing procedures are included in 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 must be issued by the MENR.

According to the regulations, field testing is possible only when applicant provides the scientific research proving the GE event’s safety for human health and the environment. This research should be based on GE Risk Assessment included in Order of the MENR # 36 "On Approval of Criteria for Risk Assessment of the Potential Impact of Genetically Modified Organisms on the Natural Environment"([in Ukrainian](#)), which lists the following criteria:

- GE safety and stability: factors that influence the event, probabilities of emergence of unforeseen effects and features;
- GE safety for the environment, including impact on decomposition of organic matter in the soil;
- GE safety for animals;
- GE impact for environmental populations and biodiversity;
- GE impact for ecosystems;
- Detection methods for GE, including ones for GE identification in the environment;
- Presence of GE handling instructions; and
- Containment and liquidation protocols in case of unintentional release of GE into the environment.

**e. Innovative Biotechnologies:**

Ukraine has not determined a regulatory status for newly developed innovative biotechnologies and Post has no information about any research with innovative biotechnologies in Ukraine.

**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 an indication of the presence of GE content 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 material, and that ingredient exceeds 0.9 percent of the food product, the seller must label it as “Containing GMO.” The same labeling requirements are mirrored in Resolution #468 ([in Ukrainian](#)), which was adopted approximately five years prior to the adoption of Ukraine #1602-VII.

The GoU 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 the 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 GE agricultural 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. The requirements for existing, accredited GE testing laboratories are included in Resolution #700 ([in Ukrainian](#)).

For the purpose of monitoring for presence of unregistered GE content in food products derived from genetic engineering, MoH 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; and
- 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).

Imports might be tested for GE presence upon arrival at the Ukrainian border by SSUFSCP. Samples are taken from shipments that arrive at the border by an inspector from SSUFSCP. If a discrepancy is found with the accompanying paperwork, samples are sent to the testing lab while the cargo remains at the customs warehouse awaiting the results.

GE tests are done by accredited laboratories. There is State Research Institute on Laboratory Diagnostics and Veterinary and Sanitary Examination ([in Ukrainian](#)) that serves as the reference laboratory and capable of conducting complex genetic testing. It works under auspices of the SSUFSCP. Under the legislation in force, the products containing GE events that are not registered in Ukraine are subject to destruction. For unregistered GE products there is a zero-tolerance policy.

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 per contractual requirements. 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. Documentation accompanying the shipment must indicate the presence of any GE material.

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

Ukraine does not have a defined LLP policy. However, currently, agricultural products testing positive for GE are prohibited from entering the market in Ukraine because there is a zero-tolerance policy with unregistered GE products and currently there are no registered products.

**j. Additional Regulatory Requirements:**

After expiration of the five-year period of registration, renewals can be attained by completing the full 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.

Ukrainian legislation requires issuance of a Permit for every transit of unregistered GE in Ukraine, in accordance with the GoU Resolution #423 ([in Ukrainian](#)). Under this procedure, an applicant submits a dossier indicating the GE’s safety to the MENR. The MENR has 45 days for either issuing a permit or rejecting application.

**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 is registered in Ukraine (which has occurred for only one event, MON 40-3-2) the owner of the plant variety would need to initiate complex legal procedures with all in-country partners to secure 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 any subsequent disputes. 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 MAPF [signed the Donau Soja 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.

Under the framework of the Association Agreement Ukraine committed to the “approximation of the Ukrainian GMO legislation to the EU one” as stated on pages 1958-1959 of the Association Agreement. Post believes that the pace of this approximation 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.



Under the Association Agreement, Ukraine has developed an action plan ([in Ukrainian](#)) to ensure harmonization of its legislation with the EU's one. Regarding the biotechnology legislation, it contains the following provisions, featuring specific deadlines:

To be completed by **December 31, 2018**

1. [Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops](#);
2. [Commission Decision of 7 May 2008 concerning the provisional prohibition of the use and sale in Austria of genetically modified maize \( \*Zea mays\* L. line MON810\)](#);
3. [Commission Decision of 16 March 2009 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a carnation \( \*Dianthus caryophyllus\* L., line 123.8.12\) genetically modified for flower colour](#);
4. [Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms](#);
5. [Commission Decision of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product \(\*Solanum tuberosum\* L. line EH92-527-1\) genetically modified for enhanced content of the amylopectin component of starch](#);
6. [Council Regulation \(EC\) No 834/2007 of 28 June 2007 on organic production and labelling of organic products](#) (prohibition of GE products uses in organic production);
7. [Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms](#);
8. [Regulation \(EC\) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms](#);

To be completed by **December 31, 2019**

1. [Commission Regulation \(EC\) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation \(EC\) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation 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 favourable risk evaluation](#);
2. [Regulation \(EC\) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed](#);
3. [Regulation \(EC\) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms](#);

To be completed by **December 31, 2020**



1. [Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed](#) (obligation to clearly mark presence of GE seeds);
2. [Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species](#) (obligation to clearly mark GE presence);
3. [Commission Implementing Directive \(EU\) 2015/1168 of 15 July 2015 amending Directives 2003/90/EC and 2003/91/EC setting out implementing measures for the purposes of Article 7 of Council Directive 2002/53/EC and Article 7 of Council Directive 2002/55/EC respectively, as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species and vegetable species](#) (approval of GE plant varieties);
4. [Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed](#) (obligation to clearly mark GE presence);
5. [Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes](#) (obligation to clearly mark GE presence);
6. [Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants](#) (obligation to clearly mark GE presence);
7. [Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material](#) (including production of GE one).

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

Ukraine has a functional regulatory system that enables access in the domestic market to GE drugs for human use ([in Ukrainian](#)), as well as inclusion in the registry of approved drugs (e.g. insulin produced using recombinant DNA technology). The basic provisions on State registration of cosmetics and human drugs are laid in Resolution #114 ([in Ukrainian](#)).

### **Part C: Marketing**

#### **a. Public/Private Opinions:**

In order to foster positive regulatory developments, strong interest and support from local producers and potential users of the technology is crucial. In general, large grain and oilseed producers and traders in Ukraine have not vocally supported the development of biotech use or commercialization. The biotechnology topic, in general, was not a priority in Ukraine from 2015 to early 2018, because of the country's internal reform efforts and the broader, emergent geo-political and economic issues.

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 based either on emotional perceptions or misleading news stories that are not based on sound science. Although the process of changing public perceptions may be slow, it is necessary to have the technology supported by the Ukrainian public in order to create regulations that allow for GE cultivation and

commercialization.

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 GoU agencies responsible for the 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 SSUFSCP. For more information on this authority, please refer to [GAIN Report UP1544](#). This merge creates opportunities for the development of streamlined and comprehensive regulatory procedures for implementation of the legislation in force.

The leadership of the SSUFSCP 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.

Another driver for streamlining national legislation, which will not necessarily result in wider GE acceptance in the domestic market, might be Ukraine’s commitments toward harmonization of national biotechnology legislation with the EU’s legislation as a result of the Association Agreement (please refer to “Regulatory Framework” and International Treaties/Forums sections of this report for more information).

#### **b. Market Acceptance:**

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

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). Developers frequently utilize cloning in conjunction with animal biotechnologies, such as genetic engineering, and is therefore included in this report.

#### **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, cloned animals, or genetics of cloned animals. Ukraine's ability to identify such products is limited, if not absent completely. These products are not included in the list in MoH's approved Order #971 (refer to Monitoring and Testing section for Chapter 1: Plant Biotechnology), so the Post believes that would be dependent on exporters' voluntary statements.

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

The lack of a regulatory base governing access to GE products of animal origin prevents them from entering the domestic market.

#### **Part E: Policy**

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

The official definition of GE organisms adopted under 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, insect 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; or

- 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. It is included in the Registry of Feeds and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms ([in Ukrainian](#)).

Unlike enacted EU legislation, Ukraine has taken no direct action to ban the cloning of farm animals, the sale of cloned livestock and/or their offspring, or the products derived from them. The EU proposed these types of policies in September 2015, after the Association Agreement 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.

**b. Approvals:**

There are no GE animals or animal products approved for use or import in Ukraine.

**c. Innovative Technologies:**

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

**d. Labeling and Traceability:**

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

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

Similar to the discussion under *Chapter 1: Plant Biotechnology*, above, GE animals fall under the same rules as other GE species. Ukrainian legislation does not allow for the 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.

**f. 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 Association Agreement and its goal of EU membership in the future. Ukraine is a 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.

**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 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, based on the lack of scientific knowledge and understanding about biotechnology among the Ukrainian public, it is believed that generally public opinion would not be favorable.

**b. Market Acceptance/Studies:**

The lack of a clear government policy, and predominately-negative press coverage of biotechnology, has resulted 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.

**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 #468**  
GE labelling in foodstuffs

**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

**GoU Resolution #808**  
Procedures for state testing and approval of GE agricultural plants for their further use in open system

**GoU Resolution #922**  
Interim safety criteria for the use of GE and bioengineering activity in a closed system

**GoU Resolution #700**  
Requirements for accredited GE testing laboratories

**GoU Resolution #423**  
Permit for Transiting GEs not registered in Ukraine

**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

**Ministry of Agriculture Order #17**  
Requirements for state veterinary and safety examination for GoU Resolution #919

**Ministry of Environment Order #36**  
Criteria for Risk GE Assessment