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Report Highlights:

As an EU member, Slovakia has fully implemented EU regulations on biotechnology, and the growing of biotech crops is not prohibited. However, Slovakia still does not have coexistence regulations in place, and no biotech crops are grown or tested in the country. There is a growing lack of consumer acceptance for biotechnology due to intense anti-biotech campaigns led by NGOs and the influence of neighboring countries. However, Slovak consumers have not been strongly averse to buying biotech products in the past, and several retail chains offer cooking oils made from biotech soybeans.

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SUMMARY

Slovakia still does not have coexistence regulations in place, and no biotech crops are grown or tested in the country. However, the growing of biotech crops is not prohibited. However, there is a growing lack of acceptance of biotechnology in Slovakia because of an intense anti-biotech campaign led by Greenpeace and the strong negative influence of neighboring countries.

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

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

U.S. seed companies interested in the Slovak market will probably not be able to introduce their biotech seeds into the Slovak market before 2006/7.

BIOTECHNOLOGY TRADE AND PRODUCTION

Biotechnology Crops in Slovakia

Currently there are no biotechnology crops produced in Slovakia. The main reason is politically motivated and due to the complicated Slovak legislation that is stricter than the EU legislation.

For the average farmer it would be very difficult to provide all the documents required by the Slovak Act on GMOs. Therefore, the growing of biotechnology crops in Slovakia is essentially precluded at the moment. This is also the main reason why U.S. biotechnology companies decided not to place their seeds on the Slovak market this year.

Currently, Slovakia can be considered a "GMO-free" country. There are no biotechnology crops under development and no field trials. Because the biotechnology companies decided not to place their seeds on the Slovak market this year, there are no seeds being planted either.

Trade/Import of Biotech Crops

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 U.S. or Brazilian.

Imports of soybean meal and oil to Slovakia have stagnated in recent years. According to the Global Trade Atlas, Slovakia imports less than 200 thousand metric tons of soybean meal (HTS code 2304) and about 6 thousand MT of soybean oil (HTS code 1507) annually.

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.

BIOTECHNOLOGY POLICY

Regulatory Framework

Slovakia is in the process of completing its legislative and administrative framework for biosafety. The basic infrastructure is already in place. Slovakia has participated since January 2003 in UNEP/GEF (United Nations Environmental Program / Global Environmental Fund) to implement the Cartagena Protocol provisions.

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 use of genetically modified organisms. This act came into force on April 1, 2002 and was recently amended by the Act on GMOs no. 77/2005, which went into force on February 3, 2005.

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 of 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 – will fulfill the function of both the focal point and the competent authority.

As of June 1, 2002, the regulation administering the Act on GMOs is Decree no. 252/2002. The Ministry of Environment has been currently working on an amendment to this decree. 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 of using genetic technologies and on the procedures and criteria for assignment of 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 of 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 on 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) other properties for applications on registering facilities and issuing consents
- k) the content of an evaluation report.

The amendment is supposed to simplify the forms used for the above-mentioned procedures (i.e. registrations, notifications).

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. Currently there are 22 registered users of genetic technologies and GMOs for contained use that are mainly Slovak research institutes and universities.

For matters regarding genetic technologies and modern biotechnology, the MoE is the national notifier to the bodies of the European Communities and the national centre for the safety of genetic engineering and modern biotechnology. The Slovak Ministry of Environment participates in OECD and EFSA (European Food Safety Authority).

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 a 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 (see more details in section CONTACTS). 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

The Slovak Ministry of Environment has quite a close relationship with the Hungarian Ministry of environment and maintains contact with the Austrian Ministry of Environment as well. The Slovak Ministers of Environment and Agriculture are members of the Hungarian Coalition party, which may influence them to follow Hungarian policy.

The neighboring countries of Slovakia (Austria, Hungary, Poland) belong to a so-called "GMO free zone" in Europe, and in this regard there is a slight political pressure on Slovakia to remain "GMO-free" as well.

According to sources, the Slovak decision-making process regarding biotech policy is influenced more by politics/political issues than by science-based facts.

Another factor that has a strong influence on regulatory decisions is the pressure from NGOs, especially Greenpeace. Greenpeace Slovakia has led an intense campaign against genetic engineering. As part of the campaign, they issued a publication in color called "Consumers Guide, How to Shop without GMOs". Based on such actions several Slovak retail chains were forced to stop selling products containing GMOs in order to avoid public criticism by Greenpeace and potential loss of their customers.

Unfortunately, the Slovak mass media pays more attention to the provocative actions of NGOs rather than the serious factual information provided by scientists or private companies.

Approved Biotechnology Crops

In Slovakia there are the same biotechnology crops approved for food, processing, and feed as in the EU. So far there have been no approvals for releasing biotechnology crops into the environment or for field-testing.

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. However, because Slovak's complicated regulatory system practically precludes the growing of biotech crops, no commercial planting of biotech crops takes place in Slovakia at present.

Field Testing

The Slovak legislation allows field-testing. However, there are no field trials taking place yet. The Research Institute of Plant Production and some private companies will probably apply for the approval for field tests next year.

Coexistence

The Act on Coexistence is in preparation, but no rules on coexistence are in place yet. The Central Institute for Supervising and Testing in Agriculture, which is directed by the Ministry of Agriculture, is in charge of preparing the act. However, the act will probably not come into force before the summer of 2006.

This may have a negative impact on U.S. exports of biotech seeds and seedlings to Slovakia. Nevertheless, U.S. biotechnology companies are interested in the Slovak market and keep making efforts to change the situation and enter the Slovak market in the near future.

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 are outlined in the Food Codex by the Ministry of Agriculture and the Ministry of Health under the second chapter, decree no. 1187/2004-100. The purpose of labeling is mainly consumer's right to know.

General Requirements on 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. 184/1993 as amended by Act no. 472/2003 was recently replaced with a new Act on Feeds no. 271/2005, which 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 Act on Coexistence is still being prepared and will probably take another year to finish. Before the act comes into force, we cannot expect U.S. biotech companies to introduce their biotech seeds to the Slovak market.

Another trade barrier has been created by NGOs (Greenpeace) that have led a strong campaign against genetic engineering and GMOs. Because of Greenpeace several retail chains stopped selling products containing biotech products. However, there are retail chains that are not afraid to sell products containing GMOs (for example cooking oils).

The pressure on retailers has a negative impact on suppliers and producers. Some retailers require a statement by the producers that their products do not come from animals that were fed with GM feed. This is a reason why U.S. soybean meal exports to Slovakia have stagnated over recent years.

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. This might change in the near future due to threatening and sometimes misleading information about "GMOs" that is systematically presented to the public by Greenpeace.

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 GAIN report LO4002.

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

According to the Ministry of Environment, Slovakia needs an institution that could provide the MoE with support in research and monitoring biotech crops and related tasks.

In regards to biotech policy, Slovakia's neighboring countries significantly influence it. If the neighboring countries (mainly Hungary) became less negative towards biotechnology, changes could be expected in Slovakia as well.

ADDITIONAL INFORMATION

For more information, related contacts, and emerging issues regarding biotechnologies in Slovakia see the following attaché reports. The reports are available on-line at <http://www.fas.usda.gov/scriptsw/AttacheRep/default.asp>.

LO5003	U.S. Seed Companies Agree Not to Plant Biotech Varieties this Year (FAS internal use only)
LO5002	Amendment to GMO Act No. 151/2002
LO5001	NGOs Urge Slovak Ministry of Environment to Ban MON 810 (FAS internal use only)
LO4011	Slovakia's Biosafety Framework
LO4002	Consumer Perception of Biotech
LO3005	Status of Biotech Regulations