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Slovakia

Biotechnology

Annual Report

2006

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Report Highlights:

Slovakia's decree on coexistence is currently being prepared and is expected to be approved by end of this year. This year the first testing field of MON 810 corn is being commercially grown on 30 hectare. Slovak farmers are expected to start regular commercial production of biotech crops next year. Slovak consumers do not have major objections to buying products with biotech content, and several retail chains sell cooking oils made from biotech soybeans.

Includes PSD Changes: No
Includes Trade Matrix: No
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I. EXECUTIVE SUMMARY

Slovakia has already implemented all necessary legislative acts and established responsible authorities for implementing all EU regulations on biotechnology. The main responsible authority for biotechnology is the Ministry of Environment.

There is a decree on coexistence in preparation that will most likely be approved by the end of this calendar year. The Ministry of Agriculture is responsible for regulating coexistence.

This growing season the first testing field of commercially grown MON 810 corn is being grown on 30 hectares in Slovakia. Next year Slovak farmers are expected to start regular commercial production of biotech crops.

Slovak consumers do not have major objections to buying products containing biotech content, and several retail chains offer cooking oils made from genetically modified soybeans.

II. BIOTECHNOLOGY TRADE AND PRODUCTION

Biotechnology Crops in Slovakia

This year Slovakia moved forward with the first planting of commercially grown MON 810 corn on 30 hectares. Next year the area of commercially grown biotech crops (corn) is expected to increase. At present, post does not know of any biotech crops under development.

Foreign Trade

Slovakia imports soybean meal and oils that are produced from biotech soybeans. Most of these biotech products are imported to Slovakia from EU countries with a large percentage of the imports coming from the Czech Republic and the Netherlands. However, the origin of most of these transshipped products is the United States or Brazil.

Imports of soybean meal and oil to Slovakia have stagnated in recent years. According to the Global Trade Atlas, Slovakia imports less than 150 thousand metric tons of soybean meal (HTS code 2304) and about 4 thousand MT of soybean oil (HTS code 1507) annually.

With the growing importance of biofuels, Slovakia might also start importing biotech corn for bioethanol production.

Food Aid

Slovakia is not a food aid recipient. In fact, the country has been facing agricultural overproduction. As a member of the EU, Slovakia is not expected to need food aid in the future.

III. BIOTECHNOLOGY POLICY

Regulatory framework for agricultural biotechnology

There is a new act by the Ministry of Agriculture no. 184/2006 on the Growing of Genetically Modified Crops in Agriculture that has been in force since June 1, 2006. However, the

decree, which will implement this act, is still in preparation. The Government of Slovakia is expected to finalize this decree by the end of this calendar year.

Act no. 151/2002 On the Use of Genetic Technologies and Genetically Modified Organisms (Act on GMOs) is the main legislative act that outlines the rules for the use of genetically modified organisms. This act came into force on April 1, 2002 and was amended by the Act on GMOs no. 77/2005, which went into force on February 3, 2005. English version of the act is available at <http://www.gmo.sk/?page=35>.

The amendment lays out provisions for implementing the Cartagena Protocol on preventing biotechnological risks, as well as implementing regulation (EC) No. 1946/2003 of the European Parliament and the Council on Transboundary Movement of Genetically Modified Organisms. The Amendment designates one focal point and competent authority in Slovakia. A single entity – the Ministry of Environment – is both the focal point and the competent authority.

Since January 2003, Slovakia participated in the United Nations Environmental Program / Global Environmental Fund (UNEP/GEF) to implement the Cartagena Protocol provisions. The Biosafety Protocol was ratified in 2003.

As of October 1, 2005, the regulation administering the Act on GMOs is Decree no. 399/2005 replacing Decree no. 252/2002. The decree outlines details regarding:

- a) the content of an emergency response plan,
- b) requirements for the containment facility of a user, in which genetic technologies shall be used,
- c) the professional qualifications and training for the heads of projects related to contained uses of genetic technologies,
- d) the environmental risk assessment for using genetic technologies and the procedures and criteria for assigning genetic technologies to risk classes; and on the content of containment levels,
- e) the procedures for evaluating the direct and indirect, immediate, and delayed effects of introducing genetically modified organisms into the environment, and the performance analysis of cumulative long-term effects of genetically modified organisms on humans and the environment,
- f) the content of a dossier on the usage of genetic technologies and genetically modified organisms and the manner for keeping its record,
- g) the content of a report on introducing genetically modified organisms into the environment,
- h) the content and keeping of registers for used genetic methods and genetic techniques and used modified genes,
- i) proprieties of particular notifications and evaluations of their content,
- j) properties for applications on registering facilities,
- k) other properties for applications issuing consents,
- l) the content of an evaluation report.

This new Decree no. 399/2005 also simplifies the forms used for the above-mentioned procedures (i.e. registrations, notifications) and makes the administrative process easier for those who want to use GMOs.

Responsible Government Ministries

The competent authority under Directive 2001/18/EC is the Ministry of Environment (MoE). The competencies of the MoE are mainly to:

- issue consents for the contained use of genetic technologies and genetically modified organisms; the introduction of genetically modified organisms into the environment; and the placing of the product on the market
- receive and assess notifications
- receive notices on accidents and on detected changes on deliberate releases
- receive applications for contained uses of genetic technologies and genetically modified organisms; the introduction of genetically modified organisms into the environment; and the placing of the product on the market
- keeping a record of used genetic techniques
- keeping a register of the facilities including the records of users of biotechnologies or GMOs, safety committees and heads of the projects

A listing of the registered users of genetic technologies and GMOs is available on the MoE web site at www.enviro.gov.sk. The users of genetic technologies and GMOs for contained use are mainly Slovak research institutes and universities.

For matters regarding genetic technologies and modern biotechnology, the MoE is the national point of notification to the bodies of the European Union and the national centre for the safety of genetic engineering and modern biotechnology. The Slovak Ministry of Environment participates in Organization for Economic Cooperation and Development (OECD) and the European Food Safety Authority (EFSA).

Other competencies are covered by the Ministry of Agriculture (food, feed, seed) and the Ministry of Health (community feeding).

Inspection and control authorities include the State Veterinary and Food Administration (food control and inspection) and Central Institute for Supervising and Testing in Agriculture (seeds, coexistence).

Biosafety Committee

On September 27, 2004, the Minister of Environment appointed the Biosafety Committee by Decision no. 46/2004. The Biosafety committee plays the role as the advisory body to the Ministry of Environment and makes recommendations.

Biosafety Committee members are specialists in biosafety. The chairman of the Committee is Mr. Igor Ferencik, Director of Biosafety Dept. of the Ministry of Environment. Other Committee members are from ministries, institutes, associations and university.

The body of experts consists of specialists from the following fields:

- GMOs and food produced from GMOs
- genetically modified plants and food produced from genetically modified material
- genetically modified animals and feed and food produced from genetically modified material
- GMOs and their impact on ecosystems
- GMOs and their impact on human health

Political factors that may influence regulatory decisions related to agricultural biotechnology

The neighboring countries of Slovakia (Austria, Hungary, Poland) belong to a so-called "GMO free zone" in Europe, and there is slight political pressure for Slovakia to remain "GMO-free" as well. NGOs, especially Greenpeace, are also another political factor that influence regulatory decisions, and Greenpeace Slovakia has initiated an intense anti-biotech campaign in the past. As a result, several Slovak retail chains stopped selling products containing biotech products in order to avoid public criticism by Greenpeace and the potential loss of customers. However, the Slovak decision-making process regarding biotechnology policy is finally becoming more science-based, even though politics remain an important factor.

Approved Biotechnology Crops

The same biotech crops that are approved by the EU for food, processing, and feed are approved in Slovakia. When the Decree on Coexistence is approved, it will lay down requirements for farmers who want to grow biotech crops.

On June 2, 2003, the Slovak Ministry of Environment issued an approval (valid for 5 years) for importing and placing MON 810 YieldGard® on the market for feed, food and technical purposes.

Field Testing

Slovak legislation allows for field-testing. The Research Institute of Plant Production is growing a quarter-hectare field of MON 810 corn this year. However, the plot does not really constitute a testing field. Rather, it serves as a demonstration field for farmers to see the characteristics of MON 810.

Coexistence

The New Act no. 184/2006 on coexistence (on Growing of Genetically Modified Plants in Agriculture Production) came into force on June 1, 2006. The decree administering this act is still being prepared. However, it will probably come into force before the end of 2006 and will be in place for the next growing season.

Labeling

In the European Union, the main legislation outlining the rules for labeling packaged foods and products is Directive 2000/13/EC. As of April 28, 2004, the labeling requirements in Slovakia were outlined in the Food Codex by the Ministry of Agriculture and the Ministry of Health under the second chapter, decree no. 1187/2004-100 updated with 1761/2005-100, 3069/2005-100, and 3493/2005-100. The purpose of labeling is mainly consumers' right to know.

General Requirements for labeling:

- A food product must be labeled in a way that is not misleading for consumers, especially in relation to the characteristics, nature, place of origin, content, quantity, shelf-life, and way of processing. Graphical representation on the label must not be in contradiction to the structure of the food product. The label can contain other written, graphical or pictured information if those are not in contradiction to obligatory labeling and do not mislead consumers. Additional information must not decrease the legibility of the text.
- Labeling by sellers is obligatory for wrapped and unwrapped food products.

- Any false identification in labeling, cleaning, overwriting, or the removal of information is qualified as "falsification" of the food product.
- According to the Food Codex, the text on labels (of distributed food products) must be in the Slovak language. Other language text is not forbidden, however it must not be an obstacle of legibility for the Slovak language.
- Food products can enter the country with standard U.S. labels or unlabeled. However, products must be labeled according to the Food Codex chapter on labeling before placement on the market.
- Stick on-labels meeting the local requirements are permitted. Food products introduced into circulation must be labeled on packages for final consumers, on external packages, or on its integral parts.

If food products require special conditions for handling, or if consumer must be informed about food product properties, the label has to indicate this information. Such cases include:

- food products for special nutritional purpose, or special use
- the presence of GMOs, their parts, derivatives and metabolites or their products
- treatment of food products or their components by ionizing radiation
- actual nutritional value of food product, package of which contains the nutritional claims
- possible unfavorable influence on human health

In the case of new food products (including GMO), the following must be stated:

- content, nutritional value or nutritional influences if the food product contains new characteristics different from the common food product with the same name
- presence of matter, which the common food product does not contain and which may have an influence on the health of certain groups of consumers
- information, that the food product contains GMOs, their parts, derivatives and metabolites or their products, if this is stated by Food Codex
- presence of the new matter, which is not present in common food products

Act on Feeds no. 271/2005 came into force on July 1, 2005 and is harmonized with EU legislation. The act lays down rules for:

- registration of feed producers
- requirements for introducing feed on the market
- control of feeds
- responsible government institutions
- penalties for infringement of the Feed Act and of valid EU regulations.

Feed labeling has to be in accordance with Regulation (EC) No. 1831/2003 of the European Parliament and of the Council of September 22, 2003 Concerning The Traceability And Labeling Of Genetically Modified Organisms And The Traceability Of Food And Feed Products Produced From Genetically Modified Organisms And Amending Directive 2001/18/EC.

The rules for labeling are enforced by the State Veterinary and Food Inspection authorities, and by the Ministry of Agriculture and by the Central Institute for Control and Testing in Agriculture.

The inspection and control authority for food labeling is the State Veterinary and Food Administration. The inspection and control authority for feed labeling is the Central Institute for Supervising and Testing in Agriculture and also the State Veterinary and Food Administration (feeds for direct feeding at farms, feeds with animal origin). These authorities take samples of products and impose fines for infringements of the rules.

Biosafety Protocol

Slovakia ratified the Cartagena Protocol on Biosafety on November 20, 2003, and it came into force on February 22, 2004. It was implemented in the Act on GMOs No. 77/2005. The Act on GMOs No. 77/2005 implements the precautionary principle for the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity and takes into account the risks to human health and includes rules on transboundary movements.

Trade Barriers

The strong campaign against biotech products organized by Greenpeace and other NGOs influenced several retail chains to stop selling products containing biotech products. However, there are still retail chains that are not afraid to sell products containing biotech products (i.e. cooking oils).

The pressure on retailers has a negative impact on suppliers and producers. Some retailers require a statement by the producer that their products do not come from animals that were fed with biotech feed. For this reason, U.S. soybean meal exports to Slovakia have stagnated during recent years.

IV. MARKETING ISSUES

Market Acceptance

The typical Slovak consumer is still quite price sensitive and biotech content in a food product would not be a major factor in the buyer's decision-making process. Although, some retailers require a statement by the producer that their products do not come from animals that were fed with biotech feed. This is a reason why U.S. soybean meal exports to Slovakia have stagnated over recent years. The pressure on retailers has a negative impact on suppliers and producers.

Country Specific Studies

In 2003, the Biosafety Department of the Ministry of Environment organized a detailed opinion poll on the acceptance of GMOs by Slovak citizens. The results can be downloaded from www.gmo.sk, and information about the poll can also be found in GAINS report LO4002.

V. CAPACITY BUILDING AND OUTREACH

Slovak officials have participated in agricultural biotechnology programs under the Cochran Fellowship Program organized and sponsored by USDA.

Country Specific Needs or Strategies

There is a need for educating the general public about biotechnology. In 2005, biotechnology specialists (members of the Academy of Sciences and university professors) founded the "The Slovak Biotechnology Society" in Slovakia. The organization's goal is to promote biotechnology in Slovakia mainly by educating the general public.