



Required Report: Required - Public Distribution

Date: November 27, 2023

Report Number: UP2023-0041

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: USDA / FAS

Report Highlights:

The biotechnology regulatory system in Ukraine is still not fully developed, but the country is gradually adjusting its domestic policies to align with the European Union's regulations. Currently no genetically engineered (GE) events are officially approved for agricultural and food production. Therefore, no GE products can be legally imported into Ukraine, restricting trade in some agricultural and food commodities. No GE events are registered for production, however, there are reports of unregistered GE production for specific crops. A new law on genetic engineering (Law # 3339-IX) was adopted on August 23, 2023. It will be replacing the current Biosafety Law in September 2026 and will harmonize procedures of government control over agriculture biotechnology in line with Ukraine's obligations under the EU-Ukraine Association Agreement.

TABLE OF CONTENTS

| CHAPTER 1: PLANT BIOTECHNOLOGY | |
|------------------------------------|----|
| PART A: Production and Trade | 3 |
| PART B: Policy | 8 |
| PART C: Marketing | 22 |
| CHAPTER 2: ANIMAL BIOTECHNOLOGY | |
| PART D: Production and Trade | 23 |
| PART E: Policy | 24 |
| PART F: Marketing | 25 |
| CHAPTER 3: MICROBIAL BIOTECHNOLOGY | |
| PART G: Production and Trade | 26 |
| PART H: Policy | 26 |
| PART I: Marketing | 27 |

Executive Summary:

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

Ukrainian opinions toward biotechnology remain divided. The general public's opinion toward GE products is generally negative and is influenced by anti-GE messaging from European countries that is reposted by local media. On the flip side, many farmers understand that GE crops are more cost-effective and provide a better financial outcome, and they are supportive of growing them. In August 2023, Rada (the Ukrainian Parliament) adopted a new version of the biotechnology law to establish an EU-compliant system for registering GE events and to eliminate the informal/unregistered production of GE crops.

In 2014, Ukraine and the EU signed the 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. On June 23, 2022, the European Council granted candidate status to Ukraine, setting up the nation's move toward an EU-compliant regulatory system on biotechnology. A new Law of Ukraine # 3339-IX "On State Regulation of Genetic Engineering Activities and State Control of the Circulation of Genetically Modified Organisms and Genetically Modified Products to Ensure Food Safety" (in Ukrainian) was adopted on August 23, 2023. It will be replacing the current Biosafety Law in September 2026. It will harmonize procedures of government control over GE circulation and ensure Ukraine compliance with Ukraine's obligations taken per Article 64 of the EU-Ukraine Association agreement.

Regardless of the statutory restrictions on the cultivation and importation of GE products, industry sources have indicated that some small farmers probably cultivate certain GE crops (mainly soybeans and some rapeseed) to reduce production costs. Based on these assumptions, FAS Kyiv estimates imports of GE events (predominantly planting seeds) were valued at around \$750,000 for Calendar Year (CY) 2021 (please refer to Imports Section for more details).

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

List of Abbreviations:

CY – Calendar Year DCFTA - Deep and Comprehensive Free Trade Area Agreement EU – European Union **GE** – Genetically Engineered GOU - Government of Ukraine **IPR** – Intellectual Property Rights MY – Marketing Year MENR - Ministry of Environment and Natural Resources MES - Ministry of Education and Science MOH - Ministry of Health ME – Ministry of Economy MEDTA - Ministry of Economic Development and Trade MAPF - Ministry of Agrarian Policy and Food MT – Metric Ton R&D – Research and Development PCR – Polymerase Chain Reaction SSFSCP - State Service for Food Safety and Consumer Protection of Ukraine

Please see our FAIRS Annual Country Report (<u>UP2022-0045</u>) discussing indications of GE content for food products and planting seeds.

Chapter 1: Plant Biotechnology

Part A: Production and Trade:

a. Research and Product Development:

Given that cultivation of genetically engineered (GE) crops is not authorized by the government, Post believes that it is unlikely that there is any commercial development of GE crops for commercial purposes in Ukraine. Some 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 in this field is the Institute of Food Biotechnology and Genomics.

Further R&D in this field will likely be stalled until the GOU establishes clear and complete regulatory standards for cultivating and importing GE products. Without a clear understanding that a final GE product could or could not be commercialized in Ukraine (please refer to Commercial Production

section below for more details), there is no motivation to proceed with such research. Moreover, the Ukrainian scientific institute system does not generally provide a process to commercializing 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. Due to Russia's full-scale military invasion of Ukraine in February 2022, Post cannot provide any meaningful estimates regarding shares of GE crops in the national output, as many agriculture producing areas have been impacted by the war.

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

The ongoing Russian invasion resulted in fundamental changes in agricultural logistics out of Ukraine. See the annual <u>Ukraine Grain Transportation Report</u> for more details about the situation in 2022. According to the estimates published in the report – farm gate prices decreased by over 31 percent due to logistics costs. Post could make an educated guess that farm gate prices would remain similar or even lower for 2023 due to difficulty for Ukraine to export as a result of <u>Russia's unilateral withdrawal from</u> the BSGI which had facilitated exports from Ukraine after Russia blockaded Black Sea ports.

For soybeans, small and medium-sized producers use seed produced on their farms as part of costcutting strategies. Some farmers indicate that GE soybeans are less costly in inputs and provide a better financial outcome than conventional production. Thus, Ukrainian farmers facing low farm gate prices might attempt to cut costs by introducing more GE crops (primarily soybeans) to their crop rotations for 2023. The same rationale applies to growing GE rapeseed. Industry sources suggest that the returns for farmers of GE varieties could be around \$70 per hectare higher due to fewer herbicide sprayings compared to herbicide requirements with conventional seeds. Sources suggest that this rapeseed variety may be a Roundup Ready canola variety. However, some soy and rapeseed shipments may test false positives for GE due to inadequate cleaning of vehicles transporting other crops. Industry sources indicate that the actual volume of GE rapeseed production may be close to three to five percent.

Unlike small farming operations, large soybean producers safeguard against inadvertent commingling of GE products (which are not approved) with their conventional (non-GE) 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 producers to obtain better prices for their exported crops 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 during the pre-invasion period. Organic (non-GE by definition) soybeans are a major export item for Ukraine.

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 international companies and local seed producers, have lessened the demand for GE corn seed.

c. Exports:

There are no GE events legally registered or allowed for production in Ukraine and commercial sale. 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 <u>G/SPS/N/RUS/128</u> of temporary restrictions on importing unregistered feed produced by Ukrainian enterprises due to repeated detection of GE components. This complaint may have been stimulated by Russian legislative amendments prohibiting the cultivation of GE plants and breeding of GE animals on the territory of the Russian Federation.

The notification published on the official web page (<u>in Ukrainian</u>) of the State Service for Food Safety and Consumer Protection of Ukraine (SSFSCP) indicates that the competent authority of Moldova detained a batch of soybean meal imported as animal feed and that tested GE-positive.

Despite the isolated cases 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 or feed purposes (such as China and the EU) or to destinations that do not require strict biotech monitoring. Moreover, Ukraine's grain and oilseed exports are tested before exportation to ensure compliance with restrictions in the importing country.

Post does not have information about the crush of soybean and rapeseeds into oils and meals by domestic processors for export. There is the possibility of inadvertent commingling of GE products with conventional ones.

It is not possible to estimate the volume of exports of GE crops, since there are no GE events in official production. Ukraine exported around two million MT of soybeans (HS Code 120190) in 2022. Post cannot verify whether some or all those shipments contained GE events. Ukraine also exported 54,000 MT organic soybeans to the United States in CY2022.

d. Imports:

According to the "Registry of Feed and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms" (link to site <u>in Ukrainian</u>), there were no officially registered GE events in Ukraine at the time of the report writing so it is not permitted to import any.

According to Ukrainian laws, the Registry's entries are limited by the following items:

- Genetically engineered plant varieties or animal breeds
- GE events in feeds
- GE events in food products

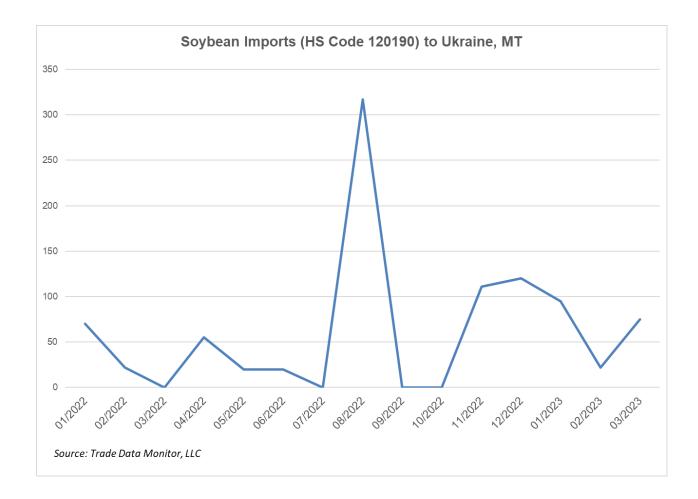
The two imported items which are primarily falling under the biotechnology regulation are soybeans (HS Codes 120190) and rapeseed (HS Codes 120590) which are not intended for planting.

| Major Imports to Ukraine Subject to Biotechnology Regulation | | | | | | | | | |
|--|-------------------------------|------------|----------------|------------|----------------|------------|----------------|--------------------|----------------|
| Product HS Code | Product Description | 2020 | | 2021 | | 2022 | | January-March 2023 | |
| | | Value (\$) | Volume (MT) | Value (\$) | Volume (MT) | Value (\$) | Volume (MT) | Value (\$) | Volume (MT) |
| 120190 | Soybeans (non-seed) | 9,126,268 | 22,918 | 569,369 | 750 | 462,067 | 735 | 88,567 | 192 |
| 120590 | Rape Or Colza Seed (non-seed) | 326,617 | 576 | 9,553 | 1 | 287,098 | 477 | 57,629 | 113 |
| Source: Trade Data Monitor, LLC | | | | | | | | | |

In most cases, these oilseeds are imported for crushing purposes. Sources have indicated to FAS Kyiv that these commodities most likely capture imported GE crops planted as unregistered seeds. On the contrary, soybeans and rapeseed intended for planting are subject to rigorous verification/testing by Ukrainian state authorities, so they would not likely contain GE events.

The hike of both soybean and rapeseed imports for CY 2020, which are reflected in the "Major Imports to Ukraine Subject to Biotechnology Regulation Table above, is mainly associated with low production numbers for MY2020/21. Domestic crushers needed large-scale oilseed imports to keep their facilities up and running. For a more comprehensive outlook on the Ukrainian oilseeds market, please refer to USDA's Ukraine Oilseeds Annual Report.

The spike in soybean imports in August 2022 could be attributed predominantly to domestic crushers' efforts to compensate for the lack of sunflower kernels that were being actively exported to the EU at that period. Based on the dynamics of soybean seed imports for CYs 2022 and the beginning of 2023 (see the relevant graph below), Post assumes that the actual GE seed imports are happening at the beginning of the year (March-April), while fluctuations during summer and autumn are more associated with crushers' activities.



According to Ukrainian Customs Service info reposted by local media outlets, at least one batch of imported soybeans tested GE-positive and was denied entry to Ukrainian territory in June 2021. Attempts to import GE soybeans into Ukraine might also indicate that they are more economically viable to domestic crushers than conventional beans.

e. Food Aid:

Ukraine is not a food aid recipient country. However, <u>the United Nations World Food Program USA</u> and the <u>American Red Cross</u> are providing food aid to areas of Ukraine that have suffered from the full-scale invasion launched by the Russian Federation in February 2022. The provided food aid does not contain GE events as it undergoes the same standard testing procedures as commercial shipments before entering Ukrainian territory. As Ukraine is also a major grain producer, they are also a source for purchases of food for humanitarian purposes around the world. The World Food Program sources a high percentage of food products for their programs from Ukraine and has continued to do so throughout 2022 and 2023.

f. Trade Barriers:

No GE events are allowed into Ukraine, and though it is theoretically possible to register them, no products are currently registered. Registration for Roundup-Ready Soybeans [MON 40-3-2], as a meal

for animal feed use expired in 2018 and nothing has been registered since. 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) is not complete and has not moved forward (please refer to Chapter 1, Part B, sub-paragraph a, 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 could allow a wider variety of products to be registered in Ukraine (please refer to Order #17 below). However, no products are currently registered.

The incomplete regulatory framework serves as a trade barrier for some food and agricultural products containing GE events (predominantly seeds and food products) to access 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, which depicts the current structure of the regulatory framework governing GE product circulation 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) effective since June 21, 2007. The primary purpose of the Law is the distribution 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 (MES): 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 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 on 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; conduct state examination of GE product safety for human health;
- Ministry of Agrarian Policy and Food (MAPF): development of regulations for ensuring biosafety of GE products during development, testing, and use in open systems; conduct state testing and registration of GE plants, animals, and microbes used in agriculture;
- State Service for Food Safety and Consumer Protection of Ukraine (SSFSCP): serves as the state registration of GE traits used in foodstuffs, feed, feed additives, and veterinary medicines; approves methods for GE event identification and detection; monitors GE-derived feed, feed additives, and veterinary medicines to verify the presence of GE events; and ensure biosafety of GE plants during development, testing, and use of GE plants in an open system.

The Law of Ukraine # 3339-IX "On State Regulation of Genetic Engineering Activities and State Control of the Circulation of Genetically Modified Organisms and Genetically Modified Products to Ensure Food Safety" (in Ukrainian) was adopted on August 23, 2023. It will be replacing the current Biosafety Law in September 2026. Law # 3339-IX harmonizes procedures of state control over GE circulation and ensures compliance with national laws in line with Ukraine's obligations taken per Article 64 of the EU-Ukraine Association agreement, including:

- <u>Regulation (EC) No 1829/2003</u> of the European Parliament and of the Council of September 22, 2003, on genetically modified food and feed;
- <u>Regulation (EC) No 1830/2003</u> of the European Parliament and of the Council of September 22, 2003, concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms;
- <u>Commission Regulation (EC) No 641/2004</u> of April 6, 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 authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favorable risk evaluation;
- <u>Regulation (EC) No 1946/2003</u> of the European Parliament and of the Council of July 15, 2003, on transboundary movements of genetically modified organisms;
- <u>Directive 2001/18/EC</u> of the European Parliament and of the Council of March 12, 2001, on the deliberate release into the environment of genetically modified organisms;
- <u>Directive 2009/41/EC</u> of the European Parliament and of the Council of May 6, 2009, on the contained use of genetically modified micro-organisms;
- <u>2009/770/EC</u>: Commission Decision of October 13, 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, to place on the market;

• <u>Commission Recommendation of July 13, 2010</u>, on guidelines for developing national coexistence measures to avoid the unintended presence of GEs in conventional and organic crops.

The significant changes between Law # 3339-IX and Biosafety Law include:

- Introduction of concept for stacked GE events. The legal text defines these as: "multiple GE modifications," "crossing single GE events that contain existing modifications," and "secondary modification of an existing GE event."
- It regulates biotechnologies solely in the agricultural and food sectors.
- Introduction the concept of obligatory coexistence rules for GE and non-GE crops, and GOU is tasked with developing these rules and setting GE-free zones near state borders.
- Introduction of the State Commission on Evaluation of GE risks.
- Added term "Non-GE. Produced using raw materials that contained GE" for labeling purposes of food products.
- Farmers must publicly declare locations and expected volumes of GE crop production.
- Declared harmonization of Ukrainian laws and regulations following the EU norms and simultaneously with the requirements of international organizations.
- GE corn is banned, including testing in open systems, state registration, trade, and imports. Farming of sugar beets and rapeseed will be possible only five years after the Law comes into force (estimated date September 2031).
- Ukraine will abolish registrations of all GE events except those already registered in the EU as of the date when it achieves EU Member State status.

Law of Ukraine #2264-VIII "On Safety and Hygiene of Feeds" (<u>in Ukrainian</u>) regulates legal aspects of registration of feed additives made of, include, or produced using GE organisms. It also contains provisions on mandatory labeling of GE animal feeds and GE organisms used in animal feeds.

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 the registration of GE products. Applicants submit a dossier containing information about the developer, the GE event(s), and conclusions of GE testing. The SSFSCP then decides regarding registration within ten working days of submitting the dossier. State registration is free of charge and is valid for five years after the GE event is included in the relevant state registry. State registration could be denied based on scientifically proven information that the GE product harms human or animal health or adversely impacts the environment. A new round of testing could be initiated if new facts about the 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 on the process for Renewals of registration, please see the "Additional Requirements" section.

Resolution #761 (<u>in Ukrainian</u>) authorizes the State Institution "<u>Institute of Food Biotechnology and</u> <u>Genomics of the National Academy of Sciences of Ukraine</u>" to perform the functions of a scientific and methodological center to determine genetically modified organisms. The Center's activity aims to carry out oversight functions, ensuring the implementation of modern methods of detection of GE organisms and the implementation of scientific and methodological coordination of testing laboratories to determine the content of GE organisms in products. Resolution #808 (<u>in Ukrainian</u>) incorporates procedures for state testing and approval of GE plant material for open systems (commercial cultivation). The owner of a GE plant variety must submit a dossier to Ministry of Economy (ME). 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 the 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 per the Biosafety Law, managed by MES. 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" (<u>in Ukrainian</u>). MENR must issue a permit for every field test of every GE event.

ME has 120 days to consider a dossier and can grant state registration of a GE plant variety for five years. MOH and MENR are tasked with routinely monitoring previously unknown factors of a GE event that might harm human health and the environment. If these are identified, the GE event will be subject to reevaluation. If the reevaluation 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. In the Biosafety Law, the roles and functions of the various government agencies that monitor or test for GE presence are defined. So far, no registration criteria that could lead to approval or rejection of a GE plant variety intended for cultivation have been identified and/or written into Law.

ME published Order #17 (in Ukrainian), establishing the requirements for state veterinary and sanitary examination of feed, feed additives, and veterinary medicines containing GE organisms. These requirements are the necessary key component (non-existent before 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 SSFSCP containing the following:

- General information about the GE event and the product containing this GE event, including names, intended use, producer, and safety certificates;
- specific information about the GE event, including its specifications, permits from country of origin, methods of identification, safety testing, 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 <u>State Scientific and Research Control Institute</u> of Veterinary Medicinal Products and Feed Additives and the <u>State Scientific Control Institute of</u> <u>Biotechnology and Strains (in Ukrainian)</u>. Within 90 days, these institutions should provide a

recommendation to the applicant on 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);
- the 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 using a GE and bioengineered activity in a confined environment were approved by Resolution #922 (in Ukrainian), and despite its name suggesting it is temporary, it remains valid at the time of this report. It differentiates bioengineering activities between four different categories depending on risk factors:

- 1. No harmful impact on human health and the environment;
- 2. Insignificant and reversible impact on human health and the environment;
- 3. Reversible negative impact on human health and the environment; and
- 4. Reversible negative impact on human health and environment or working with GE event with yet unknown impact for human health and environment.

The provision states that the two low-risk categories (i.e. #1 and #2 from the list above) do not require specific protective measures.

In March 2019, Ukraine adopted criteria for risk assessment for R&D and planting of GE plants as approved by Resolution #198 (<u>in Ukrainian</u>). 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. This regulation is part of an effort to introduce broader risk-based principles for governmental control over many kinds of activities across the economy.

On August 4, 2021, the GOU approved the Draft Law "On State Regulation of Genetic Engineering Activities and State Control over the Circulation of Genetically Modified Organisms and Genetically Modified Products to Ensure Food Security" (in Ukrainian) that has been subsequently submitted to the Ukrainian Parliament (Rada) for consideration: It empowers the GOU to place administrative fines on individuals and legal entities involved in illegal GE production, as well as increase current fines:

- individuals -\$125-\$190 (currently \$3-\$5);
- legal entities -\$125-\$629 (currently \$4-\$6).

Post Comment: Under the current Ukrainian legal framework, it is almost impossible to put a fine on an illegal GE plant producer in Ukraine since the current laws do not explicitly identify the specific governmental agency responsible for bringing cases against offenders in a court of Law.

| Legal term (in official language) | Legal Term (in English) | Laws and Regulations where the term is used | Legal Definition (in English) |
|---|--|--|--|
| Генетично модифікований організм, живий змінений організм (ГМО) | Genetically modified organisms, living modified organisms (GMO) | Law of Ukraine #1103-V | Any organism in which the genetic material has been changed using artificial methods of gene transfer that do not occur under natural conditions |
| Продукція, отримана з використанням ГМО | Products obtained with the use of GMO | Law of Ukraine #1103-V | Products, including food products and feed, developed with a production technology that involves the use of GMOs at any stage |
| Генетично-інженерна діяльність | Genetic engineering activity | Law of Ukraine #1103-V | The activity aimed at the creation, testing, and introduction of GMOs into circulation |
| Вивільнення ГМО у навколишнє середовище | Release of GMOs into the environment | Law of Ukraine #1103-V | Action or inaction that resulted in the introduction of GMOs into the environment |
| Система замкнена | Closed system | Law of Ukraine #1103-V | A system of carrying out genetic engineering activities in which genetic modifications are introduced into an organism or GMO, cultivated, processed, stored, used, subject to transportation, destruction, or burial under the condition that protection systems are in place that prevent contact with the population and the environment |
| Система відкрита | Open system | Law of Ukraine #1103-V | A system of carrying out genetic engineering activities, which involves the contact of GMOs with the population and the environment in the event of planned GMO release into the environment, use in farming, |

| Legal term (in official language) | Legal Term (in English) | Laws and Regulations where the term is used | Legal Definition (in English) |
|--------------------------------------|------------------------------|--|--|
| | | | industry, medicine, and for environmental protection purposes, technology transfer to other spheres of GMO circulation. |
| Ризик | Risk | Law of Ukraine #1103-V | The possibility of occurrence and probable scale of consequences from the negative impact on human health and the environment during the implementation of genetic engineering activities and usage of GMOs during a specific period |
| Аналіз ризику | Risk analysis | Law of Ukraine #1103-V | A process consisting of three interrelated components: risk assessment for a GMO, risk management, and notification about a risk |
| Оцінка ризику | Risk assessment | Law of Ukraine #1103-V | Scientific-based process including GMO hazard identification, hazard characterization, impact assessment, risk characteristics |
| Управління ризиком | Risk management | Law of Ukraine #1103-V | The process of choosing alternative solutions based on the results of GMO risk assessment and, if necessary, choosing and implementing appropriate management (control) tools, including regulatory measures |
| Повідомлення про ризик | Risk notification | Law of Ukraine #1103-V | The mutual exchange of GMO risk information between specialists in risk assessment, risk managers, trading partners, and other parties of interest |
| Державна реєстрація ГМО | State registration of GMO | Law of Ukraine #1103-V | Entry of GMOs into the register taking into account their risk assessment regarding the impact on human health |

| Legal term (in official language) | Legal Term (in English) | Laws and Regulations where the term is used | Legal Definition (in English) |
|---|---|--|---|
| | | | and the state of the environment with the further purpose of obtaining permission for the practical use of GMOs in Ukraine according to their intended purpose |
| Державний реєстр ГМО | State Register of GMO | Law of Ukraine #1103-V | The dedicated list of GMOs that have been registered, with the identification of their further intended purpose |
| Державний реєстр ГМО джерел харчових продуктів та кормів | The State Register of GMO Events in Food Products and Feeds | Law of Ukraine #1103-V | The dedicated list of GMOs, which have been concluded as fit for use as food products and/or feeds, and/or their events based on international rules and criteria for assessing safety for human and animal health |
| Арбітражні випробування ГМО | Arbitration tests of GMO | Law of Ukraine #1103-V | Laboratory tests conducted as per a request of a person who disputes the results of a previous laboratory test |
| Референтні зразки ГМО | GMO reference samples | Law of Ukraine #1103-V | A reference GMO material featuring sufficiently uniform properties and is suitable to evaluate the measurement method or establish specific properties of the material; |
| Трансформаційна подія | Transformational event | Law of Ukraine #1103-V | A change in the genetic material of an organism using artificial methods of gene transfer that do not occur under natural conditions |

b. Approvals/Authorizations:

No GE plants are registered in Ukraine (see Chapter 1, Part A, sub-paragraph d, for more details).

c. Stacked or Pyramided Events Approvals/Authorizations:

No specific approval process for stacked events has been defined. According to Post's knowledge, there has been 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.

The Law of Ukraine #2059-VIII "On Environment Impact Assessment" (<u>in Ukrainian</u>) sets the mandatory environmental impact assessment for any R&D activities, introduction into circulation, and any use of GE organisms and products derived from them in an open system.

According to the regulations (please see Chapter 1, Part A, sub-paragraph a, for more details), field testing is possible only when an applicant provides 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 the emergence of unforeseen effects and features;
- GE safety for the environment, including impact on the decomposition of organic matter in the soil;
- GE safety for animals;
- GE's impact on environmental populations and biodiversity;
- GE's impact on 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 innovative biotechnologies (such as genome editing technologies), and Post has no information about any research on 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 and Traceability:

Food product labeling laws require indicating the presence of GE content in food products sold to Ukrainian consumers. Per the provisions of the Law of Ukraine #2639-VIII "On Information for Consumers Regarding Foodstuffs" (in Ukrainian), 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 Chapter 1, Part B, sub-paragraph h, 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 use a "GMO-free" label. In this case, the absence of GE material must be confirmed as stipulated by existing laws and regulations. The lack of information about the presence of GE traits from ingredient suppliers may be a sufficient reason for such labeling.



The retail packaging of various commodities: chocolate, chicken eggs, cookies, and cereals (from left, down to right) bearing various designs and placement of "GMO-free" labels, indicated by red arrows.

h. Monitoring and Testing:

The presence of GE material is monitored in food products produced in Ukraine and imports of agricultural products such as food products and seeds for planting. Per the provisions of the Biosafety Law (see Chapter 1, Part B, sub-paragraph a), Ukraine established a network of accredited laboratories for GE testing; however, FAS Kyiv has no information about its operational capacities. The requirements for existing, accredited GE testing laboratories are included in Resolution #700 (in Ukrainian).

Resolution of the Cabinet of Ministers # 701 (<u>in Ukrainian</u>) has established the Scientific and Methodological Center for determining genetically modified organisms. It regulates operational procedures for the identification of GE organisms. The Center's activities aim to carry out referent functions, ensuring the implementation of modern methods of detection of genetically modified organisms and the implementation of scientific and methodological coordination of testing laboratories to determine the content of genetically modified organisms in products. Post does not have information about the actual functionality of the abovementioned institution.

For monitoring for the presence of unregistered GE content in food products derived from genetic engineering, MOH approved Order #971 (<u>in Ukrainian</u>). This Order contains a list of GE crops and/or products that are 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 abovementioned 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 incoming food and agricultural products must have the appropriate certificates showing GE product test results if the product is declared as GE, and the seller must label the product for GE presence by the Food Labeling Law (referenced in Chapter 1, Part B, sub-paragraph a).

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 a State Research Institute on Laboratory Diagnostics and Veterinary and Sanitary Examination (<u>in Ukrainian</u>) that serves as the reference laboratory and can conduct 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 a registered event, it should be appropriately labeled (see Labeling section above).

Since Ukraine abolished the "Grain Quality Certificate for Grain and Grain Products" (GOU Resolution #848 (<u>in Ukrainian</u>)) in 2014, there is no longer a formal mechanism to check for the presence of GE events in exported grains and oilseeds.

According to the industry representatives, bulk commodities (grains, oil seeds, and products of processing thereof) are routinely tested for GE event presence using PCR tests mostly by private laboratories attached to grain transshipment infrastructure (inland and port silos). In most cases, it is performed at all stages of shipment, starting from a grain silo accepting crops from the field and ending with a transshipment terminal at a port. This allows us to ensure that commodity batches intended to be sold with the premium will not have inadvertent commingling of GE events into the conventional crop. Another rationale is compliance with the Biosafety Law's requirement to exercise control 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 for unregistered GE products, and currently, there are no registered GE events. However, as noted above, some GE products enter Ukraine through informal channels. If there were registered GE products and a product contains GE material, and that ingredient exceeds 0.9 percent of the food product, the seller must label it for the consumer as "Containing GMO."

j. Additional Regulatory Requirements:

After the expiration of the five years of registration, renewals can be attained by completing the entire registration procedure once again (please refer to Resolution #919 in the "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 endanger human health or the environment.

The Law of Ukraine #771, "On basic principles and requirements for safety and quality of food products" (<u>in Ukrainian</u>), prohibits using food products derived from GE organisms or containing GE events in baby food.

Ukrainian regulations require issuing a Permit for the transit of unregistered GE in Ukraine, per the GOU Resolution #423 (<u>in Ukrainian</u>). Under this procedure, an applicant submits a dossier indicating the GE's safety to MENR. MENR has 45 days to either issue a permit or reject the application.

k. Intellectual Property Rights (IPR):

Ukraine has not yet adopted any legislation and/or policies for IPR protection for GE events specifically. If a GE plant variety or animal breed is appropriately registered in Ukraine it will receive IPR protection, just like products of conventional breeding technology. However, the owner of that plant variety would need to initiate complex legal procedures with all in-country partners to secure the 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 high. Proceedings could take years in different courts, resulting in very weak protection. Due to the lack of a functional GE registration system and/or import procedures, an IPR discussion is mainly academic, as there is minimal legal precedence or experience.

I. Cartagena Protocol Ratification:

Ukraine ratified the <u>Cartagena Biosafety Protocol</u> (CBP), which entered into force in Ukraine in 2003. Ukraine implemented national biosafety regulations that incorporated some of CBP's norms.

The complete list of Ukraine's laws and regulations governing GE, which has been reported in compliance with the Cartagena Protocol, is <u>available here</u>.

m. International Treaties and Forums:

Ukraine is a member of <u>Codex Alimentarius</u>, the <u>World Organization for Animal Health</u>, and the <u>International Plant Protection Convention</u> and is a WTO member. 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.

To promote the country's image as a non-GE soybean supplier, MAPF signed the Donau Soja Declaration (<u>in Ukrainian</u>) in June 2015.

Under the DCFTA with the EU, Ukraine committed to the approximation of Ukrainian regulations to EU regulations. It includes any Ukrainian regulations adopted on GE events. The pace of Ukraine's completion of the approximation process will depend on the GOU's administrative capacity, the specific priorities of various governmental authorities involved in the process, and the general political and economic climate in Ukraine. On June 23, 2022, the European Council granted candidate status to Ukraine, which would even further solidify the nation's course toward the EU-compliant regulatory system.

As part of the approximation process, the GOU adopted Resolution #1106 (<u>in Ukrainian</u>) outlining the implementation strategy. It also contains the action plan for the harmonization of Ukrainian laws with the EU, featuring specific deadlines.

Intended to be completed by **December 31, 2018**, as per the action plan in force:

- 1. <u>Directive 2009/41/EC of the European Parliament and of the Council of May 2009 on the</u> <u>contained use of genetically modified micro-organisms;</u>
- <u>2009/770/EC Commission Decision of October 2009 establishing standard reporting formats for</u> presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, to place on the market;
- 3. <u>Council Regulation (EC) No 834/2007 of June 2007 on organic production and labeling of organic products;</u> and
- 4. <u>Regulation (EC) No 1946/2003 of the European Parliament and of the Council of July 2003 on</u> <u>transboundary movements of genetically modified organisms</u> (establishment of transboundary movement procedure).

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

- <u>Commission Regulation (EC) No 641/2004 of April 2004 on detailed rules for the</u> implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the <u>Council as regards the application for the authorization of new genetically modified food and</u> feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favorable risk evaluation;
- 2. <u>Regulation (EC) No 1829/2003 of the European Parliament and of the Council of September</u> 2003 on genetically modified food and feed; and
- 3. <u>Commission Recommendation of July 2010 on guidelines for developing national coexistence</u> <u>measures to avoid the unintended presence of GMOs in conventional and organic crops (2010/C</u> <u>200/01)</u>.

To be completed by March 20, 2020:

- 1. <u>Directive 2001/18/EC of the European Parliament and of the Council of March 2001 on the</u> <u>deliberate release into the environment of genetically modified organisms</u> (establishing mechanism of public consultations); and
- 2. <u>Regulation (EC) No 1946/2003 of the European Parliament and of the Council of July 2003 on</u> <u>transboundary movements of genetically modified organisms</u> (establishing mechanism of public consultations).

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

- 1. <u>Council Directive 66/402/EEC of June 1966 on the marketing of cereal seed (obligation to mark GE presence);</u>
- 2. <u>Council Directive 2002/53/EC of June 2002 on the common catalog of varieties of agricultural plant species</u> (obligation to mark GE presence);
- 3. <u>Council Directive 2002/55/EC of June 2002 on the marketing of vegetable seed</u> (obligation to mark GE presence);
- 4. <u>Council Directive 2002/56/EC of June 2002 on the marketing of seed potatoes</u> (obligation to mark GE presence); and
- 5. <u>Council Directive 2002/57/EC of June 2002 on the marketing of seed of oil and fiber plants</u> (obligation to mark GE presence).

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

- 1. <u>Council Directive 1999/105/EC of December 1999 on the marketing of forest reproductive</u> <u>material;</u>
- 2. Directive 2001/18/EC of the European Parliament and of the Council of March 2001 on the deliberate release into the environment of genetically modified organisms; and
- 3. <u>Regulation (EC) No 1946/2003 of the European Parliament and of the Council of July 2003 on</u> <u>transboundary movements of genetically modified organisms</u>.

Details are available in the publicly available database EU-UA (<u>in Ukrainian</u>), which is run by the GOU and intended to track down DCFTA's implementation progress. According to this database,

implementation of the item "Development of requirements for genetically modified organisms (gradual approximation of legislation)" stopped when GOU submitted and Rada adopted Law # 3339-IX (see Chapter 1, Part B, sub-paragraph a).

n. Related Issues:

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

The Registry of Cosmetics and medical products (#23 in the following link available in Ukrainian) contains the following GE drugs available on the market: Somatropin, Interferon, Epoetin, Insulin, Heparin, Filgrastim, and Follitropin.

Part C: Marketing

a. Public/Private Opinions:

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 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 the production of GE crops through legislative amendments. Other groups are trying to tighten controls over their production or even ban GE production to promote the image of Ukraine as a GE-free country. In general, large grain and oilseed producers and traders in Ukraine have not vocally spoken in support of continued use of biotechnology or research and commercialization. The topic of agricultural biotechnology, in general, was not a priority in Ukraine from in the last ten years because of the country's internal reform efforts and the broader, geopolitical and economic issues faced by Ukraine.

Ukraine's commitments toward harmonization of EU laws under the framework of the DCFTA might be another driver for streamlining national laws on agricultural biotechnology. So far these amendments have skewed towards bans on production, and do not encourage wider GE acceptance in the domestic market.

Dr. Blume from the National Academy of Sciences of Ukraine published a video (<u>in Ukrainian</u>) on the official Academy's YouTube channel in 2021. He discussed the current situation with the GE regulatory base in Ukraine and debunked the most popular myths about GE products.

b. Market Acceptance/Studies:

Ukraine continues to be a challenging market for GE products. 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.

The study "The U.S. Food and Beverages: Perception, Expectations, and Potential in Ukraine," conducted by Nielsen Consumer Insights Ukraine in 2020, indicated that younger Ukrainian consumers (under 40 years old) perceive food products produced with biotechnology as a negative factor. At the same time, shoppers pay attention to "non-GMO" labels while buying their food.

Generally in Ukrainian media, including social media, there is a lack of information about the subject available to the general public, as well as the absence of majorly negative sentiments towards agricultural biotechnology products and the usage of GE in agriculture. This was found during a study to identify perceptions of GE products among Ukrainian consumers over three months from July to October 2021, implemented by Ukrainian company LOOQME.

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 the 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. Research and Product Development:

There are 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 the genetics of cloned animals. Ukraine's ability to identify such products is limited, if not absent altogether. These products are not included in the list in MOH's approved Order #971 (please refer to Chapter 1, Part B, sub-

paragraph h), so Post believes that governmental agencies would rely solely 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 generic. 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 animals, 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 that 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 the GE regulatory framework and roles of responsible governmental ministries, please refer to Chapter 1, Part B, sub-paragraph a.

Ukrainian laws do not currently use the term "cloning" or "cloned organisms" except for the Law of Ukraine #2231-IV, "On Prohibition of Human Cloning" (<u>in Ukrainian</u>). This Law does not apply to the cloning of other living organisms.

Enforcement of these laws is difficult in Ukraine due to the absence of adequate scientific expertise of competent authorities and the 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 the 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 soon.

b. Approvals/Authorizations:

No GE animals are registered in Ukraine.

c. Innovative Biotechnologies:

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. Additional Regulatory Requirements:

There are no related issues.

f. IPR:

Similar to the discussion under Chapter 1, Part B, sub-paragraph k, GE animals fall under the same rules as other GE species. Ukrainian laws do not allow for the registration of GE traits but do provide some protection for registered plant varieties and breeds. Please refer to the discussion in Chapter 1, Part B, sub-paragraph f.

g. International Treaties and Forums:

Please refer to the relevant Section in Plant Biotechnology.

h. 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 of biotechnology among the Ukrainian public, it is believed that general public opinion would be similar to the one for GE plants (please see Chapter 1, Part C, sub-paragraph b for more details).

b. Market Acceptance/Studies:

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:

Post has no information about the usage of microbial biotechnology in the 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 Chapter 1, Part A, sub-section d for the relevant link.

Post knows domestic production of Interferon alfa-2b medicine and research conducted on the usage of microbial biotechnology for the production of biofuels and antibiotics. Also, there is information that local scientific and research institutions are experimenting with GE bacteria. However, this information cannot be verified against 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 biotechderived 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 serves as a trade barrier to accessing GE products in the Ukrainian market.

Part H: Policy

a. Regulatory Framework:

See the relevant Section in Chapter 1, Part B.

b. Approvals/Authorizations:

See the relevant Section in Chapter 1, Part B.

c. Labelling and Traceability:

See the relevant Section in Chapter 1, Part B.

d. Monitoring and Testing:

See the relevant Section in Chapter 1, Part B.

e. Additional Regulatory Requirements:

Unknown.

f. IPR:

See the relevant Section in Chapter 1, Part B.

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

Tier I – Adopted by the Parliament of Ukraine

Law of Ukraine #2639-VIII Law of Ukraine #1103-V Law of Ukraine #152-IV Labeling requirements Cartagena Protocol Framework legislation Ratification Law of Ukraine 3339-IX Law of Ukraine #2264-VIII Updated Framework legislation Law of Ukraine #2059-VIII On Safety and Hygiene of (comes to force since **GE Environment Impact** Feeds September 2026) Assessment **Tier II – Adopted by the Government of Ukraine GOU Resolution #308 GOU Resolution #919 GOU Resolution #468** Procedures for issuing Procedures for state GE labelling in foodstuffs permits for GE field testing registration of GE sources for foodstuffs, feeds, feed **GOU Resolution #808** additives, and veterinary **GOU Resolution #700** medicines Procedures for state testing and Requirements for approval of GE agricultural plants accredited GE testing for their further use in open system laboratories **GOU Resolution #922** Interim safety criteria for the use of GE and **GOU Resolution #423 GOU Resolution #198** bioengineering activity in a Permit for Transiting GEs not Risk assessment while closed system registered in Ukraine R&D and farming of GE

GOU Resolutions #701 & #761 Scientific and methodological Center for GE identification

Tier III – 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

plants

Attachments:

No Attachments