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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. To date in 2021, Bulgaria has 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, 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 GAIN report). 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 and in 2021, to date, the pharma industry has been more proactive in public communication on advantages of pharmaceutical biotechnologies.

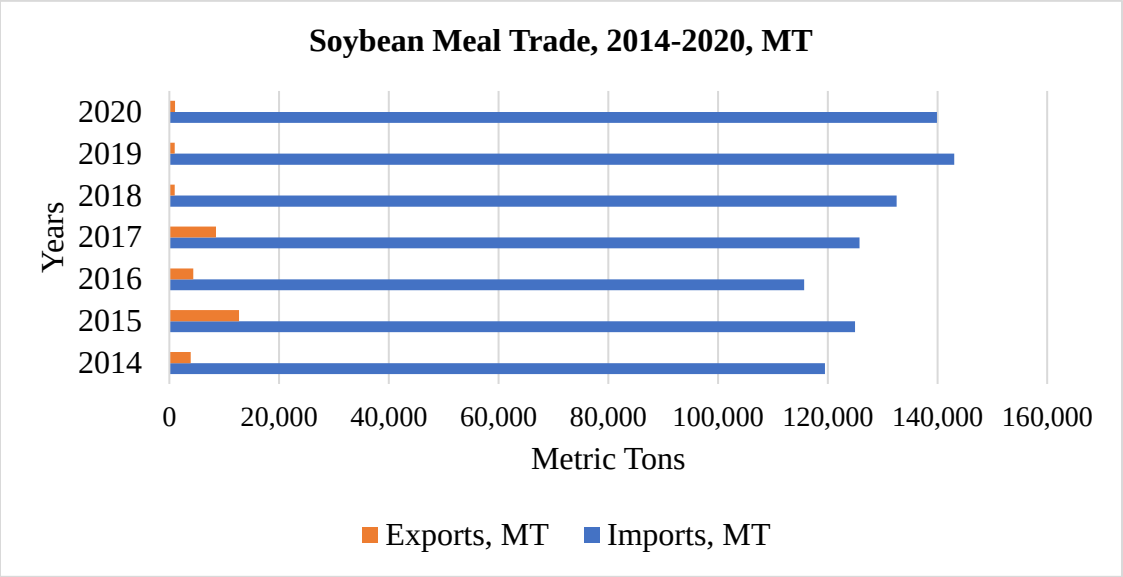
b) Commercial Production: There is no biotech commercial agricultural production or cultivation in Bulgaria. In 2015, Bulgaria chose to "opt out" of GE crops cultivation for all or part of their territories under Directive (EU) 2015/412. This regulation, also called the "opt-out" Directive, allows any 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). Since 2018 local soybean production has been small and stagnant at/or below 8,000 MT.

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

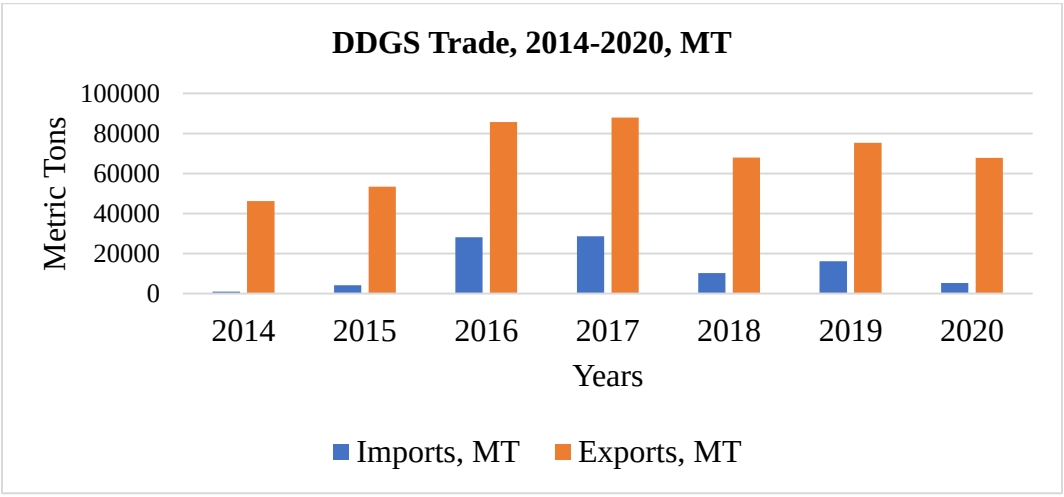
d) Imports: The livestock sector imports protein meals and feed ingredients, mostly from South America and the United States. Dairy, poultry, and pork producers support using biotech feed and derived products. Currently Bulgaria does not have any established soybeans crushing facilities and is a net importer of soybean meal and other soy products, about 130,000 MT to 140,000 MT annually. Since 2016, Bulgarian importers imported soybean meal from Romania, which was derived from U.S.- origin soybeans (see GAIN report). Despite African swine fever outbreaks in 2019-2021 and the subsequent reduction of the national swine herd by 25 percent, as of the middle of 2021, the domestic pork industry and the national swine herd has successfully recovered.

Imports of soybean meal in calendar year (CY) 2020 were at 140,000 MT, due to stable performance of the poultry and pork industries. During the first half of 2021, imports declined by 2.6 percent compared to the corresponding period in 2020, mainly due to COVID-19's negative impact on animal production and 35 percent higher prices compared to 2020.



Source: Eurostat/Trade Data Monitor

Bulgaria imports a small amount of corn-derived products, including corn gluten feed (CGF) or distiller's dried grains with soluble (DDGS). The main suppliers are Austria, Serbia, and Romania. Bulgaria does not import GE corn or feed products derived from GE corn. The country is a net exporter of DDGS.



Source: Eurostat/Trade Data Monitor

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" (the last amendment in 2016), 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) (RAC law) (in Bulgarian) 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, the RAC issued six publications on agricultural biotechnology. In 2020, there were 11 publications and none in 2021 to date.

In June 2020, the Parliament approved two major pieces of legislation including a Food Act (in Bulgarian) and the Agricultural and Food Supply Chain Act (in Bulgarian). The Food Act did not amend most of the language regarding GE foods. For example, Article 4a/4 kept the previous food legislation language banning use of products and ingredients composed of, containing, or produced from genetically modified organisms (GMOs) for baby foods. The same Article 4a/3 says that GE foods and "GMOs" for use in or as food, and foods containing ingredients produced from "GMOs" should not be harmful for human health or the environment; mislead consumers; or differ to such a degree that their usual use should not lead to unfavorable results for the consumers regarding the nutritional value.

Article 10 contained labeling provisions and requireed "GMO" quantity information and its unique code. The size and font of the "GMO" content should be based on EU Regulation 1830/2003 and Directive 2001/18/EO and must be twice as large, in color, and in different font on the label. If "GMO" food ingredients exceeded the threshold determined by EU Regulation 1830/2003, the type, quantity, the unique code, and the words "Contains GMO" must be written on the package covering not less than 25 percent of the package, with capital letters, and in color contrasting the other text on the package.

The rules for trading foods labeled as "GMO Free" are to be determined by an in implementing regulation developed jointly by the Ministry of Agriculture and Ministry of Health. Such an implementing regulation has still not been developed in 2021 to date.

Article 19b banned distribution and sales of GE foods at nurseries, kindergartens, and schools. Chapter four set the rules for release of GE foods to the market.

According to Article 23b, a Commission on New and GE Foods is established under the Minister of Health. It is composed by 15 researchers, makes evaluations of new applications, and can provide a risk assessment and a safety assessment (Note: Reportedly, due to COVID pandemics, such a Commission has not been established yet in 2021). Article 23b mandates the duties of applicants for a release of a new food or GE food on the market. The applicants should provide a risk assessment for the human health and for the environment. The other articles in the chapter describe the steps and the

administrative procedures for the release of the GE food on the market, in close coordination and after explicit permit by the EC.

In March 2021, the authorities approved an implementing Regulation to the Food Act about Information for Consumers (Food Labeling) (Council of Ministers Decision #97 of March 19,2021, published in Official Gazette #25 of March 26, 2021, enforced from April 10, 2021). The regulation fully transposes the EC Regulation 1169 (2011) about packed and non-packaged (bulk) food labeling. The regulation did not introduce any "non-GMO" labeling.

Another implementing Regulation (Regulation #2, January 20, 2021) about specific requirements to safety and quality of foods, offered at kindergartens, school canteens and retail outlets at schools, was approved and enforced from February 13, 2021 (Official Gazette #8, January 29, 2021). This regulation did not introduce any extra labeling requirements and/or "non-GMO" labeling.

(ii) Biosafety Board: Legislation created a Biosafety Commission (in Bulgarian) within the Ministry of Environment and Waters to discuss biotech-related matters and to make recommendations to the Minister of Environment. The Commission consists of 15 representatives of scientific and governmental organizations.

(iii) Political factors/influences: Bulgaria's voting patterns vis-à-vis biotechnology-related issues in the EU in 2020 and to date in 2021 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: Due to the political stalemate in 2021, currently it is unclear if the authorities will undertake any steps towards a special regulation about "non-GMO" 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 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 trials, but national regulatory conditions which make such trials 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.

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 and Traceability: The newly approved Food Act in 2020 kept the provisions about labeling and traceability of GE foods which were previously stated in two regulations/amendments. See Policy/Regulatory framework and the 2019 Agricultural Biotechnology Annual/Bulgaria GAIN.

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 1, 2021 – December 31, 2023.

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 2021-2023 the plan was to make 16 samples for testing for food or feed for GE content, including 10 for corn, four for rapeseeds and two for soybeans.

In June 2018, the Ministry of Agriculture published a report (in Bulgarian) about the implementation of the 2016 national program (GAIN). As of mid-October 2021, no report about the implementation of the annual 2018-2020 national programs has been published.

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 percent 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 GAIN for more information.

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 (DonauSoja) initiative promoting GE-free soybeans since November 2013. The Donau Soja Protein Partnership Agreement supports small and medium sized farms in Europe for production of "GMO-free" soya. 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 led to weaker interest in growing conventional soybeans. No Danube Soya events took place in 2019 - 2021.

n) Related Issues: Not applicable.

Part C: Marketing:

a) Public/Private Opinions: Public opinions tend to be negative regarding 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 (GAIN).

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) (see GAIN report). 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. In 2020 and 2021, the center held a series of events focused on plant biotechnology, biotechnology and biodiversity. In June 2020, the center had a groundbreaking ceremony for its new research complex attended by high level politicians and policy makers. The investment in the complex

is estimated at €15 million. Reportedly, most of the funds are sourced from the EU (Horizon 2020 innovation program). Currently, the research center has about 30 local and international scientists. In June 2021, the center hosted the International Conference on Plant Systems Biology and Biotechnology (hybrid event) which featured more than ten internationally renowned biotech researchers during an ambitious four-days program.

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 2020 and 2021, the anti-biotech non-governmental organization (NGO) Za Zemiata (in Bulgarian) (Friends of the Earth) continued its active communication campaign against genome editing and advanced plant breeding. In January 2021, the NGO published various articles (in Bulgarian) and a petition against genome editing. The NGO is also against industrial animal farms.

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: Genetically engineered animals and clones are not being developed at this time in Bulgaria for commercial agricultural purposes.

c) Exports: It is unknown whether products from offspring of cloned animals are being exported.

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) Intellectual property Rights (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: There is little public awareness of animal biotechnology in the country but overall, market acceptance is low among policy makers, industry, and consumers. Animal biotechnology is a controversial issue that is not widely discussed.

b) Market Acceptance/ Studies: Not applicable

Chapter 3: Microbial Biotechnology

Part G: Production and Trade

a) Commercial production: It is difficult to obtain information about the development and production practices of GE microorganisms. Reportedly, GE of micro-organisms is used in select laboratories. Bulgaria has also some commercial production of products using microbial biotechnology due to the demand of the dynamic food processing industry. The use of fermentation to produce food enzymes and food additives is reported to have advantages over the chemical production of these components. However, no public information is available about the volume of production and trade in these products.

b) Exports: Bulgaria exports alcoholic beverages, dairy products, and processed food products, which may contain microbial biotech-derived food ingredients. However, no public information, official statistics nor estimates are available at this point.

c) Imports: Microbial biotech-derived food ingredients may be present in Bulgarian imports of alcoholic beverages, dairy products, and processed products, where microbial biotech-derived ingredients are commonly used in global production. However, no public information, official statistics nor estimates are available at this point.

d) Trade Barriers: No trade barriers have been reported regarding products developed by microbial biotechnology.

Part H: Policy

a) Regulatory Framework: Bulgaria follows EU regulations regarding production and trade in products of microbial biotechnology. The Bulgarian Food Safety Agency is the authority regulating food additives, food flavorings and food enzymes. Only approved food business operators can produce, sell, and store food additives, food flavorings and good enzymes.

GE microbes and their products fall under the scope of two GE Directives, Directive 2009/41/EC on contained use of "genetically modified microorganisms" and Directive 2001/18/EC, which covers the deliberate release into the environment of genetically modified organisms. A product of microbial biotechnology has to comply with Regulation (EC) No 1829/2003 that covers the market access requirements and authorization procedure for genetically modified food and feed as well as with Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

b) Approvals: The approval of biotech microbes and/or derived food ingredients in subject to EU procedures (Regulation 2008/1331), as well as related to regulations about approval of food enzymes (Regulation 2008/1332), food additives (Regulation 2008/1333), and food flavorings (Regulation 2008/1334). GE microbial products used in food may be also subject to the EU's Regulation (EC) 2015/2283 on novel foods. All feed additives – GE and non GE – must follow Regulation (EC) 1831/2003 on additives for use in animal nutrition. Detailed rules for applications for authorization in the scope of this Regulation can be found in Commission Regulation (EC) 429/2008.

c) Labeling and Traceability: Bulgaria follows EU regulations regarding production and trade in products of microbial biotechnology. For products of microbial technology that fall under the EU's "Deliberate Release" Directive, Regulation (EC) No 1830/2003 concerning the traceability and labelling of "GMOs" and the traceability of food and feed products produced from GE events applies. The EU Regulation 2011/1169 lists the categories of food additives, food enzymes and food flavorings which must be designated by the names of their category, followed by their specific name or E-number.

d) Monitoring and Testing: Bulgaria follows EU regulations regarding production and trade in products of microbial biotechnology.

e) Additional Regulatory Requirements: No national requirements in addition to those in the EU are known at this point.

f) Intellectual property Rights (IPR): No public information is available.

g) Related Issues: Not applicable.

Part I: Marketing

a) Public/Private Opinions: Currently there is no debate in Bulgaria on microbial biotechnology.

d) Market Acceptance/ Studies: In Bulgaria, microbial biotechnology is a non-issue and is expected to remain as such.

Attachments:

No Attachments