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Bosnia Establishes Procedure for Licensed Import and Marketing of GMO Products

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Report Highlights:

Since the passage of the Food Law of November 2004, GMOs have not been permitted into Bosnia and Herzegovina's (BiH). The new Law on GMO, passed in spring 2009, permitted the importation of licensed GMOs. However, it took more than three years for BiH's Council of Ministers to adopt five implementing rulebooks that establish procedures to import and market biotech products. The regulation that would outline the process for approving biotech cultivation is still missing. BiH's anti-biotech position has influenced U.S. commercial imports, and several years ago the government even opposed biotech corn and soybean food assistance shipments. Knowledge about biotechnology is poor, even among scientists and agricultural officials. Agriculturalists and non-governmental organizations that promote organic agriculture oppose biotech applications and encourage producers, consumers, and regulators to reject biotech products. Report updated: July, 2012.

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. consumer products have been minor. However, a U.S. food donation program successfully imported U.S. bulk commodities, mostly wheat and sunflower seed oil. Although there has not been much trade between the two countries, reservations towards U.S.-origin foods has increased recently. Generally, these impressions seem to be tied to biotech applications, particularly to products containing either soy or corn.

BiH recently started adopting regulations that govern biotech products. Following the passage of the 2004 Food Law, importation and marketing of biotech products was forbidden due to the lack of detailed regulations. However, these regulations were never drafted because it seemed more appropriate to further regulate this area with the new Law on GMO instead. The new Law on GMO that the BiH Parliament passed in spring 2009 is in line with EU regulations and it technically permits the licensed use of biotech products. However, bylaws to define the approval procedures were passed only recently, more than three years later. Until these procedures were approved, no biotech products could have been officially allowed in the country.

Generally speaking, biotech products are viewed as undesirable in BiH. Consumers dislike biotech foods and have reservations towards “GM foods” due to a lack of consumer knowledge and negative influence from EU countries. Sophisticated consumers think that they do not have enough information to be for or against biotech products, and that they need more education in order to decide whether or not they will consume such products. More information could positively change consumer attitudes towards biotechnology. Additionally, more knowledgeable consumers say they would eat biotech foods after proper testing and labeling, if given enough information to decide whether they want to buy such a product. The position of the EU has influenced both regulators and consumers, but it is not the only reason for Bosnia’s resistance. Both the government and farmers tend to think that organic production is an important segment of BiH agriculture. In BiH, agricultural production is more traditionally oriented and the use of agrochemicals/pesticides is lower than elsewhere in Europe. There are also few industrial polluters. Agriculturists believe that the release of biotech products would threaten organic production in the country and cause losses of potential export markets.

Section II. Plant Biotechnology Trade and Production:

BiH does not produce biotech crops and there are no biotech crops under development in BiH. The new Law on GMO that was passed in 2009 allows the intentional release of biotech products into the environment and field trials, under license. This Law provides only general guidelines for licensing procedures, while detailed regulations on licensing should be drafted by responsible ministries/agencies and approved by the Council of Ministers. This detailed regulation is still missing.

BiH officially doesn’t import biotech crops/products and planting seeds, but unofficially it does import biotech feed. Importation of approved GMOs is permitted, following the passage of the new regulation, but there are no requests yet for GMO approval submitted to the Food Safety Office.

The country was a food aid recipient as part of the USDA monetization program from 1997 to 2003. During that period some biotech products were rejected as undesirable. In 2000, U.S. corn offered as donation under the food aid/monetization project was rejected because it had biotech content. Two years later, the country accepted biotech soybean meal imported from the U.S. as a donation only because it was approved for marketing in the EU.

Section III. Plant Biotechnology Policy:

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 conditions for limited use, importation, deliberate release into environment, and marketing of products that are composed of GMOs, contain GMOs, or derive from GMOs.

The Food Safety Agency (FSA) is the umbrella agency and coordinating body for all GMO issues. In addition to the FSA, responsible agencies are 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 biotech food and feed on the market. The PHA is responsible for approving biotech seeds and seedlings and plant protection chemicals, upon approval of the entity and canton agricultural authorities and the Brcko District agricultural authorities.

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

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 GM products placed on the market.

The Law on GMO sets general guidelines for the issuance of GMO permits. The following bylaws further regulate this area:

- Bylaw on Conditions and Procedure for Issuance of Approvals for Placing GMO Food and Feed on the BiH Market for the First Time and Conditions Regarding their Traceability and Labeling;
- Bylaw on Content of Application and technical Documentation for Placing on the Market, and Conditions for Labeling and Packaging for GMOs or Products that Contain or Derive from GMOs.
- Bylaw on Methods for Maintenance of Common Register for GMOs;
- Bylaw on Establishment of System for Development and Designation of Unique Cedes for GMOs;
- Bylaw on Content and Scope of Risk Assessment for Placing GMOs or Products that Contain or Derive from GMOs on the Market and Methodology for Risk Assessment;

These rulebooks are harmonized with EU biotech 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 permit. Issuance of permits will take from 90 to 105 days, according to the Law on GMO.

The Law on GMO has established a GMO Council to assist the responsible BiH institutions with enforcement. The GMO Council is an independent and public body with a four-year mandate

consisting of 7 members from areas of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacy, biotechnology, agriculture, forestry, veterinary medicine, nature and environmental protection, and occupational protection. The main tasks of the GMO Council are to advise on biotech usage in terms of legal procedures as outlined by the Law on GMO, to give opinions and proposals on drafting other legislation on GMO use, to provide opinions and proposals to responsible ministries on biotech use issues and other expert work as outlined by the Law on GMO and related regulations, to follow gene technology development 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 development and use. The GMO Council annually and publicly reports to the FSA and further to the Council of Ministers.

The Law on GMO says that food products that contain or are composed of GMO must be labeled as follows:

- a. For packed products the label on the packaging should read: “This product contains GMO components” or “This product contains GM (name of organism).”
- b. For products that are not packed the label should read “This product contains GMO components” or “This product contains GM (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 biotech levels above 0.9% of the product must be labeled.

The Law on Seeds and Seedlings (BiH Official Gazette # 3/05) mentions only that biotech seeds and seedlings must be labeled. In summary, no biotech crops have been approved for planting or field testing and no biotech crops have been approved for food or feed use.

Regarding the coexistence between biotech and non-biotech crops, the Law on GMO forbids planting of biotechnology crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, and in protected areas (i.e. as defined as protection impact zones with previously enlisted zones). In addition, biotech crop planting for reproduction is allowed only in areas that are approved by the Council of Ministers based on the FSA suggestion. In cases where the Law on GMO cannot be applied, the Food Law and bylaws derived from that law will apply.

Four laboratories have been authorized for biotech testing:

- a. Biotechnology Laboratory of the Agricultural Institute in Banja Luka;
- b. GMO Laboratory of the Federation Agro-Mediterranean Institute in Mostar;
- c. Laboratory for GMOs and Food of the Institute for Genetic Engineering and Biotechnology in Sarajevo;
- d. GMO Laboratory of the Federation Agricultural Institute in Sarajevo.

The Sarajevo and Banja Luka Agricultural Institutes recently received GMO testing equipment worth \$0.3 million through a World Bank loan. Using this new equipment, the laboratories will be able to use the Real-Time Polymerase Chain Reaction (PCR) technology to detect not just the presence of biotech event (as before), but also the amount of the biotech event present in food and feed samples. The labs also can conduct an event-specific detection to identify the biotech event but there is no need for such testing presently because there are no approved biotech events in BiH yet. The Istituto Zooprofilattico

Sperimentale delle Regioni Lazio e Toscana in Italy is appointed to be the reference laboratory for biotech testing because none of BiH's domestic laboratories have that capacity.

The Law on Seeds and Seedlings (BiH Official Gazette # 3/05) mentions only that biotech seeds and seedlings must be labeled. In summary, no biotech crops have been approved for planting or field testing and no biotech crops have been approved for food or feed use.

Section IV. Plant Biotechnology Marketing Issues:

The market acceptance of biotech products for producers, importers, retailers, and consumers is officially unknown, as there have been no studies regarding this topic. Knowledge about biotechnology is poor even among scientists and agricultural officials. The recent war in BiH caused a wide range of destruction, and the country still suffers from a poor economic situation. As a result, biotechnology is still a relatively new issue. Overall, the level of biotech acceptance has decreased during the last five years due to EU influence and the anti-biotech positions of some neighboring countries, especially Croatia and Serbia. Also, agriculturists and non-governmental organizations that promote organic agriculture oppose biotech applications in general and are influencing producers, consumers, and regulators to reject biotech products. Recently, the media and consumer associations in BiH criticized BiH authorities for not better controlling imported foods with biotech content and for approving the import of biotech commodities from the United States under the food aid program. This "anti-GMO" movement in BiH is moderate at the moment but will likely become stronger in the future.

Section V. Plant Biotechnology Capacity Building and Outreach:

There have been no outreaches carried out in BiH over the past two years that relate to plant biotechnology. It might be useful to support in-country biotech informational events, featuring leading U.S. scientific and/or agricultural production authorities to speak to the relevant BiH stakeholders and promote the establishment of a fair and transparent system. BiH is still in the process of creating its regulatory structure for approving biotech products, and an informational event regarding scientific and productive evidence from the United States could have a positive impact.

As part of State Department's biotechnology outreach efforts, American Embassy Sarajevo has proposed a seminar in BiH for key officials involved in formulating policy or drafting and/or approving agricultural biotech legislation, at both the entity and state-levels. The Embassy's goal is to encourage agricultural policymakers, particularly the few who are obstacles to legislative progress, to take a softer position on biotechnology. The pox-resistant plum can be used as an example of how GMOs can be an effective tool, explain how the import and cultivation of biotechnology can be carried-out within European Union law, clarify the basics of how biotech works and underscore its safety and benefits. This activity is planned in September/October 2012.

Section VI. Animal Biotechnology:

Genetic engineering has not been used in BiH for the development of agriculturally-relevant animals.

BiH has no legislation or regulations related to the development, commercial use, import, and/or disposal of genetically-engineered animals or products derived from these animals, and currently no plans to draft such regulations.

Relevant government entities that might have a role in the regulation of the genetic engineering of animals would likely be the State Veterinary Office and the Food Safety Agency, but to-date they have not been involved in such discussions or activities.

There have been no public campaigns and almost no media reports on this topic in BiH. There have been no outreach activities so far. However, 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.

Section VII. Author Defined: