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Report Highlights:

Romania continues to be one of the European Union's (EU) most progressive and pro-science Member States (MS) regarding agricultural biotechnology, although no biotech crops have been grown since 2015. Imported genetically-engineered (GE) soybean meal is widely used as a feed ingredient in Romania. The Government of Romania (GOR) permits biotech field trials, but current research is limited to GE plum trees. Post suggests that the following report be read in conjunction with the EU-28 2019 Agricultural Biotechnology Annual.

Executive Summary

Romania observes EU regulations regarding biotechnology. In 2015 when the EU approved the legislation concerning freedom of MSs to limit biotech cultivation, Romania decided not to "opt-out". Despite strong support from Romanian farmers for GE crops, no biotech crops have been planted in Romania since 2015. Rigorous traceability requirements, difficulties in marketing the crops, and co-existence rules have discouraged farmers from planting the only EU approved corn product for cultivation, Bt corn (MON 810).

Romania is a significant EU grain and oilseed producer and exporter, although it relies on imported plant protein ingredients for livestock feed. Nearly 90 percent of imported soy products originate from biotech soybean producing countries. Price competitiveness in 2018 and 2019 allowed the U.S. shippers to offset some South American soy exports to Romania.

No new biotech seed import approvals were requested and/or granted in recent years. Life-science companies are not inclined to conduct testing as the approval process is expensive and prospects for cultivation are limited. Biotech field trials for plum trees are ongoing.

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Chapter 1: Plant Biotechnology

PART A: PRODUCTION AND TRADE

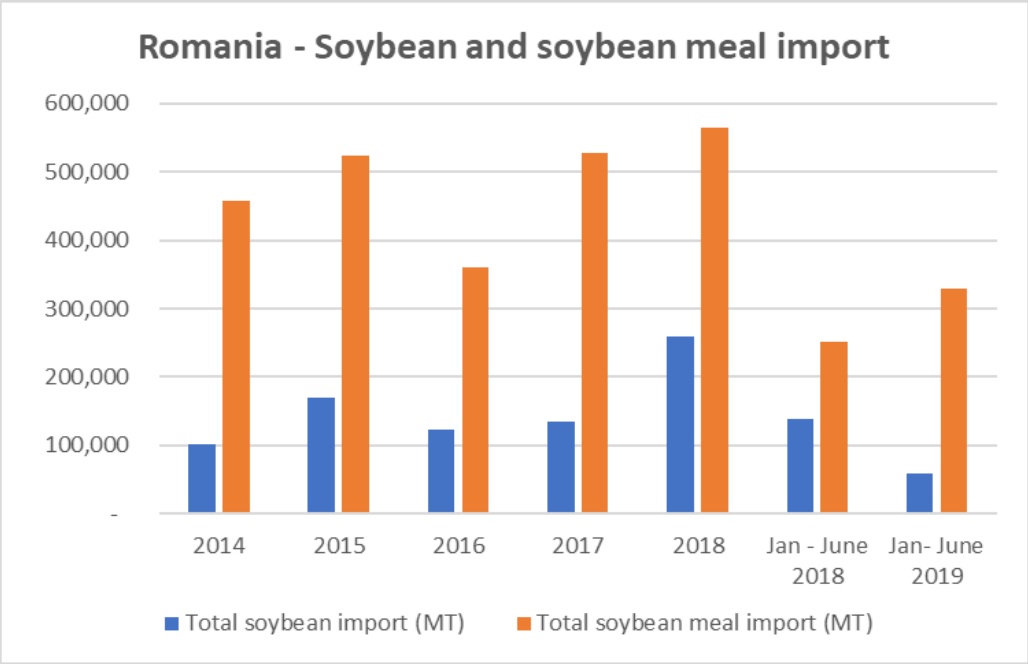
a) Product Development: FAS Bucharest is unaware of any commercial GE plants or crops under development in Romania. The National Agency for Environment Protection (NAEP) notified in November 2017 that a local university requested approval to conduct confined testing of a Listeria monocytogenes bacteria, including the use of CRISPR/Cas9. The stated objective was to establish bacterial reactions to high-pressure stress as part of the ERA-IB-16-014 Safe Food project. The notification may be viewed (in Romanian) here. In December 2017, the Biosafety Commission (BSC) approved a period of four years for testing. A second notification, from a pharmaceutical company, requesting a clinical study of the GE-drug ADXS11-001 containing a live-attenuated strain of the bacterium Listeria monocytogenes was posted by NAEP in 2017. The notification may be viewed (in Romanian) here. BSC approved this request in September 2017 and granted a six-year period for testing.

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 why farmers choose not to plant biotech Bt corn. Romania supported the European Commission's 2015 "opt-out" proposal for cultivation as an option for all countries to choose. However, Romania chose not to "opt-out".

c) Exports: Romania does not currently produce or export any GE crops.

d) Imports: Although Romanian soy production declined abruptly after its EU accession in 2007, Romania is still one of the EU's few soybean producers. Subsidies for soy production have spurred farmers to double production over the last five years, reaching about 400,000 metric tons (MT) in 2019. Romania is a supplier of non-GE soybeans to other countries. About half of the local soy production is exported mainly to EU countries whose livestock industry is strongly based on non-GE feed ingredients. Russia typically imports about a quarter of Romanian soybeans.

Romanian soybean production is substantially below domestic demand by the livestock sectors. Additionally, Romania imports soybeans and soybean meal, of which nearly 90 percent is sourced from South America and the United States. In 2018, soybean imports nearly doubled to 260,000 MT, of which 44 percent originated from the United States. 2018 soybean meal imports reached 565,000 MT, a seven-percent increase over 2017, of which U.S. meal accounted for about five percent of imports. Meal imports were more profitable during the first half of 2019, which led to a 30-percent import increase over the same period in 2018. Higher meal imports also led to a 50-percent decline in whole-bean imports (see graph below). Brazil is Romania's top supplier, followed by Argentina and the United States (please see tables below).



Source: Trade Data Monitor LLC

Table 1: Romania – Imports of soybeans (#1201)

Partner	Unit	Calendar Year					January-June		
		2014	2015	2016	2017	2018	2018	2019	%Δ 2019/18
World, of which	**MT**	**102,659**	**169,316**	**122,333**	**134,695**	**259,154**	**139,345**	**59,486**	**-57.31**
Brazil	MT	9,551	43,222	74,680	99,815	123,109	123,109	50,700	-58.82
United States	MT	1,502	69,639	3,460	4,200	113,477	-	979	0
Moldova	MT	10,906	4,987	12,859	15,694	10,282	6,117	903	-85.24
Hungary	MT	2,059	2,713	2,035	5,786	5,466	4,270	2,454	-42.53

Source: Trade Data Monitor LLC

Table 2: Romania – Export of soybeans (#1201)

Partner	Unit	Calendar Year					January-June		
		2014	2015	2016	2017	2018	2018	2019	%Δ 2019/18
World, of which	**MT**	**40,249**	**93,088**	**109,231**	**265,903**	**131,455**	**25,433**	**102,899**	**304.59**
Russia	MT	-	-	-	83,109	33,742	-	31,439	-
Hungary	MT	6,781	2,782	3,697	35,193	28,520	10,593	14,023	32.38
Italy	MT	8,114	12,674	8,959	53,797	23,437	4,102	11,057	169.55
Germany	MT	13,433	15,981	17,075	28,062	17,511	5,270	31,476	497.27

Source: Trade Data Monitor LLC

Table 3: Romania – Imports of soybean meal (#2304)

Partner	Unit	Calendar Year					January-June		
		2014	2015	2016	2017	2018	2018	2019	%Δ 2019/18
World, of which	**MT**	**457,160**	**523,193**	**361,265**	**527,199**	**565,196**	**250,946**	**328,342**	**30.84**
Brazil	MT	189,844	280,447	144,619	228,033	434,755	195,897	266,504	36.04
Argentina	MT	183,490	100,803	113,533	205,655	52,549	19,549	5,258	-73.10
Hungary	MT	47,397	54,349	46,329	48,533	24,612	14,180	14,260	0.56
United States	MT	-	-	-	22,267	22,644	-	30,000	0

Source: Trade Data Monitor LLC

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

f) **Trade Barriers**: See this section in the EU-28 2019 Agricultural Biotechnology Annual report.

Part B: POLICY

a) **Regulatory Framework**: No significant changes occurred over the last two years in terms of responsibility for implementing and enforcing regarding biotech regulations, including any products or activities. The main bodies with regulatory responsibilities are listed below:

- Ministry of Environment (MOE) is the central public authority for environmental protection. It coordinates and ensures the application of the precautionary principle;

- NAEP is the main interlocutor vis-à-vis company applications and the coordinating body of the BSC;

- National Guard for Environment (NGE) oversees enforcement of the legal provisions;

- Ministry of Agriculture and Rural Development (MARD), the Sanitary-Veterinary and Food Safety National Authority (ANSVSA), and the Ministry of Health play important roles in implementing legislation regarding GE products.

The responsibilities of these regulatory bodies are supplemented by the BSC, which is the coordinating scientific body and assists the authorities in the decision-making process regarding the issuance of authorizations. The Biosafety Commission is comprised of twelve full-members and four substitute members. Selected in September 2016 for a four-year mandate, members represent the Romanian Academy, Agricultural Science Academy, Medical Science Academy, as well as the Universities of Medicine and Agricultural Science.

Romania's agricultural biotechnology legislation remained unchanged over the past 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. Order 55 regarding the national registry for records on genetic modifications issued in 2007 by the MOE is still valid. 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 cultivation (see EU-28 2019 Agricultural Biotechnology Annual report for more detail). Romania supported this proposal based on Romanian farmers' openness to biotechnology and declined to ban the cultivation of biotech crops in 2015. As of October 2019, EU Directive 2015/412 has not been transposed into the national legislation.

b) Approvals: 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. Romanian farmers planted Bt corn MON 810 (insect resistant) until 2015. 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 in MSs 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 authorization for field-tested virus-resistant plum (resistance to plum pox) was renewed in 2019 for another nine years.

e) Innovative Biotechnologies: The GOR has not issued an official position on 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 some discussions at national level. Romania's MARD expressed with various occasions the support for amending the EU legislation since the current EU Directive no longer reflects the latest research developments.

f) Coexistence: Romania adopted and implemented a co-existence policy. 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 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 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, the rules on co-existence set

at national level apply at the borders and biotech crops cultivation is prohibited within 200 meters from the border.

g) Labeling: Order 61 provides rules concerning GE products labeling and is in line with the EU requirements (Regulation (EC) No 1830/2003). Romania adopted measures on labeling thresholds at 0.9 percent for an adventitious presence of an authorized GE event in food or feed. Operators 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 cheese manufacturers (based on milk from non-GE fed cows) and soy-based food products applied non-GE labels (samples below).

Source: Company websites, retail

h) Monitoring and Testing: Romania maintains an EU-based system of testing and verifying 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 National Reference Laboratory for GE food and feed is the Institute for Diagnosis and Animal Health (IDAH), 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. The EU has a zero-tolerance policy for LLP in feed following the measures of the EU Regulation 619/2011. This regulation lays down the methods of sampling and analysis for the official control of feed regarding the presence of GE material for which an authorization procedure is pending or authorization of which has expired. The EU defined "zero" with a "technical solution" level of 0.1 percent. There is no "technical solution" for food.

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/Forums: Romania is a member of various international treaties and conventions, including International Plant Protection Conventions (IPPC) and Codex Alimentarius (CODEX). Romania's Codex point of contact is ANSVSA. Romania's IPPC point of contact is MARD – Phytosanitary National Authority. As a member of the European Union, Romania does not express a direct position 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 continues to adopt a science-based approach to regulating agricultural biotechnology, based on the findings of EU and local scientific authorities. However, since Romanian farmers stopped planting biotech crops, discussion about this topic remains closely connected to Romania's potential contribution to the EU Protein Program, if access to biotech soybeans for cultivation is granted. In general, Romanian farm associations support agricultural biotechnology based on their earlier experiences with biotech soybeans. Academy of Agricultural Sciences and Forestry has been vocal about its strong support for agricultural biotechnology. They view biotechnology as a tool to cope with the climate change and the need to secure to food to the rising population. Entities thriving to increase awareness and knowledge about biotechnology in Romania include AgroBiotechRom Association. The association is a member of EuropaBio and an active Romanian biotech advocacy organization. They disseminate science-based information about the latest developments in modern agricultural biotechnology in Europe and around the world. Among the organizations supporting non-GE crops, the most notable is The Danube Soya Association, which promotes "biotech-free" soybean cultivation, trade, and processing. Romania is a signatory of the Danube Soya Association (DonauSoja) Agreement.

b) Market Acceptance/Studies:

Romanian farmer groups are the largest community to support biotechnology cultivation, complaining about the paradox of meeting domestic feed demand through imported biotech products, while opposing GE crop cultivation. Given the limited access to non-GE resources, Romanian livestock farmers do not oppose biotech feed for raising poultry or swine, as they strive to keep costs low and be competitive. At the retail level, the key-buyers require non-GE certification for food products from their suppliers.

Many consumers tend to resist GE-derived foods and perceive biotech products as not sufficiently safe or regulated. Debate on the "cleanliness" of agricultural commodities and locally-produced, non-GE, organic, etc. is intense on social media. The study, "Food–Romanian Consumer Perceptions" conducted in 2018 by research company Stratesys, revealed findings regarding consumers' attitude towards food and sources of information about foods. The study revealed that when purchasing food, 94 percent of surveyed consumers check the expiry terms, 57 percent check if the products contain additives, and 28 percent check if the food is organic. About 20 percent of consumers check about GE ingredients and 24 percent of consumers would oppose buying the products if they were GE. When asked about their inclination for tasting GE products about 42 percent of those surveyed responded that they would be willing to consume biotech products if they understood or saw the direct benefits. A view on the Romanian experience and perspective on the commercial cultivation of genetically modified crops in Europe may be read here.

Chapter 2: ANIMAL BIOTECHNOLOGY

Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is therefore different from the genetic engineering of animals (both in the science and often in the regulation of the technology and /or products derived from it). 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: N/A

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 other species.

e) Trade Barriers: Romania follows the EU legislation in this field.

PART E: POLICY

a) Regulatory Framework: Romania follows the EU legislation regarding animal biotechnology. The ANSVSA is the authority handling the food safety and animal welfare aspects of the GE animals/livestock clones. If Romania formulates a position on animal biotechnology, ANSVSA has a consultative body to cover various competencies and issue an opinion.

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.

b) Innovative Biotechnologies: N/A

c) Labeling and Traceability: N/A

d) IPR: Please see the same section in the Plant Biotechnology Chapter.

e) International Treaties and Forums: N/A

f) Related issues: N/A

PART F: MARKETING

a) **Public/Private Opinions:** Animal cloning 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 in the Romanian Parliament or among consumers for these advanced technologies, mainly driven by the general attitude towards biotechnology or previous cloning-project failures.

b) **Market Acceptance/ Studies**: N/A

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Attachments:

No Attachments