Required Report: Required - Public Distribution **Date:** December 09, 2025

Report Number: RO2025-0006

Report Name: Biotechnology and Other New Production Technologies Annual

Country: Romania

Post: Bucharest

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

Romania, a member of the European Union (EU), observes the EU's standards and regulations regarding biotechnology. Most farmers view biotechnology as an instrument in managing the agronomic risks and sustaining their competitiveness. However, in its interactions with EU institutions, Romania has a nuanced position regarding the proposed legislation on plants obtained by certain new genomic techniques. Romania allows biotech field trials, but trials are limited to genetically engineered (GE) plum trees. This report provides updated information on the status of biotechnology in Romania and should be read in conjunction with the EU-27 Agricultural Biotechnology Annual report.

EXECUTIVE SUMMARY

As an EU Member State (MS), Romania observes all requisite EU standards and regulations regarding biotechnology. With a few exceptions, legislation remained unchanged over the past year. In 2015, when the EU granted each MS some degree of flexibility to limit biotech cultivation, Romania decided against "opting out." Even so, no biotech crops have been planted in Romania since 2015. Rigorous traceability requirements, difficulties in selling their crops, and co-existence rules, have discouraged farmers from planting the only EU-approved corn product for cultivation, *Bt* corn (MON 810).

Over the past few years, no biotech seed import approvals have been requested and/or granted. Life science companies based in Romania do not conduct laboratory or field testing, as it is an expensive process and the current legal framework limits prospects for cultivation. Only field trials for GE-plum trees (plum-pox resistant) currently take place. According to public information available, no notifications for product development on animal biotechnology have been submitted and there is no known research on GE animals. Two import permits of biotech micro-organisms for utilization in bioethanol production were granted in 2022, but their utilization was discontinued. No information is available regarding the commercial production of food ingredients derived from microbial biotechnology.

Romania is a major EU grain and oilseed producer and exporter but relies on imported plant protein ingredients for livestock feed. A large part of the soy products imported into Romania originate from countries in which biotech crops predominate, such as Brazil, Argentina, and the United States.

The European Commission (EC) proposal to regulate plants obtained through "new genomic techniques (NGTs)" is viewed as an opportunity to address the environmental challenges by some farm organizations and as a threat to conventional varieties by other agricultural stakeholders in Romania. Over the past year, Romania's view reflected fears regarding the disappearance of the conventional varieties and the rejection of the Romanian commodities by its non-EU trading partners.

Acronym glossary:

ANSVSA	National Sanitary-Veterinary and Food Safety Authority
BSC	Biosafety Commission
EU	European Union
EC	European Commission
GE	Genetically Engineered
GMO	Genetically Modified Organism
MARD	Ministry of Agriculture and Rural Development
MEWF	Ministry of Environment, Water and Forests
MF	Ministry of Finance
MS	Member State
NAEPA	National Agency for Environment and Protected Areas
NGTs	New Genomic Techniques

Definitions:
"Genetic Engineering" is the use of transgenesis in plant or animal breeding (transgenesis is the process of introducing an exogenous gene from one organism into another with the intent of enabling the latter to exhibit a new property). In Europe, these resulting organisms are known as "Genetically Modified Organisms (GMOs)."

"Innovative biotechnologies" is used here as a synonym for the European term "New Breeding Techniques" (NBTs) and is generally referred to as genome editing. It excludes traditional genetic engineering (transgenesis).

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a. Research and Product Development:

Romania allows the development of GE plant products. Despite this, there are no commercial GE plants or crops currently under development in Romania.

b. Commercial Production:

Romanian farmers stopped planting GE corn in 2015. The rules on segregation and co-existence, market certification, and traceability requirements, were the primary reasons for excluding biotech *Bt* corn from the crop rotation. Some Romanian farmers are nostalgic for the time when biotech crops, such as soybeans, were allowed for cultivation in Romania before EU membership. Farmers remain hopeful that in the future other biotech plants will be approved for cultivation at the EU level, particularly in the context of insect attacks intensification. When the EU Directive 2015/412 (providing the possibility of

the MSs to restrict or prohibit the cultivation of "GMOs" in their territory) was approved, Romania decided against "opting out." The regulation is referred to as the "opt-out" Directive, allowing any MS to "opt out" of cultivating an approved GE crop for socio-economic reasons as opposed to scientific ones.

c. Exports:

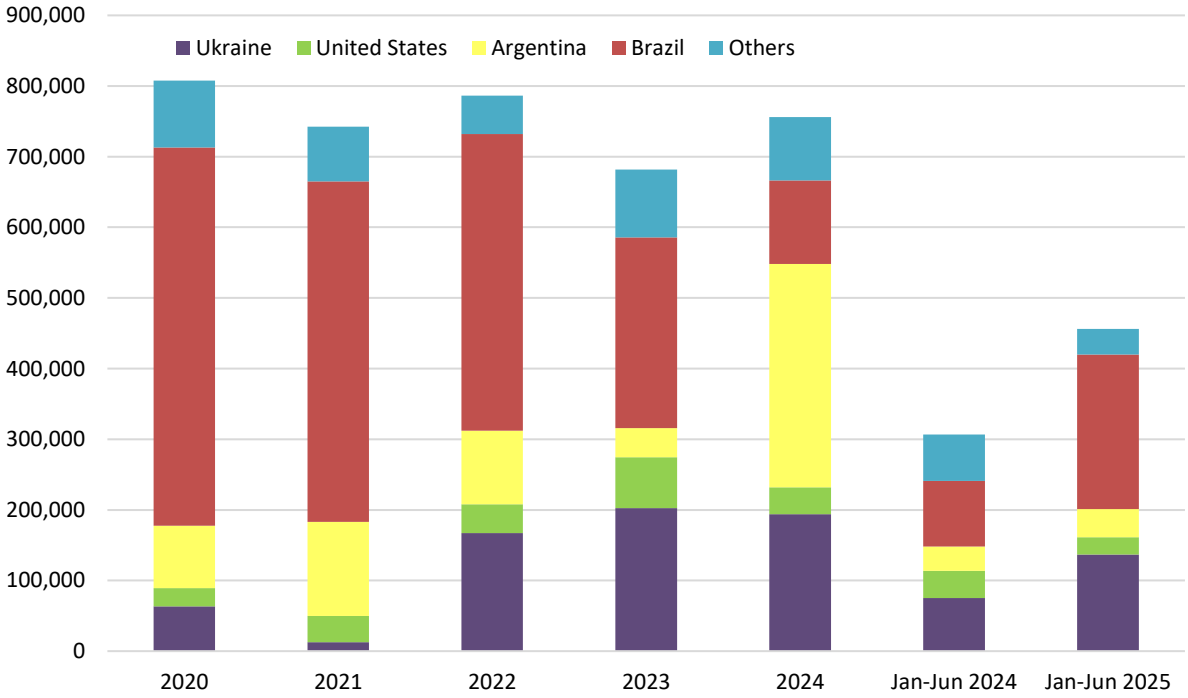
Romania does not currently produce or export any GE crops.

d. Imports:

Due to the unfavorable weather conditions in Romania, soybean area and yields have been on a declining tendency during the past several years. Because of the short supply, Romania imports soybeans and products for the livestock industry, mostly from GE-producing countries (Chart 1). In 2024, over 62 percent of soybeans and soybean meal was sourced from Brazil, Argentina, and the United States. Since 2022, Ukraine emerged as the second leading supplier of soybean products on the Romanian market. In terms of imports of by-products from corn processing, Romania procured Distiller's Dried Grains with Solubles (DDGS) in the first half of 2025 mainly from Ukraine (2,457 MT) and Bulgaria (1,547 MT). Corn Gluten Feed is used in a much lower proportion, so imports are only a fraction compared to other feed ingredients.

Chart 1 - Romania – Total Imports of Soybeans and Soybean Meal

By source, HS Code #1201 and HS Code #2304, MT



Source: Trade Data Monitor LLC

e. Food Aid:

Romania is not a food aid recipient and is not a food aid provider of biotech products.

f. Trade Barriers:

Trade barriers derive from the EU legal framework and mostly relate to asynchronous approval of GE events approved in the United States, but not approved in the EU, or mandatory labelling legislation for consumer products containing GE-ingredients over the set threshold. Please see this section in the EU-27 Agricultural Biotechnology Report.

PART B: Policy

a. Regulatory Framework:

As an EU member, Romania observes all EU regulations regarding biotechnology. Agricultural biotechnology legislation remained stable over the past year. Emergency Ordinance 43/2007, transposing the EU Directive 2001/18, outlines the main phases of the approval process for "GMO" deliberate release into the environment for placing on the market or other purposes. Emergency Ordinance 43/2007 was amended in 2023 through law 144/2023 with provisions on data confidentiality. Order 61/2012 authorizes and regulates GE crop cultivation, including co-existence rules. Government Decision 256/2006 (transposing the EU regulation 1829/2003) regulates the GE animal feed and food. Government Decision 497/2007 transposed the EC Regulation 1946/2003 on trans-boundary movements of "GMOs." Following the EU Directive 2015/412 regarding the freedom of MSs to cultivate or prohibit biotech crops cultivation on their territories, MSs could decide to implement one of two options for opting out of biotech. Romania supported this proposal based on Romanian farmers' openness to biotechnology and declined to ban the cultivation of biotech crops in 2015. In January 2020, Romania approved the Emergency Ordinance 5/2020 transposing the EU Directive 2015/412 regarding the freedom of MSs to cultivate or prohibit biotech crops into national legislation.

i. Table of terms

Legal term (in official language)	Legal term (in English)	Laws and Regulations where term is used	Legal definition (in English)
Organism modificat genetic (OMG)	Genetically modified organism (GMO)	E.O. 43/2007	An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
Organism	Organism	E.O. 43/2007	Any biological entity capable of replication or of transferring genetic material.
Microorganism	Micro-organism	E.O. 44/2007	Any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material.
Microorganism modificat genetic	Genetically modified micro-organism	E.O. 44/2007	A micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
Produs din OMG	Produced from	Government decision	Derived, in whole or in part, from

	GMOs	173/ 2006	GMOs, but not containing or consisting of GMOs.
Plante modificate genetic	Genetically modified plants	Order 61/2012	Superior plants which belong to taxonomy groups gymnosperm and angiosperms, to which through genetic engineering techniques, have been transferred genes from other organisms, giving them new non-specific characteristics: resistance to pests or diseases, tolerance to herbicides or other non-favorable environment factors, nutritional qualities, etc.
Produs agricol modificat genetic	Genetically modified agricultural product	Order 61/2012	Any product obtained from genetically modified plants, which has not been processed, with the purpose of being used for processing and/or utilization as food or feed for animals.

ii. There are several authorities responsible for implementing and enforcing activities related to the use of GE and the deliberate release into environment, per Emergency Ordinance 43/2007 provisions.

The Ministry for Environment, Water and Forestry (MEWF) is the central public authority for environment protection. It coordinates and ensures the application of the precautionary principle to avoid potential adverse effects of GMOs on human health and environment because of obtaining, using, and commercializing these organisms.

The Competent Authority (CA) is the National Agency for Environment and Protected Areas (NAEPA), and is responsible for: receiving, administering and assessing the technical content of the notification; consulting with all responsible bodies including the Biosafety Commission; issuing, revising, suspending, or cancelling authorizations/approvals; ensuring there is a functional national laboratory for "GMOs" detection and determination; establishing and administering the electronic registry for notifications, authorizations, approvals, and their status; establishing and administering the Registry for data on "GMOs" import, export, and transit.

The National Guard for Environment (NGE) is the control authority ensuring the enforcement of legal provisions. The Ministry of Agriculture and Rural Development (MARD) has responsibilities related to seed import and cultivation, while the National Sanitary-Veterinary and Food Safety Authority (ANSVSA) is responsible for food and feed import authorizations and inspections.

The responsibilities of the above regulatory bodies are supplemented by the ones attributed to the Biosafety Commission (BSC) – established in 2002 as an independent and interdisciplinary scientific body with a consultative role in assisting the authorities in the decision-making process regarding the issuance of authorizations/notifications. BSC is comprised of 12 full-members and four substitute members. There is a six-year mandate for each member, per Order 699/2024, approved by the MEWF. Members represent the Romanian Academy, the Agricultural Science Academy, the Medical Science Academy, and the Universities of Medicine and Agricultural Science.

b. Approvals/Authorizations:

Once a biotech event is approved at the EU level for cultivation, feed, or food use, MSs do not need re-authorization at the local level. Romania follows EU legislation regarding GE events authorized for import and cultivation. The full list of approved GE products at the EU level can be viewed here.

c. Stacked or Pyramided Event Approvals/Authorizations:

The EU approves stacked events after passing all phases of the regulatory procedure.

d. Field Testing:

Romania allows field-testing for GE crops specified in the notifications, submitted to the NAEPA for assessment. However, since 2014, biotechnology companies discontinued their field research activities in Romania because of the lack of prospects for cultivation. The authorization for field-tested virus-resistant plum (resistance to plum pox virus) was renewed in 2019 for another 10 years.

e. Innovative Biotechnologies:

In July 2023, EC published a proposal for a new regulation on plants produced by certain NGTs. The proposal entered the trilogue phase in April 2025 aiming to harmonize the positions on the proposal of the three EU governing bodies, Commission, Parliament, and Council.

Romania has had, in general, an open and enthusiastic attitude toward new technologies. That was the case also for innovative biotechnologies, such as genomic editing, which were viewed as potential tools in combatting the effects of unfavorable weather factors. However, during the debate following the publication in July 2023 of the EC proposed regulation on plants obtained by certain new genomic techniques it became clear that some of the agricultural stakeholders and regulatory bodies changed their views based on concerns regarding the impact of NGTs on the local market. The range of concerns varied from patentability aspects to the fear of having the local seed varieties replaced with NGTs-derived seeds and potentially losing the Romanian grain and oilseed export markets because of the lack of full traceability and labelling for such types of products. Over the past year, no notable progress has been achieved in diminishing some of these concerns.

f. Coexistence:

Romania approved and implemented a co-existence policy in 2012. Its relevance, though, is limited since no biotech crops have been cultivated since 2015 in the country. Order 61/2012 provides rules for the authorization and control of GE crops as well as measures for ensuring the co-existence of GE plants with non-GE and organic crops. According to this order, all operators along the commercial chain must transmit and retain information about products that contain or are produced through GE at each stage of the supply chain. In March 2017, MARD issued Order 73, amending Order 61/2012, to transpose the provisions of the EU Directive 2015/412 regarding MSs' ability to restrict or prohibit the GE cultivation. Through this amendment, Romania provides protection at its borders to Bulgaria and Hungary, since these two MSs prohibit GE plants cultivation. National co-existence rules are enforced along international borders and biotech crop cultivation is prohibited within 200 meters of international borders.

g. Labeling and Traceability:

Government Decision 173/2006 transposed Regulation (EC) No 1830/2003 providing the regulatory framework to ensure full traceability of biotech products in Romania. According to this decision, all

operators involved in this business along the commercial chain must transmit and retain information about products that contain or are produced from "GMOs" at each stage of placing them on the market. Accurate information concerning "GMO" presence must be retained for five years. The regulation covers all products containing or being derived from authorized "GMOs" including food and feed. The rules apply to all types of packaging, including bulk. Romania adopted measures on labeling thresholds at 0.9 percent for an adventitious presence of an authorized GE event in food or feed. Processors must demonstrate that the presence of GE material was adventitious or technically unavoidable. While the animal feed containing GE ingredients is required to be labeled, meat, milk, or eggs obtained from animals fed with GE feed or treated with GE medicinal products do not require specific labeling, per the provisions of GOR Decision 256/2006. On a voluntary basis, some manufacturers of cheese (produced with milk sourced from non-GE fed cows) and soy-based foods, choose to apply non-GE label. Order 61/2012 provides rules concerning GE products labeling specifically on biotech seeds for cultivation and crops.

h. Monitoring and Testing:

Romania has legislation which regulates the testing and verification of imported food or ingredients that may contain GE ingredients. Order 35/2016 approved by ANSVSA on the Surveillance and Control Action Plan on food safety (with subsequent amendments) sets provisions on the GE food testing and verification. The frequency and sample collection procedure depend on the type of operation (warehouse, manufacturing plant, processing plant, or food packaging facility). The same order provides for the procedure to be followed by the business operator in case the tests reveal that the shipment is not in compliance with the regulations. The Institute for Diagnosis and Animal Health (IDAH) is the National Reference Laboratory for GE food and feed, while the MARD's Laboratory for Seeds Quality is accredited for carrying out tests for GE presence in corn and soybean conventional seeds.

i. Low Level Presence (LLP) Policy:

Romania follows EU regulations regarding the thresholds for unapproved events in shipments.

j. Additional Regulatory Requirements:

United States is a supplier of soybean seeds for sowing in Romania. In 2023, MARD approved order 500 regarding the official control of seed quality through testing non-GE varieties for the inadvertent presence of GE varieties. According to the order, domestically produced corn and soybeans seeds for planting set for export to other EU member states and imported corn and soybeans from third countries are subject to testing. In case of imports, sampling will consist of at least five percent of the total number of batches imported by an operator annually in case of corn and 25 percent in case of soybeans. Seed batches found contaminated with authorized or non-authorized GE seeds are not certified and cannot be sold as planting material.

k. Intellectual Property Rights (IPR):

IPR issues are regulated via several laws and Government Decisions. The State Office for Inventions and Trademarks is the main body for overseeing the IPR issues in general. The State Institute for Varieties Testing and Registration, under the MARD, is the body responsible for approving and ensuring protection for the crop varieties since July 2011. The legal framework concerning the protection of the new plant varieties is Law 255/1998.

l. Cartagena Protocol Ratification:

Romania ratified the Cartagena Protocol on Biosafety in 2003 through Law 59/2003. The additional Protocol Nagoya-Kuala Lumpur was signed by Romania in 2011 and ratified in 2013 through Law 110/2013. Romania ratified through Law 36/2019 other provisions of the Nagoya Protocol, specifically the access to genetic resources and the fair and equitable sharing of benefits resulting from their use in the Convention on Biological Diversity. As a party in the Cartagena Protocol on Biosafety, Romania regularly participates in the Conference of the Parties serving as the Meeting of the Parties (COP-MOP).

m. International Treaties and Forums:

Romania is a member of various international treaties and conventions, including the International Plant Protection Convention (IPPC) and Codex Alimentarius (CODEX). Romania's IPPC point of contact is the Phytosanitary National Authority, while Romania's CODEX point of contact is ANSVSA. As a member of the European Union, Romania does not express a direct opinion in the decision process at the level of the international bodies, such as CODEX, unless it is a non-EU harmonized decision on which each MS has the right to vote.

n. Related issues: N/A

PART C: Marketing

a. Public/Private Opinions:

Being one of the few EU MSs in which farmers experience biotech crops cultivation –soybeans until 2007 and corn until 2015 – the topic of biotechnology is treated in Romania with interest by a diverse array of stakeholders (including regulators, farmer associations, scientists and researchers, consumers, and media). Bearing in mind the advantages offered by the biotech soybean cultivation before Romania's accession to EU, farmers represent the most vocal group advocating for access to the latest technology and for ensuring fair competition with other countries around the globe. While some farm organizations support the EC legislative efforts to ensure farmers' access to advanced technology, others share a less favorable position regarding the EC proposal on NGTs. Their reservations stem from the patentability issues and the lack of traceability and labeling. The seeds industry in Romania has been active in raising the awareness regarding biotechnology; therefore, it welcomed the EU proposed regulation which differentiates between the conventional-like "NGT" plants (Category 1) and transgenic plants and saluted the movement of the EU NGTs proposal legislation into the trilogue stage. Despite being the main drivers for the GE feed imports, the livestock and poultry industries tend to be less vocal about using GE ingredients in the feed recipes due to fear of consumer opposition. Consumers' attitude towards biotechnology has not changed. Some consumer associations and organic retailers paint biotech-derived products, including the ones obtained through NGTs, as allegedly affecting plant biodiversity and being unnatural and potentially harmful.

b. Market Acceptance/Studies:

There have been no recent Romanian studies published about agricultural biotechnology. A view of the Romanian experience and perspective on the commercial cultivation of "genetically modified crops" in Europe may be read here (2018).

Released in February 2025, the Eurobarometer survey captured Romanian citizens' knowledge and attitudes towards science and technology. According to its findings, 32 percent of the Romanian respondents believe that science and technology have a negative and very negative influence on society, the highest among the EU members, and at a far distance from the EU average of 13. The lowest

proportion of respondents who think that the new technologies in vaccines and combatting infectious diseases will have a positive impact in the next 20 years is in Romania (50 percent), as compared to the EU average of 77 percent. Specifically, on biotechnology and genetic engineering, 49 percent of the Romanian citizens believe that this area will have a positive effect in the next 20 years, well below the EU average of 67 percent and below the 55 percent figure recorded in the EU barometer of 2021. In Romania, 37 percent of respondents think that biotechnology and genetic engineering will generate a negative effect on our way of life, which is above the EU average of 22 percent and up eight percent from the previous barometer.

In 2022, the European Food Safety Authority (EFSA) conducted a Eurobarometer survey aiming to gauge Europeans' perceptions of and attitudes towards food safety by exploring various themes related to food safety. Seventy-one percent of the Romanians responded that they are interested in food safety, slightly above the EU average (70 percent). Among the problems and risks associated with food and eating, apart from the health impact, contaminants, additives, origin, price, source, the survey included "genetically modified organisms." In Romania about 20 percent of the respondents indicated the use of new biotechnology in food production as a food safety topic, as compared to the EU average of 26 percent.

CHAPTER 2: ANIMAL BIOTECHNOLOGY[1]

PART D: Production and Trade

a. Research and Product Development:

According to the information posted by NAEPA, no notifications for research and product development on animal biotechnology have been submitted for authorizations. There is no known research with GE animals.

b. Commercial Production:

There is no information available regarding livestock clones, GE animals, or products obtained for commercial production in Romania.

c. Exports:

There is no specific information about any export of livestock clones or GE animals or products from Romania.

d. Imports:

There is no specific information available on the import of products originating from cloned animals. There are no known imports of GE animals or cloned animals for agricultural purposes into Romania.

e. Trade Barriers:

The main barrier in using animal biotechnology to improve animal breeding is Romanian public opposition.

[1] *Animal genetic engineering and genome editing result in the modification of an animal's DNA to introduce new traits and change one of more characteristics of the species. Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is, therefore, different from the genetic engineering or genome editing of animals (both in the science and often in the regulation of the technology and /or products derived from it). Researchers and industry may use cloning when creating animals via other animal biotechnologies. For this reason, cloning is included in this report.*

PART E: Policy

a. Regulatory Framework:

Currently Regulation (EU) 2015/2283 is the EU legislation covering novel foods, including animal cloning. Most of its provisions took effect starting January 1, 2018. In Romania, ANSVSA is the authority handling the food safety and animal welfare aspects of the GE animal/livestock clones. When Romania formulates a position on animal biotechnology, ANSVSA has a multi-disciplinary consultative body to discuss and issue an opinion.

b. Approvals/Authorizations:

Regulation (EU) 2015/2283 provides the rules for placing novel foods on the EU market.

c. Innovative Biotechnologies:

No specific opinions have been issued on innovative biotechnologies in domestic animals. Please refer to the same section in Chapter 1, Part B, sub-paragraph e, for additional information.

d. Labelling and Traceability:

Please see the same section in the EU-27 Agricultural Biotechnology Report.

e. Additional Regulatory Requirements: Not applicable.

f. Intellectual Property Rights (IPR):

Please refer to Chapter 1, Part B, sub-paragraph k of this report for additional information.

g. International Treaties and Forums:

Romania is a member of the World Organization for Animal Health (OIE) and Codex Alimentarius (CODEX), without being deeply involved in the discussions about GE animals.

h. Related issues: Not applicable.

PART F: Marketing

a. Public/Private Opinions:

Animal biotechnology is a topic that gets very limited coverage in Romania. There is little appetite for information about these advanced technologies, mainly driven by the general attitude towards biotechnology or previous cloning-project failures. Media coverage is limited to reporting on decisions taken at the EU level, the United States, or Canada regarding the regulatory framework or marketing of GE products.

b. Market Acceptance/ Studies:

There are no known Romanian market studies on the use of animal biotechnologies or consumer perception on this topic.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: Production and Trade

a. Commercial Production:

Information regarding the commercial production of food ingredients derived from microbial biotechnology is not available. Nevertheless, considering their availability in other EU member states, their utilization in the food-industry in Romania may not be excluded.

b. Exports:

Information regarding exports of GE microbes or products that contain microbial biotech-derived food ingredients in Romania is not available.

c. Imports:

Information regarding imports of microbial biotech-derived food ingredients or processed products containing microbial biotech-derived food ingredients in Romania is not available. However, there is information related to the import of GE microorganisms for contained use for non-food purposes. According to NAEPA, two import permits for *Trichoderma reesei* and *Saccharomyces cerevisiae* for bioethanol production were issued in 2022 (link in Romanian language).

d. Trade Barriers:

Romania applies the EU legislation. Please see the EU-27 Agricultural Biotechnology Report.

PART H: Policy

a. Regulatory Framework:

The Government Ordinance 44/2007 on the contained use of the genetically modified microorganisms transposed the EU Directive 2009/41. Apart from the common measures for the contained use of GE microorganisms, the ordinance establishes the main authorities and their roles in regulating the contained use of GE microorganisms. Their roles are similar to the ones listed in Chapter 1, Part B of this report, to which few other bodies were attributed roles, such as the Ministry of Education and Research, Ministry of Labor and Social Protection, and the Customs Authority. For more detailed information on the EU regulatory framework, please see the EU-27 Agricultural Biotechnology Report.

b. Approvals/Authorizations:

The Government Ordinance 44/2007 on the contained use of the genetically modified microorganisms transposing the EU Directive 2009/41 provides information on the risk assessment undertaken by the authorities and the authorization procedure by class of risk. For more detailed information, please see the EU-27 Agricultural Biotechnology Report.

c. Labelling and Traceability:

There is no country-specific policy. Please read the EU-27 Agricultural Biotechnology Report.

d. Monitoring and Testing:

There is no country-specific policy. Please read the EU-27 Agricultural Biotechnology Report.

e. Additional Regulatory Requirements: Not applicable.

f. Intellectual Property Rights (IPR):

Please refer to Chapter 1, Part B, sub-paragraph k of this report for additional information.

g. Related Issues:

In Romania, following the positive scientific opinion issued by the BSC, NAEPA issued two authorizations for contained use of two GE microorganisms *Trichoderma reesei* (strains SCF07199, SCF010833 and SCF010840) and *Saccharomyces cerevisiae* (strain SCY05234) to be used in the industrial production of cellulosic bioethanol (link in Romanian language). In 2024 the user notified NAEPA that the activity involving the utilization of the two GE microorganisms ceased.

PART I: Marketing

a. Public/Private Opinions:

There is little to no public awareness about the use of microbial biotech for food ingredients or nutritional purposes, therefore it is difficult to assess the public or private perception.

b. Market Acceptance/Studies:

FAS Bucharest is not aware of market acceptance studies on microbial biotechnology.

Attachments:

No Attachments