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Bosnia and Herzegovina

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Report Highlights:
After a five-year moratorium on genetically modified organisms ("GMOs") that was imposed with the 2004 Food Law, Bosnia and Herzegovina (BiH) adopted the Law on Genetically Modified Organisms in 2009 setting up the framework for approval of imports and field releases of products derived from agricultural biotechnology. It took three more years for BiH's Council of Ministers to adopt the five implementing rulebooks regarding the specific procedures to import and market genetically engineered (GE) products yet the regulation outlining the process for approving GE cultivation is still missing. BiH's anti-GE border practices, which include random testing, can occasionally influence commercial imports. 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. Report updated: July, 2015.

REPORT CONTENT

Section I. Executive Summary: Bosnia and Herzegovina (BiH) imports around 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 & 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 GE foods, seeds, and feed.

BiH recently started adopting regulations that govern GE products. The 2004 Food Law did not allow GE products to be imported or marketed pending implementing regulations. However, these regulations were never drafted; instead, a new Law on Genetically Modified Organisms ("GMO") was adopted in 2009. The new Law was intended to bring BiH's legislation in line with the EU regulations and it technically permitted the licensed use of GE products. However, only recently were most of the bylaws completed to define the approval process. Until these procedures were approved, no GE products could be allowed officially into the country and, to date, no licenses have been issued yet.

As of December 2014, seven feed importers have applied to BiH's Food Safety Agency (FSA) for permits to place GE feed on the market. All of the applications were rejected by FSA's advisory body, the "GMO" Council, as being incomplete. The Council has requested a full dossier from the GE crop developer as if the crop were going to be cultivated, not just consumed as animal feed. Trade policy officials understand this position is likely to affect adversely BiH's livestock sector and thus favor grandfathering in EU approved GE events solely for food and feed use. However, the current stance of the "GMO" Council is that dossiers must be supplied equivalent to seeking approval to cultivate the crop. Although no GE crops have been approved for marketing in BiH, it is likely GE feed is imported on a regular basis as approximately 90 percent of the global soybean supply and 60 percent of the global corn supply is GE and BiH farmers depend on these imports. Active enforcement of the "GMO" law would stop feed imports and leave BiH farmers without affordable feed.

Generally speaking, GE products are viewed as undesirable in BiH due to a lack of consumer knowledge and negative media stories from some EU countries. The more sophisticated consumers on

the other hand, 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.

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. There are also few industrial polluters. Many agricultural policy makers believe the country's export markets, especially potential organic export markets, would be threatened if GE production were allowed. Recently BiH's anti-GE position has influenced commercial imports of grains. Although still infrequent, BiH randomly tests grain imports for GE content and has recently rejected soybean meal from Brazil because it was GE and did not comply with the import requirements.

Section II. Plant and Animal Biotechnology

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: Officially, no GE crops/products have been approved for feed/food or seed use. Genetically engineered products may be imported, following the passage of the new regulation, but they must first be approved by the FSA. Even products with EU approved events must pass through the BiH approval process. Currently, the FSA has seven pending requests to place GE soybean meal/feed on the market. The FSA's advisory body, the "GMO" Council, has rejected all of the applications as being incomplete. The Council has requested a full dossier from the GE crop developer as if the crop were going to be cultivated, and many developers are reluctant to share their proprietary information or shoulder the expense of preparing a dossier for such a small market, especially when they will not be selling their product (the seeds for cultivation). Meanwhile, GE feed is likely being 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 is GE and BiH farmers depend on these imports. Active enforcement of the "GMO" law would stop feed imports and leave BiH farmers without affordable feed. One solution would be to grandfather in EU approved GE events for food and feed use only, as these products have already been reviewed by the European Food Safety Authority.

e) FOOD AID RECEPIENT COUNTRIES: BiH was a food aid recipient as part of the U.S.

Department of Agriculture monetization program from 1997 to 2003. During that period, some GE products were rejected as undesirable. For example, in 2000, U.S. corn offered as donation under the food aid/monetization project was rejected because it had GE content. Two years later, the Country accepted GE soybean meal imported from the United States as a donation only because it was approved for marketing in the EU.

PART B: POLICY

a) REGULATORY FRAMEWORK: 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 products that are composed of "GMOs", contain "GMOs", or are derive from "GMOs."

The Food Safety Agency (FSA) is the umbrella agency and coordinating body for all agricultural biotechnology issues. In addition to the FSA, other responsible agencies include the State Veterinary Office (SVO), the 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 entity 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 haven't started any activities on the regulation drafting.

The entity 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. Issuance of permits can take from 90-105 days, according to the Law on “GMOs.”

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 fora on the status of gene technology developments and use. The “GMO” Council publically reports annually to the FSA and also to the Council of Ministers.

b) APPROVALS: No GE plants or plant products have been approved for import or cultivation yet.

c) FIELD TESTING: Currently 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 Sciences (FAFS) has begun the process of seeking permission to conduct field trials of a genetically engineered plum (the ‘HoneySweet’) which is resistant to the plum pox virus.

d) STACKED EVENTS APPROVAL: BiH’s existing regulations do not have any special provisions to deal with stacked events. The “GMO” Council has yet to discuss how these will be handled in the future.

e) ADDITIONAL 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 can request its recognition from the Seeds Commission (request forms available at the Ministries of Agriculture, per the Law on recognition of agricultural varieties Federation BiH Official Gazette 31/00 and the Law on Plant Protection RS Official Gazette 13/97).

f) COEXISTANCE: Regarding the coexistence between GE and non-GE crops, 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. as 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 packaged products the label on the packaging should read: "This product contains 'GMO' components" or "This product contains genetically modified (name of organism)."
- For products that are not packaged 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 by the product.

The labeling threshold is set at 0.9%, meaning that products containing approved GE events at levels above 0.9% of the product must be labeled.
The Law on Seeds and Seedlings (BiH Official Gazette # 3/05) mentions only that GE seeds and seedlings must be labeled.

h) TRADE BARRIERS: No additional information.

i) INTELECTUAL PROPERY 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. BiH adopted and put into force a new IPR framework that consists of seven laws in 2010. 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.

j) 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 is 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.

k) INTERNATIONAL TREATIES/FORA: The country doesn't actively participate in discussions

related to GE plants within the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex).

l) RELATED ISSUES: No additional information.

m) MONITORING AND TESTING: The following four laboratories have been authorized to do 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 $0.3 million to test for GE presence. Using this new equipment, the laboratories will be able to use Real-Time Polymerase Chain Reaction (PCR) technology to detect not only the presence of GE events (as before), but also the amount of the GE event present in the food and feed samples. The labs will be able to 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, because until now none of BiH's domestic laboratories have had the capacity to conduct the testing.

The country currently only conducts random testing of GE products, but in the beginning of 2013 it started implementing a national "GMO" monitoring plan per the Bylaw on Conditions of Monitoring the Environmental Impact of Genetically Modified Organisms or Products Containing and/or Consisting of or Originating from Genetically Modified Organisms. The monitoring plan covers monitoring and surveillance of "GMOs," contained use of "GMOs," procedures relating to the deliberate release of "GMOs" into the environment, placing on the market of "GMOs" and products containing and/or consisting of or originating from "GMOs," and possible adverse effects, pursuant to the Law on "GMOs" and other regulations. The Food Safety Office hasn't made available yet officially the findings of the 2013 "GMO" monitoring plan. However, the FSA presented the findings to the Council of Ministers which demonstrated that 48 of the 50 feed samples and 26 of the 50 food samples tested positive for GE content. Although the media somehow obtained this information and publish it, there were no official actions taken to withdrawal from the market the products which were found to have GE content.

n) LOW LEVEL PRESENCE POLICY: BiH has no Low Level Presence (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.

PART C: MARKETING

a) MARKET ACCEPTANCE: The market acceptance of GE products for producers, importers, retailers, and consumers is officially unknown.

b) PUBLIC/PRIVATE OPINIONS: Knowledge about agricultural biotechnology is poor even among scientists and agricultural officials. The war caused widespread destruction and the country's economy is still weak. There has not been a lot of attention on the issue of agricultural biotechnology. However, overall, 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. Also, agriculturists and non-governmental organizations that promote organic agriculture have been vocal opponents and have influenced producers, consumers, and regulators to reject GE products. Occasionally, the media and consumer associations in BiH criticize BiH authorities for not having better controls of imported foods with GE content and for approving the import of GE commodities.

c) MARKETING STUDIES: There have been no studies regarding this topic.

PART D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES: In April 2014, the U.S. Embassy - Sarajevo in cooperation with the U.S. Agency for International Development's agricultural project "FARMA" and the University of Sarajevo, Faculty of Agriculture and Food Sciences (FAFS) conducted a series of GE outreach activities. The program was designed for BiH's regulatory authorities and small and medium-sized farmers to discuss a possible field trial for a GE plum ("HoneySweet"). Romanian researcher, Dr. Ioan Zagrai, who is currently testing the "HoneySweet" plum at Romania's Fruit Research Station in Bistrita and Dr. Fuad Gasi, FAFS' led the discussions on the proposed BiH field trials. Dr. Zagrai also took the opportunity to outline for FAFS the EU government approval process and to discuss the technical details surrounding the launch of a field trial for this type of GE product. Dr. Zagrai also met with the Council for "GMOs" to discuss the procedure for approving such a field trial.

b) STRATEGIES AND NEEDS: As BiH is still in the process of creating its regulatory structure for approving GE products, future informational events regarding scientific and productive evidence from the United States could have a positive impact. Possible topics would include the approval procedures for placing GE products on the market and the development of science-based requirements for the field trial application process.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal biotechnologies such as genetic engineering and therefore included in this report. Animal genetic engineering results 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).

PART E: PRODUCTION AND TRADE

a. BIOTECHNOLOGY 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. BIOTECHNOLOGY EXPORT/IMPORTS: BiH neither exports nor imports 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 off-spring of clones.

PART F: POLICY

a) REGULATION: 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 relevant government entities that likely would have a role in the regulation of GE animals are the SVO and the FSA, but to date there have been no active discussions about these products or by-products nor were they mentioned in the new "GMO" Law. As BiH's is harmonizing its regulation with the EU regulation, the country will keep following the EU guidelines on this subject in the future.

b) LABELING AND TRACEABILTY: There is no policy on labeling and traceability of GE animals and clones.

c) TRADE BARRIERS: No additional information.

d) INTELECTUAL PROPERTY RIGHTS (IPR): The country is not considering legislation to address IPR for animal biotechnologies.

e) INTERNATIONAL TREATIES/FORA: The country doesn't actively participate in discussions related to GE animals and clones within the Codex Alimentarius (Codex) and the World Animal Health Organization.

PART G: MARKETING

a) MARKET ACCEPTANCE: 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.

b) PUBLIC/PRIVATE OPINIONS: There have been no public campaigns and almost no media reports on this topic in BiH. It can be expected that the acceptance of GE animals and clones is negative.

c) MARKET STUDIES: There are no specific marketing studies regarding GE animals and/or cloning use or acceptance.

PART H: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES: There have been no outreach activities on GE animals or cloning so far.

b) STRATEGIES AND NEEDS: It might be useful to support in-country informational events involving U.S. scientific and/or agricultural production authorities to speak to the relevant BiH stakeholders and lead discussions on this topic between BiH authorities and the scientific community. A recommended topic would be development of science-based regulation on GE animals and clones.