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Prepared By: Monica Dobrescu

Approved By: Jonn Slette

Report Highlights:

Although Romania is one of the European Union's (EU) most progressive and pro-science Member States (MSs) regarding agricultural biotechnology, it does not currently produce any commercial biotech crops. Romanian farmers widely use imported genetically engineered (GE) soybean meal as a livestock feed ingredient. Romanian farmers are hopeful that Romania will contribute to the EU Protein Program. The Romanian general public tends to view GE product with suspicion, as not natural, and potentially harmful.

Executive Summary

As an EU MS, Romania observes all requisite EU standards and regulations regarding biotechnology. In 2015 when the EU granted MSs 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. 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. Nearly 90 percent of the soy products Romania imports are from countries which have commercialized biotech products. Because of drought conditions throughout the 2020 growing season in Romania, soy product imports will likely increase 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 are 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 Romania is not currently growing biotech crops, Romanian farmers are open to other biotech crops if they become approved for cultivation by the European Commission. When the EU directive 412/2015 (flexibility for MSs to restrict or prohibit biotech cultivation within their borders) 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 the EU's third-largest soybean producer. Soy production subsidies have incentivized farmers to double production over the last five years, reaching a 400,000-metric ton (MT) peak in 2019. Generally, over half of local soy production is exported to other EU markets, notably Germany and Austria, which have strong demands for non-GE feed ingredients. Russia and Turkey are major non-EU markets. In 2020, Romania's soybean crop is projected to drop to around 330,000 MT due to dry conditions throughout the growing season. As the domestic production cannot meet local demand, Romania turns to the international market for 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	Unit	Calendar Year				January-June		
		2016	2017	2018	2019	2019	2020	%Δ 2020/19
World, of which	**MT**	**122,333**	**134,695**	**259,504**	**79,356**	**60,329**	**152,298**	**152.45**
Brazil	MT	74,680	99,815	123,109	50,700	50,700	121,882	140.40
Moldova	MT	12,859	15,694	10,282	13,676	903	11,134	1133
Serbia	MT	9,724	5,199	1,677	3,938	1,060	6,250	489.62
Italy	MT	1,538	722	3,163	1,859	1,856	1,921	3.50
Ukraine	MT	15,902	75	44	1,075	574	1,298	126.13
United States	MT	3,460	4,200	113,477	979	979	1,108	13.18

Source: Trade Data Monitor

Table 2. Romania – Imports of soybean meal (HS Code #2304)

Partner	Unit	Calendar Year				January-June		
		2016	2017	2018	2019	2019	2020	%Δ 2020/19
World, of which	**MT**	**361,265**	**527,199**	**565,196**	**583,123**	**328,342**	**271,466**	**-17.32**
Brazil	MT	144,619	228,033	434,755	431,773	266,504	166,596	-37.49
United States	MT	-	22,267	22,644	49,295	30,000	-	-100
Argentina	MT	113,533	205,655	52,549	43,969	5,258	51,655	882.41
Ukraine	MT	616	998	12,198	16,598	8,292	23,315	181.17

Source: Trade Data Monitor

e. **Food Aid**: Romania is not a food aid recipient or donor.

f. **Trade Barriers**: See this section in the Agricultural Biotechnology Annual European Union.

PART B: Policy

a. **Regulatory Framework**: No significant changes have occurred over the last two years 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) also implement 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 2016 for a four-year mandate, members represent the Romanian Academy, the Agricultural Science Academy, the Medical Science Academy, as well as the Universities of Medicine and Agricultural Science. BSC assists the authorities in the decision-making process regarding the issuance of authorizations.

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 EU Directive 2015/412 regarding the freedom of MSs to cultivate or prohibit biotech crops, MSs could decide for or against opting out of biotech cultivation. Based on Romanian farmers' openness to biotechnology, Romania 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:** Once a biotech event is approved at the EU level for cultivation, feed, or food, MSs do not need local re-authorization. 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**: 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 pessimistic outlook for biotech cultivation regionally. 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 provisions of EU Directive 2001/18/EC stirred the discussions at national level. Romania's MARD expresses occasional support for amending the EU legislation because the current language predates the most recent technology.

f. **Coexistence**: Romania adopted 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 commercial stakeholders 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 products derived from biotechnology. In March 2017, MARD issued Order 73, amending 2012's Order 61 to transpose the provisions of the EU Directive 412/2015 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 from international border.

g. **Labeling and Traceability**: Order 61 provides regulates product 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 from animals fed with GE feed or treated with GE pharmaceutical 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:** Order 35/2016 approved by ANSVSA on the Surveillance and Control Action Plan on food safety (with subsequent amendments) sets provisions for 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 law compliant. 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 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 MS has the right to vote.

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

PART C: Marketing

a. **Public/Private Opinions:** Over time, agricultural biotechnology has been widely publicly debated. Romania's first-hand experience with biotech soybeans until 2007 and biotech corn until 2015 triggered the interest among many interest groups. Farmers are the most vocal advocates for access to the latest technology. The severe drought in the southeastern and eastern regions in 2020 intensified calls for access to technologies that would help farmers better cope with weather conditions.

Apart from farmer organizations, other entities also strive to increase awareness and knowledge about biotechnology in Romania, such as 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. 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.

There are also organizations which support non-biotech crops, such as Danube Soybean Association. These groups are 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**: Large farmer support for biotechnology is derived from Romania's unique history of biotech soy cultivation before 2007. They view EU feed ingredient imports (e.g. soybean meal) as an anathema against European farmers and local production. The livestock and poultry sectors also support GE soybean access but tend to be less vocal. Many consumers, particularly in urban areas, tend to oppose GE products and perceive agricultural biotech as unnatural, unsafe, insufficiently regulated, and unnecessary. Post is not aware consumer studies regarding biotech perceptions conducted during 2019- 2020.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is therefore different from GE animals (both in the science and often in the regulation of the technology and /or products derived from it). Researchers and industry frequently use cloning when creating animals via other animal biotechnologies. For this reason, cloning is included in this report.

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 development of cloned 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 exports of livestock clones or GE animals or products from Romania.

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**: Romania follows the EU legislation in this field.

PART E: Policy

a. **Regulatory Framework**: The 1997 Novel Foods Regulation is currently the only EU legislation covering animal cloning. Under the Novel Foods Regulation, food "produced from nontraditional breeding techniques" (implicitly including cloning) – but not from their offspring – requires a pre-market authorization to be imported or sold in the EU. Romania follows the EU legislation regarding animal biotechnology. In Romania ANSVSA is the authority handling the food safety and animal welfare aspects of the GE animals/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:** Not Applicable **(**N/A)

c. **Innovative Biotechnologies**: Please see the same section in the Plant Biotechnology Chapter.

d. **Labelling and Traceability:** N/A

e. **Additional Regulatory Requirements:** N/A

f. **Intellectual Property Rights (IPR)**: Please see the same section in the Plant Biotechnology Chapter.

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**: N/A

PART F: Marketing

a. **Public/Private Opinions:** Animal biotechnology is a topic which gets almost no attention in Romania. There are no debates regarding animal biotechnology in the media or other circles. Media coverage occasionally reports on decisions taken at the EU level, the United States, or Canada regarding the regulation or marketing of GE products (*e.g.* GE salmon). That said, there is little appetite for information about these advanced technologies, mainly driven by the general attitude towards biotechnology or previous cloning-project failures.

b. **Market Acceptance/ Studies**: There are no known Romanian market studies on the use of animal biotechnologies or cloning.

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. In terms of research the NAEP notified the public in November 2017 that a local university requested approval to conduct confined testing of a Listeria monocytogenes bacteria, including the use of CRISPR/Cas9. The notification may be viewed (in Romanian) here. In December 2017, the Biosafety Commission (BSC) approved a four-year testing period. The goal of the research project is to identify the genes of the bacteria which help in recovering after being applied a high-temperature treatment.

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.

d. **Trade Barriers**: Romania applies the EU legislation. Please see the Agricultural Biotechnology Annual European Union.

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.

b. **Approvals:** No country-specific policy.

c. **Labelling and Traceability:** No country-specific policy.

d. **Monitoring and Testing:** No country-specific policy.

e. **Additional Regulatory Requirements:** No country-specific policy.

f. **Intellectual Property Rights (IPR):** N/A

g. **Related Issues:** N/A

PART I: Marketing

a. **Public/Private Opinions:** Limited information about the role of microbial biotech for food ingredients or nutritional purposes is available, hence it is hard to assess the public or private perception.

b. **Market Acceptance/Studies:** FAS Bucharest is not aware of market studies on microbial biotechnology.

Appendix Government Regulatory Agency Contacts

Ministry of Agriculture and Rural Development
Bd. Carol I nr. 2-4, sector 3, 030163 Bucuresti, Romania
Phone: +4021 3072446; +4021 3078682
E-mail: comunicare@madr.ro; relatii.publice@madr.ro
Web site: http://www.madr.ro

National Authority for Environment Protection
Splaiul Independentei nr. 294, sector 6, Bucuresti, Romania
Phone: +021 207 1101; 021 207 1102
E-mail: office@anpm.ro http://www.anpm.ro/

National Guard for Environment
General Commissary
Bd. Unirii nr. 78, Bl. J2, sector 3, Bucuresti, Romania
Phone: +40 21 3268970
E-mail: gardamediu@gnm.ro http://www.gnm.ro/

National Sanitary-Veterinary and for Food Safety Authority
Piata Presei Libere nr.1, Corp D1, sector 1, Bucuresti, Romania
Phone: +40 372 184977
E-mail: office@ansvsa.ro Website: http://www.ansvsa.ro

Ministry of Health
Str. Cristian Popisteanu nr. 1-3, sector 1, Bucuresti, Romania
Phone: +40 21 3072500, +40 21 3072600
Email: relatii.publice@ms.ro Website: http://www.ms.ro

National Authority for Consumers Protection
Bd. Aviatorilor nr. 72, sector ,1 Bucuresti, Romania
Phone: +40 21 307 6793
E-mail: cabinet@anpc.ro Web site: www.anpc.ro

The National Customs Authority
Str. Alexandru Ivasiuc nr. 34-40, Bl. 5, Sector 6 Bucuresti, Romania
Phone: +40 21 3155858, +40 21 3155859
Email: relatiipublice@customs.ro Web site: www.customs.ro

The State Institute for Variety Trials and Registration
Bd. Marasti nr.61, Sector 1 Bucuresti, Romania
Phone: +40 21 3184380
E-mail: office@istis.ro Website: www.istis.ro

Central Laboratory for Seeds Quality (LCCSMS)
10 Sandu Aldea Street Bucuresti, Romania
Phone: +40 21 2228420
E-mail: lccsms@b.astral.ro Website: http://www.lccsms.bvl.ro

Institute for Diagnosis and Animal Health (IDAH)
Str. Dr. Staicovici nr. 63, Sector 5 Bucuresti, Romania
Phone: +40 0374 322 013 / 0374 322 000
E-mail: office@idah.ro Website: www.idah.ro

AgroBiotechRom Association
Bd. Marasti nr.59, Sector 1 Bucharest, Romania
Email: office@agrobiotechrom.ro Web site: www.agrobiotechrom.ro

For further information on this report, please contact the following office in Bucharest:

Foreign Agricultural Service Bucharest
Str. Dr. Liviu Librescu 4-6, Bucuresti, Romania
Phone: 40 21 2003374 E-mail: AgBucharest@fas.usda.gov

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Attachments:

No Attachments