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Agricultural Biotechnology Annual

Agricultural Biotechnology Annual 2015

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Report Highlights:

This report is an update of the Biotechnology Annual Report 2014 providing information on the status of biotechnology in Romania.

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Section I: Executive Summary

Romania has been a member of the European Union (EU) since 2007 and national legislation concerning biotechnology has been harmonized with the EU legislation soon after the membership. In general, Romania has been supportive of biotechnology. The recent EU opt-out proposals on genetically-engineered (GE) crop cultivation and another on import ignited strong debates at both authority and industry levels regarding Romania's stance. On cultivation, Romania supported the EU Commission proposal to allow Member States to opt-out of cultivation of EU approved GE crops, based on the belief that Romanian farmers will have access to modern technologies, currently blocked at the EU level.

In 2014 Romanian farmers planted 771 hectares with GE corn, slightly lower than in 2013. The traceability rules and stringent conditions for commodity segregation along the whole chain led to a drastic drop in the area planted with GE corn this year. In 2015 the area estimated to be covered with GE corn is as low as 2.5 hectares.

The grains and oilseed production harvested in Romania covers the volume needed for the livestock and poultry industry, except for soybeans. Soybean production grew in 2014 to reach 200,000 metric tons (MT) and it is projected to rise further, encouraged by support proposed by the Romanian Government. The level of support is 325 EURO/hectare (HA) (about U.S. \$ 370) for soybeans, under the conditions that farmers prove they own soybean crushing capacity or sign a contract with a crusher for delivering their soybeans and have also sale contracts (for more details, please read the Oilseeds report. As a result of the higher domestic production, total soybean and soya meal imports dropped in 2014 by 3.6 percent to 560,000 MT (U.S. \$ 316 million), of which soybeans meal totaled 457,000 MT (U.S. \$ 259 million). Brazil and Argentina remain the major soybean product suppliers in 2014, followed by the most recent players, Bolivia and Paraguay. The U.S. position on the market as a soybean supplier deteriorated over the past year, but the United States plays a significant role as a soybean seeds supplier.

Field-testing of bioengineered seeds is permitted in Romania. This year field trials will continue solely on plum trees, as part of an earlier permit. Similar to last year, in 2015 no import approvals were requested/granted for seeds derived from biotechnology, as companies have submitted no notification to the Competent Authority.

Section II: Plant and Animal Biotechnology

Chapter 1: Plant Biotechnology

PART A: TRADE AND PRODUCTION

- a. **Product Development**: FAS Bucharest is unaware of any GE plants or crops under development in Romania.
- b. **Commercial Production**: The complex traceability rules governing biotechnology have discouraged over the past years farmers to plant GE corn. The area planted with GE corn (MON 810 insect resistant corn) is estimated to fall to 2.5 hectares from 770 hectares in 2014, according to the data recently published by the Ministry of Agriculture. The purpose is solely research.
- c. **Exports**: Genetically engineered corn is intended for testing purposes in 2015, thus it does not target foreign markets.
- d. Imports: Grains and oilseeds production obtained domestically, except soybeans, covers the volumes needed for the livestock and poultry industry. Soybean production grew in 2014 reaching 200,000 MT and in the context of an increased soybean planted area, production is projected to rise further, encouraged by the substantial financial support per hectare (please read Oilseeds report. Total soybean and soya meal imports dropped in 2014 by 3.6 percent to 560,000 MT (U.S. \$ 316 million), of which soybean meal solely totaled 457,000 MT (U.S. \$ 259 million). Brazil and Argentina remain the major soybean products suppliers in 2014, followed by the most recent players, Bolivia and Paraguay. The U.S. position on the market as a soybean supplier deteriorated over the past year, but the United States plays a significant role as a soybean seeds supplier. Other feed ingredients, such as Distillers' Dry Grains Soluble (DDGS) and Corn Gluten Feed (CGF), are utilized by the domestic industry in limited volumes, but see rising interest. In 2014, Romania imported 2,000 MT of DDGS valued at U.S. \$588,000 (compared to 248 MT in 2013) and 2,984 MT of CGF valued at U.S. \$2.4 million (compared to 1,381 MT in 2013). In terms of suppliers of these ingredients, we can mention Austria and Moldova for DDGS and Belgium and Hungary for CGF. Romania's major DDGS markets are mainly Turkey and Israel.

Concerning GE seeds importation, given the declining interest of agricultural biotechnology companies for research, there are no new import approvals for GE seeds, while for commercial production, GE corn seeds are in general produced locally.

e. **Food Aid recipient Countries**: As an EU member, Romania's less-favored population segment benefits of the EU Aid programs for few food items such as sun oil, wheat flour etc. There are no issues related to biotechnology.

Part B: POLICY

a. Regulatory Framework:

According to Emergency Ordinance 43/2007 (Directive 2001/18) regarding the deliberate release of

genetically modified organisms ("GMOs") in the environment and on the market, the competent authorities for implementing and enforcing all activities related to the use of GE products and all activities concerning the deliberate release of such products are the following:

- a. Ministry of Environment, Water and Forests (MEWF) the central public authority for environment protection which coordinates and ensures the application of precautionary principle to avoid potential adverse effects of biotechnology on human health and environment as a result of obtaining, using and commercializing these organisms;
- b. National Agency for Environment Protection (ANPM) the Competent Authority (CA), is the main interlocutor of the applicant companies in the notification process; the same body coordinates the activity of the Biosafety Commission;
- c. National Guard for Environment (NGE) the control authority ensuring the right enforcement of the above Directive provisions;
- d. Ministry of Agriculture and Rural Development (MADR), the Sanitary-Veterinary and Food Safety National Authority (ANSVSA), and the Ministry of Health (MH) play important roles in implementing this Directive.

The activity of the regulatory bodies is supplemented by the Biosafety Commission (BSC) which has been the scientific body with consultative role in assisting the authorities in the decision-making process regarding the issuance of authorizations since 2002. The Commission is comprised of twelve full-members and four substitute members. They pertain to research institutes from the Romanian Academy, Agricultural Science Academy, University of Medicine and University of Agricultural Science.

In the past, the activity of the Biosafety Commission was intense being triggered by the number of notifications for field trials submitted for Commission's approval. Nevertheless, over the past few years, the number of such notifications declined, only two entities conducted field demonstrations in 2013 and no company expressed an interest in field trials in 2014 and 2015.

Agricultural biotechnology legislation remained unaltered over the past year. <u>Directive 2001/18</u> regarding the deliberate release into the environment of genetically modified organisms was transposed through Emergency Ordinance 43/2007 (Law 247/2009), while <u>Directive 90/219</u> referring to contained use of genetically-modified micro-organisms was transposed 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 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 "GMOs".

The farming community supports the EU Commission proposal regarding the possibility for the Member States (MS) to restrict or prohibit the cultivation of "GMOs" in their territory (EU Directive

2015/412). Romanian farmers are, in general, eager to have access to more GE events, not only soybeans, which they experienced before the EU accession. This attitude was highlighted in the letter sent in May 2015 to the Prime-Minister and leadership of Ministry of Agriculture and Ministry of Environment Protection by the largest farmers' league (LAPAR), acknowledging the recent developments at the EU level in regard to legislation on GE crops cultivation and imports. In their view, the long-time awaited decision that allows MSs to decide for themselves if they will restrict or prohibit GE crop cultivation in their territories, has turned out into an unfavorable measure. Romania has the most significant potential regarding the production of soybean and corn and Romanian farmers are aware of the advantages brought by GE crops from the economic, technical, and environmental point of view. LAPAR encouraged the public authorities in Romania to base any decision concerning biotechnology on scientific criteria and in line with the interest of the Romanian farmers.

Currently there is no official position regarding the cultivation opt-out proposal in Romania. At the Government level, the Minister of Agriculture avoided displaying a clear position, stating that this decision is to be taken in the future. Most recently, a high-ranking official from the Ministry of Agriculture stated that as long as there are no concerns regarding food safety, no opposition will be exerted towards modern agricultural biotechnology, implying that the Ministry of Agriculture would be in favor of accepting GE events after they pass scientific evaluation at the EU level. In terms of timeline, per the current text, Romania has to transpose the provisions from the EU Directive 2015/412 within two years, through modification of the Ordinance 43/2007 which regulates the deliberate release into the environment of bio-engineered crops.

In the view of the Ministry of Environment, Water and Forests, the authority responsible for GE crop cultivation, the decision requires a comprehensive analysis of all aspects regarding the technic-economic advantages, social, but also the risks posed by GE crops on the environment, health, conventional and organic agriculture. In addition, the ethical aspects of modern biotechnology should be taken into account.

The Ministry of Health, as an institution with responsibility in regulating biotechnology, views that risk assessment should be carried out in a correct, scientific and transparent manner, based on the existing data. The risks associated with the introduction of the GE crops into the environment should be compared with the risks born by the conventional product. In addition, the positive or negative opinion expressed by the European Food Safety Authority (EFSA) should be weighted in.

The <u>EU Directive 2015/412</u> on cultivation generated interest at the level of the Romanian Parliament as well. In May 2015 members of the Agricultural Committee of Chamber of Deputies and interested stakeholders participated in a round-table about Romania's national position on the cultivation and use of GE products. One of the recommendations made during the discussion was to have both farmers and biotechnology companies conduct a large-scale campaign to convince citizens about the benefits of GE crops by highlighting the scientific arguments and by removing the circulating myths about GE products.

While the proposal on freedom of cultivation concerns mostly farmers, the most recent EU opt-out proposal concern traders, feed-compounders and livestock producers. The EU proposal published in April 2015 would allow MSs to restrict or prohibit the use, on part or all of their territory, of GE food and feed authorized at the EU level for other reasons than risk to human or animal health or to the

environment. It is expected that under the fear of discontinuation of GE feed supply, the affected players would become more active in rejecting such a proposal.

- **b. Approvals:** Romania follows EU legislation regarding GE events authorized for import and cultivation. Currently Romanian farmers plant GE corn MON 810 (insect resistant). The EU register of authorized genetically engineered products at the EU level can be viewed here.
- **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 see Appendix 2). In 2014 and 2015, biotechnology companies discontinued their field research activities as a result of the lack of perspective at the EU level for the events subject to research.
- **d. Stacked Event Approvals**: Approval of stacked events is granted at the EU level and valid throughout the EU, after passing all phases of the regulatory procedure.

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 GE crop farmers as well as measures for ensuring the co-existence of GE plants with conventional and organic. More details may be read here. However, in the context of the GE crop cultivation opt-out, national coexistence legislation may be subject to modification in order to avoid cross-contamination.
- **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 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 "GMO" labeling, per the provisions of Government of Romania (GOR) Decision 256/2006.
- h. Trade Barriers: 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 is 0.1 percent, with zero tolerance being required for other crops, such as soybeans. According to the above order all batches with a higher presence percentage than maximum allowed or containing the presence of GE seeds not authorized for cultivation in any degree or not authorized for any purpose, will not be placed on the market in Romania. Batches refused for planting on the Romanian territory will be either destroyed or their destination will be changed to load the shipment elsewhere.

This order increases the likelihood of non-compliance for both domestic and U.S. companies interested in supplying soybean seeds in Romania. The United States is the preferred source of Romanian farmers

for soybean seeds originating from foreign countries. Total soybean seeds imports doubled in 2015 reaching 4,229 MT (U.S. \$5.076 million), of which the United States counted for almost half of the imported amount (1,781 MT worth of U.S. \$2.5 million).

- **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). Since July 2011, the State Institute for Varieties Testing and Registration (ISTIS) is the body responsible for protecting the crop varieties. 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 has been a member of the International Plant Protection Convention (IPPC) and Codex Alimentarius (CODEX).
- **l. Related issues:** There is limited knowledge about new breeding techniques and these topics have not been subject to open discussion.
- m. Monitoring and Testing: Romania has a monitoring system for GE crops in place derived from the EU legislation. The authorities bearing responsibilities for inspection and control activities are listed here. In terms of testing, the National Reference Laboratory for GE food and feed is the Institute for Diagnosis and Animal Health (IDAH). Under the Ministry of Agriculture, the laboratory for seeds quality is accredited for carrying out tests for GE presence in corn and soybean seeds.
- **n. Low Level Presence Policy (LLP)**: Romania follows EU regulations regarding the thresholds for unapproved events in shipments.

Part C: MARKETING

a. Market Acceptance:

Biotechnology remains an area where various entities express a position, from government authorities to regular consumers. Inevitably all conferences organized for agricultural stakeholders tackle the idea offering farmers freedom in choosing the type of agriculture which they prefer practicing. These are always opportunities for scientists, members of the Agricultural Science Academy, farmers, industry representatives, and environmental activists to express their opinions concerning modern biotechnology.

At the level of farmers' community, there is a wide support for cultivation in case such seeds are approved for planting in the EU/Romania. No significant concerns regarding GE components of feeding are expressed at the level of feed-compounders and livestock producers as they already utilize GE soybean meal in their products or feed ratios. Most recently they became concerned about the negative

effects from the recent EU proposal extending freedom to Member states to restrict or prohibit the use of GE products. Domestic livestock producers fear their competitiveness will be affected, and they will face competition from producers located in countries where utilization of GE crops is allowed. GE soybeans and soybean meal are widely used in the feed ratios by the livestock producers.

At the retail level, key-players require non-GE certification for food products from their suppliers. Several poultry producers choose to inform consumers that birds have been fed with non-GE grains, without any mention about the protein meal component.

Romanian consumers continue to perceive agricultural biotechnology as harmful and believe that Romania has enough resources to satisfy domestic food demand through conventional agriculture. Social media and on-line media offer readers opportunities to comment regarding the content of the articles. On-line comments reveal consumers' fears related to extinction of traditional seeds, farmers' dependence on GE seed companies, risk of unknown GE presence in food, feed, or seed, or insufficient research on long-term effects to the human body.

b. Public/Private Opinions:

There are very few organizations targeting biotechnology actions in Romania. AgroBiotechRom Association, a strong pro-biotechnology organization, aims to help developing a coherent, stable and predictable regulatory framework in biotechnology area. The organization has been very active in sharing with stakeholders messages related to the availability of modern technology, worldwide acceptance approvals and latest research outcomes. The association is a member of Europa-Bio (European Association for Bio-industry) along with dozens of corporate and national biotechnology associations.

Organizations opposing GE products use any opportunity to spread their distrust in science when it comes to agricultural biotechnology. More recently, some of these organizations used the anti-TTIP movements for spreading their fears.

Content of media articles varies according to internal policy of the organization. These articles range from messages spreading fears about the effects GE crops may produce on the environment or human health, to very informative, well-written, and supportive papers.

c. Marketing Studies:

As an EU member cultivating GE crops, Romania is included in the publications of the 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. Romania has been a partner in the PRactical Implementation of Coexistence in Europe (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. According to the message of the PRICE project leader: "PRICE has found that coexistence of GM [genetically modified] and non-GM products in Europe is possible under current EU legislation. The availability of non-GM soybean in third Countries, the non-GM price premium, the segregation costs along the supply chain, and the willingness to pay by EU consumers for the non-GM attribute are crucial factors for the economic sustainability of non-GM voluntary standards in the long

run. Lower thresholds, or other stricter measures, would cause difficulties for the supply of non-GM feedstock." More details about this project, concluded in December 2014, may be read at http://price-coexistence.com/.

Part D: CAPACITY BUILDING AND OUTREACH

a. Activities:

In June 2014, AgBucharest collaborated with AgroBiotechRom Association to organize 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 GE products and the importance of a science-based and transparent approach in regulating biotechnology within the EU framework. AgBucharest invited the FEFAC Secretary General to talk about the EU Feed industry experiences and future challenges with regard to the EU agricultural biotechnology policy framework.

The rapid expansion of agricultural biotechnology adoption at global level and the asynchronous approval process at the 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 GE 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. Friendly information inserted into public on-line media outlets is likely to reach consumers who do not specifically look for such information and who might have a uninformed opinion about biotechnology.

Chapter 2: ANIMAL BIOTECHNOLOGY

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal biotechnologies such as genetic engineering and therefore included in this report. Animal genetic engineering results in the modification of an animal's DNA to introduce new traits and change one or more characteristics of the animal. 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).

PART E: PRODUCTION AND TRADE

- a. **Biotechnology Product Development**: According to information provided by the Agency for Environment Protection Agency, there are no notifications having animals as subject of biotechnology research.
- b. **Commercial Production**: There is no information available regarding livestock clones or GE

animals or products obtained for commercial production in Romania.

- c. **Biotechnology Exports:** N/A
- d. **Biotechnology imports**: Imports of frozen semen into Romania as part of the continuous efforts to improve the dairy and beef herds were worth of U.S. \$1 million in 2014, of which the United States had a market share of 13 percent. There is no specific data available on the import of products originating from cloned animals.

PART F: POLICY

- a. **Regulation**: 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:** Animal cloning is a topic frequently mentioned by local experts as being an area which requires further examination through education and research work. There is no debate regarding the animal genetic engineering in media or other circles. Occasionally media conveys opinions or decisions taken at the EU level regarding regulation of such products. At the level of the local Parliament and consumers there is a strong resistance towards such advanced technologies, mainly driven by the failure of previous cloning projects.
- c. Marketing Studies: N/A.

PART H: CAPACITY BUILDING AND OUTREACH

a. Activities:

No activities were pursued in relation to animal biotechnology.

b. Strategies and Needs:

If needed and appropriate, outreach programs should concentrate on the scientific arguments which

assess the technologies as safe, and the negative impact that a ban at the EU level would have on the EU/U.S. trade in products originating from cloned animals. As the decision process is mainly driven by the EU bodies, perhaps some outreach programs should include decision makers at national and the EU level, focused on the technology's benefits.

Section III: Appendix 1 RELEVANT REFERENCES

Ministry of Agriculture and Rural Development

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National Authority for Environment Protection

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Fax: +4021 4934010 E-mail: office@anpm.ro http://www.anpm.ro/

National Guard for Environment

General Commissary

Bd. Unirii nr. 78, Bl. J2, sector 3

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E-mail: gardamediu@gnm.ro http://www.gnm.ro/

National Sanitary-Veterinary and for Food Safety Authority

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

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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: <u>dirrp@ms.ro</u>

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

National Authority for Consumers Protection

Bd. Aviatorilor nr. 72, sector 1

Bucuresti, Romania Phone: +40 372 131951 Fax: +40 21 3143462 E-mail: office@anpc.ro Web site: www.anpc.ro

The National Customs Authority

Str. Matei Millo nr. 13, Sector 1

Bucuresti, Romania

Phone: +40 21 3155858, +40 21 3155859

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Email: relatiipublice@customs.ro

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The State Institute for Variety Trials and Registration

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Central Laboratory for Seeds Quality

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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 insects	2012-2015
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)

End of report.