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## **Serbia**

### **Biotechnology - GE Plants and Animals**

#### **Biotechnology Annual Report**

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**Report Highlights:**

After a year long pressure from the U.S. and EU Serbia is currently preparing amendments to the very restrictive Law on GMO that was adopted in 2009. Amendments are expected to be adopted by October 2010 and will allow importing and growing GMO crops and products but under strict control of the state. Restrictive GMO Law is one of the obstacles left for Serbia in the process of accession to WTO. Amended Law on GMO will represent general framework on biotechnology that will be fully harmonized with EU regulations. All specifics will be further regulated by already existing four by-laws and additional eight by-laws that Serbia is planning to adopt in the near future.

## **Section I. Executive Summary:**

As a result of the Law on GMO, adopted in May 2009, Serbia strictly prohibits all imports, production and commercial growing of GMO crops or products containing GMO. This law was adopted without any scientific basis and represents one of the main obstacles for Serbia's WTO accession process. Beside a ban on trade and commercial cultivation of GMO products, law is extremely problematic in the compliance with WTO rules.

After encountering strong reaction from the U.S., the EU and other WTO members, problems with the 2009 GMO law were immediately recognized by the Serbian trade and agriculture officials. The government of Serbia (GOS) is planning to have final version of the amended law for adoption by the Serbian Parliament most probably in October 2010. It is expected that when adopted, the new amended amended GMO Law and other by-laws will be fully in accordance with EU Directives on biotechnology 2001/18/EC; No.1829/2003; No.1830/2003; No.65/2004 and No.641/2004. The proposed amendments will allow to import and to grow GMO crops and products but only under very strict control of the state. Amended Law on GMO will represent the general framework on biotechnology in Serbia, while all specifics will be regulated by additional eight by-laws that are planned to be adopted in 2011 and will cover the use of GMO in closed systems, placing GMO on the market, labeling and traceability, authorized laboratories and others. In addition to those new by-laws, there will be some changes in terminology in already existing four by-laws.

Since 2001, Monsanto Europe S.A. started field trials on RR corn with local research institutes in Serbia. In July 2009, the Ministry of Agriculture issued to Monsanto last approval for field trails valid for a year. Since the approval was issued too late in the year, there was not enough time for RR corn field trails to take place in 2009. In 2010, Monsanto did not require a new approval for RR corn field trials since it decided to put RR corn field trails in Serbia on hold for the time being. Therefore, currently there is no foreign company in Serbia engaged in biotech experimental research.

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 FY09/10, USDA technical assistance was targeted at assisting Serbian biotech experts in preparing amendments to GMO Law. In May 2010, FAS/Belgrade organized visit of Professor Martina McGloughlin from University of California Davis to Serbia, as a part of the State Department's Program "Biotech Outreach Strategy". Professor McGloughlin's presentations were about "Modern Trends in Biotechnology" and "Environmental Impacts of Biotechnology" at Agriculture Faculties in Zemun and

Novi Sad. Three Biotech Roundtables were organized at the Institute for Biological Research, Institute for Crops and Vegetables and Expert Biosafety Council of Serbia and number of meetings were held with Serbian Government officials responsible for biotechnology legislation. In addition to these events Professor McGloughlin gave interviews to two national TV stations and daily newspapers that brought up significant interest of the scientific community in Serbia. The purpose of this program was to initiate discussion about agriculture biotechnology trends and to reach media, government officials, food industry, agriculture faculties and scientists in order to create more favorable environment for pro-biotech policies.

## **Section II. Plant Biotechnology Trade and Production:**

As a result of the Biotech Law adopted in June 2009, Serbia does not produce any genetically modified organism (GMO) crops and no biotechnology varieties are permitted for imports to Serbia. According to this law, biotechnology crops are only allowed for laboratory work, research and field tests. Imports of biotech crops and products including soybean meal that was allowed for import before this law, soybeans and corn are prohibited. All shipments of soybeans, corn, potato and rapeseed and their products entering Serbia must be tested for GMO content, and are allowed to be imported only if they 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 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 Serbian Ministry of Agriculture after meeting the state's regulatory requirements.

According to the 2009 GMO Law, Serbia is no longer able to import soybean meal from Round-Up Ready soybeans or feed stuffs that contain GMO soybean meal. Thus, for the past year local cattle feed producers were left to buy only locally produced soybean meal, very often almost \$100/MT higher than in other EU countries allowing imports of RR soybean meal. The leading producer of soybean meal in Serbia is the largest soybean crushing facilities in this part of Europe called "Sojaprotein" from Becej in Vojvodina. "Sojaprotein" is owned by the local company "Victoria Group", one of the leading company in agriculture production and processing in Serbia. Prior to adopting the 2009 GMO Law, only GMO products that were allowed for import to Serbia was GMO soybean meal. However, every shipment was required to obtain approval from the Ministry of Agriculture through very complicated procedure.

Only non-GMO soybeans are allowed to be grown in Serbia. Area planted to non-GMO soybeans has been growing steadily from 2001 to 2010, mainly as a result of the increased demand for soybean meal for animal feed. Since 2005, Serbian phytosanitary inspection services started to inspect and to restrict illegal planting of GMO soybeans. The amount of illegally planted GMO soybeans that was confiscated in the past was crushed under state control and allowed to be used for animal feed or for export.

Area planted to non-GMO soybeans in MY09/10 was 144,000 HA and with average yield of 2.42 MT/HA, total production of soybeans in MY09/10 was 349,000 MT. For MY10/11 soybeans were planted this spring on 168,000 HA, or about 16 percent more than the previous year. It is estimated

that soybean production in MY10/11 can reach 440,000 MT. It is estimated that in MY10/11 Serbia produced 250,000 MT of non-GMO soybean meal. Due to a ban on imports of RR soybean meal, in MY09/10 Serbia imported only 20,000 MT of non-GMO soybean meal. In the previous years Serbia was importing about 92 percent of GMO soybean meal from Brazil (71 percent) and Argentina (21 percent) and the remaining quantity (8 percent) from neighboring countries and Moldova.

Consumption of soybean meal in Serbia is estimated at around 330,000-350,000 MT, with possible deficit of around 80,000-100,000 MT that can be covered only by imports. Due to the shortage of soybean meal in spring 2010 according to some trade sources, in May 2010, "Victoria Group" imported around 33,000 MT of Brazilian non-GMO soybeans for crushing.

Current market price of soybean meal at Novi Sad Commodity Exchange is 38-40 din/kg (463-480 USD/MT), which is about 120-140 USD/MT higher comparing to price of soybean meal from Argentina (44/45%) on parity FOB Hamburg Germany (340 USD/MT). Even with adding transportation costs and customs taxes price of 463-480 USD/MT for Serbian soybean meal remains one of the highest in Europe. This is the result of the monopoly on soybean meal supply by only one local company at the Serbian market and official ban on imports of soybean meal from abroad. Monopoly of soybean meal supply puts Serbian farmers and cattle producers in very bad situation. Because of the high price of inputs for cattle feed, Serbian cattle production is reducing for the last couple of years. Price of meat can not follow price of inputs, due to the limited incomes of the local population causing meat demand to be very low.

For every shipment of soybeans and soybean meal at the border phytosanitary inspectors at border are instructed to carry out surveillance of possible unauthorized imports of biotech crops or products, while the internal inspectors from the Ministry of Agriculture control what is planted on the field in Serbia. The phytosanitary inspectors use test strips "Reveal for CP4" on testing for RR soybeans presence or apply herbicides on small areas of the soya fields to identify illegal GMO soybean planting. When border or field tests are positive samples are sent to an accredited laboratory by the Ministry of Agriculture for further testing. There are three accredited laboratories that the Ministry of Agriculture is using for GMO testing:

- SP Laboratory (member of "Victoria Group"),  
Address: Industrijska Zona bb, Becej  
Phone: +381 21 453 191  
Web page: <http://www.victoriagroup.rs/en/content/view/22/58/lang.english/>
- 2. Laboratory for Seed Tasting (part of Institute for Crops and Vegetables Novi Sad),  
Address: 30 Maksima Gorkog, Novi Sad  
Phone: +381 21 421 248  
Web page: <http://www.nsseme.com/en/contact/?opt=lis&cat=contact>
- 3. A Bio Tech Lab,  
Address: Vojvode Putnika bb, Sremska Kamenica  
Phone: + 381 21 489 3661

All three 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.

In 2001, Monsanto first obtained approval for contained use for Roundup Ready herbicide corn (NK603) from the Ministry of Agriculture for a period of four years. Field trials of the RR corn took place in two research institutes, the Maize 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 due to uncompleted application submitted by Monsanto. In July 2009, Ministry of Agriculture issued to Monsanto a new approval for one year, but since the approval was issued too late in the year, no RR corn field trials took place that year. In 2010, Monsanto did not require a new approval for RR corn field trials since it decided to put RR corn field trials in Serbia on hold for the time being. Therefore, currently there is no foreign company in Serbia engaged in biotech experimental research.

### **Section III. Plant Biotechnology Policy:**

Law on Genetically Modified Organisms (GMO) was adopted by the Serbian Parliament in May 2009. Law was published on 06/02/09 in the Official Gazette No.41/2009 and became effective from June 12, 2009. This law completely banned all trade and commercial cultivation of biotech products, or trade with biotech products and products delivered from biotechnology and regulates basic conditions for the use GMO in closed systems and deliberate release into the environment.

The current 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 Biosafety Expert Council, which is composed of representatives of scientific research institutions in the fields of agriculture, ecological and biological science.

Since June 2009, 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 the law is not in accordance with EU Directives and it does not include any regulations concerning trade, transport, marketing, packaging, traceability and labeling of GMO products. When adopted, the new amended GMO Law and other by-laws will be fully in accordance with EU Directives on biotechnology 2001/18/EC; No.1829/2003; No.1830/2003; No.65/2004 and No.641/2004.

Four by-laws (Rulebooks) that were adopted in 2002 are still in effect (of which number 3. and 4. are not in use with the current law, but will be once the law gets amended).

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 (will be amended with new terminology after adoption of the amendments to the current GMO Law)
- 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 (will be amended with the new terminology after adoption of the amendments to the current GMO Law)

Following the adoption of the current Serbian GMO law, Ministry of Agriculture is planning to implement regulations in the new rulebooks. After a year long pressure from representatives of different countries, Serbia is currently preparing amendments to the current very restrictive Law on GMO adopted in 2009. Amendments are expected to be adopted by October 2010. The amendments will allow to import and to grow GMO crops and products but only under very strict control of the state. Amended Law on GMO will represent general framework on biotechnology that will be fully harmonized with EU regulations on biotechnology, while all specifics will be regulated by additional eight by-laws that Serbia is planning to adopt in addition to already existing four by-laws.

List of additional by-laws that Serbia will need to adopt after changing current GMO Law in order to harmonize its legislation on biotechnology with EU Directives:

- Regulation on the use of GMOs in closed systems (*Directive 2009/41/EC*);
- Regulation on deliberate release of GMOs into the environment (*Directive 2001/18*);
- Regulation on the placing on the market of GMOs and products of GMOs (*Directive 2001/18, Regulation 1829/2003, Regulation 1830/2003, Regulation 641/2004, Regulation 1946/2003*);
- Regulation on labeling and traceability of GMOs and products of GMOs (*Regulation 1830/2003, Regulation 65/2004*);
- Regulation on the content and data of the Register of GMOs and products of GMOs;
- Regulation of the authorized laboratories (*Commission Recommendation 2004/787/EC*),
- Regulation of confidential information;
- Regulations for the handling, packaging and transport of GMOs and GMO products.

Current GMO Law regulates the work of the Biosafety Expert Council (before known as National Biosafety Committee), the network of 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.

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 Biosafety Expert Council.

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 IV. Plant Biotechnology 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. With the adoption of GMO Law in 2009, 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. During 2009 and 2010, Serbian officials continued to strongly promote 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 and in favor of a strict control over GMO production, reaching 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 Ministry of Agriculture decided to adopt the 2009 GMO

Law completely bans any growing or trading of GMOs.

Concerning marketing of non-GMO, the Ministry of Agriculture is supporting local soybean producers and 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. Serbian soybean producers are receiving production subsidies of 14,000 dinars/HA (169 USD/HA) as a state assistance for purchasing seeds, fertilizers and diesel.

### **Section V. Plant Biotechnology Capacity Building and Outreach:**

In the past 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 included 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. The Netherlands' activities were mainly focused on conducting workshops and training in the area of biosafety.

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 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 FY2010**

#### **USDA/OCBD**

As part of OCBD activities, USDA consultant visited Belgrade two times in FY2010 in order to continue to work with Serbian officials on amending current GMO Law. Serbian side expressed their strong interest to communicate with the U.S. experts in regarding drafting amendments to the current GMO law. Serbian biotech experts in Working Group for GMO Law are continuing to communicate with U.S. experts in order to finalize amended GMO Law that should go to the parliament procedure in in October 2010 for adoption.

#### **Public Diplomacy Program “Biotech Outreach Strategy”**

Through State Department “Biotech Outreach Strategy” Program from 6 to 12 May, 2010 FAS Office



Belgrade organized a visit to Serbia for biotech speaker Professor Martina McGloughlin from University of California Davis. Through this program Professor McGloughlin gave presentations on topics “Modern Trends in Biotechnology” and “Environmental Impacts of Biotechnology” at Agriculture Faculties in Zemun and Novi Sad. Three Biotech Roundtables were organized at the Institute for Biological Research, Institute for Crops and Vegetables and Expert Biosafety Council of Serbia and number of meetings were held with Serbian Government officials responsible for biotechnology legislation. In addition to these events Professor McGloughlin gave interviews to two national TV stations and daily newspapers that brought up significant interest of the scientific community in Serbia. The purpose of this program was to initiate discussion about agriculture biotechnology trends and to reach media, government officials, food industry, agriculture faculties and scientists in order to create more favorable environment for pro-biotech policies.

### **Possible future activities**

After changing a Law on GMO, probably in the fall 2010, 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 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 VI. Animal Biotechnology:**

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 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 four existing by-laws is also available at the FAS Office Belgrade, Serbia: Phone: + 381 11 306 4802; Fax: + 381 11 306 4922, e-mail: [tatjana.maslac@usda.gov](mailto:tatjana.maslac@usda.gov)

### **Government Institutions**

Ministry for Agriculture, Forestry and Water Management  
<http://www.minpolj.gov.rs>

Ministry for Science and Technological Development  
<http://www.nauka.gov.rs/eng/>

Ministry of Environment and Spatial Planning  
<http://www.ekoplan.gov.rs/en/index.php>

Serbian Environmental Protection Agency  
<http://www.eco-web.com/reg/index.htm>

Ministry for Health  
<http://www.zdravlje.gov.rs>

UNEPGEF/UN Environment Program/Global Environment Facility  
<http://www.unep.org/biosafety/files/YUNBFrep.pdf>

### **Research Institutions**

Institute for Field and Vegetable Crops, Novi Sad  
<http://www.nsseme.com/en/>

Maize Research Institute, Zemun Polje  
<http://www.mrizp.co.rs/index-en.php>

Institute for Molecular Genetics and Genetic Engineering  
<http://www.imgge.bg.ac.rs>

Institute for Biological Research "Siniša Stanković"  
<http://www.ibiss.bg.ac.rs/>

Faculty of Agriculture, University of Novi Sad  
<http://polj.uns.ac.rs/english/index.html>

Faculty of Biology, Belgrade University  
<http://www.bio.bg.ac.rs/>

Faculty of Agriculture, Belgrade University  
<http://www.agrif.bg.ac.rs/>

Fruit Research Institute Čačak  
[http://institut-cacak.org/index.php?option=com\\_content&task=view&id=26&Itemid=38&lang=en](http://institut-cacak.org/index.php?option=com_content&task=view&id=26&Itemid=38&lang=en)