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Report Highlights:

In 2009, Serbia adopted the current Law on Genetically Modified Organisms (GMOs), which strictly prohibits the importation, production, or commercial growing of genetically engineered crops. However, this law does not conform to EU regulations nor the World Trade Organization precepts. Serbia currently is considering some amendments that would, in theory, set up a general framework for biotechnology that is harmonized with EU regulations. It would create a mechanism for biotech crops and products to be reviewed by the government for consideration to import and cultivate.

Section I. Executive Summary:

In 2009, Serbia adopted the current Law on Genetically Modified Organisms (GMOs), which strictly prohibits the importation, production, or commercial growing of genetically engineered crops. The ban was adopted without a risk assessment being done based on a scientific review as required by the World Trade Organization and the law does not provide any mechanism for future products to be reviewed as

there is no transparent science based risk assessment/approval process.

Serbia is currently considering amendments to the law that would make it WTO compliant. Namely it would create a mechanism for a risk assessment of applications to import or grow biotech crops and products. The new Law will establish the general framework for regulating biotechnology in Serbia and eight by-laws will cover the use of GE products in closed systems, the placing of GE products on the market, labeling and traceability, authorized laboratories, packaging, transportation, and other related issues. In addition to these new by-laws, there will be some changes in terminology to the four existing by-laws.

There remains strong resistance to accepting biotech crops and products derived from GE crops. Last year, a number of Serbian mayors signed a so called "Declaration on GMO" calling for a ban on GE products in their municipalities. In January 2013, Serbia signed the "Danube Soya Association" promoting non-GE soya cultivation and processing in the Danube region of Europe. Also during the last few years, a number of new civil society groups have appeared sponsoring anti-GE crop campaigns.

USDA has provided extensive technical assistance in the area of agricultural production and some of this has included developing Serbia's research capacities and regulatory oversight. USDA/OCBD has trained Serbian participants to critically examine the technical and economic aspects of crop production and how to optimize the various tools available to increase yields, including integrated pest management, good agricultural practices and biotechnology.

In May 2013, the North American Export Grain Association (NAEGA), sponsored a speaker for two feed events in Serbia. The events focused on best practices in grain production, biotech legislation in the U.S. and EU, some practical suggestions for mycotoxin management, and the importance of adopting international science based standards that foster innovation and trade.

In September 2012, the US Embassy sponsored two speakers - Dr. Ralph Scorza, USDA/ARS plant breeding scientist and Victor Felix Nicolescu, member of Romania's National Sanitary, Veterinary and Food Safety Authority to discuss US and EU regulatory frameworks. Dr Scorza also described his research on a disease resistant GE plum.

Section II. Plant Biotechnology Trade and Production:

Part A: Production and Trade

- a. **PRODUCT DEVELOPMENT:** In Serbia, there are no GE crops under development.
- b. **COMMERCIAL PRODUCTION:** Serbia does not commercially cultivate any GE crops.
- c. **EXPORTS:** Serbia does not export GE crops.
- d. **IMPORTS:** Imports of GE crops are not allowed. While there is no mechanism to approve GE crops, there is a frame work for doing research work which is governed by a strict application and monitoring process. Currently there are no GE field trials being conducted. However, in theory, permits for research work and contained use of biotech materials can be obtained from the Serbian Ministry of Agriculture after the State's regulatory requirements have been met. Prior to the adoption of the current Law on GMOs in 2009, Serbia imported soybean meal which contained approved Round-Up Ready soybeans. Imported quantities reached 70-100,000 metric tons annually, valued at \$40-60 million.

- e. **FOOD AID RECIPIENT COUNTRIES:** Serbia is not a food aid recipient country.

Section III. Plant Biotechnology Policy:

a) **REGULATORY FRAMEWORK:** The Serbian Parliament adopted the current Law of Genetically Modified Organisms (GMOs) in May 2009. This Law, which was published in Official Gazette No.41/2009, went into effect on June 12, 2009 and it completely banned all trade and commercial cultivation of biotech products. The ban was adopted without a risk assessment being done based on a scientific review as required by the World Trade Organization and the law does not provide any mechanism for future products to be reviewed as there is no transparent science based risk assessment/approval process. Reportedly the Ministry of Agriculture has drafted a revision to the GMO Law that incorporates U.S. and EU suggestions to make it more WTO compliant. Namely it would create a mechanism for a risk assessment of applications to import or grow biotech crops and products. The new Law will establish the general framework for regulating biotechnology in Serbia and eight by-laws will cover the use of GE products in closed systems, the placing of GE products on the market, labeling and traceability, authorized laboratories, packaging, transportation and other related issues. In addition to these new by-laws, there will be some changes in terminology to the four existing by-laws. The four by-laws (Rulebooks) that were adopted in 2002 are still in effect, although some of the provisions are not in use under the 2009 law, but will become active again once the law is amended.

The following are the Rulebooks that are still valid:

- 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 new GMO Law);
- Rulebook on “Commercial release of ‘GMOs’ or products derived from same”, No.1245/1 issued November 13, 2002 (not used due to the current Law on GMO);
- 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 new GMO Law).

The new draft law is currently being reviewed by Serbia’s 18-member National Biosafety Council. The final version of the law has to be adopted by the Serbian Parliament. Once adopted, the Ministry of Agriculture is planning to implement the following eight by-laws:

- 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, and Regulation

1946/2003);

- Regulation on labeling and traceability of GMOs and products of GMOs (Regulation 1830/2003 and Regulation 65/2004);
- Regulation on the content and data of the Register of GMOs and products of GMOs;
- Regulation on authorized laboratories (Commission Recommendation 2004/787/EC),
- Regulation on confidential information;
- Regulations on the handling, packaging and transport of GMOs and GMO products.

The Ministry for Agriculture, Forestry, and Water Management is the competent authority responsible for all GE issues in Serbia. The Ministry deals with all contained use of GEs and is the focal point for the 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 to the Biosafety Expert Council.

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

b) **APPROVALS:** 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 GE 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 from the scientific research institutions in the fields of agriculture, ecological, and biological science. The applicant must submit to the Ministry of Agriculture any renewal requests six months prior to the expiry of the original approval.

c) **FIELD TESTING:** The application for field testing must be submitted to the Serbian Ministry of Agriculture for review and approval. Risk assessments are evaluated by the Biosafety Expert Council. The application must provide all the necessary data on the particular biotech event or biotech crop and stipulate the safety procedure parameters and measures.

d) **STACKED EVENT APPROVALS:** No stacked event approvals have been issued by the Serbian Ministry of Agriculture. Furthermore, it is expected that even with amendments to the current GMO law, each GE event would have to be approved individually.

e) **ADDITIONAL REQUIREMENTS:** N/A

f) **COEXISTENCE:** Serbia does not have a coexistence policy, it has a strict ban on planting GE crops. However, a coexistence policy may be incorporated into amendments to the current GMO.

g) LABELING AND TRACEABILITY: Under the current GMO Law, labeling and traceability are not defined. Once the GMO law is amended, the Ministry of Agriculture plans to adopt a separate Regulation on the labeling and traceability of GMOs and products of GMOs, per EU Regulation 1830/2003 and Regulation 65/2004.

h) TRADE BARRIERS: The current Law on GMOs adopted in 2009 is a major trade barrier as it strictly prohibits all imports, production, and commercial growing of GMO crops or products containing GMOs. The ban was adopted without a risk assessment being done based on a scientific review as required by the World Trade Organization and the law does not provide any mechanism for future products to be reviewed as there is no transparent science based risk assessment/approval process.

i) INTELLECTUAL PROPERTY RIGHTS (IPR): The legal regime for IPR protection has improved substantially in recent years as Serbia has revised laws to meet the WTO's TRIPs standards, although Serbia is not yet a WTO member. IPR Intellectual property rights are treated in a series of laws, as follows: The Law on Copyright and Related Rights (2009), The Law on Patents (2004), The Law on Trademarks (2009) and the Law on Geographical Indications (2010).

j) CARTAGENA PROTOCOL RATIFICATION: Serbia is a party to the Convention on Biological Diversity, ratified in 2002, and ratified the Cartagena Protocol on Biosafety in 2006. According to Serbia's obligations under the protocol, it must create a Biosafety Clearing House (BCH) consisting of a national database keeping record of all biotech trials, production, and trade activities in the country.

k) INTERNATIONAL TREATIES/FORA: Serbia is currently a member of CODEX Alimentarius, the European Plant Protection Organization (EPPO), the Convention on 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 (IPPC).

l) RELATED ISSUES: N/A

m) MONITORING AND TESTING: In Serbia, the responsibility for monitoring and testing of GE food, feed and seeds falls under the Ministry of Agriculture, as defined by the Law on GMO and the Food Safety Law. Serbia's phytosanitary inspectors are instructed to carry out surveillance of possible unauthorized imports of biotech crops or products at the border and the internal inspectors from the Ministry of Agriculture control what is planted in the fields. The phytosanitary inspectors use "Reveal for CP4" test strips to test for RR soybeans and apply herbicides to small test areas in soybean fields to determine if any illegal GE soybeans have been planted. The Ministry of Agriculture works with the following four accredited laboratories for GE testing:

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

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: www.nsseme.com

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

4. Institute for Molecular Genetics and Genetics Engineering
Address: Vojvode Stepe 444a, Belgrade
Phone: +381 11 3975 744
Fax: + 381 11 3975808
Web page: <http://www.imgge.bg.ac.rs>

n) **LOW LEVEL PRESENCE POLICY:** According to the current GMO Law, agriculture products of non-animal origin are considered genetically modified organisms if they exceed a 0.9% threshold for genetically modified content. For seeds and reproductive material the threshold is 0.1%.

Section IV. Plant Biotechnology Marketing Issues:

a) **MARKET ACCEPTANCE:** Over the past several years, the profile of the issue has been raised and it is now a topic for debate amongst politicians, scientists, farmers, and industry representatives as well as the media. Generally there appears to be a negative attitude towards the acceptance of GE crops in most of the social media outlets, although consumer awareness of GEs and public discussion of biotechnology related issues is very limited. The Ministry of Agriculture is keen to promote Serbia's non-GE and organic production and has done little to dispel any misinformation about biotechnology and EU approved GE events. Several Serbian crushing plants have long-term contracts with EU buyers to export non-GE soybeans and products. Serbian soybean producers are receiving government production subsidies of 6,000 dinars/MT (70 USD/MT).

b) **PUBLIC/PRIVATE OPINIONS:** Public opinion is generally negative towards biotechnology, but the government has done little to educate consumers and the media consistently chooses to reinforce the negative image rather than report on technological advances. The issue has proven to be too politically charged, so that even politicians in favor of innovation do not take a public stance. Grain farmer and trader organizations are not united on the issue, as there is both an import and export interest involved. Serbian researchers are well educated and are not anti-GMO, but are not active in passing these messages to the general public. Serbian livestock and poultry farmers are aware of the fact that with adoption of GMO Law in 2009, the Serbian Government blocked all imports of GE soybean meal for cattle feed that resulted in drastic increases in feed prices over the last few years. Livestock farmers and cattle feed producers are eager to buy EU approved GE soybean meal from Argentina, Brazil or the United States to reduce input costs. Serbian consumers continue to reject biotechnology publicly in the erroneous belief that domestic production is effectively "organic". Several mayors have adopted "Declaration on GMOs" and designated their territories as GMO-free. In 2013, Serbia officially supported the Danube Soya Association. The Danube Soya Association is promoting biotech-free soya cultivation and processing in the Danube region. This Association was founded in 2012 as an

international multi-stakeholder association based in Vienna with farmers, agricultural traders, feed companies, major retailers, and green organizations as members.

c) **MARKET STUDIES:** There are several reports published by international organizations that include Serbia in their analysis, such as the Balkan Studies, research foundation <http://www.balkanstudies.org/> and International Service for the Acquisition of Agri-biotech Applications at <http://www.isaaa.org/>.

Section V. Plant Biotechnology Capacity Building and Outreach:

a) **ACTIVITIES:** USDA has provided extensive technical assistance in the area of agricultural production and some of this has included developing Serbia's research capacities and regulatory oversight. USDA/OCBD has trained Serbian participants to critically examine the technical and economic aspects of crop production and how to optimize the various tools available to increase yields, including integrated pest management, good agricultural practices and biotechnology.

In April 2013, five Serbian experts participated on an "Open World" program on biotech research and legislation. "Open World" programs provide an opportunity for countries to exchange views on a particular theme. The team visited Washington DC and Tulsa, OK.

In May 2013, the North American Export Grain Association (NAEGA), sponsored a speaker for two feed events in Serbia. The events focused on best practices in grain production, biotech legislation in the U.S. and EU, some practical suggestions for mycotoxin management, and the importance of adopting international science based standards that foster innovation and trade.

In September 2012, the US Embassy sponsored two speakers - Dr. Ralph Scorza, USDA/ARS plant breeding scientist and Victor Felix Nicolescu, member of Romania's National Sanitary, Veterinary and Food Safety Authority to discuss US and EU regulatory frameworks. Dr Scorza also described his research on a disease resistant GE plum.

b) **STRATEGIES AND NEEDS:** The lack of awareness concerning agricultural biotechnology and its potential is significant. Activities should encourage a scientific discussion of the technology in an environment that would generate media coverage. Not only do key decision makers and the public need to be better informed, but an opportunity needs to be created for Serbian scientists to take a public stance and help deliver the message that biotechnology is an important tool for innovation. Journalists also need to have access to reliable scientific information and the opportunity to learn more about the issue, in order not to contribute to the misinformation being circulated by some of the social media outlets.

Section VI. Animal Biotechnology:

PART E: PRODUCTION AND TRADE

a. **BIOTECHNOLOGY PRODUCT DEVELOPMENT:** According to the Serbian Ministry of Agriculture, no applications have been submitted to conduct research in this area.

b. **COMMERCIAL PRODUCTION:** There are no livestock clones or GE animals or GE genetics

being used in commercial production in Serbia.

- c. BIOTECHNOLOGY EXPORTS: N/A
- d. BIOTECHNOLOGY IMPORTS: N/A

PART F: POLICY

- a. **REGULATION:** The institutions listed under Plant Biotechnology have the same responsibilities relating to Animal Biotechnology.
- b. **LABELING AND TRACEABILITY:** There are no laws or regulations covering animal biotechnology nor do they appear to be envisioned in the amendments to the GMO law currently being considered.
- c. **TRADE BARRIERS:** No country-specific legislation.
- d. **INTELLECTUAL PROPERTY RIGHTS (IPR):** Please see Plant Biotechnology Chapter.
- e. **INTERNATIONAL TREATIES/FORA:** Serbia is a member of Codex Alimentarius and the World Organization for Animal Health.

PART G: MARKETING

- a. **MARKET ACCEPTANCE:** Currently no GE imports are permitted and no applications have been made to do research. However, with current public perceptions about biotechnology, it is likely that animal biotechnology would have a difficult time with market acceptance.
- b. **PUBLIC/PRIVATE OPINIONS:** Generally unfavorable
- c. **MARKETING STUDIES:** N/A

PART H: CAPACITY BUILDING AND OUTREACH

- a. **ACTIVITIES:** The focus has been on encouraging Serbia to work with WTO recognized organizations to adopt international standards and to create a transparent consistent science based system for assessing risk/approving new technologies.
- b. **STRATEGIES AND NEEDS:** The US will continue to focus on working with Serbia to work with WTO recognized organizations to adopt international standards and to create a transparent consistent science based system for assessing risk/approving new technologies. Serbia's scientific community needs to have access to peer reviewed recognized scientific information and Serbia's media needs to be better informed and base its reporting on credible information obtained from reliable sources.

Section VII. Author Defined:

Appendix 1. Relevant References

Serbian Ministry of Agriculture, Forestry and Water Management

Nemanjina 22-26,
11000 Belgrade, Serbia

Phone: ++ 381 11 260 7960
E-mail: info@minpolj.gov.rs
Web page: www.mpt.gov.rs

Serbian Ministry of Health

Nemanjina 22-26,
11000 Belgrade, Serbia
Phone: ++ 381 11 3616 596
E-mail: kabinet@zdravlje.gov.rs
Web page: www.zdravlje.gov.rs

Serbian Ministry of Internal and External Trade and Telecommunications

Bulevar Mihajla Pupina 2,
11070 New Belgrade
Phone: ++ 381 11 311 3432
E-mail: kabinet@mtt.gov.rs
Web page: www.mtt.gov.rs

Ministry for Science and Technological Development

Nemanjina 24,
11000 Belgrade, Serbia
Phone: ++ 381 11 361 6489
E-mail: kabinet@mpn.gov.rs
Web page: <http://www.mpn.gov.rs/sajt/>

Serbian Ministry of Environment, Mining and Spatial Planning

Nemanjina 11,
11000 Belgrade, Serbia
Phone: ++ 381 11 361 7717
E-mail: kabinet@mprpp.gov.rs
Web page: <http://www.mprpp.gov.rs/kontakt/>

GMO approvals and registrations

Serbian Ministry of Agriculture, Forestry and Water Management

1, Omladinskih Brigada St.
11070 New Belgrade, Serbia
Contact person: Mrs. Vanja Kojic
Phone: ++ 381 11 311 7591
E-mail: Vanja.Kojic@minpolj.gov.rs

Serbian Environmental Protection Agency

Ruze Jovanovica 27a,
11160 Belgrade, Serbia
Phone: ++ 381 11 2861080

E-mail: office@sepa.gov.rs

Web page: <http://www.sepa.gov.rs/>

National Authority for Consumer Protection/APOS

Zmaj Jovina 26,

21000 Novi Sad, Serbia

Web page: <http://www.apos.org.rs/cms/index.php>

Serbian Consumer Association

Ravanicka 11,

21000 Novi Sad, Serbia

E-mail: info@potrosac.info

Web page: <http://potrosac.info/>

Institute for Molecular Genetics and Genetics Engineering

Vojvode Stepe 444a

11001 Belgrade, Serbia

Phone: ++ 381 11 3975 744

Web page: <http://www.imgge.bg.ac.rs>

United States Department of Agriculture

Economic Research Service

1400 Independence Ave., SW, Mail Stop 1800

Washington, DC 20250-0002, USA

Web page: <http://www.ers.usda.gov/Briefing/Biotechnology>

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