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**Report Highlights:**

Romania is one of the European Union's (EU) most progressive and pro-science Member States (MSs) regarding agricultural biotechnology. Currently, Romanian farmers cultivate no commercial biotech crops, but they widely use imported genetically engineered (GE) soybean meal as a livestock feed ingredient. Romanian farmers are hopeful that favorable changes in the EU legal framework will allow Romania to respond to the future challenges posed by climate change.

## EXECUTIVE SUMMARY

As an EU 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 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).

No additional 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 expensive and prospects for cultivation are limited. An import authorization was granted in 2021 for the import and utilization of biotech micro-organisms in bioethanol production. Biotech field trials for plum trees are ongoing.

Although Romania is a major EU grain and oilseed producer and exporter, it continues to rely on imported plant protein ingredients for livestock feed. Due to the poor domestic soybean crop and the fear for supply chain disruptions, soybean imports tripled in 2020. Nearly 90 percent of the soy products Romania imports originate from countries which have commercialized biotech products.

In the context of the EU Farm to Fork (F2F) strategy, there was considerable discussion in Romania about having access to new tools, such as new genomic techniques, in order to reach the set goals of the strategy. This debate is expected to continue over the next year.

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## CHAPTER 1: PLANT BIOTECHNOLOGY

### PART A: Production and Trade

**a. Product Development:** Romania allows the development of GE plant products. However, there is no commercial GE plants or crops currently under development in Romania.

**b. Commercial Production:** Romanian farmers have not planted GE corn since 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.

**b. Exports:** Romania does not currently produce or export any GE crops.

**c. Imports:** Romania is the third largest soybean producer in the EU. Soy production subsidies have incentivized farmers to double production over the last five years. Soybean production is estimated to reach about 370,000 metric tons (MT) in 2021, 20 percent above 2020 when drought trimmed the yields. Generally, over half of local soy production is exported to other EU markets, notably Germany and Austria, which have strong demand for non-GE feed ingredients. Russia and Turkey are the major non-EU markets. As the domestic production cannot meet local demand, Romania must import soybeans and soybean meal, of which nearly 90 percent is sourced from South America and the United States (Tables 1 and 2).

**Table 1. Romania – Imports of Soybeans (HS Code #1201)**

Partner Country	Unit	Calendar Year				January-June		
		2017	2018	2019	2020	2020	2021	%Δ 2021/20
World, of which	MT	134,695	259,504	79,356	250,790	151,605	93,757	-38.2
Brazil	MT	99,815	123,109	50,700	151,807	121,882	80,000	-34.4
Ukraine	MT	75	44	1,075	27,766	1,298	4,501	246.7
United States	MT	4,200	113,477	979	26,108	1,108	1,829	65.07
Serbia	MT	5,199	1,677	3,938	21,019	6,250	1,374	-78.0
Moldova	MT	15,694	10,282	13,676	11,940	11,134	2,021	-81.9

Source: Trade Data Monitor LLC

**Table 2. Romania – Imports of Soybean Meal (HS Code #2304)**

Partner Country	Unit	Calendar Year				January-June		
		2017	2018	2019	2020	2020	2021	%Δ 2021/20
<b>World, of which</b>	MT	<b>527,199</b>	<b>565,196</b>	<b>584,314</b>	<b>554,734</b>	<b>271,040</b>	<b>241,662</b>	<b>-10.84</b>
Brazil	MT	228,033	434,755	431,773	383,302	166,596	178,334	7.05
Argentina	MT	205,655	52,549	43,969	88,288	51,655	13,112	-74.62
Ukraine	MT	998	12,198	16,598	35,554	23,315	8,272	-64.52
Hungary	MT	48,533	24,612	26,808	22,286	14,125	10,129	-28.29
Egypt	MT	-	-	-	6,749	6,749	21,885	224.27
United States	MT	22,267	22,644	49,295	0	0	0	0

Source: Trade Data Monitor LLC

**d. Food Aid:** Romania is not a food aid recipient.

**e. 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:** No significant changes have occurred over the past year in terms of implementing and enforcing biotech regulations vis-à-vis any products or activities. The main body with regulatory responsibilities is the Ministry of Environment (MOE), as the central public authority for environmental protection. It coordinates and ensures the application of the EU precautionary principle. The National Authority for Environment Protection (NAEP) is the main interlocutor vis-à-vis company applications and implementation of the legislation. The National Guard for Environment (NGE) enforces legal provisions. The Ministry of Agriculture and Rural Development (MARD), the National Sanitary Veterinary and Food Safety Authority (ANSVSA), and the Ministry of Health (MH) have roles in implementing GE product legislation.

The responsibilities of these regulatory bodies are supplemented by the ones attributed to the Biosafety Commission (BSC), which is the coordinating scientific body comprised of twelve full-members and four substitute members. Selected in September 2019 for a four-year mandate per Order 984/2019 issued by MOE, members represent the Romanian Academy, Agricultural Science Academy, Medical Science Academy, as well as the Universities of Medicine and Agricultural Science. The BSC has the role of a consultative body for NAEP.

Romania's agricultural biotechnology legislation remained unchanged from last year. Order 61/2012 issued by the MARD 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.

**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 EU register of authorized 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 perspectives for biotech cultivation. The existing authorization for field-tested virus-resistant plum (resistance to plum pox) was renewed in 2019 for another ten years.

**e. Innovative Biotechnologies:** The July 2018 ruling by the EU Court of Justice which determined that organisms produced with new breeding techniques (NBT) are subject to the same restrictive provisions of [EU Directive 2001/18](#) stirred the discussions at national level. Public administration, specifically Romania's MARD, and private entities have expressed the support for amending the EU legislation because the current one does not reflect the most recent technology.

MARD officials have been consistent in their favorable attitude towards agricultural biotechnology. This view has been extended to innovative biotechnology. In May 2021, through the voice of the Agriculture Minister at the AgriFish Council, *“Romania considered it is appropriate to act as soon as possible to amend the current legislation governing the field of genetically modified organisms and mutagenesis in order to be in line with scientific and technological developments in the field of biotechnology, ensuring a high degree of protection of human and animal health and environment. Given the sufficient scientific knowledge on plant improvement, including those for risk assessment, as well as the wide applicability of the resulting products, Romania supports the Commission's position to prioritize the development of policies on targeted mutagenesis and cisgenesis, which may occur in the wild and without human intervention”*. In his view, *“actions on plant improvement can help achieve the goals of the Green Deal and Farm to Fork and the sustainability and resilience of the EU food system.”*

**f. Coexistence:** Romania approved and implemented a co-existence policy. However, as there are no biotech crops planted in the country, its relevance in case of cultivation is limited. The MARD's 2012 Order 61 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. According to Ministerial Order 61, 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. This Order includes provisions for all food and feed containing authorized biotech events. In March 2017, MARD issued Order 73, amending

2012's Order 61 to transpose the provisions of the [EU Directive 2015/412](#) regarding MS' ability to restrict or prohibit the GE cultivation. This amendment was for Romania to provide protection at its borders to Bulgaria and Hungary, since these MSs prohibit GE cultivation. Basically, national co-existence rules are enforced along international borders and biotech crops cultivation is prohibited within 200 meters of an international border.

**g. Labeling and Traceability:** Order 61/2012 provides rules concerning GE products labeling and is in line with the EU requirements. 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

**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 law. 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:** 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 corn intended for cultivation in case of approved events is 0.1 percent, with zero tolerance for other crops, such as soybeans.

**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.

**m. International Treaties and Forums:** Romania is a member of various international treaties and conventions, including the International Plant Protection Conventions (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 where each Member State has the right to vote.

**n. Related issues:** N/A

## PART C: Marketing

**a. Public/Private Opinions:** Romania's history with biotech soybean cultivation until 2007, and biotech corn cultivation until 2015, triggered the interest of many groups for expressing an opinion. The discussion about the new genomic techniques intensified when in April 2021, the EU Commission published a study which revealed that the EU legislation on this field does not correspond to the current scientific progress. Farmers are the most vocal group advocating for access to the latest technology and a fair competition playground with other countries around the globe. They claim the farm community needs advanced tools in order to achieve the goals set out in the Farm to Fork strategy, including 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 livestock and poultry sectors also support GE soybean use, but tend to be less vocal about using these ingredients, while advertising the utilization of non-GE grains in the feed ratios. The seed industry remains reluctant to initiate research projects or field trials in biotechnology because of the restrictive EU legislation and limited prospects for cultivation at large scale. At the consumer level, the attitude towards biotechnology remains largely driven by the biotech opponents, according to which biotech products are allegedly unnatural and potentially harmful.

Most agricultural scientists support the use of GE crops. With its valuable network of research institutes, the Academy of Agricultural Science and Forestry (ASAS) has been a strong supporter of agricultural biotechnology criticizing the non-scientific policy developments and European Court of Justice's 2018 decision on gene-editing techniques. In their view, the unfavorable environment for research in the gene-editing techniques discourages investment and weakens the interest of researchers in such areas.

One of the organizations striving to increase awareness and knowledge about biotechnology in Romania is the AgroBiotechRom Association, an active Romanian advocacy organization and member of EuropaBio. The updated science-based information provided by the organization regularly maintains the interest of a large array of stakeholders, including regulators, farmer associations, scientists and researchers, media and others.

The organization supporting biotech-free crops, especially at the farm-level, is the Danube Soybean Association. That is driven by the demand of some of its members for non-GE soybeans. Romania is a signatory of the Danube Soya Association (DonauSoja) Agreement.

**b. Market Acceptance/Studies:** Post is not aware of a study on consumers' perceptions on biotechnology conducted during 2020- 2021 in Romania. Nonetheless, Romanian citizens' knowledge and attitudes towards science and technology was revealed in September 2021 by the [Eurobarometer survey](#). 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 the 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 BIOTECHNOLOGY<sup>1</sup>

### PART D: Production and Trade

**a. Product Development:** According to the information posted by NAEP, no notifications for product development having animals as subject of biotechnology research 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 are no data about any export of livestock clones or GE animals or products from Romania.

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<sup>1</sup> *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.*



**d. Imports:** There are no specific data 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:** The procedure for authorizing the placing on the EU market of a novel food is provided by the [Regulation \(EU\) 2015/2283](#).

**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 on 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.

## 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, on non-food purpose, there is information related to the import of GE-micro-organisms for contained use. According to NAEP, an import permit for *Trichoderma reesei* and *Saccharomyces cerevisiae* for biofuel production, was issued this year 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 Government Ordinance 44/2007 on the contained use of GE 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 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:** No country-specific policy, please read 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 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