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Agricultural Biotechnology Annual

Annual Biotechnology Report – Romania

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Report Highlights:

This report is an update of the Biotechnology Annual Report 2013 providing information on the status of biotechnology in Romania.

Section I. Executive Summary:

Over the past year, Romania has preserved its position among the EU countries adopting modern agricultural biotechnology. Although the area planted with biotech corn slightly dropped from 834 hectares to 771 hectares this year, the increase in number of farmers planting biotech corn is notable (five compared to two the previous year).

Romania's current grains production volume does offer livestock and poultry domestic industry access to the adequate volumes to cover their needs. However, the domestic production of soybeans remains insufficient in comparison with the demand, thus this protein is sourced from outside. Total soybean and soya meal imports grew further in 2013 (by 6.6 percent); reaching about 581,000 MT (\$333 million), of which soybeans meal solely totaled 464,000 MT (\$263 million). The major suppliers are the large biotech producing countries: Brazil, Argentina and United States (39,000 MT in 2013). Part of the reduction of soybean meal imports was compensated with soybean imports from Brazil and Ukraine. The area planted with conventional soybeans has not advanced much, although an increase of 7-10 percent is expected this year, bringing the total figure to 76-78,000 hectares.

Romania remained opened to import for feed and food over the past year and no legislative initiatives for banning biotech products or for restrictive labeling have been placed for debate. In line with most of the EU member states, Romania supported the EU Commission proposal to permit Member states opt-out of cultivation of EU approved GE products, based on the belief that Romanian farmers will have access to modern technologies, currently blocked at EU level.

Prior to February 2014 Romania had been noted for its openness to biotechnology reflected in its positive votes on new events approval, regardless the purpose. In early February the Romanian government voted against the petition to approve Pioneer 1507 biotech corn event for EU wide cultivation, signaling a possible change in its attitude.

Field-testing of bioengineered seeds is permitted in Romania. This year field trials will continue on plum trees, as part of an earlier permit, but not on crop. 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. Nevertheless, in 2014 no import approvals were requested/granted for biotech seeds, as companies have submitted no notification to the Competent Authority.

Section II. Author Defined:

Plant and Animal 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:**

Despite the administrative burden imposed by the EU legislation on biotech crops cultivation, Romanian farmers continue to embrace modern technology. The area planted with biotech corn (MON 810 insect resistant corn) is estimated to reach 770 hectares in 2014 (slightly lower than 2013), according to the data recently published by the Ministry of Agriculture. The purpose is entirely commercialization, though one research station is planning to conduct testing.

Apart from the biotech corn which is authorized for cultivation, Romanian farmers were eager to regain access to biotech soybeans, considering their positive experience with this crop before EU accession. In this respect, farmers were extremely disappointed with Monsanto's decision last year to withdraw the dossier for soybean cultivation submitted to the EU Commission. The EU proposal on the member states freedom to restrict or prohibit the cultivation of biotech crops in their territory is regarded as a gate to having access to new biotech events in Romania. Member States traditionally opposing biotech events may be more prone to approve new events, thus raising the chances of obtaining the qualified majority.

c. **Exports:** In the past, a major part of the domestic biotech corn production was exported to other EU countries, as seeds production was the main purpose. In 2014, the expectation is that the biotech corn 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 2013 by 6.6 percent in volume, reaching MT 581,000 (\$ million 334) versus 2012, of which soybeans meal imports totaled MT 463,000 MT (\$263 million). Brazil (233,000 MT) and Argentina (179,000 MT) remain the leading soybean suppliers, with United States ranking third with about 41,000 MT (\$25 million) exported in 2013. 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 1,381 MT of CGF in 2013, about a quarter less than the previous year.

In terms of seeds importation, biotech companies conducting research activities partially import genetically engineered seeds. However, considering the declining interest for research, there are no imports of biotech seeds this year for research purpose. The biotech corn seeds for commercial cultivation have been produced locally or imported from other EU member states.

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

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:

- Ministry of Environment and Climatic Changes (MECC) - 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,
- National Agency for Environment Protection (NAEP) - the Competent Authority (CA), is the main interlocutor of the applicant companies in the notification process
- National Guard for Environment (NGE) - 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 Health (MH) play important 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 up the major responsibilities of the Biosafety Commission, including the list of members.

The Biosafety Commission conducted its activities in this structure since March 2012, when Ministry of Environment and Forests approved Order 950/2012, appointing the members of the Biosafety Commission 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.

The number of notifications for field trials submitted for Commission's approval has been gradually declining. Only two entities ran field demonstrations in 2013, while for 2014 no company expressed an interest for field trials.

Danube Soya Declaration

Founded in 2012 as an international multi-stakeholder association based in Vienna, the Danube Soya Association is comprised of major retail chains, animal feed companies, farmers' associations and green organizations. The Danube Soya Association is promoting biotech-free soya cultivation and processing in the Danube region. Romanian Ministry of Agriculture signed the Declaration in February 2013 based on the belief that by endorsing the declaration, the farmers will be stimulated to plant more soybeans. In 2014, the association conducted a couple of events in Romania in an effort to convince the farmers switch to the soybeans, but the area has not increased significantly. In terms of membership though, the association succeeded this year to attract one of the Romanian agricultural federations as a member.

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: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

c. Field tests: Romania allows field-testing for GE crops specified in the notifications submitted to the National Agency for Environment Protection (NAEP), which forwards these notifications for assessment and approval to the Biosafety Commission. The latter will approve/disapprove the requests. Following these evaluations, the National Agency for Environment Protection issues the authorizations which are valid for several years (please check Appendix 2). In 2014 though, no biotech company expressed an interest in conducting field testing, despite the existent authorizations. The delays in receiving the authorizations (2011 and 2012), the high costs incurred by these approvals as well as the lack of perspective at EU level for the events subject to research may be cited as reasons determining companies to limit their field research activities.

d. Stacked Event Approval: N/A.

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. Co-existence section of the previous report remains unchanged and may be read [here](#).

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

h. Trade Barriers: Post is unaware of any initiatives that may pose a risk to biotech products in the near future. Links to reports describing past years banning intentions are described in the following reports: [GAIN RO1308](#) and [GAIN RO1317](#).

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).

State Institute for Varieties Testing and Registration (ISTIS) is the body responsible for protecting the crop varieties since July 2011. Information regarding the steps to be undertaken by any party interested in applying for a patent is available on the ISTIS website (www.istis.ro). The legal framework concerning the protection of the new plant varieties is Law 255/1998.

j. 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 Questionnaire filled out by the Ministry of Environment representative concerning the status of implementation dates back in 2011 and may be accessed [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. Please read the report issued in 2013 for the list of authorities bearing responsibilities for inspection and control activities.

In terms of testing, the National Reference Laboratory for biotech food and feed is the Institute for Diagnosis and Animal Health (IDAH). Recently the laboratory for seeds quality, under the Ministry of Agriculture, received accreditation to conduct tests for GM presence in corn seeds.

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:

Media has become an important vector for the public debate on the biotech products. During the past

year, this topic was brought to the public attention in the context of TTIP negotiation, Romania's position in Brussels or following specific public events (conferences, workshops etc.). Scientists, members of the Agricultural Science Academy and more recently, the Medical Science Academy, farmers and industry representatives express opinions concerning modern biotechnology. Social media is becoming an important conveyer of opinions/comments/attitudes concerning biotech food at consumers' level. Major concerns expressed by commenter on-line refer to the monopolistic positions biotech companies may achieve or the potential harm brought through the consumption of biotech products.

At the level of farmers' communities, there is a wide support for cultivation in case such seeds are approved for planting in the EU/Romania. Farmers have been open to biotechnology, in particular to soybean crop, as they cultivated Round-up Ready soybean in the past and experienced the cost savings.

At the level of feeding manufacturers and livestock farms, no concerns regarding the biotech components of the feeding are expressed as they already utilize biotech soybean meal and oil in the feed ratio. However, some of these farms manifest some reluctance in using domestically produced corn as they prefer to avoid segregation in the warehouses and reduce the paperwork (flow of invoices etc.).

At retail level, key-players require non-GE certification for food products from their suppliers. Several poultry producers state on product labels that birds have not been fed with biotech grains, hence the stagnation of the biotech corn area expansion. Romanian consumers continue to perceive biotechnology as harmful and not tested enough and they believe Romania is able to satisfy the domestic food demand through conventional methods.

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, aims to help developing a coherent, stable and predictable regulatory framework in biotechnology area. The association carries out activities meant to build a constructive dialogue with the authorities and other associations with the purpose to expand the knowledge about the biotechnology. The association is a member of Europa-Bio (European Association for Bio-industry) along with dozens of corporate and national biotech associations.

On the other hand, there are organizations opposing biotech products which align their policies and actions to their mother-companies' or related foreign counterparts. Often they use social networks to spread their beliefs and occasionally they organize public protests, although the latter occurred at a very small scale during the past year.

c. Marketing Studies:

Several reports published by international organizations cite 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/>. No country-specific studies concerning the marketing of GE plants in Romanian have been published. Nevertheless, Romania is a partner in the PRICE project, which is a project based on a multi-disciplinary approach, conducted by a consortium of Eastern and Western European research partners

working in the areas of gene flow modeling, agricultural and environmental sciences and economics (<http://price-coexistence.com/>).

Part D: CAPACITY BUILDING AND OUTREACH

a. Activities:

Over the past two years, various entities conducted programs aiming to keep the audience abreast of latest biotechnology developments at the global, regional or Romanian level.

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.

In September 2013, AgBucharest in partnership with the Embassy of Argentina and with the support of local biotechnology providers, Monsanto, Pioneer, and Syngenta organized the Forum on Agricultural Sustainability. US Embassy Charge D'Affairs, Duane Butcher. In his opening remarks, the Charge noted that “in order to produce more with less in a changing environment, Romanian producers, as well as American and other producers of the world, must become more innovative, and be willing to examine every tool and every technology available to ensure that productivity is increased in a sustainable manner.”

Dr. Ralph Scorza, the U.S. conference speaker from USDA/ARS gave a presentation on the global status of agricultural biotechnology and specific research on plum-pox, the common virus decimating stone fruits in Romania and other EU member states. The forum was very well received by the attendees who spoke very highly about the quality of the presentations.

In association with the large-audience forum, AgBucharest organized jointly with the Academy of Agricultural Science two separate round-tables in Bucharest and Bistrita where Dr. Scorza delivered to the audience a more detailed presentation on *HoneySweet* Plum Resistant from the perspective of the agricultural research conducted by ARS in the United States. Dr. Ioan Zagrai, with Romania's counterpart research organization, shared with the audience the outcomes on Plum-Pox Virus (PPV) plum research in Romania. More information about these events may be read in [GAIN RO1332](#).

More recently, in June 2014, AgBucharest collaborated with AgroBiotechRom Association for organizing a seminar dedicated to the role of biotechnology in the Romanian and European feed market. The purpose of the activity was to consolidate past efforts for raising the public awareness on the safety of biotech products and the importance of a science-based and transparent approach in regulating biotechnology within the EU framework. In this regard, AgBucharest invited FEFAC Secretary General to talk about the EU Feed industry experiences and future challenges with regard to the EU Biotech policy framework.

The rapid biotech expansion at global level and the asynchronous approval process at EU level were topics addressed by the EuropaBio representative. The recent EU proposal to give Member States the possibility to restrict or prohibit the cultivation of biotech crops on their territories was discussed in details. The target audience was comprised of government officials, members of diplomatic missions, academics, farmers, feed-manufacturers, swine and poultry industry, grains and oilseeds traders as well as other members of the agricultural community. A wide range of agricultural media outlets attended the event.

b. Strategies and Needs

The need for further education concerning agricultural biotechnology may be addressed through programs which encourage discussion based on technology science, in a format that generates media coverage. On-line specific information friendly inserted into general public media outlets is likely to reach consumers who do not specifically look for such information and who might have a uninformed opinion about biotechnology.

Communication and presentation skills improvement would greatly contribute to effective conveyance of current knowledge about the technologies to interested parties including key decision makers, academia, and media. Therefore, developing successful programs that would help interested parties draft clear and facile messages or even help them effectively challenge audience with a hostile or prejudiced attitude would be mitigating the spread of negative emotions.

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 no notifications having the submitted animals as subject of research. Nevertheless, animal cloning is a topic frequently mentioned by local experts as being an area, which requires further examination through education and research work.

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: There is no data available on the imported genetics originating from cloned animals, thus it is hard to assess the market.

PART F: POLICY

a. Regulations: In Romania, 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.

b. Labeling and traceability: No country-specific legislation, Romania follows the EU legislation.

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

d. Intellectual Property Rights (IPR): Please see the same section in the 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: Unlike GE crops and foods, which are widely debated in various circles, discussion about animal genetic engineering has been very limited. It is worth noting though that the political resistance emanating from the EU, despite the positive scientific opinion expressed by the European Food Safety Authority (EFSA), and has been spread in Romania.

c. Marketing Studies: N/A.

PART H: CAPACITY BUILDING AND OUTREACH

a. Activities: In January 2013, the nomination submitted by AgBucharest to Department of State for the Program *Technology in Animal Production: a Voluntary Visitor Regional Project for EU* in the United States was accepted. The representative of the Sanitary-Veterinary and Food Safety National Authority was given the opportunity to learn about the use of assisted reproductive technologies for animal breeding and to learn about new animal technologies from the scientists developing them. In the Romanian participant's view, the program was very well organized and extremely useful, as it covered a wide range of topics associated with animal biotechnologies, from purpose of the animal cloning and the difference between cloning and transgenic animals to the current Government regulations on the regime of products from cloned animals and public perception of animal biotechnologies. The participant was impressed with the wealth of research conducted on animal cloning already in the United States.

b. Strategies and Needs: Outreach programs should concentrate on the scientific arguments which assessed the technologies as being safe, on one hand, and the negative impact that a ban at EU level would have on the EU – US trade in products originating from cloned animals, on the other hand. As the decision process is mainly driven by the EU Parliament, when designing outreach programs, it may be considered inviting members of the legislative bodies at the local and the EU level in order to expand their understanding about these new technologies.

Section III: Appendix 1 RELEVANT REFERENCES

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National Authority for Environment Protection

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National Guard for Environment

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National Sanitary-Veterinary and for Food Safety Authority

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Ministry of Health

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Web site: <http://www.ms.ro>

National Authority for Consumers Protection

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The National Customs Authority

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Appendix 2: Table of Biotechnology Products authorized for field trials in Romania

Crop	Trait Category	Applicant(s)	Transformation Event	Trait Description	Authorization validity
Corn/ Zea Mays	Herbicide Tolerance	Monsanto	NK 603	Glyphosate tolerant	2012-2015
Corn/ Zea Mays L.	Insect resistant	Pioneer Hi-Bred Seeds Agro	DAS-59122-7	Glufosinate ammonium tolerant and resistance to Coleopteran	2012-2015

				insects	
Corn/ Zea mays L.	Staked 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	2012-2015
Plum Tree/Prunus Prunus Domestica	Virus resistant	Research and Development Station Bistrita	PPV	Plum-pox resistant	2012-2019
Corn/Zea Mays	Stacked genes (Herbicide Tolerance and Insect resistance)	Monsanto	NK 603 X MON 810	Glyphosate tolerant and resistant to Lepidopteran insects	2013-2017

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)