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## Biotechnology

## Annual

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**Report Highlights:**

This report describes the status of production and trade of biotechnology crops and products derived from biotech materials in Serbia and Montenegro. It outlines the country's regulatory framework, oversight and enforcement bodies and the role that government agencies play in setting up and implementing biotechnology policy. The report also highlights the main capacity building activities in the biotechnology area conducted under USDA technical assistance programs in Serbia and Montenegro.

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## EXECUTIVE SUMMARY

Under the current Law on Genetically Modified Organisms (GMO) and its supporting regulations, Serbia and Montenegro have a regulatory framework for the introduction of products derived from modern agricultural biotechnology through research and trade. The Ministries of Agriculture in Serbia and Montenegro are the competent authorities to regulate such introductions. Since Montenegro has very limited resources for agriculture biotechnology it generally follows decisions made by the Serbian Ministry of Agriculture. While the statutory instruments for regulating biotechnology have been established, operational experience with the framework in Serbia is lacking among regulators, technical advisers and scientists. Serbia's anticipated entry into the European Union and their intent to ratify the Cartagena Protocol on Biosafety prompted ongoing efforts to rewrite the laws and regulations to be consistent with these future obligations. In the meantime, the national biosafety system is functional, while the Ministry of Agriculture maintains a positive but precautionary position on biotechnology. The level of interest in Serbia's nascent biotechnology sector seems to be increasing. Last year, there was one permit issued for the development of a local transgenic corn cultivar but this research program has been interrupted. In May 2005, work on the transgenic corn was suspended because the research team failed to renew its lapsed permit in time for spring sowing. With a completed application to renew the biosafety permit, the research is anticipated to resume in the next corn-growing season. Additional applications for contained-use and deliberate release permits are currently in the pipeline.

## BIOTECHNOLOGY TRADE AND PRODUCTION

Serbia and Montenegro currently does not produce any biotechnology crops for commercial use. The 2001 Federal Law on GMO is currently applied at the Republic's level in both Serbia and Montenegro and is allowing research and commercial use of biotech products under very strict supervision of the state. Permits for research work, contained use and marketing of biotech materials can be obtained by meeting the state regulatory requirements.

At the present time, the only application approved in Serbia is for commercial import of soybean meal obtained from Roundup Ready (RR) soybeans. RR soybeans for crushing or other commercial use are not allowed for import. Serbia has a constant deficit of soybean meal and annually imports around 120,000 MT of soybean meal, mostly from Argentina and Brazil, due to their price competitiveness over U.S. soybean meal. In previous years, Serbia and Montenegro imported soybean meal from the U.S. under food donation programs. During 2001-2003, Serbia received donations of 70,000 MT U.S. soybean meal under section 416-b and Food for Progress Programs. During the same time, Montenegro also received 10,000 MT of U.S. soybean meal under section 416-b and Food for Progress Programs. Through those donations, the RR soybean meal was introduced to the Serbian and Montenegro markets for the first time.

No other biotechnology crops or products have been permitted in Serbia. At border posts, official inspectors carry out surveillance for possible introductions of biotech crops and products. In 2003, the Ministry of Agriculture identified and destroyed approximately 1,000 individual plots of transgenic (i.e., glyphosate tolerant) soybeans, which were illegally imported and sowed at local farms.

Field trials on Roundup Ready corn (NK603), "not to be released or marketed in country", have been conducted by Monsanto and two local seed institutes in Novi Sad and Zemun Polje for the last four years. In May 2005, a Monsanto research team applied for renewal of license

for four more years to continue the same research but was rejected by the National Biosafety Committee because of lack of detailed information on the new application. The rulebook on "Contained use of genetically modified organisms" specifies the requirements for safe field-testing of biotech products. The applicant who is granted an approval of contained use of GMO must apply the following preventive measures:

- 1) Implement and apply technical measures and devices for protection of persons and buildings, including sites
- 2) Carry out tests on the presence of the GMOs in use beyond the site designated in the approval of the contained use
- 3) The packages used for keeping and transportation must satisfy the following requirements:
  - It is safe from uncontrolled GMO release (emission);
  - All constituent parts of the packaging must comply with manipulation requirements, and that they cannot be damaged in transportation;
  - Labeling must provide the following data: name and address of the producer, or a representative of the foreign producer, including logo, contents of the packaging, genetic name, date of production, and expiry date, with a clearly visible label "genetically modified organism".
- 4) Destroying empty packaging used for holding a GMO shall be carried out by the end user, by known physical and chemical means
- 5) The site of the contained use of a GMO must satisfy the following requirements:
  - "GMO handling" labels must be posted
  - conditions and criteria specified in the approval of the contained use must be met
- 6) Access to the site of the contained use of the GMO may be available only to the staff of the laboratory or institute.

## BIOTECHNOLOGY POLICY

### Laws and Regulations

Serbia and Montenegro apply the same Law on Genetically Modified Organisms adopted in 2001 in addition to five rulebooks issued in 2002 and 2003. The implementation of the law has been designed to follow the regulations of the European Union and is in accordance with EU directives 90/220 and 90/219. These five rulebooks are:

- Rulebook on "Commercial release of 'GMOs' or products derived from GMO crops", 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

Serbian officials are currently working on revising the existing law and rulebooks on products derived from modern agricultural biotechnology. The current law will be expanded, while the number of rulebooks will be increased and will be written in accordance with EU Regulations EC 1829/2003, 1830/2003, 1946/2003 for governing labeling, traceability and trade of biotech products and products derived from biotech materials.

While the statutory instruments for regulating biotechnology have been established in Serbia, operational experience with the framework is lacking among regulators, technical advisers, and scientists. Serbia's anticipated entry into the European Union and its intent to ratify the Cartagena Protocol on Biosafety prompted an ongoing effort to rewrite the law and regulations to be consistent with these future obligations.

The Law on GMO allows the research and use of biotech products under strict control of the state. The GMO law regulates three fields: work under contained use (experimental use); deliberate use of biotech crops (production of biotech seeds which are prohibited for sales in country); and marketing of biotech events (allowed for sale locally). The rulebooks set forth the detailed application process for obtaining a permit. The application must provide all the necessary data on the particular biotech event or biotech crop, parameters for estimating safety and safety measures. All applications are to be submitted to the Serbian or Montenegrin Ministry of Agriculture. Risk assessments are conducted by the National Biosafety Committee, which is composed of representatives of scientific research institutions in the fields of agricultural, ecological and biological sciences. Following the risk assessment and the scientific recommendation of the Biosafety Committee, the Ministry of Agriculture, as the administrative authority in charge, must issue a decree on the specific biotech event. Every application is evaluated on a case-by-case basis.

### **Monitoring and Enforcement Authorities**

The Serbian Ministry of Agriculture is the main administrative authority in charge of monitoring biotechnology in Serbia. The contact information at the Ministry of Agriculture is Ms. Sandra Kojic, Associate, Tel: ++381 11 3616 278, e-mail: sandrakojic@minpolj.sr.gov.yu.

The Montenegrin Ministry of Agriculture is the main administrative authority of monitoring biotechnology in Montenegro. The Phytosanitary Inspection Department is responsible for taking samples of food and food products for testing of biotech content in Montenegro. Contact information: Mr. Spaso Popovic, Chief Phytosanitary inspector, Tel/Fax: ++ 381 81 621 007. Currently, Montenegro does not have laboratories equipped for biotech testing and samples are usually sent to the laboratory of the Novi Sad Institute's for Crops and Vegetables. Montenegro has very limited expertise in agriculture biotechnology and generally follows decisions made in Serbia by the National Biosafety Committee and the Serbian Ministry of Agriculture.

The Serbian Ministry of Agriculture is authorized to supervise the application of the GMO law and its subsequent regulations through a system of Republic inspectors. These field inspectors control and take samples at the border and inland for materials suspected to be of biotech origin. A company or individual can be fined from 150,000 to 450,000 dinars (USD 2,500 to 8,000) if they are found to have allowed the release, production or trade of biotech crops and products derived from biotech crops for which no approval was issued by the legal authority.

### **Traceability and Labeling**

Currently, Serbia and Montenegro are not implementing any traceability systems for products from agriculture biotechnology, but a new rulebook on traceability (expected to be published by the end of 2005) will be in accordance with EU Regulation 1829/2003 and 1830/2003. The lack of resources is the main factor holding Serbia back from full implementation such a traceability system.

Labeling of food products is currently the responsibility of the Republic's Ministry of Health, both in Serbia and in Montenegro. In February 2003, labeling regulations were issued by the Federal Ministry of Internal Trade and Economy but were never enforced due to the lack of authority and staff. The Federal Ministry of Internal Trade and Economy was abolished at the end of 2003. According to labeling regulations, all retail food labels on products with biotech content (0.9 percent minimum) must include a yellow triangle, framed with a red border and containing the English letters "GMO" (in black). A new rulebook on labeling that will be published by the end of 2005 is expected to be in accordance with EU Regulation 1829/2003 and 1830/2003. The stated purpose of the new labeling regulation is to fully inform consumers about the product GMO contents and leave them the choice to decide.

## **MARKETING ISSUES**

The general public in Serbia has a negative attitude towards market acceptance of biotech crops and products derived from GMOs. Newspaper articles and reports against biotechnology are often circulated in the Serbian media. Public opinion about biotechnology in Montenegro is not as radical as in Serbia. However, due to lack of expertise, the Montenegrin officials mostly follow Serbia's lead in the biotech issues.

Some Serbian soybeans crushing plants have entered long-term contracts with EU buyers to export non-biotech soybeans and products. This is the main reason why Serbia has a very strict field control system in order to prevent any illegal planting of biotech seeds and preserve its image as a non-biotech crop producer. Serbian officials are likely to follow the EU lead in most biotech issues, thus any future market development for biotech events will mainly depend, to large extent, on EU decisions on growing and trading of transgenic crops.

## **CAPACITY BUILDING AND OUTREACH**

### **USDA activities and accomplishments 2001-2005**

USDA has been funding capacity building activities in Serbia and Montenegro since 2001. In 2001, Serbian and Montenegrin regulators, scientists and journalists participated in the USDA's Cochran Fellowship Program, where they visited the U.S. to examine the regulatory framework for agricultural biotechnology. Shortly thereafter, the Federal Ministry of Agriculture completed the law on GMO, which established a National Biosafety Committee to oversee introductions of transgenic crops and products into Serbia. Under this law, U.S. shipments of transgenic soybean meal were approved for import into Serbia. Also, in partnership with the Institute of Vegetable and Field Crops, Monsanto was permitted to initiate research on transgenic maize cultivars.

In early 2004, USDA launched a three-year initiative to intensify cooperation with Serbia's Ministry of Agriculture and National Biosafety Committee on the development of a national system for agricultural biosafety. A delegation of National Biosafety Committee members visited the U.S. to examine the biosafety system. Later in 2004, two Biosafety Committee members participated in a USDA/APHIS workshop on genetic confinement of transgenic crops in research settings. Both of these activities afforded the Serbian participants opportunities to establish working relationships with U.S. counterparts and experts, consider U.S. approaches to risk assessment and regulation of transgenic crops, and clarify priorities for U.S. cooperation. It was mutually agreed that bilateral cooperation would focus upon four critical areas: systematic assessment of biosafety risks, field inspection and enforcement of biosafety regulations, management of confidential business information, and Institutional Biosafety Committees. In 2005, these critical areas were addressed through

two workshops in Serbia, where participants concentrated upon risk assessment exercises, procedures for managing confidential business information, and implementation of institutional biosafety committees. A third workshop will be conducted in the U.S., where participants will observe biosafety features of experiment designs and also practice field inspection methods to assess compliance with biosafety guidelines. The Chair of the National Biosafety Committee reported that information and capacities gained through such exchanges have already been applied in Serbia to assess recent biosafety applications as well as to justify proposed revisions to the current Law on GMOs. With each additional activity, the National Biosafety Committee clearly gained confidence to exercise its authority, build its capacities, and encourage agricultural biotechnology in Serbia.

#### **USDA future activities**

In 2006, the workshop on biosafety enforcement and compliance will be replicated in Serbia, where local scientists and field inspectors will participate in training exercises on mock plots. In addition, USDA will provide assistance to launch institutional biosafety committees at Serbian organizations that desire to manage transgenic crops.

#### **REFERENCE MATERIAL**

Relevant information can be found at the web page of Ministries of Agriculture in Serbia and Montenegro:

[www.minpolj.sr.gov.yu](http://www.minpolj.sr.gov.yu) (Ministry of Agriculture, Republic of Serbia)

[www.gom.cg.yu/minpolj](http://www.gom.cg.yu/minpolj) (Ministry of Agriculture, Republic of Montenegro)

The full texts of Law on GMO and relevant Rulebooks in English are available at the FAS Office Belgrade, Serbia and Montenegro Tel: ++ 381 11 306 4927; Fax: ++ 381 11 306 4922, e-mail: [tatjana.buric@usda.gov](mailto:tatjana.buric@usda.gov).