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Romania

Agricultural Biotechnology Annual

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Report Highlights:
This report is an update of the Biotechnology Annual Report 2012 providing information on the status of biotechnology in Romania.

Section I. Executive Summary:

Over the past years, Romania remained open to biotechnology, for testing, importing and cultivating. Despite all the bureaucracy who results from applying both EU and national regulations, farmers remain attached to modern technologies. According to the latest information, the planted area with biotech corn (MON 810) expanded in 2013 four times compared to the previous year, from 217 hectares to 834 hectares. Unlike the previous year, when seed propagation was the purpose of the crop, in 2013 commercialization is the purpose of the crop.

Soybean remains one of the most valuable feed ingredients for the livestock and poultry domestic industry. 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 2012 by 11.5 percent, reaching about 545,000 MT ($275 million), of which soybeans meal solely totaled 482,000 MT ($237 million). The major suppliers are the large biotech producing countries: Brazil, Argentina, and United States (47,000 MT exported in 2012, from only 21,000 MT soybean meal exported in 2010 and zero in 2011).

Field-testing of bioengineered seeds is permitted in Romania. Appendix 2 provides the list of events approved in 2013 for field trials (corn and plum trees).

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

In February 2013, in an attempt to achieve an expansion in the area cultivated with soybeans, Romanian Ministry of Agriculture signed the Danube Soya Declaration, a private initiative supported by the Austrian Ministry of Agriculture, aiming to reduce the European dependence on imported soybean products.

The opposition to biotechnology has expressed its views at the level of Parliament. In February this year, one member of the Chamber of Deputies placed for debate a draft law intended to prohibit the cultivation and importation of biotech products or products containing GE ingredients. The draft is currently with the Chamber of Deputies, after the Romanian Senate rejected the proposal in May 2013 (please read GAIN RO1317).

Section II. Animal and Plant Biotechnology

Chapter 1: PLANT BIOTECHNOLOGY

Part A: Production and Trade

a. **Product Development**: FAS Bucharest is unaware of any GE plants or crops under development in Romania.

b. **Commercial Production**: Romanian farmers have planted biotech crops for the past years, biotech soybeans until 2007 and biotech corn since 2007. According to data provided by the Ministry of Agriculture, in 2012, 217 hectares were cultivated with biotech corn (MON 810 insect resistant corn), entirely for seeds production. That was 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. In order to cultivate biotech seeds, farmers seek authorization from the Ministry of Agriculture, per the provisions of Order 61/2012. Despite all these burdens, farmers continue to embrace the technology. The area planted with biotech corn rose in 2013 four times (feed consumption).

Apart from the biotech corn which is authorized for cultivation, Romanian farmers are eager to regain access to biotech soybeans, considering their positive experience with this crop before EU accession. Although not producing direct effects, the developments that occurred in the beginning of 2013, when the Romanian Ministry of Agriculture signed the Danube Soy Declaration, and non-Government organization promoting non-GE soybeans, heavily disappointed farmers.

c. **Exports**: In the past years, most of the domestic biotech corn plantings were intended for seeds production and a significant percentage was exported to countries such as Spain. However, in 2013, the expectation is that the harvest will be utilized internally for animal feed.

d. **Imports**: Romania imports large volumes of GE soybean and soybean meal in order to cover the feeding needs in animal production. Total soybeans and soya meal imports grew in 2012 by 11.5 percent, reaching 545,000 MT ($275 million), of which soybeans meal totaled 482,000 MT ($237 million). The major suppliers are the large biotech producing countries: Brazil (339,000 MT) and Argentina (52,000 MT). It is noteworthy to mention that the United States ranks third in this hierarchy, with about 47,000 MT ($31 million) exported in 2012, from only 21,000 MT soybean meal exported in 2010 and no exports in 2011. Other feed ingredients, such as Distilled Dry Grains Soluble (DDGS) and Corn Gluten Feed (CGF), are utilized by the domestic industry in limited volumes. Romania imported 1,857 MT of CGF in 2012, almost double compared to the previous year.

Biotech companies that conduct research activities partially import genetically engineered seeds. In 2012, two companies tested three biotech events, single and stacked, for which an amount of 80 kg seeds was imported. Despite the fact that the seeds companies had approvals for field trials valid for a couple of more years, some of them decided to cease the trials. The delays in receiving the authorizations (2011 and 2012) and the high costs incurred by these approvals prompted companies to limit their field research activities. In 2013 there are two entities planning to conduct field trials, on corn and plum trees. The events subject to testing in 2013 are NK 603 and NK 603XMON 810 corn in five locations (about 50 kg of seeds imported) and plum trees.

e. **Food Aid recipient Countries**: Romania runs the EU Aid programs for less-favored population (sun oil, wheat flour etc.). No issues related to biotechnology.

Part B: POLICY

a. **Regulatory Framework**: Legislation enacted in recent years as 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.

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 biotech 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.

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 remain the following:

- the central public authority for environment protection - Ministry of Environment and Climatic Changes (MECC), 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,

- Competent Authority (CA) which is in this case, the National Agency for Environment Protection (NAEP),

- National Guard for Environment (NGE) is the control authority ensuring the right enforcement of this Directive provisions,

- 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)

Biosafety Commission has been the scientific body with consultative role in assisting the authorities in the decision-making process regarding the issuance of authorizations since 2002. Ministry of Environment is responsible for setting the major responsibilities of the Biosafety Commission, including the list of members.

In 2011, the Commission interrupted its activities due to funding issues and members lost their membership. In March 2012, Ministry of Environment and Forests approved 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. Unlike in previous years when several companies submitted notifications for field trials, in 2013 only two entities intend to run field demonstrations (please see the Appendix 2).

Proposed Moratorium on biotech products

In February 2013, a draft law proposing the interdiction of biotech crops cultivation and import of products containing GE ingredients advanced for Parliamentary vote. The first Chamber to debate the draft was the Romanian Senate. All the Senate Committees required to provide a resolution rejected the proposal. The Legislative Council and the Romanian Government opposed the proposal as well. Following the plenary vote, the Romanian Senate rejected the initiative. The decisional Chamber is the Chamber of Deputies, which is currently debating the draft.

In March 2013, the Chamber of Deputies rejected the previous draft law introduced in 2010 with the purpose to prohibit biotech crops planting in Romania for 5 years and to introduce labeling of food products containing GE ingredients or originating from animals fed with GE feed.

Danube Soya Declaration

This year local biotech opponents became more active as they join the regional efforts in promoting biotech-free soybeans. The most recent is the support received by the Danube Soya Association from the Romanian Ministry of Agriculture. Founded in 2012 as an international multi-stakeholder association based in Vienna, the Association is comprised of members active as farmers, agricultural traders, feed companies, major retailers, as well as green organizations. The Danube Soya Association is promoting biotech-free soya cultivation and processing in the Danube region sufficient to supply Europe. Romanian Ministry of Agriculture signed the Declaration in February 2013 as they viewed it as a mean to encourage the Romanian farmers for expanding soybean planting areas, despite strong farmers' opposition. For further details please read reports RO1301, RO1303 and RO1304.

b. **Approvals:** Romania follows the EU legislation regarding the biotech events authorized for import and cultivation. Currently Romanian farmers plant biotech corn MON 810, insect resistant. The EU register of authorized genetically engineered products at EU level can be viewed here.

c. **Field tests**: Romania allows field-testing for GE crops following the notifications to the Agency for Environment Protection Agency, which submits these notifications to the Biosafety Commission for assessment and approval. The latter will approve/disapprove the requests. In 2013 one company and one research station expressed an interest on conducting research on maize, respectively on plum tree (please see the Appendix 2). Field testing authorizations are valid for several years.

d. **Stacked Event Approval**: Similar to above. In 2013, one company will conduct field-testing on maize stacked event NK 603 X MON 810 (herbicide tolerance and lepidopteron insects' resistance).

e. **Additional requirements**: N/A

f. **Coexistence**: Romania adopted and implemented coexistence policy. Order 61 approved by the Ministry of Agriculture in 2012 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.

According to Order 61/2012, all operators along the commercial chain must transmit and retain

information about products that contain or produced through agricultural biotechnology at each stage on the market. The regulation covers all products, including food and feed, containing or 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. 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 planning 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 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 MARD 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 MARD data on production obtained and its purpose. When delivering the GE products further on the commercial chain, farmers have to specify clearly on the enclosed documents and labels, the GE product unique identifier and the statement "this product contains genetically modified organisms."

The public register concerning the commercial biotech fields is available on the website of Ministry of Agriculture and Rural Development. It is updated every year with the following data about the farmers and the biotech seeds: Genetically modified organism *(species, transformation event, unique identification code other specific data*), the owner of authorization for commercial cultivation at European Union level, information about the economic operator, as well as info about the area (locations, planted area etc.).

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 thresholds for labeling, set at 0.9% for an adventitious presence of an authorized biotech event in food or feed. Operators must demonstrate that the presence of GE material was adventitious or technically unavoidable.

Although the animal feed containing GE ingredients, is required to be labeled, per the provisions of GOR Decision 256/2006, meat, milk or eggs obtained from animals fed with biotech feed or treated with GE medicinal products do not require biotech labeling.

h. **Trade Barriers**: Please read reports "Romania Proposes to Prohibit Import and Cultivation of Biotech Products" and "Romanian Senate rejects Proposal to Prohibit Biotech Products"

i. **Intellectual property Rights (IPR):** IPR issues are 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 that date, State Institute for Varieties Testing and Registration (ISTIS) is the body responsible for protecting the crop varieties (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).

j. **Cartagena Protocol Ratification**: Romania ratified the Cartagena Protocol on Biosafety in 2003 through law 59/2003. The fourth national report for Romania covering the timeframe 2004-2008 may be read here. The status of the protocol implementation may be read here.

k. **International Treaties/FORA**: Romania is a member of the International Plant Protection Convention (IPPC) and Codex Alimentarius (Codex).

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

m. **Monitoring and testing:** 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:

- **Ministry of Environment and Climate Changes (MECC)** – 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).

- **Ministry of Agriculture and Rural Development (MARD)** holds several departments with official inspection and control capacity responsibilities related to biotechnology. Departments include: (1) *Division for Agricultural Policies Implementation* - with roles in authorizing local biotech plantings and in gathering information about farmers; (2) *National Inspection for Seed Quality*, and *(3) State Institute for Variety Trials and Registration* (Romanian acronym ISTIS) which investigate varieties from the technical point of view requested to be registered in the Variety Register and the Official Variety Catalogue.

- **Veterinary and Food Safety National Authority (ANSVSA**); With respect to biotechnology, ANSVSA is involved in (i) endorsing approvals for biotech 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.

- **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 GE components.

In terms of testing, several laboratories are operational and able to perform tests for GE components detection. The National Reference Laboratory for biotech food and feed is the Institute for Diagnosis and Animal Health (IDAH). The Institute of Food Bioresources (IBA) is responsible for official control analysis of GE detection in seeds. In addition, the National Research and Development Institute for Biotechnologies in Horticulture Stefanesti-Arges has the capability to perform analysis of biotech presence in feed.

n. **Low Level Presence Policy (LLP)**: Romania follows the EU regulations regarding the threshold for unapproved events in shipments.

Part C: Marketing

a. **Market Acceptance**:

Over the past years, 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. In addition, social media is becoming an important conveyer of opinions/comments/attitudes concerning biotech food at consumers' level.

Romanian farmers plant biotech corn and if it were approved in the European Union, they would adopt biotech soybean on a large scale. Farmers have been in general open to biotechnology, in particular to soybean crop, as they cultivated Round-up Ready soybean in the past and enjoyed its gains. One of the reasons for which the biotech corn area does not expand rapidly may be linked to the feeding manufacturers' resistance in including biotech corn in the feed ratio, in order to avoid segregation in the warehouses and reduce the paperwork (flow of invoices etc.).

Nevertheless, feed manufacturers use GE raw materials for producing feeding-stuff, mainly soybean meal and oil, imported usually by large traders in Romania. Livestock and poultry do introduce the resulting GE feed into the animals' nutrition. At retail level, key-players do require non-GE certification from their suppliers.

b. **Public/Private Opinions:**

In Romania there are few organizations that focus their activities on bio-engineered crops and products. AgroBiotechRom Association, a strong pro-biotech organization, has under its umbrella biotech-seed companies, farmers, and representatives of the academic environment. The major objective is to help developing a coherent, stable, and predictable regulatory framework in biotechnology area through activities meant to build a constructive dialogue with the authorities and other associations. AgroBiotechRom aims also to increase the knowledge about biotechnology benefits among consumers. The association is a member of Europa-Bio (European Association for Bio-industry) along with other 25 national associations.

On the other hand, the organizations opposing biotech products align their policies and actions to their mother-companies' or related foreign counterparts. Often they use social networks to spread their

beliefs and sometimes they organized public protests in conjunction with seminars/conference organized by third parties, with the purpose to determine consumers oppose biotechnology.

Romanian consumers continue to reject biotechnology publicly as they are convinced they have avoided so far consumption of food products for which GE ingredients have been used. In the same time, Romanian consumers perceive backyard production as organic, despite the fact that these small households do not hold lack of proofs of certification, which means there is a continuous need for further education.

Concerning the biotech free-areas, so far few mayors have assigned this title to some of the territories under their jurisdiction. Most of these areas are located in regions less favorable for agriculture or represent either small villages/municipalities with no agriculture on large-scale. Declarations referring to "biotech-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.

c. **Marketing Studies:** There are several reports published by international organizations that include Romania in their analysis, such as PG Economics, an advisory and consultancy organization (http://www.pgeconomics.co.uk/) and International Service for the Acquisition of Agri-biotech Applications at http://www.isaaa.org/.

PART D: Capacity Building and Outreach

a. **Activities**:

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 versions.

In July 2012, a group of members of Iowa Soybean Association (ISA) and their leadership conducted a trip to Romania in an effort to understand the challenges that Romanian farmers are facing because of application of EU legislation. During the meeting with farmers' leaders, the US delegation had the opportunity to exchange information with the Romanian farmers on the crop situation – given the drought occurring in both countries, yields, costs and margins, mainly on corn and soybeans. Referring to the biotech soybean, local farmers complained about the number of treatments they have to apply now on conventional soybeans in order to fight the weeds as opposed to RR soybeans where one treatment was sufficient. In their view, conventional soybeans are not profitable.

There is an increasing tendency among media groups to organize conferences/round-tables focused in agriculture. Due to the higher frequency of such events, Agricultural biotechnology, whether focused

on basic principles, worldwide expansion or market acceptance climbs among the interests of the audience.

b. **Strategies and Needs**

The lack of awareness concerning agricultural biotechnology and its potential in future applications may be addressed through additional projects designed for these purposes. Activities meant to encourage scientific discussion on the technology in an environment that would generate media coverage should also be considered.

Dissemination of information about the technology's application/advantage to key public/private sector decision makers in an environment of higher education/research should create conditions for a greater possible acceptance among the target and secondary audiences (academia/students).

Chapter 2: ANIMAL BIOTECHNOLOGY

PART E: Production and Trade

a. **Biotechnology Product Development**: According to the information provided by the Agency for Environment Protection Agency, there are not notifications submitted having the animals as subject of research.

b. **Commercial Production**: There are no livestock clones or GE animals or products obtained for commercial production in Romania.

c. **Biotechnology Exports:** N/A

d. **Biotechnology imports**: N/A

PART F: Policy

a. **Regulation**: The institutions listed for Plant Biotechnology are in charge with Animal Biotechnology. Romania follows the EU policy in this field.

b. **Labeling and traceability**: N/A.

c. **Trade Barriers**: No country-specific legislation, Romania follows the EU legislation.

d. **Intellectual Property Rights (IPR)**: Please see Plant Biotechnology Chapter.

e. **International Treaties/FORA**: Romania is a member of Codex Alimentarius and World Organization for Animal Health.

PART G: Marketing

a. **Market Acceptance**: N/A

b. **Public/Private Opinions:** N/A

c. **Marketing Studies:** N/A

PART H: Capacity Building and Outreach

a. **Activities**: N/A

b. **Strategies and Needs**: N/A

Appendix 1. Relevant References

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Appendix 2: Table of Biotechnology Products authorized for field testing in Romania (2013)

Crop	Trait Category	Applicant(s)	Transformation Event	Trait Description
Corn/ Zea Mays	Herbicide Tolerance	Monsanto	NK 603	Glyphosate tolerant
Plum Tree/Prunus Prunus Domestica	Virus resistant	Research and Development Station Bistrita	PPV	Plum-pox resistant
Corn/Zea Mays	Stacked genes (Herbicide Tolerance and Insect resistance)	Monsanto	NK 603 X MON 810	Glyphosate tolerant and resistant to Lepidopteran insects

Source: National Agency for Environment Protection

You can also visit the FAS website to read previous GAIN reports produced by the FAS/Bucharest office and the US EU Mission (www.fas.usda.gov)