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## **Croatia**

### **Biotechnology - GE Plants and Animals**

#### **Standing Report**

**Approved By:**

**Prepared By:**

Andreja Misir

**Report Highlights:**

Croatia is a net food importer and government policy is geared towards raising agricultural productivity and, to a lesser extent, limiting imports. EU membership is also a priority for the Croatian government, and new laws and agricultural policies increasingly mirror those of the EU. The Croatian public remains very skeptical about agricultural biotechnology. There has also been a general demonization of U.S. food products as "Frankenstein Foods." In Croatia, several pieces of legislation have been introduced to regulate the importation and cultivation of biotech crops and foods.

All sections of the report have been updated.

### **Section I. Executive Summary:**

Croatia is a net food importer and government policy is geared towards raising agricultural productivity and, to a lesser extent, limiting imports. EU membership is also a priority for the Croatian government, and new laws and agricultural policies increasingly mirror those of the EU.

The Croatian public remains very skeptical about agricultural biotechnology. There has also been a general demonization of U.S. food products as “Frankenstein Foods.”

In 2004, samples of foodstuffs and seed taken from the market were randomly tested for biotech traces, which resulted in the withdrawal of some products from the market because the biotech products were not labeled. The Croatian Government penalized the importers.

In Croatia, several pieces of legislation have been introduced to regulate the importation and cultivation of biotech crops and foods. The laws regulating biotechnology include the Food Act and the Law on Genetically Modified Organisms. Additional important legal documents on biotechnology are the Government Ordinances on GMO Levels in Products Under Which Products Placed on the Market Do Not Have to be Labeled as Products Containing GMO passed on July 31, 2008 (Governmental Gazette 92/2008), March 18, 2009 (Governmental Gazette 36/2009) and March 11, 2010 (Governmental Gazette 33/2010). These list the trace amounts of biotech ingredients that can be contained in a product.

### **Section II. Plant Biotechnology Trade and Production:**

- a. In Croatia there are neither commercially produced biotech crops nor seeds.
- b. In Croatia there are no biotech crops under development.
- c. Croatia is not importing biotech crops/products for market release.
- d. Croatia is not a food aid recipient.
- e. Croatia does not produce any biotech crops developed outside of the United States or any biotech crops in general.

### **Section III. Plant Biotechnology Policy:**

- a. Agricultural biotechnology regulatory framework:

The Food Act governs the possible importation, licensing, and labeling of any foods/feed containing biotech ingredients. The latest Food Act was approved by Parliament on April 25, 2007 and published in Government Gazette number 46 on May 7, 2007. This law outlines many regulations that would enable biotech products to enter the market and be labeled. Publication of many of those regulations was on hold until recently when due to the approaching Croatian EU accession many regulations had/have to be published. The labeling threshold for biotech content is governed by the three new

Government Ordinances on GMO Levels in Products Under Which Products Placed on the Market Do Not Have to be Labeled as Products Containing GMO passed on July 31, 2008 (Governmental Gazette 92/2008), March 18, 2009 (Governmental Gazette 36/2009) and March 11, 2010 (Governmental Gazette 33/2010) (see section IIIbi for additional details). Company penalties for violating the "novel food" provisions of the Food Law concerning placing novel foods on the market or labeling are from Kn 100,000 to Kn 500,000 (\$ 17,415 – \$ 87,074), with responsible individuals fined from Kn 5,000 to Kn 10,000 (\$ 870 – \$ 1,742).

The Law on Genetically Modified Organisms (Law on GMOs) is an overarching law for biotechnology. The Law on Genetically Modified Organisms (Governmental Gazette 70/2005, 137/2009) together with the Food Act and subsequent regulations regulate the importation, transshipment, production, usage, and sale of products of agricultural biotechnology (all food, feed, and seed). This Law established a testing and licensing regime that is very restrictive. The highest penalties for breaching the provisions of this Law range from Kn 500,000 to Kn 1,000,000 (\$ 87,074 – \$ 174,148) for the responsible company and from Kn 20,000 to Kn 70,000 (\$ 3,483 - \$ 12,190) for the responsible employee in the company.

i. Responsible Ministries and Their Roles:

Ministry of Science (MOS), Education and Sport: According to the Law on GMOs, the MOS is responsible for the limited and contained use of GMOs.

Ministry of Health and Social Welfare (MOHSW): According to the Food Act, the MOHSW is responsible for all the issues regarding food, foodstuff, and feed containing biotechnology content and inspections. Additionally, the Law on GMOs proscribes that MOHSW is responsible for the usage and inspection of the GMO products in cosmetics, pharmaceutical products, and products for human health protection. According to the Law on GMOs, the MOHSW is the umbrella ministry and coordinating body for all biotechnology issues.

Ministry of Culture (MOC) - Environment Protection Directorate: According to the Law on GMOs the MOC is responsible for the intentional introduction of GMOs into the environment.

Ministry of Agriculture, Fishery (MOAF) and Rural Development: According to the Food Act, the Ministry of Agriculture is the central body of the Government responsible for food/feed safety, food/feed quality, and food/feed hygiene. This Ministry is also a contact point for the EU for related issues. The Ministry of Agriculture and the Ministry of Health have joint responsibility concerning all issues regarding food, foodstuff, and feed containing plant or animal biotechnology content and their

inspections. According to the Law on GMOs, the MOAF has responsibility for inspections of biotech feed; biotech reproduction material in agriculture and veterinary medicine; and drugs in veterinary medicine and pesticides. Furthermore, the MOAF is responsible for giving its consent for the intentional release of biotech products into the environment.

Ministry of Regional Development, Forestry (MRDF) and Water Management: According to the Law on GMOs, the MRDF has responsibility for inspections of biotech reproduction material in forestry.

State Inspectorate: According to the Law on GMOs, the State Inspectorate has responsibility for inspecting GMO labeling.

ii. Role and Membership of Biosafety Committee (if any):

The Law on GMOs required 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 GMOs; giving opinions and proposals for preparing other legislation on GMO usage; and giving opinions and proposals to responsible ministries on biotech usage issues and other expert work as outlined by the GMO Law and related regulations. According to the law, these two boards should report to the GMO Council once a year.

The old and new Food Act/s called for the establishment of the Croatian Food Agency, which began its work in 2004. The Agency's work consists of providing scientific and technical support to legislators as well as providing scientific advice in all areas that have direct and indirect influence on food and feed safety. Apart from that, the Food Agency is required to work on many other issues concerned with feed, food, and nutrition and provides scientific opinions to the Ministry of Health and Social Welfare and the Ministry of Agriculture, Fishery, and Rural Development when deciding on placing on the market GMO food and/or feed.

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

Although EU membership is a priority for the Croatian government and the country's new laws and agricultural policies increasingly mirror those of the EU, biotech opponents in Croatia have been emboldened by the perceived success of Austria and Slovenia in standing up to the European Commission on biotech approvals. Thus, complying with EU regulations has little meaning as long as Croatia positions itself within a regional group of "healthy," GMO-free countries.

At the moment Croatia clearly sees its future as a "niche market for healthy food" (NOTE: In Croatia, the word "healthy" encompasses everything from conventional and organic to non-biotech products), and biotech seed imports are not necessary for Croatia given a lack of agricultural demand for biotech products to combat drought, pests, or soil problems. Government officials acknowledge the legal obligation to open their agricultural market to foreign imports and openly acknowledge that Croatia is positioning itself as a GMO-free, "healthy" tourist destination. The Croatian public is generally very opposed to biotech products (HR9006).

iv. Distinctions between the regulatory treatment of approval for food, feed, processing, and environmental release are the following:

There are similar long and complicated procedures to approve 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 be placed on the market. All agricultural seed varieties (biotech and conventional), however, must first go through a variety registration process.

After the seed variety is registered by the Croatian Seed and Seedlings Institute 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 GMOs.

b. Biotechnology crops approved for:

i. Food, processing and feed:

No biotech crops have been approved for food or feed use in Croatia, but there is a 0.9% threshold level for some biotech content in food and feed. Under a special ordinance from 2008 and its amendment from 2009 and 2010 the threshold for biotech content in food depends upon whether or not the biotech event is on the Ordinance's list of permitted GMO events (the list is created from the list of biotech events previously tested and licensed in the EU). If the biotech event is on the Ordinance's list, it does not need to be labeled for sale on the Croatian market--provided separate tests within Croatia confirm that the product contains up to 0.9% biotech content (for products that consist of more than one ingredient, the 0.9% threshold is permitted per product's ingredient). However, if the biotech content is above 0.9%, the product has to be labeled. The biotech threshold level drops to 0.0% for biotech products that are not on the Ordinance's list. The same applies to feed.

List of GMOs allowed up to the 0.9% threshold level:

<b>Num.</b>	<b>Code</b>	<b>Plant</b>	<b>Producer</b>	<b>Modification</b>	<b>Possible Usage</b>
1.	Carnation Moonlite (Dianthus caryophyllus L. line 123.2.38)	carnation	Florigene Ltd	flower color	import and processing
2.	Carnation Mooshadow 1	carnation	Florigene Ltd	flower color	cultivating
3.	Carnation Moonshadow 2	carnation	Florigene Ltd	long life	
4.	Carnation Moondust	carnation	Florigene Ltd	flower color	import and processing
5.	1507	corn	Pioneer/Dow AgroScience	insect resistance and herbicide tolerance	food and feed
6.	59122	corn	Pioneer Hi-Bred/Mycogen seeds	insect resistance and herbicide tolerance	food, food ingredient and feed
7.	1507 X NK603	corn	Pioneer Hi-Bred/Mycogen seeds	insect resistance and herbicide tolerance	

8.	MON863	corn	Monsanto	insect resistance	food, feed and processing
9.	GA21	corn	Syngenta	herbicide tolerance	
10.	MON863X MON810	corn	Monsanto	insect resistance	food, feed and cultivating
11.	NK603	corn	Monsanto	herbicide tolerance	food and feed
12.	Bt11	corn	Syngenta	insect resistance	
13.	MON810	corn	Monsanto	herbicide tolerance	
14.	T25	corn	Monsanto	herbicide tolerance	
15.	MON863 X NK603	corn	Monsanto	insect resistance and herbicide tolerance	
16.	NK603 X MON810	corn	Monsanto	insect resistance and herbicide tolerance	
17.	MON1445	cotton	Monsanto	herbicide tolerance	
18.	MON531	cotton	Monsanto	insect resistance	
19.	MON15985	cotton	Monsanto	herbicide tolerance	
20.	MON15985 X MON1445	cotton	Monsanto	insect resistance and herbicide tolerance	
21.	MON531 X MON1445	cotton	Monsanto	insect resistance and herbicide tolerance	
22.	MON40-3-2	soybean	Monsanto	herbicide tolerance	food, feed, cultivating and processing
23.	MS8 X RF3	canola	Bayer CropScience	sterility, herbicide resistance	food, feed, import and processing
24.	GT73	canola	Monsanto	herbicide resistance	
25.	T45	canola	Bayer CropScience	herbicide resistance	food and feed

26.	H7-1	sugar beet	KWS Saat AG/Monsanto	herbicide resistance	food, food ingredient and feed
27.	A2704-12	soybean	Bayer CropScience	herbicide resistance	* food, food ingredient and feed * products different than food and feed with and exception of cultivation
28.	LL Cotton 25	cotton	Bayer CropScience	herbicide resistance	
29.	MON-89788-1	soybean	Monsanto Europe S.A	herbicide resistance	
30.	T45	canola	Bayer CropScience	herbicide tolerance	
31.	MON 88017	corn	Monsanto Europe SA	insect resistance and herbicide tolerance	
32.	59122xNK603	corn	Pioneer Overseas Corporation	insect resistance and herbicide tolerance	
33.	MON 89034	corn	Monsanto Europe SA	insect resistance	
34.	MIR604	corn	Syngenta Seeds S.A.S.	insect resistance ( <i>Diabrotica</i> spp.)	

ii. Environment:

No biotech seed varieties have been approved for planting in Croatia. In addition there are no seed varieties in the process of approval. Thus, currently, there is a de facto ban on biotech seed plantings in Croatia with a biotech seed threshold level in regular varieties of 0.0%.

c. Situation for within-country biotech crop field-tests:

According to the Law on GMOs and consequent Regulations, field tests of biotech crops are allowed after all the conditions prescribed by the Law and Regulations are satisfied. However, such tests are not conducted in Croatia.

d. Treatment of stacked events:

To date, Croatian legislation does not specifically deal with or specifically outline the treatment of stacked events. Future regulations may address this issue.



e. Additional product registration required, above and beyond approval, prior to use:

Biotech food and feed products require special permission as GMO products to be placed on the market and permission as GMO food and/or feed products to be placed on the market. Additionally, all agricultural seed varieties (regular and biotech) must go through a variety registration process before they are placed on the list of seeds 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 GMOs.

f. Legal framework for coexistence between biotech and non-biotech crops:

Details on coexistence between biotech and non-biotech crops will be defined in the Croatian National Strategy for Coexistence of GMO Crops, Conventional and Ecological Agricultural Plant Production. However, the Law on GMOs forbids planting of registered biotech crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, in protected areas (i.e. as defined as protection impact zones with previously enlisted zones), and in areas that were by local government defined as GMO-free zones.

In addition, biotech crop plantings for reproduction are allowed only in the areas that are suggested by the Ministry of Agriculture, Fishery, and Rural Development and the Ministry of Culture (Environment Protection Directorate) and approved by the Croatian Government in a special ordinance.

g. Labeling of packaged foods or feeds:

According to the Food Act, food and feed containing agricultural biotechnology ingredients must have special, additional information on the label that informs consumers of all characteristics of that kind of food/feed.

h. Biosafety Protocol:

Croatia signed and ratified the Cartagena Biosafety Protocol. Officially there is no trade in biotech products, especially not in seeds. However, it is currently difficult to tell whether or not the Biosafety Protocol is being applied and working in practice.

i. Croatia is a member of the International Plant Protection Convention (IPPC), Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE), but Croatia does not appear to take an

active position regarding plant biotechnology in these organizations.

j. The Croatian legislative framework for biotechnology is very strict and Croatian consumers are very negative towards modern, biotech foods.

k. Beyond legislation that is currently in-use there is no additional pending, plant-biotechnology legislation with potential to affect U.S. exports. A potential future exception could be legislation regarding bioengineered animals.

l. Biotech crops are not commercially planted in Croatia. Croatia has intellectual property rights legislation in place.

#### **Section IV. Plant Biotechnology Marketing Issues:**

##### **a. Market acceptance issues:**

The average Croatian consumer has a negative opinion about food derived from biotech crops. Farmers are afraid of growing biotech plants. There is a feeling that biotechnology is something unnatural and that food should be natural. The reasons for such negative opinions are varied and based on values and emotions.

##### **b. Country-Specific Studies on Acceptance of Biotechnology:**

A Croatian market research agency carried out a study in May 2008 on “Food” that among other things researched the opinions and knowledge of Croatian consumers on GMOs. In this study, 58% of respondents said that they wouldn’t eat GMO food products under any circumstances and 26% of respondents thought that they didn’t know enough about GM foodstuffs. The study showed that 90% of respondents think that GM foodstuffs must be clearly labeled on the store shelves.

The same agency did a study in 2005 on public opinion on GMOs. In this study, 67% of respondents said that they wouldn’t eat GM food products under any circumstances and only 16% of respondents thought that they didn’t know enough about GM foodstuffs.

#### **Section V. Plant Biotechnology Capacity Building and Outreach:**

##### **a. List of the U.S. Government / USDA funded capacity-building / outreach activities that have been carried out in Croatia over the past two years:**

2009: Sponsorship for a feed conference KRMIVA. The topic of the conference was Biotechnology in Feed. Sponsorship was done through and in cooperation with the U.S. Grains Council, with the U.S. Grains Council providing funding and USDA providing logistics.

#### **Section VI. Animal Biotechnology:**

## I. Development and Use:

- a. Genetic engineering and/or cloning are not used in Croatia for the development of agriculturally-relevant animals.
- b. There are no genetically–engineered animals or products derived from the animals intended for or currently in commercial production in Croatia.

## II. Regulation:

- a. Croatia does not have in place any legislation specifically related to the development, commercial use and/or import of these animals or products. However, last amendment to the Law on GMOs (Governmental Gazette 137/2009) mentions briefly that it is forbidden to plant registered biotech crops *or breed registered biotech animals* in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, in protected areas (i.e. as defined as protection impact zones with previously enlisted zones) and in areas that were by local government defined as GMO-free zones. Additionally the Law on GMOs mentions that The Ministry of Agriculture, Fisheries, and Rural Development and the Ministry of Health and Social Welfare have joint responsibility concerning all issues regarding food, foodstuff, and feed containing plant *or animal biotechnology* content and their inspections.
- b. Currently, the FAS office in Croatia is not aware of any discussions of related regulatory or research policies on these technologies.
- c. Government entities that would likely regulate these technologies, regarding both food and environmental safety issues related to research on or commercial use of these animals, include: Ministry of Agriculture, Fisheries, and Rural Development; Ministry of Health and Social Welfare; Ministry of Culture (Environment Protection Department); Ministry of Science, Education and Sport; Croatian Food Agency, and Council for GMOs.
- e. Labeling and/or traceability of these animals or products is expected to be an issue in Croatia. There are indications that the Croatian Government might require mandatory labeling of products derived from GE or cloned animals.

## III. Stakeholder/Public Opinions:

- f. There are active organizations that lobby against the genetic engineering or cloning of agriculturally-relevant animals. In addition, the Croatian press is expected to actively oppose this technology.
- g. In Croatia, it can be expected that the market would reject these products.

## IV. International Organizations:

- a. We are not aware that Croatia actively participates in discussions in international organizations related to the genetic engineering of agriculturally-relevant animals.

V. Outreach, Needs, and Strategies:

Croatia is strongly opposed to bioengineering in plants and efforts to promote animal biotechnology are unlikely to succeed.

**Section VII. Author Defined:**

Exchange rate on 07/05/2010: \$1:Kn5.742232