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## **Romania**

### **Agricultural Biotechnology Annual**

**2017**

**Approved By:**

Jonn Slette

**Prepared By:**

Monica Dobrescu

**Report Highlights:**

In 2017, Romania maintained a balanced view regarding agricultural biotechnology. Although no biotech corn was planted in 2017, farm communities continue to view biotechnology as a mean to increase competitiveness and many Romanian farmers remain supportive of the technology. The Government of Romania (GOR) permits biotech field trials, but current research is limited to genetically engineered (GE) plum trees. This report provides updated information on the status of biotechnology in Romania and should be read in conjunction with the [EU-28 Agricultural Biotechnology Annual report](#).

## **Section I. Executive Summary:**

Romania is a member of the European Union (EU) and observes EU regulations regarding biotechnology. Romania refrained from the EU-approved “opt-out” legislation which authorized Member States (MS) to unilaterally ban biotech crop cultivation. Despite large support for genetically engineered (GE) crops by Romanian farmers, no biotech crops were planted in Romania since 2015, and no significant legislative changes occurred over the past year. Stringent rules on traceability, difficulties in marketing the products, and low disease pressure discourage farmers to plant Bt corn (MON 810), the biotech event approved for planting by the EU.

Romania imports some feed ingredients to cover the demand from livestock producers. In 2016, soybean and soybean meal imports reached nearly 500,000 metric tons (MT), a 30-percent decrease from the previous year. These imports began to rebound during the first half of 2017 by 35 percent.

Romania remains open to biotech seed field trials. In 2017 and 2018, field trials will continue, although only on plum trees, under an earlier permit. Similar to most recent years, in 2017 no 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 is limited.

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# Chapter 1: PLANT BIOTECHNOLOGY

## ***PART A: PRODUCTION AND TRADE***

a. **Product Development:** FAS Bucharest is unaware of any current, commercial GE plants or crops under development in Romania. There is however an interest in testing GE-pharmaceuticals. According to the information posted by the National Environment Protection Agency in June 2017, a private health operator submitted a notification for conducting a clinical study the therapeutic GE-drug ADXS11-001, which contains a live-attenuated strain of the bacterium *Listeria monocytogenes*. The notification, still pending authorization, can be viewed (in Romanian) [here](#).

b. **Commercial Production:** Romanian farmers have not planted GE corn since 2015. The segregation requirements, difficulties in marketing, traceability, and co-existence rules are among the main reasons for not using the technology. Concerning the EU cultivation “opt-out” legislation, Romania supported the EU Commission proposal to allow Member States to “opt-out” of cultivation of approved GE crops, but chose not to “opt-out”.

c. **Exports:** There is no local GE corn production and therefore no Romanian GE corn exports.

d. **Imports:** Romania imports significant quantities of feed ingredients for livestock producers. Generally, soybean meal is more efficient to import than soybeans. However, depending on the price and origin, crushing beans domestically may be more profitable. In 2016, soybean meal imports declined by one-third to 361,000 MT, but they recovered during the first half of 2017. The main suppliers were Brazil (144,000 MT) and Argentina (133,000 MT). The United States supplies soybean meal when U.S. prices were competitive with South American suppliers. In 2017, a 22,000 MT consignment of U.S. soybean meal arrived in Romania, marking the first soybean meal shipment to Romania since 2013. Only a very small percentage of imported soybean and/or soybean meal is non-GE. There are no GE seeds imported for research due to the low interest in field testing.

e. **Food Aid:** Romania’s lower-income population receives benefits under EU nutritional support programs, mostly for sunflower oil, wheat flour, 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 vis-à-vis implementation and/or enforcement of regulations related to the use of GE products, and/or activities concerning the deliberate release of such products. Further information on regulatory responsibilities may be read [here](#).

The Biosafety Commission’s membership changed in 2016. Membership was approved in 2012

through a Ministry of Environment order which specified four-year terms. The Commission is comprised of twelve full-members and four substitute members. New members were selected in September 2016 and were selected from the Romanian Academy, Agricultural Science Academy, Medical Science Academy, as well from the Universities of Medicine and Agricultural Science.

Romania's agricultural biotechnology legislation was unchanged over the past year. Order 61/2012 issued by the Ministry of Agriculture 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 Ministry of Environment and Forests (MEF) 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 cultivation on their territories, EU MSs can decide to implement either option. 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 2017, EU Directive 2015/412, regarding the freedom of MSs to cultivate or prohibit biotech crops, 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, Member States do not need re-authorization 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 2016. 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 to be submitted to the National Agency for Environment Protection (NAEP) for assessment. Nevertheless, since 2014, biotechnology companies discontinued their field research activities in Romania as a result of the lack of perspectives for biotech events cultivation at the EU level (see Appendix 1).

**e. Innovative Biotechnologies:** The Romanian Government has not determined its official position on innovative biotechnologies.

**f. Coexistence:** Romania adopted and implemented co-existence policy. Order 61 approved by the Ministry of Agriculture in 2012 provides rules for the authorization and control of the GE crop farmers as well as measures for ensuring the co-existence of GE plants with conventional and organic.

According to the above Ministerial Order all operators along the commercial chain must transmit and retain information about products that contain or are produced through agricultural biotechnology at each stage of placing them on the market. The regulation covers all products, including food and feed, containing or being derived from authorized biotech events.

Farmers planting biotech crops can only use certified seed. Seed consignments have to be accompanied by label or document stating “genetically modified seeds” as well as the biotech product unique identifier code. Seed suppliers prepare yearly an annual register for biotech seeds (to be stored for five years), where information regarding the names and coordinates of the farmers, the amount of seeds and crop location are provided. It is compulsory for seed suppliers to submit to the Ministry of Agriculture the information to be inserted into the annual register before June 15 each year or August 1 for the double-crops.

In March 2017 the Ministry of Agriculture issued Order 73, amending Order 61/2012, in order to transpose the provisions of the [EU Directive 412/2015](#) as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. That was required as Romania is surrounded by Bulgaria and Hungary, countries that prohibit biotech crops 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 the biotech crops are observed, the official inspectors from the Agriculture Departments at county-level will check the compliance with the rules.

**g. Labeling:** Order 61/2012 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 set 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.

**h. Monitoring and Testing:** Romania maintains an EU-based system of testing and verification for imported foods or ingredients which may contain GE ingredients. Order 35/2016 on the Surveillance and Control Action Plan on food safety sets provisions on the testing and verification frequency for each type of warehouse, manufacturing plant, processing plant or food packaging facility.

In terms of testing, the National Reference Laboratory for GE food and feed is the Institute for Diagnosis and Animal Health (IDAH), while the laboratory for seeds quality under the Ministry of Agriculture 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 the Ministry of Agriculture 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 provisions, 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):** Please see this section in [Romania Agricultural Biotechnology Report 2016](#).

**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 Romania/Ministry of Environment 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 the Ministry of Agriculture – Phytosanitary National Authority. Being an EU member, 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, wherein each MS 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 the findings of EU and local scientific authorities. The Ministry of Agriculture's leadership has issued public support for all types of agriculture. During his Parliamentary confirmation in 2016, the current Minister of Agriculture noted that issues pertaining to biotech should be tackled in consultation with producers and researchers as a means to identify the national interest, calculate the costs, and adopt a decision. Several months later, the Minister restated that Romania's objective should be to produce as many soybeans and other protein crops as needed in order to become self-sufficient, as well as become a supplier of these products for other countries, expressing a general support for all types of agriculture.

Most Romanian farm associations support agricultural biotechnology based on earlier experiences with biotech Roundup Ready soybeans. Many farmers remain hopeful that they will regain access to more advanced technologies able to help them maintain their competitiveness in grain and oilseed production.

Few organizations in Romania develop and conduct biotechnology outreach programs. As a member of EuropaBio (European Association for Bio-industry), the AgroBiotechRom Association is a strong biotechnology organization in Romania. During 2017 the association developed new tools for disseminating information related to the latest developments in biotechnology field. The association ensured a constant flow of updated information to public through both specialized and wide media channels and organized international workshops and activities associated with the European Biotech Week.

The DanubeSoya (DonauSoja) organization promotes “biotech-free” soybeans. According to the information posted on its website, the association has about 250 members from 20 countries including soy producers, agricultural traders, primary processors, food retailers, and food processors. As a member of DonauSoja, Romania hosts yearly events through local members to convince more farmers to apply for this certification.

Given the limited access to non-GE resources, Romanian livestock farmers do not oppose utilization of biotech feed for raising poultry or swine as they strive to keep their competitiveness.

#### **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, key-buyers tend to require non-GE certification for food products from their suppliers. Although meat products do not need non-GE labels, several poultry producers choose to market their birds as not fed with GE grain (although these claims conspicuously fail to mention about the oilseed component). Meanwhile, consumers tend to be disinclined toward GE food products and continue to perceive biotech products as not sufficiently safe or regulated. The Romanian public is also barraged by abundant social media campaigns which highlight a wide variety of anti-biotech propaganda (*e.g.* the potential risks of consuming GE-derived foods).

There are no recent Romanian studies published about agricultural biotechnology. Upon becoming an EU member, Romania was denied the use of GE technologies in their soy cultivation through EU-regulations. This economic impact was studied by PG Economics, which 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 the Agency for Environment Protection Agency, 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:** In the first part of 2017 bovine semen imports grew significantly, by 72 percent in value, respectively 68 percent in terms of volume. These spectacular increases may reflect both an improvement in the dairy market conditions and also availability of resources due to EU payment disbursal to farmers. The United States is the leading supplier of high-quality genetics with a market share of nearly 20 percent in value (among the foreign suppliers). There is no specific data available on the import of products originating from cloned animals. There is no known import 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 Sanitary-Veterinary and Food Safety National Authority (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 Sanitary Veterinary and Food Safety National Authority (ANSVSA) has a consultative body and would be responsible for issuing 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. Intellectual Property Rights:** 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 limited attention in Romania. There are no debates regarding animal biotechnology in the Romanian media or other circles. Media coverage occasionally reports on decisions taken at the EU level, in the United States or Canada regarding to regulation or marketing of such products (*e.g.* GE salmon). That said, there is little appetite at the local

Parliament level 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

## Chapter 3: RELEVANT REFERENCES

### *Appendix 1 Biotechnology Products authorized for field trials in Romania*

Table of Biotechnology Products authorized for field trials in Romania

<b>Crop</b>	<b>Trait Category</b>	<b>Applicant(s)</b>	<b>Transformation Event</b>	<b>Trait Description</b>	<b>Authorization validity</b>
Plum Tree/Prunus Prunus Domestica	Virus resistant	Research and Development Station Bistrita	PPV	Plum-pox resistant	2012-2019

Source: National Agency for Environment Protection

### *Appendix 2 Government Regulatory Agency contacts*

#### **Ministry of Agriculture and Rural Development**

Bd. Carol I nr. 2-4, sector 3  
030163 Bucuresti, Romania  
Phone: +4021 3072300; +4021 3078682; +4021 3072446  
Fax: +4021 3078554  
E-mail: [comunicare@madr.ro](mailto:comunicare@madr.ro); [relatii publice@madr.ro](mailto:relatii publice@madr.ro)  
Web site: <http://www.madr.ro>

#### **National Authority for Environment Protection**

Splaiul Independentei nr. 294, sector 6  
060031 Bucuresti, Romania  
Phone: +021 207 1101; 021 207 1102  
Fax: +4021 2071103  
E-mail: [office@anpm.ro](mailto: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  
Fax: +40 21 3268971  
E-mail: [gardamediu@gnm.ro](mailto:gardamediu@gnm.ro) <http://www.gnm.ro/>

#### **National Sanitary-Veterinary and for Food Safety Authority**

Piata Presei Libere nr.1, Corp D1, sector 1

013701 Bucuresti, Romania  
Phone: +40 374 150200  
Fax: +40 21 3124967  
E-mail: [office@ansvsa.ro](mailto:office@ansvsa.ro)  
Website: <http://www.ansvsa.ro>

### **Ministry of Health**

Str. Cristian Popisteanu nr. 1-3, sector 1  
010024 Bucuresti, Romania  
Phone: +40 21 3072500, +40 21 3072600  
Email: [dirrp@ms.ro](mailto:dirrp@ms.ro)  
Web site: <http://www.ms.ro>

### **National Authority for Consumers Protection**

Bd. Aviatorilor nr. 72, sector 1  
Bucuresti, Romania  
Phone: +40 21 307 6762  
E-mail: [cabinet@anpc.ro](mailto:cabinet@anpc.ro) Web site: [www.anpc.ro](http://www.anpc.ro)

### **The National Customs Authority**

Str. Matei Millo nr. 13, Sector 1  
Bucuresti, Romania  
Phone: +40 21 3155858, +40 21 3155859  
Fax: +40 21 3138251  
Email: [relatiipublice@customs.ro](mailto:relatiipublice@customs.ro) Web site: [www.customs.ro](http://www.customs.ro)

### **The State Institute for Variety Trials and Registration**

Bd. Marasti nr.61, Sector 1  
011464 Bucuresti, Romania  
Phone: +40 21 3184380  
Fax: +40 21 3174442  
E-mail: [office@istis.ro](mailto:office@istis.ro) Website: [www.istis.ro](http://www.istis.ro)

### **Central Laboratory for Seeds Quality**

10 Sandu Aldea Street  
Bucuresti, Romania  
Phone: +40 21 2228420  
Fax: +40 21 2240291  
E-mail: [lccsms@alba.astral.ro](mailto:lccsms@alba.astral.ro) Website: [www.incs.ro/lccsms\\_bucuresti.htm](http://www.incs.ro/lccsms_bucuresti.htm)

### **Institute for Diagnosis and Animal Health (IDAH)**

Str. Dr. Staicovici nr. 63, Sector 5  
050557 Bucuresti, Romania  
Phone: +40 0374 322 013 / 0374 322 000  
E-mail: [office@idah.ro](mailto:office@idah.ro) Website: [www.idah.ro](http://www.idah.ro)

### **AgroBiotechRom Association**

Bd. Marasti nr.59, Sector 1  
Bucharest, Romania  
Phone: +40 721 070095  
Email: [office@agrobiotechrom.ro](mailto:office@agrobiotechrom.ro) Web site: [www.agrobiotechrom.ro](http://www.agrobiotechrom.ro)

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

Foreign Agricultural Service Bucharest  
American Embassy, Romania  
Str. Dr. Liviu Librescu 4-6, Bucuresti, Romania  
Phone: 40 21 2003374 E-mail: [AgBucharest@fas.usda.gov](mailto:AgBucharest@fas.usda.gov)

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