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Czech Republic

Biotechnology

New GMO Law

2004

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Report Highlights:

In February 2004, the Czech Republic passed law 78/2004 on genetically modified organisms (GMO) replacing law 153/2000. The law officially came into force on February 25, 2004, and major changes include an easier approval process for contained use GMOs, as well as changes for the participation of civic associations in the approval process. In January 2004, the Ministry of Environment approved Monsanto's YieldGuard corn (MON810) for release on the market.

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

New GMO Law

Law 78/2004 on the handling of genetically modified organisms and genetic products ('GMO law') came into force on February 25, 2004 and replaced Law 153/2000 on GMOs. Law 74/2004 reflects the new EU Directive 2001/18/EC (GMO – release into environment and on the market) and removes flaws from the first law on GMO and prepares the Czech Republic for EU membership (it establishes relations for the European Commission, which is common in the current EU countries).

Major changes in the new law 74/2004 include:

- Easier approval process for contained use (law 53/2000 was more strict than the EU directives, now it's in line with EU directives)
- Approvals for release on the market at the EU level
- Approval processes are described in more detail
- Information sharing with the public is different in law 53/2000 civic associations (e.g. Greenpeace) could participate in the approval process; according to law 74/2004 the Ministry of Environment informs the public (on Ministry webpage: www.env.cz and in a Ministry bulletin) about the most important part of the application and the Ministry's decision – within 30 days; anybody may appeal; if comments concern risks, the Ministry must set up a public hearing, and the Ministry must take the public hearing's vote into account when making a decision
- Exchange of information with the EU

Law 74/2004 concerns only living organisms and products containing living organisms (according to Cartagena Protocol). It does not concern drugs, feeds, foodstuffs, herbicides containing GMO, and contained use of safe genetically modified microorganisms (GMM).

Like 53/2000 law 74/2004 regulates GMO for:

- Contained use laboratories, greenhouses (approval is issued to users; easier procedure now: 1st and 2nd risk category only announcement, 3rd and 4th risk category request for approval)
- Release into environment field trials, growing on small areas (approval is issued to users)
- Release on the market import, processing, sale, growing including variety testing (approval is issued for GMO, anyone can use it if approved); after accession European Commission will be part of approval process; member states voting; complicated procedure

Requirements on GMO approval for release on the market:

- Labeling
- Growers of GM crops must inform Ministry of Environment about place of the growing
- Co-existence rules (Ministry of Agriculture is working on the decree)
- Monitoring and sending samples to the Ministry of Environment (according to regulation ES 1830/2003 on labeling and monitoring)

When a GMO is approved for release on the market, it is automatically approved for the whole EU. However, plant varieties containing a GMO registered on the national registers are not automatically registered at the EU level.

So far the Ministry of Environment approved the following biotech products:

- In the environment: Bt corn, RR corn, potatoes, flax, rapeseed
- On the market: Bt corn, RR soya (only for import, not for growing)

After EU accession on May 1, 2004, the following regulations will apply for the Czech Republic directly (sanctions will be applied according to national regulations) in regards to GMOs:

- Regulation 1829/2003 on genetically modified foodstuffs and feeds
- Regulation 1830/2003 on labeling and monitoring of GMO, foodstuffs and feeds
- Regulation 1946/2003 on border-crossing of GMO (Cartagena Protocol regulates export; 74/2004 will regulate import)

Results of test on GMO in food products

Last year the State Agricultural and Food Inspection (SAIF) tested over 192 products and detected 24 containing GMOs. All contained soybeans or products made of soybeans. GMO content was 0.9 %, and therefore products did not require labeling (they have to labeled if GMO content is over 1 %).

Monsanto's YieldGard corn (MON810) approved

In January 2004, the Ministry of Environment finally approved Monsanto's YieldGuard corn (MON810) for commercial planting (in compliance with the seed legislation) and import (approval for release on the market). For more background information on problems with this approval – please see report GAIN Report EZ3018 at <u>www.fas.usda.gov</u>.

Related Reports:

- EZ4010 National Biosafety Framework
- EZ4001 Status of Biotech Regulations Central Europe
- EZ3020 Consumer Perceptions of Biotechnology
- EZ3015 Biotechnology from a Czech Perspective

Steps in the registration process Applicant Min.of Env. Min.of E. sends copies of publicity ••••• **Min.of Health** Min.of Agr. **Czech Commission for GMO** comments Their comments to Min. of New process incl. MoH, MoA, Min.of Env. asks Completed for additional application CC GMO comments Min.of information to Enviro

application