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Serbia

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Biotechnology

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Report Highlights:

The new Serbian law on Genetically Modified Organisms (GMO) became effective on June 12, 2009. This new Law completely banned all trade and commercial cultivation of biotech products and only regulates basic conditions for the use of GMO in closed systems and experimental work in the field. With this law, import of soybean meal from biotech Round-Up Ready soybeans for cattle feed to Serbia will no longer be possible. The U.S. Government, the EU and other WTO members, strongly expressed their dissatisfaction with the new Law. Serbian trade officials recognized the negative implications of the ban for the Serbian WTO accession and are committed to changing the law soonest, most probably in the fall.

Section I. Executive Summary:

According to the Law on GMO adopted by the Serbian Parliament on May 29, 2009, production, imports and commercial growing of GMO crops are strictly prohibited in Serbia. The Law came into effect on June 12, 2009. The new Law is prohibiting all commercial use of GMO crops, which has no scientific basis and will have an adverse effect on Serbia's WTO accession negotiations. The new Law states in Article 2 that: "No genetically modified organisms or products containing genetically

modified organisms can be traded or grown for commercial use at the territory of the Republic of Serbia”.

In the new biotech law, beside the ban on trade and commercial cultivation of GMO products without providing any scientific justification for such action, other provision of the law are also problematic and do not provide a clear pathway for the commercialization and marketing of GMO products in the future. Law is extremely problematic from the perspective of compliance with WTO rules, since scientific and risk-based system for food, feed and cultivation of biotech products is not included in the law. The U.S. Government, the EU and other WTO members, expressed strong dissatisfaction with the adopted new Law. The implications of the ban for Serbian WTO accession were immediately recognized by Serbian trade officials and others who are committed to the accession. According to the senior Serbian officials, the law will be changed in the shortest possible procedure, possibly at the next Serbian Parliament session in the fall of this year. At the July 10th WTO Working Party meeting in Genève, Switzerland, USTR intends to present to the Serbian delegation full detailed comments on this problematic law.

According to the 2001 GMO Law on GMO, all imports of soybeans, corn, rapeseeds and potato products had to be tested for GMO content. According to this previous law, research, field-testing and trade of biotechnology crops was allowed. Despite the previous law that was allowing trade of GMO crops, Serbian Officials for number of years were encouraging a GMO-free Serbian agriculture and were in favor of a strict control over GMO production. The Serbian government's efforts to restrict planting of GMO started in 2005 with reducing illegal planting of GMO soybeans. The amount of illegally produced GMO soybeans confiscated by the plant inspection authority and crushed into soybean meal in 2007 was 106 MT, compared to 7,890 MT in 2005 and 1,200 MT in 2006. For the first time in 2008 illegally produced soybeans were not crushed for cattle feed but destroyed on some 68 plots, mainly in Vojvodina.

Currently, there is only one foreign company, Monsanto Europe S. A., involved in biotech experimental research in Serbia. In April 2009, 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. Another company that was active in experimental research with transgenic crops in Serbia during 2007 and 2008 was ARESA Co., a Danish company. This company obtained permissions, for experimental research with transgenic tobacco used for the detection of explosives.

Marketing or promotion of GMO food does not exist 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 technical assistance activities on biotech are also assisting Serbian scientists to design and conduct field trials of genetically modified crops. In FY 2008/09, USDA technical assistance was 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.

Section II. Biotechnology Trade and Production:

Serbia does not produce any GMO crops and no biotechnology crop varieties are permitted for imports into Serbia. The new law on GMO only allows laboratory work, research and field tests of biotech crops. Imports of biotech crops and products including soybeans and corn are prohibited. Soybean, corn, potato and rapeseed products are regularly tested for GMO content and are allowed imports only if are GMO-free.

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 genetically modified organisms (GMO) but 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 new GMO law, Serbia will no longer be able to import soybean meal from Round-Up Ready soybeans or feed stuffs that contain GMO soybean meal. Thus local cattle feed producers will be left to buy only soybean meal from the local producers. The leading producer of soybean meal in Serbia is crushing facilities "Sojaprotein" Becej. "Sojaprotein" is owned by the local company "Victoria Group", one of the leading company in agriculture production in Serbia. European Bank for Reconstruction and Development (EBRD) recently approved a credit line of 40 million EUR (54 million USD) for further development of its crushing capacities. Prior to adopting the new law, only GMO product that was allowed for import to Serbia was GMO soybean meal. However, every shipment was required to obtain approval from the Ministry of Agriculture through a cumbersome procedure.

Area planted to non-GMO soybeans in Serbia has been growing during 2001-20008 period, mostly due to an increased demand of soybean meal for animal feed. In 2009, soybean area was estimated at 160,000 HA, 11 percent higher than in 2008. Local production of soybean meal has increased for the last couple of years due to increased area planted with soybeans and expanded local crushing facilities. For MY09/10 is forecast to reach 220,000 MT. Consumption of soybean meal is estimated at around 250-270,000 MT, with possible deficit of around 30-50,000 MT that can be covered only by imports. Total imports of GMO and non-GMO soybean meal in MY2008/09 is estimated at 37,000 MT. Almost 92 percent 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. After adoption of the new Law on GMO it is not possible to import GMO soybean meal to Serbia and due to this the price of soybean meal has increased. Current market price of soybean meal at the Novi Sad Commodity Exchange is 42 din/kg (620 USD/MT), which is very high comparing to soybean meal price in Europe. For example soybean meal from Argentina (44/45%) at the parity CIF Rotterdam, the Netherlands, last week was offered at 457 USD/MT.

No import of GMO products is possible. 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 four accredited laboratories that the Ministry of Agriculture is using for GMO testing:

1. SP Laboratory (member of "Victoria Group"),
Address: Industrijska Zona bb, Becej
Phone: +381 21 453 191

2. Laboratory for Seed Tasting,
Address: 30 Maksima Gorkog, Novi Sad
Phone: +381 21 421 248

3. A Bio Tech Lab,
Address: Vojvode Putnika bb, Sremska Kamenica
Phone: + 381 21 489 3661

4. SGS Agri Laboratory,
Address: Danila Kisa 20, Novi Sad
Phone: + 381 21 422 404

All four laboratories have accreditation for work from the National Accreditation Board of Serbia and they are following the International Seed Testing Association (ISTA) proficiency testing on GMO. Laboratory accreditation insures that the laboratory follows seed testing according to the requirements of the ISTA regulations.

Serbian government's efforts by the phytosanitary inspection service to restrict illegal planting of GMO crops have started in 2005. The amount of illegally produced GMO soybeans confiscated by the plant inspection authority and crushed into soybean meal in 2007 was 106 MT, compared to 7,890 MT in 2005 and 1,200 MT in 2006. For the first time in 2008 illegally produced soybeans were not crushed for cattle feed but destroyed on some 68 plots mainly in Vojvodina

Currently, there is only one foreign company engaged in biotech experimental research in Serbia, Monsanto Europe S. A. 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. In 2007, the National Biosafety Committee and the

Ministry of Agriculture did not grant Monsanto a renewal to resume their RR corn field trials. Monsanto requested approval to continue its RR corn field trials at the beginning of this year and they obtained a one year license in April 2009.

Another company that was active in experimental research with transgenic crops during 2007 and 2008 was Danish company ARESA Co. This company obtained permissions from the Serbian authorities to plant transgenic tobacco variety used for the detection of buried explosives and to conduct open-air trials with modified gene “Thale Cress” (*Arabidopsis Thaliana*) that is used as a plant indicator for the detection of explosives leakage from landmines in the soil. Both experiments are now completed.

Section III. New Technologies:

Genetic engineering and/or cloning are not used in Serbia for the development of agriculturally-relevant animals. Serbia does not have in place any legislation related to the development, commercial use and/or import of these animals or products.

Section IV. Biotechnology Policy:

Laws and Regulations

The new Serbian law on genetically modified organisms (GMO) which was published on 06/02/09 in the Official Gazette 2009 (#41) became effective June 12. This new Law Serbia completely bans all trade and commercial cultivation of biotech products. The law also prohibits the possibility of commercial cultivation of biotech products, or trade with biotech products and products derived from biotechnology and regulates basic conditions for the use of GMO in closed systems and deliberate release into the environment. With this law, Serbian importers of soybean meal from biotech Round-Up Ready soybeans for cattle feed will no longer be possible.

The new law regulates only conditions for the contained use, research activities and field trials of biotech products under the strict control of the state. There is a strict and detailed application process for obtaining a permit for GMO 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 adoption of the current Serbian GMO law, Ministry of Agriculture is planning to implement regulations in the new rulebooks. Only two of five Rulebooks that were adopted in 2002 and 2003 are still effected, while other three are not longer applicable with the new law.

Rulebooks that are still valid are:

Rulebook on “Contained use of genetically modified organisms”, No.1244/1 issued November 13, 2002

Rulebook on “Regulation on the content and data of products derived from GMOs“, No. 1669/1 issued December 15, 2002.

Rulebooks that were abolished with adoption of new law are:

- Rulebook on “Commercial release of ‘GMOs’ or products derived from same”, No.1245/1 issued November 13, 2002
- Rulebook on “Deliberate release of biotech products into the environment”, No.1246/1 issued November 13, 2002
- Rulebook on “Labeling of genetically modified products”, No.16/18 issued February 27, 2003. It was regulating only human food labeling but did not regulate imported animal feeding materials.

The new law regulates the work of the National Biosafety Council, the National Laboratories responsible for analysis of biotech events, and defines the role of the Institutional Biosafety Committee (IBC). Serbia is a 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.

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.

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 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:

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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.

Section V. Marketing:

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. With the adoption of the new GMO law, the Ministry of Agriculture in Serbia openly expressed their attitude against GMOs. Consumer awareness of GMO and public discussions of biotechnology related issues are very limited. Last year, Serbian officials were strongly promoting a campaign in the Serbian Province of Vojvodina, for creation of this region known as the Serbian “bread-basket” as a GMO-free region. The government is also encouraging a GMO-free Serbian agriculture is in favor of a strict control over GMO production, eyeing some of the potential EU markets for non-GMO and organic products. As a result of this campaign and strong support to domestic soybean crushing capacities dealing only with non-GMO soybeans, the current Ministry of Agriculture adopted the new Law on GMO.

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 the past, Serbia was following the EU’s lead in most of the biotech issues. The Serbian Government received negative comments on the new law from the European Union, since law is not in accordance with EU Directives 1829 and 1830 and it does not include any regulations concerning trade, transport, marketing, packaging, traceability and labeling of GMO products.

Section VI. Capacity Building and Outreach:

There were several technical assistance and capacity building activities provided in the areas of biotechnology and biosafety areas by various international donors in Serbia. These include OCBD/USDA, the United Nations Environment Program (UNEP) and the EU (The Netherlands). The UNEP technical assistance activities focused mostly on providing support in the areas of risk assessment, risk management and establishing a Biosafety Clearing House in Serbia. The Netherlands’ activities were 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 Serbia to develop its capacities in the research and regulations of agricultural biotechnology since 2001. Through numerous seminars, workshops, and field visits (in the U.S. and Serbia) OCBD 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. The 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/OCBD recent activities in Serbia.

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 has under the name "Expert body for the assessment of the risk for the use in closed systems" became an integral part of the new biotech law.

Activities in 2009

After changing a new Law on GMO, Serbia will need significant expertise in various fields relevant to biosafety. More emphasis will be 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.

Section VII. Author Defined:

REFERENCES AND RELATED NATIONAL WEB LINKS

The full text of the current Serbian Law on GMO is attached. The full text of the relevant rulebooks in English are available at the FAS Office Belgrade, Serbia: Phone: + 381 11 306 4802; Fax: + 381 11 306 4922, e-mail: tatjana.maslac@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.nauka.gov.rs>

Directorate for Environmental Protection

<http://www.ekoplan.gov.rs>

Agency for Environmental Protection

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

Ministry for Health

<http://www.zdravlje.gov.rs>

Research Institutions

Institute for Field and Vegetable Crops, Novi Sad

<http://www.nsseme.com>

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 Stanković"

<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, Čačak

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

SP Laboratory

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