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Report Highlights:

A revised draft of new Serbian GMO law has been through public discussion and is currently in the interagency approval process. The new law is expected to go for a final approval by the Serbian Parliament this fall. The new GMO law will be in accordance with EU regulations and will cover a wider range of issues than the existing law. The Serbian government's efforts to restrict planting of GMO have been successful in reducing illegal planting of GMO soybeans. The Monsanto Co. obtained Serbian government approval to resume RR corn field trials in 2008. USDA continues its technical assistance and capacity building activities in Serbia in 2008 on various aspects of biotech policy formulation and bio-safety.

Includes PSD Changes: No
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EXECUTIVE SUMMARY

Production and imports of GMO crops are prohibited in Serbia. Imports of soybeans, corn, rapeseeds and potato products are now tested for GMO content. The law on GMO approved in 2001 is still in effect and only allows for research and field-testing of biotechnology crops. The Serbian government's efforts to restrict planting of GMO have been successful in reducing illegal planting of GMO soybeans. The amount of illegally produced GMO soybeans confiscated by the plant inspection authority in 2007 was 106 MT, compared to 7,890 MT in 2005 and 1,200 MT in 2006.

A draft of the new Serbian law on GMO, which was initially completed in September 2006, has been revised and is currently in the approval process. The draft law will likely go before the Serbian Parliament for final approval in fall 2008. We expect the scope of the new law on GMO to expand and its regulations to cover a wider range of issues than the existing law. There will be a larger number of rulebooks to stipulate regulations of the new law and it is anticipated that these rulebooks will be written in accordance with EU regulations.

Currently, there are two foreign companies, Monsanto Europe S. A. and ARESA Danish Plant Biotechnology Company, involved in biotech experimental research in Serbia. In June 2008, the Ministry of Agriculture approved Monsanto's request to resume their RR corn field trials in collaboration with the Institute of Fields and Vegetable Crops Novi Sad. In May 2008, the ARESA Co. obtained permission to plant transgenic tobacco used for the detection of explosives.

Marketing or promotion of GMO food does not exist at the present time in Serbia. There is a strong negative public attitude towards the acceptance of biotech crops and products derived from GMO crops. Consumer awareness of GMO is very low and public discussions of biotechnology related issues are very limited.

USDA has been assisting in developing Serbia's capacities in the research and regulations of agricultural biotechnology since 2001. Through numerous seminars, workshops and field visits (both in Serbia and in the United States) USDA/OCBD has been training Serbian participants to critically examine the technical and economic aspects of biotechnology policies and pursue strategies to optimize their implementation. USDA biotech activities are also assisting Serbian scientists to design and conduct field trials of genetically modified crops. In FY 2008/09, USDA technical assistance will be targeted at training activities related to the Institutional Biosafety Committee operation, risk assessment for commercial approval of transgenic plants, collaborative efforts of education and training programs that link bio-safety to other biodiversity, environmental and health issues.

BIOTECHNOLOGY TRADE and PRODUCTION

Serbia does not produce any GMO crops and no biotechnology crop varieties are permitted for imports into Serbia. The law on GMO approved in 2001 still applies and it only allows for research and field tests of biotech crops. Imports of GMO soybeans and corn are prohibited. Soybean, corn, potato and rapeseed products are now tested for GMO content and are allowed entry on an ad hoc basis. There is a valid 10-year import permit issued in 2002 by the Ministry of Agriculture to a Serbian trading company (TMT Co.) to import Roundup Ready (RR) soybean meal for animal feed production. Imports of RR soybeans for crushing or other commercial purpose are not allowed in Serbia. The current law does not prohibit the research work with and use of genetically modified organisms (GMO) but only puts them under the strict supervision of the state. Permits for research work and contained use of

biotech materials can be obtained from the Ministry of Agriculture, Forestry and Water Management by meeting the state's regulatory requirements.

According to the existing Serbian GMO law, the importer of GMO soybean meal must request approval from the Ministry of Agriculture through a cumbersome procedure. However, under the new GMO Law import procedures will be simplified. Importers will no longer need to request an import permit but will only be obliged to notify the Ministry of Agriculture when they intend to bring a GMO soybean meal shipment into the country. In addition, to simplifying the import procedures, importers will no longer be charged for administrative taxes for importing GMO soybean meal. The Ministry of Agriculture will continue to be the government agency to be notified by the importers under the new law.

Area planted to non-GMO soybeans in Serbia has been growing during 2001-2007 period, mostly due to an increased demand of soybean meal for animal feed. In 2008, however, soybean area was estimated at 132,000 HA, 12 percent smaller than in 2007. Total imports of GMO and non-GMO soybean meal in 2007 was 33,304 MT and valued at \$12.5 million. Almost 92 percent (30,530 MT) of total soybean meal import was GMO soybean meal, with the bulk of these imports coming from Brazil (71 percent), Argentina (21 percent) and the remaining quantity from Bosnia-Herzegovina and Moldova. During the first four months of 2008, imports of GMO and non-GMO soybean meal are estimated at 18,515 MT, valued at \$9.68 million.

Apart from the RR soybean meal, there are no other GMO products imported into Serbia. Corn, rapeseed, potato and soybean products are tested for GMO content as well and are not allowed entry into Serbia. Phytosanitary inspectors at border posts are instructed to carry out surveillance of possible unauthorized imports of biotech crops or products, while internal Agricultural Ministry's inspectors control what is planted on fields within Serbia. The phytosanitary inspectors use test strips "Reveal for CP4" on testing for the RR soybeans presence or apply herbicides on small areas of the soya fields to identify illegal GMO soybean planting. When field samples test positive, the soybean seeds are sent to an accredited Ministry laboratory for further testing. There are three accredited laboratories run by the Ministry of Agriculture for GMO testing:

1. The Institute for Molecular Genetic and Genetic Research, Vojvode Stepe br. 444a, Belgrade. Contact person: Vesna Maksimovic; phone: +381 11 3976 414,
2. The SP Laboratory, Industrijska Zona bb, Becej. Contact Person : Aleksandra Bauer, phone: +381 21 453 191
3. The National Laboratory for Seed Tasting, 30 Maksima Gorkog, Novi Sad. Contact person: Milka Vujakovic; phone: +381 21 421 248

All three laboratories follow the International Seed Testing Association (ISTA) proficiency testing on GMO. Lab accreditation insures that the laboratory follows seed testing according to the requirements of the ISTA regulations.

Recent Serbian government's efforts by the phytosanitary inspection service to restrict illegal planting of GMO crops have been successful. The amount of illegally produced GMO soybeans confiscated by the Ministry of Agriculture declined from 7,890 MT in 2005 to 1,200 MT in 2006 and only 106 MT in 2007. In July 2007, phytosanitary inspectors inspected about 3,000 soybean fields in Macva, South-Backa, Srem and Western-Backa regions using total herbicides methods. Production of GMO soybean was reported in 24 locations and testing confirmed the presence of GMO in 106 MT. The GMO soybeans were collected for to be used of biodiesel production. In addition, the border phytosanitary inspectors confiscated

two illegal import shipments, one in May 2007 of 100 MT GMO soybeans from Croatia and the other in December 2007 of 32 MT of GMO corn (LibertyLink) from Turkey.

Currently, there are two foreign companies engaged in biotech experimental research in Serbia, Monsanto Europe S. A. and ARESA Danish plant Biotechnology. Monsanto first obtained approval for contained use for Roundup Ready herbicide corn (NK 603) from the Ministry of Agriculture in 2001 for a period of four years. Field trials of the RR corn took place in two research institutes, the Maize Research Institute-Zemun Polje near Belgrade and the Institute for Vegetables and Crops in Novi Sad. Field trials were conducted in accordance with Serbia's requirements for biotech contained- use of GMO materials, i.e. confinement measures that included 200 meters isolation distance, four border rows and 14 days of temporal isolation. In May 2006, the Ministry of Agriculture granted Monsanto an approval to continue its RR corn field trials for another year. However, the National Biosafety Committee and the Ministry of Agriculture did not grant Monsanto a renewal to resume their RR corn field trials in 2007.

In June 2008, the Ministry of Agriculture approved Monsanto's request to resume RR corn field trials in collaboration with the Institute of Fields and Vegetable Crops Novi Sad. The MK Commerce Company currently represents Monsanto as its sales agent in Serbia. The ARESA Co. also obtained permission from the Serbian authorities in May 2008 to plant transgenic tobacco variety used for the detection of buried explosives. This is the second time that ARESA Co. got permission to plant transgenic plants in Serbia. Last year, the company conducted open-air trials with modified gene "Thale Cress" (*Arabidopsis Thaliana*) that is used a plant indicator for the detection of explosives leakage from landmines in the soil.

BIOTECHNOLOGY POLICY

Laws and Regulations

As of June 2008, the Serbian law on genetically modified organisms (GMO), published in the Official Gazette in 2001 (#21) and amended in 2003 is still enforced. Essentially, this law regulates the conditions for the contained use, deliberate release of GMOs and their placement on the market. The current law does not prohibit the work with and the use of GMO and allows research activities and use of biotech products under the strict control of the state. There is a strict and detailed application process for obtaining a permit for GMO event or research. The application must provide all the necessary data on the particular biotech event or biotech crop and stipulate parameters for safety procedures and measures. All applications must be submitted to the Serbian Ministry of Agriculture for review and approval. Risk assessments are evaluated by the National Biosafety Committee, which is composed of representatives of scientific research institutions in the fields of agriculture, ecological and biological science. Following the risk assessment and the scientific recommendation of the Biosafety Committee and the Ministry of Agriculture, the competent administrative authority must issue a decree on the specific biotech event. Every application is evaluated on a case-by-case basis.

Following the adoption of the current Serbian GMO law in 2001, implementing regulations were issued in five Rulebooks in 2002 and 2003. The implementation of the GMO law has been designed to follow regulations of the European Union in accordance with the EU directives 90/220 and 90/219. The five rulebooks are:

- Rulebook on "Commercial release of 'GMOs' or products derived from same", No.1245/1 issued November 13, 2002
- Rulebook on "Contained use of genetically modified organisms", No.1244/1 issued November 13, 2002

- Rulebook on "Deliberate release of biotech products into the environment", No.1246/1 issued November 13, 2002
- Rulebook on "Regulation on the content and data of products derived from GMOs", No. 1669/1 issued December 15, 2002.
- Rulebook on "Labeling of genetically modified products", No.16/18 issued February 27, 2003. It regulates human food labeling but does not regulate imported animal feeding materials.

The Serbian National Agriculture Strategy adopted in 2005 recognized the importance of modern biotechnology and supporting the development of modern agriculture. A working group from various government agencies and universities was tasked by the Ministry of Agriculture to draft a new law on GMO. In September 2006, a draft of the new GMO law was completed but the review process of the draft law was interrupted by the resignation of the Minister of Agriculture in October of that year. Following the formation of a new government in May 2007 and the appointment of a new Agricultural Minister, the review process of the new GMO Law re-started with opening the draft for debate and public comments. For over a year, the new draft of GMO law has gone through public discussion and the committee for the evaluation of comments and recommendations on the draft of the GMO law concluded public discussion of the draft in December 2007. The approval process was again interrupted by the collapse of the coalition government in March 2008 and the ensuing parliamentary elections in May 2008. The revised technical draft of the GMO law, which received positive reviews from the Serbian Chamber of Commerce, relevant ministries and the industry, was sent for a final legal review at the Ministry of Agriculture. Upon the formation of a new government, the new law will be forwarded to the legal departments of the relevant Ministries for further review and comments. The Ministry of Agriculture will then send the final draft of the revised law to the Parliament for final approval procedure that is expected to take place in the fall of 2008.

It is anticipated that the scope of work of the new Serbian law on GMO will be expanded and its regulations to cover more issues than the existing law. There will be a larger number of rulebooks (about 15 to be drafted) to stipulate the implementing regulations of the law. It is also anticipated that these rulebooks be written in accordance with EU Regulations EC 2001/18, 1829/2003, 1830/2003, 1946/2003. Beside the three fields of work that are already covered by the existing law (work under contained use; deliberate use of biotech crops; and marketing of biotech events) the new law on GMO will regulate several new areas including the following:

- Internal and international trade of biotech events
- Handling; transportation; packaging; transit
- Traceability; labeling and processing of GMO
- Conditions and measures for removal of potential risks from GMO
- Supervision of the application of the existing law and its regulations through the system of the Republic inspection service
- Responsibilities and fees for illegal use of GMO crops

The new law will also regulate the work of the National Biosafety Council, the National Laboratories responsible for analysis of biotech events, and will define the role of the Institutional Biosafety Committee (IBC). Serbia is party to the Convention on Biological Diversity, ratified in 2002 and the Cartagena Protocol on Biosafety has been accepted by Serbia since May 2006. According to Serbia's obligations under the protocol, it must create a Biosafety Clearing House (BCH) consisting of a national database to keep record of all biotech trials, production and trade activities of GMO in the country. In March 2008, representatives from the Serbian Ministry of Agriculture participated at the Regional Workshop on the Biosafety Clearing House for Central and Eastern Europe held in Cairo.

This workshop was organized with the support of the UNIP-GEF project on "Capacity Building for Effective Participation in the BCH".

Serbia is currently a member of the CODEX Alimentarius; the European Plant Protection Organization (EPPO), the Convention of Biodiversity (CBD); the International Union for the Protection of the new Varieties of Plants (UPOV); the World Intellectual Property Organization (WIPO); the European Cooperative Program for Crop Genetic Resources Networks (ECP/GR); and is a signatory of the Aarhus Convention and the International Plant Protection Convention. Serbia hosted the Eastern European Seed Network (EESNET) conference on the co-existence between traditional, organic and GMO production that took place in Novi Sad, from 19th to 21st of November 2007.

Monitoring and Enforcement Authorities

The Ministry for Agriculture, Forestry and Water Management is the competent authority responsible for all GMO issues in Serbia. The Ministry deals with all contained use, deliberate release, placing on the market and trans-boundary movements of GMOs and is the focal point for Cartagena Protocol; Biosafety Clearing House; plant varieties registration and protection; genetic resources and accreditation of laboratories. The Agricultural Ministry is also responsible for appointing members of the National Biosafety Committee.

Contact information for GMO issues at the Ministry of Agriculture is:

Mrs. Vanja Kojic or Marina Cvetkovic, adviser

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Serbia

Phone: + 381 11 3620-773

Fax: + 381 11 3131 971

E-mail: vanja.kojic@minpolj.sr.gov.yu and/or m.cvetkovic@minpolj.sr.gov.yu

The Ministry of Agriculture supervises the application of the GMO law and its subsequent regulations through a system of Republic Inspectors. It manages all phytosanitary inspectorates and quality control of food and feed production. It is also responsible for financing research projects in the fields of agriculture and protection of genetic resources.

The Serbian Ministry of Health, which is responsible for sanitary inspection of food, currently does not have, and as per the draft of new Law on GMO, will not have an active role on regulating or testing of food products containing GMO. The Ministry of Health is generally guided by the EU regulations in this matter, tolerating the presence of GMO content with a maximum 0.9% of total mass to be considered non-GMO product.

MARKETING ISSUES

Marketing or promoting GMO food does not exist in Serbia. There is a strong negative public attitude towards the acceptance of biotech crops or products derived from GMOs. Consumer awareness of GMO and public discussions of biotechnology related issues are very limited. In the Province of Vojvodina, a campaign has started for promoting the region as a GMO-free region. The new government is also encouraging the GMO-free Serbian agriculture trend and is in favor of a strict control over GMO production, eyeing some of the potential EU markets for non-GMO and organic products. There are, however, no GMO-free regions declared at the present time. The Ministry of Agriculture is considering organizing some working groups, round table discussions and training workshops in order to increase public awareness and the participation of relevant institutions at local levels.

Concerning marketing of non-GMO, the Ministry of Agriculture is supporting local soybean crushing plants to promote Serbia as a non-biotech soybean producer and support the notion that Serbian producers can realize higher profits through marketing non-biotech crops. Several Serbian crushing plants have long-term contracts with EU buyers to export non-GMO soybean meal and products.

In general, Serbia follows the EU's lead in most of the biotech issues, although the current GMO does not stipulate any regulations concerning marketing and labeling of GMO products. As mentioned before, the new GMO draft Law addresses several marketing related issues such as handling, transportation, packaging, transit, traceability, labeling and processing of GMO products. Marketing rules, conditions and measures of the new Serbian GMO Law will have a strong EU leaning.

CAPACITY BUILDING AND OUTREACH/US

There are several technical assistance and capacity building activities currently provided in the areas of biotechnology and biosafety areas by various international donors in Serbia. These include OCB/USDA, the United Nations Environment Program (UNEP) and the EU (The Netherlands). The UNEP technical assistance activities focus mostly on providing support in the areas of risk assessment, risk management and establishing a Biosafety Clearing House in Serbia. The Netherlands' activities are mainly focused on conducting workshops and training in the area of biosafety.

Currently, there are no academically accredited courses related specifically to GMO or biosafety being offered in Serbian universities or academic institutions. Serbia relies mostly on external support to develop its capacity in biotechnology research and education and to adopt appropriate biosafety policies and legislations.

USDA Technical Assistance and Capacity Building Activities in Serbia

USDA has been assisting in developing Serbia's capacities in the research and regulations of agricultural biotechnology since 2001. Through numerous seminars, workshops, and field visits (in the U.S. and Serbia) OCB/USDA experts have been training participants in Serbia to critically examine technical and economic aspects of biotechnology policies and pursue strategies to optimize their implementation. USDA biotech activities are also assisting Serbian scientists to design and conduct field trials of genetically modified crops (e.g., insect resistant maize, disease resistant plum) and utilize molecular genetics for food safety assessments.

In addition, USDA has been providing technical assistance in establishing biosafety councils at key agricultural research institutions in Serbia in response to increased interest in establishing internal bodies to provide guidance on carrying out biotech activities. This initiative to establish a biosafety council was a result of cooperative efforts between USDA experts and the Serbian National Biosafety Council (NBC). The following is a summary of USDA/OCB/USDA activities in Serbia in the past year.

Activities in 2007

In 2007, USDA technical assistance activities in the area of biotechnology and biosafety were limited to the organization of the Institutional Biosafety Committee (IBC) Study Tour that took place in February 2008.

Activities in 2008

IBC Study Tour in the U.S. Feb 16-21, 2008

FAS organized a study tour in the U.S. at the University of Georgia and Cornell University for representatives from three major agricultural research institutes in Serbia to see the work of the Institutional Biosafety Committee (IBC) in action. The Serbian team included members from the National Biosafety Committee and the Ministry of Agriculture. The participants gained a better understanding on how the IBC functions and obtained lessons-learned from established IBCs as a guide in establishing IBC in Serbia. This study tour increased participants' understanding of risk assessment and gave them the opportunity to learn more about the U.S. approach in dealing with non-target risk assessment. It should be mentioned that this project has played a major role for introducing Serbian regulators to the IBC concept, which is now formalized and is expected to be an integral part of the new biotech law.

Future Work

Serbia has gained significant expertise in various fields relevant to biosafety. More emphasis needed on training in risk assessment for commercial approval of transgenic plants; on collaborative efforts of education and training activities that link biosafety to other biodiversity; environmental and health issues, e.g. biological, social, legal, and medical aspects. These programs should be tailored to specific needs, particularly in the area of risk assessment and public participation in biotech issues in Serbia.

REFERENCES AND RELATED NATIONAL WEB LINKS

The full text of the current Serbian Law on GMO and relevant rulebooks in English are available at the FAS Office Belgrade, Serbia: Phone: + 381 11 306 4802; Fax: + 381 11 306 4922, e-mail: dragana.dimitrijevic@usda.gov .

Government Institutions

Ministry for Agriculture, Forestry and Water Management

<http://www.minpolj.sr.gov.yu>

Ministry for Science and Environmental Protection

<http://www.mntr.sr.gov.yu>

Directorate for Environmental Protection

<http://www.ekoserb.sr.gov.yu>

Agency for Environmental Protection

<http://www.sepa.sr.gov.yu>

Ministry for Health

<http://www.zdravlje.sr.gov.yu>

Research Institutions

Institute for Field and Vegetable Crops, Novi Sad

<http://www.ifvcns.co.yu/index.php>

Maize Research Institute, Zemun Polje

<http://www.mrizp.co.yu/index-en.php>

Institute for Molecular Genetics and Genetic Engineering

<http://www.imgge.bg.ac.yu>

Institute for Biological Research "Siniša Stankovic

<http://www.ibiss.bg.ac.yu>

National Institute for Seed Testing "NIST"

http://www.nlis.co.yu/english/index_english.htm

Faculty of Agriculture, University of Novi Sad

<http://polj.ns.ac.yu/english/index.html>

Faculty of Biology, Belgrade University

<http://www.bio.bg.ac.yu>

Faculty of Agriculture, Belgrade University

<http://www.agrifaculty.bg.ac.yu/english/index-en.htm>

Fruit and Grape Research Center, Cacak

<http://www.centar-cacak.kg.ac.yu/vocee.htm>

Accredited laboratories for GMO testing: Laboratory for Plant Molecular Biology, IMGGI,
University of Belgrade

<http://www.imgge.bg.ac.yu/lab08/lab08.htm>

SP Laboratory

<http://www.splaboratorija.co.yu>