

Required Report: Required - Public Distribution

Date: November 21, 2024

Report Number: UP2024-0023

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: Megan Francic

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 European Union regulations. Currently no genetically engineered (GE) events are officially approved for agricultural and food production and the Government of Ukraine (GOU) does not permit the cultivation of GE crops. Therefore, no GE products can be legally imported into Ukraine, which restricts trade in some agricultural and food commodities. However, there are reports of unregistered GE production for specific crops. The GOU adopted a new law on genetic engineering (Law #3339-IX) on August 23, 2023. It will replace the current Biosafety Law in September 2026 and will harmonize procedures of government control over GE circulation in line with Ukraine's obligations under the EU-Ukraine Association Agreement.

TABLE OF CONTENTS

Executive Summary	3
Chapter 1: Plant Biotechnology.....	5
Part A: Production and Trade.....	5
Part B: Policy.....	9
Part C: Marketing.....	22
Chapter 2: Animal Biotechnology	24
Part D: Production and Trade:.....	24
Part E: Policy.....	24
Part F: Marketing.....	26
Chapter 3: Microbial Biotechnology	27
Part G: Production and Trade.....	27
Part H: Policy	27
Part I: Marketing.....	28
Annex	29

Executive Summary

The current biosafety laws and regulations in Ukraine ban the cultivation of unregistered genetically engineered (GE) crops and require the registration of any GE events in products imported into Ukraine. So far, the Government of Ukraine (GOU) has no comprehensive regulatory framework establishing procedures for approving and registering GE events. Therefore, no GE products are registered or approved in Ukraine, and no GE products can legally be cultivated in or imported into 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 other hand, many farmers understand that GE crops are more cost-effective and can provide better financial outcomes, and they are supportive of growing them.

In 2014, Ukraine and the European Union (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. This commitment also applies 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, further setting up the move toward an EU-compliant biotechnology regulatory system. Ukraine adopted the Law of Ukraine #3339-IX ([in Ukrainian](#)), "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," on August 23, 2023. It will replace the current Biosafety Law in September 2026. It will harmonize procedures of government control over GE circulation and ensure Ukraine's compliance with its obligations per Article 64 of the EU-Ukraine Association Agreement. This necessitates developing a new GE regulatory framework for Ukraine.

Regardless of the statutory restrictions on the cultivation and importation of GE products, industry sources have indicated that some small farmers likely cultivate certain GE crops (mainly soybeans) to reduce production costs.

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
MAPFU - Ministry of Agrarian Policy and Food of Ukraine
MT – Metric Ton
R&D – Research and Development
PCR – Polymerase Chain Reaction
SSUFSCP – State Service of Ukraine for Food Safety and Consumer Protection

See our FAIRS Annual Country Report [UP2024-0014](#) for more details regarding GE content for food products and planting seeds.

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a. Research and Product Development:

Given that the GOU does not authorize the cultivation of GE crops, Post believes the development of GE crops for commercial purposes in Ukraine is unlikely. Some scientific institutions in Ukraine are conducting GE laboratory research, but this research is mainly 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 remain on hold until the end of 2026 when the GOU will establish clear and complete regulatory standards for the registration, cultivation, and importation of GE products (see Chapter 1, Part B, sub-paragraph a, for more details). Without a clear understanding that a final GE product could be commercialized in Ukraine, there is little motivation to proceed with such research. Moreover, the Ukrainian scientific institute system does not generally provide a process for commercializing scientific advancements.

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 there is GE crop production in Ukraine. Note that some soy and rapeseed shipments may return false positives for GE material due to inadequate cleaning of vehicles transporting other crops. Industry sources indicate that the actual volume of GE rapeseed production may be close to 3 to 5 percent of total production. Due to Russia's full-scale invasion of Ukraine beginning in February 2022, Post cannot provide any meaningful estimates regarding shares of GE crops in the national output, as Russian aggression against Ukraine has impacted many agricultural areas.

Over the last few years, sources indicate that the share of production of GE soybeans in total output is believed to have remained stable. According to some industry estimates, non-GE soy accounted for 35-50 percent of Ukraine's total soy production by volume during the pre-full-scale Russian invasion period. Usually GE soy, as well as other GE crop 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, as some oilseeds are consumed domestically as oil and meals. See our Oilseeds Report [GAIN UP2024-0007](#) for more details.

The ongoing full-scale Russian invasion resulted in fundamental changes in agricultural logistics out of Ukraine. See the annual [Ukraine Grain Transportation Report](#) for more details about the situation in 2023. Increases in logistical costs caused by uncertainties in marine logistics, as well as missile and drone attacks on Ukraine's logistics infrastructure, are forcing farmers to cut their production costs to stay in business.

For soybeans, small and medium-sized producers use seed produced on their farms as a cost-cutting strategy. Some farmers indicate that GE soybeans are less costly in terms of inputs and provide a better

financial outcome than conventional products. Thus, Ukrainian farmers facing low farm gate prices might attempt to cut costs by introducing more GE crops (primarily soybeans) to their rotations.

In 2024, GE cotton was introduced into production in the Odesa region of Ukraine. Recent changes in Ukrainian law allowed temporary imports of GE cotton seeds without passing the obligatory certification of seed material. See Chapter 1, Part B, sub-paragraph a, for more details about recent regulatory changes. According to the Ministry of Agrarian Policy and Food of Ukraine (MAPFU), about 10 cotton varieties were planted in the Odesa region at various test plots, including test plots by several private entrepreneurs. FAS/Kyiv is unable to verify what share of cotton planted area was GE.

Unlike small farming operations, large soybean producers safeguard against inadvertent commingling of GE products with their conventional 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 many importers are willing to pay a premium for a non-GE product. 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 multinational companies and local seed producers, have lessened the demand for GE corn seed.

c. Exports:

No GE events are legally registered or allowed for production or commercial sale in Ukraine; however, there have been documented cases of commodities exported 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](#) for temporary restrictions on importing unregistered feed produced by Ukrainian enterprises due to repeated detections 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.

A notification published ([in Ukrainian](#)) on the official web page of the State Service of Ukraine for Food Safety and Consumer Protection (SSUFSCP) indicates that the competent authority of Moldova detained a batch of soybean meal imported as animal feed 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 monitoring. Moreover, Ukraine's grain and oilseed exports are normally tested by independent surveyors before export to ensure compliance with restrictions in the importing country.

It is not possible to estimate the volume of GE crop exports since there are no GE events in official production.

d. Imports:

According to the “Registry of Feed and Veterinary Drugs that Were Produced with or Derived from Genetically Modified Organisms,” ([in Ukrainian](#)) there are no officially registered GE events in Ukraine; therefore, it is not permitted to import any.

According to Ukrainian law, the Registry’s entries are limited to the following items:

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

In accordance with MAPFU Order #78 ([in Ukrainian](#)), the SSUFSCP is authorized to take dedicated samples of seed batches intended for planting and send these for analysis to accredited laboratories for GE testing. For more information about these laboratories, see Chapter 1, Part B, subparagraph h.

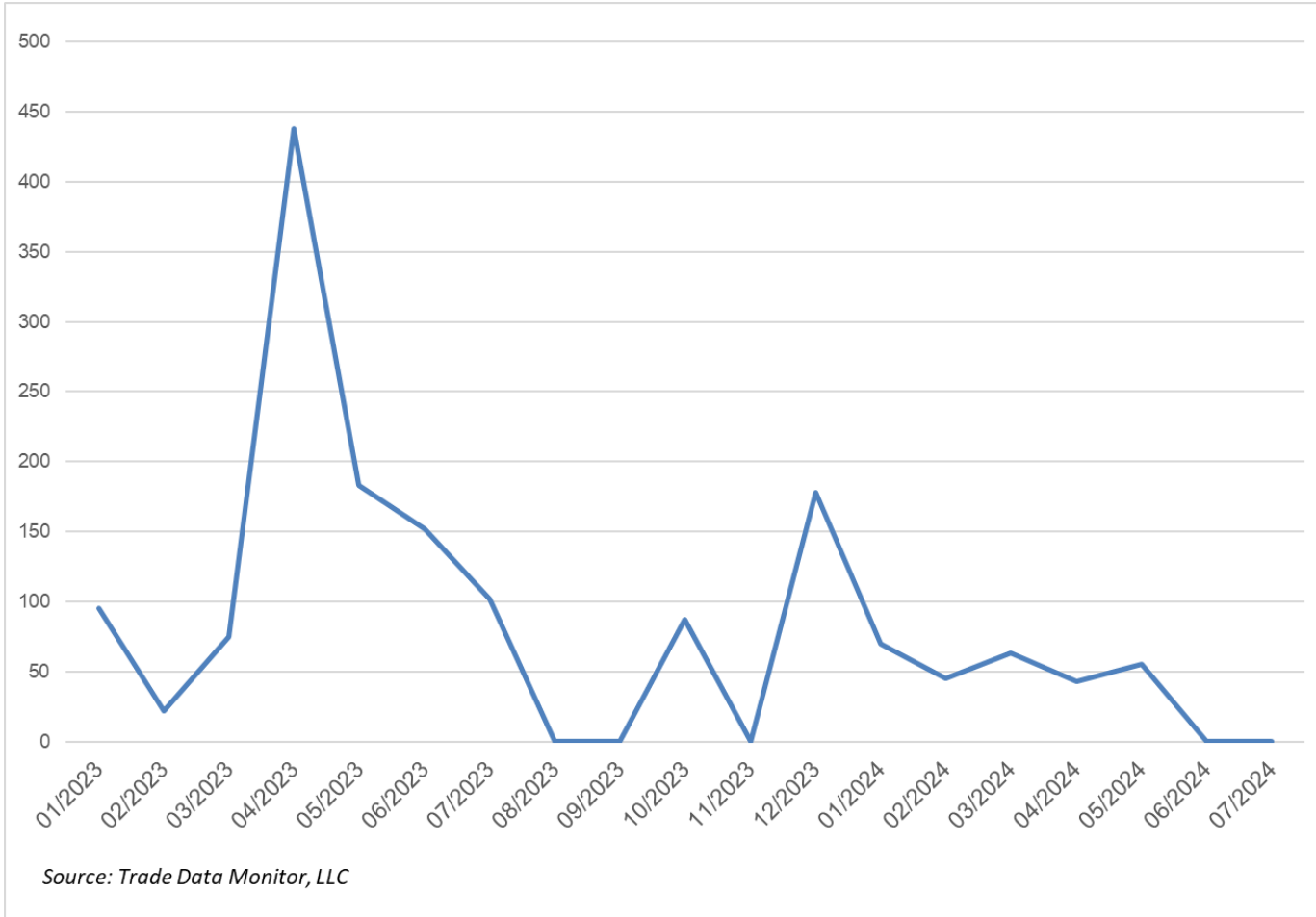
The two imported items primarily falling under biotechnology regulation are soybeans (HS Code 120190) and rapeseed (HS Code 120590) not intended for planting. In most cases, these oilseeds are imported for crushing purposes. Sources have indicated that some of these commodities are most likely also used for planting as unregistered seeds. Imported soybeans and rapeseed intended for planting are subject to rigorous testing and verification by Ukrainian state authorities, so they would not likely contain GE events.

There was a soybean and rapeseed import hike in CY2023, mainly associated with low oilseed production for CY2022 in combination with a spike in sunflower seed exports (over 2.1 million MT) to the EU (Table 1 and Figure 1). Domestic crushers needed large-scale oilseed imports to keep their facilities up and running.

Table 1: Major Ukrainian Imports Subject to Biotechnology Regulation

Product HS Code	Product Description	2021		2022		2023		January-July 2024	
		Value (\$)	Volume (MT)	Value (\$)	Volume (MT)	Value (\$)	Volume (MT)	Value (\$)	Volume (MT)
120190	Soybeans (non-seed)	569,369	750	462,067	735	803,482	1,332	236,480	277
120590	Rape Or Colza Seed (non-seed)	9,553	1	287,098	477	3,228,399	5,998	2,188	0

Source: Trade Data Monitor, LLC

Figure 1: Dynamics of Soybean Imports (HS Code 120190) to Ukraine, MT

For a more comprehensive look at the Ukrainian oilseeds market, see our Oilseeds Annual Report [UP2024-0007](#).

According to Ukrainian Customs Service information reposted by local media outlets, at least one batch of imported soybeans tested GE-positive and was denied entry to Ukraine in June 2021.

e. Food Aid:

Ukraine is not a food aid recipient country. However, the [United Nations World Food Program](#) and the American Red Cross are providing small-scale food aid to certain areas of Ukraine due to the full-scale Russian invasion. The provided food aid does not contain GE events as it undergoes the same standard testing procedures as commercial shipments before entering Ukraine.

Ukraine, in cooperation with the World Food Program, provides food aid to other countries through its [“Grain from Ukraine”](#) program.

f. Trade Barriers:

No GE events are allowed in Ukraine. 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. Despite establishing a legal registry, the underlying regulatory framework for establishing an approval process for the release of GE crops for commercial cultivation is not complete and has not moved forward (see Chapter 1, Part B, sub-paragraph a, for more details).

In 2018, the GOU enabled procedures for the state registration of GE events in feed, feed additives, and veterinary medicines. These procedures could allow for a wider variety of products to be registered in Ukraine [see Order #17 ([in Ukrainian](#))]. However, no products are currently registered at the time of report writing. Given the adoption of the new GE Law (Law #3339-IX) in 2023 and the need for the GOU to review the regulations, Post believes that registration of a GE event would not be possible before the second half of 2026.

The incomplete regulatory framework could effectively be considered 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-tiered system: laws (tier I), GOU regulations (tier II), and regulations by individual governmental agencies (tier III). See the Annex, which depicts the general structure of the regulatory framework governing GE product circulation in Ukraine, for more information.

The current principal law that governs GE events in Ukraine is the Law of Ukraine #1103-V ([in Ukrainian](#)), "On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms (“GMOs”),” also called the "Biosafety Law,” effective June 21, 2007. The primary purpose of the Law is the distribution of responsibilities between various government agencies, including:

- Cabinet of Ministers: oversight and control over various governmental agencies implementing the Biosafety Law; approval of regulations for GE products moving along the supply chain (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 Intellectual Property Rights (IPR): protection of national and international patents safeguarding IPR for GE product R&D
- State Environmental Inspection: state examination of GE products intended to be released into the open system; state registration of plant protection products made using GE technology;

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 an open system

- Ministry of Environment and Natural Resources (MENR): development of the criteria for the evaluation of the potential risks of 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
- MAPFU: 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
- SSUFSCP: serve as the state registration of GE traits used in foodstuffs, feed, feed additives, and veterinary medicines; approve methods for GE event identification and detection; monitor 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 an open system

The Law of Ukraine #3339-IX ([in Ukrainian](#)), “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,” was adopted on August 23, 2023. In September 2026, it will replace the current Biosafety Law. Law #3339-IX harmonizes procedures of state control over GE circulation and ensures compliance with national laws in line with Ukraine’s obligations per Article 64 of the [EU-Ukraine Association Agreement](#), including:

- [Regulation \(EC\) No 1829/2003](#) of the European Parliament and of the Council of September 22, 2003, on genetically modified food and feed
- [Regulation \(EC\) No 1830/2003](#) 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
- [Commission Regulation \(EC\) No 641/2004](#) of April 6, 2004, on detailed rules for the implementation of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council in regard to the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favorable risk evaluation
- [Regulation \(EC\) No 1946/2003](#) of the European Parliament and of the Council of July 15, 2003, on transboundary movements of genetically modified organisms
- [Directive 2001/18/EC](#) of the European Parliament and of the Council of March 12, 2001, on the deliberate release into the environment of genetically modified organisms

- [Directive 2009/41/EC](#) of the European Parliament and of the Council of May 6, 2009, on the contained use of genetically modified microorganisms
- [2009/770/EC](#) 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
- [Commission Recommendation of July 13, 2010](#), 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 the Biosafety Law include:

- Introduction of the concept of stacked GE events. The legal text defines these as “multiple GE modifications,” “crossing single GE events that contain existing modifications,” and a “secondary modification of an existing GE event.”
- Law #3339 regulates biotechnologies solely in the agricultural and food sectors.
- Introduction to obligatory coexistence rules for GE and non-GE crops. The 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 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 it achieves EU Member State status.

This report includes an attachment of an unofficial translation of Law #3339-IX.

Law of Ukraine #2264-VIII ([in Ukrainian](#)), “On Safety and Hygiene of Feeds,” regulates the legal aspects of registration of feed additives made of, including, or produced using GE organisms. It also contains provisions on mandatory labeling of GE animal feeds and GE organisms used in animal feeds.

Law of Ukraine #3645-IX ([in Ukrainian](#)), “On Amendments to Laws of Ukraine Regarding the Turnover of Cotton Varieties in Ukraine,” was adopted in April 2024. It introduced amendments to Law #1103-V, allowing the state registration of GE cotton seeds without prior state GE registration and obtaining of relevant permits. This law is temporary and expires within 36 months after the termination or cancellation of martial law in Ukraine. General information about the procedure for temporary registration of GE cotton in Ukraine is included in [GAIN Report UP2024-0011](#).

Resolution #919 ([in Ukrainian](#)) incorporates procedures for state registration of GE events in foodstuffs, feed, feed additives, and veterinary medicines. The SSUFSCP 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 SSUFSCP then decides on the registration within 10 working days after submission of 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, state registration will be revoked. For more information on the registration renewal process, see Chapter 1, Part B, sub-paragraph j.

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 to determine genetically modified organisms. The Institute aims to carry out oversight functions, ensure 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 ([in Ukrainian](#)) 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 the 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 the MOH
- Data confirming that the GE plant variety is safe to use
- 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 the MES. The detailed field-testing procedures are included in Resolution #308 ([in Ukrainian](#)), ‘On Approval of Procedures for Issuing Permits for State Testing (Approval) of “GMOs” in an Open System.’ 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 and environmental health. 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. 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.

The 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 component, and were non-existent before Order #17, that will allow for the transparent requirements 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 SSUFSCP containing the following:

- General information about the GE event and the product containing the 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, and risk assessments
- Information about the applicant and the producer of the GE product, including packaging and the commercial name

Upon receipt of a dossier, the SSUFSCP 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](#). 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 SSUFSCP 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 information)
- 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
- Information about the producer of the GE product (name and contact information)

The GOU approved “interim safety criteria” for using a GE and bioengineered activity in a confined environment in Resolution #922 ([in Ukrainian](#)) in 2008. This resolution remains valid at the time of this report. The Resolution differentiates bioengineering activities into 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
4. Irreversible negative impact on human health and environment or working with a GE event with yet unknown impact for human health and environment.

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

In March 2019, Ukraine adopted criteria for risk assessments for R&D and the planting of GE plants as approved by Resolution #198 ([in Ukrainian](#)). Post believes this regulation does not foster a system enabling 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 should be considered a by-product of an effort to introduce broader risk-based principles for governmental control.

Table 2: List of Terms Used in Ukrainian GE Law

Legal term (in Ukrainian)	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	GE 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 GE 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, industry, medicine, and for environmental protection purposes, technology transfer

Legal term (in Ukrainian)	Legal Term (in English)	Laws and Regulations where the term is used	Legal Definition (in English)
			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 GE 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	Science-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 and the state of the environment with the further purpose of obtaining permission for the practical use

Legal term (in Ukrainian)	Legal Term (in English)	Laws and Regulations where the term is used	Legal Definition (in English)
			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, which is also 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.

c. Stacked or Pyramided Events Approvals/Authorizations:

No specific approval process for stacked events has been defined. Post is unaware of any 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. However, MAPFU Order #385 ([in Ukrainian](#)) approves a Unified Control form for compliance with the requirements of legislation on biological and genetic safety for agricultural plants during the creation, research, and practical use of GE organisms in an open system, to be used by SSUFSCP.

The Law of Ukraine #2059-VIII ([in Ukrainian](#)) “On Environment Impact Assessment,” 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 GOU regulations, 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 ([in Ukrainian](#)), “On Approval of Criteria for Risk Assessment of the Potential Impact of Genetically Modified Organisms on the Natural Environment,” 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 impact on environmental populations and biodiversity
- GE impact on ecosystems
- Detection methods for GE, including for GE identification in the environment
- Presence of GE handling instructions
- 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 established a coexistence policy at the time of report writing.

It should be noted that the new GE Law (Law #3339-IX) contains concepts of rules for the parallel usage of GE and non-GE products. These rules should be applicable at all stages, including production (growing), storage, transportation, and disposal of products.

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 ([in Ukrainian](#)) “On Information for Consumers Regarding Foodstuffs,” if a product contains GE material and that ingredient exceeds 0.9 percent of the food product, the seller must label it as “Containing GMO.”

The GOU discontinued “GMO-free” compulsory labeling for products that do not contain GE traits. However, producers/importers may use a “GMO-free” label (Figure 2). 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.

Figure 2: Examples of “GMO-free” Labels in Ukraine



Clockwise from top left: snacks, fruit-flavored sparkling water, sunflower oil, eggs, tomatoes, and cookies.

h. Monitoring and Testing:

The GOU monitors the presence of GE material in food products produced in Ukraine and imports of agricultural products, such as food products and planting seeds. Per the provisions of the Biosafety Law, 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](#)).

Resolution of the Cabinet of Ministers #701 ([in Ukrainian](#)) 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 its functionality.

For monitoring 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 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
- Yeast and leavening, 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, and the seller must label the product for GE presence according to the Food Labeling Law.

SSUFSCP inspectors may test imports for GE presence upon arrival at the Ukrainian border. They take samples from shipments that arrive at the border. If an inspector finds a discrepancy with the accompanying paperwork, samples are sent for testing, while the cargo remains at the customs warehouse awaiting the results.

Accredited laboratories carry out GE tests. The State Research Institute on Laboratory Diagnostics and Veterinary and Sanitary Examination ([in Ukrainian](#)) serves as the reference laboratory and can conduct complex genetic testing. It works under the auspices of the SSUFSCP. Under the laws and regulations in force, products containing GE events that are not registered in Ukraine are subject to destruction. There is a zero-tolerance policy for unregistered GE products.

Since Ukraine abolished the “Grain Quality Certificate for Grain and Grain Products” [GOU Resolution #848 ([in Ukrainian](#))] 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, oilseeds, 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, testing 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 commodity owners to ensure that commodity batches intended to be sold at a 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. Agricultural products testing positive for GE events are prohibited from entering the Ukrainian market because there is a zero-tolerance policy for unregistered GE products and no registered GE events. However, as noted, some GE products enter Ukraine through informal channels.

j. Additional Regulatory Requirements:

After the expiration of the five years of registration, renewals can be attained by completing the entire registration procedure again (see Resolution #919). 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 health of the environment.

The Law of Ukraine #771 ([in Ukrainian](#)), “On Basic Principles and Requirements for Safety and Quality of Food Products,” 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 products in Ukraine, per GOU Resolution #423 ([in Ukrainian](#)). Under this procedure, an applicant submits a dossier indicating the GE product’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. Ukrainian legislation, at its current level of development, does not accommodate a registration process for GE events. If a GE plant variety or animal breed is appropriately registered in Ukraine, it will receive IPR protection. However, the owner of that plant variety would need to initiate complex legal procedures with 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.

l. Cartagena Protocol Ratification:

Ukraine ratified the [Cartagena Biosafety Protocol](#) (CBP), which entered into force in 2003. Ukraine implemented national biosafety regulations that incorporated some CBP norms.

Please find the complete list of Ukraine's laws and regulations governing GE reported in compliance with the CBP [here](#).

m. International Treaties and Forums:

Ukraine is a member of Codex Alimentarius, the World Organization for Animal Health, the International Plant Protection Convention, and the WTO. Post is unaware of Ukraine's active participation in GE discussions in these fora. Please note that the GOU changed its representation in Codex from an official governmental organization [to a member of the Ukrainian scientific community](#).

To promote the country's image as a non-GE soybean supplier, MAPFU signed the Donau Soja Declaration ([in Ukrainian](#)) in June 2015.

Under the DCFTA, Ukraine committed to approximating EU regulations. This includes any Ukrainian regulations adopted regarding GE events. On June 23, 2022, the European Council granted Ukraine candidate status, and on December 14, 2023, it opened accession negotiations that further solidified the nation's course toward an EU-compliant regulatory system.

In the "Sanitary and Phytosanitary Measures" section of the [Report on Implementation of the Association Agreement between Ukraine and the European Union for 2023](#), the GOU declared its adoption of Law of Ukraine #3339-IX as a milestone of the approximation process. Since the [monitoring system for the implementation of the Association Agreement between Ukraine and the EU](#) is currently not functional, Post cannot identify other laws and regulations required to bring Ukraine's biotechnology regulatory system in line with that of the EU.

n. Related Issues:

Ukraine has a functional regulatory system, approved by Resolution #114 ([in Ukrainian](#)), that enables access in the domestic market to GE drugs for human use, as well as their inclusion in the State Registry of Cosmetics and Medical Products that Contain GE Organisms or Derived from Them (e.g., insulin produced using recombinant DNA technology).

The Registry is #23 in the following link ([in Ukrainian](#)) and 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 of biotechnology based either on emotional perceptions or misleading news stories, not on sound science.

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 spoken in support of the continued use of biotechnology or research and commercialization.

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

In 2021, Dr. Yaroslav Blume from the National Academy of Sciences of Ukraine published a video ([in Ukrainian](#)) on the Academy's official YouTube channel. In it, he discussed the current situation of GE regulations in Ukraine and debunked 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 generally negative public opinion, inconsistent regulatory framework, gaps in testing regimes for GE products, and gaps in the approval system.

Nielsen Consumer Insights Ukraine 2020 study, “U.S. Food and Beverages: Perception, Expectations, and Potential in Ukraine,” indicated that Ukrainian consumers under 40 perceive food products produced with biotechnology negatively and shoppers pay attention to “non-GMO” labels while buying food.

A 2021 study by the Ukrainian company LOOQME on perceptions of GE products among Ukrainian consumers outlined, in general in the Ukrainian media, including social media, there is a lack of information about the subject. However, there are no major negative sentiments toward agricultural biotechnology and the usage of GE in agriculture.

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, therefore, is 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 it is therefore included in this report.

Part D: Production and Trade:

a. Research and Product Development:

At the time of publication, no known animal cloning or GE animal products were under research or production in Ukraine.

b. Commercial Production:

There are 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 unknown 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 MOH's approved Order #971 list. Post believes that governmental agencies rely 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 species and covers all live forms capable of self-replication or transfer of inheritable factors (including sterile organisms, viruses, and viroids). Therefore, the term "genetically engineered" covers animals, fish species, and insects. The definition in the Biosafety Law 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
- cell fusion (including protoplasm fusion) or hybridization methods when live cells with a new combination of genetic materials are formed through two or more cells fusing in a way that does not occur in nature

Ukrainian laws do not currently use the term “cloning” or “cloned organisms,” except for the Law of Ukraine #2231-IV ([in Ukrainian](#)), “On Prohibition of Human Cloning.” 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 and regulatory norms governing cloning and biotechnology. Voluntary declaration of the importer or 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 circulating 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 and 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 for Plant Products under Chapter 1, Part B, sub-paragraph k, GE animals follow the same rules as other GE species. Ukrainian laws do not allow for the registration of GE traits but provide some protection for registered plant varieties and breeds.

g. International Treaties and Forums:

See Chapter 1, Part B, sub-paragraph m.

h. Related Issues:

None.

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 that of GE plants.

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 use 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 report writing.

Post is aware of domestic production of Interferon alfa-2b medicine and research conducted using microbial biotechnology to produce biofuels and antibiotics. In addition, there is information that local scientific and research institutions are experimenting with GE bacteria. However, this information cannot be verified.

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 countries where microbial biotech-derived ingredients are commonly used.

d. Trade Barriers:

The incomplete regulatory framework serves as a trade barrier 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

Regulatory Framework Governing GE Circulation in Ukraine

Tier I – Adopted by the Parliament of Ukraine

Law of Ukraine #1103-V Framework legislation	Law of Ukraine #2639-VIII Labeling requirements	Law of Ukraine #152-IV Cartagena Protocol
Law of Ukraine 3339-IX Updated framework legislation	Law of Ukraine #2264-VIII On Safety and Hygiene of Feeds	Law of Ukraine #2059-VIII GE Environment Impact Assessment

Tier II – Adopted by the Government of Ukraine

GOU Resolution #468 GE Labeling in Foodstuffs	GOU Resolution #308 Procedures for issuing permits for GE field testing	GOU Resolution #919 Procedures for state registration of GE sources for foodstuffs, feeds, feed additives, and veterinary medicines
GOU Resolution #808 Procedures for state testing and approval of GE agricultural plants for their further use in open system	GOU Resolution #700 Requirements for Accredited GE testing Laboratories	GOU Resolution #922 Interim safety criteria for the use of GE and bioengineering activity in a closed system
GOU Resolution #423 Permit for Transiting GEs not Registered in Ukraine	GOU Resolution #198 Risk Assessment while R&D and Farming of GE Plants	
GOU Resolutions #701 and #761 Scientific and Methodological Center for GE Identification		

Tier III – Ministry-level Regulations

SSUFSCP Registry Ukraine's register of sources of feed and veterinary drugs that were produced with or derived from genetically modified organisms	Ministry of Health Order #971 List of Products Subject to GE Testing	Ministry of Agriculture Order #17 Requirements for State Veterinary and Safety Examination for GOU Resolution #919
	Ministry of Environment Order #36 Criteria for Risk GE Assessment	

Attachments: [Ukraine GE Law \(3339-IX\) Translation.pdf](#)