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Romania

Agricultural Biotechnology Annual

Annual Biotechnology Report Romania 2016

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Report Highlights:

This report is an update of the Biotechnology Annual Report 2015 providing information on the status of biotechnology in Romania. The report should be read in conjunction with the EU-28 Agricultural Biotechnology Annual report.

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Section I: Executive Summary

Romania is a member of the European Union (EU) and observes the EU regulations regarding biotechnology. No significant change in legislation occurred over the past year. The EU “opt-out” proposals on genetically-engineered (GE) crop cultivation and on import ignited strong debates at both authority and industry levels regarding Romania’s stance.

Faced with complex rules of traceability, Romanian farmers no longer find that it is worth planting the only biotech event (MON 810) allowed for cultivation at EU level. In 2015 the area planted with GE corn was as low as 2.5 hectares, while in 2016 Romanian farmers planted no GE corn.

Romania imports part of its feed ingredients in order to cover demand from livestock producers despite budgetary outlays for protein crops cultivation. In 2015 total soybean and soya meal imports rose by 23 percent increasing from 559,000 metric tons (MT) in 2014 to 691,000 MT, of which soybean meal solely totaled 523,000 MT.

Field-testing of bioengineered seeds is permitted in Romania. In 2016 and 2017 field trials will continue solely on plum trees, as part of an earlier permit. Similar to last year, in 2016 no import approvals were requested/granted for seeds derived from biotechnology, as companies have submitted no notification to the Competent Authority. The interest of biotech seed companies for testing diminished, as authorizations are expensive and prospects for cultivation in the European Union are limited.

Section II: 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: Over the past years the complex traceability rules governing biotechnology have discouraged farmers from planting GE corn. The area planted with GE corn (MON 810 insect resistant corn) dropped to 2.5 hectares in 2015 and corn plants were solely produced for

research purpose. Farmers planted no GE corn in 2016. Regarding the EU cultivation “opt-out” legislation, although Romania supported the EU Commission proposal to allow Member States to “opt-out” of cultivation of approved GE crops, Romania did not choose to “opt-out” of any cultivation authorizations. The support was based upon the belief that Romanian farmers will have access to modern technologies, currently blocked at the EU level.

c. Exports: No GE corn exports.

d. Imports: Romania imports part of the feed ingredients in order to cover demand from livestock producers. In 2015 total soybean and soya meal imports rose by 23 percent. Soybean meal and seeds increased from 559,000 MT in 2014 to 691,000 MT in 2015, of which soybean meal solely totaled 523,000 MT. The main soybean meal suppliers were Brazil, Argentina, Paraguay and Bolivia. Hungary gradually is becoming a major supplier, due to its processing capacity and proximity to Romania. United States did not supply soybean meal to the Romanian market in 2015 and the first semester of 2016, but it was the major soybean seed supplier to Romania in 2015 with about 70,000 MT, followed by Brazil (43,000 MT) and Ukraine (37,000 MT). In general, soybean meal imports are more competitive than soybeans, but in some cases, depending on the price and origin, crushing beans domestically may be more profitable.

Romanian livestock producers are slowly becoming accustomed to new feeding ingredients. Distillers’ Dried Grains and Soluble (DDGS), a feed ingredient obtained as residual from bioethanol production, is gaining a place in the animal diet. In 2015 Romania imported approximately 4,000 MT of DDGS compared to 2,028 MT in 2014. However, the growing DDGS availability for export reflects sluggish internal demand. Export volumes reached 106,000 MT in 2015 from 43,000 MT in 2014 and continued the upper trend in the first part of 2016. The major destinations are Turkey, followed by Hungary and Bulgaria.

Romania also imports Corn Gluten Feed (CGF) for the livestock industry. In 2015 Romania imported almost 4,000 MT of CGF from 3,000 MT in 2014, mostly from other EU members states. The imported amount is small, as Romania produces and exports CGF to non-EU markets in 2015 such as Turkey (64,000 MT) and Egypt (5,000 MT).

Concerning the share of GE and non-GE feed, only a very small percentage of the soybean imports is non-GE. There are no imports of GE-seeds for planting, as the lack of interest in field testing practically eliminated this need.

e. Food Aid: As an EU member, Romania’s less-favored population segment benefits from the EU Aid programs for a few food items such as sun oil, wheat flour etc. There are no issues related to biotechnology with these products. Romania occasionally donates food aid to other countries.

f. Trade Barriers: N/A

Part B: POLICY

a. Regulatory Framework: No significant changes occurred over the past year in terms of responsibility for implementing and enforcing all activities related to the use of GE products and all

activities concerning the deliberate release of such products. Please read GAIN report Agricultural Biotechnology Annual 2015, which can be found here:

<http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx>.

The Biosafety Commission membership changed recently. The composition was approved in 2012 through a Ministry of Environment order for a four-year mandate, so new members were selected in September 2016. The Commission is comprised of twelve full-members and four substitute members. The members are from the research institutes: Romanian Academy, Agricultural Science Academy, Medical Science Academy as well as the Universities of Medicine and Agricultural Science.

Agricultural biotechnology legislation remained unaltered over the past year. Order 61/2012 issued by the Ministry of Agriculture outlines the rules for authorization and control of the farmers planting GE crops, including the co-existence rules, while the Government Decision 256/2006 (transposing Regulation (EC) No. 1829/2003) regulates the GE animal feed and food. Order 55 regarding the national registry for records on genetic modifications issued in 2007 by the Ministry of Environment and Forests (MEF) is still valid. Government Decision 497/2007 transposed the EC Regulation 1946/2003 on trans-boundary movements of “GMOs”.

Following the EU Directive 2015/412 regarding the freedom of member States (MSs) to cultivate or prohibit biotech crops cultivation on their territories, EU Member States could decide to either option. Romanian farmers are, in general, eager to have access to more GE events, not only soybeans, so Romania supported this proposal. In September 2015 the Ministry of Agriculture announced that it will not ban the cultivation of the biotech crops in Romania under the EU “opt-out” legislation. In February 2016 the new Minister of Agriculture Achim Irimescu reconfirmed the fact that Romania will not prohibit biotech crops cultivation, but the European Food Safety Authority agreement is needed in order to have a biotech crop approved for cultivation at EU level, including Romania. Furthermore, Agriculture Minister underlined the fact that when a decision for a new biotech crop cultivation is to be taken, Ministry of Agriculture and Ministry of Environment will conduct an assessment.

Until October 2016 the EU Directive 2015/412 regarding the freedom of MSs to cultivate or prohibit biotech crops has not been transposed into the national legislation, but this process is expected to take place in the upcoming months.

b. Approvals: Once a biotech event is approved at EU level for either purpose (cultivation, feed, or food use) there is no need for re-authorization at country-level. Romania follows EU legislation regarding GE events authorized for import and cultivation. Romanian farmers planted GE corn MON 810 (insect resistant) until 2016, when no farmer or research entity expressed the intention to plant. The EU register of authorized genetically engineered products at the EU level can be viewed here:

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

c. Stacked or Pyramided Event Approvals: Approval of stacked events is granted at the EU level and valid throughout the EU, including Romania, after passing all phases of the regulatory procedure.

d. Field testing: Romania allows field-testing for GE crops specified in the notifications submitted to the National Agency for Environment Protection (NAEP), which forwards these notifications for assessment and approval to the Biosafety Commission. The latter assesses the requests and

approves/disapproves them. Following these evaluations, the National Agency for Environment Protection issues the authorizations which are valid for several years (please see Appendix 2). Biotechnology companies discontinued their field research activities since 2014 as a result of the lack of perspective at the EU level for the events subject to research.

e. Innovative Biotechnologies: In absence of an official position released by the European Commission, Romania has not issued an official position on Innovative Biotechnologies. Scientific community and seeds producer groups share the view that through breeding technologies one can use agricultural resources more efficiently, improve disease resistance, increase yields and improve the traits of the product. According to their opinion, the current EU regulatory framework should be upgraded in order to seek solutions to the politic malfunctioning system that leads to delays in approval and to support science and encourage research and innovation.

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

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

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

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: *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.).*

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.

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. Monitoring and Testing: Romania has in place a system of testing and verification for imported foods or ingredients which may contain GE ingredients derived from the EU legislation. According to Order 35/2016 on the Surveillance and Control Action Plan on food safety clear provisions regarding the testing and verification frequency are approved for each type of warehouse, manufacturing plant, processing plant or food packaging facility.

In terms of testing, the National Reference Laboratory for GE food and feed is the Institute for Diagnosis and Animal Health (IDAH), while the laboratory for seeds quality under the Ministry of Agriculture is accredited for carrying out tests for GE presence in corn and soybean conventional seeds.

i. Low Level Presence (LLP) Policy: Romania, as a Member State of the EU follows EU regulations regarding the thresholds for unapproved events in shipments. The EU has a zero tolerance policy for low-level presence of GE products in feed following the measures of the EU Regulation 619/2011. This regulation lays down the methods of sampling and analysis for the official control of feed in regards to the presence of GE material for which an authorization procedure is pending or authorization of which has expired. The EU defined “zero” with a “technical solution” level of 0.1 percent. There is no “technical solution” for food.

j. Additional Regulatory Requirements: In 2014 the Ministry of Agriculture published Order 1573/2014 regarding the official control of seeds quality through tests of non-GE varieties for the inadvertent presence of GE varieties, which was enforced starting June 1, 2015. According to the order provisions, seed testing is conducted through methods approved by the Reference EU Laboratory for GE food and feed. The maximum percentage of inadvertent presence of GE seeds in batches of corn intended for cultivation in case of approved events is 0.1 percent, with zero tolerance being required for other crops, such as soybeans.

k. 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 approving and for ensuring protection for the crop varieties. The legal framework concerning the protection of the new plant varieties is Law 255/1998.

l. Cartagena Protocol Ratification: Romania ratified the Cartagena Protocol on Biosafety in 2003 through Law 59/2003. The additional Protocol Nagoya-Kuala Lumpur was signed by Romania in 2011 and ratified in 2013 through Law 110/2013. The Third National Report on the implementation of the Cartagena Protocol on Biosafety was submitted by Romania/Ministry of Environment in October 2015 and it may be accessed here: <https://bch.cbd.int/database/record.shtml?documentid=109132>

m. International Treaties/FORA: Romania is a member of various international treaties and conventions, including International Plant Protection Conventions (IPPC) and Codex Alimentarius (CODEX). Romania’s Codex point of contact is the Sanitary-Veterinary and Food Safety Authority. Romania’s IPPC point of contact is the Ministry of Agriculture – Phytosanitary National Authority.

Being an EU member, Romania does not express a direct position in the decision process at the level of the international bodies, such as CODEX, unless it is a non-EU harmonized decision where each Member State has the right to vote.

n. Related issues: N/A

Part C: MARKETING

a. Public/Private Opinions:

Few organizations target agricultural biotechnology in Romania. As a member of EuropaBio (European Association for Bio-industry) at the organization at EU level, AgroBiotechRom Association is a strong pro-biotechnology organization in Romania. Over the past year it has significantly contributed to ensuring a consistent and relevant flow of information in Romania about agricultural biotechnology in Europe and at global level. The association designed partnerships with students from the Faculty of Biotechnology Bucharest for disseminating information related to communication of benefits of biotechnology. AgroBiotechRom Association also conducts activities for disseminating technical information about innovative biotechnologies mainly targeting students from Agricultural Universities.

Farming groups support agricultural biotechnology and they are hopeful that the EU Directive 2015/412 concerning EU MS freedom to cultivate biotech crops will open up access to new biotech opportunities for them.

On the other hand, there are entities promoting “free-of biotech” products. One of them, DanubeSoya (DonauSoja), was founded in 2012 and promotes “free-biotech” soybean. According to the information posted on its website, the association has about 240 members, of which agricultural traders, primary processors, food retailers, food processors, and soya producers. Several members of the organization originate from Romania, so every year the association conducts events at farm-level meant to attract farmers in applying for the “biotech-free” certification. It is unclear though at this point how many local farmers supply soybean through this chain.

Organizations opposing GE products use any vehicle to spread their distrust in science when it comes to agricultural biotechnology, the latest are the anti-Transatlantic Trade and Investment Partnership (TTIP) movements.

b. Market Acceptance/Studies:

Farmer groups remain the largest community in favor of modern biotechnology. Farm leaders are very active at the EU level, complaining about the paradox of importing biotech products, such as biotech soybean and biotech corn, and the interdiction to plant these crops. The EU coupled-support for protein crops, such as soybeans (approximately 270 EURO/hectare [HA] or 295 U.S. \$/HA) was meant to encourage farmers to expand the soybean area. Indeed the planted area increased, but the eligibility conditions, such as minimum yield of 1.3 MT/HA, may be a barrier for farmers experiencing adverse weather in receiving the subsidies. Soybean yields below farmers’ expectations allowed for another opportunity to complain about the lack of access to advance biotech seeds, as their competition with weeds remains strong.

At the retail level, key-buyers require non-GE certification for food products from their suppliers. Several poultry producers went further and placed labels on their products, informing consumers that their birds had been fed with non-GE grains, without any mention about the protein meal component.

Romanian consumers continue to perceive agricultural biotechnology as unsafe. On-line comments to media articles on TTIP theme reflect consumers' fear that agricultural biotechnology will bring harm to European citizens.

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 D: PRODUCTION AND TRADE

a. Product Development: According to the information posted by the Agency for Environment Protection Agency, no notifications for product development having animals as subject of biotechnology research have been submitted for authorizations. There is no known development of cloned animals.

b. Commercial Production: There is no information available regarding livestock clones or GE animals or products obtained for commercial production in Romania.

c. Exports: N/A

d. Imports: Driven by the desire to improve animal genetic performances, imports of frozen semen continued growing in 2015 in terms of volume, but stagnated in terms of value to approximately USD 1 million. United States is the leading supplier of high-quality genetics with a market share of 20 percent in value (among the foreign suppliers). There is no specific data available on the import of products originating from cloned animals. There is no known import of GE animals, or other species.

e. Trade Barriers: Romania follows the EU legislation in this field.

PART E: POLICY

a. Regulatory Framework: Romania follows the EU legislation in regard to animal biotechnology. The Sanitary-Veterinary and Food Safety National Authority (ANSVSA) is the authority handling the food safety and animal welfare aspects of the GE animals/livestock clones. In case Romania must formulate a position on a topic related to Animal Biotechnology, the Sanitary-Veterinary and Food Safety National Authority (ANSVSA) has a consultative body covering various

competencies which will issue an opinion.

With regards to EU legislation, the EU Novel Foods Regulation from 1997 is currently the only EU legislation covering animal cloning. Under the Novel Foods Regulation, food “produced from nontraditional breeding techniques” (implicitly including cloning) – but not from their offspring – requires a pre-market authorization in order to be imported or sold in the EU. The European Commission has presented two new proposals - one on the cloning of animals and one on food from cloned animals.

b. Innovative Biotechnologies: N/A

c. Labelling and Traceability: N/A

d. Intellectual Property Rights (IPR): Please see the same section in the Plant Biotechnology Chapter.

e. International Treaties/FORA: Please see the same section in the Plant Biotechnology Chapter.

f. Related issues: N/A.

PART F: MARKETING

a. 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 animal biotechnology in media or other circles. Occasionally media conveys opinions or decisions taken at the EU level or US level regarding regulation of such products (as it was the case for GE salmon). At the level of the local Parliament and consumers there is a strong resistance towards such advanced technologies, mainly driven by the general attitude towards biotechnology or failure of previous cloning projects.

b. Market Acceptance/ Studies: N/A.

Section III: RELEVANT REFERENCES

Appendix 1

Ministry of Agriculture and Rural Development

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030163 Bucuresti, Romania

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

National Authority for Environment Protection

Splaiul Independentei nr. 294, sector 6

060031 Bucuresti, Romania

Phone: +021 207 1101; 021 207 1102

Fax: +4021 2071103
E-mail: office@anpm.ro
<http://www.anpm.ro/>

National Guard for Environment

General Commissary
Bd. Unirii nr. 78, Bl. J2, sector 3
Bucuresti, Romania
Phone: +40 21 3268970
Fax: +40 21 3268971
E-mail: gardamediu@gnm.ro <http://www.gnm.ro/>

National Sanitary-Veterinary and for Food Safety Authority

Piata Presei Libere nr.1, Corp D1, sector 1
013701 Bucuresti, Romania
Phone: +40 374 150200
Fax: +40 21 3124967
E-mail: office@ansvsa.ro
Website: <http://www.ansvsa.ro>

Ministry of Health

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

National Authority for Consumers Protection

Bd. Aviatorilor nr. 72, sector 1
Bucuresti, Romania
Phone: +40 21 307 6762
E-mail: cabinet@anpc.ro
Web site: www.anpc.ro

The National Customs Authority

Str. Matei Millo nr. 13, Sector 1
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Fax: +40 21 3138251
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Web site: www.customs.ro

The State Institute for Variety Trials and Registration

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Central Laboratory for Seeds Quality

10 Sandu Aldea Street

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Phone: +40 21 2228420

Fax: +40 21 2240291

E-mail: lccsms@alba.astral.ro

Website: www.incs.ro/lccsms_bucuresti.htm

Institute for Diagnosis and Animal Health (IDAH)

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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
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

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

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