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Report Highlights:

The Government of Bulgaria (GOB) views agricultural biotechnology skeptically and Bulgarian non-governmental organizations (NGO), green activists, the organic industry, bee keepers, and small-farm advocacy organizations actively push an anti-biotech agenda. To date in 2017, Bulgaria has generally positioned itself as anti-biotech vis-à-vis European Commission (EC) policy development. It has also decided to “opt-out” in terms of cultivation. Bulgarian poultry and livestock stakeholders continue to import biotech soybeans and derived feed ingredients.

Section I. Executive Summary:

Bulgarian voting patterns on biotech-related issues at the EC in Brussels tend to vary between neutral (abstention) and against, with a few exceptions. To date in 2017, Bulgaria has voted against any new agricultural biotech-related legislation in Brussels.

Bulgaria does not currently develop or cultivate any ag biotech products, or conduct research and/or

field trials. Moreover, Bulgaria decided to “opt-out” in production in 2015 ([Attaché Report](#)). It also imposed a safeguard clause on the cultivation of MON 810 in 2011. Bulgaria is a net importer of oilseeds and plant proteins feed for the dairy, poultry and livestock sectors.

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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 2010 biotechnology law was approved, laboratories are required to seek Ministry of Environment approval/registration regime. Currently, there are five laboratories approved for biotech research work although none of them work on research projects with biotech projects ([Attaché Report](#)).

According to the 23-member Association of Research-Based Pharmaceutical Manufacturers in Bulgaria, a few local researchers are contributing to international pharma-related biotech projects.

b) Commercial Production: There is no biotech commercial production or cultivation.

c) Exports: Bulgaria does not export biotech products.

d) Imports: The livestock sector imports protein meals and feed ingredients, mostly from South America. Dairy, poultry, and pork producers support using biotech feed and derived products. In 2016 and to date in 2017, Bulgarian stakeholders imported 116,000 metric tons (MT) of genetically engineered (GE) soy products (mainly soybean meal) from Brazil or Argentina. In 2016 and 2017, Bulgaria also imported soybean meal that was crushed in Romania from imported U.S. soybeans.

Imports of soybeans have fluctuated over recent years. 2015 soybean imports, mostly from Romania and Serbia, reached over 40,000 MT (reportedly, non-GE soybeans). In 2016 imports declined to 14,000 MT, and trade data for the first half of 2017 reflect only 4,000 MT (mainly from Romania).

Some local crushers are considering imports of whole soybeans for crushing to complement traditional sunflower and rapeseeds crushing and to achieve better capacity utilization

Bulgaria imports small varieties of corn-derived products. Imports of corn gluten feed (CGF) or distillers dried grains and soluble (DDGS) in 2016 declined from 6,000 MT in 2015 to about 4,000 MT, mostly from Romania. During the first half of 2017, imports declined further to under 2,000 MT (source: World Trade Atlas, HS#230210). Volumes are small because the local feed industry is not familiar with these products and locally-produced corn is abundant.

e) Food Aid: Bulgaria is not a food aid recipient or donor.

f) Trade Barriers: Bulgaria follows EU policies regarding trade in biotech products. Biotechnology has not affected the 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 United States .

Part B: Policy

a) Regulatory Framework:

(i) Responsible GOB ministries: In 2010 Bulgaria passed legislation, commonly referred to as the “GMO Law”, which establishes the basis for Bulgaria’s regulatory framework and is one of the most restrictive in the EU ([Attache Report](#)). Per legislation, Ministry of Agriculture, Food, and Forests (MinAg) and the Ministry of Environment and Waters are the main regulatory authorities on biotechnology regulations.

Bulgaria established a single Bulgarian Food Safety Agency (BFSA) in 2011, which included a Risk Assessment Center (RAC) to review all studies, policies, and decisions related to biotechnology. To date the BFSA has adopted EFSA positions and has recommended either a positive or a neutral position to MinAg on biotech-related matters. In 2016 the MinAg initiated a major reform in its food safety legislation in response to changes in EU-level regulations. The role and the functions of the RAC were changed as a result of the new legislation. A new RAC Law was enacted on June 10, 2016, which provided new legislation provided for more autonomy for staff researchers at the RAC. The RAC became a special advisory body to the Agricultural Minister and is no any longer associated with the BFSA.

(ii) Biosafety Board: Legislation created a Biosafety Commission within the Ministry of Environment to discuss biotech-related matters and to make recommendations to the Minister of Environment. The Commission consists of fifteen representatives of scientific and governmental organizations.

(iii) Political factors/influences: Bulgaria’s voting patterns vis-à-vis biotechnology-related issues in the EU in 2016 and to date in 2017 has been to abstain or oppose new legislation. This positioning is largely driven by public pressure from environmental activists and organizations.

(iv) Differing regulatory treatments exist between food and feed, processing, and environment release (cultivation): Bulgaria continues to allow biotech feed grains, oilseeds, and derived products for livestock feed.

(v) Pending legislation: In 2016, MinAg initiated a major reform in food safety legislation aiming for full harmonization with European regulations and began to develop a new Food Act. Due to the Presidential elections in November 2016 and Parliamentary elections in April 2017, the work on the legislation was renewed in mid-2017. As of mid-October, the Food Act legislation remains in Parliament, although its initial draft has been approved by the relevant Parliamentary Commissions. MinAg's stated goal is to have the legislation approved and enforced from January 1, 2018.

The Food Act will likely contain clauses regarding GE labeling. To date the local legislation was silent on this issue. The bill contains an article which says that "Without GMO" label can be applied on a voluntary basis for foods of plant and animal origin. The terms and requirements for such labeling are to be developed by industry groups and approved by the Minister of Agriculture, per the current bill. MinAg rejected a proposal submitted by some green NGOs to establish a national, non-GE label and a national governmental body to guarantee the integrity of such labeling.

(vi) Timeline for approvals: Bulgaria follows EU approval procedures.

(vii) Discussions about regulations, research, or trade policies on biotechnologies: There is little current general public or political focus on biotechnology.

b) Approvals: Bulgaria accepts EU approved GE products for food, feed, and industrial use. However, it maintains a safeguard clause 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. Controls should cover all production stages: production or imports; trade, treatment, packaging of seeds, and storage. Seed imports 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. Samples are tested in the Executive Agency for Planting Seeds and Planting Material laboratory. Inspections are usually routine, but can be unannounced if noncompliance is reported/expected.

e) Innovative Biotechnologies: Bulgaria usually takes a neutral position regarding innovative biotechnologies.

f) Coexistence: The 2010 "GMO Law" includes coexistence requirements under Attachment 2 to Articles 51/4 and Art.71/3, regarding distances GE crops should be kept from non-GE. Distances vary

from 20 meters (soybeans, flax, and peanuts), 6,000 meters for sunflowers, and 800 meters for corn.

g) Labeling: Bulgaria has two regulations (amendments to the Food Act) imposing requirements on labeling and a ban on sales of foods containing GE products in schools, kindergartens and nurseries ([Attaché Report](#)). The new Food Act which is under consideration is not likely to change these labeling requirements.

h) Monitoring and Testing: Bulgaria follows EU policies 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 are authorized to intervene as necessary (Art.18).

The National Annual Program for Biotech Testing is part of the Multiyear National Food and Feed 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.

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.

For feeds and feed grains/oilseeds imports, 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 yearly for such feed testing for GE content.

The National Program for Control of GE Foods samples and tests food products to verify the presence of GE foods. The program set up to provide risk-based analysis.

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 for biotech content of products imported from China per EC Decision 2011/884. BFSA also designated Eurofins, GeneScan, Gmbh Germany, and SGS Bulgaria as labs for official control for biotech content of feed.

The Ministry of Environment, in conjunction with the Executive Agency for Planting Seeds and Planting Material, conducts GE field monitoring and sampling to identify any illegal GE planting. This is authorized under the annual plan for control of legal or illegal environmental GE release.

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.

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 EU and international standards on IPR.

Bulgaria's 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.

l) Cartagena Protocol Ratification: Bulgaria is a signatory to Cartagena protocol and the Parliament ratified the protocol on July 19, 2000.

m) International Treaties/Forums: Bulgaria is a member of OECD, International Plant Protection Convention, and Codex Alimentarius. Although the country observes strictly these international conventions, it does not regularly and actively take part in promoting its position on agricultural biotechnology or in various debates on this issue at the international level.

Bulgaria is a member of the Danube Soya initiative since November 2013. 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 and in 2017. Areas planted under soybeans in 2016 were only 39 percent of that in 2015 (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. In 2017 areas under soybeans declined further to 11,500 HA and production to 14,000 MT (as of October 12, source: Ministry of Agriculture Weekly Bulletin #42)

n) Related Issues: Not applicable.

Part C: Marketing:

a) Public/Private Opinions: Public opinion tends to be negative towards agricultural biotechnology and is influenced by green organizations, the organic industry, and consumer organizations. Surveys reflect that consumers are opposed to food products derived from biotech.

Since 2016, the GOB has taken steps to reform agricultural research and development. The Agricultural Academy, which unites about 25 research institutes, is currently preparing new draft legislation designed to provide more independence to the research teams. Post sources note that increased financial autonomy will encourage stronger cooperation with the EU and other foreign research institutions,

including cooperation in biotech research.

b) Market Acceptance/Studies: Market acceptance at the consumer level low. Most urban consumers do support anti-biotech and are unaware of the supporting body of scientific research. Farmers, feed and livestock producers, and ag stakeholders have a better understanding of the issue and availability and prices of non-GE and GE protein feed and the world market situation. Most imported plant-protein feed and feed ingredients are derived from GE crops.

Chapter 2: Animal Biotechnology:

Part D: Production and Trade

- a) Product Development: Bulgaria has not pursued genetic engineering or cloning of 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 other than those imposed by the EU rules. Bulgaria follows EU policies regarding trade in biotech products and cloning.

Part E: Policy

- a) Regulatory Framework: The Ministry of Agriculture, Foods and Forests and the Ministry of 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 IPT information specific to these technologies.
- e) International Treaties/Forums: Bulgaria is a member of the Organization for Economic Cooperation and Development, World Organization for Animal Health, and Codex Alimentarius Commission. Bulgaria 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