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Report Highlights:

Croatia is a net food importer and the government policy is geared towards raising agricultural productivity and, to a lesser extent, controlling imports. Although Croatia has adopted the European Union's (EU) biotech legislation, Croatia is a part of a group of EU member states that "opted-out" from planting genetically engineered (GE) seeds. Croatia believes its competitive advantage in agricultural products will be realized by seeking a premium for high quality "natural" products rather than competing on volume. Thus, there is a concern about the potential market consequences of adopting pro-biotech policies as well as a strong bias against GE products as somehow being "unnatural." Additionally, Croatian politicians and the public remain misinformed about biotech products and view them as potentially dangerous.

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EXECUTIVE SUMMARY

Croatia is a net food importer. While the current goal of Croatia's agricultural policy is to increase productivity, the focus is on greater market recognition of Croatia's geographic indications and linking agricultural production to tourism.

Although Croatia has adopted the EU's biotech legislation, Croatia remains part of a group of EU member states that maintain more stringent national biotech policies than the EU norm. Croatia opted-out from planting GE seeds, and has adopted legislation that reflects this decision. Croatia believes its competitive advantage in agricultural products will be realized by seeking a premium for high quality "natural" products rather than competing on volume. There is a concern in Croatia about the potential market consequences of adopting pro-biotech policies, and there is a strong bias against GE products as somehow being "unnatural." Additionally, Croatian politicians and the public remain misinformed about biotech products and view them as potentially dangerous.

In 2004 and 2005, the government randomly tested foods and seeds specifically for biotech content. Several products had to be withdrawn from the market due to a lack of proper biotech labeling. Croatia now regularly tests products for biotech events at the border and in the market. The testing is performed in accordance with Croatia's annual inspection plans, which is determined based on available fiscal resources. According to EU law, all biotech products must be labeled.

Several pieces of Croatian legislation regulate the importation and cultivation of GE crops, animals, and foods. Croatia's 2019 *Law on Genetically Modified Organisms (GMOs)* legally incorporated Croatia's decision to opt-out of GE planting and incorporated some additional changes (e.g. elaborating

procedures for the application and use of GMOs for the purpose of scientific research, detailing the procedures for the restricted use of GMOs in closed systems, detailing the procedures for the introduction of GMOs into the environment). This law replaces the 2005 *Law on Genetically Modified Organisms* (NN 70/05), which was amended five times to bring it in line with the evolution of EU GMO legislation.

For more information on the EU- biotech situation please refer to EU-28 Agricultural Biotech Report (https://gain.fas.usda.gov/#).

Chapter 1: PLANT BIOTECHNOLOGY

Part A: Production and Trade

a. Product Development: Croatia is not developing any biotech crops.

b. Commercial Production: Croatia's 2019 *Law on Genetically Modified Organisms (GMOs)* legally incorporated the EU legislation allowing member states to opt-out of planting EU approved GE seeds without scientific justification. Prior to this law, no permits were granted in Croatia for the deliberate release of GE plants -- either for field trials or commercial cultivation.

Croatia is a signatory of the Danube Soya Agreement an initiative to increase non-GE soy production in Europe and reduce GE imports. The Danube Soya aims to create a "GMO"-free soy producing region in countries along the Danube River. Another goal of the project is to connect poorer farmers in Eastern European countries, such as Slovakia, Hungary, Croatia, and Serbia, to more affluent consumers in Western Europe who want non-GE soy for feed or food.

c. Export: Croatia does not export GE crops/products.

d. Import: EU approved events if/when placed on the market must be appropriately labeled. Some imported GE soybean meal is used in feed.

e. Food Aid: Croatia is neither a food aid recipient nor a food aid donor.

f. Trade Barriers: Beyond the current legislation, there are no additional plant-biotechnology requirements with the potential to affect U.S. exports.

Part B: Policy

a. Regulatory framework: *Croatia's 2019 Law on GMOs* legally incorporated the EU legislation allowing member states opt-out of planting EU approved GE sees without scientific justification. Additionally it added changes such as elaborating procedures for the application and use of GMOs for the purpose of scientific research, detailing the procedures for the restricted use of GMOs in closed systems, and detailing the procedures for the introduction of GMOs into the environment. This law replaces the 2005 *Law on Genetically Modified Organisms* (NN 70/05), which was amended five times to bring it in line with the evolution of the EU GMO legislation. In Croatia, the following laws together regulate the importation, transshipment, production, usage, and sale of products of agricultural biotechnology (all food, feed, and seed): *the Law on GMOs* (Governmental Gazette 126/19); the Law on the Application of EU Regulation 1829/2003 (Governmental Gazette 18/2013) that incorporates the EU "GMO" Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed

Derived from "GMOs" Amending EU Directive 2001/18/EC; the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of "GMOs" (Governmental Gazette 81/2013); the Law on the Application of EU Regulation 2015/2283 on Novel Food (Governmental Gazette 15/2018); and the Food Act (Governmental Gazette 81/2013, 14/2014, 30/2015, 115/18).

The *Law on GMOs* incorporates the EU regulations and directives: Directive 2001/18/EC; Directive 2009/41/EC; Directive 2015/412EC; Directive 2018/350 EC; Regulation 1829/2003; EC Regulation 641/2004, EC Regulation 1981/2006, EC Regulation 1830/2003; EC Regulation 65/2004; EC Regulation 536/2014, EC Regulation 503/2013; EC Regulation 120/2014 and EC Regulation 2017/625.

The Law on the Application of EU Regulation 2015/2283 on Novel Food (Governmental Gazette 15/2018; 114/18) deals with all aspects of the novel food.

The Law on Application of the EC Regulation 1829/2003, EC Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from "GMOs" that Amends EU Directive 2001/18/EC, and the Law on Application of the EC Regulation 1946/2003 on Trans-boundary Movement of "GMOs" came into effect with Croatian EU accession. These two laws establish the responsible bodies and their tasks relating to the handling of biotechnology products as well as the penalties for breaching the provisions of these laws.

Although not specific to biotech products, the Croatian Food Act governs the responsible governmental bodies and their tasks, responsibilities of stakeholders in food and feed handling, official controls and legal measures for the application of the following EU legal documents: EC Regulation 178/2002; EC Regulation 1304/2003; EC Regulation 2230/2004; EC Regulation 608/2004; EC Regulation 115/2010; EC Regulation 16/2011; EU Regulation 931/2011; EU Regulation 208/2013; Decision 2004/478/EC; EC Regulation 1760/2000; and all other EU legal acts enacted for application of the before mentioned legislation.

i. The responsible government ministry or ministries and their role in the regulation of GE plants (food, feed, seed, and environmental safety issues):

> The Ministry of Science and Education (MSE): According to the *Law on GMOs*, the MSE is responsible for the limited and contained use of GE products. If an institute wants to conduct research on GE products, it must apply to the MSE.
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> The Ministry of Health (MOH): According to the *Law on GMOs*, the MOH is responsible for GE in food and feed. According to the Food Act, the MOH is responsible for all issues relating to food, foodstuff, and feed containing biotechnology. Additionally, the *Law on GMOs* proscribes that MOH oversee the usage of GE products in cosmetics, pharmaceutical products, and products for human health protection. Furthermore, Croatian Law on the Application of EU Regulation 1829/2003 names the Ministry of Health as the lead Ministry for implementation of the mentioned EU Regulations, although sometimes the Ministry of Agriculture must be consulted.
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> The Ministry of Economy and Sustainable Development (MESD): The Government body responsible for the intentional introduction of GE products into the environment. Until the 2020 elections this was a responsibility of the Ministry of Environmental Protection and Energy (MEPE). After the 2020 elections MEPE was merged into newly formed MESD. Actual transfer of responsibilities is still not fully established. According to the Law on the Application of EU

Regulation 1946/2003 on Trans-boundary Movement of GE products, the government body responsible for intentional release into the environment is also responsible for implementing the regulation and coordinating its activities with the Ministry of Health, the Ministry of Agriculture and Croatian Customs.

The Ministry of Agriculture (MOA): According to the Food Act, the MOA is the EU's contact point for food. According to the *Law on GMOs*, the MOA is responsible for GE seed and other GE plant reproduction material, GE veterinary medicine and GE plant protection products. Starting in December 2018, State Inspectorate is the body responsible for the inspection of food, feed and seed products that may contain "GMOs."

ii. Role and Membership of Biosafety Council:

The *Law on GMOs* requires the establishment of a Council for "GMOs" with the specific task of assisting governmental bodies to apply the Law. The Council has 17 members appointed by the Government of Croatia based on nominations from the pertinent Ministries. Council membership lasts for four years. The Council's work is independent and public. According to the Law, the Council's tasks include: tracking gene technology development and usage; tracking scientific breakthroughs and giving opinion and incentives for usage of gene technology and "GMOs" giving opinions on social, ethical, technical, scientific, and other conditions of "GMO" use; advising responsible institutions on "GMO" and gene technology issues; informing the public on "GMO" and gene technology development, and presenting viewpoints and opinions.

The *Law on GMOs* also calls for establishing a Board for Limited Usage of "GMOs" with 11 members composed of scientists from the fields of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacy, biotechnology, agriculture, forestry, veterinary medicine, nature and environmental protection, and occupational protection.

In addition, the *Law on GMOs* requires the establishment of a board for the introduction of biotech products into the environment that consists of nine scientists from the fields of: genetics, ecology, nature protection, environmental protection, agriculture, forestry, veterinary medicine, biochemistry, molecular biology, microbiology, and medicine.

The tasks of these boards include: giving opinions on biotech usage in terms of legal procedures as outlined by the *Law on GMO*s; giving opinions and proposals for preparing other legislation on GE product usage; and giving opinions and proposals to responsible ministries on biotech usage issues and other expert work as outlined by the *Law on GMOs* and related regulations. According to the law, these two boards should report to the "GMO" Council once a year. Croatian Agency for Food and Agriculture (before December 2018 it was the Croatian Food Agency) provides scientific and technical support to legislators as well as scientific advice in all areas that directly or indirectly influence food and feed safety. Additionally, the Food Agency provides scientific opinions to the MOH and the MOA regarding the placement of GE food and/or feed on the market and/or into the environment.

iii. Assessment of political factors that may influence regulatory decisions related to agricultural biotechnology:

Biotech opponents in Croatia have been emboldened by the perceived success of Austria and Slovenia in declaring themselves to be "GMO" free and have long advocated that Croatia position itself within this regional group of "healthy," "GMO"-free countries. Currently, Croatia

clearly sees its future as a niche market for "healthy foods" (NOTE: In Croatia, the word "healthy" includes conventional (non-biotech) and organic products). There has been limited demand for biotech seed imports to combat drought, pests, or soil problems. Government officials acknowledge the legal obligation to open their agricultural market to imports, but actively declare Croatia to be "GMO"-free, as part of a strategy to promote the country as a "healthy" tourist destination. The Croatian public generally is opposed to biotech products. Therefore, if given an option, Croatia could be expected to opt-out on all EU approved biotech products, to include GE products for feed use, although this could affect the cost of inputs for the livestock sector.

iv. Distinctions regarding the regulatory approval process for food, feed, processing, and environmental release are as follows:

There are similar long and complicated procedures to approve conventional and biotech food and feed products, but the approval process for environmental release is different. At the end of the regulatory procedure for food and feed, biotech products must gain special permission to market the product. Some agricultural seed varieties (biotech and conventional) must first go through a variety registration process. After the Croatian Seed and Seedlings Institute register the variety, it is placed on the list of seed varieties that can be marketed in Croatia. Biotech seeds, in addition to variety registration, require special permission to be placed on the market, including permission for the intentional environmental release of GE products. However, as noted above, Croatia has opted-out from planting GE seeds.

b. Approvals: There have been no direct applications to Croatian authorities to approve the domestic planting of biotech crops for food or feed use and Croatia has never approved any biotech seed varieties for planting nor is any biotech seed variety in the process of being approved on the Croatian level. Furthermore, when it comes to planting Croatia opted-out.

c. Stacked Events or Pyramided Events Approvals: Stacked events are treated the same as in the EU. Croatia has not issued its own specific guidelines.

d. Field Testing: According to the *Law on GMOs* and subsequent Regulations, field tests of biotech crops are allowed after all the conditions prescribed by the Law and Regulations are satisfied. However, no such tests are currently being conducted in Croatia.

e. Innovative biotechnologies: Innovative biotechnologies are treated the same as in the EU legislation.

f. Coexistence: The *Law on GMO* proscribes that the coexistence between organic agriculture, integrated agriculture (short definition: integrated agriculture involves farming systems with environmental, economic, social, and intergenerational sustainability), and genetically modified crops will be regulated by the separate legal act. However, since Croatia has opted out from planting EU registered varieties of GE seeds, this is a non-issue and is not a priority when it comes to legislation.

g. Labeling: According to the Law on the Application of EU Regulation 1829/2003, food and feed containing agricultural biotechnology ingredients must have special, additional information on the label that informs consumers of all its characteristics. Based upon EU law, for any food or feed product, if the biotech content is above 0.9% (per ingredient), the product must be labeled. The biotech threshold is 0.0% for seed and biotech products that are not EU approved.

h. Monitoring and Testing: Croatia regularly tests products for biotech events at the border and in the market.

i. Low Level Presence Policy: Croatia does not have a policy on low level presence. It does follow the "technical solution" guidance that defines zero as an allowance of 0.1 percent, as outlined in EU Regulation 619/2011. This regulation lays down the methods of sampling and analysis of official control of feed regarding the presence of any agricultural genetically modified product for which an authorization procedure is pending or the authorization of which has expired.

j. Additional Regulatory Requirements: Biotech food and feed products require special permission as GE products to be placed on the market.

k. Intellectual Property Rights: Biotech crops are not planted commercially in Croatia. Croatia has intellectual property rights legislation in place and is a member of The International Union for the Protection of New Varieties of Plants (UPOV).

l. Cartagena Protocol Ratification: Croatia signed the Cartagena Protocol on Biosafety in September 2000 and ratified the Protocol in September 2003. Officially, there is no trade in Living Modified Organisms (viable seeds).

m. International Treaties/Forums: Croatia is a member of the International Plant Protection Convention (IPPC) and Codex Alimentarius (Codex). However, Croatia does not appear to take an active position regarding plant or animal biotechnology in these organizations.

n. Related Issues: Strict biotech legislation acts as a barrier to trade when it comes to biotechnology.

Part C: Marketing

a. Public/Private Opinions: Croatia has Non-Governmental Organizations (NGOs) such as Green Peace and Green Action that are actively campaigning against biotechnology and the Croatian press has generally taken a negative stance on biotech.

b. Marketing Acceptance/Studies: A Croatian market research agency carried out a study in 2009 on "consumer recognition of healthy foods" that among other things researched the opinions and knowledge of Croatian consumers on biotech products. In this study, 51% of respondents said that they would not eat GE food products under any circumstances and 29% of respondents thought that they did not know enough about GE foodstuffs. The study showed that 90% of respondents thought that GE foodstuffs should be clearly labeled on the store shelves.

The same agency did a study in 2005 and 2008 on the public opinion of GE products. In this study, 67% (2005) and 58% (2008) of respondents said that they would not eat GE food products under any circumstances and only 16% (2005) and 26% (2008) of respondents thought that they didn't know enough about GE foodstuffs.

The average Croatian consumer views food derived from biotech crops negatively. Consequently, many farmers are afraid to grow biotech crops. There is a feeling that biotechnology is something unnatural and food should be natural. These negative opinions are based largely on emotions, not on an informed study of the issue.

Chapter 2: ANIMAL BIOTECHNOLOGY

Part D: Production and Trade

a. Product Development: In Croatia, genetic engineering and/or cloning are not being used to develop the production of agricultural animals. Nor are such techniques used to develop animals to produce pharmaceuticals, or organs for transplants. There is no ban on these techniques, but public perception is preventing companies from engaging in these activities.

b. Commercial Production: The Croatian livestock sector is not actively employing the use of GE animals or products derived from GE animals or clones. There is no ban, but public perception is preventing companies from engaging in these activities.

c. Export: Croatia is not exporting GE animals, livestock clones, or products from these animals.

d. Imports: Croatia is not importing GE animals, livestock clones, or products from these animals. There is no legal ban.

e. Trade barriers: No additional trade barriers are known.

Part E: Policy

a. Regulatory Framework: Beyond *Law on GMOs* and EU legislation, Croatia does not have in place any legislation specifically related to the development, commercial use and/or import of GE animals or their products. At present, food from clones falls under the scope of the EU Regulation on Novel Foods (EU Regulation 2015/2283).

b. Approvals: There are no animal clones, GE animals, or products thereof, approved for import or use in Croatia.

c. Innovative Biotechnology: Innovative biotechnologies are treated the same as in the EU legislation.

d. Labeling and Traceability: There are indications that the Croatian Government may consider traceability and mandatory labeling requirements for products derived from GE and cloned animals. The government entities that would likely regulate these technologies for food and environmental safety issues relating to research on or commercial use of these animals include: the Ministry of Agriculture; the Ministry of Health; the Ministry of Economy and Sustainable Development; the Ministry of Science and Education; the Croatian Agency for Food and Agriculture, and the Council for "GMOs."

e. Additional regulatory requirements: Beyond *Law on GMOs* and EU legislation, Croatia does not have in place any additional regulatory framework.

f. Intellectual Property Rights (IPR): Croatia has legislation on intellectual property rights but does not have IPR legislation on animal biotechnology nor is that kind of legislation currently being considered.

g. International Treaties/Forums: Croatia is a member of Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE). However, Croatia does not appear to take an active position regarding animal biotechnology in these organizations.

h. Related Issues: Strict biotech legislation acts as a barrier to trade when it comes to products derived from agricultural biotechnology.

Part F: Marketing

a. Public/Private Opinions: There are active organizations that lobby against the genetic engineering or cloning of agricultural animals and Croatia's press historically has not been favorable to these types of innovations.

b. Market Acceptance/Studies: Currently, there are no known cloning or GE animal production market studies. The initial reaction to these products is unlikely to be favorable.

Chapter 3: MICROBIAL BIOTECHNOLOGY

Part G: Production and Trade

a. Commercial Production: There is no information available for the use of microbial biotechnology in commercial applications.

b. Export: There is no information available for the use of microbial biotechnology in products that may be exported.

c. Imports: Croatia applies EU legislation regarding microbial biotechnology.

d. Trade barriers: Beyond current EU legislation, no additional trade barriers are known.

Part H: Policy

a. Regulatory Framework: Beyond *Law on GMOs* and EU legislation, Croatia does not have in place any additional regulatory framework.

b. Approvals: Microbial biotechnology-derived product approvals are treated the same as in the EU.

c. Labeling and Traceability: Microbial biotechnology-derived product labeling and traceability is treated the same as in the EU.

d. Monitoring and Testing: Microbial biotechnology-derived product monitoring and testing are treated the same as in the EU.

e. Additional Regulatory Requirements: Beyond *Law on GMOs* and EU legislation, Croatia does not have in place any additional regulatory framework.

f. Intellectual Property Rights (IPR): Croatia has legislation on intellectual property rights but does not have IPR legislation specifically on microbial biotechnology nor is that kind of legislation currently being considered.

g. Related Issues: There is no information available for other issues related to this topic.

Part I: Marketing

a. Public/Private Opinions: There are active organizations that lobby against the genetic engineering and Croatia's press historically has not been favorable to these types of innovations.

b. Market Acceptance/Studies: Currently, there are no known market studies on microbial biotechnology. The initial reaction to the discussion on these products is unlikely to be favorable. It seems that Croatians are not widely aware that food ingredients are derived from microbial biotechnology and are commonly used globally, including in Europe.

Attachments:

No Attachments