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Czech Republic

Biotechnology

Annual Report

2005

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Report Highlights:
The Czech Republic, as a member of the EU, follows the EU's legislative framework for biotechnology. Act 78/2004 replaced the first Act on GMO 153/2000. The Ministry of Environment is the competent authority for handling biotech product notifications, and the Ministry of Agriculture is responsible for notifications of biotech food and feed. The Czech Republic ratified the Cartagena Protocol on Biosafety in October 2001. This year about 300 hectares of Bt corn (MON 810) is being grown in the Czech Republic for the first time. The Czech Republic's coexistence rules require isolation distances and notifications to the Ministry of Agriculture and the Ministry of Environment. When voting on biotech approvals at various levels in the EU, the Czech Republic takes a case-by-case approach and bases its decision on scientific evidence.

Includes PSD Changes: No
Includes Trade Matrix: No
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[EZ]

SECTION I.

EXECUTIVE SUMMARY

The U.S. exports soybean meal and soybean oil to the Czech Republic. It is difficult to estimate the exact amount, since most soybean meal comes from Germany where U.S., Brazilian, and other soybean meal is mixed. In 2004, the Czech Republic imported over 600,000 MT of soybean meal, which was double the amount from 2001. The higher demand for soybean meal is the result of Europe's BSE outbreak in 2001, when meat-bone-meal was replaced by soybean meal in feed mixtures.

Round-up Ready (RR) soybeans were one of the first biotech varieties approved by the Ministry of Environment, when the first Act 153/2000 on Genetically Modified Organisms (GMO) came into effect. The impact of biotech regulations has not impacted U.S. exports of soybean meal or soybean oils significantly, but it did impact the export of some food products (e.g. corn chips or products containing soybeans) as retailers requested certification products do not contain biotech ingredients. An importer of U.S. products has to assess which products may contain biotech products and have those products tested in the Czech Republic, which is very costly. If the test result is less than 0.9% for biotech content, the importer receives a certificate that states that the product does not contain "GMOs". If biotech content is higher than 0.9%, the importer will most probably not import this product, since retailers refuse to carry products containing biotech products. However, there are exceptions for products with labels stating "contains GMO" (e.g. soybean oil) and consumers buy these products. These consumers either do not read the label or do not think biotech products (or GMOs) are dangerous. On the other hand, there are products (especially organic), which carry a voluntary 'negative' label "does not contain GMO" as a marketing tool.

Czech biotechnology regulatory system – recent developments

The Czech Republic, as a member of EU, follows the EU's legislative framework for biotechnology. Even before EU accession on May 1, 2004 and during the 'legislation harmonization process', Act 153/2000 on the use of genetically modified organisms and genetic products was in effect since January 1, 2001. According to this Act, the Ministry of Environment evaluates applications and registers biotech products for contained use, release into the environment, and on the market. The Ministry keeps a list of all approved biotech products and a list of users.

Act 153/2000 was replaced by Act 78/2004, which came into effect on February 25, 2004. The competent authority handling notifications and regulating the use of biotech products in the Czech Republic is the Ministry of Environment (according to EU Directive 2001/18/EC). It cooperates with the Ministry of Health in respect to human health risks and with the Ministry of Agriculture in respect to agricultural risks including crops, feeds, and animal health. The Czech Commission for the Use of GMOs and Genetic Products ("Commission"), the expert advisory body to the Ministry of Environment, has 14 members and consists of representatives of administrative authorities, scientists, and researchers. The main task of the Commission is conducting the environmental risk assessment of the notified GMOs. The Czech Republic ratified the Cartagena Protocol on Biosafety in October 2001.

Under EC Regulation 1829/2003 on Genetically Modified Food and Feed, the competent authority for handling notifications and approvals of biotech food and feed is the Ministry of Agriculture, Food Safety and Technology of the Living Environment Department.

The Ministry of Agriculture prepared rules for coexistence of biotech crops with conventional and organic farming in preparation for planting Bt corn in the spring of 2005. The rules are

valid only for 2005, since they are included in the Government Regulation on Conditions for Providing Top-up Payments to Direct Payment for 2005, and next year will be in the amended Act on Agriculture 252/1997. The rules for coexistence regulate the isolation distances and require reporting on locations where Bt corn is grown.

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

Production of biotech crops

In 2005, Czech farmers were allowed for the first time to plant Bt corn (MON 810), which is marketed under the name YieldGard Cornborer and distributed by Pioneer. As a result, over 60 farmers planted Bt MON810 corn on a total area of about 300 ha.

Czech farmers worry about the marketing and sales of products made from biotech products (e.g. even though milk from animals fed by biotech soybean meal does not have to be labeled, farmers fear that dairy plants will request certification that his/her animals were not fed biotech products). This initiative from dairy plants stems from retailers' requirements for "GMO-free" products, not from legislation.

Currently BASF is doing several field trials with potatoes on a small area (tens of hectares). Monsanto plans to start field trials next year with YieldGard Corn Rootworm.

Import of biotech crops

The Czech Republic imports soybean meal and soybean oil from RR soybeans. Even though statistics show most imports originate from Germany, the soybean meal comes from other countries (mostly from the U.S. or Brazil depending on the season). Soybeans are mixed in Germany and sold by quality type--not country of origin, so it's hard to know exactly how much product is exported to the Czech Republic from the U.S. In 2004, the Czech Republic imported over 600,000 MT, which was 100% increase since 2001.

A small quantity of corn is also imported from the U.S. (in 2004 about 500 MT). The Czech Republic is increasing its growing area of corn, which reduces the need for corn imports. In 1999, the Czech Republic imported 76,000 MT of corn, last year it was only 10,000 MT. Over 90% of total imported corn comes from Slovakia.

For U.S. exporters there is an opportunity for export of soybean meal, soybean oil, and corn seeds.

The Czech Republic is not a food aid recipient, and as a member of the EU it is not likely to be a food aid recipient in the near future.

No biotech crops developed outside of the U.S. are produced in the Czech Republic.

SECTION III. BIOTECHNOLOGY POLICY

Responsible government Ministries and their role

Under Directive 2001/18 EC and Act 78/2004, the competent authority responsible for handling notifications and regulating the use of biotech products in the Czech Republic is the Ministry of Environment. It cooperates with the Ministry of Health in respect to human health risks and with the Ministry of Agriculture in respect to agricultural risks including

crops, feeds, and animal health. After receiving comments from these cooperating Ministries, and an expert assessment from the Czech Committee on GMOs (see below) the Ministry of Environment issues an authorization for field trials or contained use of biotech products. In the case of notifications for placing biotech products on the market in the EU, the Ministry of Environment sends comments or assessment reports to the European Commission and formulates all final positions of the Czech Republic for a vote in the Regulatory Committee under Directive 2001/18/EC or the Environmental Council. If Regulatory Committee's decision is negative, additional voting is carried out by the Council of Ministers. If positive, it may be released on the market; if negative, the Commission may then authorize release on the market.

A slightly different situation applies to biotech products for food and feed. Under Regulation 1829/2003 EC on Food and Feed, a company can apply for biotech product approvals at the Ministry of Agriculture, Food Safety and Technology of the Living Environment Department, which has to forward the application to the European Food Safety Authority (EFSA) within 14 days for review. EFSA will conduct a risk assessment and if it issues a positive recommendation, the application is forwarded to the European Commission, which sends it to member states for assessment. Member states then vote on the proposal in a Regulatory Committee and if a qualified majority votes "yes", the biotech event concerned may be released on the market. If the Regulatory Committee's decision is negative, a second voting is carried out by the Council of Ministers. If positive, it may be released on the market; if negative, the Commission may then authorize release on the market.

In summary, the approval of biotech products for import, cultivation and processing falls under Directive 18/2001, transferred to national acts (in the Czech Republic Act 78/2004) and the competent authority is the Ministry of Environment, which has to generate an expert assessment and then forward it to the European Commission and other member states for voting. In the case of biotech products for food and feed, Regulation 1829/2003 applies and the competent authority is the Ministry of Agriculture, which only collects applications, which it forwards to EFSA for an expert assessment. EFSA sends the assessment to the European Commission and other member states for voting.

Role and membership of Biosafety Committee

An expert advisory body to the Ministry of Environment is the Czech Commission for the Use of GMOs and Genetic Products. The Commission has 14 members and consists of representatives of administrative authorities, scientists, and researchers. The main task of the Commission is the environmental risk assessment of the notified biotech products. A list of members is on Ministry of Environment's webpage:

http://www.env.cz/AIS/web-pub.nsf/$pid/MZPMVF8OSAI0

Political factors

Non-government-organizations (NGOs), among which the strongest one in the Czech Republic is Greenpeace, have a strong influence on the Ministry of Environment and the public. According to the first Act on GMOs No. 153/2000, NGOs were part of the regulatory process, which made GMO approvals much more complicated. For example, when the Czech GMO Commission made a positive recommendation and the Ministry of Environment had approved a biotech product but the NGO's recommendation was negative, the NGO, as a member of the administrative process, could appeal the decision to the Analytical Commission of the Ministry of Environment. This delayed the approval of biotech products by months (e.g. in the case of Bt corn MON 810).

Act 78/2004, which replaced Act 153/2000, does not include NGOs in the regulatory process. Under this Act, NGOs may send comments to the Ministry of Environment during the registration process, but once the decision is made, it is not delayed by any NGO appeals. An amendment to Act 78/2004 that was strongly influenced by the Minister of Environment again included NGOs in the regulatory process and required that addresses of farms with biotech crops be made available to the public (on the internet). The amendment was approved by the Parliament at the end of June 2005 without the two changes, so NGOs will not be part of the official regulatory process and farmers need only inform competent authorities of their biotech plantings, which will keep information about the exact location of biotech fields for government purposes only. The government will only publish information on how many hectares of biotech crops were planted in each district of the Czech Republic. The exact scope of information that will be made available to the public is still being negotiated.

Organic farmers are fearful that the planting of biotech varieties may negatively affect their organic production. According to EU Regulations 2092/1991 and 1804/1994, the use of biotech products in organic production is prohibited. Even though Czech farmers grow organic corn on a very small area (around 300 hectares), farmers are worried that pollen from biotech corn, for example, may drift into their nearby fields. The rules of coexistence only list sanctions for farmers that fail to comply. There are no provisions for handling cases in which an organics' farmer meets all the requirements and yet his neighbor's biotech crop cross-pollinates with his organic production.

The debate about biotechnology in the Czech Republic is, like in the EU, highly politicized and opponents of biotechnology admit that they are concerned not only about food safety or the impacts of biotech products on the environment but also about economic factors. Opponents also argue that 'if consumers want "GMO-free" products, we have to deliver them'.

Approved biotech crops

Since the EU accession on May 1, 2004, biotech food and feed products approved by the EU are valid in the Czech Republic.

For the register of existing biotech products, see:

http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm

Specific legislation governing these products can be found at:

http://europa.eu.int/comm/food/food/biotechnology/gmfood/legisl_en.htm

The Ministry of Environment handles notifications and approvals for contained use, field trials and cultivation. The Ministry of the Environment has so far received about 100 notifications for biotech products for use, mostly for contained use. All contained uses involve class 1 and 2, there are no cases of class 3 nor 4 contained use in the Czech Republic.

The Czech Ministry of Environment issued approvals for small-scale field testing of oilseed rape, potato, flax and virus-resistant plum trees for scientific and breeding purposes before EU accession. Field trials with Monsanto Bt maize MON 810 were approved in 2002. Following approval for placing the maize MON 810 on the market, more testing of this crop, including variety registration trials took place in 2004. Field trials with Monsanto Roundup

Ready maize NK 603 have been approved for the period 2002 - 2004. The field trials with GM-herbicide-tolerant-rapeseed, notified by Aventis, were terminated in 2002 by the company. Presently, the Ministry of Environment has issued an approval for field trials of genetically modified potatoes with altered starch content notified by BASF (notification under part B of the Directive 2001/18/EC, the same GM potatoes are being tested also in other EU member countries, similar notification submitted in Sweden in 2003 for placing on the market – part C of the Directive and is pending in the EU approval process).

A list of authorized users and a list of approved biotech products, together with the relevant legislation and other information, is available to the public and updated on the website of the Czech Ministry of the Environment at the address: www.env.cz.

Field tests

The Czech Republic allows field tests of biotech crops. Currently there are only two research projects with very small areas of biotech flax and biotech potatoes. BASF Inc. also has biotech potatoes on several tens of hectares. Monsanto plans to start field trials next year with YieldGard Cornrutworm.

Coexistence rules

The Czech Republic's rules of coexistence had to be prepared very quickly. Normally there is a three-year period for variety tests after a biotech product is approved. Bt corn MON810 was approved by the Ministry of Environment in February 2004, and in September 2004 the EU registered 17 varieties with MON810, which means that Czech farmers may plant Bt corn for this first time in spring 2005. The Ministry of Agriculture prepared provisional rules, which are included in the Government Regulation on Conditions of Receiving Additional Payments to Direct Payments ("top-ups") for 2005. Next year they will be in the amendment to the Act on Agriculture 252/1997, which was just recently passed by the Parliament.

The rules of coexistence set isolation distances of 100 m (or 50m and a barrier of 6 rows of non-biotech corn) for conventional agriculture and 600 m (or 300 m and a barrier of 6 rows of non-biotech corn) for organic agriculture. Farmers also have to notify the Ministry of Agriculture (at the time of sowing) and the Ministry of Environment (by February of 2005). These conditions may change next year, since the amendment to Act on Agriculture contains only basic rules for growing all biotech crops. The distances and notification requirements will be specified in a decree, which will come later.

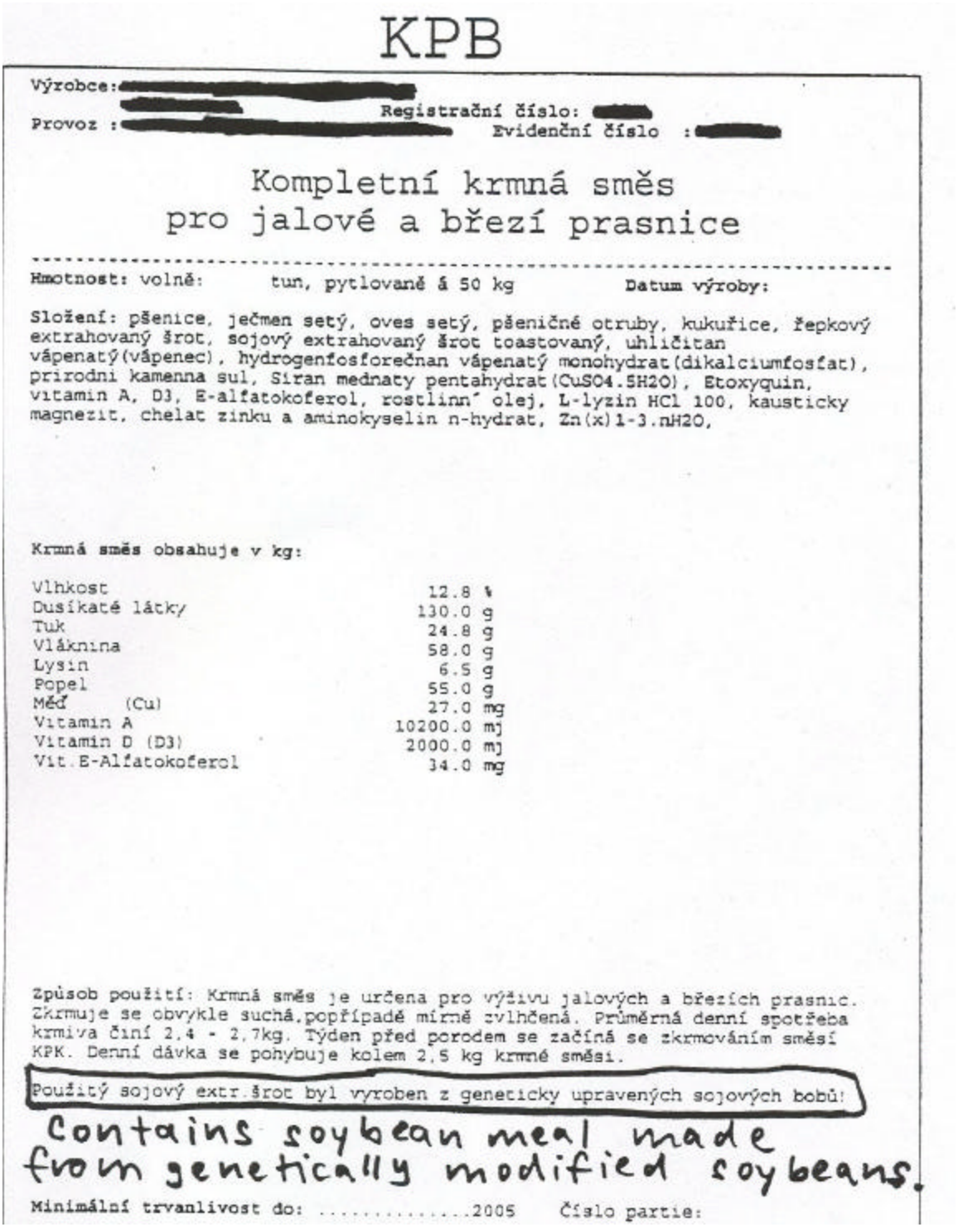
Labeling

Labeling regulations for products containing biotech products are presented in EU Regulation 1830/2003 on Labeling and Traceability. In general, these labeling regulations apply to bulk agricultural commodities such as whole grains and oilseeds.

Labeling regulations for food and feed products produced from biotech products are presented in EU Regulation 1829/2003 on Food and Feed. In general, all food and feed products containing biotech products, or produced from biotech products, must be labeled. The allowable presence level for EU-approved varieties of biotech products for use in food and feed is 0.9%. Above this level, all products must be labeled. The regulation does not require labeling of products that are not food ingredients, such as processing aids. Meat, milk, or eggs obtained from animals fed with biotech feed do not require labeling.

Products are labeled for consumer's right to know, not for health/safety reasons.

Below is an example of labeling on feed mixture containing biotech product:



KPB

Výrobce: [redacted]

Provoz : [redacted] Registrační číslo: [redacted]

Evidenční číslo : [redacted]

Kompletní krmná směs
pro jalové a březí prasnice

Hmotnost: volně: tun, pytlovaně á 50 kg Datum výroby:

Složení: pšenice, ječmen setý, oves setý, pšeničné otruby, kukuřice, řepkový extrahovaný šrot, sojový extrahovaný šrot toastovaný, uhličitan vápenatý(vápenec), hydrogenfosforečnan vápenatý monohydrat(dikalciumfosfat), prirodni kamenna sul, Siran mednaty pentahydrat(CuSO4.5H2O), Etoxyquin, vitamin A, D3, E-alfatokoferol, rostlinný olej, L-lyzin HCl 100, kausticky magnezit, chelat zinku a aminokyselin n-hydrat, Zn(x)1-3.nH2O,

Krmná směs obsahuje v kg:

Vlhkost	12.8	%
Dusíkaté látky	130.0	g
Tuk	24.8	g
Vláknina	58.0	g
Lysin	6.5	g
Popel	55.0	g
Měď (Cu)	27.0	mg
Vitamin A	10200.0	mj
Vitamin D (D3)	2000.0	mj
Vit.E-Alfatokoferol	34.0	mg

Způsob použití: Krmná směs je určena pro výživu jalových a březích prasnic. Zkrmuje se obvykle suchá,popřípadě mírně zvlhčená. Průměrná denní spotřeba krmiva činí 2,4 - 2,7kg. Týden před porodem se začíná se zkrmováním směsí KPK. Denní dávka se pohybuje kolem 2,5 kg krmné směsi.

Použitý sojový extr.šrot byl vyroben z geneticky upravených sojových bobů!

Contains soybean meal made from genetically modified soybeans.

Minimální trvanlivost do: .....2005 Číslo partie:

Cartagena Biosafety Protocol

The Czech Republic ratified the Cartagena Protocol on Biosafety in October 2001 and has a Biosafety Clearing House in place (see www.biosafety.cz).

Czech's position on biotech products in the EU

The Czech Republic takes a 'case-by-case' approach in terms of voting on biotech products in the Regulatory Committee or the Ministers' Council. Here are examples of how the Czech Republic voted in recent cases:

Event	Czech Republic's vote
Rapeseed GT73	CR abstained at the Council voting
Corn MON863	CR abstained at the Council voting
Corn1507	CR in favor for import and processing at Committee voting

The Czech Republic is one of the most open countries to biotechnology among new member states of the EU. It takes a science-based approach, however, some decisions may be politically motivated.

SECTION IV. MARKETING ISSUES

Market acceptance by producers, importers, and retailers

Many Czech importers and producers of food products have in their 'mission statement' that they do not use biotech products in their products. Since they want to sell products on the whole EU market, they are afraid that negative attitudes of European consumers (at least this is what they read in various articles in Czech newspapers and magazines) would damage their sales.

All Czech retail chains (Makro, Ahold, Tesco, Carrefour etc.) are owned by strong European companies and follow their European headquarters in their policy on biotech products.
E.g. UK Tesco says: "Our customers continue to tell us that they are not yet convinced of the benefits of GM. We do not therefore have any own-brand GM foods on our shelves." (http://www.tescocorporate.com/page.aspx?pointerid=6A750D771BFE4E98A3F0741AA32E5489)
Other chains have the same policy and tell suppliers that their consumers do not want biotech products. In fact, retailers are afraid of the negative impact of a Greenpeace campaign if they found biotech products (even though approved) in the stores.

Importers of commodities for feed, e.g. soybeans import biotech crops and label them.

Study on public opinions

The State Health Institute, Center for the Hygiene of Food Chains, conducted several studies of public acceptance of biotech products. Results of the last one are summarized in a report EZ5003 (see end of report). It states: "A recent poll on the public perception of biotechnology, organized by the market research company GfK at the request of the State Health Institute, has shown a positive trend in Czech consumers' perception of food containing biotech products (or genetically modified organisms, GMOs). The first poll was done in September 2003, the second study was completed in November 2004. The new poll shows a higher share of those who would eat biotech products without fear (25% versus 20.4%), slightly higher share of those who would not buy food-containing biotech content

(20.3% versus 19.6) and a lower share for those who claim to have inadequate information on the subject (31.2% versus 41.5). There is a growing share of people who are not interested in the issue (24.2% versus 19.1%)."

SECTION V. CAPACITY BUILDING AND OUTREACH

USDA and State Department's programs

During the past six or seven years Czech scientists, researchers, regulators, and journalists visited the U.S. under the Cochran Fellowship Program. A few people also participated in the State Department's VolVis (Volutary Visitors) and IVP (International Visitor Program) programs on biotechnology.

In 1999, a Czech scientist and promoter of biotechnology Prof. Drobnik of the civic association Biotrin visited the United States under the Cochran Fellowship Program, and he with a small, two-person TV crew made a documentary film called "Genes of Controversy", which was dubbed into several languages and broadcasted in several central European countries. The film can be found at www.biotrin.cz

Suggestions for increasing science-based regulations

All of these programs (CFP, IVP, VolVis) have been extremely useful for Czech participants and the participants have gained a lot of information on biotechnology. Continuing these programs would be beneficial.

Seminars with good U.S. biotech speakers on U.S. regulatory system and experience from other European countries for Czech regulators, journalists, and food producers would help increase consumer awareness (articles in papers and magazines) and would stir up a debate among food producers and regulators about use of biotech products in foods.

Financial support of NGOs (e.g. Biotrin's project of translating and printing a Belgium textbook on biotechnology) would be extremely useful.

Communication with Czech decision-makers before voting on biotech products at various EU levels is very important.

SECTION VI. REFERENCE MATERIAL

Important webpage links

European Union:
http://europa.eu.int/comm/food/food/biotechnology/index_en.htm

European Food Safety Authority (EFSA):
http://efsa.eu.int/

Czech Ministry of Environment (in Czech):
http://www.env.cz/AIS/web.nsf/pages/gmo

Biosafety Clearing House – Czech Republic (in English):
http://www.biosafety.cz/

Czech Ministry of Agriculture (in Czech):
http://www.mze.cz/default.asp?ids=2292&ch=73&typ=2&val=2292

Text of the Strategy for Food Safety (document prepared by the Ministry of Agriculture, Food Safety and Technology of the Living Environment Dept.) (in English):
http://www.mze.cz/attachments/Food_Safety_Strategy_compl..doc

NGO (for biotech) Biotrin (in English):
http://www.biotrin.cz/

NGO (against biotech) Greenpeace (in Czech):
http://www.greenpeace.cz/gmo/

Related reports

Previous reports on biotechnology regarding the Czech Republic may be found on FAS homepage http://www.fas.usda.gov/scriptsw/AttacheRep/default.asp under the following numbers:

EZ5003	Biotechnology - Consumer Perceptions
EZ4011	New GMO Law
EZ4010	National Biosafety Framework
EZ4001	Status of Biotech Regulations – Central Europe
EZ3020	Consumer Perceptions of Biotechnology
EZ3018	Status of Bt Corn Registration in Czech Republic
EZ3015	Biotechnology from a Czech Perspective
EZ3012	Status of Biotech Regulations
EZ3003	Biotechnology - Status of GM Approvals
EZ1016	Implementation of GM Labling Law - Consumer Products
EZ1011	GMO Approval Process
EZ0020	New Law Comes Into Force January 1, 2001
EZ0015	Biotechnogy – GMO Survey and Press Roundup
EZ0003	Update on Biotechnology Legislation