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Czech Republic

Biotechnology

GMO Approval Process

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Report Highlights:

A law detailing the rules and regulations for GMO approval was instituted. This law is onerous in appearance but has been remarkably flexible in its application to date.

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

GMO Approval Process in the Czech Republic

Summary

The GOC implemented Law 153/2000 on the use of genetically modified organisms (GMO) in January 2001. This Law details rules and regulation on the GMO approval process. All GMOs must now be approved and registered. The Ministry of Environment (MOE) is responsible for collecting requests for GMO approval from seed companies, importers, research institutions, laboratories etc., consulting with other ministries and interested parties (NGOs - if interested in the case, they become part of administrative procedure), assessing them and registering users and GMOs. Note: This has potentially made Greenpeace and other NGOs full members of the approval process.

The law requires that MOE maintain four lists - in brackets are current listings:

list of GMO users (Monsanto, Aventis)

list of GMOs approved for contained use (laboratories etc.) (no agricultural commodity at this time)

list of GMOs approved for release to environment (rapeseed)

list of GMOs approved for release on the market (rapeseed, soybeans)

The Approval Process

The following describes the step by step approval process for genetically modified organisms in the Czech Republic.

Example: To register GM soy beans for market release

Steps:

1. Interested party fills out the application (on www.env.cz) and sends four copies to Ms. Zuzana Doubkova, Department of Environmental Risks, the Ministry of Environment, Vrsovicke 65, 100 10 Praha 10, Czech Republic.
2. GMO section of MOE sends copies to the Ministry of Agriculture (MOA), the Ministry of Health (MOH), the Chairman of the Czech Commission for GMO approval at MOE, and maintains one for its own reference and use.
3. NGOs are informed about the request and, if they are interested, become part of the administrative process, which means that they send their comments to MOE. If MOE approves GMO that NGOs advised not to approve, NGOs may appeal to the Analytical Commission of MOE, whose lawyers and experts will solve the dispute. This has not yet occurred. This GMO approval process started in January 2001, and most requests have been returned to applicants for additional information.

4. MOA and MOH have 45 days to send their comments to MOE.
5. The Department of Hygiene, Epidemiology, and Microbiology (Dr. Hammerova), 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. Dr. Ruprich, Food Hygienist, is the chairman of this working group. 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 it to MOE.
6. The Ministry of Agriculture's (MOA) Commission of Agricultural Production Department approves and assesses GMOs. It has six members - the chairman is the director of the department, two other members are also from the department and two members are from Control and Testing Institute in Agriculture, one person is from Food Inspection.
7. When the Ministry of Environment receives comments from both MOA and MOH, the GMO section assesses the requests and comments and decides whether it approves and registers GMO in at least two lists (it always registers the applicant in the list of users and then it registers the GMO in one of the three lists according to their release).
8. If the request cannot be approved it is returned to the applicant, who can add missing information and resubmit the request.
9. According to Law 153/2000, MOE has to reply to the applicant within 90 days of receiving the request for GMO approval.
10. If MOE approves a new variety, and Greenpeace became part of the administrative procedure and does not agree with the decision, it can appeal to Analytical Commission of the Ministry of Environment, whose lawyers (Chairman Dr. Sembera) consult specialists and make a decision. This has not happened yet.
11. Once MOE approves a new variety, it has to be registered in the Control and Testing Institute for Agriculture.

Czech Commission

The Commission at the Ministry of Environment is called Czech Commission and its members are listed on www.env.cz. The sixteen members are named by the Minister. The chairman of the commission is Dr. Ondrej from Institute of Molecular Biology of Plants. Among members are employees of the MOE, scientists, researchers, food hygienists, veterinarians and representatives of NGOs. (Note: Greenpeace did not want to be a member).

Facts about the approval process

The MOE has received 42 requests for GMO approval since the beginning of 2001. Thirty concern microbiological bacteria and only 12 requests have been for agricultural commodities. So far Monsanto's soybeans have been approved for release on the market (for 10 years) and Aventis's rapeseed to be released on the market (for 4 years). Other crops approved for field trials, prior to January 2001 (e.g. herbicide resistant sugar beet and corn and insect resistant (Bt) corn) have been banned and must now be approved according to the new Law 153/2000. Pioneer's request for Bt corn approval from February 2001 for release into environment was turned down because of insufficiently filled out application forms. MOE returned the application to Pioneer with a two months deadline for amending it. Since Pioneer did not resubmit their application, MOE closed the case. If Pioneer fills out the application properly, it may still be approved.

Most of the requests to date have been returned to applicants, who must include more information, usually on risk assessment.

The MOE has mostly approved GMO requests or returned the application requesting more information. Recently newspapers published an article in which Greenpeace says that MOE turned down Monsanto's wheat. However, the MOE only returned the request to Monsanto asking for a more detailed analysis. The MOE states it will sue the writer of the article for providing misleading information.

Once a GMO variety is approved for the market, other companies may import the crop and do not have to register it. However, all commodities containing GMO must be labeled.

Related webpages

www.env.cz (list of Czech Commission members, information on the requests)

www.biotrin.cz

www.mze.cz

www.mzcr.cz

www.apend.org/index.php?a=4&b=4107