Required Report: Required - Public Distribution **Date:** November 25, 2025

Report Number: BU2025-0018

Report Name: Biotechnology and Other New Production Technologies Annual

Country: Bulgaria

Post: Sofia

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Mila Boshnakova-Petrova

Approved By: Benjamin Petlock

Report Highlights:

The Government of Bulgaria (GOB) continues to oppose agricultural biotechnology. Non-governmental anti-biotech organizations, local activists, and Bulgaria's organics industry actively spread nonscientific disinformation about biotechnology. Meanwhile, 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 European Commission (EC) tend to vary between neutral (abstention) and against. So far in 2025, Bulgaria has voted "against" or "abstain" on new agricultural biotech-related EC legislation in Brussels.

Currently, Bulgaria does not conduct agricultural biotech research with field trials or cultivate any genetically engineered (GE) products. In 2015, Bulgaria decided to adopt the European Union (EU)'s Directive allowing Member States to "opt out" of biotech plant cultivation.

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

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT: No public data is available about any agricultural plant research or product development.

Since the major biotechnology law was approved in 2010 (See Part B. Policy), laboratories are required to seek Ministry of Environment approval through its registration regime. Currently, there are 11 laboratories (in Bulgarian) approved for biotech research. The last two laboratories were approved in 2023, with no new laboratories approved since then.

Bulgaria has a well-developed pharmaceutical industry which has enjoyed stable growth and consistent local and foreign investment. While most pharmaceutical manufacturers in Bulgaria produce generic

drugs, the sector regularly develops new GE products, although little product-specific information is publicly available on these products. The Association of Research-Based Pharmaceutical Manufacturers (in Bulgarian) supports local researchers contributing to international pharma-related biotech projects. Since 2018, the pharmaceutical 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 crop 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.

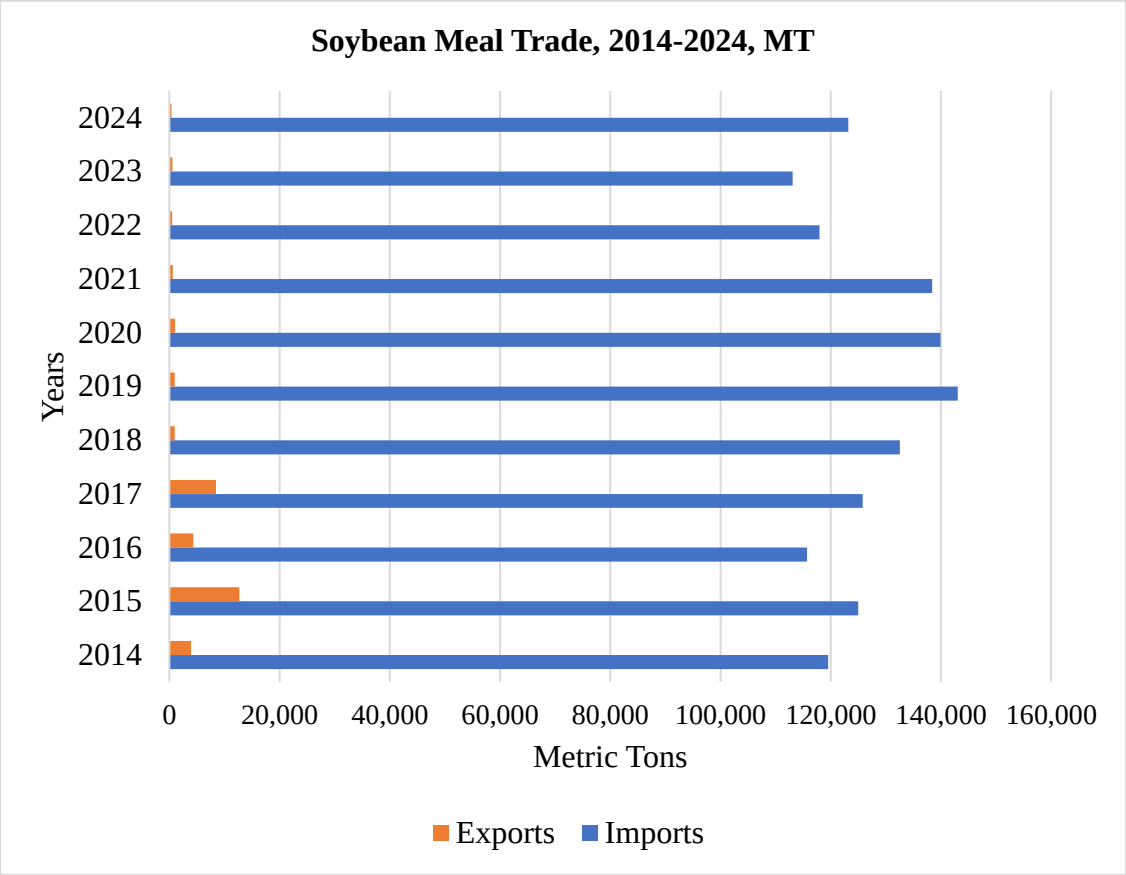
Bulgaria has been a member of the Danube Soya initiative since 2013 (see PART B: Policy paragraph for more information). Since 2018, local soybean production has been small. In 2024 and 2025, area under soybeans was under 1,000 hectares (HA) and production below 1,000 metric tons (MT). In the near future, soybeans will be only kept for crop rotation practices in a few regions in the country and will not have any commercial role.

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

d) IMPORTS: The livestock sector imports GE protein meals and feed ingredients, mostly from South America and the United States, and dairy, poultry, and pork producers support using biotech feed and derived products. Currently, Bulgaria does not have any established commercial soybean crushing facilities and is a net importer of soybean meal and other soy products (about 140,000 MT annually). Since 2016, Bulgaria has imported soybean meal from Romania and Greece, which has been derived from U.S.-origin soybeans.

In 2023/2024, although the domestic poultry and pork industry faced challenges related to increased production costs (energy, labor, feed, inflation) consumer demand remained favorable. The swine inventory recovered and has been relatively stable over the last 2 years with small variations. At the end of 2024, it was 3.3 percent lower than 2023. Lack of African Swine Fever outbreaks and consistent inventory kept imports and use of soybean meal stable to slightly growing. Between 2023 to 2025, Avian Influenza (AI) outbreaks hit the poultry industry, although most of the impact was in egg production with only a few broiler farms being affected. These developments resulted in higher use of soybean meal although the main industry users remain price sensitive.

In 2024, Bulgarian imports of soybean meal (source: Trade Data Monitor), increased by 9 percent compared to 2023 to 123,000 MT. This growth continued in 2025 and, in the first half of the year, imports increased by another 10 percent. Declining global prices have also supported this trade. The average import price in 2024 was at $511.52/MT, 14 percent lower than in 2023; in January-June 2025, the average import price dropped further to $442.67/MT or 16.5 percent less than a year before. Growth in imports is forecasted to expand due to the current recovery of swine and poultry numbers. Private sources estimate potential imports of soybean meal at over 130,000 MT.



Source: Eurostat/Trade Data Monitor (PSD Soybean meal)

Bulgaria imports a small amount of corn-derived products, including corn gluten feed (CGF) or distillers' dried grains with soluble (DDGS). The main suppliers are Serbia and Romania. Bulgaria has not imported GE corn or feed products derived from GE corn. The country is a net exporter of corn and of (primarily corn-based) DDGS. However, in the last 3 years, Bulgarian corn production has drastically declined due to increasingly hot and dry summer seasons. This has made the country a net importer of corn. In MY 2024/25, corn imports were 462,000 MT, while exports were 250,000 MT (source: Bulgarian Ministry of Agriculture weekly bulletins). The prospects for MY 2025/26 are for a similar pattern and higher corn imports. This has the potential to change the previous trade pattern and drive more imports of processed corn products into feed use.

Source: Eurostat/Trade Data Monitor (BICO-Distillers Grains)

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, Türkiye, and the United States.

PART B: POLICY

a) REGULATORY FRAMEWORK:

Legal term (in official language)	**Legal Term (in English)**	**Laws and Regulations where term is used**	**Legal Definition (in English)**
Genetichno Modificirani Organismi (GMO)	Genetically Modified Organisms (GMO)	• Law on Genetically Modified Organisms (Official Gazette 102, December 23, 2022, last revision) • Food Act (Official Gazette 52, June 9, 2020, last revision) • Agricultural and Food Supply Act (Official Gazette 51, June 5, 2020)	A genetically modified organism is any organism, including microorganisms, in which the genetic material has been changed in a way that does not occur naturally upon coupling and/or natural recombination. This definition does not include the human

			organism as well as organisms obtained using techniques stated in art.2/a. Art.2a: The following techniques/methods are considered to not lead to creation of genetically modified organisms: -in-vitro fertilization; -natural processes such as conjugation; transduction and transformation; -polyploid induction; provided they do not include the use of recombinant nucleic acid molecules or GMOs created by techniques and/or methods other than those specified in art. 2, para. 2.

(i) Responsible GOB ministries: In 2010, Bulgaria passed legislation commonly referred to as the "GMO Law" (the last amendment in 2022), which established that country's regulatory framework as one of the most restrictive in the EU. According to the legislation, the Ministry of Agriculture (MinAg) and the Ministry of Environment and Waters are the main regulatory authorities on biotechnology regulations.

As a result of 2016 reform, 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 MinAg. Since then, the RAC has adopted European Food Safety Authority (EFSA) positions and has recommended either a positive or a neutral position on biotech-related matters.

In September 2025, the RAC published a scientific overview on the GE crops and their impact on honeybees. The overview was based on the available published international research. The overview

does not make any clear conclusions and appeals for ongoing studies and exchange of information on the topic.

In 2023, RAC issued a position about the public discussion on "New Genomic Techniques (NGTs)." The position was negative and stated that the plants obtained through "NGTs" should be considered as GE products and be subject of the same legislation. It also stated that the premature release of "NGT" crops on the market could create risks and violate the EU precautionary principle. The position stated the risk assessment and labeling of "NGT" products should be identical to those for GE ones. The RAC also stated that if the EU approved a new Regulation (applied in all member states as it is) on "NGTs", it would contradict Bulgarian legislation. Therefore, the RAC appealed for the new legislation to be in the form of a Directive (transposed in the local legislation with a certain degree of flexibility).

In 2022, the Parliament made minor amendments to the biotech law (in Bulgarian) updating the principles and criteria for risk assessment of "genetically modified organisms ("GMOs")" upon their release into the environment. According to then Minister of Environment and Vice Prime Minister Mr. Borislav Sandov, the legislative changes aimed to prohibit the release into environment of "GMOs" and will not allow any such use in the field. Despite counterreaction by the political opposition that a number of biotech microorganisms are widely used in daily life for production of bread, beer, insulin, and many medicines, the law was approved.

In 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 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 required "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 a different font on the label. If "GMO" food ingredients exceeded the threshold determined by EU Regulation 1830/2003, the type, quantity, 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 implementing regulation developed jointly by the MinAg and Ministry of Health. However, any implementing regulation has yet to be developed.

Article 19b banned distribution and sales of GE foods at nurseries, kindergartens, and schools. Chapter 4 established the rules for release of GE foods to the market.

According to Article 23b, a Commission on New and GE Foods was established under the Ministry of Health. It is to be composed of 15 researchers and will make evaluations of new applications and provide risk and safety assessments. However, to date, this commission has yet to be formed. Article

23b mandates the duties of applicants for the release of a new food or GE food on the market. The applicants should provide a risk assessment for human health and for the environment. The other articles in the chapter describe the steps and the administrative procedures for the release of GE food on the market, in close coordination with and after explicit permit by the EC.

In 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 packaged 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 pattern vis-à-vis biotechnology-related issues in the EU in 2024 and so far in 2025 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 GE products used for food and those used for feed, or for processing, and/or for environment release (cultivation). Bulgaria continues to allow biotech feed grains, oilseeds, and derived products for livestock feed.

(v) Pending legislation: Due to political instability, it is unclear if the authorities will undertake any steps toward a special regulation about "non-GMO" labeling. Currently, Bulgaria has a ruling coalition with priorities focused mainly on political stability and economic recovery due to the impacts of Russia-Ukraine War and national goals targeting the country's acceptance in the Eurozone in 2026.

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

(vii) Discussions about regulations, research, or trade policies on biotechnologies: There is little current 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 the fact that Bulgaria "opted out" of cultivation (see chapter 1, part A, sub-paragraph b) commercial 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 make such trials practically impossible.

The Executive Agency for Planting Seeds and Planting Material (in Bulgarian) under MinAg is mandated by legislation to carry out official control of planting seeds for GE content under the 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 sub-paragraph h) monitoring and testing). In 2021, the Executive Agency for Planting Seeds and Planting Materials issued an ordinance defining the list of laboratories for official control on presence of "genetically modified organisms" in grain planting seeds. Two laboratories were approved to perform GE presence tests (one private lab and one public lab).

The Executive Environment Agency under the Ministry of Environment 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 or "NGTs"). There is little awareness in both the industry and public about 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 TRACEBILITY: The 2020 Food Act kept provisions about labeling and traceability of GE foods which were previously stated in two regulations/amendments.

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, 2024 - December 31, 2026.

For planting seeds already on the market, a National Monitoring Plan is carried out by the Executive Agency for Planting Seeds and Planting Material. This plan is based on risk analysis. For the period 2024-2026, the plan was to make ten samples for testing for food or feed for GE content, including five for corn, three for rapeseeds and two for soybeans annually.

i) LOW LEVEL PRESENCE (LLP) POLICY: Bulgaria does not have an LLP policy. 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 sub-paragraph g) labeling and traceability).

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Bulgaria follows EU and international standards on IPR.

l) CARTAGENA PROTOCOL RATIFICATION: Bulgaria is a signatory to the Cartagena Protocol, and the Bulgarian parliament ratified the protocol on July 19, 2000.

m) INTERNATIONAL TREATIES/FORUMS: Bulgaria is a member of the Organization for Economic Cooperation and Development (OECD), International Plant Protection Convention, and Codex Alimentarius. Bulgaria strictly observes these international conventions but does not regularly or actively take part in promoting its position on agricultural biotechnology nor does it 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 2016. 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 initial enthusiasm, disappointing production and economic results since 2016 led to weaker interest in growing conventional soybeans. No Danube Soya events have taken place since 2020.

n) RELATED ISSUES: Not applicable.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Public opinion tends to be negative regarding agricultural biotechnology and is influenced by propaganda from anti-biotech organizations, the organic industry, consumer organizations and social media. Surveys reflect that consumer opinions 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, and curiosity towards science.

In 2019, Bulgaria established the Research Center of Plant System Biology and Plant Biotechnology (Research Center of Plant System Biology and Plant Biotechnology/RCPSBPB PlantaSyst]). The center makes efforts to integrate 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. From 2021 to 2025, the center held a series of events focused on plant biotechnology, biotechnology, and biodiversity. A new research complex was completed in 2023. The Center has an excellent research reputation and well-developed international network. Currently, the research center has about 50 local and international scientists.

In 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 4-day program. In 2022 and 2023, it organized well attended international research conferences. The 2023 conference focused on "NGTs" applied on drought tolerant crops with more than 10 prominent international lecturers presenting. In 2024, the Center hosted a working meeting with representatives of eight countries (respective ministries, academies of sciences, and research agencies) in

the region: Armenia, Greece, Czechia, Malta, Türkiye, Morocco, Romania, and Albania under a transnational network project funded by the EC (so called WIDERA NET). The meeting was under the auspices of the Bulgarian Ministry of Education. In 2024, the Center was visited by a People's Republic of China (PRC) delegation (details here). The Center discussed potential opportunities for collaboration between RCPSBPB and PRC Universities and institutes for mutual research projects in the domains of plant biotechnology and metabolomics, incl. metabolite profiling for standardization and modernization of traditional Chinese medicine. In May 2025, the Center organized and international conference on natural products utilization for medicine, pharmacy and the cosmetic industry that welcomed about 230 researchers from 33 countries. Cutting-edge research was presented, related to the isolation, identification and application of bioactive compounds derived from plants and foods with potential and proven beneficial effects on human health.

In 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 great interest with young people such as students, start-ups, and others. It acts as an incubator for biotech-related businesses and promotes biotech innovations. CASI's main target is to teach science graduates how to become entrepreneurs and demonstrate the benefits of advanced biotechnology for everyday life.

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 2024 and 2025, 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 2021, the NGO published various articles (in Bulgarian) and a petition against genome editing. The NGO is also against industrial animal farms and against use of pesticides. In 2022 and 2023, the NGO published its position against NGTs due to high related risks. The NGO was very active on the NGTs debate in 2024 when Bulgaria had to formulate its official position on NGTs in the EU.

Farmers, feed and livestock producers, and agricultural 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.

CAPTER 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 regulations. Bulgaria follows EU policies regarding trade in biotech products and cloning.

PART E: POLICY

a) REGULATORY FRAMEWORK: MinAg and the Ministry of Health are the governing entities charged with regulating such technology. 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. Bulgaria follows existing EU requirements on this issue.

e) INTELECTUAL PROPERTY RIGHTS (IPR): There is no public IPR information specific to these technologies.

f) INTERNATIONAL TREATES/FORUMS: Bulgaria is a member of the OECD, 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.

a) 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 microorganisms are used in select laboratories. Bulgaria also has 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 food 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 is 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.

b) MARKET ACCEPTANCE/STUDIES: In Bulgaria, microbial biotechnology is a non-issue and is expected to remain as such.

Attachments:

No Attachments