



# GENETIC MODIFICATIONS THEIR USE AND MANAGEMENT CZECH REPUBLIC



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Inspection of the GM crop locality (Photo S. Rakouský)



Marking locality with the GM crop (Photo M. Těhník)

## Foreword

Development of modern biotechnology during the last fifty years and the dramatic increase in their application over the last two decades have opened new and unforeseen possibilities. Living modified/genetically modified organisms resulting from this biotechnology offer a great potential for development of human society, e.g. through enhancing food productivity, enriching nutrition, ameliorating health care and introducing new methods in remediation of the environment and sustainable use of natural resources. On the other hand they could adversely affect biological diversity and human health. To prevent or minimise these negative effects, biosafety principles need to be followed, encompassing a wide range of strategies, policies and measures, both at international and national, as well as at regional levels.

The Czech Republic participated in international negotiations resulting in adoption of the Cartagena Protocol on Biosafety in January 2000 since the very beginning, as a country of the Eastern European Group. It was among the first countries ratifying the Protocol, on October 8, 2001. After becoming a member of the European Union in May 2004, the Union legislation has been transposed into the national legislation system.

The current situation, as well as historical development in the biosafety area are described in this publication. The similar publication “Genetic Modifications – Possibilities of their Use and Risks” (December 2008) was focused primarily on Czech readers, therefore published in Czech with only short English Summary. The new publication aim is to inform about the Czech Republic current biosafety policy and measures primarily abroad. The publications were edited thanks to the UNEP/GEF Project “Support for the Implementation of the Draft National Biosafety Framework for the Czech Republic”.

*Milena Roudná*  
*National Project Coordinator*

...“The Cartagena Protocol on Biosafety, the first major international environmental treaty of the twenty-first century ...has reached significant achievements over the past years ...

At the national level, more than 100 countries have developed legal and administrative frameworks and other measures necessary to implement the Protocol. They have also implemented projects to build and strengthen human and institutional capacities in the safe use of biotechnology. The impressive work undertaken in a very short period of time in translating the provisions of this unique legal instrument into reality is unprecedented.” ...

*(Ahmed Djoghlaif, SCBD Executive Secretary. Biosafety Protocol News, 5th Anniversary Edition, 2008)*

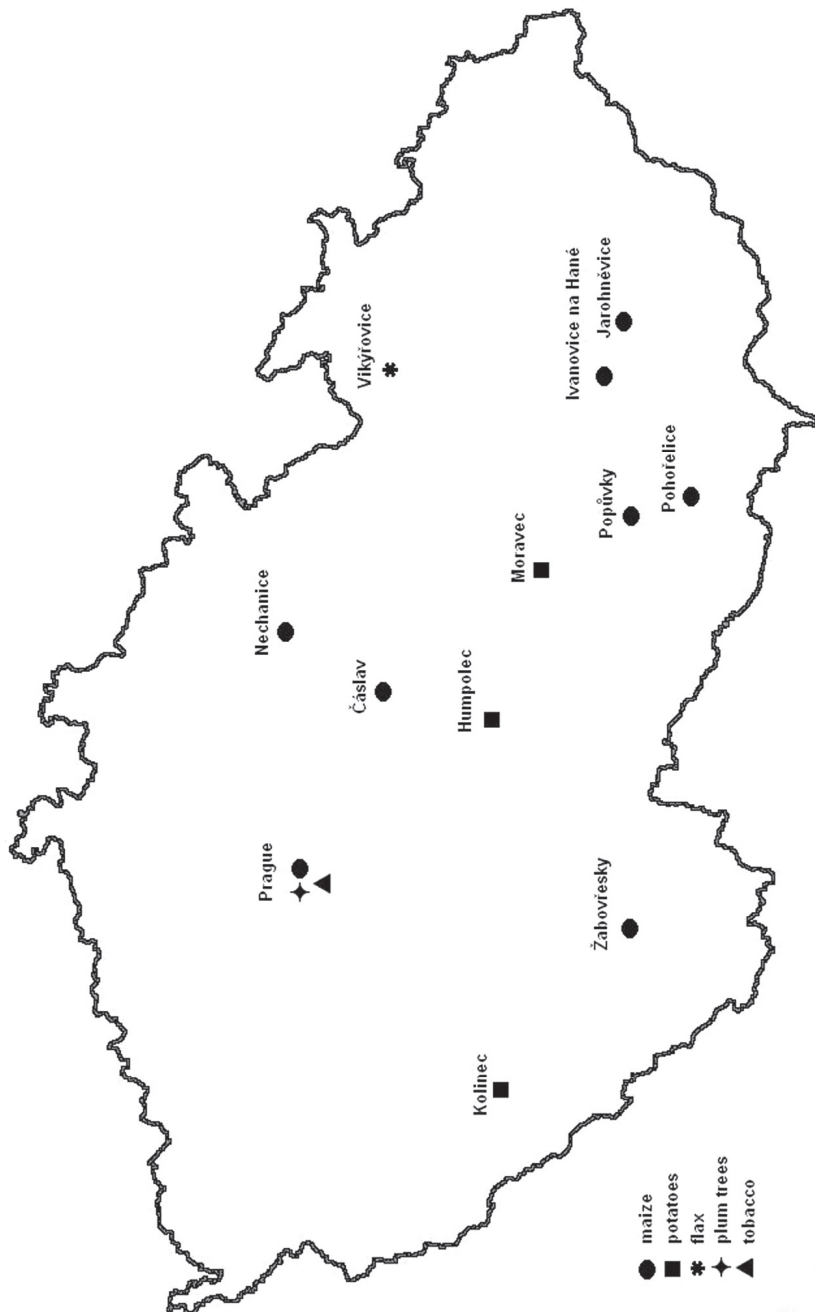
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Overview of the field trials with GM plants – Czech Republic, 2009



# Czech Republic Biosafety Framework

*Zuzana Doubková, Hana Jiráková, Milena Roudná*

The Czech Republic belongs to the first countries ratifying the Cartagena Protocol on Biosafety (October 8, 2001) and to countries signing the Protocol on the occasion of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity, on May 24, 2000, in Nairobi. Consequently, appropriate regulations had to be taken at national level on the basis of related commitments. The first Act regulating use of genetically modified organisms entered into force already on January 1, 2001.

The present situation as to five main components of the National Biosafety Framework is described in this Chapter.

## 1. Biosafety policy

No special Strategy on Biosafety exists in the Czech Republic. Nevertheless its principles are reflected in important national political and strategic documents (in their thematically related chapters), namely: State Environmental Policy (regularly updated, current valid for the period 2004-2010), Report on the Environment (annual), Strategy on Sustainable Development (updated version under national debate, officially to be presented in November 2009), and some more specific documents, such as State Programme on Nature Conservation and Landscape Protection (adopted by the Government of the Czech Republic in 1998), Strategy on Biodiversity Conservation (adopted in May 2005), Strategy on Food Safety (adopted in December 2004), Action Plan on Health and the Environment.

## 2. Regulatory regime – legislation

The basic national regulation represents the Act 78/2004, on the Use of Genetically Modified Organisms and Genetic Products, which entered into force in February 2004, and was later amended by the Act 346/2005, and its implementing Decree 209/2004. The Act transposes the EU Directive 2001/18/EC and Directive 2009/41/EC, covering the contained use of genetically modified organisms (GMOs), deliberate release of GMOs into the environment and placing on the market of GMOs as/or in products. EC Regulations 1829/2003 and 1830/2003 concerning authorisation of GM food and feed, traceability and labelling of GMOs and GM food and feed and Regulation 1946/2003 implementing the Cartagena Protocol have been directly applicable in the Czech Republic since its accession to the EU in May 2004. General rules on the co-existence of genetically modified crops

with conventional and organic farming are specified by the amendment to the Czech Act on Agriculture, which implementing Decree defines specific measures for each GM crop (so far for maize and potatoes).

### 3. Administrative system – Request for permits

Pursuant to the Directive 2001/18/EC, the **Competent Authority** handling the notifications and regulating the use of GMOs is the Ministry of the Environment. It closely co-operates with the Ministry of Agriculture as to agricultural risk, animal health, crops and feeds, and with the Ministry of Health as regards risks for human health. The Ministry of the Environment is also the National Focal Point for the Cartagena Protocol on Biosafety and for Regulation (EC) 1946/2003. The Ministry of Agriculture is the Competent Authority under Regulation (EC) 1829/2003 on genetically modified food and feed, and responsible for the rules of coexistence.

The **Czech Commission for the Use of Genetically Modified Organisms and Genetic Products** is an expert advisory body to the Ministry of the Environment. It was established in January 2001 and consists of scientists, representatives of administrative authorities and NGOs. On the basis of the Act on the Use of Genetically Modified Organisms and Genetic Products, the Minister of the Environment designates and recalls the chair and members of the Commission after consulting the Ministers of Health and Agriculture, from amongst professionals nominated by the administrative bodies referred to in the Act, by the Academy of Sciences of the Czech Republic, universities and special research institutes. The terms of reference and the rules of procedure issued by the Minister set the constitution of the Commission. It should consist of experts on botany, zoology, molecular genetics of plants, animals and micro-organisms, biodiversity, ecology in general, risk assessment of food and feed, labelling of food and feed, consumer protection and appropriate legislation, registration of crop varieties and appropriate legislation, organic farming, medicinal products and appropriate legislation, laboratory detection of GMOs, supervision of the GMOs use (maximum 18 members plus the chairman). The term of office for the chairman and members of the Commission is two years.

The activities of the Commission cover the risk assessment of contained use, deliberate release into the environment and placing on the market of GMOs and products containing or consisting of GMOs, including the export and import thereof. The Commission is authorised by the Ministry particularly to:

- Follow scientific and technical developments in the area of the use of genetically modified organisms and products and, when necessary, to inform the Ministry and recommend appropriate measures.

- Issue its expert positions on specific topics or documents, including the international exchange of information.
- Co-operate with the Authorities in the process of developing the legislative framework.
- Assess the information contained in notifications of the use of GMOs and to express view on these notifications, including the notifications for the placing of GMOs on the market submitted in other countries.
- Check and assess reports on the use of GMOs and other documents submitted by the users, etc.
- Carry out the environmental risk assessment and consider the socio-economic aspects of the notifications for placing on the market under Directive 2001/18/EC and Regulation 1829/2003.
- Inform the public on scientific developments and its activities.
- Prepare documents, suggestions or refer to new biosafety problems or issues.

The Commission further co-operates with external experts (about 20) and consultants due to the wide spectrum of GMOs used both in the Czech Republic and in the EU and due to number of institutions authorised for the use of GMOs.

The Commission meets regularly 4 times a year. Most of the work is done by e-mail correspondence. Once a year the Commission organises a public session, where it informs the public, NGOs and other stakeholders about its activities.

## **Deliberate release of GMOs**

### **Field trials**

#### ***Authorisation process and conditions for issuing permit***

According to the Act on the Use of Genetically Modified Organisms and Genetic Products, the process of authorisation for a release into the environment for other purposes than placing on the market (Part B of Directive 2001/18/EC, field trials) is as follows:

- A notification is submitted by the applicant to the Ministry of the Environment (ME).
- The ME assesses the completeness of the notification. If the dossier meets all the requirements pursuant to the Act, the ME forwards the copies to the Ministry of Agriculture, Ministry of Health (hereinafter “the Ministries concerned”) and to the Regional Authority of the region where the deliberate release is planned. At the same time the ME makes a summary of the notification available to the public on the Internet and on the official board of the Ministry, and ensures its publication by the relevant municipality and regional authorities according to the intended release location. The notification is

- also circulated to the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products. The summary of the notification is made available to the European Commission and other Member States by entering the data into JRC WebSNIF database.
- The Ministries and the region concerned as well as the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products send to the ME their views regarding the notification, including the request for additional information, if appropriate, within 30 days of receiving the dossier. Consequently, the ME may ask the notifier for additional information. The ME forwards the received additional information to the Ministries concerned and to the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products. If the applicant fails to provide the requested information within the set time-period (30 days), the Ministry suspends the administrative procedure.
  - Everybody may send to the ME his/her opinion or make comments within 30 days of publication of the summary of the notification. If the ME receives negative opinion/comments from the public, in which environmental risk assessment results are doubted or an objection to insufficient protection of the health and the environment is made, the ME is obliged to arrange public hearing prior to making a decision.
  - The ME shall take a decision on the notification within 90 days of receiving the dossier. For the purpose of calculating this time-period, any period of time for completing the notification by the notifier upon request for additional information (the “clock stops” until the required documents are provided) and the period during which public hearing is organised are not taken into account; however, the public consultation cannot extend the period beyond 30 days.
  - When making the decision, the ME is obliged to consider the views of the Ministries concerned, the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products and the results from the public consultation. The ME also takes into account opinions and comments of the Competent Authorities of other Member States submitted through the WebSNIF database. The ME can lay down in its decision special conditions for the release of genetically modified organisms.
  - The final decision is made available to the public after its entry into force on the Internet and in the municipality of the release. The information about the consent is provided to the WebSNIF database.

The applicant is obliged to provide **control samples** of the genetically modified organism to the Ministry of the Environment or to a laboratory carrying out the detection of GMOs for the Ministry and Czech Environmental Inspectorate under contract, at the time of submitting the notification or at the latest within 10 days after doing this. It is recommended to consult with the Ministry the specification of the sample material, its quantity and the designated laboratory in advance.

**Methods of detection and identification** of the GM material need to be specified in the notification dossier.

**The Risk Assessment** must be carried out by the notifier and submitted to the Ministry of the Environment as a part of the notification dossier in accordance with the procedure as described in the implementation Decree 209/2004, on Detailed Conditions for the Use of Genetically Modified Organisms and Genetic Products. The assessment should be based on all available information, references, experience and comparison with relevant non-modified organisms. After the authorisation, the updated risk assessment is submitted by the authorization holder every 5 years or in case of new information concerning the risks of the GMO use. The authorization holder is obliged to keep records on the risk assessment for at least 10 years from the date of its submission, and provide it on request to the Competent Authorities referred to in the Act. The risk assessment provided by the notifier / authorization holder is reviewed by the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products.

**The Emergency response plan** is a part of the notification dossier. The plan is defined in the Czech Act on the Use of Genetically Modified Organisms and Genetic Products as a document describing activities and measures carried out in case of an accident. The detailed requirements are described in the implementation Decree 209/2004. The emergency response plan has to be submitted to the Ministry of the Environment by the authorization holder every 5 years or in case of new information concerning the risks of the GMO use. The notifier is obliged to submit the emergency response plan prior to commencement of the use of GMOs also to the municipalities where the deliberate release is to take place, to the local Fire Rescue Brigade, to the regional authority and on request also to any persons that may be directly affected by an accident. The Ministry of the Environment makes the information on emergency response plan available to the public.

**The location of the field trial** has to be described in detail in the notification. The isolation distance from the nearest field with the same non-modified crop is to be respected but it is not prescribed in the legislation, as it is crop-specific and therefore set on the case by case basis. In the field trials approved so far this distance was 200 m for GM maize as the minimum distance from the nearest maize grown conventionally (the distance from organic maize should be minimally 600 m) and 10 m for GM potatoes. The field trial has to be marked with signs clearly bearing the text “Genetically Modified Organism” or “GMO”.

**Monitoring** defined as identification of the presence of a genetic modification in an organism and observation of the impacts of the genetically modified organism or genetic product on the health of human beings and animals, the environmental components and biological diversity, need to be done by the authorisation holder. It must correspond to the monitoring plan provided as a part of the notification and to any additional requirements set in the consent. The duration of the monitoring of the site following the field trial is crop-specific.

Every year the authorisation holder shall submit a short written **report on the trial** according to the Act on the Use of Genetically Modified Organisms and Genetic Products. The final report is required after the end of the trial and than after the period of required monitoring of the site. The formats for these reports are available on the website of the Ministry of the Environment. The final report is required both in Czech and in English (in accordance with the relevant Decision 2003/701/EC), as it is submitted also to the EU database of field trials.

The authorisation holder / notifier is obliged to ensure that **no GM material derived from field trials is placed on the market**. GM plants are usually destroyed on the trial site, except for the samples that are taken for later analyses and which have to be destroyed afterwards. Handling with the GM material and the waste management have to be described in detail in the notification. The requirements for a storage facility are the same as for the contained use, risk category 1 (the lowest) as described in the Act and in the Decree. The storage place and the ways of transport have to be described in the notification as well.

The authorisation holder is obliged to ensure proper **labelling**. Packaging of the genetically modified organism must have a visible label clearly stating “Genetically Modified Organism”, or “This product contains a genetically modified organism”/ “This product contains genetically modified organisms”. This text has to appear also in the accompanying documents during the transport.

A separate notification has to be submitted by each institution that intends to participate in the field trials. Each subject (legal person) that will handle GM seed, cultivate plants or analyse them after the harvest has to be authorised, including the company importing and distributing GMOs. According to the Czech legislation, authorisation for the use of GMOs may only be granted to a legal person or a natural person with a business licence. This means that only a company (affiliate) registered in the Czech Republic is entitled to submit a notification.

The notifier has to pay an **administrative fee** CZK 20 000 (approx. EUR 700) for authorisation for the deliberate release into the environment. The notifier is requested to pay the fee shortly before the Ministry issues the consent. No fee is paid when the notification is rejected or withdrawn.

### **Overview of field trials**

During the last two decades, a number of field trials have been conducted with various crops, mostly maize, sugar beet, oilseed rape, potatoes and flax. Field trials with the herbicide tolerant oilseed rape were stopped in 2002 and the sites were monitored for several years for volunteer plants. In the growing season 2009 the following trials with GM crops are conducted:

GM Crop	Characterization	Name of the Institute or Company	Total area
Potatoes	Altered starch composition (various modifications including Amflora potatoes pending in the EU approval process for placing on the market)	BASF	11,33 ha (10,8 ha Amflora, + 0,53 ha others)
	Modified sugar content	Institute of Experimental Botany, Academy of Science of the Czech Republic	
	Increased resistance to late blight ( <i>Phytophthora infestans</i> )	BASF	
	Change of late blight resistance	Institute of Experimental Botany, Academy of Science of the Czech Republic	
Maize	GA 21 – glyphosate tolerant	Syngenta	11,91 ha
	NK 603, NK 603 x MON 810 - tolerance to herbicides containing glyphosate and resistance to corn borer	Monsanto	
	DP-98140-6 – tolerance to herbicides containing glyphosate and sulfonylureas	Pioneer	
	MON 88017 – tolerance to glyphosate and resistance to selected coleopteran pests (A new field trial conducted from the growing season 2009)	Monsanto	
	MON 890 x NK 603 ; MON 89034 x MON 88017 – tolerance to herbicide and resistance to a corn borer and selected coleopteran pests (A new field trial conducted from the growing season 2009)	Monsanto	
	Bt 11x MIR 162 x MIR 604 x GA 21; Bt 11 x MIR 604 x GA21; Bt 11 x GA 21; MIR 162; MIR 604 – hybrids with stacked genes conferring different combinations of tolerance to herbicides containing glyphosate and glufosinate ammonium and resistance to selected lepidopteran and coleopteran pests (A new field trial conducted from the growing season 2009)	Syngenta	

GM Crop	Characterization	Name of the Institute or Company	Total area
Plum trees	Virus-resistant (A small trial for research purposes)	Crop Research Institute, Prague	0,09 ha
Flax	Various modification (A small trial for research purposes)	Agritec	0,03 ha
Tobacco	Inserted fission yeast mitotic activator (A small trial for research purposes)	Charles University, Prague	0,002 ha

For more details see the SNIF database: [http://gmoinfo.jrc.ec.europa.eu/gmp\\_browse.aspx](http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx)

## Placing on the market

Only GMOs authorised for placing on the market in EU (under Part C of Directive 2001/18/EC and/or under Regulation 1829/2003) can be used for commercial purposes in the Czech Republic. Therefore e.g. imported GM soybeans could be present in feedstuffs or manufactured for edible oil and some types of GM maize may be used in food and feed.

(See the lists of GMOs and products authorised in EU: [http://ec.europa.eu/food/food/biotechnology/authorisation/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm))

Requirements for **labelling** of these GMOs and products are set by Regulation (EC) 1830/2003.

## Commercial cultivation and principles of co-existence

The Czech Republic total agricultural land area is about 4 264 000 ha, which represents about 54 % of the total country area. Arable land covers 3 050 000 ha. Other agricultural area is used as hop-gardens, vineyards, orchards, gardens and grasslands (meadows and pastures). Conventional agriculture prevails, whereas organic farming represents 8.04 % and cultivation of GM crop (GM maize) about 0.20 % of agricultural land (data of 2008).

The cultivation is regulated through the rules of **co-existence**, which define principles with respect to conventional cultivation, organic farming and cultivation of GM crops. The basic principles are set by the Act 252/1997 on Agriculture, later amended (2005, new amendment ongoing). The principles of organic farming are set by the Act 242/2000 on Organic Farming. Cultivation of GM crops is further regulated by the Decree 89/2006, on detailed conditions for growing of genetically modified variety, of the Ministry of Agriculture.

Organic farming has been developed in the Czech Republic since 1990 as shown in the following Table.

<b>Year</b>	<b>Area in ha</b>	<b>Number of farms</b>
1990	480	3
1991	17 507	132
1992	15 371	135
1993	15 667	141
1994	15 818	187
1995	14 982	181
1996	17 022	182
1997	20 239	211
1998	71 621	348
1999	110 756	473
2000	165 669	563
2001	217 869	564
2002	235 136	721
2003	254 995	810
2004	236 299	836
2005	254 982	829
2006	281 535	963
2007	312 890	1 318
2008	341 632	1 946

Permanent grass areas represent 88.4 %, arable land 10.6 %, permanent cultures (orchards and vineyards) 1 % of the total organic farming area. Mainly oat, barley, wheat, rye, potatoes, pulse crops, vegetable, small fruits, herbs (medicinal plants) and some special crops have been cultivated for production of the organic foodstuffs.

As to farm animals, the total number in organic farms is more than 227 000 animals, mostly cattle (66.8 %), further sheep (28.42 %), goats (2.38 %), horses (1.7 %) and pigs (0.69 %). (2008 data)

Inspection organizations appointed by the Ministry of Agriculture (ABCERT AG, BIOCONT CZ, LLC) supervise implementation of prescribed conditions for organic farming. The European Commission included in 2001 the Czech Republic (before becoming a member of the European Union) in the List of Third Countries allowing free access of bio-products and bio-foodstuffs of the Czech origin to the markets of EU countries.

As to GM crops, only GM maize variety MON 810 with resistance to a corn borer (*Ostrinia nubilalis*) is cultivated in the Czech Republic. Following the registration of varieties into the European seed catalogue, this GM maize was commercially cultivated for the first time in the 2005 season, on the area of 270 ha. In the following years the total area and number of farmers using this variety have gradually increased, as shown in the following Table.

Year	Area in ha	Share of total maize area (%)	Number of farmers
2005	270	0,05	52
2006	1 290	0,47	85
2007	5 000	1,83	131
2008	8 380	2,91	171

Lower damage of plants, decreased use of pesticides and a higher yield (about 10 % in average) are the main reasons of this GM maize cultivation.

Growers of GM crops need to follow rules stipulated in the above mentioned legislation. Based on this legislation, the Ministry of Agriculture defines 10 basic principles for cultivation praxis:

- Notify the Ministry of Agriculture before sowing/planting GM crop.
- Notify neighbouring farmers before sowing/planting GM crop.
- Keep the prescribed isolation distance between GM crop and the fields with the same non-GM species and/or surround the GM plantings with a buffer strip of the same conventional crop.
- Keep the prescribed isolation distance between GM crop and the fields with the same species crop grown in the organic way.
- Notify the Ministry of Agriculture after sowing/planting GM crop.
- Notify neighbouring farmers after sowing/planting GM crop.
- Inform the Ministry of the Environment about location of GM crop cultivation.
- Mark the locality of GM crop cultivation.
- Label the GM crop product.
- Keep record and store data on growing and on further use of GM crop and its product.

The Ministry of Agriculture in cooperation with the Regional Agricultural Agencies and the State Phytosanitary Administration monitor the compliance with the rules of GM cultivation. A penalty up to CZK 500 000 may be imposed on the grower for infringement of the rules. (See also Monitoring and Enforcement.)

The Ministry of the Environment registers the locations where MON 810 is grown and the maps are available to the environmental and agricultural authorities and to the farmers in the Land Parcel Identification System (LPIS). The LPIS is a Geographic Information System established by the Ministry of Agriculture (functioning since April 2005) serving primarily as a basis for granting subsidies (with the aim to avoid duplication from different sources). It serves also to farmers to get topical information on parcels used by them – access to the system is through accredited password obtainable from the corresponding Regional Agricultural Agency.

## Contained use

Contained use of GMOs means handling with GM micro-organisms, cell cultures, plants or animals in confined space as in laboratories, glasshouses and animal units. The risk assessment of contained use results in determination of a risk category (class) of the GMO use that is crucial for the authorisation procedure and for the requirements regarding the containment. The description of the containment measures is an important part of the notification and consists of the description of the facilities and handling of the GMOs including their transport, storage and disposal of waste.

The risk assessment should be based on all available information, references, experience and comparison with relevant non-modified organisms (e.g. national and international classification of micro-organisms and other biological agents).

The Ministry of the Environment, Ministry of Health and Czech Commission for the Use of Genetically Modified Organisms and Genetic Products review the risk assessment provided by the notifier and the resulting classification of the use. If the contained use is classified as the first risk category (the lowest risk), the notifier can commence the activity immediately after the submission of the notification, provided the dossier complies with the requirements of the GMO legislation. However, within 30 days after the submission of the notification, the Ministry of the Environment may ask the notifier for any additional information or may require him/her to modify the conditions of the use described in the notification. In the case of the second class contained use, the notifier is allowed to start the activity 45 days after the submission of the notification in the absence of any negative opinion of the Ministry of the Environment.

The activities classified as the third or fourth risk category (class 3 and class 4 of contained use) may start only after a written authorisation decision for the contained use is issued by the Ministry of the Environment, and only within the scope and under conditions defined herein. The administrative procedure for granting a consent for classes 3 and 4 contained use is set by the Article 5 of the Act on the Use of Genetically Modified

Organisms and Genetic Products and corresponds to the procedure for authorisation of deliberate release of GMOs into the environment as described above. The notifier has to pay an administrative fee CZK 2 000 (approx. EUR 80) for issuing the authorisation for the class 3 and class 4 of contained use.

An emergency response plan (a document describing activities and measures carried out in case of an accident) has to be submitted to the Ministry of the Environment as a part of the notification for contained use and consequently by the authorised user every 5 years or in case of new information concerning the risks of the GMOs use. The notifier is obliged to submit the emergency response plan prior to commencement of the use of GMOs and in the above mentioned cases also to the municipalities where the contained use is to take place, to the local Fire Rescue Brigade, to the regional authority and on request also to any person that may be directly affected by an accident. The Ministry of the Environment makes the basic information on emergency response plan available to the public.

Description of waste management for each facility using GMOs is required in the notification. Inactivation of any viable organisms in the waste is the key step in a waste disposal.

### ***Overview of contained use***

GMOs are widely used in laboratories and other confined facilities, mostly for scientific purposes. In the Czech Republic 84 institutions are authorised for the contained use of GM micro-organisms, plants and laboratory animals. In addition to universities and research institutes, several industrial enterprises use GM micro-organisms for commercial production of enzymes (Lonza), vaccines (Baxter), fine chemicals (Contipro) and diagnostics (Exbio). All contained use notifications so far have concerned class 1 or 2 (minimum risk), there are no cases of class 3 nor 4 of contained use.

### **Specific case of GMOs use – medicinal products**

According to the Czech legislation on medicinal products, applicants for authorisation to conduct a clinical trial/study involving products containing genetically modified organisms (GMOs) are required to obtain an authorisation for the use of GMOs as specified by the Act on the Use of Genetically Modified Organisms and Genetic Products. Such authorisation, issued by the Ministry of the Environment, should either be attached to the documentation on making application for a clinical trial authorisation to the State Institute for Drug Control (SUKL), or submitted subsequently, however no later than three days prior to the final outcome of the SUKL assessment process. Should the applicant fail to submit authorisation for the GMOs use by the end of clinical trial assessment process, the application for clinical trial authorisation is refused.

As the first step, the company planning the study must decide whether the clinical trial represents contained use only or if the GMO will be released into the environment, based on the way and conditions of application of the product to humans or animals, metabolism of the product, shedding, characteristics of the GMO, etc. The reasons for the chosen notification procedure have to be described in detail in the dossier.

## **Import and export**

Only genetically modified organisms or genetic products authorised for placing on the market in the EU may be imported or exported to and from the Czech Republic. (Applies for third countries outside the EU.)

Furthermore, the person authorised for contained use may import or export GMO to which this authorisation applies, provided that they are exclusively intended for contained use.

The person authorised for deliberate release under Part B of Directive 2001/18/EC may import or export genetically modified organisms to which the authorisation applies, provided that they are exclusively intended for the authorised deliberate release.

The authorised person that intends to import or to export genetically modified organisms for contained use or deliberate release (see above) is obliged to inform the Ministry of the Environment on the species and number / volume of genetically modified organisms that will be imported or exported and on the anticipated place of entry to or exit from the territory of the Czech Republic, 5 days before the import or export at the latest.

The authorisation holder is obliged to ensure a proper labelling: Packaging of the genetically modified organism or genetic product must have a visible label clearly stating “Genetically Modified Organism” or “This product contains a genetically modified organism / organisms”. This text has to appear also in the accompanying documents during the transport. Any further requirements for the labelling defined in the authorisation decision must be followed. Detailed requirements for import and export documentation are defined in § 25 of the Act on the Use of Genetically Modified Organisms and Genetic Products.

Transboundary movements within the EU are not considered as export nor import. However, such transport has to be described in the notification for contained use or release into the environment, as appropriate (packaging, way of transport, emergency measures, etc.).

## 4. Monitoring and enforcement

The Czech Environmental Inspectorate is the Competent Authority on state supervision of the use of GMOs, as to contained use both in research and in production institutions, as well as to deliberate release into the environment. It cooperates with other state supervision bodies responsible for different areas:

- Czech Agriculture and Food Inspection Authority, in charge of food inspections and control.
- Central Institute for Supervising and Testing in Agriculture, in charge of seeds and feed.
- State Veterinary Administration as to animal related supervision.
- State Institute for Drug Control as medicinal products are concerned.
- Custom Authorities in charge of export and import.
- Regional Agricultural Agencies of the Ministry of Agriculture in charge of field control of cultivation (compliance with coexistence rules).

Six authorized detection laboratories are available for these authorities.

The authorities are so far not aware of any illegal cultivation of GMOs in the Czech Republic. Since 2008, general surveillance of Bt maize and conventional maize fields has been carried out with no findings of non-authorized GM plants up to date. Regarding the legal cultivation of Bt maize MON810, Ministry of Agriculture controls whether farmers comply with coexistence measures. In 2008 samples were taken from the buffer zones of 4 plots with Bt maize.

The State Phytosanitary Administration monitored the biological efficiency of Bt-maize hybrids. No evidence of resistance of the corn borer was found.

All field trials under part B of the Directive are controlled by the Czech Environmental Inspectorate several times a year. Monitoring and elimination of volunteers are done by the authorization holder and checked by the Czech Environmental Inspectorate after the harvest and during the following year (maize) or more years (potatoes).

The Central Institute for Supervising and Testing in Agriculture has been testing both Czech-produced and imported seeds since 2006, namely maize, soy and rapeseed for the adventitious presence of GMOs.

The Czech Agriculture and Food Inspection Authority tests every year food containing or produced from maize, soy and rice for the presence of GM material. The detection laboratories are able to check for genetic modification also tomatoes, potatoes, oilseed rape and papaya.

## 5. Public information

The list of the authorised users and the issued approvals together with the relevant legislation and other information are made available to the public and updated on the websites of the Ministry of the Environment: <http://www.mzp.cz/> and <http://www.mzp.cz/biosafety>.

The summaries of notifications for deliberate release of GMOs provided to the public correspond with the information required in summary notification information format according to the Council Decision 2002/813/EC. Only very technical information, confidential information, annexes and the personal data included in the dossier are not made public. The exact location of field trials (the municipality and the land register number, cadastral number) is provided to the public by the Ministry of the Environment. The maps are available to the Authorities, Regional Agricultural Agencies and to farmers in the Land Parcel Identification System (LPIS).

The notifier may indicate certain data as confidential in the notification provided that he/she is in the position to give verifiable justification that disclosure of such information might harm his/her competitive position. Following information cannot be indicated as confidential business information:

- General description of the genetically modified organism.
- Identity of the notifier.
- Location of the site of field trials.
- Risk assessment.
- Emergency response plan.

The information indicated as confidential business information is only accessible to:

- State Authorities referred in the Act.
- Czech Commission for the Use of Genetically Modified Organisms and Genetic Products (as advisory body to the Ministry of the Environment).
- Laboratories carrying out the detection of GMOs for the Ministry and Czech Environmental Inspectorate under contract.
- Relevant Authorities of other EU Member States.
- European Commission.

Public consultation is a part of the approval process.

According to the administrative procedure any final decision on authorisation always contains a detailed settlement of all received opinions and comments and also the results of the public hearing. The whole text of the decision is made public.

## References

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Secretariat of the Convention on Biological Diversity (2000): Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Montreal, ISBN 92-807-1924-6, 30 pp.

Website of the Ministry of the Environment: <http://www.mzp.cz>

Website – BCH (Ministry of the Environment): <http://www.mzp.cz/biosafety> (in English)

Website of the Ministry of Agriculture: <http://www.mze.cz>

## Monitoring of Genetically Modified Crops

*Slavomír Rakouský*

### Historical aspects of GM crops monitoring in the Czech Republic

Research of biological safety as well as monitoring of genetically modified (GM) crops released into the environment following Part B (field experiments) and Part C (marketing including the cultivation) of the Directive 2001/18/EC has now reached over 10 years of experience in the Czech Republic. First attempts to supervise and regulate field experiments were initiated already at the end of the nineties of the last century by members of the Czech Committee for Plant Transgenesis – a spontaneously formed board of specialists of different scientific areas aiming at safe cultivation of GM crops and initiating the establishment of the national legislation on the use of genetically modified organisms (GMOs). Before entering into force of the first Czech Act regulating the use of genetically modified organisms (January 2001), numerous activities were focusing on the assessment of potential risks of GM crops to human and animal health, the environment and biodiversity, designing and performing introductory biosafety experiments, creation and consultations of the draft national GM legislation. Later on, the Czech Republic has joined various international programmes, such as ESF - European Science Foundation, 6<sup>th</sup> EU Framework Programme, COST - European Cooperation in Science and Technology, ENGL - European Network of GMO Laboratories, TEMPUS – European Union Programme Supporting Modernisation of Higher Education, UNEP (United Nations Environment Programme) - GEF (Global Environment Facility), enabling sharing of knowledge about the current status of the GM crops biosafety research as well as education of specialists in various fields of research.

The first GM crops experiments started in 1996 when academic institutes established small field trials (plots sizes up to 10 m<sup>2</sup> only), mostly on annual basis. Soon, leading international plant biotech companies, such as AgrEvo, Aventis, Monsanto, Pioneer, and others expressed their interests to initiate field trials with GM herbicide tolerant (HT) maize, sugar beet and oilseed rape to analyze crop performance and/or authorize particular herbicide use as well as to assure GM crop safety to the receiving environment. Thus the monitoring of possible impacts of GM crops on the environment started. Especially possible changes in crop persistence, spreading and formation of feral populations were studied. In some cases study focused on pollen transfer of GM oilseed rape to non-GM oilseed rape and on influence of Bt maize on non-target arthropods. At that time also universities and agricultural research institutes joined the GM biosafety research. Some experience and results obtained are further described.

## **First field studies, legislation, education and public awareness**

Shortly after its establishment the Czech Committee for Plant Transgenesis started to organize regular inspections of GMO laboratories and field experiments with GM crops, focusing on:

- Verification of GMOs characteristics, i.e. presence of specific foreign genes coding for newly introduced traits using the biotests and molecular biology methods.
- Monitoring of possible GM plants occurrence in the areas of previous field trials.
- Possible gene transfer to related wild species.

About twenty field locations (especially those where the herbicide tolerant HT winter oilseed rape and sugar beet, as well as the maize resistant to the European corn borer – Bt-maize were grown) were supervised annually, some of them repeatedly, and plant samples were collected for analyses. The Committee organized also courses for GMO advisors, plant breeders, Ph.D. students and actions for public (lectures, discussions, presentations in media, articles in newspapers and journals, broadcast- and TV-interviews and films). The members of the Committee participated in preparation of the first Czech Act 153/2000 on the Use of Genetically Modified Organisms and Products, and amendment of some related Acts, entering into force on January 1, 2001, as well as of the Decree 374/2000, on Specific Conditions of Handling with Genetically Modified Organisms and Products. This legislation covered necessary aspects of possible risks of GMOs to the environment. The other risks, e.g. potential effects to human and animal health were covered by different acts and decrees prepared by the Ministry of Agriculture and the Ministry of Health. Based on the Act 153/2000, the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products was established as an advisory body of the Ministry of the Environment.

The new Act 78/2004, on the Use of Genetically Modified Organisms and Genetic Products and its amendment - Act 346/2005, together with the implementing Decree 209/2004 represent national legislation harmonized with the Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment, the important part of which deals with monitoring of possible (predictable) impacts on the environment (during field experiments preceding commercial GMO release) and with a post-release monitoring aimed at identification of possible unexpected or delayed GMO effects on the environment after a specific GM crop and trait combination market release.

Studies were supported by the Ministry of the Environment and the Ministry of Agriculture, some projects by the Ministry of Education, Youth and Sports of the Czech Republic. Certain funds were granted by the Grant Agency of the Academy of Sciences of the Czech Republic and the Grant Agency of the Czech Republic.

## Cooperation within the EU biosafety programmes

Participation in the European research programmes is important for the Czech Republic as a relatively small EU member state. Thus the Czech Republic joined a project within the 6<sup>th</sup> EU Framework Programme, known under the acronym SIGMEA “Sustainable Introduction of GM Crops into European Agriculture”. The Czech Republic cooperated in this programme with EU countries especially in biosafety studies of oilseed rape (University of South Bohemia, České Budějovice – USB) and sugar beet (Czech University of Agriculture, Prague). One of the main outputs of this 3,5 year-lasting programme was the recommendation of systematic tools for a sustainable co-existence of different agricultural systems (conventional, organic and farming using GM crops), officially submitted to EC representatives on the occasion of the Third International Conference on Coexistence between Genetically Modified (GM) and Non-GM based Agricultural Supply Chains held in Seville, Spain (November 20-21, 2007). Some of the recent results of biosafety studies and GM crops monitoring were also presented at the 10th International Symposium on Biosafety of Genetically Modified Organisms in Wellington, New Zealand (November 16-21, 2008). Other programmes of international cooperation deal with standardization of methods used for sampling and detection of GMOs (e.g. cooperation of the Czech accredited laboratories with the Joint Research Centre EC, Ispra, Italy and within the European Network of Laboratories Analysing GMOs - ENGL).

## Examples of Czech biosafety studies and monitoring

### **Monitoring of transgenic oilseed rape (OSR)**

Oilseed rape (*Brassica napus* L. var. *napus*) (OSR) represents one of the most important agricultural crops in the Czech Republic. Its cultivation area ranges annually between 250 000 to 350 000 hectares and a great deal of the harvested crop is exported to other EU countries for processing to oil. Relevant rules for coexistence need to be based on the results of studies performed under specific geographic conditions and within the agricultural systems typical for the Czech Republic. Winter OSR is known as an invasive species, grown usually in large areas of fields and producing huge amounts of pollen and seeds. OSR can persist in fields for years and slowly spread to surrounding ecosystems. Naturally, the main attention was thus paid to GM OSR field trials inspections, running of experiments and post-harvest monitoring.

The Faculty of Biological Sciences USB in cooperation with the Institute of Plant Molecular Biology of the Academy of Sciences, České Budějovice and other institutions, such as Faculty of Agronomy USB, Research Institute of Fodder Crops, Troubsko (RIFC) developed projects in different locations of the country, sponsored by the Ministry

of the Environment and the 6<sup>th</sup> EU Frame Programme. The following main goals were followed:

- Monitoring of HT-transgene transfer by pollen to conventional (non-GM) OSR or to its wild related plant species.
- GM OSR volunteer dynamics on experimental fields during the next years.

The results showed a relatively low frequency of pollen transfer to non-GM OSR, similarly as observations from several other European countries. The frequency of admixtures of transgenic seeds in non-transgenic rape cultivars cultivated in the vicinity of GM OSR (in the distance 5–20 m) was within the officially tolerated level (under 0.9 %), actually it did not exceed 0.4 %. In the distance of 500 m of the GM field, no admixtures of transgenic seeds (due to cross-contaminations caused by pollen transfer) have been detected. No feral GM OSR populations were found close to any of the eight GM field trial areas monitored for a longer period (in total – in different locations - 6 years, but not evenly systematically monitored). On the other hand, survival of GM OSR seeds was comparable to that of conventional OSR, a low number of GM volunteer plants arising from the soil seed bank could be detected in some fields even 6 years after the field trial. Based on the results of GM OSR monitoring a set of recommendations have been submitted to the Czech national regulatory authorities (Ministry of Agriculture and Ministry of the Environment) to broaden the science-based platform for the preparation of co-existence rules aimed at possible future winter GM HT-OSR cultivation and use. The recommendations are based on the specific geographical and biological conditions and agricultural practices used in the Czech Republic and they are not necessarily fully valid in other geographic and climatic conditions and in different agricultural production systems used in other countries.

### ***Effect of Bt-maize on agricultural ecosystems and mycotoxin levels in kernels and silage***

Genetically modified maize MON 810 expressing the toxin Cry1Ab and thus resistant to the European corn borer (*Ostrinia nubilalis*, ECB) is the only transgenic event approved in the Czech Republic for cultivation. Since 2005, when grown for the first time on 270 ha only, its cultivation area has increased to 8 300 ha in 2008 making thus Czech Republic the second-largest GM maize grower in the EU, after Spain. Its release was preceded by the field trials aimed mainly at studies of possible effects of Bt-maize on non-target organisms and comparisons of the efficiency of various crop protection systems to ECB. As shown in the results of four-year field experiments of the Institute of Entomology of the Academy of Sciences, České Budějovice, obtained after the analysis of arthropod communities in which about 50 thousand specimens were identified, the scientists concluded that the presence of Cry1Ab toxin (and Bt-maize) has no adverse effect on the ecosystem. In their studies highly represented taxa such as spiders, aphids, predatory bugs, thrips, ground beetles (Carabidae), and rove beetles (Staphylinidae) were evaluated using statistical methods. Considerable variability in species diversity and abundance proved to be dependent on the year and occasionally on the plot

location, but not on the Cry expression. Also studies of carabid beetles communities carried out by the Institute of Crop Production, Prague in two other localities showed no effect of planting transgenic insect resistant maize on this insect group.

Comparison of the efficacy of ECB control using various measures (traditional used insecticides, biological control based on *Trichogramma* wasps, and use of Bt-maize) has shown the full (100 %) plant protection against ECB only in case of Bt-maize. Moreover, the harmful mycotoxin content in Bt-maize kernels decreased up to 60 % as compared to non-treated control, depending on a year and pest abundance. As indicated by the RIFC the corn borer can be dangerous not only for maize grain production but also for silage production from maize. The protection against this pest is especially important in localities with the higher pest occurrence and in late-maturing maize hybrids, where the interval between the corn borer invasion and the harvest is longer than in conventional maize plants.

### **Monitoring of GM potato, flax and other crops**

Other examples include field testing of the GM potato lines with increased metabolism of reducing sugars in the tubers (since 2000, Institute of Experimental Botany, Academy of Sciences, Prague; Sativa Keřkov and VESA Velhartice) and of the potato cv. Amflora with enhanced ratio of amylopectin in tuber starch (starting from 2005, BASF, Germany). In the first case the gene *Lbpfk* from *Lactobacillus bulgaricus* coding for phosphofructokinase, together with the gene *nptII* coding for resistance to kanamycin as a selectable marker, were introduced using *Agrobacterium tumefaciens* mediated transformation. In case of cv. Amflora the plant own gene *gbss* coding for starch synthase was incorporated in an anti-sense orientation to decrease the synthetic activity of the enzyme. Monitoring of both GM variants during the 3–5 year period did not reveal any changes in the ability of the potatoes to survive and disseminate in nature or influence on other components of the environment. Field testing of different GM flax variants (with insertion mutagenesis, tolerance to Basta herbicide, model genes) in Agritec Research, Breeding and Services, Šumperk has started already shortly after 2000. No adverse environmental effects or changes in flax dissemination have been detected so far. To avoid possible negative effect of GMO on the environment in some experiments, e.g. with pea and wheat, non-GM analogues have been used to simulate the GM crop performance.

Studies of the biological safety of GM crop varieties during the field trials represent an important part of the knowledge necessary for conducting highly qualified risk assessment before the commercial crop release into the environment (according to the Part C of the Directive 2001/18/EC). They enable, together with the post-release monitoring data, to manage successfully possible risks to the environment and agricultural systems. The Czech research activities contribute to international databases with data resulting from GM crops growing under specific geographic, climatic and agricultural conditions of the Central Europe.

## Laboratory Monitoring

*Jaroslava Ovesná, Kateřina Demnerová*

The Czech Environmental Inspectorate is the Competent Authority on state supervision of the GMOs use in the Czech Republic. Several other institutions or bodies assist the Inspectorate in its mission, as described in the Chapter on Biosafety Framework. To fulfil their task, these inspection bodies need the service as to identification and quantification of genetically modified organisms and of genetically derived ingredients in food and feed products, which are the activities of laboratories. In the Czech Republic, three main laboratories were accredited in the environmental sphere: Laboratories of the Crop Research Institute, Prague, the Institute of Chemical Technology, Prague and the National Institute of Public Health, Brno.

All laboratories have been accredited by the Czech Accreditation Institute as the testing laboratories according to the ISO 17025:2005 and operate according certain quality standards. The laboratories use methods for GMO identification validated by the Community Reference Laboratory, approved operation procedures and internationally recognized standards. Quality assurance is essential for their activities. Their equipment corresponds to the required standards. Besides routine analyses they develop also research activities and they test methods for detection of GMOs invented by the Czech Research Institutions. Their research is focused mainly on the following:

- Development and verification of detection methods and identification of GMOs in plants and derived food and feed (PCR based, DNA arrays based).
- Verification of DNA isolation procedures from various matrices ranging from plant tissue to complex processed food and feed matrices.
- Proposals for sampling strategies of field plants (e.g. the laboratory of the Crop Research Institute has developed a sampling protocol for GMO field controls).
- Biosafety of GMOs developed in the Czech research laboratories (flax, pea, potatoes) and of important crops (wheat including possible gene flow in wild weedy species).
- Development of basic data required for establishment of coexistence measures.
- GENOMON project.

The laboratories form the National Network of GMO Laboratories. The reference laboratory at the Crop Research Institute acts as the National Reference Laboratory. All laboratories are members of the European Network of GMO Laboratories (ENGL) which was established in the context of the Regulation (EC) 1829/2003 on GM Food and Feed. The ENGL cooperates closely with the Community Reference Laboratory for GM Food and Feed (CRL) which core task is the scientific assessment

and validation of detection methods for GM Food and Feed as part of the European Commission authorisation procedure. The Joint Research Centre (JRC) of the European Commission has been given the mandate for the operation of the CRL through the above mentioned collaboration with the European Network of National Control Laboratories. The Community Reference Laboratory for GM Food and Feed operates according to a quality management system fulfilling the requirements of standard ISO 9001:2000 and ISO 17025:2005. The relationship between ENGL and CRL is described in the Regulation (EC) 1981/2006, where the laboratories are listed. They should assist mainly in method validations. The Czech laboratories have participated in the ENGL plenary sessions and working groups activities.

The laboratories use PCR (polymerase chain reaction) based methods that are internationally recognized for the GMOs detection and quantification. They assist in developing of sampling protocols, of new methods and discuss detection methods performance (national inter-laboratory comparison on method performance is organized).

The Czech Agriculture and Food Inspection Authority processes about 300 samples (food control), the Central Institute for Supervising and Testing in Agriculture about 200 samples (feed, seeds) per year. The reference laboratory at the Research Institute of Crop Production analyses around 350 samples per year (co-existence and various). They report their results every year, including cases of non-conformity, to the Rapid Alert System for Food and Feed (RASFF). This System has been functioning since 1979, on the basis of the Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Its purpose is to provide the control authorities with an effective tool for exchange of information on measures taken to ensure food safety.

Czech laboratories have elaborated numerous documents and publications, generally in Czech, the most important documents in English (listed in the Annex).

## Biosafety Clearing House

*Hana Jiráková, Miroslav Večeřa*

The Czech node of the Biosafety Clearing-House Central Portal ([www.mzp.cz/biosafety](http://www.mzp.cz/biosafety)) has been established in line with the Article 20 of the Cartagena Protocol on Biosafety, in order to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms (LMOs) and to assist Parties to implement the Protocol. This website was initiated and supported by the UNEP/GEF within the Project “Building Capacity for Effective Participation in the Biosafety Clearing-House”. It has been set up and it is managed by the Department of Environmental Risks of the Ministry of the Environment.

The Ministry of the Environment publishes information related to living modified organisms (genetically modified organisms according to the Czech corresponding legislation) at the Ministry website, in the Czech language. The BCH website serves as a source of information in English, therefore for other countries and for contact with the CBD/CPB Secretariat. The present menu consists of eight basic headings, i.e. Home; National Contacts; Acts, Regulations and Guidelines; Decisions; Co-existence; Other Resources; Reporting and Relevant Links. Each of these headings contains introductory information, relevant links and documents for downloading.

**Home** – gives introductory basic information.

**National Contacts** - contains detailed contacts of persons and institutions dealing with biosafety issues in the Czech Republic, i.e. the National Focal Points for both the Cartagena Protocol on Biosafety and Biosafety Clearing-House, National Competent Authorities and other authorities responsible for monitoring of genetically modified organisms and enforcement.

**Acts, Regulations and Guidelines** – this part contains information required by the Article 20 (3) of the Protocol, according to which each Party must make available to the BCH any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by Parties for implementation of the Advance Informed Agreement (AIA) procedure. Pursuant to this articles the Act 78/2004 on the Use of Genetically Modified Organisms and Genetic Products, as amended by the Act 346/2005, as well as the corresponding Decree of the Ministry of the Environment on Detailed Conditions for the Use of Genetically Modified Organisms and Genetic Products have been made available at this website. Additionally, the document on risk assessment procedure performed in the Czech Republic, a document with the latest overall information on LMOs in the Czech

Republic as well as a document with instructions for notifiers regarding both field and clinical trials, with relevant forms are at disposal there.

**Decisions** – the list of decisions on deliberate release of genetically modified organisms into the environment (i.e. field trials) in the Czech Republic is available there. As the Czech Republic is a member state of the European Union, the decisions have been adopted in accordance with the Part B of the Directive 2001/18/EC.

**Co-existence** - the Ministry of Agriculture is a competent authority in related issues, including rules of co-existence of GM crops cultivation with conventional and organic farming in the Czech Republic. Report on existing experience with cultivation of genetically modified maize MON 810 (cultivated in the Czech Republic since 2005), including the implementation of the Coexistence Guidelines in the Czech Republic is now available.

**Other resources** - this part includes information on two UNEP/GEF projects developed in the Czech Republic. The first project (July 2002 - March 2004) focused on development of the national biosafety framework for the Czech Republic. The second project, planned for the period 2006 – 2010, is focused on assisting in implementation of adopted measures within the biosafety framework in the country. Detailed information as well as the main outcomes of both projects are presented.

**Reporting** – the First Regular National Report on the Implementation of the Cartagena Protocol on Biosafety in the Czech Republic, compiled pursuant to the Article 33 of the Protocol, is available in this part.

**Relevant links** – the most important and interesting websites are referred to under this heading of the menu. The links are structured at two levels for better orientation - national (Czech) and European.

## Biosafety Related UNEP/GEF Projects

*Milena Roudná*

Most activities and measures taken in biosafety area in the Czech Republic have been supported by the UNEP/GEF Projects: Development of the National Biosafety Framework for Czech Republic (2002 – 2004), Implementation of the Draft National Biosafety Framework for the Czech Republic (2006 – 2010) and Add-on Project - Building Capacity for Effective Participation in the Biosafety Clearing House (2006 – 2008), and also Access to Genetic Resources and Benefit-sharing, Conservation and Sustainable Use of Biodiversity (2004 - 2006).

The first mentioned Project assessed the existing national capacity and role of responsible bodies. The results are summarised in the final Report “National Biosafety Framework for the Czech Republic” (Ministry of the Environment, Prague, March 2004).

The ongoing implementation project (2006 – 2010) assists in implementation of measures adopted during the preceding years, with the focus on five components of the National Biosafety Framework: Biosafety policy, Regulatory regime, Handling requests for permits, Monitoring of environmental effects and enforcement, Public information, participation and awareness. The present status in the five mentioned spheres is described in the preceding Chapter on Biosafety Framework. The Ministry of the Environment serves as the National Executing Agency of the Project. National Coordinating Committee (NCC) assists in coordination of scheduled activities and consists of representatives of authorities and institutions responsible for biosafety policy, regulations and monitoring and other important stakeholders (Ministry of Agriculture, Ministry of Health, Ministry of the Environment, universities, research institutions, organic farming, NGOs represented by Greenpeace). A close cooperation has been developed with the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products. The Project is supported (through co-financing) by the Ministry of the Environment, Ministry of Agriculture and Ministry of Health, as the main sectors responsible for biosafety regulation in the Czech Republic.

The Add-on BCH Project resulted in establishing of the National BCH System. New website has been developed and serves for communication with CBD/CPB Secretariat and information sharing in English ([www.mzp.cz/biosafety](http://www.mzp.cz/biosafety)), whereas Ministry of the Environment website ([www.mzp.cz](http://www.mzp.cz) – Environmental Risks – GMOs) offers information in national – Czech language (see also the Chapter Biosafety Clearing House).

Within the projects the capacity building, education and public awareness have been greatly enhanced through trainings, specially focused meetings, thematic workshops, different ways enabling access to information and various publications.

The right to access to biosafety related information is done by the Act 78/2004, on the Use of Genetically Modified Organisms and Genetic Products, later amended by the Act 346/2005 and supported by two more general national acts – Act on Free Access to Information (within state administration) and Act on Right to Environmental Information. Moreover, the Czech Republic is a Party to the Aarhus Convention (ratification – adoption of the Amendment on genetically modified organisms, January 2008) which led to the amendment of the Act 78/2004 enabling wider public participation in decision procedures. On the basis of the Act, information is available to the public on the official board of the Ministry of the Environment, through the Internet and in the region where contained use or introduction into the environment are expected.

Education in a broad sense has centuries long tradition in the territory of the Czech Republic, reaching in certain periods a high standard. Environmental education as to its content has been developed in the last decades, already before this term was officially used. Nowadays, the State Programme on Environmental Education and Public Awareness (2000) represents the official document for environmental education in general, with its Action Plan – regularly updated for a 2-year period (since 2001). The Ministry of the Environment as the main actor cooperates with the Ministry of Education in this field. Thanks to national network of centres for environmental education different activities can be developed at local level, in cooperation and even with support of local governments and various stakeholders. So far, biosafety aspects have not been sufficiently reflected in the Programme. This fact initiated certain activities supported by the UNEP/GEF projects.

Education and public awareness have been developed within the UNEP/GEF projects in cooperation with universities, Scientific-technical Society, civil societies, NGOs, schools and centres for environmental education, museums and Nature Protected Areas administrations. Workshops for public and schools, Academy of Sciences conferences on topical issues, dissemination of information through media (newspapers, magazines), promotion of education on biosafety at schools (secondary schools and universities), production and dissemination of information on biosafety through the Internet, posters, publications and CD-ROMs for decision-makers, experts, public and schools, as well as regional workshops organized in cooperation with FAO and UNEP. One meeting per year of the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products is open for public and offers possibility to meet with representatives of responsible authorities and experts.

List of publications resulted from the UNEP/GEF Projects is available in the Annex.

## Annexes

### **Publications related to biosafety** (prepared within UNEP/GEF Projects)

Demnerová K., Pazlarová J. (2003): Genetically Modified Microorganisms. Ministry of the Environment, Prague, 18 pp. (in Czech)

Doubková Z. (Ed.) (2003): Genetically Modified Organisms – Issues Related with their Origin and Use. Ministry of the Environment, Prague, ISBN 80-7212-259-2, 38 pp. (in Czech)

Doubková Z., Roudná M. (2004): Legally Binding Instruments on Biosafety. Ministry of the Environment, Prague, ISBN 80-7212-313-0, 48 pp. (in Czech, English Summary)

Káš J., Roudná M. (Ed.) (2004): National Biosafety Framework for the Czech Republic. Ministry of the Environment, Prague, ISBN 80-7212-281-9, 36 pp.

Káš J. (Ed.) (2004): Genetically Modified Organisms – Present Status and Perspectives. Institute of Chemical Technology in cooperation with Ministry of the Environment, Prague, ISBN 80-86313-13-1, 67 pp. (in Czech)

Roudná M. (2003): Biological Diversity and Biosafety Related Issues. Ministry of the Environment, Prague, ISBN 80-7212-275-4, 66 pp. (in Czech, English Summary)

Roudná M. et al. (2004): Genetic Resources of Plants and Animals. Ministry of the Environment, Prague, ISBN 80-7212-312-2, 60 pp. (in Czech, English Summary)

Roudná M. (Ed.) (2008): Genetic Modifications – Possibilities of their Use and Risks. Ministry of the Environment, Prague, ISBN 978-80-7212-493-0, 48 pp. (in Czech, English Summary)

Roudná M., Dotlačil L. et al. (2007): Genetic Resources – Importance, Use and Conservation. Ministry of the Environment, Prague, ISBN 978-80-7212-469-5, 28 pp. + Annex 98 pp. (in Czech, English Summary)

Team of Authors (2008): Terms on Genetic Resources and Biosafety. Ministry of the Environment, Prague. Part I. Genetic Resources, 53 pp. Part II. Biosafety, 48 pp. (Czech – English terminology)

Tošovská E. (2006): Conservation of Biological Diversity, Patent Protection and Liability. Ministry of the Environment, Prague, 66 pp. (in Czech, English Summary)

Tošovská E., Roudná M. (2006): Legislation Related to Access and Rights to Genetic Resources – Czech Republic. Ministry of the Environment, Prague, ISBN 80-7212-442-0, 16 pp.

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Ovesná J. (Ed.)(2003): Proceeding of the Workshop “GMOs in Agriculture and Food Production” (Prague, Ministry of Agriculture, October 30, 2003). Research Institute of Crop Production, Prague, December 2003, 39 pp. (in Czech)

Ovesná J., Kučera L. (Eds.)(2004): Proceedings of the Workshop “Issues of Biosafety, Genetically Modified Organisms and International Commitments of the Czech Republic” (Prague, Research Institute of Crop Production, February 18, 2004). Research Institute of Crop Production, Prague, February 2004, 80 pp. (In Czech, English Summaries)

Roudná M. (Ed.) (2003): Proceedings of the Sub-regional Meeting on Biosafety Framework. Prague, April 24-25, 2003. Ministry of the Environment, Prague, 38 pp.

Káš J., Roudná M. (Eds.) (2004): Final Workshop of the UNEP/GEF Project Development of the National Biosafety Framework for the Czech Republic, Prague, 23.-24.3.2004. Ministry of the Environment, Prague, 26 pp. (in Czech, Slovak and English)

Roudná M. (Ed.) (2006): Proceedings of the Joint UNEP/GEF Biosafety Inception Workshops – Czech and Slovak Republics, Prague, November 8-9, 2006. Ministry of the Environment, Prague, 20 pp.

Roudná M. (Ed.) (2007): Genetic Modifications and Biosafety Framework. Workshop, Czech Scientific-Technical Society, Prague, 8.10.2007. Ministry of the Environment, Prague, 18 pp. (in Czech, English Summary)

Káš J. (Ed.), Kotrba P., Angelis K., Macek T. (2008): Proceedings of the Workshop “News from Genetic Modifications Field”. Institute of Chemical Technology, Prague, 28.5.2008. Institute of Chemical Technology, 18 pp. (in Czech)

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Photos on the back cover:

Environmental education workshop – Centre for Environmental Education (Photo M. Roudná)

Field trials with GM plants (Photo S. Rakouský)

Map on p. 4:

Overview of the field trials with GM plants – Czech Republic, 2009 (H. Jiráková)