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Croatia

Biotechnology

Annual Report

2005

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Report Highlights:
Croatia is a net food importer and government policy is geared toward 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 will 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 foodstuff and seed taken from the market were randomly tested for biotech traces, which resulted in the withdrawal of some products from the market and penalties because the biotech products were not labeled. In Croatia, several pieces of legislation have been introduced that seek to regulate the import and cultivation of biotech crops and foods. However, there is a lack of political will to proceed with further legislation that would enable actual imports of biotech products.

Includes PSD Changes: No
Includes Trade Matrix: No
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SECTION I

EXECUTIVE SUMMARY

Croatia is a net food importer and government policy is geared toward 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 will 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 foodstuff and seed taken from the market were randomly tested for biotech traces, which resulted in the withdrawal of some products from the market and penalties because the biotech products were not labeled.

In Croatia, several pieces of legislation have been introduced that seek to regulate the import and cultivation of biotech crops and foods. The laws regulating biotechnology are: Food Act, Law on Genetically Modified Organisms and to a partial extent, the Law on Consumer Protection. Another important legal document on biotechnology is the "Ordinance on Levels of GMO in Products Under Which Products that are Placed on the Market Do Not Have to be Labeled as Containing GMO" (with list of biotech products that can be contained in a product in trace amounts).

SECTION II

BIOTECHNOLOGY TRADE AND PRODUCTION

a. In Croatia there are no commercially produced biotech crops
b. In Croatia there are no biotech crops under development.
c. Croatia is not importing biotech crops/products because there are no laws or acts outlining the registration process for 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 biotechnology crops in general.

SECTION III

BIOTECHNOLOGY POLICY

a. Agricultural biotechnology regulatory framework:

The Law on Consumer Protection was the first biotech-related law to be passed. It was published in the government gazette, number 96/03 on June 10, 2003, after being approved on May 29, 2003. Its relevance lies in the fact that it outlines the legal requirements for the clear labeling of biotech products. The highest penalty for violating this Law by misleadingly marketing products includes fines for the manufacturer or trader in the range of Kn 50,000 to Kn 100,000 and fines for each responsible employee in the range of Kn 3,000 to Kn 5,000 (see end of report for current exchange rate).

The Food Act governs the possible import, licensing and labeling of any foods/feed containing biotech products. The Food Act was approved by Parliament on July 14, 2003 and published in government gazette number 117 on July 23, 2003. This law outlines many regulations

that would enable biotech products to enter the market and be labeled. However, the regulations have not yet been passed, so the labeling threshold is governed by the Government Ordinance on GMO Levels in Products Under which Products Placed on the Market Do Not Have to be Labeled as Products Containing GMO passed on December 3, 2004 (see section IIIb for additional details). Company penalties for violating the "novel food" provisions of the Food Law concerning placing novel food on the market or labeling are from Kn 100,000 to Kn 500,000, with each responsible individual fined from Kn 5,000 to Kn 10,000.

Until recently, the Law on Protection of Nature was the overarching law for biotechnology issues, but it was replaced on May 20, 2005 by a separate piece of legislation entitled the Law on Genetically Modified Organisms (Law on GMOs). The Law on Genetically Modified Organisms (Governmental Gazette 70/2005) together with the Food Act (and forthcoming future 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 so restrictive that it constitutes a de facto ban. The highest penalties for breaching the provisions of this Law range from Kn 500,000 to Kn 1,000,000 for the responsible company and from Kn 20,000 to Kn 70,000 for the responsible employee in the company.

i. Responsible Ministries and their Roles:

Ministry of Science, Education and Sport

- According to the GMO Law, is responsible for limited-contained use of GMOs

Ministry of Health and Social Welfare

- According to the Food Act responsible for all the issues regarding food and foodstuff containing biotechnology content
- According to the GMO Law, the umbrella ministry and coordinating body for all biotechnology issues

Ministry of Culture (Environment Protection Department)

- According to the GMO Law, responsible for the intentional introduction of GMOs to the environment
- According to the Food Act is responsible for also giving its consent for approving foods that contain live GMOs

Ministry of Agriculture, Forestry and Water Management

- According to the Food Act responsible for all the issues regarding feed containing biotech content and cooperates with the Ministry of Health on some other novel food related issues such as labeling
- According to the GMO Law responsibilities for feed and animal food; reproduction material in agriculture, forestry and veterinary medicine; drugs in veterinary medicine and pesticides; is also responsible for giving its consent for the intentional release of biotech products into the environment

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

The GMO Law 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 also giving viewpoints and opinions.

The GMO Law also calls for establishing a Board for Limited Usage of GMOs with 11 members made up 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 GMO Law requires establishing a board for the introduction of biotech products into the environment and consisting of nine scientists from the fields of: genetics, ecology, nature protection, and environment 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 GMO Law, giving opinions and proposals for preparing other legislation on GMO usage, 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 Food Act calls for the establishment of the Croatian Food Agency, which already began its work in 2004. The Agency work consists of conducting scientific and professional business regarding food/feed safety and hygiene that is to analyze risks regarding food/feed safety. Apart from that the Food Agency is also required to: develop guide books for good production practices and the application of the HACCP system and on good laboratory practices; offer scientific opinion regarding human nutrition, animal feed and other issues regarding the health and well-being of animals, as well as plant health; cooperate with international institutions and organizations that deal with food and nutrition issues.

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 will increasingly mirror those of the EU, biotech opponents in Croatia have been emboldened by the perceived success of Austria, Slovenia, and to a certain degree Italy 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, organic to non-biotech products), and Croatian officials see little need to implement a procedure to allow biotech seed imports 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. Also the Croatian public is generally very negative towards biotech products.

b. Biotechnology crops approved for food, processing and feed:

No biotech seed varieties have been approved for planting in Croatia. The Law on GMO outlines the approval process, but there are no regulations that define the actual process. Thus there is a de facto ban on biotech seed plantings in Croatia with a biotech seed threshold level of 0.0%.

No biotech crops have been approved for food or feed use in Croatia, but there is a 0.9% threshold level for some GMOs in food and feed. Under the Food Act (special ordinance from 2004, see section IIIa), the threshold for biotech content in food depends upon whether or not the product has previously been tested and licensed in the EU. If the product has been approved by an EU member state (a list is contained in the ordinance), it does not need to be labeled for sale on the Croatian market--provided separate tests within Croatia confirm the product contains less than 0.9% biotech content. However, if the biotech content is above 0.9%, the product has to be labeled. The biotech threshold level drops to 0.0% for products that have not yet been approved by an EU member. The same goes for feed.

List of 0.9% threshold level allowed GMOs:

1.	GTS 40/3/2	Soybeans	Monsanto
2.	Br 176	Corn	Ciba-Geigy
3.	TOPAS 19/2	Oil rape	AgrEvo
4.	MS1/RF2	Oil rape	Plant Genetic Systems
5.	MS1/RF1	Oil rape	Plant Genetic Systems
6.	GT 73	Oil rape	Monsanto
7.	MON 810	Corn	Monsanto
8.	T 25	Corn	AgrEvo
9.	Bt 11	Corn	Novartis
10.	MON 809	Corn	Pioneer
11.	Falcon GS 40/90	Oil rape	Hoechst/AgroEvo
12.	Liberator L62	Oil rape	Hoechst/AgroEvo
13.	MS8/RF 3	Oil rape	Plant Genetic Systems
14.	1445	Cotton	Monsanto

15.	531	Cotton	Monsanto

c. Situation for with-in country biotech crop field-tests:

According to the Law on Genetically Modified Organisms, field tests of biotechnology crops are allowed. However, the regulations governing such plantings have not been issued yet.

d. Treatment of stacked events:

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

e. Legal framework for coexistence between biotechnology and non-biotechnology crops:

The GMO Law forbids planting of biotechnology crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco tourism, and in protected areas (i.e. as defined as protection impact zones with previously enlisted zones). In addition, biotech crop plantings for reproduction are allowed only in areas that are suggested by the Ministries of Agriculture and Culture and approved by the Croatian Government in a special ordinance.

f. Labeling of packaged foods or feeds:

Food and feed containing agricultural biotechnology products must be labeled according to the Food Act, the Law on GMOs, and the Consumer Protection Law.

Excerpt from the Food Act:

The Declaration or Labelling of Novel Foods

Article 57

1) Novel foods placed on the market of the Republic of Croatia, apart from the general declaration or indication requirements from Article 42 of this Act, must also contain on the declaration additional special information to keep the consumers informed about all the characteristics and features by which the novel food or its ingredient no longer corresponds to the existing food or food ingredient.

2) In that case the declaration must contain information about the changed characteristics or features including the method used to get that indication or characteristic.

3) The food and food ingredients containing or consisting of GMOs, must have a visible indication that it contains or consists of GMOs including the term GMO.

4) The indication must clearly state “genetically modified organisms” or contain the sentence “This product contains genetically modified organisms.”

5) The food and food ingredients originating from GMOs but not containing them must have a visible indication that they originate from GMOs.

The requirements regarding the declaration of novel food shall be provided for by an enforced regulation by the Minister of Health in accordance with the Minister of Agriculture and Forestry.

Declaration and Indication of Feed Containing or Consisting of GMOs

Article 86

1) Feed and feed ingredients containing or consisting of GMOs marketed in the Republic of Croatia, among the general declaration or indication requirements from Article 52 of this Act must contain on the declaration, packaging and accompanying documentation a visible indication that it contains or consists of GMOs and which GMO or its contents it contains.

2) The indication must clearly state the following" this product contains a genetically modified organism."

3) More detailed requirements regarding feed and feed ingredients declaration containing or consisting of GMOs shall be provided for by an enforced regulation by the Minister of Agriculture and Forestry.

The specific regulation with requirements for the declaration for novel foods/feed is still nonexistent, so nobody labels their product as such. However, products have been withdrawn from the market if it was established that they contain biotech components that were not labeled. However, companies would be reluctant to label anyway because of a possible consumer boycott. Therefore, they will rather avoid manufacturing products that contain biotech components.

Under the Food Act (special ordinance see section IIIa from 2004), the threshold for biotech content in food depends upon whether or not the product has previously been tested and licensed in the EU. If the product has been accepted by an EU member state (ordinance contains a list IIIa), it does not need to be labeled for sale on the Croatian market provided separate tests within Croatia confirm that the product contains less than 0.9% biotech content. However, a product has to be labeled if it contains over 0.9% of biotech content. The threshold drops to 0.0% for products that have not yet been approved by an E.U. member. The same applies for feed.

Labeling requirements were established by different legislation and for many reasons including consumer health/safety concerns and consumers' right to know.

g. Biosafety Protocol:

Croatia signed and ratified the Cartegena Biosafety Protocol. Officially there is no trade of biotech products, especially not with seeds. However, at present it is hard to tell whether or not the Biosafety Protocol is being applied and working in practice.

h. Biotechnology - related trade barriers:

The biggest and most important biotechnology-related trade barrier that is hurting U.S. exports is consumers' lack of acceptance for biotechnology which has resulted in restrictive basic legislation and the lack of political will to proceed with further legislation that would enable imports of biotech products.

SECTION IV

MARKETING

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 food should be natural. The reasons for such negative opinions are various and based on values and emotions.

b. Country-Specific Studies on Acceptance of the biotechnology:

A Croatian market research agency recently released the results of a study conducted in March 2004 on Croatian consumers' perception of pesticides use and biotech content in food. The results indicated that consumers view both pesticide use and biotech content in food as harmful to human health. However, excessive pesticide use was perceived as more harmful than biotech food. On average, women rated biotech food as more harmful to health than compared to men. Respondents over 60 years of age rated biotech food as more harmful than compared to younger respondents. There was an interesting trend among respondents in regards to their education levels. As education levels increased, the harmfulness of excessive pesticide use increased while the harmfulness of biotech content in food decreased. (see GAIN report HR 5001)

SECTION V

CAPACITY BUILDING AND OUTREACH

SECTION VI
a. List of U.S. Government / USDA funded capacity building / outreach activities that have been carried out in Croatia:

2001 – Press conference held by Agricultural Counselor and Agricultural Attache on the topic of biotechnology (Sponsored by USDA)

2001/2002 – Promotional leaflets in Croatian language explaining agricultural biotechnology (Sponsored by USDA)

2002/2003 Lisa Katic, Food Industry Spokesperson – meetings with politicians, parliamentarians and government officials, roundtable discussion on biotechnology issues (sponsored by State Department)

2003 – James Maryanski, Biotechnology Coordinator for the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition - participated and held presentation (An Approach to Assessing the Safety of Foods Derived From Plants Modified by Recombinant DNA Techniques) at the Biotechnology and Food Conference, interview with one Croatian daily news paper, embassy hosted lunch with biotech stakeholders (Sponsored by USDA)

2003 – Cochran candidate from the College of Food and Biotechnology, Scientific Assistant – Biotechnology Program (Sponsored by USDA)

2004 – Ann Marie Thro, National Program Leader for Plant Breeding and Genomics in USDA's Cooperative State Research, Education, and Extension Service – meetings with biotechnology stakeholders, press round table on biotechnology issues (Sponsored by USDA)

2005 – Dr. Peter Schmeissner, Agricultural Biotechnology Advisor, USDA/Foreign Agricultural Service (Sponsored by State Department)- meetings and lunches with biotechnology stakeholders, presentation at Agricultural College (The uses of biotechnology for providing resistance to plant diseases), radio 101 show on biotechnology issues

2005 – Cochran candidate from the College of Agronomy, Scientific Assistant – Food Safety Control Methods (Sponsored by USDA)

REFERENCE MATERIAL

Gain HR 5008
Gain HR 5005
Gain HR 5004
Gain HR 5001
Gain HR/BK 4015
Gain HR 4022
Gain HR 4021
Gain HR 4016
Gain HR 4014
Gain HR 4013
Gain HR 4006
Gain HR 4002
Gain HR 3024
Gain HR 3023 (Translation of the Food Act)
Gain HR 3019

Exchange rate on 6/27/2005: $1 = Kn 6.07