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Agricultural Biotechnology Annual

Bulgaria Hesitant on Biotechnology

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Report Highlights:
Consumers' attitude in Bulgaria towards biotechnology remains negative. The anti-biotech alliance includes Non-Governmental Organizations (NGO's) and some smaller ag industry groups such as organic, bee-keeping and small farms groups. Over the last year, this alliance expanded to include anti-Transatlantic Trade and Investment Partnership (TTIP) organizations. Some of the leaders of the organic and green movement are now more politically proactive through the Green Party.

In June 2014 the previous administration re-confirmed the safeguard ban on corn MON810 despite the fact that the ban was questioned by the European Commission (EC). In December 2014, EFSA announced that Bulgaria's ban on the cultivation of MON810 is unjustified, due to no new scientific evidence being presented to support the ban. In 2015 to date, the country continued to follow a negative position on agricultural biotechnology production and supported an opt-out in cultivation. However, it still remains to be seen what will be the national position on trade with biotech feed and related products.

In the spring of 2015 Bulgaria launched its first production of non-genetically engineered (GE) soybeans stimulated by the EU greening requirements for direct subsidies. This year is expected to be a test for the future development of this crop and related industry/trade. The success or a failure may play a critical role for further farm and feed group positions towards biotechnology. The progress of TTIP negotiations is another challenge which may force local policy makers to be more decisive on determination of the national position.

Section I. Executive Summary:

Bulgaria used to be a leading country in plant biotechnology research and development in the mid 1990's until early 2000's. Shortly before and after EU accession in 2007, the situation changed. Major biotechnology legislation was passed in 2010 following massive anti-biotechnology campaign, and the approved legislation is believed to be one of the most restrictive in the EU.

Bulgarian voting positions in Brussels vary from neutral "abstain" to "against" with a few exceptions. As of today, the country does not develop any biotech products, does not grow commercially or for research purposes biotech crops, and has imposed a safeguard clause on MON 810 in 2011.

Bulgaria notified the European Commission (EC) on its decision to opt-out on September 30 2015. The notification was done through sending of 10 notification letters from the Ministry of Agriculture to the EC. In these letters Bulgaria declared its decision to choose so called Option 1 and ban cultivation of the following GE products on the entire territory of the country:

Corn: Bt11xMIR604xGA21; MIR604; GA 21; Bt11; 1507 x 59122; 59122; 1507; MON 810;
Soybeans: 40-3-2
Carnation: Moonshadow 1

The ban also extends on any field experiments for research purposes.

Bulgaria is a net importer of protein feed, mainly genetically enhanced, for the dairy, poultry and livestock sectors.

In June 2014, the Bulgarian Cabinet voted a modification of the Decision #56 of February 3, 2011 which imposed a ban on cultivation of MON 810, in a way to be legally relevant and in line with EU law. The re-consideration was caused by EC questioning the arguments Bulgaria used to impose the safeguard ban. At the end of 2013 the EC notified Bulgaria that if the ban was not revoked, the EC would launch an infringement under Art. 258 of the EU Treaty. With this decision, the Cabinet changed the legal justification for the ban (See FAS GAIN report BU1422 dated 06/27/2014 for more details).

In December 2014 the European Food Safety Authority (EFSA) announced that Bulgaria's ban on the cultivation of Monsanto's genetically engineered corn MON810 was unjustified, due to no new scientific evidence being presented to support the ban.

In its assessment of Bulgaria's action, EFSA said that "*Neither the arguments put forward by Bulgaria nor the documentation reveal new scientific evidence, in terms of risk to human and animal health or*

the environment, that would support the adoption of an emergency measure on the cultivation of maize MON 810". "In the absence of new relevant scientific evidence, EFSA concludes that its previous risk assessment conclusions and risk management recommendations on maize MON 810 and those of its GMO [genetically modified organism] Panel remain valid and applicable."

Bulgarian authorities and media were silent on this decision, and the verdict has not been commented officially by the authorities. Public statements of senior policy makers revealed that the government had no plan to change its anti-biotech position. (See FAS GAIN report BU1503 dated 01/26/2015 for more details).

Section II. Author Defined:

Section II. Plant and Animal Biotechnology Trade and Production:

Chapter 1 Plant Biotechnology

Part A: Production and Trade

a. Product Development:

No public data is available about any biotech product development. Since the major biotechnology law has been approved in 2010, biotechnology laboratories have been under an approval/registration regime by the Ministry of Environment and some were not allowed to deal with biotech products developments before their final approval is ready.

Currently, there are five laboratories approved for biotech research work. http://www.moew.government.bg/?show=top&cid=229. All five laboratories are public as three of them are under the research institutes of the Bulgarian Academy of Sciences, one is under the Agricultural Academy/Ministry of Agriculture and one under the Biological Faculty of Sofia University. Since four out of five labs received their approval for biotechnology only over the last 10-12 months, these labs are not involved in any major projects. The fifth lab is involved in two biotech projects. Projects are focused on research only and not product development. The first one is a collaborative project with the Netherlands, University of Wageningen, on potato resistance to blight, using cis-genesis. The lab carries a hazard analysis and no field experiments are involved. The second project, funded by national sources, is about tomato using RNAi. In general, New Breeding Techniques (NBT) are treated as GE technology by the legislators and labs involved in research and development (R&D) using NBTs should observe the biotechnology legislation.

b) Commercial Production:

There is no commercial production of biotech products.

c) Exports:

Bulgaria does not export biotech products.

d) Imports:

The livestock sector depends on imported protein feed from third countries. Given the price sensitivity of the consumer market, the livestock industry imports biotech enhanced soybean meal to reduce production costs. Poultry and pork producers are in favor of importing biotech feed and derived products for their production value. However, the general consumers' opinion towards the technology is negative with some consumer organizations and NGOs advocating for import restrictions on such feed.

Corn-derived products are not imported to Bulgaria. Bulgaria is not an importer of corn gluten feed (CGF) or Distillers' Dried Grains and Soluble (DDGS). The local feed industry is not too familiar with either product. In addition, the supply of locally produced corn is in abundance.

e) Food Aid Recipients Countries:

Bulgaria is not a food aid recipient country. In the 1990's, the country used to accept food aid. One food aid program imported and monetized U.S. soybean meal. It is not known if the product was GE.

Part B: Policy

a) Regulatory Framework:

(i) Responsible government ministries:

Bulgaria undertook a reform and established a single Bulgarian Food Safety Agency (BFSA) in 2011. The BFSA had a Risk Assessment Center to review all studies, policies, and decisions related to biotechnology. The center has researchers on-staff involved in biotech-related work. In 2014 and in 2015 to date the BFSA has been adopting EFSA positions and has been recommending either a positive or a neutral position to the Ministry of Agriculture (MinAg) on biotech-related matters. In the second half of 2013 and in 2014 to date, BFSA modified its approach and most of its recommendations were neutral to negative.

In April 2015 the MinAg initiated a major reform in the food safety legislation and related regulations to respond to the reform in this area at the EU level. Reportedly, the new reform should affect the biotech legislation as well but it is still unknown how. The first draft of the new Food Act is expected in the fall of 2015. Currently there are ongoing consultations on this issue with the industry groups and NGOs. The role and the functions of the Risk Assessment Center might change as a result of the new legislation but the consultations are still ongoing.

Local legislation did not provide any formal participation of NGOs in BFSA biotech work although the BFSA policy has been to take all GE-related decisions after public debate. The Coalition "Bulgaria free of GMOs," which united green and organic NGOs, demand active participation in BFSA work to guarantee the "civil society" voice in decisions of this institution.

(ii) Biosafety Board:

Legislation created a Bio-safety Commission within the Ministry of Environment to discuss biotech-related matters and to make recommendations to the Minister of Environment. The Commission consists of scientific and non-governmental organizations.

(iii) Political factors/influences:

Biotechnology Legislation:

In 2010 Bulgaria passed the Biotechnology legislation, commonly referred to as the "genetically modified organism" ("*GMO*") law, that governs biotechnology and that establishes the basis for a regulatory framework which is one of the most restrictive in the European Union (EU). This Law is recognized as pushing the legal limits under European and World Trade Organization (WTO) guidelines. See FAS GAIN report BU1216 dated 06/08/2012 for more details.

In April 2012 the EC notified Bulgaria to revise its legislation on biotechnology related to transposition of Directive 2009/41 on contained use of plants and plant products derived from GE (2010/2152 C(2012) 2588 of April 26, 2012 on Infringement #2010/2152). The EC considered the transposition of this directive as incorrectly completed. The EC encouraged Bulgarian authorities to revise Art.17/1 by including activities related to agricultural biotechnology without a risk for human health and environment. In this way Bulgaria could harmonize local legislation with Directive 2009/41 thus eliminate the risk of sanctions due to infringement. Under the Law, Art.23 required all GE-related work to be executed in premises (or other words laboratories) registered with the Ministry of Environment and Water Resources even in cases when this work does not pose any health/environmental risks. In response, Bulgarian authorities suggested amendments to the Law which had been developed and announced publicly on December 3, 2013 as follows:
http://www.moew.government.bg/?show=konsultacii&kid=89.

The same amendments to the Law also suggested changes related to full harmonization of local legislation with Directive 2004/35 which references ecological responsibility related to prevention and elimination of environmental damage. The Bio-safety Commission received through amendments to Art.6/2 and 6/3 additional members: Consumer Protection Commission, Executive Agency on Environment, Bulgarian Food Safety Agency, Executive Pharmaceutical Agency etc. The Bio-safety Commission also received authority to hire, on a case-by-case basis, up to three outside scientific experts with voting rights. These amendments entered into force in early 2014.

Other biotechnology related legislation which has been passed over the past year includes: Amendments to the Feed Act (#202-01-58) November 2012 which aimed to harmonize local legislation with certain EU regulations in the area of feed safety and traceability (Regulation 619/2011; Regulation 1069/2009; Regulation 142/2011, Regulations 1830/2003 and others). The Feed Act made trade in feed containing GE even stricter then before and increased the fines against illegal trade/trade with improperly labeled feed products.

The Feed Act, published in Official Gazette #97/December 7, 2012, under Decree 415 approved by the Parliament on November 23 same year:
http://dv.parliament.bg/DVWeb/showMaterialDV.jsp?idMat=70784

Bulgaria Voting Position on Biotechnology-related issues in the EU

During 2014 and 2015 to date Bulgaria's political approach has been to "abstain" or vote "against" on issues such as biotechnology for various reasons including public pressure from green groups. Since the anti-biotech campaigns in the winter 2009/10, the country has issued no positive vote on biotechnology with the exception of the legislation on the technical solution (defining zero for low-level presence) in feed. The "abstain" positions have been because the country had no local research experiments or studies to provide sufficient evidences for or against respective cases.

In 2014 the Ministry of Environment and Waters and the Ministry of Agriculture and Foods voted "against" the approval of GE corn 1507. Then Agricultural Minister Grekov's position was firm not only against corn 1507 but also against all GE protein crops. The Ministry of Agriculture also supported production of non-GE soya. In the fall of 2013 Bulgaria joined the Danube Soya initiative (see FAS GAIN report BU1356 dated 12/04/2013 for more details).

On April 24 2014 at EC- Standing Committee on the Food Chain and Animal Health session, Bulgaria voted against approval of T25 corn and MON87709 soybeans. On May 23 Bulgaria voted against the DuPont/Pioneer Plenish product. At the EC Appeals Committee on June 10 Bulgaria voted against Plenish and 4 more biotech products.

In May/June 2015 the Cabinet had to formulate its position on EC proposal for Member States to restrict or prohibit "opt-out" from the use of GE food and feed on their territory. It questioned various aspects of the EC proposal such as the breach of common market principles, the principle of competitiveness and some pending legal issues. The industry unanimously supported a position against the proposal as detrimental for the feed and dairy/poultry/livestock industries, and even for the grain trade. Bulgaria may oppose the EC proposal if consultations with the industry take place as currently planned. (see FAS GAIN report BU1517 dated 06/03/2015 for more details)

Current Cabinet Program:

The current Cabinet (since October 2014) program has two major priorities – support for the horticulture sector and support for the dairy/livestock sectors. This is a major shift compared to the period 2007-2014 when the domestic support policies were more focused on field crops. The new policy makes the issue of feed availability and its price and competitiveness very important. This is likely to affect the national positions on any policy positions related to feed trade. The Cabinet also continued to support the organic sector that is eligible for specific support under the Common Agriculture Policy and demonstrated willingness to invoke various policies in order to protect markets to encourage more local production.

(iv) Differing treatments between food and feed:

Treatments of food and feed differ as per EU legislation.

(v) Pending legislation:

There is pending legislation as described above in Part B/Policy/ iii- Biotechnology legislation.

b) Approvals:

Bulgaria accepts EU approved GE products for food, feed, and industrial use. However, a safeguard clause is imposed on MON 810.

c) Field Testing:

No field testing is conducted in country. The biotechnology law does not explicitly prohibit field testing but introduced conditions which make this impossible in practice.

d) Stacked Events Approvals:

Bulgaria follows EC policy in this respect.

e) Additional Requirements:

Bulgaria's 2010 biotech law prohibits growing — for research or commerce — biotech crops in all protected areas. Protected areas cover approximately 34 percent of the country's territory. The ban also extends to the surrounding area within 30 km of the protected territory (which ultimately covers the entire country and effectively bans all biotech crop trials and production), within 10 km of beehives, and within 7 km of land where organic crops are cultivated. These conditions leave no available place in the country for any field trials. The Ministry of Environment and Waters published a map showing the areas of protected areas together with respective buffer zones as follows.
http://www.moew.government.bg/files/file/Nature/Biodiversity/Tatiana/GMO_buffer.pdf

There are also additional restrictions on sales of foods with GE ingredients (see g/Labeling).

f) Coexistence:

The biotechnology law contains coexistence requirements as stated in Attachment 2 to Art. 51/4 and Art.71/3 in a list of distance from which GE crops should be kept. Distances vary from 20 meters (soybeans, flax, and peanuts) to 6,000 meters for sunflower. The distance for corn is 800 meters.

g) Labeling:

Bulgaria has two regulations (amendments to the Food Law) imposing requirements on labeling and a ban on sales of foods containing GE products in schools, kindergartens and nurseries.

The first amendment to the Food Law was published in Official Gazette #59, dated July 31, 2010. It bans use of GE products in baby food (art 5/ 4) and sales of any food containing GE products in nurseries, kindergartens and in retail outlets around them (in radius of 100 meters) - art. 5/5. The ban is valid for all GE products regardless of whether or not they are approved by EC. The same is valid for

sales of food with GE ingredients. In addition, sales of any food containing GE materials should be done on explicit, clearly separated shelves or stand at the retail level (art. 19). The fines for violations were increased to unheard levels of U.S. $25,000 and U.S. $34,000.

The second amendment calls for special labels on GE foods when the threshold is above 0.9 percent with a clear identification of the exact quantity and type of the GE event (art. 10/2). This marking should be not less than 25 percent of the package, in capital letters and in contrast color. Food service outlets have to declare if the products they cook contain GE products even if the final products may not contain GE products in a changed form (art.12/3-5). Imports of GE foods should be accompanied by documentation with lab analysis about the exact quantity of GE and the exact event (art.24/4).

h) Trade Barriers:

The biotechnology issue has not had an impact on production and trade in conventional hybrid corn seeds for planting. Seed companies secure non-biotechnology enhanced planting seeds for the market produced in other EU Member States, Turkey and/or the U.S.

i) Intellectual Property Rights (IPR):

Bulgaria follows international norms on IPR although violations occur.

j) Cartagena Protocol Ratification:

Bulgaria is a signatory to Cartagena protocol and the Parliament ratified the protocol on July 19, 2000.

k) International Treaties/Fora:

Bulgaria is a member of Danube Soya initiative since November 2013 (see BU1356). Several outreach and training events occurred during the past year with the emphasis on growing non-GE soybeans and prospects for trade in the EU.

l) Related Issues:

Bulgaria usually takes a neutral or a conservative position regarding new breeding technologies.

m) Monitoring and Testing:

In the spring of 2015, the BFSA reported that from over 100 food/feed samples tested during the past year for GE content, all were negative.

n) Low-Level Presence Policy:

Bulgaria follows EU policy on LLP.

Part C: Marketing:

a) Market Acceptance:

Market acceptance at the end-consumer level is negative. Majority of consumers have strong anti-biotech attitude without having proper knowledge or information, often accompanied by a number of myths. Sometimes it goes beyond common sense to anecdotal extremes. At a farmer level, feed and livestock producers are well aware about the availability and prices of non-GE and GE protein feed and the world market situation. Due to high price sensitivity of local consumers, most if not all imported protein feed is GE.

b) Public/Private Opinions:

Public opinion is negative towards agricultural biotechnology, and is unduly influenced by green, organic, health and consumer organizations. Surveys show consumers against any food products containing biotech components. The media does not publish anything in support of biotechnology. Political parties do not show public support for biotechnology. Farm organizations are not united on biotech issues. For example, the powerful Grain Producers Association is against biotechnology given the lack of secure markets in the EU and the stringent non-GE event requirements of their major local corn buyer, a starch manufacturing facility. Researchers are few, underfunded, and are not united in their position.

The new administration undertook major reform in agricultural R&D in 2015. The Agricultural Academy which united about 25 research institutes will be reformed and draft legislation is being prepared to provide more independence to the research teams. Another goal is to encourage more project-based financing and research. It is believed that expected financial autonomy will encourage stronger cooperation with the EU and other foreign research institutions, including cooperation in biotech research. The legislation is currently for discussions and consultations at the Parliament and is expected to be voted before the fall.

c) Market Studies:

There are no market studies about GE products.

Part D: Capacity Building and Outreach

a. Activities:
Post activities over the year focused on outreach developments relative to plant biotechnology. These included meetings, visits, and seminars for U.S. and EU visitors (Europa Bio visits in the fall of 2014 and in May 2015, industry research, and farm organizations representatives), aiming to facilitate bilateral information flow, and understanding.

b) Strategies and Needs:

The following strategy for plant biotechnology capacity building and outreach is being applied:

- Provide unbiased, scientific information regarding imported animal feed and EU and world market of feed grains and protein feed including the latest product innovations, trends and their economic impact;

- Promote rational policies towards biotechnology including that for adventitious presence of non-approved biotech events and that for acceptability of products from animals fed with biotech-enhanced feed.

Chapter 2: Animal Biotechnology:

Part E: Production and Trade

a. Product Development:

Bulgaria has not pursued genetic engineering involving farm livestock.

b) Commercial Production:

Not applicable.

c) Exports:

Not applicable.

d) Imports:

Bulgaria does not have a system to monitor the imports of GE animals and cloned offspring or genetics from clones. Not applicable.

Part F: Policy

a) Regulation:

The Ministries of Agriculture and Health are the governing entities charged with regulating such technology.

b) Labeling and Traceability

Currently there are no labeling and traceability requirements for GE animals or cloned products

c) Trade Barriers:

There are no known trade barriers

d) Intellectual Property Rights (IPR):

There is no public information on IPR on these technologies.

e) International Treaties/Fora:

Bulgaria is not known to be a member of any international group that supports or opposes GE animals or cloning.

Part G: Marketing

a) Market Acceptance:

Not applicable

b) Public/Private Opinions:

Not applicable

c) Market Studies:

Not applicable

Part H: Capacity Building and Outreach

a) Activities:

Not applicable

b) Strategies and Needs:

Not applicable