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Report Highlights:

Bosnia and Herzegovina (BiH) allows permitted import of genetically engineered (GE) products based on the 2009 Law on “Genetically Modified Organisms” (“GMOs”) and its pertaining bylaws. To date, the first and only GE product approved for import is GE soybean meal for feed. BiH’s anti-GE border practices, which include random testing, can occasionally influence commercial imports of grains. Knowledge about agricultural biotechnology is still very limited, even among scientists and agricultural officials. The policy makers and farmers’ main concern is that the country’s export markets could be threatened if GE production were allowed in the country.

Executive Summary:

Bosnia and Herzegovina (BiH) imports approximately two-thirds of its overall food needs. Its principal trading partners are neighboring countries such as Croatia, Serbia, and European Union (EU) countries. Imports of U.S. agro-food products have been limited and mainly consist of bulk commodities and some intermediate products (animal/vegetable fats and oils, nuts and fruits).

Although there has not been much trade between BiH and the United States, reservations towards U.S.-origin foods appear to have increased over the last ten years. Generally, these impressions seem to be tied to fears about genetically engineered (GE) foods, seeds, and feed.

Soybean meal is currently the only GE product imported. No GE crops are cultivated in BiH. A regulation outlining the process for approving GE field trials and cultivation is still missing from the legislation.

BiH neither exports nor imports GE animals, livestock clones, nor products from these animals. No GE animals or cloned animals are being developed in BiH for agricultural livestock production.

GE products are viewed as undesirable in BiH. The anti-GE position of many EU Member States has influenced both regulators and consumers, but it is not the only reason for BiH's resistance. Both the government and farmers tend to think that organic production is an important economic segment of BiH's agriculture. In BiH, traditional agricultural production practices predominate, and the use of agrochemicals/pesticides is generally lower than elsewhere in Europe due to cost. There are also few industrial polluters, allowing for organic production. Many agricultural policy makers believe the country's export markets, especially its organic export markets, would be threatened if GE production were allowed.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: BiH does not produce GE crops, and there are no GE crops under development in BiH.

b) COMMERCIAL PRODUCTION: There is no commercial production of GE plants in BiH.

c) EXPORTS: BiH does not export GE plants or products thereof.

d) IMPORTS: Genetically engineered products may be imported, following the passage of the amended regulation of 2015, but they must first be approved by the Food Safety Agency (FSA).

In 2014, several feed importers applied to BiH's FSA for permits to place GE feed on the market, but were rejected by FSA's advisory body, the "GMO" Council. The Council stated that the applications were incomplete and requested a full application from the GE crop developer as if the crop were going to be cultivated, not just consumed as animal feed. However, many developers are reluctant to share their proprietary information or shoulder the expense of preparing applications for such a small market, especially when they would not be selling seeds for cultivation.

Meanwhile, the inspection authorities began testing and rejecting shipments of GE soybean meal. This caused traders and farmers to protest due to the lack of affordable feed in the country. As a result, in July 2015, the BiH Council of Ministers adopted the Amended Bylaw on the Conditions and Procedures for Issuance of Approvals for Placing "GMO" Food and Feed on the BiH Market for the First Time and the Conditions Regarding their Traceability and Labeling. The amended ordinance allowed importers to seek authorization from the FSA by submitting basic documentation for GE products that have been reviewed and approved by the European Food Safety Authority (EFSA). However, even for the EU-approved GE products, companies that wish to import

and market GE products in BiH must obtain a formal permit from the FSA. To date, BiH's FSA has issued approvals to 36 importers for placing GE soybeans (MON-Ø4Ø32-6) on the market for animal feed use.

BiH annually imports approximately 55,000 metric tons (MT) of GE soybean meal (largely from Brazil) and produces around 20,000 MT of non-GE soybeans. Production of soybeans has tripled over the last five years because of BiH's active participation in the "Danube Soya Initiative" (an international non-profit association that promotes sustained GE-free soybean cultivation in Europe <https://www.donausoja.org/en/home/>) and subsidies provided by the agricultural ministries to soybean producers.

e) FOOD AID: BiH is not a food aid recipient or donor. Nor is BiH provide food aid to other countries.

f) TRADE BARRIERS: The BiH public often criticizes the inspection authorities for not conducting more testing of U.S. products for GE presence. Currently, agri-food imports from the United States are not significant, but should they increase, it is expected that testing will also increase. Traders and inspectors informed Foreign Agricultural Service (FAS)/Sarajevo that adding a non- "GMO" statement on the export certificate can speed up a shipment's clearance, especially for wheat shipments.

PART B: POLICY

a) REGULATORY FRAMEWORK: After a five-year moratorium on GE products, which was introduced with the 2004 Food Law, a new Law on Genetically Modified Organisms (GMOs) was adopted in 2009. The law was in line with EU regulations and it technically permitted the licensed use of GE products, but adoption of the implementing bylaws took several years. In August 2015, BiH Food Safety Agency issued the first permits for import and marketing GE feed. Before that, GE feed was likely imported into the country on a regular basis since approximately 90 percent of the global soybean supply and 60 percent of the global corn supply are GE. BiH farmers depend on these imports for livestock feed.

The main laws that regulate agricultural biotechnology are the Food Law (BiH Official Gazette # 50/04) and the Law on Genetically Modified Organisms (BiH Official Gazette #23/09). The Law on Genetically Modified Organisms is an overarching law for biotechnology. This law sets the conditions for limited use, importation, deliberate release into environment, and marketing of plant products that are composed of "GMOs," contain "GMOs," or are derived from "GMOs."

The Food Safety Agency (FSA) is the national umbrella agency and coordinating body for all agricultural biotechnology issues. In addition to the FSA, other responsible agencies include the national State Veterinary Office (SVO), the national Plant Health Administration (PHA), and the entity-level and canton-level ministries of agriculture, health, and environment. The FSA is responsible for placing GE food and feed on the market. The PHA is responsible for approving GE seeds and seedlings and plant protection chemicals, but first the entity and canton agricultural authorities and the Brcko District agricultural authorities must approve the product.

The SVO is responsible for approving veterinary medicines and genetic materials containing GE products.

The ministries of agriculture, health, and environment are responsible for regulating the contained use of “GMOs” or the deliberate release of “GMOs” into environment; however, they have not drafted any regulations.

The Ministries of Health and the Brcko District Health Department are responsible for approving cosmetics and pharmaceutical products containing “GMOs.” The entity and cantonal inspectorates, and the Brcko District inspection department are responsible for checking proper labeling of GE products placed on the market.

The law on “GMOs” sets general guidelines for the issuance of “GMO” permits. The following bylaws further regulate this area:

- The Bylaw on the Conditions and Procedure for Issuance of Approvals for Placing “GMO” Food and Feed on the BiH Market for the First Time and the Conditions Regarding their Traceability and Labeling
- The Bylaw on the Content of the Application and the Technical Documentation for Placing on the Market, and the Conditions for Labeling and Packaging of “GMOs” or Products that Contain or are Derive from “GMOs”
- The Bylaw on the Methods for Maintenance of a Common Register for “GMOs”
- The Bylaw on the Establishment of a System for the Development and Assignment of Unique Codes for “GMOs”
- The Bylaw on the Content and Scope of the Risk Assessment for Placing “GMOs” or Products that Contain or are Derive from “GMOs” on the Market and the Methodology for a Risk Assessment
- The Bylaw on Conditions of Monitoring the Environmental Impact of” GMOs” or Products Containing and/or Consisting of or Originating from “GMOs.”

The above-mentioned bylaws, or rulebooks, are harmonized with EU GE regulations and directives.

The FSA will process all permits in cooperation with the “GMO” Council and other responsible institutions. A risk assessment will be required with the request for a permit to import or place a GE food or feed product on the BiH market. Only legal entities authorized by the Council of Ministers, on the proposal of the FSA, can undertake a risk assessment. The responsible authority prescribes the content and scope of the risk assessment, the assessment methodology, as well as the conditions to be met by a legal entity for the development of risk assessment. According to the Law on “GMOs,” issuance of permits can take from 90-105 days.

The law on “GMOs” established a “GMO” Council to assist the responsible BiH institutions with enforcement. The “GMO” Council is a public independent body with a four-year mandate consisting of seven members from the fields of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacology, biotechnology, agriculture, forestry, veterinary medicine, environmental protection, and occupational protection. The main tasks of the “GMO” Council are: to advise on GE usage in terms of legal procedures as outlined by the law on “GMOs;” to give opinions and proposals on draft legislation on “GMO” use; to provide opinions and proposals to

responsible ministries on GE use issues and other expert work as outlined by the law on “GMOs” and related regulations; to follow gene technology developments and use; to follow scientific progress in this area; to advise on social, ethical, technical, scientific and other conditions for “GMO” use; and to inform the public using media and professional forums on the status of gene technology developments and use. The “GMO” Council publicly reports annually to the FSA and to the Council of Ministers.

b) APPROVALS: The FSA of BiH has approved MON-Ø4Ø32-6 GE soybeans for import for animal feed. No GE seeds or planting material have been approved for cultivation or for confined field trials.

c) STACKED or PYRAMIDED EVENT APPROVALS: BiH’s existing regulations do not have any special provisions to deal with stacked events. The “GMO” Council has yet to discuss this issue.

d) FIELD TESTING: There are no field tests of GE plants being conducted. The 2009 “GMO” Law established the general guidelines to allow for the intentional release of GE products into the environment and field trials, under license, but the detailed regulations on licensing are still missing. The University of Sarajevo/Faculty of Agriculture and Food Science (FAFS) began the process of seeking permission to conduct field trials of a GE plum (the ‘HoneySweet’ plum which is resistant to the plum pox virus [Sharka]), asking for clarification on the application procedure.

The “GMO” Council’s opinion related to the plum field trial is that it represents a deliberate “GMOs” introduction into the environment, and therefore the competent authorities should draft and adopt a clear procedure for submitting a request for deliberate introduction of “GMOs” into the environment. However, the Council also concluded that the “GMO” control system at all levels in BiH it is not functional and recommend that the competent authorities should first amend and harmonize BiH’s legislation with the latest EU legislation before any other action.

e) INNOVATIVE BIOTECHNOLOGIES: The country has not determined the regulatory status of innovative biotechnologies at this time.

f) COEXISTENCE: The Law on “GMOs” forbids planting of crops derived from modern biotechnology in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, and in protected areas (i.e. defined as registered protected impact zones). In addition, GE crop planting for reproduction is allowed only in areas that are approved by the Council of Ministers based on FSA’s recommendations. In cases where the Law on “GMOs” cannot be applied, the Food Law and the bylaws derived from that law will apply.

g) LABELING: The Law on “GMOs” says that food products that contain or are composed of “GMOs” must be labeled as follows:

- For individually packaged products the label on the packaging should read: “This product contains ‘GMO’ components” or “This product contains genetically modified (name of organism).”

- For bulk packaged products the label should read “This product contains ‘GMO’ components” or “This product contains genetically modified (name of organism)” and should be placed directly on the product or near the product (as it is being sold).

The labeling threshold is set at 0.9%, meaning that products containing approved GE events at levels above 0.9%, per ingredient, of the product must be labeled.

The Law on Seeds and Seedlings (BiH Official Gazette # 3/05) only mentions that GE seeds and seedlings must be labeled.

In 2017, the FSA adopted a voluntary standard for “GMO-Free” foodstuff and issued guidelines for production and labeling of foodstuff produced without “GMOs.” Plant or animal origin products that will be labeled as “GMO-free” must be produced using raw materials and additives that are not GE nor derived from GE products. Compliance checks with the “GMO”-free label will be carried out according to the guidelines for the control of production of “GMO”-free products, which uses a risk-based model. So far, table eggs and vegetable oils are only products certified as “GMO –free.” BiH created its standard within the framework of the “Danube Soya Initiative” (an international non-profit association that promotes sustained GE-free soya bean cultivation in Europe), and with the support of the Austrian Federal Environment Agency and German Organization for International Cooperation (GIZ).

h) MONITORING AND TESTING: The following four laboratories have been authorized to perform GE testing:

- The Biotechnology Laboratory of the Agricultural Institute in Banja Luka;
- The “GMO” Laboratory of the Federation Agro-Mediterranean Institute in Mostar;
- The Laboratory for “GMOs” and Food of the Institute for Genetic Engineering and Biotechnology in Sarajevo;
- The “GMO” Laboratory of the Federation Agricultural Institute in Sarajevo.

In 2013, via a World Bank loan, the Sarajevo and Banja Luka Agricultural Institutes received equipment worth \$300K to test for GE presence. Using this new equipment, the laboratories can use Real-Time Polymerase Chain Reaction (PCR) technology to detect not only the presence of GE events, but also the amount of the GE event present in the food and feed samples. The labs can conduct an event-specific detection to identify the GE event. The Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana in Italy currently is the designated reference laboratory to do GE testing.

i) LOW LEVEL PRESENCE (LLP) POLICY: BiH has no LLP policy. The “GMO” Council has stated that BiH’s regulation is currently harmonized with the EU regulation and that BiH will keep following the EU guidelines on this subject in the future. The EU does not have an LLP policy. It has a “technical solution” that defines zero as outlined in EU Regulation 619/2011. This regulation lays down the methods of sampling and analysis of official control of feed regarding the presence of GE products for which an authorization procedure is pending or the authorization has expired. The allowance is 0.1 percent.

j) ADDITIONAL REGULATORY REQUIREMENTS: Seeds can be imported only if the varieties are recognized in the country. The National List of Recognized Varieties (BiH OG #59/10) is available at the Plant Health Administration. If a variety is not on the list, importers must request its recognition from the Seeds Commission.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): The Law on Industrial Property Rights (BiH Official Gazette No. 3/02) and the Law on Copyrights (BiH Official Gazette 7/02) protect trademarks and brand names. Domestic and foreign applications must be submitted to the BiH Institute for Intellectual Property. According to research done by the U.S. Foreign Commercial Service, intellectual property rights (IPR) are often inadequately enforced and intellectual property, patents, copyrights and trademarks inadequately protected. In 2010, BiH adopted and put into force a new IPR framework that consists of seven laws. This new legislation is compliant with the Agreement on Trade-Related Aspects of IPR (TRIPS) and EU regulations and includes laws on copyrights, patents, trademarks, geographical indications, and the topography of integrated circuits. Although existing legislation provides a basic level of protection, stronger enforcement is sought. Jurisdiction over IPR investigations is split between customs officials, entity inspectorates, and state and entity law enforcement agencies, and no institution has specialized IPR investigation teams. IPR crimes are prosecuted primarily at the state level.

l) CARTAGENA PROTOCOL RATIFICATION: BiH is party to the Cartagena Biosafety Protocol. It was ratified on October 1, 2009, and it entered into force on December 31, 2009. The country's necessary legal, administrative and other measures for the implementation of the Protocol are partially in place, and a mechanism for budgetary allocations for operating its national biosafety framework is missing. Detection and identification of living modified organisms are done to some extent, but there is a lack of proper risk assessment and risk management, as well as information exchange and data management. There is no mechanism addressing emergency measures in case of unintentional trans-boundary movements, and public awareness and education on biosafety are missing.

m) INTERNATIONAL TREATIES/FORUMS: The country does not actively participate in discussions related to GE plants within the International Plant Protection Convention (IPPC) or the Codex Alimentarius (Codex).

n) RELATED ISSUES: No additional information.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Knowledge about agricultural biotechnology is inadequate even among scientists and agricultural officials. There has been a lack of attention on the issue of agricultural biotechnology. Additionally, the level of biotechnology acceptance has decreased over the last five years due to reporting on EU attitudes and the anti-GE views held by neighboring countries, such as Croatia and Serbia. Occasionally, the media and consumer associations criticize BiH authorities for not having better controls of imported foods with GE content and for approving the import of GE commodities.

Agriculturists and non-governmental organizations that promote organic agriculture are vocal biotech opponents of biotechnology and have influenced producers, consumers, and regulators to reject GE products.

BiH currently has 71 certified organic producers, of which 18 can export to the EU market. The single BiH certification body, "Organic Control" (OK), mainly certifies, wild berries, medicinal herbs, raspberries and greenhouse-produced peppers and tomatoes. Essential oils, jams and juices are also certified organic, as well as the Bosnian traditional flat bread "somun." In 2017, exports of organic products reached \$4.7 million and local experts believe organic products have great export potential.

b) MARKET ACCEPTANCE/STUDIES: The market acceptance of GE products for producers, importers, retailers, and consumers is officially unknown. A recent German Organization for International Cooperation (GIZ) study showed 70 percent of surveyed BiH consumers were against GE food products. The survey results were presented on September 23, 2016 at an event organized by the BiH Food Safety Agency in cooperation with the Foreign Trade Chamber and GIZ. The event was an activity of the GIZ project "GMO-free high-quality soybeans from the Danube Region" with the objective of informing the public of the current situation with GE products in BiH, its imports, the perception of consumers, and an initiative to introduce labeling of non-GE food in BiH. "Danube Soya" is an international non-profit association based in Vienna, founded in 2012 with the goal to promote sustained GE-free soya bean cultivation in Europe. The GIZ survey also showed that approximately 90 percent of surveyed consumers (1000 respondents) are willing to pay more for non-GE foodstuff. This research showed a low level of awareness and knowledge about GE foods among BiH citizens, even among the youth.

The most current survey of 1,000 consumers conducted in BiH within the "Danube Soya" initiative showed that that 60 percent of consumers did not know if import of "GMOs" into BiH was allowed and 70 percent was unsure if "GMOs" were grown in BiH. Allegedly, 90 percent of consumers wanted each packaging of meat, milk and eggs to indicate if animals were fed with "GMO" or non- "GMO" feed.

Conversely, according to unofficial FAS - conducted survey, the more sophisticated consumers think that they do not have enough information to be for or against GE products and believe they need more reliable sources of education. More information from credible sources could positively change consumer attitudes towards agricultural biotechnology, as currently the more knowledgeable consumers say they would eat GE foods after proper testing and labeling, if given enough information to make an informed decision.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Animal genetic engineering and genome editing result in the modification of an animal's DNA to introduce new traits and change one or more characteristics of the animal.

Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is therefore different from the genetic engineering of animals (both in the science and often in the regulation of the technology and/or products derived from it). However, since researchers and industry use cloning along with other animal biotechnologies, it is included in this report.

PART D: PRODUCTION AND TRADE

- a) PRODUCT DEVELOPMENT: Genetic engineering and cloning are not being developed in BiH for the production of agricultural animals.
- b) COMMERCIAL PRODUCTION: The livestock sector in BiH is not actively employing the use of GE animals or products derived from GE animals or clones.
- c) EXPORTS: BiH does not export GE animals, livestock clones, or products from these animals.
- d) IMPORTS: BiH does not import GE animals, livestock clones or products from these animals, although it is unknown whether any imported genetic material was produced with modern biotechnology techniques or originated from clones or from the offspring of clones.
- e) TRADE BARRIERS: No additional information.

PART E: POLICY

- a) REGULATORY FRAMEWORK: BiH has no laws or regulations relating to the development, commercial use, import, and/or disposal of GE animals and clones, or products derived from these animals, and currently there are no plans to draft such regulations. The Law on “GMOs” does not apply to animals.

The relevant government entities that likely would have a role in the regulation of GE animals are the State Veterinary Office and the Food Safety Agency, but to date there have been no active discussions about these products or by-products nor were they mentioned in the “GMO” Law. As BiH is harmonizing its regulation with the EU regulation, the country will keep following the EU guidelines on this subject in the future.

- b) APPROVALS: No approvals have been granted for these products.
- c) INNOVATIVE BIOTECHNOLOGIES: The country has not determined the regulatory status of innovative biotechnologies at this time.
- d) LABELING AND TRACEABILITY: There is no policy on labeling and traceability of GE animals and their products, and clones.
- e) INTELLECTUAL PROPERTY RIGHTS (IPR): The country is not considering legislation to address IPR for animal biotechnologies.

f) INTERNATIONAL TREATIES and FORUMS: The country does not actively participate in discussions related to GE animals and clones within the Codex and the World Animal Health Organization.

f) RELATED ISSUES: No additional information.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: There have been no public campaigns and almost no media reports on this topic in BiH.

b) MARKET ACCEPTANCE/ STUDIES: There is only very little awareness of GE animals or cloning in BiH. The market acceptance of GE animals and clones for producers, importers, retailers, and consumers is unknown. There are no specific marketing studies regarding GE animals and/or cloning use or acceptance.

Attachments:

No Attachments