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## **Romania**

### **Agricultural Biotechnology Annual**

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**Approved By:**

Michael Henney, Agricultural Attaché

**Prepared By:**

Monica Dobrescu, Agricultural Specialist

**Report Highlights:**

This report is an update of the previous Biotechnology Annual Report providing information on the current status of biotech products in Romania.

In 2012 the Biosafety Commission was resurrected by appointment of new board members. In May the commission released its approved list of notifications previously submitted by biotech companies. Both commercial planting and field testing are approved in Romania. Farmers continue to seek rapid EU approval of GM soybeans.

## **Section I. Plant Biotechnology Trade and Production**

Romanian farmers continue to remain in the group of EU member states utilizing the opportunity to cultivate biotech crops. Currently the only genetically modified (GM) crop under commercial cultivation in Romania is MON 810 insect resistant corn. In 2012 it is estimated that about 300 hectares will be cultivated with biotech corn, mainly for planting seeds production. This is a drop of 48 percent compared to the previous year, mainly as a result of extensive traceability requirements, minimum isolation distance in the context of corn plantings expansion as well as the difficulties in marketing the harvest.

Romanian farmers are eager to regain access to biotech soybeans, considering their positive experience with this crop before EU accession. Over the past several years, the soybean acreage has declined drastically, dropping to about 72,000 HA in 2011, which is 38 percent of the area registered five years ago. In 2012 a similar area of soybeans is expected to be harvested. Soybeans high production cost and lower productivity influence farmers' decision.

The low domestic availability led to increasing imports of biotech soybean for the livestock and poultry industry. Total soybeans and soya meal imports grew in 2011 by 5 percent, reaching about 490,000 MT (\$213 million), of which soybeans meal totaled 455,000 MT (\$195 million). The major suppliers are the large biotech producing countries: Brazil (346,000 MT) and Argentina (82,000 MT). Other feed ingredients, such as Distilled Dry Grains Soluble (DDGS) and Corn Gluten Feed (CGF) are accepted by the domestic industry in limited volumes (Romania imported 1,039 MT of CGF in 2011).

Field testing is allowed for biotechnology crops in Romania. Appendix 1 provides the list of biotech events for which field trials or demo plots were conducted in 2011 in specific locations. Appendix 2 lists the events approved in 2012 for field trials, as a result of the notifications submitted by the seeds companies (field testing for corn, sugar beet, and plum trees). Although submitted in 2011, these notifications had not been assessed that year as the Biosafety Commission was not functional. Only at the beginning of 2012, when the Biosafety Commission was re-established, the dossiers were assessed and the competent authority issued the authorizations.

Import permits for biotech seeds are needed only for the first shipment, based on the import approval issued each year by the Ministry of Agriculture for the imported types of seeds.

## **Section II. Plant Biotechnology Policy**

Legislation enacted over past years as a result of EU legal framework transposition process remains in place. Romania transposed the [Directive 2001/18](#) regarding the deliberate release into the environment of genetically modified organisms through Emergency Ordinance 43/2007 (Law 247/2009) and [Directive 90/219](#) referring to contained use of genetically-modified micro-organisms through Emergency Ordinance 44/2007.

In addition to these, other major pieces of legislation were passed prior to accession in accordance with the country's EU accession commitments, specifically related to traceability and labeling of food products derived from GMO, which are Government Decision 173/2006 (transposing Regulation (EC) No 1830/2003), replaced in March 2012 by Order 61/2012, and Government Decision 256/2006

(transposing Regulation (EC) No. 1829/2003). 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.

### **The Regulatory Bodies**

According to Emergency Ordinance 43/2007 (Directive 2001/18) regarding the deliberate release of GMOs in the environment and on the market, the competent authorities for implementing and enforcing all activities related to the use of GMOs, and all activities concerning the deliberate release of GMOs are:

1. the central public authority for environment protection - Ministry of Environment and Forestry (MEF), which coordinates and ensures the application of precautionary principle to avoid potential adverse effects of GMOs on human health and environment as a result of obtaining, using and commercializing these organisms
1. Competent Authority (CA) which is in this case, the National Agency for Environment Protection (NAEP)
1. National Guard for Environment (NGE) is the control authority ensuring the right enforcement of this Directive provisions
1. Ministry of Agriculture and Rural Development (MARD), the Sanitary-Veterinary and Food Safety National Authority (ANSVSA), and the Ministry of Public Health (MPH) also have roles in implementing this Directive.

### **Biosafety Commission (BSC)**

Since 2002 the Biosafety Commission has existed in Romania as a scientific body with consultative role in assisting the authorities in the decision-making process regarding the issuance of authorizations. In 2008, the Ministry of Environment issued Order 98, setting the main responsibilities of the Biosafety Commission, including the list of members. In 2011, issues related to funds availability affected the functioning of Commission in proper conditions, inactivity, and lack of quorum leading to its self-dissolution. As a result, in 2011 no notification for new field trials was assessed.

In March 2012, Ministry of Environment and Forests published Order 950/2012, establishing the new Biosafety Commission, appointing its members, and setting the internal working procedure. The Commission is comprised of twelve full-members and four substitute members. They pertain to research institutes from the Romanian Academy, Agricultural Science Academy, as well as University of Medicine and University of Agricultural Science. Field trials notifications submitted for approval in 2011 were reviewed and approved in May 2012 (please see the Appendix 2).

### **Co-existence between biotech and non-biotech crops**

Order 237/2006 concerning the authorization of the biotech crops cultivators was recently replaced by Order 61/2012. The new order approved by the Ministry of Agriculture provides rules for the authorization and control of the biotech crop farmers as well as measures for ensuring the co-existence

of biotech plants with conventional and organic. Nevertheless, the new order does not amend significantly the previous provisions, the only significant changes being related to the documents templates (authorization, statutory-declaration, inventory maintenance).

The public register concerning the commercial biotech fields, available on the website of Ministry of Agriculture and Rural Development, is updated every year with the following data about the farmers and the biotech seeds:

1. Year
2. Genetically modified organism:
  - a) *species*,
  - b) *transformation event*,
  - c) *unique identification code*,
  - d) *other specific data*
3. The owner of authorization for commercial cultivation at European Community level
4. Information about the economic operator: name, address (premises for commercial company, home address for individuals), fiscal accounting number, / personal code
5. Locations (locality/county)
6. Planted area (HA)
7. Information regarding the distances to conventional/organic crops
8. Information concerning the authorization for commercial planting (validity term, provisions)
9. Monitoring report issued by the owner of the authorization or other bodies in charge with monitoring. Similar information is published in the register concerning the field trials.

## **Labeling**

National legislation concerning GM labeling was brought in line with the EU requirements (Regulation (EC) No 1830/2003) through GOR Decision No. 173/2006, which was repealed in 2012 through Order 61 issued by the Ministry of Agriculture. Romania adopted measures on thresholds for labeling, set at 0.9% for an adventitious presence of an authorized GM in food or feed. Operators must demonstrate that the presence of GM material was adventitious or technically unavoidable.

Animal feed, if produced from GM crops, is required to be labeled, according to GOR Decision 256/2006 in place starting with January 1, 2007. Nevertheless, meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

## **Traceability**

According to Order 61 issued by the Ministry of Agriculture in March 2012, all operators along the commercial chain must transmit and retain information about products that contain or are produced from GMOs at each stage of placing them on the market. The regulation covers all products, including food and feed, containing or being derived from authorized GMOs.

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. Seeds 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 seeds suppliers to submit to the Ministry of Agriculture the information inserted into the annual register before June 15 each year or August 1 for the double-crops.

Farmers intending to cultivate biotech crops have to seek approvals from the county office of Ministry of Agriculture for planting such crops for commercial use, consumption, or field trials. The dossier has to contain the following data:

- copy of ID identification for individuals or Copy of certificate of fiscal registration in case of commercial operators
- documents proving the records in the Farms Registry, according to Ministry of Agriculture Order 22/2011
- Statutory declaration according to the Appendix of the order.

The order also sets a minimum size of one HA for a compact field to be planted with biotech crops (except the field trials). Upon sowing completion, within 7 working days, the farmers must report to the county office of MADR facts on planted area, seeds source and the varieties/hybrids used. A copy of their declaration should be retained for 5 years. Similarly, upon harvesting completion, within 7 working days of each month, farmers must submit to the county office of MADR data on production obtained and its purpose. When delivering the GM products further on the commercial chain, farmers have to clearly specify on the accompanying documents and labels, the GM product unique identifier and the statement “this product contains genetically modified organisms.”

## **Enforcement**

Various governmental agencies play different roles in enforcing the legislation related to the national biosafety system. The following authorities bear responsibilities for inspection and control activities:

1. **Ministry of Environment and Forests (MEF)** – through the National Guard for Environmental (NGE), as NGE is in charge with enforcing the whole package of environmental protection legislation (via inspection and control).
2. **Ministry of Agriculture and Rural Development (MARD)**, in which several departments with official inspection and control capacity have responsibilities related to GMOs, such as the *Division for Agricultural Policies Implementation* - with roles in authorizing local GMO plantings and in gathering information about biotech farmers and *the National Inspection for Seed Quality* and *the State Institute for Variety Trials and Registration* (Romanian acronym ISTIS) that investigates from the technical point of view the varieties for which requests have been made to be registered in the Variety Register and the Official Variety Catalogue.
3. **Veterinary and Food Safety National Authority (ANSVSA)**. With respect to GMOs, ANSVSA is involved in (i) endorsing approvals for GM products from the perspective of assessing potential risks to human and animal health; (ii) exerting control regarding the enforcement of food and feed traceability requirements.
4. **National Authority for Consumer Protection (NACP)**, which verifies the enforcement of food product labeling requirements in order to ensure that correct, complete, and accurate information is provided to consumers, including products containing or consisting of GMOs.

Several laboratories are operational and able to perform tests for GMOs detection. The National Reference Laboratory for GM food and feed is the Institute for Diagnosis and Animal Health (IDAH) with the Molecular Biology and GMO Unit. IDAH has under it a network of ten regional molecular biology laboratories.

The Institute of Food Bioresources (IBA) and the National Research and Development Institute for Biotechnologies in Horticulture Stefanesti-Arges are under Ministry of Agriculture and Rural Development (MARD). IBA is responsible for official control analysis of GMOs in seeds, while the latter is in charge with official control analysis of GMOs in feed.

### **Intellectual Property Rights**

This aspect is regulated via a number of laws and Government Decisions: Law 285/2004 on copyright and connected rights, Government Decision 1424/2003 for approving the National Strategy in Intellectual Property Rights with amendments in 2005, Government Decision 573/1998 concerning the Organization of the State Office for Inventions and Trademarks (OSIM).

Until July 2011, OSIM was the authority where plant companies could have submitted their application when seeking protection for their plant varieties. Starting with July 2011, State Institute for Varieties Testing and Registration (ISTIS) is the body responsible for protecting the crop varieties ([www.istis.ro](http://www.istis.ro)). Information regarding the steps to be undertaken by any party interested to apply for a patent is available on the ISTIS website ([www.istis.ro](http://www.istis.ro)).

In respect to the biotech seeds available for cultivation (MON 810 corn), farmers acquiring biotech seeds for planting pay a “technology fee” to the supplier, unlike before 2007 when royalties were not collected for biotech soybean technology.

### **Proposal for a moratorium on biotech crops cultivation**

The draft law introduced in 2010 with the purpose to prohibit biotech crops planting in Romania for 5 years and introduce labeling of food products containing GM ingredients or originating from animals fed with GM feed has not moved forward and remains under debate within the Chamber of Deputies. The Upper Chamber of the Parliament, the Romanian Senate has already rejected it. Romanian Government opposed the proposal as well.

### **Section III. Plant Biotechnology Marketing Issues**

Given the weight of Romania’s votes in the Council of the European Union, Romania’s stance on biotech products became an important topic for debate in circles of scientists, farmers and industry representatives as well as media players.

The view of the current Government on biotech crops has not been clearly stated. In general, Ministers of Agriculture have been prone to follow and adopt science-based decisions. Minister Valeriu Tabara (2011-2012) was a strong supporter of new technology application in agriculture, acknowledging their role in increasing the agriculture efficiency. Stelian Fuia, who was appointed as Minister of Agriculture in February 2012 continued the position adopted by his predecessor. Green organizations had sought

his resignation based on the fact that Mr. Fuia had worked for several years for the seed company Monsanto. Unlike Ministry of Agriculture, Ministry of Environment expressed a strong support for a 5-year moratorium on biotech crops cultivation.

Farmer organizations strongly advocate at all levels, domestic and European, for expediting the process of approving biotech soybeans for cultivation. They estimate that Romania loses about one billion Euros per year because of the prohibition in soybean cultivation. Farmers intend to bring a law suit against the Government of Romania (GOR), based on the fact that the GOR withdrew the country's right to cultivate GM soybeans in 2007 without justification, namely evidence that biotech crops have created some harm.

Some mayors have declared the territory under their jurisdiction "GMO free-areas." Most of these areas are located in regions less favorable for agriculture or represent either small villages or municipalities with no agriculture on large-scale. Declarations referring to "GMO-free areas" and the statements that trade and cultivation are prohibited inside those areas have only a threatening purpose since such initiatives should be notified and accepted by the EU Commission.

For the past few years, agricultural biotechnology has been the core theme in every agricultural conference organized. Most of the debate is centered on the fact that despite the proper climatic conditions and farmers demand, Romanian farmers are not allowed to plant biotech soybeans.

Livestock industry remains their potential customer, as large volumes of biotech soybeans continue to be sourced from outside Romania.

#### **Section IV. Plant Biotechnology Capacity Building and Outreach**

In October 2011, AgBucharest in cooperation with the Economic Section of the Embassy organized a series of events meant to increase the knowledge about agricultural biotechnology and facilitate the information exchange. The guest-speaker was Michael Phillips, a well-known adviser of governments, industry, and non-governmental organizations on biotechnology issues. The round-tables with the members of the Romanian Parliament and members of the Agriculture Academy organized during the three-day program were a great opportunity for the audience to learn about the benefits brought by agricultural biotechnology to farmers - net economic benefits - and environment - greenhouse gas emissions and pesticide application. Several articles were published by the journalists who attended the media roundtable in both written and online form.

In June 2011, US Soybean Board (USSB) representatives conducted a second trip to Romania for a round-table with feed producers, livestock associations, and farmers. During the event, USB delegates described for audience the benefits of biotech crops and the negative impact of the EU's biotech policy on European agriculture and soybeans imports. In order to give the audience a flavor of the future biotech events, products in the pipeline were also introduced. Given the fact that the main speaker was a soybean farmer, participants were very much interested in the cost comparison between conventional, biotech and organic crops. They also requested advice concerning the message that feed compounders should convey to the authorities and the means to educate consumers about the safety of biotech products.

Producers and users of agricultural biotechnology have a strong voice under the organization called AgroBiotechRom Association. Their members are biotech seed companies, farmers, and representatives

of the academic environment. The association organizes events several times a year with the purpose to augment awareness among consumers of the benefits of biotechnology in health, agriculture, and industry sectors and to support the expansion of biotechnology utilization in Romania.

On the other hand, organic producers occasionally express their concern for cross-contamination supporting the prohibition of biotech crops cultivation and import.

## **Section V. RELEVANT REFERENCES**

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

24 Bd. Carol I, sector 3  
020921 Bucharest, Romania  
Phone: +40 21 3072300, +40 21 3072345, +40 213078500  
Fax: +40 21 3078685  
E-mail: [comunicare@madr.ro](mailto:comunicare@madr.ro)  
Web site: <http://www.madr.ro>

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

294 Splaiul Independentei, sector 6  
060031 Bucharest, Romania  
Phone: +40 21 2071101, +40 21 2071127  
Fax: +40 21 2071133  
E-mail: [office@anpm.ro](mailto:office@anpm.ro)  
<http://www.anpm.ro/>

### **National Guard for Environment**

General Commissary  
78 Unirii Blvd., Bl. J2, sector 3  
Bucharest, Romania  
Phone: +40 21 3268970  
Fax: +40 21 3268971  
E-mail: [gardamediu@gnm.ro](mailto:gardamediu@gnm.ro)

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

1 Piata Presei Libere Corp D1, sector 1  
Bucharest, 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 Public Health**

1-3 Cristian Popisteanu Str., sector 1  
010024 Bucharest, Romania  
Phone: +40 21 3072500, +40 21 3072600  
Fax: +40 21 3141526  
Web site: <http://www.ms.ro>

**National Authority for Consumers Protection**

72 Blvd. Aviatorilor, sector 1  
Bucharest, Romania  
Phone: +40 372 131951  
Fax: +40 21 3143461  
E-mail: [office@anpc.ro](mailto:office@anpc.ro)  
Web site: [www.anpc.ro](http://www.anpc.ro)

**The National Customs Authority**

13 Matei Millo St. Sector 1  
Bucharest, 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**

61 Marasti Blvd. Sector 1  
Bucharest, 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)

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

63 Dr. Staicovici Street Sector 5  
050557 Bucharest Romania  
Phone: +40 374 322013  
Fax: +40 21 4113394  
E-mail: [office@idah.ro](mailto:office@idah.ro)  
Website: [www.idah.ro](http://www.idah.ro)

**AgroBiotechRom Association**

59 Marasti Blvd. 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)

**United States Department of Agriculture  
Economic Research Service**

1800 M Street NW  
Washington, DC 20036-5831 USA  
<http://www.ers.usda.gov/Briefing/Biotechnology>

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

**Foreign Agricultural Service Bucharest**

American Embassy, Romania

4-6 Liviu Librescu St.

Phone: 40 21 2003374

E-mail: [AgBucharest@fas.usda.gov](mailto:AgBucharest@fas.usda.gov)

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**Section VI. APPENDIXES**

**APPENDIX 1 Table of Biotechnology Products approved for field trials or demo plots in Romania (2011)**

<b>Crop</b>	<b>Trait Category</b>	<b>Applicant</b>	<b>Transformation Event</b>	<b>Quantity imported in 2011 (kg)</b>
Corn/ Zea mays L.	Herbicide Tolerance	Monsanto	NK 603	63.8
Corn/ Zea mays L.	Staked genes (Herbicide Tolerance and Insect Resistance)	Monsanto	NK 603 x MON810	7.5
Corn/ Zea mays L.	Staked genes (Herbicide Tolerance and Insect resistant)	Monsanto	MON-88017-3	12.5
Corn/ Zea mays L.	Insect resistance	Syngenta	Bt11	3
Corn/ Zea mays L.	Herbicide Tolerance	Syngenta	GA 21	5
Corn/ Zea mays L.	Herbicide Tolerance	Limagrain Central Europe SE France	6981 VCO-01981-5	17
Corn/ Zea mays L.	Herbicide Tolerance	Euralis	NK 603	2.5
Corn/ Zea mays L.	Staked genes (Herbicide Tolerance and Insect Resistance)	Euralis	NK 603 x MON 810	2.5
Corn/ Zea mays L.	Herbicide Tolerance	Pioneer	NK 603	5
Corn/ Zea mays L.	Insect Resistance	Pioneer	1507	0

**APPENDIX 2 Table of Biotechnology Products authorized for field testing in Romania (2012)**

<b>Crop</b>	<b>Trait Category</b>	<b>Applicant(s)</b>	<b>Transformation Event</b>	<b>Trait Description</b>	<b>Approved for/until</b>
Plum tree/Prunus Prunus Domestica	Virus resistant	Research and Development Station Bistrita	PPV	Plum pox virus resistant	Field Trials /December 31, 2019
Corn/ Zea mays	Herbicide Tolerance	Monsanto	NK 603	Glyphosate tolerant	Field Trials/ December 31, 2015
Corn/ Zea mays L.	Insect resistant	Pioneer Hi-Bred Seeds Agro	DAS-59122-7	Glufosinate ammonium tolerant and resistance to Coleopteran insects	Field Trials/ December 31, 2015
Corn/ Zea mays L.	Stacked genes (Herbicide Tolerance and Insect resistant)	Pioneer Hi-Bred Seeds Agro	DAS-59122-7 x 7-DAS01507-1x MON 603	Glyphosate and glufosinate ammonium tolerance and resistance to Coleopteran and Lepidopteran insects	Field Trials/ December 31, 2015