Required Report: Required - Public Distribution **Date:** November 23,2020

Report Number: UP2020-0057

Report Name: Biotechnology and Other New Production Technologies Annual

Country: Ukraine

Post: Kyiv

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Denys Sobolev

Approved By: Robin Gray

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's regulations. Political debate over agricultural biotechnology is active in Ukraine. Currently, there are no genetically engineered (GE) events officially approved for agricultural and food production and therefore no GE products can be legally imported into Ukraine. The Government of Ukraine does not permit cultivation of GE crops, however there are reports of illegal GE production for certain crops.

TABLE OF CONTENTS

Executive Summary	2
CHAPTER 1: PLANT BIOTECHNOLOGY	3
PART A: Production and Trade	3
PART B: Policy	6
PART C: Marketing	16
CHAPTER 2: ANIMAL BIOTECHNOLOGY	17
PART D: Production and Trade	17
PART E: Policy	17
PART F: Marketing	18
CHAPTER 3: MICROBIAL BIOTECHNOLOGY	19
PART G: Production and Trade	19
PART H: Policy	20
Part I: Marketing	21
ANNEX I	22

Executive Summary:

The current biosafety laws/regulations ban the cultivation of unregistered GE crops in Ukraine and require the registration of any GE events in products that are imported into Ukraine. However, the Government of Ukraine (GOU) has yet to develop a regulatory framework establishing the procedures for the approval of and registration of GE events. Therefore, there are currently no GE products registered/approved in Ukraine and no GE products can legally be cultivated or imported into Ukraine.

Ukrainian opinions toward biotechnology remain divided. Public opinion toward GE products is generally negative and is very influenced by propaganda from the European Union (EU). However, many farmers understand that GE crops are more cost effective and provide a better financial outcome. Both opinions are usually reflected in legislation considered by the Rada, the Ukrainian Parliament.

In 2014, Ukraine and the EU signed a Deep and Comprehensive Free Trade Area Agreement (DCFTA), under which Ukraine committed to approximate its food and agricultural regulations to the EU's regulations. This commitment applies also to Ukrainian laws/regulations for biotechnology. The DCFTA contains specific approximation milestones that Ukraine is committed to meeting.

In 2018, Ukrainian governmental agencies established registration procedures of GE events in feed, feed additives and veterinary medicines. This registration procedure could potentially enable the inclusion of a wider variety of products in the registry of approved GE products. However, at the time of this report, no new feed products have been included in the registry.

Previously, Ukraine approved the import 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 to date no request for renewal of the registration has been filed.

Regardless of the statutory restrictions on the cultivation and/or importation of GE products, industry sources have indicated to Post that some small farmers probably cultivate certain GE crops (mainly

soybeans) in order to achieve economies on production costs. Based on these assumptions, FAS Kyiv estimates imports of GE events (seeds) on the level of around 1 million U.S. dollars (USD) for 2019, please refer to Imports Section for more details.

Post does not have consistent information about microbial biotechnology production in Ukraine.

Chapter 1: Plant Biotechnology

Part A: Production and Trade:

a. Product Development:

Currently, Post is not aware of any GE crop development for commercial purposes in Ukraine. Given that cultivation is not legal, Post believes that it is unlikely that there is any commercial development. Post has been informed that scientific institutions in Ukraine are conducting GE laboratory research, but this research is mainly done to confirm scientific information that is already widely available. One of the institutions working on GE research is the Institute of Food Biotechnology and Genomics.

Post believes that 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 or 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 legitimate commercial production of GE crops in Ukraine. However, positive test results for corn, rapeseed and soybeans at export facilities indicate that there is GE crop production in Ukraine. Industry rumors in Ukraine suggest that 50-65 percent of soybeans, 10-12 percent of rapeseed and less than one percent of corn produced for export test positive for GE events.

In 2018, a report by a Romanian NGO confirmed the presence of GE soybean plantings in the Ukrainian regions of Poltava, Khmelnytskiy, Kyiv, Kirovograd, Zhytomir and Vinnytsya.

Over the last few years, the share of production of GE soybeans is believed to have remained stable. However, it is difficult to accurately estimate the volume of GE production in Ukraine. Usually GE soy (as well as other GE crop) estimates are based on tests completed at port silos in order to ensure compliance of a shipment with the requirements of the importing country. Thus, these likely do not fully reflect GE crop production for the whole Ukrainian market.

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. Industry sources suggest that the economy on GE varieties could be around $70 per hectare due to fewer herbicide sprayings compared to herbicide requirements with conventional seed. 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 of other crops. Industry sources indicate that the actual volume of GE rapeseed production may be closer to two to three percent.

Unlike small farming operations, large soybean producers can safeguard against cross-contamination of their soy products (oilseed, oil and meal) at all stages - including production, storage, in-land shipment, processing and export. Under these circumstances, they 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 35-50 percent of Ukraine's total soy production, by volume.

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

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/or 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 a WTO Notification G/SPS/N/RUS/128 of temporary restrictions on the importation of unregistered feed produced by Ukrainian enterprises due to repeated detection of 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.

Despite the isolated case mentioned above, most grains and oilseeds exported from Ukraine are delivered to destinations that have established agricultural biotechnology regulations that authorize specific GE crops to be used for food and/or feed purposes (such as China and the EU) or to destinations that do not require strict biotech monitoring. Moreover, because Ukraine's grain and oilseeds exports are tested prior to exportation, there is rarely a conflict with restrictions in the importing country.

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

d. Imports:

According to the "Registry of Feed and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms" (in Ukrainian) published on the official website of the State Service for Food Safety and Consumer Protection of Ukraine (SSFSCP) there are no officially registered GE events in Ukraine.

The sole item included in the GE import estimate (see Table "Major Imports to Ukraine Subject to Biotechnology Regulation" for more details) is "Soybeans (non-seed)." These beans are not intended for planting (HS Code 120190). Theoretically these soybeans are imported for crushing purposes, but sources have indicated to FAS Kyiv that this commodity item most likely captures imports of GE soybeans planted as unregistered seed. On the contrary, soybean seed intended for planting (HS Code 120110) is subject to rigorous verification/testing by Ukrainian state authorities, so it would not likely contain GE events. Sources have indicated to FAS Kyiv, that an increase in soybean imports is an indication that farmers are "refreshing" their seed stock to obtain better yields or an oilseed crusher importing a batch of beans to support his operations. One exception may be the hike in Ukrainian soybean imports between January and August 2020. During this period Ukrainian crushers were legitimately switching to imported beans due to the deficit in domestically produced soybeans. For a more comprehensive outlook at the Ukrainian oilseeds market, please refer to our Annual Oilseeds Report.

Major Imports to Ukraine Subject to Biotechnology Regulation

Product HS Code	Product Description	2017		2018		2019		January-August 2020	
		Value ($)	Volume (MT)	Value ($)	Volume (MT)	Value ($)	Volume (MT)	Value ($)	Volume (MT)
120190	Soybeans (non-seed)	3,264,345	8,393	1,541,696	3,700	943,130	2,545	8,986,507	22,658

Source of Data: State Fiscal Service of Ukraine

e. Food Aid:

Ukraine is not a food aid recipient country. However, the United Nations World Food Program was providing food aid to conflict-affected areas of Eastern Ukraine from August 2014 to February 2018.

f. Trade Barriers:

The main trade barrier is that no GE events are allowed into Ukraine. Registration for Roundup-Ready Soybeans [MON 40-3-2], in the form of meal for the purpose of animal feed use, expired in 2018. Despite establishing a legal registry, the underlying regulatory 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).

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:

The GE regulatory framework in Ukraine operates as a three-tier system: laws (tier I), GOU's regulations (tier II) and regulations by individual governmental agencies (tier III). Please refer to Annex I at the end of this report, depicting the regulatory framework governing GE product circulation in place in Ukraine. When the new oversight is formally established, FAS Kyiv updates the names of the newly established governmental authorities. We provide this information for reference only and cannot guarantee its total correspondence with the regulatory norms currently in force in Ukraine.

The principal law 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 Economic Development, Trade and Agriculture of Ukraine (MEDTA): 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. *Note: on August 29, 2019 the Ukrainian Parliament defined the new Government of Ukraine structure that merged the Ministry of Agrarian Policy and Food (MAPF) into the Ministry Economic Development and Trade resulting in establishment of MEDTA. For readers' convenience Post uses the name of the new Ministry thorough-out this report, although the original documents contain references to MAPF in their texts*;

- SSFSCP: the 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; and

- According to the recent amendments to Biosafety Law, which were introduced in October 2018, all the above-mentioned governmental authorities are entitled to submit digitally signed copies of permits and information of the state registration of GE traits as GE products to unified government-owned web page "Single Window for International Trade." At the time of the report writing, Post has not been able to verify whether this system is operational.

Resolution #919 (in Ukrainian) incorporates procedures for state registration of GE events in foodstuffs, feed, feed additives and veterinary medicines. The SSFSCP 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. The SSFSCP then makes a decision regarding registration within 10 working days from the 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. If new negative information is confirmed, the state registration will be revoked. For more information of the process for Renewals of registration, please see the "Additional Requirements" section.

Resolution #761 (in Ukrainian) authorizes the State Institution "Institute of Food Biotechnology and Genomics of the National Academy of Sciences of Ukraine" to perform the functions of a scientific and methodological center for the determination of genetically modified organisms. The purpose of the Centre activity is to carry referent functions, ensuring the implementation of modern methods of detection of GE organisms, the implementation of scientific and methodological coordination of testing laboratories to determine the content of GE organisms in products.

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 MEDTA. The dossier should contain:

- information about the owner (individual or legal entity);
- a detailed technical description of the GE plant variety;

- conclusions indicating compliance of the GE plant variety with bio- and genetic safety requirements by MOH;
- data confirming that GE plant variety is safe to use; and
- a report by the accredited institution that conducted the testing.

Field testing is part of the official approval process in accordance with the Biosafety Law, managed by the Ministry of Education and Science. 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 MENR.

MEDTA has 120 days to consider a dossier and can grant state registration of a GE plant variety for a five-year period. MOH and MENR are tasked with routine monitoring of previously unknown factors of a GE event that might be harmful for human health and environment. If these are identified, the GE event will be subject to reevaluation. If the reevaluation's results are negative, state registration of the GE event will be revoked.

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 law defines the roles and functions of the various government agencies that monitor or test for GE presence. So far, no registration criteria that could lead to approval or rejection of a GE plant variety intended for cultivation have been clearly identified and/or written into law.

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. This law introduced several amendments to the Biosafety Law. These amendments were mainly intended to eliminate duplicative control functions of various governmental authorities.

MEDTA 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). 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 feed, feed additives and veterinary medicines.

According to the guidelines, the applicant must submit a dossier to the State Service for Food Safety and Consumer Protection of Ukraine (SSFSCP) containing the following:

- general information about the GE event and the product containing this GE event, including names, intended use, producer, safety certificates;
- specific information about the GE event including its specifications, permits from country of origin, methods of identification, safety testing and trial results, risk assessments, etc.; and
- information about the applicant and the producer of the GE product, including packaging, commercial name, etc.

Upon receipt of a dossier, SSFSCP will forward it to the State Scientific and Research Control Institute of Veterinary Medicinal Products and Feed Additives and the State Scientific Control Institute of

Biotechnology and Strains (in Ukrainian). Within 90 days these institutions should provide a recommendation to the applicant whether the specific GE product can be registered in Ukraine. The applicant must then submit the recommendations from those institutions back to SSFSCP for registration of the GE product.

The remainder of the dossier for feed, feed additives and veterinary medicines should contain:

- information about the applicant (name and contact data);
- common name of the GE organism;
- commercial name of the GE product;
- intended use of the GE product;
- packaging type of the GE product;
- methods of detection and identification; and
- information about the producer of the GE product (name and contact data).

The SSFSCP has ten working days to either register or decline the application for the GE product.

Interim safety criteria for the use of a GE and bioengineered activity in a confined environment was approved by Resolution #922 (in Ukrainian) and remains valid at the time of this report. It differentiates bioengineering activities between four different categories depending on risk factors:

1. no harmful impact for human health and environment;
2. insignificant and reversable impact for human health and environment;
3. reversable negative impact for human health and environment; and
4. reversable negative impact for human health and environment or working with GE event with yet unknown impact for human health and environment.

The provision states that two low-risk categories do not require specific protective measures in place.

In March 2019, Ukraine adopted criteria for risk assessment for R&D and planting of GE plants as approved by Resolution #198 (in Ukrainian). Post contends that this regulation does not foster a system that would enable the practical use of GE events in Ukrainian agriculture. Every activity that falls under government control/supervision requires the establishment of a risk profile; and as such this regulation should be considered a by-product of an effort to introduce broader risk-based principles for governmental control over business.

At the time of this report the webpage of the Ukrainian Parliament does not contain information about GE-related legislative initiatives (draft laws). However, FAS Kyiv has information that a Government-sponsored daft law has been developed to address Ukraine's commitments towards approximation of its laws with the EU's GE norms. Please refer to International Treaties/Forums Section of the Report for more details. The two main political factors affecting legislative decisions regarding GE are public opinion and Ukraine's international commitments on approximation of national laws.

b. Approvals:

No GE plants are registered in Ukraine.

c. Stacked or Pyramided Events Approvals:

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

d. Field Testing:

There are currently no field tests being conducted in Ukraine.

According to the regulations (please refer to Regulatory Framework section for more details), field testing is possible only when an applicant provides the scientific research proving the GE event's safety for human health and the environment. This research should be based on a 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 termination 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 (also known as genome editing) and Post has no information about any research with innovative biotechnologies in Ukraine.

f. Coexistence:

Since Ukrainian regulations for GE product cultivation are not fully developed, Ukraine has not yet established a coexistence policy.

g. Labeling:

Food product labeling laws 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 #2639-VIII "On Information for Consumers Regarding Foodstuffs" (also 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.” Please see “Monitoring and Testing” section, below, for information on Ukrainian testing procedures.

The GOU discontinued the “GMO-free” compulsory labeling for products that do not contain GE traits. However, producers/importers may choose to use a “GMO-free” label. In this case, the absence of GE material must be confirmed as stipulated by existing laws and 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: soft drink, juice, pasta (from left to right) bearing various designs and placement of “GMO-free” label, indicated by red arrows.

h. Monitoring and Testing:
The presence of GE 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 with the provisions of the Biosafety Law (referenced in Regulatory Framework section), Ukraine 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 monitoring for the 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 these ingredients.

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 may be tested for GE presence upon arrival at the Ukrainian border by SSFSCP. Samples are taken from shipments that arrive at the border by an inspector from SSFSCP. 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 is capable of conducting complex genetic testing. It works under the auspices of the SSFSCP. Under the laws and regulations in force, products containing GE events that are not registered in Ukraine are subject to destruction. For unregistered GE products there is a zero-tolerance policy. If a product contains an event that was registered, then it would be a labeling issue if the GE presence were above 0.9%.

Since Ukraine abolished the “Grain Quality Certificate for Grain and Grain Products” (GOU Resolution #848 (in Ukrainian)) there is no longer a formal mechanism to check for the presence of GE events in exported grains and oilseeds. However, according to industry sources, per contractual requirements, commercial commodity batches are routinely express-tested for the presence of GE events at both inland silos and port transshipment terminals. This is primarily done to avoid a detection of low-level presence of a GE event in the GE-free shipments 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 Ukrainian market 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). An event registration could be revised and/or subsequently revoked in cases when there are identifiable factors that the event endangers human health or the environment.

Ukrainian regulations require the issuance of a Permit for the 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 MENR. MENR has 45 days for either issuing a permit or rejecting the application.

k. Intellectual Property Rights (IPR):

Ukraine has not yet adopted any legislation and/or policies for the protection of the Intellectual Property Rights for GE events. 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 properly registered in Ukraine, the owner of that plant variety would need to initiate complex legal procedures with all in-country partners to secure owner's rights. In most cases, the owner of the plant variety 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 a GE registration system and/or import procedures, this IPR discussion is largely academic in nature, as there is very limited legal precedence or experience.

l. Cartagena Protocol Ratification:

Ukraine ratified the Cartagena Biosafety Protocol (CBP), which entered into force in Ukraine in 2002. Ukraine implemented national biosafety regulations that incorporated some of CBP's norms.

m. International Treaties/Forums:

Ukraine is a member of Codex Alimentarius, as well as the World Organization for Animal Health and International Plant Protection Convention. The Post is unaware of Ukraine's active participation in GE discussions in these organizations. Please note that the previous government administration removed Ukrainian representation to Codex from an official governmental organization and established it within the Ukrainian scientific sector. The new governmental organization has indicated that it does not intend to change the status quo.

In order to promote the country's image as a non-GE soybean supplier, MEDTA signed the Donau Soja Declaration in June 2015.

As explained previously, under the DCFTA with the EU, committed to the "Approximation of Ukrainian regulations to EU regulations. This includes any Ukrainian regulations adopted on GE events. Post believes that the pace of Ukraine's completion of the Approximation process will depend on the GOU's administrative capacity and the specific priorities of various governmental authorities involved in the process, as well as the general political and economic climate in Ukraine.

As part of the Approximation process, the GOU adopted Resolution #1106 (in Ukrainian) outlining the implementation strategy. Resolution #1106 also contains the action plan (in Ukrainian) for the harmonization of Ukrainian laws with the EU. Specifically, regarding GE legislation Resolution #1106 contains the following provisions and specific deadlines:

Intended to be completed by **December 31, 2018,** as per the action plan in force. *Note: FAS Kyiv cannot verify whether these have been actually implemented into the national laws at the time of this report because the GOU has not established a reporting system.*

1. 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;
2. 2009/770/EC Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market;
3. Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products; and
4. Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (establishment of transboundary movement procedure).

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; and
3. 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 (2010/C 200/01).

To be completed by **March 20, 2020**

1. 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 (establishing mechanism of public consultations); and
2. Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (establishing mechanism of public consultations).

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 GE presence);
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. Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (obligation to clearly mark GE presence);
4. Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (obligation to clearly mark GE presence); and
5. 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).

To be completed by **December 31, 2021**

1. Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material;
2. 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; and
3. Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

According to page 61 of the Report on DCFTA's implementation in 2019, Ukraine committed to the development and adoption of the law on state control of genetically modified products in agriculture and food industry in 2020. According to the information available to Post, at the time of this report, MEDTA has developed draft legislation that attempts to approximate Ukraine's national GE framework with the European Union's framework.

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 established in Resolution #114 (in Ukrainian).

Although the official Registry of cosmetics and medical products that contain genetically modified organisms or derived from them (#23 in the following link available in Ukrainian) contains no entries,

Post has anecdotal evidence of the following GE drugs available on the market: Somatropin, Interferon, Epoetin, Infliximab, Trastuzumab, Insulin, Heparin, Filgrastim, and Follitropin.

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 mid-2020, 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 on 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.

Ukraine's commitments toward harmonization of national biotechnology laws with the EU's laws, as a result of the DCFTA might be another driver for streamlining national laws, which will not necessarily result in wider GE acceptance in the domestic market (please refer to "Regulatory Framework" and International Treaties/Forums Section 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.

The study "The U.S. Food and Beverages: Perception, Expectations, and Potential in Ukraine" ordered by FAS Kyiv and conducted by Nielsen Consumer Insights Ukraine in 2020 indicates that younger

Ukrainian consumers (under 40 years old) perceive GE events in food products as a negative factor. At the same time, shoppers pay attention to “non-GMO” labels while buying their food.

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 (please refer to Monitoring and Testing section for Chapter 1: Plant Biotechnology for more details), 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 laws 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, fish species and insects. 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.

For more information about GE regulatory framework and roles of responsible governmental ministries please refer to the relevant section in Plant Biotechnology.

Ukrainian laws 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 laws 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.

Unlike enacted EU laws, 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 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.

FAS Kyiv is unaware of any Ukrainian position on cloning or GE animals.

b. Approvals:

No GE animals are registered in Ukraine.

c. Innovative Technologies:

There are no known laws or 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. IPR:

Similar to the discussion under Chapter 1: Plant Biotechnology, above, GE animals fall under the same rules as other GE species. Ukrainian laws do 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:

Please refer to the relevant section in Plant Biotechnology.

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.

Chapter 3: Microbial Biotechnology

Part G: Production and Trade

a. Commercial production:

The Post has no information about usage of microbial biotechnology in production of food products as there are no officially registered microbial biotech-derived products in Ukraine at the time of the report writing. Please refer to section “Imports” in Part A: Production and Trade, Chapter 1: Plant Biotechnology for the relevant link.

Post has knowledge about domestic production of Interferon alfa-2b medicine as well as research conducted on usage of microbial biotechnology used for production of biofuels and antibiotics. Also,

there is the information that local scientific and research institutions are experimenting with GE bacteria. However, this information cannot be verified against the publicly available sources.

b. Exports:

Unknown due to the absence of official state registration of GE products.

c. Imports:

Unknown due to the absence of official state registration of GE products. However, microbial biotech-derived food ingredients likely are in Ukrainian imports of alcoholic beverages, dairy products, and processed products from these countries, where microbial biotech-derived ingredients are commonly used in global production.

d. Trade Barriers:

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

Part H: Policy

a. Regulatory Framework:

See relevant section in Part B: Policy for Chapter 1: Plant Biotechnology

b. Approvals:

See relevant section in Part B: Policy for Chapter 1: Plant Biotechnology

c. Labelling and Traceability:

See relevant section in Part B: Policy for Chapter 1: Plant Biotechnology

d. Monitoring and Testing:

See relevant section in Part B: Policy for Chapter 1: Plant Biotechnology

e. Additional Regulatory Requirements:

Unknown

f. IPR:

Please refer to the discussion on IPR for plants in Chapter 1, Part B of the report.

g. Related Issues:

None

Part I: Marketing

a. Public/Private Opinions:

Unknown

b. Market Acceptance/Studies:
Unknown

Annex I

Regulatory Framework Governing GE Circulation in Ukraine

<u>Tier I</u> – 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 #2639-VIII "On Information for Consumers regarding Foodstuffs"

Law of Ukraine #152-IV
Cartagena Protocol Ratification

<u>Tier II</u> – Adopted by Government of Ukraine

GOU Resolution #468
GE labelling in foodstuffs

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

GOU Resolution #423
Permit for Transiting GEs not registered in Ukraine

GOU Resolution #308
Procedures for issuing permits for GE field testing

GOU Resolution #700
Requirements for accredited GE testing laboratories

GOU Resolution #198
Risk assessment while R&D and farming of GE plants

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

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

<u>Tier III</u> – Ministry-level Regulations

SSFSCP Registry
Ukraine's register of sources of feed and veterinary drugs that were produced with or derived from genetically modified organisms

Ministry of Environment Order #36
Criteria for Risk GE Assessment

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

Attachments:

No Attachments