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Agricultural Biotechnology Annual

Agricultural Biotechnology Annual Report 2016

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Report Highlights:

Serbia's Law on Genetically Engineered Organisms (GMOs), was signed in 2009. It strictly prohibits the importation, production, or commercial growing of genetically engineered crops. The law does not conform to European Union (EU) regulations or the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) agreement. In order to become a member of the EU and the WTO, Serbia needs to amend the current law. After seven years, Serbia still has not implemented the changes. The amended law would create a mechanism for biotech crops and products to be reviewed by the government for import and cultivation consideration. There are no livestock clones, genetically engineered (GE) animals (including fish, birds, insects, mammals), or GE genetics used in commercial production in Serbia.

Section I. Executive Summary:

Under the 2009 Law on Genetically Engineered Organisms (here forward referred to as the Law on "GMOs"), Serbia strictly prohibits all imports, production, and commercial growing of genetically

engineered (GE) crops or products containing GE traits. There is no mechanism to review GE product applications and this represents one of the main obstacles to Serbia's World Trade Organization (WTO) accession process. Because of repeated interventions from the European Union (EU), the United States, and other WTO members during the last several years, Serbian trade and agriculture officials recognize the international trade issues caused by the restrictive agricultural biotechnology law.

According to the European Commission's Progress Report for 2016, there has been limited progress in Chapter 12 of the report (food safety, veterinary, and phytosanitary policy). The European Commission especially emphasized the Serbian need to align its GE legislation with the EU's legislation to enable WTO accession.

Serbia is considering potential amendments to make the law WTO compliant. When adopted, amendments to the law and its by-laws will be fully harmonized with the EU Directive 2001/18/EC on Biotechnology and the Amendments to Directive 412/2015 adopted in March 11, 2015. The amended law is expected to allow for the import of GE products and cultivation of GE crops, but under very strict control of the national government.

Agricultural biotechnology remains extremely unpopular in Serbia and there is strong political resistance to make any changes to the current law. According to the Serbian Organic Association, over 100 Serbian cities and municipalities have signed the so-called Declaration on "GMOs" calling for a ban on GE products in their municipalities.

Serbia's agriculture experts believe that the country's competitive advantage will be realized by seeking a premium for high quality "natural" or "organic" products rather than competing on volume. Thus, there is concern about the potential market consequences of adopting pro-GE policies as well as a strong bias against GE products as being "unnatural." Additionally, Serbian politicians and the general public remain misinformed about GE products and view them as potentially dangerous.

Marketing or promotion of GE food does not exist in Serbia. There is a strong, negative public attitude towards the acceptance of GE crops and products derived from GE crops. Consumer awareness of genetic engineering is very low and public discussions of biotechnology related issues are very limited. Currently there is no foreign company in Serbia engaged in GE experimental research.

Section II. Author Defined:

SECTION II. PLANT AND ANIMAL BIOTECHNOLOGY

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CHAPTER 1: PLANT BIOTECHNOLOGY

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. The area planted for non-GE soybeans in marketing year (MY) 2015/16 was 185,000 hectare (HA). With an average yield of 2.5 MT/HA, total production of soybeans in MY 2015/16 was approximately 455,000 MT. During 2015, Serbia's soybean exports totaled 66,000 MT, mostly non-GE soybeans and products, while imports reached approximately 100,000 MT of non-GE soybeans mostly from the neighboring countries. Serbia mostly exports soybeans and products to EU countries such as Hungary, Austria, Germany, Belgium, Italy, and Romania
- c) **EXPORTS:** Serbia does not export GE crops and only exports non-GE crops (mostly corn and soybeans). In order to receive a better price on the world market the Serbian Ministry of Agriculture and Environmental Protection issues confirmation to Serbian exporters that Serbia is producing only non-GE crops.
- d) **IMPORTS:** Imports of GE crops are not allowed. Prior to the adoption of the current Law on "GMOs," Serbia imported soybean meal which contained approved Round-Up Ready soybeans. Imported quantities reached 70,000-100,000 metric tons (MT) annually, valued at US\$40-60 million.
- e) **FOOD AID:** Serbia is not a food aid recipient country. Serbia is also not providing food aid to other countries.
- f) **TRADE BARRIERS:** The current Law on "GMOs" is a major trade barrier as it strictly prohibits all imports, production, and commercial growing of GE crops or products containing GE traits. The ban does not provide any mechanism for the review of future products and there is no transparent science based risk assessment/approval process.

PART B: POLICY

- a) **REGULATORY FRAMEWORK:** The Serbian Parliament adopted the current Law on "GMOs" in May 2009. The government published this law in Official Gazette No.41/2009, and it went into effect on June 12, 2009. The law completely banned all trade and commercial cultivation of biotech products. The ban was adopted without a risk assessment, was not based on a scientific review as required by the WTO, and the law does not provide any transparent mechanism for the review of future products. Reportedly, the Ministry of Agriculture and Environmental Protection drafted a revision to the Law on "GMOs" that incorporates United States and EU suggestions to make it WTO compliant.

The new law will establish the general framework for regulating biotechnology in Serbia and ten by-laws will cover the use of GE products in closed systems, the placing of GE products on the market, labeling and traceability, trans-border movement, sampling, authorized laboratories, packaging, transportation and other related issues. Specifically, it would create a risk assessment mechanism for the review of import and cultivation applications. In addition to the new by-laws, there will be changes in terminology to the four existing by-laws. The four by-laws (Rulebooks) that were adopted in 2002 are still valid, although some of the provisions are not in use under the 2009 law.

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 Genetically modified Organisms,” No. 1669/1 issued December 15, 2002 (will be amended with new terminology after adoption of the new Law on “GMOs”);
- 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 “GMOs”);
- 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 Law on “GMOs”).

Serbia’s 18-member National Biosafety Council reviewed and approved The new draft law. The Serbian Minister of Agriculture and Environmental Protection needs to approve the final version of the law and adopted is required by the Serbian Parliament. Once adopted, the Ministry of Agriculture and Environmental Protection is planning to implement the following ten by-laws:

- Regulation on the use of “GMOs” in closed systems;
- Regulation on deliberate release of “GMO” into the environment;

- Regulation on the placing on the market of “GMOs” and products of “GMOs;”
- Regulation on labeling and traceability of “GMOs” and products of “GMOs;”
- Regulation on the content and data of the Register of “GMOs” and products of “GMOs;”
- Regulation on authorized laboratories;
- Regulation on confidential information;
- Regulation on the handling, packaging and transport of “GMOs” and “GMO products;”
- Regulation on trans-border movement of “GMOs” and products of “GMOs;”
- Regulation on sampling of “GMOs” and products of “GMOs;”

The Ministry for Agriculture and Environmental Protection is the competent authority responsible for all GE issues in Serbia. The Ministry deals with all contained use of GE products 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 and Environmental Protection is also responsible for appointing members to the Biosafety Expert Council.

The Ministry of Agriculture and Environmental Protection supervises the application of the Law on “GMOs” 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 contained use, research activities, and field trials of biotech products under the strict control of the national government. There is a strict and detailed application process for obtaining a permit for biotechnology research on plants. 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 and Environmental Protection 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 any renewal requests to the Ministry of Agriculture and Environmental Protection six months prior to the expiry of the original approval.

c) **STACKED or PYRAMIDED EVENT APPROVALS:** No stacked or pyramided event approvals have been issued by the Serbian Ministry of Agriculture and Environmental Protection. It is expected that the amended Law on “GMOs,” will require a separate approval for stack and pyramided GE applications (similar in legislation to the EU).

d) **FIELD TESTING:** Currently there are no GE field trials in Serbia. The application for field-testing must be submitted to the Serbian Ministry of Agriculture and Environmental Protection for review and approval. The Biosafety Expert Council evaluates risk assessments. The application must provide all the necessary data on the particular biotech event or biotech crop and stipulate the safety procedure parameters and measures.

e) **INNOVATIVE BIOTECHNOLOGIES:** Serbia has not determined the regulatory status of innovative biotechnologies (such as genome editing) in plants or plant products. With amending the current restrictive Law on “GMOs,” Serbia will most probably cover this topic with the separate Rulebook.

f) **COEXISTANCE:** Serbia does not have a coexistence policy; it has a strict ban on planting GE crops. However, a coexistence policy is incorporated into amendments that are being considered to the current Law on “GMOs.”

g) **LABELING:** The current Law on “GMOs,” does not define labeling and traceability. Once the Law on “GMOs” is amended, the Ministry of Agriculture and Environmental Protection plans to adopt a separate regulation on the labeling and traceability of GE traits and products of biotechnology, per EU regulations.

h) **MONITORING AND TESTING:** In Serbia, the responsibility for monitoring and testing of GE food, feed, and seeds falls under the Ministry of Agriculture and Environmental Protection, as defined by the Law on “GMOs” and the Food Safety Law. These laws instruct Serbia’s phytosanitary inspectors to carry out surveillance of possible unauthorized imports of GE crops or products at the border and the internal inspectors from the Ministry of Agriculture and Environmental Protection control field plantings. The phytosanitary inspectors use “Reveal for CP4” test strips to test for Roundup Ready™ soybeans and apply herbicides to small test planted areas in soybean fields to determine if any illegal GE soybeans.

During 2015, the Serbian Phytosanitary Inspectorate of the Ministry of Agriculture and Environmental Protection inspected approximately 1,600 plots or approximately 50 HA of land with soybeans. From 49 samples that were taken from the fields, the Inspectorate detected GE soybeans in 45 samples. The largest number of GE soybean plots was located in parts of Mačva, South Bačka and Srem (Vojvodina). The GE soybeans were destroyed or removed from the field and the farmers were fined according to the

current Law on “GMOs” (30,000-50,000 dinars or US\$273-455) for the deliberate release into the environment without obtaining an approval.

The Ministry of Agriculture and Environmental Protection 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 Testing (part of the 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>

i) LOW LEVEL PRESENCE (LLP) POLICY: According to the Serbian Law on “GMOs,” agriculture products of non-animal origin are not considered genetically engineered (GE) organisms if they contain up to 0.9 percent threshold of GE organism and impurities of GE organisms. Seed and reproductive material are not considered GE organisms if they contain up to 0.1 percent threshold of GE organisms and impurities of GE organisms.

j) ADDITIONAL REGULATORY REQUIREMENTS: N/A

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Although Serbia is not yet a WTO member, the legal regime for IPR protection has improved substantially in recent years as Serbia has revised laws to meet the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) standards. The TRIPS Agreement is a multilateral WTO Agreement and, as such, applicable to all 147 members of the WTO. It is also binding for every country that accedes to the WTO. The agreement’s general obligations require countries to apply the principles of national treatment (same treatment of foreign title holders and domestic title holders) and most favored nation treatment (same treatment of foreign title holders regardless of their country of origin). TRIPS sets minimum standards of protection with respect to all forms of intellectual property: copyright, trademarks and service marks, geographical indications, industrial designs, patents, layout designs of integrated circuits, and trade secrets. In Serbia,

IPR is dealt with in a series of laws: 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).

l) CARTAGENA PROTOCOL RATIFICATION: Serbia is a party to the Convention on Biological Diversity, ratified in 2002, and Serbia 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.

m) 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). Serbia has not taken any positions pertaining to agricultural biotechnologies, the use of agricultural biotechnologies and products in international treaties or conventions.

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

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Serbian politicians and the general public remain misinformed about GE products and view them as potentially dangerous. Public opinion is generally negative towards biotechnology as there have not been any systematic attempts by the government to educate consumers. The media consistently chooses to reinforce negative perceptions rather than report on technological advances. The issue has proven to be very politically charged, so much 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-agricultural biotechnology but are not active in passing these messages to the general public. Serbian livestock and poultry farmers are aware of the fact that with the adoption of the 2009 Law on "GMOs," Serbia blocked all GE soybean meal imports for cattle feed resulting in a significant increase in feed prices. 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. However, Serbian consumers continue to reject biotechnology publicly in the erroneous belief that domestic production is effectively "organic."

Several mayors have adopted a Declaration on "GMOs" and designated their territories as GE-free. Additionally, during the last few years, a number of new civil society groups have appeared sponsoring anti-GE crop campaigns. The number of public events and the level of media coverage on the agricultural biotechnology issue have increased over the last 3-5 years. However, GE products remain extremely unpopular in Serbia – and it is this angle that is typically covered by the press. Several political organizations on the extremes of the political spectrum have also taken up the GE issue, hoping to use it to fuel anti-EU and anti-U.S. sentiments. Both the Green Party and right wing groups are vocal

opponents of lifting the current ban on products from agricultural biotechnology.

In January 2013, Serbia officially supported the “Danube Soya Association” <http://www.donausoja.org/en-en>. This association is an international non-profit that promotes non-GE soy cultivation and processing the Danube region of Europe Founded in 2012 and based in Vienna, Austria. Its primary members are farmers, agricultural traders, feed companies, major retailers, and green organizations. The “Danube Soya Association” opened a representational office in Serbia and is active in organizing different events in promoting production of non-GE soybeans and products with assistance of GIZ in Serbia (German organization for International Cooperation). The purpose of the activities in Serbia is to promote non-GE varieties of soybeans to the Serbian Farmers Associations and to encourage production in accordance with the "GE Free" standards <https://www.giz.de/en/worldwide/27898.html> . There are several reports published by international organizations that include Serbia in their analysis, such as the West Balkan Research Center <http://www.westbalkanresearch.net> and the International Service for the Acquisition of Agri-biotech Applications at <http://www.isaaa.org> .

b) MARKET ACCEPTANCE: Serbian agricultural experts believe that Serbia’s competitive advantage depends on seeking a premium for high quality “natural” or “organic” products rather than competing on volume. Thus, there is a concern about the potential market consequences of adopting pro-agricultural biotechnology policies as well as a strong bias against GE products as somehow being “unnatural.” 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. The negative attitude towards the acceptance of GE crops appears in most social media outlets, although consumer awareness of GE products and public discussion of biotechnology related issues are limited. The Ministry of Agriculture and Environmental Protection is keen to promote Serbia’s non-GE and organic production and has done little to dispel any misinformation about agricultural biotechnology and EU approved GE events. Several Serbian crushing facilities have long-term contracts with EU buyers to export non-GE soybeans and products.

In 2016, the Ministry of Agriculture and Environmental Protection offered reduced subsidies of 4,000 dinars/HA (US\$36/HA), compared to the previous 12,000 dinars/HA (US\$110/HA) direct payments for certified seeds and fertilizers to the Serbian grain and oilseeds farmers. The Ministry of Agriculture and Environmental Protection has limited the payments to smaller/medium agricultural producers by reducing the maximum eligible farm size from 100 HA to only 20 HA. Also, farmers that lease government-owned agricultural land are not entitled to government subsidies.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

- Animal genetic engineering and genome editing result in the modification of an animal's DNA to introduce new traits and change one or more characteristics of the animal.
- Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is therefore different from the genetic engineering of animals (both in the science and

often in the regulation of the technology and/or products derived from it). However, since researchers and industry use cloning along with other animal biotechnologies, it is included in this report.

PART D: PRODCUTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** According to the Serbian Ministry of Agriculture and Environmental Protection, no applications have been submitted to conduct research in this area.
- b) **COMERCIAL PRODUCTION:** There are no livestock clones, GE animals (including fish, birds, insects, mammals), or GE genetics used in commercial production in Serbia.
- c) **EXPORTS:** Exports of GE animals, livestock clones, or products from these animals, including genetics (semen and embryos) do not exist from Serbia.
- d) **IMPORTS:** Serbia is not importing GE animals, livestock clones, or products from these animals, including genetics (semen and embryos).
- e) **TRADE BARRIERS:** No country-specific legislation.

PART E: POLICY

- a) **REGULATORY FRAMEWORK:** There are no laws or regulations covering animal biotechnology, nor do they appear to be envisioned in the amendments to the Law on “GMOs” that is currently being considered. The institutions listed in the Plant Biotechnology Chapter of this report have the same responsibilities for animal biotechnology.
- b) **INNOVATIVE BIOTECHNOLOGIES:** Serbia has no regulation for the use of innovative biotechnologies in animals.
- c) **LABELING AND TRACEABILITY:** There are no regulations in Serbia on the traceability and labeling of livestock clones, GE animals and their products (including genetics), and/or offspring.
- d) **INTELLECTUAL PROPERTY RIGHTS (IPR):** Serbia currently has no legislation that would address IPR for animal biotechnologies. Please see Plant Biotechnology Chapter for other details.
- e) **INTERNATIONAL TREATIES/FORA:** Serbia is a member of Codex Alimentarius and the World Organization for Animal Health (OIE). Serbia has not taken any positions pertaining to agricultural biotechnologies, the use of agricultural biotechnologies and products in international treaties or conventions.
- f) **RELATED ISSUES:** N/A

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: As with plant biotechnology, the public and private opinion in Serbia towards animal biotechnology is expected to be unfavorable. The Serbian public is not provided with basic information on this topic.

b) MARKET ACCEPTANCE/STUDIES: Currently no GE imports are permitted and no applications have been made to do research, even for GE animals or cloning. However, with current public perceptions about biotechnology, it is likely that animal biotechnology would have a difficult time with market acceptance in Serbia.

Appendix 1: Relevant References

Serbian Ministry of Agriculture and Environmental Protection

Nemanjina 22-26,
11000 Belgrade, Serbia
Phone: ++ 381 11 260 7960
E-mail: info@minpolj.gov.rs
Web page: www.mpzss.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 Trade, Tourism 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, Education 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/>

“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

Ruže Jovanovića 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>

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