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Czech Republic

Biotechnology

Status of Biotech Regulations

2003

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Report Highlights:
The Czech Republic is harmonizing its biotech legislation to that of the European Union (EU) in anticipation of EU accession May 1, 2004. Act 153/2000 is the current law regulating registration and use of biotech products in the Czech Republic. The law came into force in January 2001 and is based on EU rules on biotechnology. Currently, there is a new law in the Parliament that should replace 153/2000. U.S. biotechnology companies operating in the Czech Republic are working to achieve public acceptance of biotech products. They are explaining biotechnology to regulators, so that new member states will be able to stand together and defend scientific views and oppose political arguments of current EU members.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Vienna [AU1]
[EZ]

Relevant Laws And Regulations

Act 153/2000 is the current law regulating registration and use of biotech products in the Czech Republic. The law came into force in January 2001 and is based on EU rules on biotechnology. It only regulates living organisms and products containing living organisms (e.g. tomatoes), not foods made from these products (e.g. ketchup), and not feed. Foods and feeds have additional regulations.

The responsible government authority for controlling biotech product use and biosafety is the Ministry of Environment (Environmental Risks Department). It cooperates with the Ministry of Health and the Ministry of Agriculture. The law establishes a Commission for the Use of Genetically Modified Organisms (GMOs), which acts as an advisory body to the Ministry of Environment. The Commission is made up government officials, scientists, and representatives from non-government organizations (NGOs). The Commission assesses applications for biotech product releases or uses and provides its recommendation to Ministry.

Act 153/2000 defines several lists:
List of users – companies and organizations using and working with biotech products (e.g. Monsanto, universities, research institutions)
List for contained use (List A) – for microorganisms; used more for medical and pharmaceutical purposes ('red biotechnology')
List for introduction into the environment (List B) – field trials of biotech crops
List of placement on the market (List C) – for import and growing biotech crops

If biotech products are to be used in foods, they must be registered according to Act 153/2000 and then according to Food Act 306/2002. The State Health Institute tests the products and sends its comments to the Ministry of Health, which is the responsible authority for approving biotech products in foodstuffs.

If a biotech product is to be used in feed, it first has to be registered according to Act 153/2000, and then Feed Act 91/1996 is applied. Feed companies have to notify the Central Control and Testing Institute in Agriculture (CCTIA, in Czech UKZUZ). Currently, there is a draft of the amendment to Act 91/1996 in the Parliament in which feed companies would not need to notify CCTIA. In addition, feeds would come under the EU's Food and Feed Regulation as of May 2004.

If a biotech product is to be used as seed, it has to be registered according to Act 153/2000, and then the Plant Varieties Act 219/2003 is applied.

Pesticides for use on biotech crops (e.g. Round-up Ready herbicide) are regulated by Phytosanitary Act 147/1996. If the herbicide itself contains some biotech product, it first has to be registered according to Act 153/2000, and then 147/1996 is applied.

Before a variety is approved for commercial growing, it has to be field tested for three years and approved according to Act 153/2000 for placement on the market.

The New Act on GMOs, which should replace Act 153/2000 and which implements EU Directive 18/2001, is now in the Parliament. Major (expected) changes include:
Market release is approved by competent authority of the EU member state
Establishes links to the EU approval process (Czechs will also have some say in the approval process in the EU and varieties approved in the EU will be automatically approved in the Czech Republic)

Tracebility – public registration (farmers); however, information about their location will not be available on the Internet
NGOs are removed from direct participation in the approval process
There is more information on monitoring

If approved by Parliament, it should become effective in the last quarter of 2003.

Feed Act 91/1996 has now been amended in the Parliament, and the conditions for labeling and registration for biotech feeds has been withdrawn. In May 2004, the EU's new Food and Feed Regulation will be applied.

Biotech Crops Registered in the Czech Republic

Approved:
RR Soya – registered in List C for placement on the market (January 2001) with approval granted for 10 years. The Czech Republic does not have the climatic conditions to grow soya. Therefore, it is only approved for import. It is also approved for use in food according to Act 306/2002 and for use in feeds according to Act 91/1996.

YieldGard corn (Bt corn) – registered in List B for field trials (January 2002) with approval granted for 3 years. For field trials only, registration according to Act 153/2000 is necessary.

YieldGard corn (Bt corn) – applied (October 2002) for placement on the market (List D, for import, processing, and growing). Still in registration process. If approved, biotech product can be grown commercially after three years of variety registration trials (according to Plant Varieties Act 219/2003).

RR corn – registered in List B for field trials (February 2002) with approval granted for 3 years. Again, only registration according to Act 153/2000 is necessary.

Not approved:
RR wheat – applied for registration in List B for field trials (June 2001). The Ministry of Environment returned the application for incomplete documentation. After many discussions the applicant (a biotechnology company) decided not to provide the requested confidential information.

Regulatory Process

The approval process for registration of biotech products contains the following steps:
Interested party fills out the application (on www.env.cz) and sends four copies to the Department of Environmental Risks at the Ministry of Environment (MoE).
GMOs section of MoE sends copies to the Ministry of Agriculture (MoA), the Ministry of Health (MoH), the Chairman of the Czech Commission for GMOs Approval at MoE, and maintains one copy for its own reference and use.
Non-government organizations (NGOs) are informed about the request and, if they are interested, become part of the administrative process and send their comments to MoE.
If the MoE approves a biotech product that NGOs advised not to approve, NGOs may appeal to the Analytical Commission of MoE, whose lawyers and experts will solve the dispute.
MoA and MoH have 45 days to send their comments to MoE.
The Department of Hygiene, Epidemiology, and Microbiology at MoH sends the request to the State Health Institute (SHI) in Brno. The Institute has a Working Group of five people for studying the request and preparing comments for the Ministry of Health. If necessary the working group asks various external specialists for their views. The comment from the

working group is sent to MoH, where the Chief Hygienist signs and sends the comment to the MoE. MoA's Commission of Agricultural Production Department assesses the biotech product from an agricultural standpoint. The six member committee includes: the director of the department as chairman, two department officials, two officials from the Control and Testing Institute in Agriculture, and one official from the State Agricultural and Food Inspection.
When MoE receives comments from both MoA and MoH, the GMOs section of MoE assesses the comments and decides whether to approve and register the biotech product.
If the request cannot be approved it is returned to the applicant, who can add missing information and resubmit the request. According to Act 153/2000, MoE has to reply to the applicant within 90 days of receiving the request for a biotech product approval.
If MoE approves an application and a civic organization such as Greenpeace becomes part of the administrative procedure and does not agree with the decision, the civic organization may appeal the decision to the Analytical Commission of the Ministry of Environment within 15 days.

Once MoE approves a biotech crop for growing, it has to be registered according to Plant Variety Act 219/2003 in the Control and Testing Institute for Agriculture (3 years of variety registration trials).

Documentation

A complete packet of information required for consideration of approval of biotech crop is in supplements of Decree 374/2000 and is available on Ministry of Environment webpage (see end of report). It contains the following requirements:
Detailed information about the user (person or a company)
Information on a scientific advisor
Purpose and time period of use for biotech product
Detailed risk assessment
Detailed information on GMO, method of its insert into the crop, its detection, if it was approved in some country, amount of biotech product to be used, etc.
Detailed information about biotech product, use, method of biotech detection, packaging, labeling
Handling biotech products. In case of import, country of origin, importer, transportation, etc.
Supplementary information including evidence of biotech products, storage, communication with the Ministry, etc.

Penalties

The State Agricultural and Food Inspection Service tests agricultural products for biotech content on a random basis. If a product with containing over 1 percent of biotech product is not labeled, the Ministry of Environment may issue a fine from 100,000 CZK to up to 3 million CZK. Soybeans are tested quite often, while corn is seldom tested.

Labeling and Tracebility

There is no tracebility system being implemented yet. The Czech Republic is waiting until EU accession and then will apply the EU's Tracebility and Labeling Regulation. Registered products (e.g. RR soya) have to be labeled as biotech products.

One percent is the threshold requirement for labeling. There is no documentation needed for agricultural products containing over 1 percent of biotech product. However, they must be labeled.

Information on the label must say, “contains genetically modified organism”. Terms like “biotech-free”, “non-biotech”, “GMO-free”, or “may contain” do not appear in the Czech legislation. Some companies put “non GMO” or “GMO-free” on their products (e.g. on oils) as part of it’s marketing strategy to attract customers. All products that have ingredients containing over 1 percent of biotech product must be labeled (including consumer ready products).

Feeds containing RR soya will not have to be labeled until May 2004 according to the amended Feed Act 91/1996.

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