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Report Highlights:

Romania, a member of the European Union (EU), maintains a balanced view regarding agricultural biotechnology. Although no biotech crops are cultivated in Romania, farmers continue to view biotechnology as an instrument in managing the agronomic risks and sustaining their competitiveness. Romania permits biotech field trials, but interest is 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. Legislation has not been updated 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”. Despite Romanian farmers’ support for genetically-engineered (GE) crops, no biotech crops have been planted in Romania since 2015. Rigorous traceability requirements, marketing difficulties, and co-existence rules have discouraged farmers from planting the only EU-approved corn product for cultivation, Bt corn (MON 810).

Over the past year, 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 prospects for cultivation are limited. Field trials for GE-plum trees (plum-pox resistant) are ongoing. According to the information available, no notifications for product development on animal biotechnology has been submitted and there is no known research with GE animals. An authorization for the import and utilization of biotech micro-organisms in bioethanol production was granted in 2021. Information regarding the commercial production of food ingredients derived from microbial biotechnology is not available.

Romania is a major EU grain and oilseed producer and exporter, but relies on imported plant protein ingredients for livestock feed. Fear of supply chain disruption and supply availability in the major producing countries triggered nearly a double import volume in the first half of 2022 as compared to the previous year. About 90 percent of the soy products imported into Romania originate from countries in which biotech crops predominate. The United States is the second soybean supplier in Romania.

Military conflict in Ukraine, poor crops in certain regions, and deficient distribution channels have led to soaring global input costs and heightened volatility for agricultural commodities. In this context, discussion about accessing new tools, such as innovative biotechnologies, intensified at both public and private entities level. The European Commission (EC) plans to formulate new legislation on plants obtained through new genomic techniques (NGTs) in 2023.

Acronyms used in this report:

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
NAEP	National Agency for Environment Protection
NGTs	New Genomic Techniques

Glossary:

“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. Nonetheless, there are no commercial GE plants or crops currently under development in Romania.

b. Commercial Production:

Romanian farmers ceased planting GE corn in 2015. The segregation, co-existence, market certification, and traceability requirements, as well as lower insect pressure, are primarily the reasons farmers choose not to plant biotech Bt corn. Although not currently a biotech plant producer, Romania remains open to other biotech plants in case they become approved for cultivation at EU level. When the [EU directive 2015/412](#) (providing the possibility of the member states to restrict or prohibit the cultivation of genetically modified organisms (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 as opposed to scientific reasons.

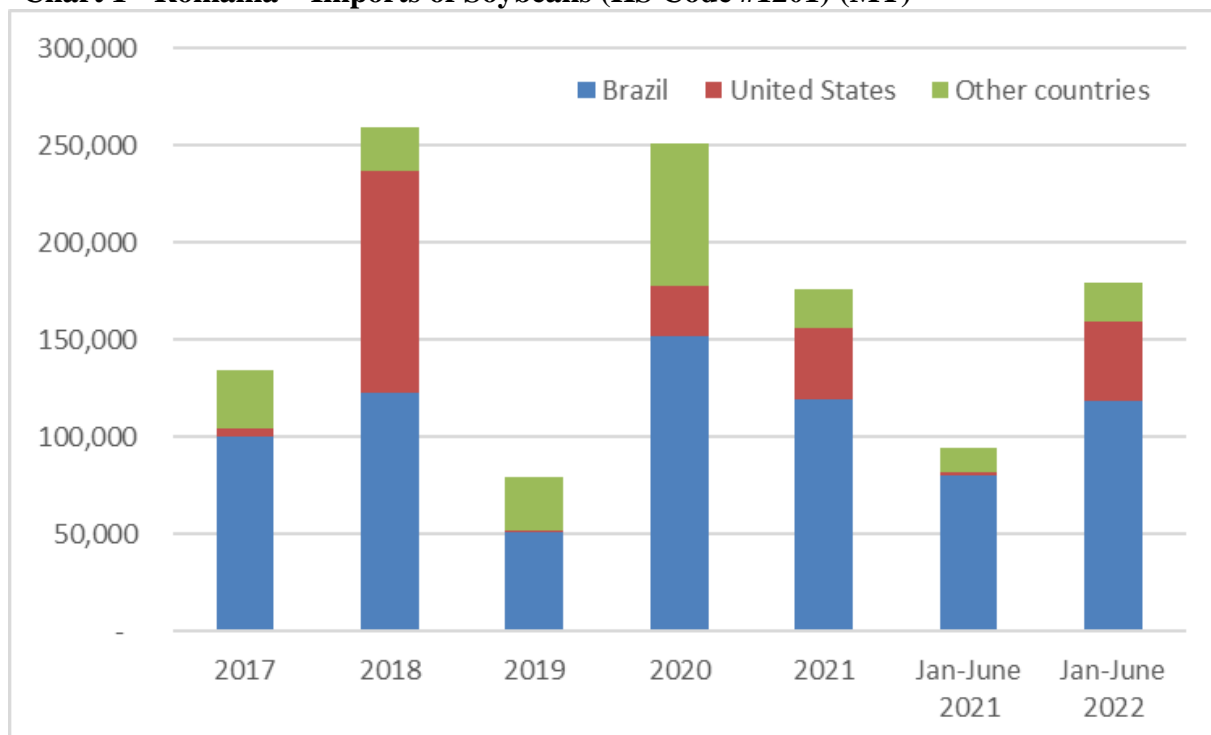
c. Exports:

Romania does not currently produce or export any GE crops.

d. Imports:

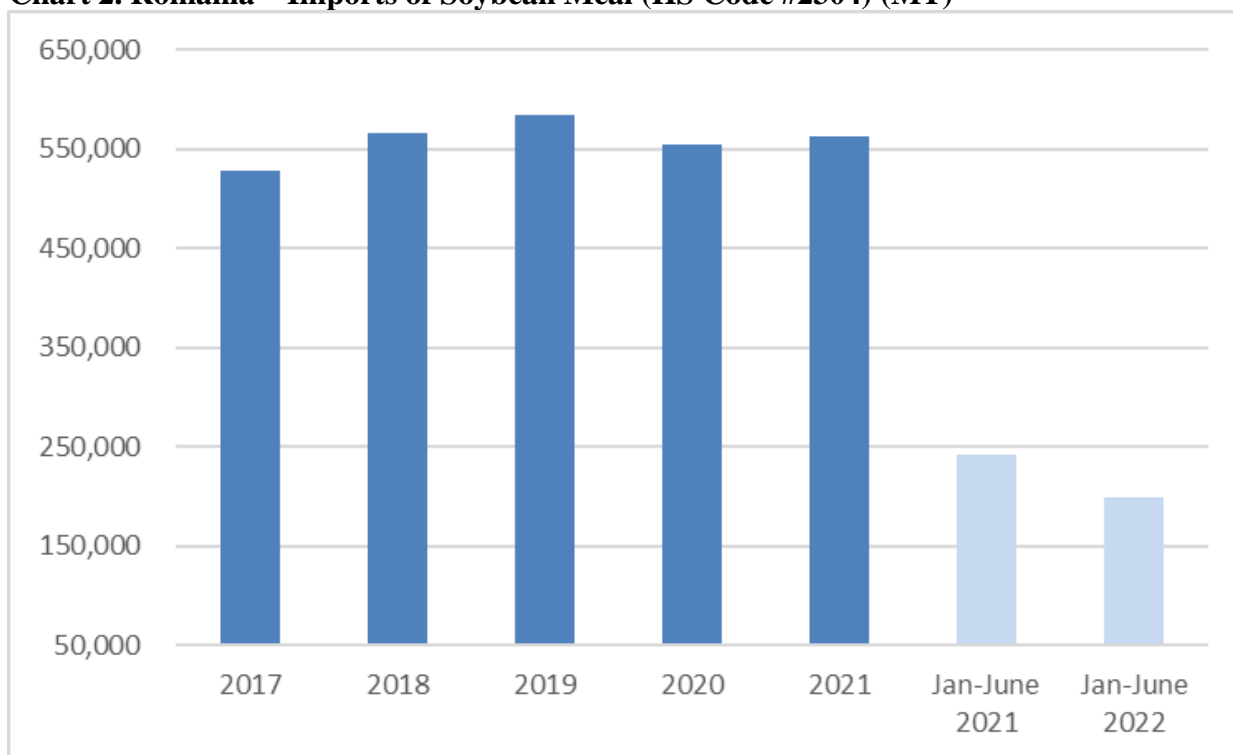
Romania is a net exporter for grains and oilseeds, with the exception of soybeans. In 2022, domestic soybean production is estimated to fall by 14 percent year-on-year to 300,000 metric tons (MT), due to drought, hence imports are on an upward curve. Romania exports over half of local soy production to other EU countries, notably Germany, Italy, Hungary and Austria, which have strong demand for non-GE feed ingredients. Turkey has been the major non-EU market in 2022, after exports to Russia plunged. To cover its feed demand, Romania imports soybeans and soybean meal, mostly from GE-producing countries. In 2021, about 90 percent of soybeans was sourced from Brazil (118,723 MT) and the United States (40,575 MT) (Chart 1). Imports of soybean meal are relatively stable (Chart 2) and originate mostly from South America. In terms of imports of corn processing-by products, Romania imports Distiller’s Dried Grains with Solubles (DDGS) mainly from Hungary, and the import volume depends on supply availability from the neighboring country. Corn Gluten Feed is used in a much lower proportion in Romania, so imports are only a fraction as compared to other feed ingredients.

Chart 1 - Romania – Imports of Soybeans (HS Code #1201) (MT)



Source: Trade Data Monitor LLC

Chart 2. Romania – Imports of Soybean Meal (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 unchanged from last year. Emergency Ordinance 43/2007, transposing the [EU Directive 2001/18](#), lays down the main phases of approval process for GMO deliberate release into the environment for placing on the market or other purposes. Order 61/2012 authorizes and regulates GE crop cultivation, including co-existence rules. Government Decision 256/2006 (transposing [Regulation \(EC\) No. 1829/2003](#)) regulates the GE animal feed and food. Government Decision 497/2007 transposed the [EC Regulation 1946/2003](#) on trans-boundary movements of genetically-modified organisms. Following the [EU Directive 2015/412](#) regarding the freedom of MSs to cultivate or prohibit biotech crops cultivated 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 GMOs	Government decision 173/ 2006	derived, in whole or in part, from 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 central public authority for environment protection, the Ministry for Environment, Water and Forestry (MEWF), coordinates and ensures the application of the precautionary principle to avoid potential adverse effects of GMOs on human health and environment as a result of obtaining, using, and commercializing these organisms.

The Competent Authority (CA) is the National Agency for Environment Protection (NAEP), which is responsible to:

- receive, administer and assess the technical content of the notification
- consult with all responsible bodies including the Biosafety Commission
- issue, revise, suspend or cancel authorizations/approvals
- ensure there is a functional national laboratory for GMOs detection and determination
- establish and administer the electronic registry for notifications, authorizations, approvals and their status
- establish and administer 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 seeds 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), which was established in 2002 as an independent and interdisciplinary scientific body with 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. Selected in September 2019 for a four-year mandate per Order 984/2019 issued by MEWF, members represent the Romanian Academy, Agricultural Science Academy, 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 NAEP for assessment. Nevertheless, 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) was renewed in 2019 for another ten years.

e. Innovative Biotechnologies:

A regulatory approach for innovative biotechnologies is pending at EU level. In 2021, the EC published a study, which revealed the limitations of the legislation currently in place in keeping pace with the new scientific developments. In 2022, EC launched a consultative process seeking views from major stakeholders about the best approaches for regulating plants obtained through genome-editing. An impact assessment and a potential legal proposal are expected in the second quarter of 2023.

The Romanian Government has not issued and assumed a country position for innovative biotechnologies, such as genome editing. In general, the leadership of the MARD has shown a favorable opinion toward agricultural biotechnology, regardless of the political party holding this position. During the informal AGRIFISH meeting held in September 2022, the Romanian Minister of Agriculture expressed a favorable position on the new genomic techniques, stating that new genomic techniques can offer responses to the challenges of climate change and help achieve the objectives of the European Green Deal, by obtaining new varieties of plants resistant to water shortages, diseases and pests, and move to a sustainable model of agriculture in a shorter time. The minister mentioned that increasing public and consumer awareness of products obtained through new genome editing techniques is important for bringing them to market. He further added that it would be good to have genomic techniques approved as quickly as possible at the EU level and benefit from the allocation of funds for research in this field.

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 the 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 MS' 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 from international borders.

g. Labeling and Traceability:

Government Decision 173/2006 transposed [Regulation \(EC\) No 1830/2003](#) and provides 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 GMOs 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 (based on milk from non-GE fed cows) and soy-based foods choose to apply non-GE labels (samples below).



Source: Retail Outlets

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 foods 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 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 to Romania. In 2014, MARD published Order 1573/2014 regarding the official control of seeds quality through tests of non-GE varieties for the inadvertent presence of GE varieties. According to the order, seed testing is conducted through methods approved by the Reference EU Laboratory for GE food and feed. The maximum percentage of inadvertent presence of GE seeds in batches of non-GE corn intended for cultivation in case of approved events is 0.1 percent, with zero tolerance for other crops, such as soybeans. Seeds are not approved for commercialization in Romania in case this percentage is exceeded.

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 is the body responsible for approving and for 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. 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 an EU member, 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 where each MS has the right to vote.

n. Related issues: N/A

PART C: Marketing

a. Public/Private Opinions:

Romania's legacy related to agricultural biotechnology, including biotech soybean cultivation until 2007, and biotech corn cultivation until 2015, maintains the attention of a diverse array of stakeholders (regulators, farmer associations, scientists and researchers, consumers, and media). On the government side, the Ministry of Agriculture, has shown a favorable opinion on agricultural biotechnology, including new genomic techniques (please see section Innovative Biotechnologies).

Farmers represent the most vocal group advocating for access to the latest technology and for ensuring a fair competition with other countries around the globe. Farm representatives claim that they need advanced tools in order to achieve the goals set out in the Farm to Fork strategy, which include access to the new genomic techniques. They fear the new strategy will disadvantage Romanian farmers and leave them un-equipped to manage plant diseases.

The seed industry perceives the EU legislation as restrictive and advocates for a fair legal framework on innovative biotechnologies. The livestock and poultry sectors support GE feed production, but tend to be less vocal about using GE ingredients due to fear of consumer opposition. Consumers' attitude towards biotechnology remains largely shaped by the biotech opponents. Many consumers perceive agricultural biotechnology as profitable solely to farmers, while some consumer associations and organic retailers paint biotech-derived products as allegedly unnatural and potentially harmful.

Most agricultural scientists support agricultural biotechnology. With its valuable network of research institutes, the Academy of Agricultural Science and Forestry (ASAS) views agricultural biotechnology as an opportunity to invigorate Romanian agricultural research. ASAS is generally critical toward non-scientific policy development, including the European Court of Justice's 2018 decision on gene-editing techniques ([Case C-528/16](#)). In its view, the absence of a clear regulatory framework on gene-editing

discourages investments and weakens the interest of researchers and young students in agricultural research. ASAS advocates for a solid and resourceful research and development sector able to use genome-editing for creating local seed varieties, which would be more likely to perform in the local environment.

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](#), an article published in 2018.

Post is not aware of a study on consumers' perceptions on biotechnology conducted recently in Romania. Nevertheless, the [Eurobarometer survey](#) released in September 2021 captured Romanian citizens' knowledge and attitudes towards science and technology. According to its findings, nearly three quarters of Romanian citizens manifest a high or moderate interest in new scientific discoveries and technological development. This is an improvement from 10 years ago when 58 percent of Romanian citizens were interested in science. Specifically, on biotechnology and genetic engineering, 55 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 70 percent, while 29 percent believe they will generate a negative effect, which is above the EU average of 21 percent. In terms of means of engagement with science and technology issues, a third of Romanian citizens watch documentaries or read science and technology-related publications as opposed to EU's average of 59 percent.

CHAPTER 2: ANIMAL BIOTECHNOLOGY¹

PART D: Production and Trade

a. Research and Product Development:

According to the information posted by NAEP, 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 or 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:

¹ *Animal genetic engineering and genome editing result in the modification of an animal's DNA to introduce new traits and change one or 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.*

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 the public opposition.

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 of novel foods on the EU market.

c. Innovative Biotechnologies:

No specific opinions have been issued on innovative biotechnologies in domestic animals. Please see the same section in the Plant Biotechnology Chapter on this report.

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 see the same section in the Plant Biotechnology Chapter on this report.

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 which 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 (*e.g.* GE salmon).

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-micro-organisms for contained use for non-food purposes. According to [NAEP](#) (in Romanian language), an import permit for *Trichoderma reesei* and *Saccharomyces cerevisiae* for bioethanol production, was issued in July 2021 with validity until April 2031.

d. Trade Barriers:

Romania applies the EU legislation. Please see the [EU-27 Agricultural Biotechnology Annual](#).

PART H: Policy

a. Regulatory Framework:

The Emergency Ordinance 44/2007 on the contained use of the genetically modified microorganisms transposes 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 the 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, please see the [EU-27 Agricultural Biotechnology Report](#).

b. Approvals/Authorizations:

The Emergency 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:

No country-specific policy, please read the [EU-27 Agricultural Biotechnology Report](#).

d. Monitoring and Testing:

No country-specific policy, please read the [EU-27 Agricultural Biotechnology Report](#).

e. Additional Regulatory Requirements: Not applicable.

f. Intellectual Property Rights (IPR):

Please see the Plant Biotechnology Section of this report.

g. Related Issues: Not applicable.

PART I: Marketing

a. Public/Private Opinions:

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

b. Market Acceptance/Studies:

Post is not aware of market acceptance studies on microbial biotechnology.

Attachments:

No Attachments