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Report Highlights:

The Government of Bulgaria (GOB) continues to oppose agricultural biotechnology and supports anti-biotech policy initiatives within the European Commission (EC). Non-governmental anti-biotech organizations, local activists, and Bulgaria's organics industry actively spread nonscientific disinformation about biotechnology. Bulgaria's poultry, dairy, and livestock stakeholders continue to import biotech-derived feed ingredients.

Executive Summary:

Bulgarian voting patterns on biotech-related issues at the EC tend to vary between neutral (abstention) and against. Throughout 2019, Bulgaria consistently voted against new agricultural biotech-related legislation in Brussels.

Currently, Bulgaria does not conduct agricultural biotech research or field trials or cultivate any genetically engineered (GE) products. In 2015, Bulgaria decided to adopt the EU Directive allowing Member States to “opt-out” of biotech plant cultivation. Additionally, Bulgaria maintains the safeguard clause regarding the cultivation of MON810, seven varieties of corn, soybeans 40-3-2, and carnation Moonshadow 1. Bulgaria has also banned field research for GE crops.

Bulgaria is a net importer of oilseeds and plant-protein feeds used for dairy, poultry, and other livestock sectors. The local crushing industry imports soybeans, including from the United States, to meet the meat and poultry sectors’ growing demand for plant protein feeds.

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Chapter 1: Plant Biotechnology

Part A: Production and Trade

a. Product Development: No public data is available about any product development.

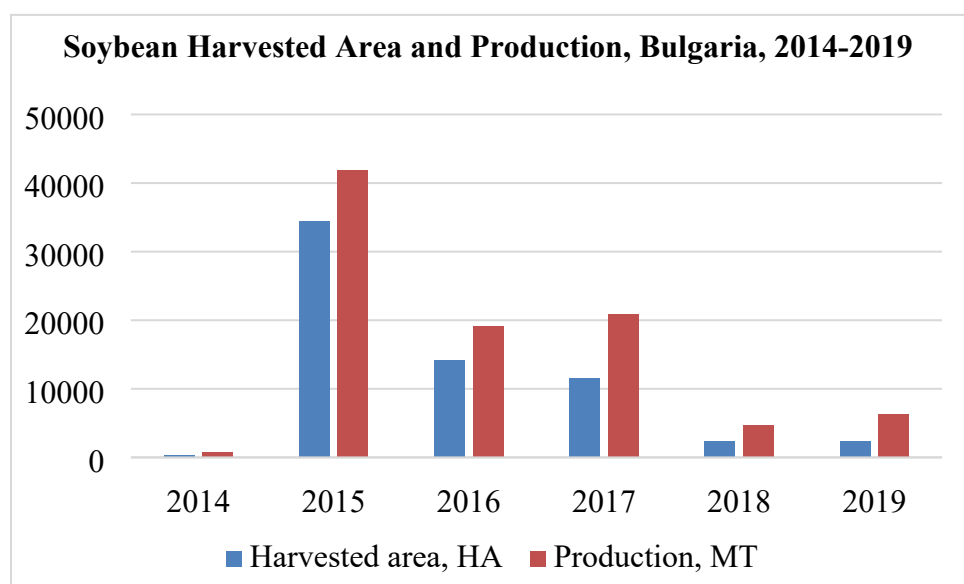
Since the 2010 biotechnology law was approved, laboratories are required to seek Ministry of Environment approval through its registration regime. Currently, there are [five laboratories](#) (in Bulgarian) approved for biotech research work although none of them currently work on research projects with GE products.

Bulgaria has a well-developed pharmaceutical industry, which has enjoyed stable growth, and consistent local and foreign investment (see: [Agricultural Biotechnology Annual | Bulgaria | November 2018](#)). Most pharmaceutical manufacturers in Bulgaria produce generic drugs. Although the pharmaceutical sector regularly develops new GE products in Bulgaria, little product-specific

information is publicly available. The [Association of Research-Based Pharmaceutical Manufacturers](#) (In Bulgarian) supports local researchers contributing to international pharma-related biotech projects. Since 2018 to date, the pharma industry been proactive in its public communications about the advantages of pharmaceutical biotechnologies.

b) Commercial Production: There is no biotech commercial agricultural production or cultivation in Bulgaria. In 2015, Bulgaria chose to “opt-out” of GE crops cultivation for all or part of their territories under [Directive \(EU\) 2015/412](#). This regulation, also called the “opt-out” Directive, allows any member State (MS) to “opt out” of cultivating an approved GE crop for socio-economic as opposed to scientific reasons. The country also maintains a safeguard clause on the cultivation of MON810, seven varieties of corn, soybeans 40-3-2, and carnation Moonshadow 1. The ban also extended to field research.

Bulgaria has been a member of the Danube Soya initiative since November 2013 (see Policy paragraph for more information). In 2018 areas under soybeans declined sharply from 2017 to only 2,320 HA and production dropped from 21,000 MT in 2017 to 4,730 MT in 2018. In 2019, area stagnated at 2,400 HA and production was slightly higher at 6,280 MT due to better weather (Eurostat).



c) Exports: Bulgaria does not export biotech agricultural products.

d) Imports: The livestock sector imports protein meals and feed ingredients, mostly from South America and the United States. Dairy, poultry, and pork producers support using biotech feed and derived products. Currently Bulgaria does not have own soybeans crushing facilities and is a net importer of soybean meal and other soy products, about 140,000 MT to 150,000 MT annually. Since 2016, Bulgarian importers imported soybean meal from Romania, which was derived from U.S.-origin soybeans (see: [Agricultural Biotechnology Annual | Bulgaria | November 2018](#)). Industry sources

report that the volume of this trade will likely grow in 2020, following a temporary drop in 2019 due to the African Swine Fever outbreak in the middle of the year.

Bulgaria imports small amounts of corn-derived products, including corn gluten feed (CGF) or distiller's dried grains with soluble (DDGS), mainly from Hungary. Volumes are small because local feed millers are not familiar with these products. Local corn is abundant, with excellent corn crops in 2018 and in 2019. Bulgaria is an exporter of non-GE DDGS. Turkey is Bulgaria's largest DDGS export market.

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 of conventional corn hybrid seeds for planting. Seed companies offer non-biotech planting seeds for cultivation in Bulgaria other EU Member States, Turkey, and 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 established the basis for Bulgaria's regulatory framework as one of the most restrictive in the EU. Per legislation, the Ministry of Agriculture, Food, and Forests (MinAg) and the Ministry of Environment and Waters are the main regulatory authorities on biotechnology regulations.

As a result of a reform in 2016, the [Risk Assessment Center](#) (RAC) in charge of independent scientific analysis and recommendations including biotechnology, became an independent advisory body to the Agricultural Minister. Since then, the RAC has adopted the European Food Safety Authority positions and has recommended either a positive or a neutral position on biotech-related matters. In 2019 to date, the RAC website has issued six publications on agricultural biotechnology.

(ii) Biosafety Board: Legislation created a [Biosafety Commission](#) (in Bulgarian) within the Ministry of Environment and Waters to discuss biotech-related matters and to advise the Minister of Environment. The Commission consists of fifteen scientific and governmental representatives.

(iii) Political factors/influences: Bulgaria's voting patterns vis-à-vis biotechnology-related issues in the EU in 2018 and to date in 2019 has been to abstain or oppose new legislation. This positioning is largely driven by public pressure from environmental 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 reform in food safety legislation aiming for full harmonization with European regulations and began to develop a new Food Act. Due to various

political and other circumstances, the work on the legislation was temporarily put on hold, although public and industry consultations were carried out in 2017, 2018 and in the first half of 2019. The first version of the bill was notified to the EC in 2017 and as a result, the local authorities needed to address some of the deficiencies identified by the EC. As of mid-October 2019, the Food Act legislation remains in the Parliament. MinAg's stated goal is to have the legislation approved and enforced as of January 1, 2020.

The Food Act is likely to 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 anti-biotech non-governmental organizations (NGOs) to establish a national, non-GE label and a national governmental body to guarantee the integrity of such labeling.

Currently, many food traders place non-GE labels on their products. However, this labeling is not based on any legislation and/or adopted standards and/or independent oversight.

(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 agricultural biotechnology.

b) Approvals: Bulgaria accepts EU approved GE products for food, feed, and industrial use. However, no EU approved GE seed is allowed for cultivation due to the safeguard clause and that Bulgaria "opted out" of cultivation (see commercialization production section above).

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 it practically impossible.

The [Executive Agency for Planting Seeds and Planting Material](#) (in Bulgarian) under the Ministry of Agriculture is mandated by the legislation to carry out official control of planting seeds for GE content under National Monitoring Plan. Controls should cover all production stages: production or imports; trade, treatment, packaging and labeling of seeds, and storage. Inspections are carried out in the field, in seed production establishments, storage facilities, and during transportation in transport vehicles. See more information below under '(h) monitoring and testing'.

The [Executive Environment Agency](#) under the Ministry of Agriculture and Waters performs monitoring and control in open fields for identifying a release of non-authorized GE crops. The agency carries out analytical tests through sample analysis of plants in its accredited lab. Results from the implementation of 2016 annual plan were published in the middle of 2018 and are shown below under

(h) monitoring and testing. No publication has been made yet about the implementation of the annual 2017 plan.

e) Innovative Biotechnologies: Bulgaria has taken a neutral position regarding innovative biotechnologies (i.e. genome edited plants and animals). There is little awareness in the industry and public about the 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 labeling requirements and banning sales of foods containing GE products in schools, kindergartens, and nurseries. The new Food Act, which is under consideration, is unlikely to change these requirements.

h) Monitoring and Testing: Bulgaria follows EU policies and has a National Annual Program for Biotech Testing. It is a [part of the Multiyear National Food and Feed Control Plan](#) (in Bulgarian) for control of food, feed, animal health, animal welfare and plant protection which follows EC Regulation 882 (Art. 41) for the period January 01, 2018-December 31, 2020. The program includes GE testing in the food chain from the field to the table (seeds, crops, feed and food) with the goal to identify illegal use of non-authorized GE organisms/ingredients. For planting seeds already on the market, a National Monitoring Plan is carried out the Executive Agency for Planting Seeds and Planting Material. This plan is based on risk analysis. For the period 2018-2020 the plan is to make 14 samples for testing for food or feed for GE content, including 10 for corn and four for rapeseeds.

In June 2018, the Ministry of Agriculture published a [report](#) (in Bulgarian) about the implementation of the 2016 national program. To date, no further information about the implementation of the annual 2017 national program has been published.

In November 2018, the Bulgarian Food Safety Agency acted upon EU Rapid Alert System for Food and Feed (RASFF) notification and recalled feed delivered from Germany and containing vitamin B2 produced by fermentation with banned genetically engineered *Bacillus subtilis* KCCM 10445. The authorities recalled 875 kilograms out of total imported 3,000 kilograms of feed. Lots of the feed were delivered to five final users, swine farms which used it as a supplement for starter pigs.

i) Low level presence (LLP) policy: Bulgaria does not have a policy on LLP. It follows the “technical solution” guidance of an allowance of 0.1 percent outlined in EU Regulation 619/2011. The 0.1% is only applied to feed (not food or seed) and is for unapproved GE events that have a valid application submitted to EFSA.

j) Additional Regulatory Requirements: There are additional restrictions on sales and marketing of foods with GE ingredients (see g/Labeling)

k) Intellectual Property Rights (IPR): Bulgaria follows EU and international standards on IPR. See: [Agricultural Biotechnology Annual | Bulgaria | November 2018](#)

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 strictly observes these international conventions, it does not regularly or actively take part in promoting its position on agricultural biotechnology nor participate in various debates on this issue at the international level.

Bulgaria is a member of the [Danube Soya](#) initiative promoting GE-free soybeans since November 2013. This initiative supports small- and medium-sized farms which produce biotech-free soy. By participating in the partnership program, farmers receive training and advice and are certified free of charge. Despite the initial enthusiasm, disappointing production and economic results since 2015 have weakened interest in growing conventional soybeans. No Danube Soya events took place in 2019.

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 propaganda from anti-biotech organizations, the organic industry, and consumer organizations. Surveys reflect that consumers are opposed to food products derived from biotech.

The public opinion about agricultural biotechnology is part of a more general attitude of lacking interest, understanding or curiosity towards science. At the end of 2018, a representative poll of Alfa Research Agency showed that only 35 percent of Bulgarians are interested in science compared to 53 percent on average for the EU, mainly because the local educational system does not motivate students to address science. At the same time, 67 percent of respondents think that development of R&D should be a national priority for Bulgaria. The Bulgarian Academy of Sciences is the most recognizable scientific body, followed by the universities.

In the fall of 2018, the Biological Faculty of Sofia University launched a [Center for Applied Studies and Innovations](#) (CASI). CASI is a public-private partnership, established in cooperation with Harvard University. It promotes commercial applications of advanced biotechnology in food, pharma, agriculture and other industries. CASI has enjoyed a great interest by young people such as students, start-ups and other. It acts as an incubator for biotech-related businesses and promotes biotech innovations. CASI's main target is to teach life science graduates how to become entrepreneurs and demonstrate the benefits of the advanced biotechnology for everyday life.

In 2017, Bulgaria established the Research Center of Plant System Biology and Plant Biotechnology ([PlantaSyst](#)) ([Agricultural Biotechnology Annual | Bulgaria | November 2018](#)). The center makes

efforts to integrated molecular biology, functional genomics, metabolomics, bioinformatics, and bioprocessing in practical plant genetics and breeding, to unravel the plant biology and translating the scientific knowledge into new horticultural and industrial applications.

b) Market Acceptance/Studies: Market acceptance at the consumer level is low. Most urban consumers support anti-biotech efforts and are unaware of the supporting body of scientific research.

In 2019, the anti-biotech NGO [Za Zemiata](#) (Friends of the Earth) launched an active communication campaign against genome editing and advanced plant breeding. In June/July 2019, the NGO published its report against genome editing and provided many news publications against foods developed based on the technology.

Farmers, feed and livestock producers, and ag stakeholders have a better understanding of the trade issues, global availability situation, and costs of non-GE versus GE protein feed. 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. There is no known import of GE animals, or other species.

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. The EU regulations apply.

b) Approvals: Not available.

c) Innovative Biotechnologies: Bulgaria does not have a formulated position on innovative biotechnologies (i.e. genome edited plants and animals).

d) Labeling and Traceability: Currently there are no labeling and traceability requirements for GE animals or cloned products.

e) IPR: There is no public IPR information specific to these technologies.

f) 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.

g) Related Issues: Not applicable

Part F: Marketing

a) Public/Private Opinions: Not applicable

b) Market Acceptance/ Studies: Not applicable

Attachments:

No Attachments