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Report Highlights:

In 2009, Serbia adopted the current Law on Genetically Engineered Organisms (GEOs), which 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. There are no livestock clones or other GE animals (including fish, birds, insects, mammals) or GE genetics being used in commercial production in Serbia.

Section I. Executive Summary:

In 2009, Serbia adopted the Law on Genetically Engineered Organisms (“GEOs”) which strictly prohibits all imports, production, and commercial growing of genetically engineered (GE) crops or products containing GE traits. This law does not provide any mechanism to review applications to cultivate or sell GE products and represents one of the main obstacles to Serbia’s World Trade Organization (WTO) accession process.

Since the adoption of the restrictive law, Serbia has been considering potential amendments to make the law WTO compliant. Namely, it would create a mechanism that would allow for a scientific risk assessment of applications to import or grow GE crops and products. The current proposal being considered would establish a general framework for regulating biotechnology and adopt several by-laws to cover the use of GE products in closed systems, the placement of GE products on the market, labeling and traceability, authorized laboratories, packaging, transportation, and other related issues. There also would be changes in terminology to the four existing by-laws.

As a result 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 2009 agricultural biotechnology law, but have yet to change the problematic provisions. It is expected that, when adopted, the new amended “Law on GEOs” and other by-laws will be fully harmonized with EU Directive 2001/18/EC on Biotechnology and the Amendments to Directive 412/2015 adopted in March 11, 2015. The amended “Law on GEOs” is allowing the import and cultivation of GE crops and products, but only under very strict control of the State. EU Directive 2001/18/EC will be a general framework for preparing the law on biotechnology in Serbia and all the specifics will be provided in additional by-laws that will be adopted immediately after passing the amended “Law on GEOs”. The additional by-laws will cover such topics as the use of GE products in closed systems, the placing of products derived from agricultural biotechnology on the market, labeling and traceability, and authorized laboratories. In addition to those new by-laws, there will be changes in terminology in the already existing four by-laws.

There has been strong political resistance to make any changes to the current law. According to the Serbian Organic Association “Serbia Organica” <http://www.serbiaorganica.info> over 120 Serbian cities and municipalities have signed the so called “Declaration on GEOs” calling for a ban on GE products in their municipalities. Serbia has signed the “Danube Soya Association” declaration to promote non-GE soy cultivation and processing in the Danube region of Europe. Danube Soya Association <http://www.donausoja.org/en-en> is an international non-profit association based in Vienna, Austria which was founded in 2012, whose main members are farmers, agricultural traders, feed companies, major retailers, and green organizations. The association's intention is to promote sustained GE-free soya bean cultivation in Europe. A number of new civil society groups have appeared sponsoring anti-GE crop campaigns in the last few years. The number of public events and the level of media coverage dealing with the agricultural biotechnology issue have increased over the last 3-5 years. However, agricultural biotechnology remains 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 issue of genetic engineering, hoping to use it to fuel anti-EU and U.S. sentiments. Both the Green Party and right-wing groups have representatives in the Serbian Parliament and are very vocal opponents of lifting the current ban on GE products and crops.

According to the European Commission reports on Serbia's progress in the EU accession process for the past several years, it was stated that Serbia had limited progress in the area of Chapter 12 (food safety, veterinary and phytosanitary policy) that also include regulating GE products. The European Commission is especially emphasizing that Serbia needs to align its GE legislation with the EU's legislation to enable WTO accession. Serbia will not be able to become a full EU member before changing current “GEO” law that does not conform to EU regulations or the WTO Sanitary and

Phytosanitary (SPS) agreement.

Serbia's agriculture experts believe that the country's competitive advantage can 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 somehow 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.

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PLANT AND ANIMAL BIOTECHNOLOGY

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.
- c) Exports: Serbia does not export GE crops. Serbia is only exporting non-GE crops (mostly corn and

soybeans) and for this purpose, the Serbian Ministry of Agriculture, Forestry and Water Management (MAFWM) is issuing confirmation to Serbian exporters that Serbia is implementing a currently restrictive law and is producing only non-GE crops in order to receive a better price on the world market.

d) Imports: Imports of GE crops are not allowed. While there is no mechanism to approve GE crops, there is a framework 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 MAFWM after the State's regulatory requirements have been met. Prior to the adoption of the current "Law on GEOs" in 2009, Serbia imported soybean meal which contained approved Round-Up Ready soybeans.

Imported quantities reached 70,000-100,000 metric tons annually, valued at USD 40-60 million.

e) Food aid: Serbia is not a food aid recipient country, nor does it provide food aid for other countries.

f) Trade barriers: The current "Law on GEOs" adopted in 2009 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 future products to be reviewed as there is no transparent science based risk assessment/approval process.

PART B: POLICY

a) Regulatory framework: The Serbian Parliament adopted the current Law on Genetically Engineered Organisms (GEOs) in May 2009. This law, which was published in the 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 WTO, 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, seven years ago the MAFWM, drafted a revision to the "Law on GEOs" that incorporates U.S. and EU suggestions to make it more WTO compliant. 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 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. In addition to these 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 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 GEOs", No. 1669/1 issued December 15, 2002 (will be amended with new terminology after adoption of the new Law on GEOs);

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

The revised law was reviewed and approved by Serbia’s 18-member National Biosafety Council. The final version of the law needs to be approved by the Minister of Agriculture, Forestry and Water Management and adopted by the Parliament. Once adopted, the MAFWM, is planning to implement the following ten by-laws:

- Regulation on the use of GEOs in closed systems;
- Regulation on deliberate release of GEOs into the environment;
- Regulation on the placing on the market of GEOs and products of GEOs;
- Regulation on labeling and traceability of GEOs and products of GEOs;
- Regulation on the content and data of the Register of GEOs and products of GEOs;
- Regulation on authorized laboratories;
- Regulation on confidential information;
- Regulation on the handling, packaging and transport of GEOs and GE products;
- Regulation on trans-border movement of GEOs and products of GEOs;
- Regulation on sampling of GEOs and products of GEOs;

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 “GEOs” 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. Members are appointed for the period of five years. In 2017, the Biosafety Expert Council extended the terms of all current members to 2022. .

In April 2017, the Serbian MAFWM, established a new Food Safety Risk Assessment Expert Council. The main coordinator of this council is a special adviser to the Minister of Agriculture, Forestry and Water Management. The Food Safety Council consists of 15 members, from scientists, representatives of consumer associations, representatives of academia and the MAFWM,. According to the Serbian Minister of Agriculture, this Food Safety Risk Assessment Expert Council will also be involved in the future process of amending and adopting the current “Law on GEOs.”

The MAFWM supervises the application of the “Law on GEOs” 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 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 MAFWM for review and approval. Risk assessments are evaluated by the Biosafety Expert Council, which is composed of representatives from scientific research institutions in the fields of agriculture, ecological, and biological science. The applicant must submit any renewal requests to the MAFWM 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 MAFWM. Furthermore, it is expected that even with amendments to the current “Law on GEOs,” each GE event would have to be approved individually.

d) Field testing: The application for field-testing must be submitted to MAFWM 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.

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

f) Coexistence: 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 GEOs.”

g) Labelling: Under the current “Law on GEOs,” labeling and traceability are not defined. Once the law is amended, the MAFWM plans to adopt a separate regulation on the labeling and traceability of GEOs and products of GEOs, per EU regulations.

h) Monitoring and testing: The responsibility for monitoring and testing of GE food, feed, and seeds falls under MAFWM, as defined by the “Law on GEOs” and the Food Safety Law. Serbia’s phytosanitary inspectors are instructed to carry out surveillance of possible unauthorized imports of GE crops or products at the border and the internal inspectors from the MAFWM control what is planted in the fields. The phytosanitary inspectors use “Reveal for CP4” test strips to test for Roundup Ready™ soybeans and apply herbicides to small test areas in soybean fields to determine if any illegal GE soybeans have been planted.

During 2017, the Serbian Phytosanitary Inspectorate of the Ministry of Agriculture, Forestry and Water Management, Plant Protection Directorate inspected approximately 1,500 plots or approximately 40 hectares of land with soybeans. The Inspectorate detected 60 soybean samples that were GE, out of a total of 90 samples taken from 1,500 plots randomly. 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 GEOs” (30,000-50,000 dinars or USD 273-455) for deliberate release into the environment without obtaining approval.

The MAFWM works with the following four accredited laboratories for the testing of “GEOs”:

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 GEOs” adopted in 2009, agriculture products of non-animal origin are not considered “GEOs” if the presence of “GEOs” fall under the 0.9% threshold of “GEOs” and impurities of “GEOs.” Seed and reproductive material are not considered “GEOs” if they contain up to 0.1% threshold of genetically engineered organisms and impurities of “GEOs.”

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. IPR in Serbia 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).

l) 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.

m) International treaties/forums: 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 often speak out on the subject of GE at international forums but with negative connotation.

n) Related issues: The current "Law on GEOs" adopted in 2009 is a major trade barrier as it strictly prohibits all imports, production, and commercial growing of GE crops or products containing GEOs. The ban was adopted without a risk assessment being done based on scientific review as required by the WTO 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.

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 choose to reinforce negative perceptions rather than report on technological advances. The issue has proven to be too 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 GEOs," 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."

A significant number of city mayors in Serbia have adopted a "Declaration on 'GEOs'" and designated their territories as GE-free. Also 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 in public, but also as members of the National Parliament, of lifting

the current ban on products from agricultural biotechnology.

Serbia is officially supporting the “Danube Soya Association”. “Danube Soya Association” <http://www.donausoja.org/en-en> , is an international non-profit association based in Vienna, Austria.

This association was founded in 2012 and its main members are farmers, agricultural traders, feed companies, major retailers, and green organizations. The association's intention is to promote sustained non-GE soybean cultivation in Europe. “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 genetically GE 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. Generally, there appears to be a negative attitude towards the acceptance of GE crops in most social media outlets, although consumer awareness of GE products and public discussion of biotechnology related issues are fairly limited. The MAFWM 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 2017, MAFWM offered 4,000 dinars per hectare (USD 41 per hectare) of subsidies as direct payments for certified seeds and fertilizers to Serbian grain and oilseeds farmers.

The area planted for non-GE soybeans in marketing year (MY) 2017/18 was 230,000 hectares, 24 percent higher compared to MY2016/17. Due to the record summer drought, soybean production was significantly damaged. With an average yield this year of 2 metric tons per hectare (usual average yield is 3 metric tons per hectare) a total production of soybeans in MY2017/18 is approximately 460,000 metric tons or 190,000 metric tons less than last year. During MY2016/17, Serbia’s soybean exports totaled 196,000 metric tons, mostly non-GE soybeans and products, while imports were of 12,000 metric tons of non-GE soybeans mostly from neighboring countries (Romania and Croatia). Serbia mostly exports soybeans and products to EU countries such as Hungary, Austria, Germany, Belgium, Italy and Romania. For the last several years there is increased demand for Serbian non-GE soybeans from Japan and South Korea. For the last five years, Serbian soybean exporters have been able to secure official certificates from MAFWM that the “Law on GEOs” banning all commercial growing, trade and transit of GE varieties in Serbia has been implemented. With this official confirmation, exporters have been able to secure a premium for their non-GE crops and be more competitive internationally.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

- a) Production development: According to the Serbian MAFWM, no applications have been submitted to conduct research for producing GE animals or cloned animals.
- b) Commercial production: There are no livestock clones or GE animals (including fish, birds, insects, mammals) or GE genetics being used in commercial production in Serbia.
- c) Exports: Not applicable as Serbia does not produce GE animals, livestock clones, or products from these animals, including genetics (semen and embryos).
- d) Imports: It is unknown whether genetic material produced with modern biotechnology techniques is being imported. It is also unknown whether products from offspring of cloned animals are being imported.
- 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 GEOs” that is currently being considered. The institutions listed under Plant Biotechnology have the same responsibilities relating to Animal Biotechnology.
- b) Innovative biotechnologies: Currently Serbia has no regulation that addresses 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 their offspring.
- d) Intellectual property rights (IPR): Serbia currently has no legislation that would address intellectual property rights for animal biotechnologies. Please see Plant Biotechnology Chapter for other details.
- e) International treaties/forums: Serbia is a member of Codex Alimentarius (Codex) and the World Organization for Animal Health (OIE). Serbia is not discussing any GE animals and their products on expert forums.
- f) Related issues: N/A

PART F: MARKETING

- a) Public/private opinions: Generally unfavorable. The Serbian public is not provided with even basic information on this topic.
- b) Market acceptance/studies: 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.

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.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 Education, Science and Technological Development

Nemanjina 24,
11000 Belgrade, Serbia
Phone: ++ 381 11 361 3 734
E-mail: kabinet@mpn.gov.rs
Web page: <http://www.mpn.gov.rs>

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/>

Consumer Protection Reporter/APOS

E-mail: apos@apos.org.rs

Web page: <http://apos.rs/#about-us>

National Association for Consumer Protection

E-mail: pravnitim@nops.org.rs

Web page: <http://www.nops.org.rs>

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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