USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 11/14/2018
GAIN Report Number: BU1837

Bulgaria

Agricultural Biotechnology Annual

Bulgaria Continues to Oppose Agricultural Biotechnology

Approved By:
Jonn Slette
Prepared By:
Mila Boshnakova

Report Highlights:
The Government of Bulgaria (GOB) continues to oppose agricultural biotechnology and generally advocates for anti-biotech policies within the European Commission (EC). Non-governmental anti-biotech organizations (some of which are funded directly by the EC), local activists, and Bulgaria's organics industry actively spread nonscientific disinformation in Bulgaria about biotechnology, as well as regularly protest its use in agriculture. Bulgaria's poultry, dairy, and livestock stakeholders continue to import biotech-derived feed ingredients.

Section I. Executive Summary:
Bulgarian voting patterns on biotech-related issues at the EC tend to vary between neutral (abstention) and against. To date in 2018, Bulgaria has consistently voted against new agricultural biotech-related legislation in Brussels.

Currently, Bulgaria does not research or cultivate any genetically engineered (GE) products and/or conduct any biotech field trials. Bulgaria decided to "opt-out" in production in 2015 (Attaché

Report) and 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.

Section II. Author Defined:
TABLE OF CONTENTS

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 work on research projects with GE products.

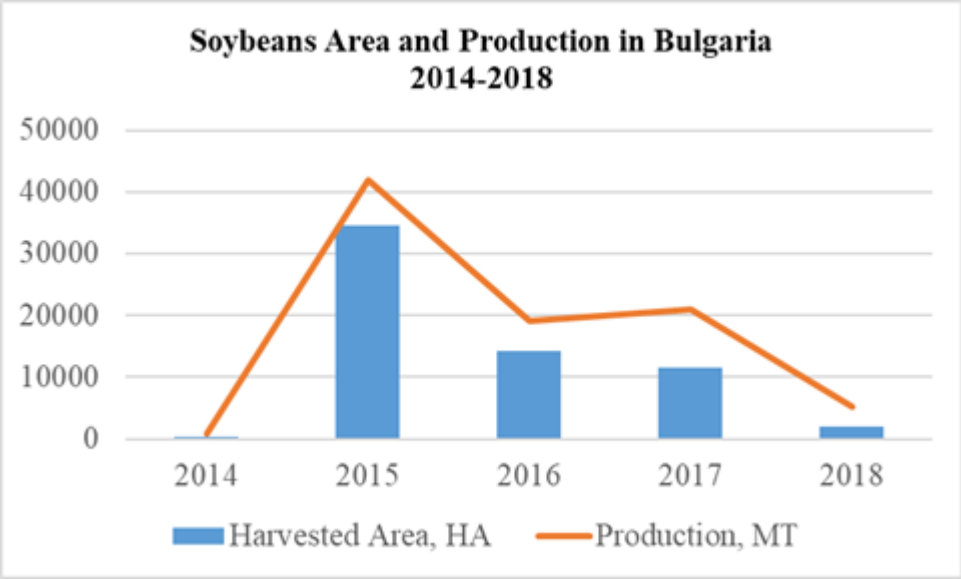
Bulgaria has a well-developed pharmaceutical industry, which has enjoyed stable growth, and consistent local and foreign investment. Most pharmaceutical manufacturers in Bulgaria produce generic drugs (Bulgarian Generic Pharmaceutical Association) (in Bulgarian). The main players are Sopharma Group, Teva-Actavis (in Bulgarian), and Antibiotic AD, among others. Huvepharma has three manufacturing facilities in Bulgaria, two in the United States, and is focused on developing and manufacturing of human and veterinary drugs. This company also manufactures enzymes for food, feed, and industrial applications and has a strong global presence. Although the pharmaceutical sector regularly develops new GE products in Bulgaria, little product-specific information is publically available.

Another major pharma-industry group is the Association of Research-Based Pharmaceutical Manufacturers in Bulgaria which has 25 member companies. According to this organization, local researchers are increasingly contributing to international pharma-related biotech projects. The major partner of the pharmaceutical industry is the National Genetics Laboratory (in Bulgarian) under the Medical University Sofia. The lab works in the area of molecular medicine and maintains the national

DNA database and the national genetics register. In 2018, the pharma industry changed its approach and became more proactive in public communication vis-à-vis the advantages of pharmaceutical biotechnologies and innovations. The industry ran several TV documentaries on pharmaceutical biotech science and personalized medicine.

b) Commercial Production: There is no biotech commercial agricultural production or cultivation. In 2015, Bulgaria chose to "opt-out" of biotech production (Attaché Report) and it 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 is a member of the Danube Soya initiative since November 2013 (see Policy paragraph m for more information on this organization). Areas planted under non-GE soybeans in 2017 were at 81 percent of that in 2016 (11,000 hectare [HA] compared to 14,000 HA in 2016). In 2018 areas under soybeans declined sharply to tiny 2,000 HA and production dropped from 21,000 MT in 2017 to 5,000 MT in 2018 (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. Dairy, poultry, and pork producers support using biotech feed and derived products. In 2017 Bulgarian stakeholders imported 126,000 metric tons (MT) of GE soy products (mainly soybean meal) from Brazil and Argentina, nine percent more than in 2016. In the first half of 2018 these imports grew by eight percent compared to the corresponding period in 2017. Currently Bulgaria is a net soybean meal importer. Since 2016, some local importers have soured soybean meal from Romania, including meal derived from U.S.-origin soybeans. Industry sources report that this trade is increasing and will likely grow through 2019.

Soybean imports have fluctuated in recent years. In 2017, imports declined to only 4,600 MT, down from 13,900 MT in 2016. During the first half of 2018, soybean imports dropped sharply by 94 percent

to 247 MT, mostly from Romania. Some local crushers are considering whole-bean imports for crushing in 2019 to complement traditional sunflower and rapeseed meal mixtures in feed rations to achieve better capacity utilization.

Bulgaria imports a small amount of corn-derived products, including corn gluten feed (CGF) or distiller's dried grains with soluble (DDGS). The 2017 imports, mainly from Hungary, declined to 5,800 MT from 20,500 MT in 2016 (source: Word Trade Atlas, HS#230310). During the first half of 2018, imports declined further by 49 percent to 2,800 MT. Import volumes are small because the local feed industry is still unfamiliar with these products. Locally-produced corn is abundant and in 2018 Bulgaria expects a record corn crop. The country is an exporter of non-GE DDGS. Total 2017 DDGS exports were at 89,000 MT and 41,000 MT during the first half of 2018. Turkey is Bulgaria's largest DDGS export market.

Table 1. Bulgaria's Soybean Meal Imports (HS#230400 and HS#120810), 2013-2018 (July)

Bulgaria Import Statistics **Commodity: Soybean meal, (2017)**									
Annual Series: 2013 - 2017, Year To Date: 07/2017 & 07/2018 Quantity									
Partner Country	**Unit**	**Calendar Year**					**Year To Date**		
		2013	**2014**	**2015**	**2016**	**2017**	**07/2017**	**07/2018**	**% Change**
World	T	111,643	119,473	124,963	115,654	125,721	69,283	73,885	6.64
Romania	T	106,221	113,240	118,146	106,685	119,628	66,858	67,324	0.7
Greece	T	2,683	3,193	3,369	4,977	3,119	766	5,014	554.76
Serbia	T	805	972	589	2,090	1,290	760	998	31.38
India	T	333	195	536	450	756	423	68	-84.05
China	T	389	603	567	269	444	191	393	105.76

Source: World Trade Atlas

Table 2. Bulgaria's DDGS Imports 2013-2018 (July)

Bulgaria Import Statistics **Commodity: 230310, Residues Of Starch Manufacture And Similar Residues, Whether Or Not In The Form Of Pellets**									
Calendar Year: 2013 - 2017, Year To Date: 07/2017 & 07/2018 Quantity									
Partner Country	**Unit**	**Calendar Year**					**Year To Date**		
		2013	**2014**	**2015**	**2016**	**2017**	**07/2017**	**07/2018**	**% Change**
World	T	692	1,586	1,557	20,494	5,783	5,413	2,787	-48.52
Hungary	T	0	51	760	17,73	4,949	4,949	2,200	-55.54

					2				
Netherlands	T	0	77	339	463	415	200	296	48.01
Denmark	T	18	14	45	64	185	107	233	117.04
Austria	T	109	170	97	109	103	57	53	-6.36

Source: World Trade Atlas

Table 3. Bulgaria's DDGS Exports 2013-2018 (July)

Bulgaria Export Statistics **Commodity: 230310, Residues Of Starch Manufacture And Similar Residues, Whether Or Not In The Form Of Pellets**									
Calendar Year: 2013 - 2017, Year To Date: 07/2017 & 07/2018 Quantity									
Partner Country	**Unit**	**Calendar Year**					**Year To Date**		
		2013	**2014**	**2015**	**2016**	**2017**	**07/2017**	**07/2018**	**%Change**
World	T	68,914	72,719	91,945	95,171	88,898	57,038	47,911	-16
Turkey	T	40,486	51,385	69,232	68,907	61,989	41,725	30,935	-25.86
Greece	T	15,481	11,682	7,925	12,561	16,121	8,688	7,817	-10.03
Romania	T	872	153	1,822	6,088	5,471	3,087	4,752	53.96
Norway	T	1,623	0	0	0	2,388	2,388	1,450	-39.3
Cyprus	T	0	1,796	1,909	1,502	1,613	308	897	191.33

Source: World Trade Atlas

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 (Attaché Report). 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.

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. In 2016 the MinAg initiated a major reform in its food safety legislation (RAC law) (in Bulgarian) in response to changes in EU-level regulations. The new legislation provided for more autonomy for staff researchers and the RAC 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 2018, to date, the RAC website has issued 16 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 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 2017 and to date in 2018 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 major 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 a number of public and industry consultations were carried out in 2017 and in the first half of 2018. The first version of the bill was notified to the EC in the fall of 2017 and as a result, the local authorities needed to address some of the deficiencies identified by the EC. As of mid-October 2018, the Food Act legislation remains in the Parliament. MinAg's stated goal is to have the legislation approved and enforced from January 1, 2019.

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. 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. 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. Often such tests are done based on notifications submitted from anti-biotech NGOs or activists. Results from the implementation of 2016 annual plan were published in the middle of 2018 and are shown under section (h) Monitoring and Testing below.

e) Innovative Biotechnologies: Bulgaria usually takes a neutral position regarding innovative biotechnologies. There is little to no 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 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. 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.

In June 2018, the Ministry of Agriculture published a report (in Bulgarian) about the implementation of the national program in 2016. The main findings of the report are as follows:

- Plantings seeds: For planting seeds already on the market, a National Monitoring Plan is followed by the Executive Agency for Planting Seeds and Planting Material. This plan is based on risk analysis. In 2016, the Executive Agency for Planting Seeds and Planting Material made over 1,000 on-site documentary checks, including seed package labels. In addition, 20-22 samples were tested and showed negative results for GE content.

- Field crops: 12 field samples from corn (seven samples), soybeans (two samples), and rapeseeds (two samples) were taken and analyzed by the Executive Environment Agency for illegal presence of GE content. Samples were taken from different locations in Northern Bulgaria which is the major grain production region. All tests were negative. The oversight did not identify any plant protection products or fertilizers produced from or containing GE organisms.

- Feed: Imports and use of feed and feed grains are subject of National Monitoring Plan for GE testing based on EC Regulation 882 (Articles 14 and 15). Border authorities are authorized to intervene as necessary (Art.18). The monitoring plan for GE testing is based on risk analysis. In 2016, 29 samples were tested for GE presence. A lack of compliance was identified in 3.44 percent of the samples. Out of total samples, 24 were taken from soybean meal, corn, soybeans, corn gluten, and rapeseed meal; one sample from a compound feed; one from milk substitute for calves, and one from a supplement compound feed. One sample showed presence of soya event GTS 40-3-2 (MON04032-6) at 1.45 percent due to cross contamination during transportation of feed between feed operators. Seventeen samples found no presence of GE content. In addition, BFSA performed 782 documentary checks for traceability of GE feed and labeling.

- Food: The National Program for Control of Genetically Modified Foods (in Bulgarian) tested 60 food samples out of 80. Samples included higher risk products such as soybeans and soy products, corn and corn products, chocolate, cocoa and confectionary products, meat, rice and rice products imported from China. Only one sample showed positive results for GE organisms' presence in tofu produced in Varna region. The inspection identified that the raw material used for the product was from locally produced soybeans from the 2015 and 2016 crops. The soybeans from 2016 crop had a presence of 2.75 percent of GE content. In addition, 19 samples were taken from organic foods and all showed negative results for GE content.

- The Risk Assessment Center under the MinAg reported that in the first quarter of 2018, Bulgaria made two notifications under EU Rapid Alert System for Food and Feed (RASFF) for imports of non-authorized GE events. The first was about Chinese rice gnocchi and the second about GE corn in a cooked meal with seafood from Thailand. In the second quarter of 2018, the country made five notifications, four for imports of Chinese rice (resulting in banned market access) and one about U.S. corn (for not providing traceability documents notification). There has been a trend for a small number of RASFF notifications for non-authorized GE events: nine in 2015, 15 in 2016 and 16 in 2017.

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 and marketing 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, whereby a patent recognized by the European Patent Convention is also immediately implemented 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. 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 strictly observes 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. This organization promotes "biotech-free" soybean cultivation, trade and processing. Several outreach and training events occurred during the past years 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. No Danube Soya events took place in 2018.

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.

In 2018 the GOB undertook a reform in agricultural research and development. The Agricultural Academy, which unites about 25 research institutes, is currently preparing new 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.

At the end of 2017 and in 2018, Bulgaria established the Research Center of Plant System Biology and Plant Biotechnology (PlantaSyst) in the town of Plovdiv. The center is supported by Plovdiv municipality, the Ministry of Education and the Ministry of Agriculture. The project is a beneficiary of EU funds under Horizon 2020 program. Major players are the Institute of Molecular Biology and Biotechnology Plovdiv, Microbiology Institute under the Bulgarian Academy of Sciences and Agricultural Academy's Research Institute for Vegetable Crops (Maritsa). Two institutes are partners in the project – Potsdam University and max Planck Institute of Molecular Plant Physiology. The ambition of the center is to stand at the forefront of plant sciences in Bulgaria and Eastern Europe by integrating molecular biology, functional genomics, metabolomics, bioinformatics, bioprocessing, and long-standing expertise in practical plant genetics and breeding, to unravel the plant biology and translating the scientific knowledge into new horticultural and industrial applications.

Reportedly, two applications for EU funding for science and intelligent growth were rejected by the authorities, including the FoodBioHealth of the University of food technologies, and a project for personalized medicine of the Medcial University. Both projects were supported a science-based approach to innovative food and medial biotechnologies.

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

In 2018, a major foreign retailer made a campaign to advertise sales of non-GE bread, a local product which was on sale before the campaign without such advertising. Since there is no GE wheat/wheat flour/bread in the country, this caused embarrassment in the industry and because most consumers were unware of these facts it spurred negative comments in some social media.

According to a survey carried out by anti-biotech NGO Za Zemiata in November 2017, 75 percent of respondents would appreciate an introduction of a voluntary non-GE label and 78 percent would like to see that such label guarantees production of animal products with non-GE feed. A preference towards non-GE labels was preferred by 83 percent of respondents compared to non-labeled analogues. About 70 percent of respondents showed readiness to pay higher prices for non-GE products.

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.

b) Approvals: Not available.

c) Innovative Biotechnologies: Bulgaria does not have a formulated position on innovative biotechnologies.

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