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Agricultural Biotechnology Annual

Bulgaria Still Hesitant on Biotechnology Development

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Report Highlights:
There has been no change in Bulgarian consumers' attitude towards biotechnology which remains negative. Non-Governmental Organizations (NGO's), the Green Party, organic, bee-keeping, and small farms groups also share the same stance. In 2016 to date, the country has continued to follow a negative position on agricultural biotechnology production and has supported an "opt-out" in cultivation. However, Bulgaria continues to import biotech feed and related products to meet the demand of the poultry and livestock industries. Following the initial enthusiasm of growing non-genetically engineered (GE) soybeans in 2015 stimulated by the European Union (EU) subsidies, the production failure has resulted in a disappointment and shift towards other alternative crops in 2016.

Section I. Executive Summary:
Bulgarian voting positions in Brussels vary from neutral "abstain" to "against" with a few exceptions. As of today, the country does not develop any biotech products, does not grow commercially or for research purposes any biotech crops, and imposed a safeguard clause on the cultivation of MON 810 in

2011. Bulgaria decided to apply for "opt-out" in production in 2015 (see GAIN report BU1523). Bulgaria is a net importer of protein feed, mainly genetically enhanced, for the dairy, poultry and livestock sectors.

Section II. Author Defined:
Section II. Plant and Animal Biotechnology:

Chapter 1 Plant Biotechnology

Part A: Production and Trade

a. Product Development:

No public data is available about any product development.

Since the major biotechnology law was approved in 2010, biotechnology laboratories have been under an approval/registration regime by the Ministry of Environment. Currently, there are five laboratories approved for biotech research work.

All five laboratories are public: three of the laboratories are under the research institutes of the Bulgarian Academy of Sciences; one is under the Agricultural Academy/Ministry of Agriculture (MinAg) and one under the Biological Faculty of Sofia University; two of the labs (Microbiology Research Institute and Plant Physiology Research Institute) renewed their certification for biotech approvals in February 2016. One lab is involved in two biotech projects (Please see GAIN report BU1523).

According to the Association of Research-Based Pharmaceutical Manufacturers in Bulgaria (ARPharM) which unites 24 companies, a few local researchers take part in international biotech projects.

b) Commercial Production:

There is no commercial production of biotech products due to the ban on cultivation.

c) Exports:

Bulgaria does not export biotech products.

d) Imports:

The livestock sector depends on imported protein feed from third countries. Poultry and pork producers are in favor of importing biotech feed and derived products for their production value. In 2015 and 2016, imports of GE feed (mainly soybean meal) were valued over U.S. $50 million (120,000 metric tons [MT]). These products originating from Brazil or Argentina, are usually shipped through Romanian Black Sea ports.

In 2015 and 2016, local crushers began to explore the opportunity to import soybeans for crush to complement traditional sunflower and rapeseeds crushing and to achieve better capacity utilization (See GAIN BU1607). Imports of soybeans skyrocketed from 1,000 MT in 2014 to over 40,000 MT in 2015 and 2016 with major suppliers being Romania and Serbia (reportedly, non-genetically engineered soybeans).

In August 2016, a small local importer was fined for importing 22 MT soybeans from Ukraine which was found to be GE above the allowed limits and not properly labeled.

Corn-derived products are imported in small quantities to Bulgaria. Imports of corn gluten feed (CGF) or Distillers' Dried Grains and Soluble (DDGS) in 2014 and 2015 were at 6,000-7,000 MT, most of it from Romania. The amounts are small because the local feed industry is not familiar with these products. In addition, the supply of locally produced corn is in abundance.

e) Food Aid:

The country is not a recipient or a donor of food aid.

f) Trade Barriers:

Bulgaria follows EU policy regarding trade in biotech products. The biotechnology issue has not had an impact on production and trade in conventional hybrid corn seeds for planting. Seed companies secure non-biotechnology enhanced planting seeds for the market produced in other EU Member States, Turkey and/or the U.S. See GAIN BU1614.

Part B: Policy

a) Regulatory Framework:

(i) Responsible government ministries:

Biotechnology Legislation: In 2010 Bulgaria passed the Biotechnology legislation, commonly referred to as the "genetically modified organism" ("*GMO*") law that governs biotechnology and that establishes the basis for a regulatory framework which is one of the most restrictive in the European Union (EU). This "GMO Law" is recognized as pushing the legal limits under European and World Trade Organization (WTO) guidelines. See FAS GAIN report BU1523 and BU1216. Per the legislation, MinAg and the Ministry of Environment are the main government institutions implementing biotechnology regulations.

Bulgaria established a single Bulgarian Food Safety Agency (BFSA) in 2011. The BFSA had a Risk Assessment Center (RAC) to review all studies, policies, and decisions related to biotechnology. The center has researchers on-staff involved in biotech-related work. In 2015 and in 2016 to date the BFSA has been adopting EFSA positions and has been recommending either a positive or a neutral position to the MinAg on biotech-related matters.

In mid-2016 the MinAg initiated a major reform in the food safety legislation (referred to as the Food Bill) and related regulations to respond to the reform in food safety area at the EU level. The role and the functions of the RAC were changed as a result of the new legislation. The Risk Assessment Center Law was accepted on June 10, 2016 (Official Gazette #44 of June 10, 2016). The new legislation provided for more independence of research and opinion of on-staff researchers at the RAC. The RAC became a special advisory body to the Agricultural Minister and is not any longer a part of the Bulgarian Food Safety Agency.

(ii) Biosafety Board:

Legislation created a Bio-Safety Commission within the Ministry of Environment to discuss biotech-related matters and to make recommendations to the Minister of Environment. The Commission consists of scientific and non-governmental organizations.

(iii) Political factors/influences:

Bulgaria Voting Position on Biotechnology-related issues in the EU:

During 2015 and 2016 to date Bulgaria's political approach has been to "abstain" or vote "against" on issues such as biotechnology for various reasons including public pressure from "green" groups. See GAIN report BU1523.

The current Cabinet Political Program for Agriculture (since October 2014) has two major priorities, support for the horticulture sector and support for the dairy/livestock sectors. This policy makes the issue of feed availability and its price and competitiveness important. See GAIN report BU1523.

(iv) Differing regulatory treatments exist between food and feed, processing, and environment release (cultivation):

(v) Pending legislation:

In 2016 the MinAg initiated a major reform in food safety legislation aiming for full harmonization with European regulations. The Food Bill was approved by the Council of Ministers in late July and is currently submitted to the Parliament. Due to upcoming Presidential elections in early November, it is likely that the legislation will be approved by the end of 2016 or in early 2017.

The current Food Bill contains two clauses which affect biotech products. According to "green" NGOs, the texts were not discussed or agreed by all stakeholders. One of the clauses introduces a reduction of the fine for improper biotech content labeling from 35,000 leva (U.S. $20,600) to 6,000 leva (U.S. $3,400). The other clause eliminates the labeling requirement for biotech content products to cover 25 percent of the package. The two clauses were interpreted by "green" NGOs as opening the door for weakened control on imported biotech products and they announced future protests if the MinAg does not revise the Food Bill.

The Food Bill will contain a clause for requirements that foods can be labeled as "GMO Free." To date

the local legislation was silent on this issue.

(vi) Timeline for approvals

Bulgaria follows EU approval procedures.

(vii) Discussions about regulations, research, or trade policies on biotechnologies

Biotechnology is not currently in the focus of public or political attention.

b) Approvals:

Bulgaria accepts EU approved GE products for food, feed, and industrial use. However, a safeguard clause is imposed on the cultivation of MON 810.

c) Stacked or Pyramided event approvals:

Bulgaria follows EU approval procedures.

d) Field Testing:

No field testing is conducted in Bulgaria. The"GMO Law" does not explicitly prohibit field testing but introduced conditions which make this impossible in practice.

The Executive Agency for Planting Seeds and Planting Material under the Ministry of Agriculture is mandated by the legislation to carry out official control of planting seeds for GE content. The control should cover all production stages: production or imports; trade, treatment, packaging of seeds, and storage. Imports of planting seeds with the goal for variety/hybrid testing and approval in the official seed catalogue are also subject of this type of control. Inspections are carried out in the field, in seed production establishments, storage facilities, and during transportation in transport vehicles. The samples ate tested in Executive Agency for Planting Seeds and Planting Material laboratory. Inspections can be done based on a plan and advance notification or unexpectedly based on hot line complains.

e) Innovative Biotechnologies:

Bulgaria usually takes a neutral position regarding innovative biotechnologies.

f) Coexistence:

The "GMO Law" contains coexistence requirements as stated in Attachment 2 to Art. 51/4 and Art.71/3 in a list of distance from which GE crops should be kept. Distances vary from 20 meters (soybeans, flax, and peanuts) to 6,000 meters for sunflower. The distance for corn is 800 meters. In reality, coexistence policy is not applied since the biotech crop cultivation is prohibited.

g) Labeling:

Bulgaria has two regulations (amendments to the Food Bill) imposing requirements on labeling and a ban on sales of foods containing GE products in schools, kindergartens and nurseries. See GAIN BU 1523.

h) Monitoring and Testing:

Bulgaria follows EU policy and has National Annual Program for Biotech Testing. Imports of feed and feed grains are subject of a special national control plan for GE testing based on EC Regulation 882 (Articles 14 and 15). In addition, border authorities can act in case of suspicion (Art.18). Such recent case was a discrepancy between GE information in the accompanying documents and GE information on the label of the product.

National Annual Program for Biotech Testing is part of the Unified National Control Plan for control of food, feed, animal health, animal welfare and plant protection which follows EC Regulation 882 (Art. 41) for the period January 1, 2015 – December 31, 2017.

Upon imports of planting seeds, Border Control of the Bulgarian Food Safety Agency notifies the Executive Agency for Planting Seeds and Planting Material so that the respective control on import shipments and storage of seeds can be executed.

For planting seeds which are already on the market, a national monitoring plan is followed.
This plan is based on a risk analysis and includes 20 samples per year 2015-2017. For the period 2015-2017, the Executive Agency for Planting Seeds and Planting Material does not plan any audits of GE seeds and planting materials.

Upon imports of feeds and feed grains/oilseeds, a national monitoring plan for GE testing is followed. Feed which is already on the market is also subject of GE control, along with control of a number of other substances such as heavy metals, dioxins etc. The plan for 2015-2017 includes 40 samples a year for such feed testing for GE content.

Regarding foods, there is a National Program for Control of GE foods, sampling and testing of foods in order to verify the official control of GE foods. The program is based on a risk analysis.

In the spring of 2015, the BFSA reported that from over 100 food/feed samples tested during the past year for GE content, all were negative. No such data is available for 2016.

In July 2016, the BFSA approved three labs to carry out official monitoring and control of biotech content in foods upon imports and/or the market. One of the labs is a private lab of the Swiss surveyor SGS in Varna. The list of the labs can be seen here.

The Ministry of Environment in cooperation with the Executive Agency for Planting Seeds and Planting Material conducts GE field monitoring and sampling aiming identification of illegal planting of GM crops. The field sampling is based on an annual plan for control of legal or illegal GM release into environment.

i) Low level presence (LLP) policy:

Bulgaria does not have a policy on LLP. It does follow the "technical solution" guidance of an allowance of 0.1 percent outlined in EU Regulation 619/2011. This regulation lays down the methods of sampling and analysis of official control of feed regarding the presence of genetically modified for which an authorization procedure is pending or the authorization of which has expired.

j) Additional Regulatory Requirements:

There are additional restrictions on sales of foods with GE ingredients (see g/Labeling)

k) Intellectual Property Rights (IPR):

Bulgaria follows international norms on IPR although violations occur.

Bulgarian patent law has been harmonized with EU law for patents and utility patent protection. Bulgaria joined the Convention on Granting of European Patents (European Patent Convention) in 2002. Bulgaria is a contracting state of the European Patent Office (EPO), whereby a patent recognized by the European Patent Convention must immediately take effect in Bulgaria after validation. Bulgaria has also signed the London agreement for facilitating the validation process, which allows rights holders to submit only a translation of the patent claim and not of the whole patent. But, Bulgarian law has still not been amended to correspond to this agreement. Bulgaria is also part of the Patent Cooperation Treaty (PCT). Bulgaria grants the right to exclusive use of inventions for 20 years from the date of patent application, subject to payment of annual fees, depending on the time remaining before the patent expires. Innovations can also be protected as utility models (small inventions). They are registered without novelty examination. The term of validity of a utility model registration is four years from the date of filing with the Patent Office. Inventions eligible for patent protection must be new, involve an inventive step, and be capable of industrial application. With regard to utility models, no registration is granted for methods, chemical formulations and their use and objects in the field of biotechnology. There is no accessible database for the registered and valid patents and utility models in Bulgaria.

Pursuant to the 1996 Protection of New Plant Varieties and Animal Breeds Act, the Patent Office can issue a certificate which protects new plant varieties and animal breeds for between 25 and 30 years. In 1998, Parliament ratified the 1991 International Convention for the Protection of New Varieties of Plants. In addition, all new types of plants registered by the EU's Community Plant Variety Office are considered effective in Bulgaria. In 1999, Parliament passed a series of laws on trademarks and geographical indications, industrial designs, and integrated circuits in accordance with TRIPs (WTO's Trade Related Aspects of Intellectual Property) requirements and the EU Association Agreement. The Trademarks and Geographical Indications Act (TGIA), as amended in 2005 and 2006 to comply with EU standards, regulates the establishment, use, suspension, renewal, and protection of trademarks, collective and certificate marks, and geographic indications. Bulgaria is a member of the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration. Right of priority with respect to trademarks that do not differ substantially is given to the application that was filed in compliance with Article 32 of the TGIA. Right of priority is also established on the basis of a request made in one of the member countries of the Paris Convention for the Protection of Industrial

Property or of the WTO. Bulgaria is a contracting state of The Hague Agreement Concerning the International Deposit of Industrial Designs. With respect to third parties, an international registration shall have effect in Bulgaria as of the date of expiration of the six-month period under Article 8 (1) of the Hague Agreement.

i) Cartagena Protocol Ratification:

Bulgaria is a signatory to Cartagena protocol and the Parliament ratified the protocol on July 19, 2000.

m) International Treaties/Fora:

Bulgaria is a member of OECD, Plant Protection Convention and Codex Alimentarius. The country makes efforts to participate more actively in these organizations' work but has not been taking a significant role to date.

Bulgaria is a member of Danube Soya initiative since November 2013 (see GAIN BU1356). Several outreach and training events occurred during the past year with the emphasis on growing non-GE soybeans and prospects for trade in the EU. After the initial enthusiasm, disappointing production and economic results in 2015 led to much weaker interest in growing conventional soybeans in 2016 (see GAIN BU1621). Areas planted under soybeans in 2016 were only 39 percent of that in 2016 (14,000 hectare [HA] compared to 36,000 HA in 2015) and production decreased from 40,000 MT in 2015 to 15,000 MT in 2016 (as of mid-October 2016).

n) Related Issues:
n/a

Part C: Marketing:

a) Public/Private Opinions:

Public opinion is negative towards agricultural biotechnology, and is unduly influenced by "green," organic, health and consumer organizations. Surveys show consumers against any food products containing biotech components. See GAIN BU1523.

The new administration undertook major reform in agricultural research and development in 2016. The Agricultural Academy which united about 25 research institutes will be reformed and draft legislation is being prepared to provide more independence to the research teams. Another goal is to encourage more project-based financing and research. It is believed that expected financial autonomy will encourage stronger cooperation with the EU and other foreign research institutions, including cooperation in biotech research. The legislation is currently for discussions and consultations at the Parliament and is expected to be voted in December 2016.

a) Market Acceptance/Studies:

Ultimately, market acceptance at the consumer level is negative. The majority of consumers have

strong anti-biotech attitude without having proper knowledge or information, often accompanied by a number of myths. At a farmer level, feed and livestock producers are well aware about the availability and prices of non-GE and GE protein feed and the world market situation. Due to high price sensitivity of local consumers, most if not all imported protein feed is GE. There are no market studies about GE products.

Chapter 2: Animal Biotechnology:

Part D: Production and Trade

a) Product Development:

Bulgaria has not pursued genetic engineering or cloning involving farm livestock, insects, birds, or fish.

b) Commercial Production:

Not applicable.

c) Exports:

Not applicable.

d) Imports:

Bulgaria does not have a system to monitor the imports of GE animals, cloned offspring, or genetics from clones. Not applicable.

e) Trade Barriers:

There are no known trade barriers.

Part E: Policy

a) Regulatory Framework:

The Ministries of Agriculture and Health are the governing entities charged with regulating such technology.

b) Innovative Biotechnologies:

Bulgaria does not have a formulated position on innovative biotechnologies.

c) Labeling and Traceability

Currently there are no labeling and traceability requirements for GE animals or cloned products.

d) Intellectual Property Rights (IPR):

There is no public information on IPR on these technologies.

e) International Treaties/Fora:

Bulgaria is a member of the Organization for Economic Cooperation and Development, World Organization for Animal Health, and Codex Alimentarius Commission. However, the country usually takes a neutral position regarding GE animals and cloning.

f) Related Issues:

Not applicable

Part F: Marketing

a) Public/Private Opinions:

Not applicable

b) Market Acceptance/ Studies:

Not applicable