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Romania

Agricultural Biotechnology Annual

Agricultural Biotechnology Annual

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Report Highlights:
Romania continues to be one of the European Union's (EU) most progressive member states regarding agricultural biotechnology. Although no biotech crops were grown in 2018, Romanian farmers continue to support modern technologies. The Government of Romania (GOR) permits biotech field trials, but current research is limited to genetically engineered (GE) plum trees. The Biosafety Commission (BSC) issued two positive opinions on the notifications aiming to test GE-microorganisms and GE-pharmaceuticals. Post suggests that the following report be read in conjunction with the EU-28 Agricultural Biotechnology Annual.

Section I. Executive Summary:

Romania is an EU member state (MS) and observes the 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 rules, difficulties in marketing the crops, and low disease pressure have discouraged farmers from planting the only EU approve corn product for cultivation, Bt corn (MON 810).

Romania is an importer of feed ingredients, including over 500,000 metric tons (MT) of soybean meal in 2017, a 46-percent increase over 2016. Nearly 90 percent of imported soybean meal originates from biotech soybean producers in South America and the United States.

There is little interest in conducting biotech field trials, despite that Romania allows it. In 2018, field trials continued on plum trees under an earlier permit. In 2018 no new import approvals were requested and/or granted for biotech seeds, as companies did not make any requests to the Competent Authority. Life-science companies are not inclined to conduct testing within the EU, as authorizations are expensive and prospects for local cultivation are limited.

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Chapter 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. **Product Development**: FAS Bucharest is unaware of any GE plants or crops currently under development in Romania. Some stakeholders are interested in testing GE-microorganisms and GE-pharmaceuticals. According to the information posted by the National Environment Protection Agency in November 2017, a local university submitted a notification to conduct confined testing of Listeria monocytogenes bacteria. The stated objective was to obtain genetically-modified strains and establish the reaction to the stress exerted by high pressure (HPP). According to the notification, the genetic modification would use CRISPRi/dCas9. The study is part of the ERA-IB-16-014 Safe Food project. The notification may be viewed (in Romanian) here. BSC issued a positive response in December 2017 and granted four years for testing. A second notification posted by the National Environment Protection Agency was submitted in 2017 by a pharmaceutical company requesting a clinical study of the GE-drug ADXS11-001, which contains a live-attenuated strain of the bacterium Listeria monocytogenes. The notification may be viewed (in Romanian) here. BSC issued its positive response in September 2017 and granted six years for testing.

b. **Commercial Production**: Romanian farmers have not planted GE corn since 2015. The segregation requirements, traceability, co-existence and market certification rules are the main reasons farmers choose not to use the technology. Romania supported the EU Commission's proposal to allow MSs to "opt-out" of cultivating approved GE crops, but chose not to "opt-out".

c. **Exports**: As there is no local GE production, there are no Romanian GE exports.

d. **Imports**: Romania imports soybeans for crushing and soybean meal, of which nearly 90 percent originates from biotech soybean producers in South America and the United States. In 2017, soybean meal imports rose by 47 percent, reaching 165,000 MT. Soybean meal imports increased an additional five percent during the first half of 2018 over the same period in 2017. Imported soybeans and meal cover the market gap left by Romania's large level of exports of domestically produced non-GE soybeans to other MS markets, especially to those which prioritize feeding non-GE feeds to livestock.

In terms of imports of soybeans and meal, Brazil remains the predominant supplier, followed closely by Argentina. The United States supplies soybean meal when U.S. prices become competitive with South American suppliers. In 2017, a 22,000-MT consignment of U.S. soybean meal arrived in Romania, marking the first U.S. soybean meal shipment to Romania since 2013. U.S. market share of soybeans looks poised to increase during the latter half of 2018, as U.S. bean prices are increasingly price competitive.

e. **Food Aid**: Romania's low-income population segment receives yearly benefits under EU nutritional support programs, mostly for sunflower oil, wheat flour, corn flour, rice, sugar, sun oil and other basic staples. There are no issues related to biotechnology with these products. Romania occasionally provides food aid to other countries, albeit on a very limited basis.

f. **Trade Barriers**: Please see this section in the EU-28 Agricultural Biotechnology Annual report.

PART B: POLICY

a. **Regulatory Framework**: No significant changes occurred over the past two years in terms of responsibility for implementing and enforcing all activities related to the use of GE products and all activities concerning the deliberate release of such products. The main bodies with regulatory responsibilities are listed below:

a. Ministry of Environment (MOE) - the central public authority for environment protection which coordinates and ensures the application of precautionary principle to avoid potential adverse effects of biotechnology on human health and environment as a result of obtaining, using and commercializing these organisms;

b. National Agency for Environment Protection (NAEP) - the Competent Authority (CA), is the main interlocutor of the applicant companies in the notification process; the same body coordinates the activity of the Biosafety Commission;

c. National Guard for Environment (NGE) - the control authority ensuring the right enforcement of the legal provisions;

d. Ministry of Agriculture and Rural Development (MARD), the Sanitary-Veterinary and Food Safety National Authority (ANSVSA), and the Ministry of Health (MH) 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. BSC 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 outlines the rules for authorization and control of the farmers planting GE

crops, including the co-existence rules, while the 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 (GMO).

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 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 2018, 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 genetically engineered products at the EU level can be viewed here.

c. **Stacked or Pyramided Event Approvals**: Approval of stacked events is granted at the EU level and valid throughout the EU, including Romania, 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 perspective users for biotech cultivation. The only field-tested GE product is virus-resistant plum (resistance to plum pox, also known as Sharka).

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 the discussions at the EU technical-committee level. MSs were tasked to provide updated information regarding their respective situations regarding "NBTs."

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, the 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 necessary for Romania so that it could provide protection at its borders to Bulgaria and Hungary, as they prohibit GE cultivation. Basically, the rules on co-existence set at national level will apply at the borders and biotech crops cultivation is prohibited within a distance of 200 meters from the border. In order to check the extent to which the legal provisions concerning coexistence practices of biotech crops are observed, the official inspectors from the Agriculture Departments at county-level will check the compliance with the rules.

g. **Labeling**: Order 61 also 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 manufacturers selling soy-based food products choose to apply the non-GE soybean labels (samples below).

Source: Company websites

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 the 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 (LCCS) 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 low-level presence of GE products 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 in regards to 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, which was enforced starting June 1, 2015. 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 a number of laws and Government Decisions. The State Office for Inventions and Trademarks (OSIM) is the main body for overseeing the IPR issues in general. The State Institute for Varieties Testing and Registration (ISTIS) 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. The most recent National Report on the implementation of the Cartagena Protocol on Biosafety was submitted by the MOEF in October 2015 and it may be accessed here.

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 the Sanitary-Veterinary and Food Safety Authority. 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:**

Traditionally Romania favors a science-based approach to regulating agricultural biotechnology based on EU findings and local scientific authorities. However, since Romanian farmers stopped planting biotech corn in 2015, discussion about this topic became limited. That is also due to the EU's slow biotech approval process and absence of any meaningful debate at the EU level. The topic of biotechnology is raised in conjunction with the EU Protein Program, in which Romania may play an important role, due to its favorable soil and climate conditions for soybean production. Other topics, such as glyphosate authorization and neonicotinoids derogations, increasingly overshadow biotechnology during discussions among MSs and major agricultural stakeholders. Nevertheless, most Romanian farm associations support agricultural biotechnology based on their earlier experiences with glyphosate-resistant soybeans. Many Romanian farmers remain hopeful that they will regain access to biotechnology, which they view as a tool to make them more economically viable vis-à-vis grain and oilseed production.

The AgroBiotechRom Association, a member of EuropaBio and an active Romanian biotech advocacy organization, regularly contributes science-based information and news about the latest developments in modern agricultural biotechnology in Europe and around the world. AgroBiotechRom partners with other interested parties and disseminates technical information about biotechnology. It regularly targets both specialized and mainstream media.

Among the organizations supporting non-GE crops, the most notable is The Danube Soya Association.

Romania is a signatory of the Danube Soya Association (DonauSoja) Agreement which promotes "biotech-free" soybean cultivation, trade, and processing. According to the information posted on its website, the association has about 265 members from Europe including soy producers, agricultural traders, primary processors, food retailers, and food processors. The Romanian subsidiary of the DonauSoja Association organizes yearly field events over the summer in different locations with the aim to gain additional membership.

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.

b. **Market Acceptance/Studies**:

Farmer groups remain the largest community to support biotechnology, complaining about the paradox of having Europe covering its feed deficit through imported biotech products, but showing a strong opposition towards planting these crops. At the retail level, the key-buyers require non-GE certification for food products from their suppliers. Meanwhile, consumers tend to show resistance to GE food products and continue to perceive biotech products as not sufficiently safe or regulated. The Romanian public is also barraged by abundant disinformation and anti-biotech propaganda on social media and through conventional media platforms. These nonscientific, scaremongering campaigns seek to spread disinformation about consuming GE-derived foods.

There have been no recent Romanian studies published about agricultural biotechnology. 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 genetic engineering and genome editing result in the modification of an animal's DNA to introduce new traits and change one of more characteristic 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 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 in regard to animal biotechnology. The ANSVSA is the authority handling the food safety and animal welfare aspects of the GE animals/livestock clones. If Romania must formulate a position on a topic related to Animal Biotechnology, the ANSVSA has a consultative body covering various competencies which will issue an opinion.

With regards to EU legislation, the EU Novel Foods Regulation from 1997 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 in order to be imported or sold in the EU. The European Commission has presented two new proposals - one on the cloning of animals and one on food from cloned animals.

b. **Innovative Biotechnologies**: N/A

c. **Labelling 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 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

Appendix Government Regulatory Agency contacts

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