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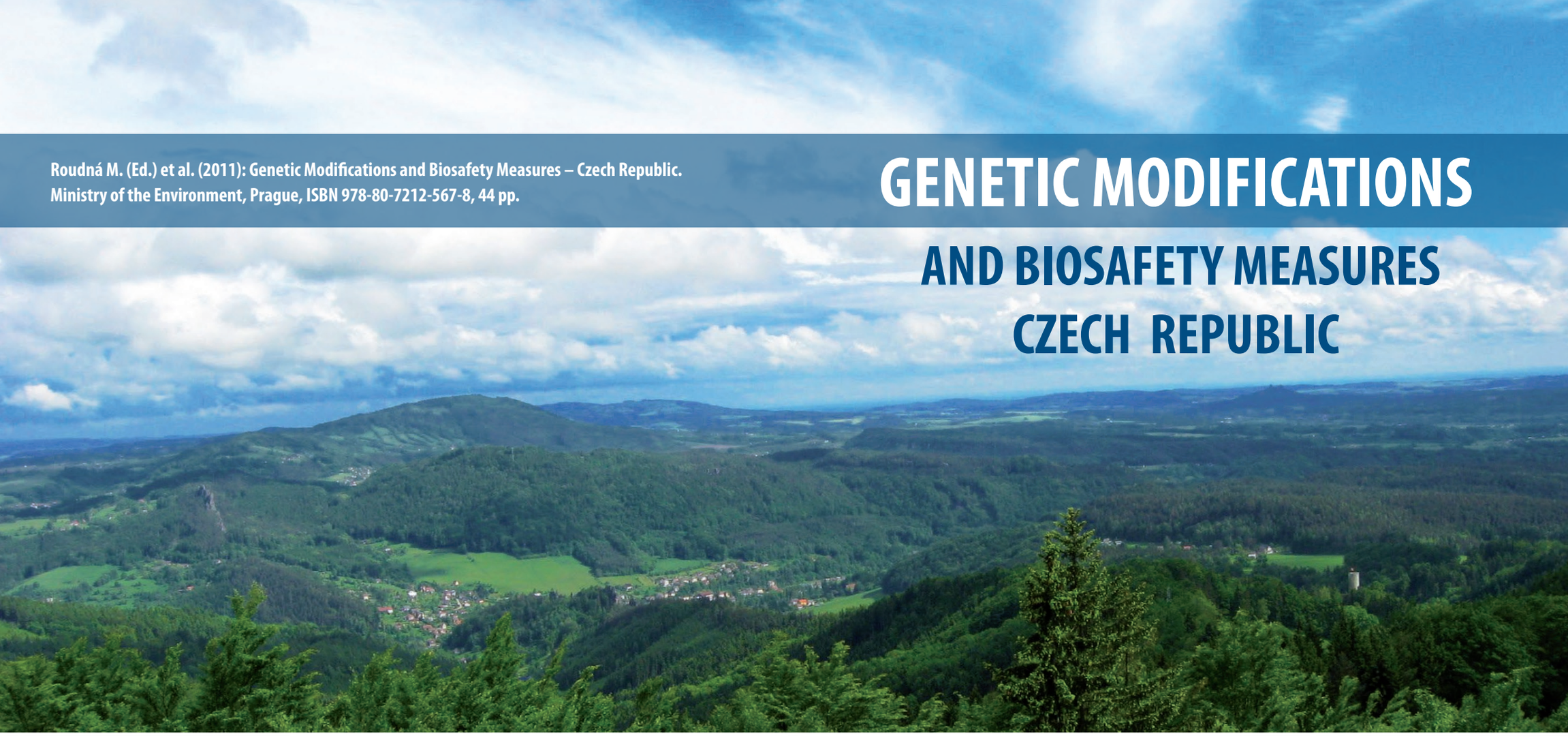
GENETIC MODIFICATIONS
AND BIOSAFETY MEASURES
CZECH REPUBLIC







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Ministry of the Environment
of the Czech Republic

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2011

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FOREWORD

Biotechnology as a technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (Convention on Biological Diversity, 1992) is in this sense applicable to both traditional and modern biotechnology. Whereas the traditional applications dated as far as to prehistoric time, the use of modern biotechnology, based on gene techniques, has developed mainly during the last three decades. Using of these new techniques resulted in creation of genetically modified organisms which contain genetic elements from foreign sources and posses novel traits and characteristics. Application of these organisms can be beneficial in various areas, such as industry, medicine including forensic medicine, agriculture or the environment. Nevertheless, as potential harmfulness of genetically modified organisms to the environment and human health cannot be excluded, use of modern biotechnology is strictly regulated. A set of adopted measures resulted in a biosafety system, which aim is to prevent, manage, minimize or eliminate hazard to human health and security and to protect the environment from biological agents and organisms used in research and trade (FAO, 2011). The biosafety system includes measures at different levels – policy, legislation, administrative procedures, monitoring and enforcement, as well as public awareness, participation and education.

Due to a recent intense development of modern biotechnology and its application in different fields, some international organizations, such as UNEP, GEF or FAO, undertook initiatives aiming at establishment and implementation of the biosafety framework. For this purpose they launched special programmes and projects, primarily for developing countries and countries with economy in transition, and organized workshops at international or regional levels. The Czech Republic implemented the UNEP/GEF Project, the first phase Development of National Biosafety Framework in the period 2002 – 2004, the second phase Support for the Implementation of the National Biosafety Framework in the period 2006 – 2011. Basic experience and outcomes are summarized in this publication, which includes also the List of Workshops organized at national level and the List of Publications edited within the UNEP/GEF Projects. At the same time the Czech experts participated in activities of certain regional and international bodies and the Czech Republic hosted several regional workshops for Central and East European Countries.

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I. Biosafety Policy

Zuzana Doubková

The biosafety policy as a stand-alone document has not been developed in the Czech Republic. Instead of that, the Ministry of the Environment, as the main responsible body in this area, has decided to take another way – incorporate biosafety principles into relevant strategic documents. The reasons for this decision were, among others, negative experience of some other countries with similar political and economic conditions and their difficulties with approval of such a governmental document. Therefore, in the Czech Republic the biosafety principles are reflected in the following important documents:

- Strategy for Sustainable Development
- State Environmental Policy
- State Programme of Nature Conservation and Landscape Protection
- National Biodiversity Strategy
- Food Safety Strategy
- Action Plan on Health and the Environment
- State Programme of Environmental Education and Public Awareness
- Reports on the Environment in the Czech Republic.

In this process, the UNEP/GEF Project, focused on the development and implementation of the National Biosafety Framework (2002 – 2004, 2006 – 2011), played an important role. Various supporting activities were conducted within the project, namely:

- Meetings with relevant authorities
- Discussions with experts and stakeholders
- Surveys of developments in modern biotechnology
- Surveys of existing international and national documents
- Participation in the process of drafting and updating strategic and policy documents.

The **Sustainable Development Strategy of the Czech Republic** was approved by the Government of the Czech Republic in 2004 as a long-term framework for political decision-making. It represented the starting point for the development of strategic materials (sectoral policies and action programmes), for strategic decision-making in the state administration and territorial public administration, and for co-operation with stakeholders in these activities.

The updated Strategy for Sustainable Development under the title "The Strategic Framework for Sustainable Development in the Czech Republic" was adopted by the Government in January 2010. The priorities and objectives of the sustainable development are classified in this document into five priority axes:

1. Society, people and health
2. Economy and innovation
3. Spatial development
4. Landscape, ecosystems and biodiversity
5. Stable and secure society.

The axis 4 "Landscape, ecosystems and biodiversity" is further structured into three priorities that may include biosafety aspects:

Priority 4.1: Landscape conservation as a prerequisite for biodiversity conservation

Priority 4.2: Responsible farming and forestry

Priority 4.3: Adaptation to climate change.

Genetically modified organisms are mentioned especially under Priority 4.1., Objective 3 "Halting the decline in biodiversity": "... In the area of genetically modified organisms, it is necessary to ensure that these organisms are used in accordance with the existing strict legislation that is currently in force both at the EU level and at national level, and that they do not pose an increased risk to biodiversity compared to traditional methods of agricultural production."

As regards the **State Environmental Policy** for the period 2004 – 2010, the implementation of the document was evaluated in 2006. The chapter 3.5.3. "Ensure safe use of genetically modified organisms" analysed in detail specific tasks and their fulfilment: the system of liability for damage caused by genetically modified organisms, availability of information on releases of genetically modified organisms, public participation in decision-making, information sharing among authorities, development of the legislative framework, system of supervision and inspections. An updated evaluation at the end of the six years period will serve as the basis for the following policy document that is to be finalized in 2011. According to the Programme Declaration of the current Government, issued in August 2010, the State Environmental Policy should be in line with strategic documents for other areas, i.e. energy, raw materials, climate, agriculture and forestry.

The **State Programme of Nature Conservation and Landscape Protection** was updated in November 2009. The updated version includes the **Action Plan of National Biodiversity Strategy** (National Biosafety Strategy was adopted in 2005). The use of genetically modified organisms is mentioned in chapter 3.2.4.1. "The state and development of agroecosystems and soil" in relation to changes in ecosystems and their potential impacts on biodiversity: "The use of genetically modified organisms has become widespread globally and in the near future the area of cultivation of genetically modified crops can increase in EU as well. As our knowledge of the impacts of genetically modified organisms on the environment are by far not complete, it is not possible to evaluate fully potential hazards for biodiversity (increase of pesticide applications linked to herbicide-tolerant crops, establishment of modified crops as weeds, hybridisation with wild relatives, negative effects on non-target insects etc.). In spite of partial regulation, clear rules for monitoring and elimination of potential impact related to genetically modified organisms at various levels of biodiversity (genes / individuals, populations / species, functional groups / ecosystems / landscape) are still missing."

The first governmental document on food safety – the **Strategy for Safeguarding Food Safety in the Czech Republic 2004 – 2006** was adopted by the Government at the end of the year 2004. The following Evaluation of the Strategy of 2006 identified additional tasks for the period 2007 – 2008. The current document - the **Food Safety and Nutrition Strategy for 2010 – 2013** (adopted by the Government in January 2010) was prepared in close cooperation between the Ministry of Agriculture and the Ministry of Health, with contributions of other entities involved in the food safety system in the Czech Republic, including the Ministry of the Environment. In a long-term perspective the Food Safety and Nutrition Strategy seeks to strengthen the protection and promotion of health as well as consumer rights.

The chapter on the current status of safeguarding the food safety in the Czech Republic emphasises that the risk assessment means a science-based process the aim of which is to provide a detailed description of the risk in order to be able to efficiently manage it. The process consists of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. To ensure the protection of health and to support consumer rights as to food safety, a high level collaboration and coordination of activities of all stakeholders from among governmental as well as non-governmental institutions is required. To this end, the inter-sectoral Food Safety Co-ordination Unit was established in 2002, composed of deputy ministers of the relevant ministries (including the Ministry of the Environment), directors of supervision authorities and representatives of consumer organisations.

The Strategy emphasizes further enhancement of collaboration with the European Food Safety Authority (EFSA), communication with and education of consumers

as well as of the State administration staff. In response to the establishment of EFSA, expert panels – scientific committees composed of prominent experts were nominated in the Czech Republic with the aim to elaborate independent expertises, including proposals for adoption of measures to ensure safety throughout the whole food production chain. The Scientific Committee on Genetically Modified Food and Feed established by the Ministry of Agriculture in 2006 closely co-operates with the Ministry of the Environment as regards biosafety measures.

The **National Environment and Health Action Plan** (NEHAP) is the main national strategic document on health, developed under auspices of the Ministry of Health, in close cooperation with the Ministry of Agriculture and Ministry of the Environment. It was adopted by the Government in December 1998. The biosafety issues are included in the reports on its implementation and in updated versions of the original document.

The **Reports on the Environment in the Czech Republic** were published until 2007 in a detailed descriptive way, including a paragraph on the use of genetically modified organisms and relevant legislation. Since 2008 the yearly reports are based on a set of indicators that do not cover biosafety specifically. A detailed report on the status and outlook of the environment is to be published every five years, where the biosafety data and information will be included.

The **Survey on Biosafety Strategic and Policy Documents** is a significant outcome of the UNEP/GEF Project. This document gives the overview of:

- Use of modern biotechnology at global level, in EU and in the Czech Republic
- Relevant international organisations, conventions etc. and their activities
- Policy and regulations in EU, including the Czech positions
- Strategic and policy documents concerning biosafety in the Czech Republic.

The Survey serves primarily to biosafety experts, e.g. members of the Czech Commission on the Use of Genetically Modified Organisms and Genetic Products, as a background document.

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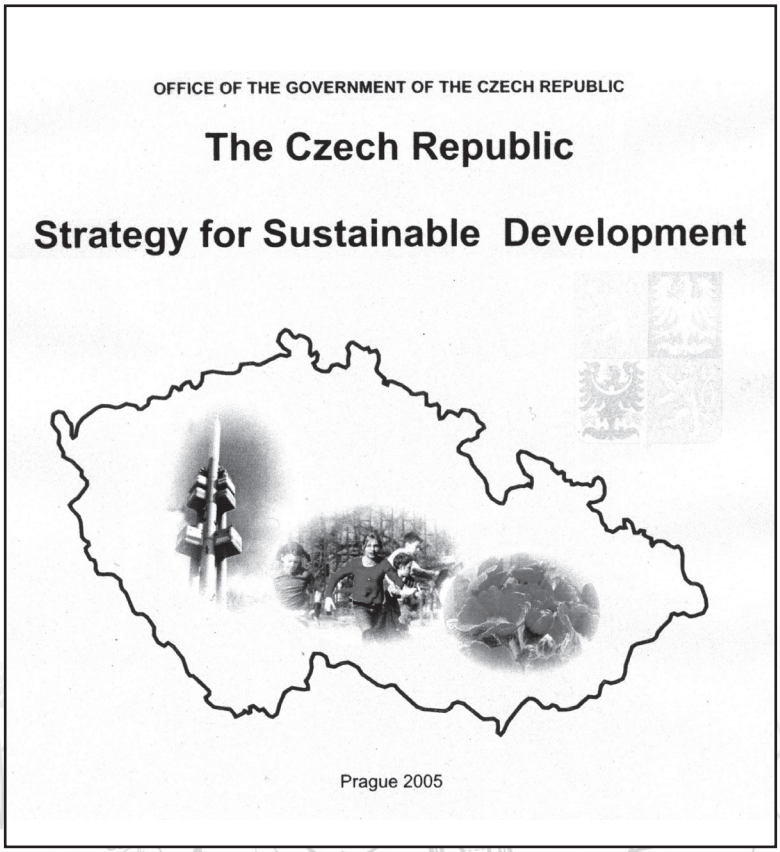

II. Regulatory Regime – Legislation

Zuzana Doubková

The first Czech Act on the use of genetically modified organisms was adopted in 2000. The current national regulatory framework is set up by the Act No. 78/2004, on the Use of Genetically Modified Organisms and Genetic Products, which entered into force in February 2004, and by the implementing Decree No. 209/2004, on Detailed Conditions for the Use of Genetically Modified Organisms and Genetic Products. The Act transposes EU Directives 2001/18/EC and 2009/41/EC, covering the contained use, deliberate release into the environment and placing on the market of genetically modified organisms as or in products. EC Regulations 1829/2003 and 1830/2003 concerning authorisation of genetically modified food and feed, traceability and labelling of genetically modified organisms and genetically modified 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.

The Act on the Use of Genetically Modified Organisms and Genetic Products was several times amended. The amendments concerned mostly legislative-technical aspects (not changing the content). Substantial changes were made by the Act No. 346/2005, in response to the EU Regulations adopted in 2003 and as reflection of the experience gained with the implementation of the legislative framework at national level. The Decree No. 209/2004, on Detailed Conditions for the Use of Genetically Modified Organisms and Genetic Products, was amended as regards the provisions on emergency plans for contained use. For security reasons the scope of published information has been limited. In 2010, a provision specifying the requirements for genetically modified organisms classified in the first class and some details on risk assessment of contained use were added.

General rules of coexistence of genetically modified crops with conventional and organic farming are set by the Act No. 252/1997, on Agriculture, as amended in 2005 and 2009, and specified for various crops by the implementing Decree No. 89/2006, on Detailed Conditions for Growing of Genetically Modified Variety, as amended by Decree No. 58/2010.

Depending on the diverse use of genetically modified organisms, other relevant legislation needs to be respected and kept in line with the basic biosafety framework. Therefore the Ministry of the Environment has to follow the development of national and EU rules for:

- Nature protection, incl. liability and redress
- Seeds, propagating material and variety registration
- Phytosanitary regulations
- Organic farming
- Food and feed
- Medicinal products
- Biosecurity
- Access to information
- Administrative and supervision procedures etc.

For full texts of the Czech legislation on GMOs see the Czech Biosafety Clearing House: http://www.mzp.cz/biosafety

III. Administrative System

Zuzana Doubková, Hana Jiráková, Marie Křístková, Petr Beneš

Pursuant to Directive 2001/18/EC and the Czech Act No. 78/2004, the Ministry of the Environment is the ***Competent Authority*** handling the notifications and regulating the use of genetically modified organisms in the Czech Republic. It closely co-operates with the Ministry of Agriculture as agricultural risk, animal health, food and feed are concerned, 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 it is responsible for the rules of coexistence.

As set up by the Act No. 78/2004, the Ministry of the Environment established its expert advisory body – ***The Czech Commission for the Use of Genetically Modified Organisms and Genetic Products***, consisting of scientists, representatives of administrative authorities and NGOs. The chair and the members of the Commission are designated by the Minister of the Environment after consulting the Ministers of Health and Agriculture, from amongst professionals nominated by the administrative bodies, Academy of Sciences, universities and research institutes. The terms of reference and rules of procedure issued by the Minister of the Environment set the constitution of the Commission, which 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, registration of crop varieties, organic farming, medicinal products, laboratory detection and supervision of the use of genetically modified organisms, including the connected legislation (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 genetically modified organisms and products containing or consisting of genetically modified organisms, 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, 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 genetically modified organisms and issue opinions on these notifications;
- Check and assess reports on the use of genetically modified organisms and other documents submitted by the users;
- Carry out the environmental risk assessment and comment on the notifications for placing on the market under Directive 2001/18/EC and Regulation 1829/2003;
- Inform the public on scientific developments and its own activities;
- Prepare documents, identify emerging biosafety issues and provide *ad hoc* consultations for the Authorities.

Due to the wide spectrum of genetically modified organisms used both in the Czech Republic and in EU and due to the high number of Czech institutions authorised for the use of genetically modified organisms, the Commission further co-operates with about 20 external experts and consultants. The Commission meets at least 4 times a year, most of the work is done by e-mail correspondence and via the password-protected website. Once a year the Commission organises a public session, where it informs the public, NGOs and other stakeholders about its activities.

Contained use of genetically modified organisms

Contained use of genetically modified organisms means handling with genetically modified micro-organisms, cell cultures, plants and 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 activity that is crucial for the authorisation procedure and for the requirements regarding the level of containment**.** The description of the containment measures makes an important part of the notification and consists of the description of the facilities and of handling with the genetically modified organisms 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 (ME), Ministry of Health and Czech Commission for the Use of Genetically Modified Organisms and Genetic Products (CC GMO)

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 start with activity immediately after the submission of the notification, provided the dossier complies with the requirements of the corresponding legislation. However, within 30 days after the submission of the notification, ME 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 case of the second class of contained use, the notifier is allowed to start the activity 45 days after the submission of the notification if no negative decision is received from ME.

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 for the contained use is issued by the ME and only within the scope and under the conditions defined herein. The administrative procedure for granting a consent for classes 3 and 4 of 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 genetically modified organisms into the environment. The notifier has to pay an administrative fee of CZK 2 000 (approximately EUR 80) for the authorisation in case of the class 3 and class 4 of contained use.

An emergency response plan (a document describing activities and measures needed in case of an accident) has to be submitted to ME as a part of the notification for contained use and consequently by the authorised user every 5 years or in case of any substantial change in the release. The notifier is obliged to submit the emergency response plan also to the municipalities where the contained use will 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. ME makes the basic information on emergency response plans available to the public. A description of waste management for each facility using genetically modified organisms is required in the notification, inactivation of any viable organisms in the waste being the crucial step in the waste disposal.

Overview of contained use

Genetically modified organisms are widely used in laboratories and other confined facilities, mostly for scientific purposes. In the Czech Republic, 90 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 and recombinant proteins (Lonza Biotec, Ascoprot Biotech, rEcoli), vaccines (Baxter BioScience), fine chemicals (CPN) and diagnostics (Exbio). All contained use notifications so far have concerned class 1 or 2 (minimum risk), no cases of class 3 nor 4 have been notified.

Specific case of genetically modified organisms 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 are required to obtain an authorisation for the use of genetically modified organisms 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 the application for a clinical trial authorisation to the State Institute for Drug Control (SIDC), or submitted subsequently, however no later than three days prior to the final outcome of the SIDC assessment process. Should the applicant fail to submit an authorisation for the genetically modified organisms use by the end of clinical trial assessment process, the application for a clinical trial authorisation is refused.

As the first step, the company planning the study must decide whether the clinical trial involves contained use only or if the genetically modified organisms 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 genetically modified organism, etc. The reasons for the chosen notification procedure have to be described in detail in the dossier.

Import and Export (applies to third countries outside EU)

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. Furthermore, the person authorised for contained use may import or export genetically modified organisms covered by the authorisation, provided that they are exclusively intended for contained use. The person authorised for deliberate release for other purpose than placing on the market may import or export genetically modified organisms covered by the authorisation, provided that they are exclusively intended for the authorised deliberate release (e.g. field trials).

The authorised person that intends to import or export genetically modified organisms for contained use or deliberate release 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 or exit to / from the territory of the Czech Republic, at the latest 5 days before the import or export.

The authorisation holder is obliged to ensure proper labelling during export, import and transport. Packaging of a genetically modified organism or genetic product must bear 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 decision on authorisation 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 considered neither as export nor import. However, such transport has to be described in the notification for contained use or deliberate release for other purpose than placing on the market, as appropriate (packaging, way of transport, emergency measures, etc.).

Deliberate release of genetically modified organisms for any other purpose than for placing on the market - field trials

Authorisation process and conditions for issuing a permit

According to the Czech 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).
- ME assesses the completeness of the notification. If the dossier meets all the requirements pursuant to the Act, 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 intended. At the same time ME makes the 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 complete notification is sent to the members of the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products (CC GMO). The summary of the notification is made available in English to the European Commission and other EU Member States by entering the data into JRC WebSNIF database.

- The Ministries and the region concerned as well as the CC GMO send to ME their views regarding the notification, including the request for additional information, if needed, within 30 days of receiving the dossier. Consequently, ME asks the notifier for additional information, if appropriate. ME forwards the received additional information to the Ministries concerned and to the CC GMO. If the applicant fails to provide the requested information within the set time-period (30 days), ME suspends the administrative procedure.
- Everybody may send to ME his/her opinion or make comments within 30 days of publication of the summary of the notification. In case ME receives any negative comments from the public, in which environmental risk assessment results are doubted or an objection to insufficient protection of health and the environment is raised, ME is obliged to arrange a public hearing prior to making the final decision.
- 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 additional 30 days.
- When making the decision, ME is obliged to consider the views of the Ministries concerned, the CC GMO and the results of the public consultation. ME also takes into account any opinions and comments of the Competent Authorities of other EU Member States submitted through the WebSNIF database. ME can include in its decision special conditions for the release of genetically modified organisms, if necessary.
- 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 an accredited laboratory for detection of genetically modified organisms, contracted for this purpose by ME and the Czech Environmental Inspectorate. The samples should be deposited at the time of submitting the notification or at the latest

within 10 days after the submission. It is recommended to consult with ME in advance the specification of the sample material, its quantity and the designated laboratory. ***Methods of detection and identification*** of the genetically modified material have to be specified in the notification dossier.

Risk Assessment of the deliberate release must be carried out by the notifier and submitted to ME 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 obtaining the authorisation, the updated risk assessment should be submitted by the authorization holder every 5 years or in case substantial new information concerning the risks emerges. The authorization holder is obliged to keep records regarding 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 on the Use of Genetically Modified Organisms and Genetic Products. The risk assessment provided by the notifier / authorization holder is reviewed by the CC GMO.

Emergency Response Plan should be a part of the notification dossier. The plan is defined in the 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 updated emergency response plan has to be submitted to the Ministry of the Environment by the authorization holder every 5 years or in case of any substantial change in the release. The notifier is obliged to submit the emergency response plan 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. ME 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 it is set on case-by-case basis in individual authorisations. In the field trials approved so far this distance was 200 m for genetically modified 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 genetically modified potatoes. The trial plot has to be marked with signs clearly bearing the text "Genetically Modified Organism" or "GMO". Identification of the location is made public as described in the text of the

application (the region, municipality and the field plot identification number) with the exception of the map of the site.

The authorisation holder is responsible for ***monitoring,*** which is defined as identification of the presence of a genetic modification in organisms and products and as observation of the potential impacts of genetically modified organism or genetic product on the health of human beings and animals, the environment and biodiversity. Monitoring activities must correspond to the monitoring plan provided as a part of the notification and to any additional requirements set in the consent. 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***. The final report is required after the end of the trial and than again after the period of required monitoring of the site. The formats for these reports are available on the website of ME. The final report is required both in Czech and in English as it is submitted also to the EU database of field trials.

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

The authorisation holder is obliged to ensure proper ***labelling***. Packaging of the genetically modified organism must bear a visible label clearly stating "Genetically Modified Organism", or "This product contains a genetically modified organism" or "This product contains genetically modified organisms". This text has to appear also in the accompanying documents during the transport. The ***documentation*** on the release has to be kept at least 10 years after the authorisation expires.

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 the genetically modified seed, cultivate plants or analyse them after the harvest has to be authorised, including the company importing and transporting the genetically modified organisms. According to the Czech legislation, an authorisation for the use of genetically modified organisms 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 (approximately EUR 800) for authorisation of the deliberate release for any other purpose than placing on the market. 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, field trials have been conducted with several genetically modified (GM) crops: maize, sugar beet, oilseed rape, potatoes, and for research purposes also with flax, tobacco, pea and plum trees. 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 2010 the field trials with the following GM crops were conducted:

GM Crop	Characterization	Name of the Institutes or Companies	Total area (incl. buffer zones)
Potatoes	Modified sugar content	Institute of Experimental Botany, Academy of Sciences of the Czech Republic	0,28 ha
	Change of late blight resistance	Institute of Experimental Botany, Academy of Sciences of the Czech Republic	
Maize	GA 21 – glyphosate tolerant	Syngenta	22,52 ha
	NK 603, NK 603 x MON 810 - tolerance to herbicides containing glyphosate and resistance to corn borer	Monsanto	
	MON 88017 – tolerance to glyphosate and resistance to selected Coleopteran pests	Monsanto	
	VCO-Ø1853-3, VCO-Ø1896-1, VCO-Ø1902-7, VCO-Ø1936-5, VCO-Ø1981-5 – tolerance to glyphosate	Limagrain	

GM Crop	Characterization	Name of the Institutes or Companies	Total area (incl. buffer zones)
Plum trees Flax Tobacco Pea	Virus-resistant (small trial for research purposes)	Crop Research Institute, Prague	0,09 ha
	Various modifications (small trial for research purposes)	Agritec	0,01 ha
	Inserted fission yeast mitotic activator (small trial for research purposes)	Charles University, Prague	0,003
	Various modifications (small trial for research purposes)	Agritec	0,07 ha
Total area of field trials in the Czech Republic in 2010 was 22,9 ha			

For more details see the SNIF database: http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx or the Czech Biosafety Clearing-House http://www.mzp.cz/biosafety.

Placing on the market

Only genetically modified organisms 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 can 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 genetically modified organisms and products authorised in EU: http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm)

Requirements for ***labelling*** of these genetically modified organisms and products are set by Regulation 1830/2003.

Ministry of Agriculture is the competent authority responsible for administration of applications on placing on the market of genetically modified food and feed submitted according to Regulation (EC) No 1829/2003 on genetically modified food and feed. Since this regulation has come into force, the Czech Republic has been one of only eight EU countries, whose competent authorities received corresponding applications. In the time period 2004 – 2010, four applications were sent to Ministry of Agriculture, all of them submitted by Monsanto (once in 2005 and 2006 and twice in 2008 – one application in co-operation with Dow Agro Sciences). All four applications

concerned placing on the market of GM maize. The European Food Safety Authority (EFSA) issued its scientific opinion to three of them; one assessment has not been finished yet. The appointed Czech experts carried out environmental risk assessment of the notification on placing on the market, including cultivation, of GM maize GA 21 (herbicide-tolerant) in 2009 – 2010 on EFSA request.

The Scientific Committee on Genetically Modified Food and Feed (SCGMFF) was established in 2006 by the Ministry of Agriculture to elaborate scientific opinions to all the applications submitted for new GM food and feed in the EU and to review how EFSA deals with Member States comments to these applications. SCGMFF is an independent body, whose members are Czech experts on risk assessment, especially from the human and animal health point of view. The SCGMFF closely cooperates with the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products - a scientific advisory body of the Ministry of the Environment.

Genetically modified crops and their products on the Czech market

In line with the lists of genetically modified organisms and products authorised in EU, the following genetically modified crops are registered for placing on the market in the Czech Republic: 6 modifications of cotton, 22 modifications of maize, 3 modifications of GM oilseed rape, 3 modifications of soybean, 1 GM potatoes and 1 GM sugar beet. No official statistics exists as to the modifications and amount of GM food and feed imported, processed and consumed in the Czech Republic. However, it should be noted that the most frequent GM product available on the market is vegetable oil derived from GM soybean MON 40-3-2 1.

Regarding GM crops cultivation, Czech growers can use such GM varieties, that contain genetic modification approved at the EU level and that have been registered in the National Plant Variety Register of the Czech Republic or in the Common Catalogue of Varieties of Agricultural Plant Species of the EU.

So far only Bt maize line MON810 (resistant to the European corn borer) and GM potatoes Amflora (with modified starch content) have been authorised for cultivation in EU. Bt maize has been commercially cultivated in the Czech Republic since 2005 (see the table), GM potatoes Amflora for the first time in 2010 (total area 150 ha). The share of this two GM crops in total crop acreage remains still very limited.

GM Maize Cultivation in the Czech Republic

Year	Area in ha	Share of total maize area (%)	Number of farmers
2005	270	0,05	51
2006	1 290	0,47	82
2007	5 000	1,83	126
2008	8 380	2,91	167
2009	6 480	2,39	121
2010	4 680	1,66	82

Source: Ministry of Agriculture of the Czech Republic

Genetically modified products consumed or commercially grown in the Czech Republic do not differ from other products with regard to their potential risks for human and animal consumption or for the environment. However, special rules exist for their sale (obligatory labelling) and field production (rules of coexistence).

Coexistence concept in the Czech Republic

The concept of coexistence aims at a parallel existence of different agricultural production systems: conventional, organic and based on GM crops. The goal of this concept is to separate these systems and their products and to avoid unwanted admixtures of genetic modifications in conventional and organic products. The most critical point in the coexistence concept is the separation of GM-based systems from organic production, where the use of genetically modified organisms and their products (with the exception of pharmaceuticals) is banned. In case of unintentional mixing, organic farmers are facing not only financial loses at the output but also the impossibility to continue their certified organic production.

The coexistence concept in the Czech Republic is obligatory for every farmer growing genetically modified crop since the first year of genetically modified crop cultivation in 2005. The coexistence measures as general rules are incorporated in the Act No. 252/1997 on Agriculture, as amended in 2006 (Act No. 441/2005) and in 2009 (Act No. 291/2009). More detailed conditions for cultivation of genetically modified variety are given by the Decree No. 58/2010 (originally the Decree No. 89/2006).

In line with the mentioned legislation, the Ministry of Agriculture defines basic principles for genetically modified crops (so far for maize, potatoes and soybean) growers:

- Inform neighbouring farmers about the intention to cultivate GM crop (before sowing, for all three crops at the latest by the 1st March of the current calendar year).
- After sowing, inform about the cultivation of GM crop the neighbouring farmers (at the latest within 15 days from the beginning of cultivation), Ministry of Agriculture (within 30 days) and Ministry of the Environment (within 60 days).
- Keep minimum isolation distance of GM crop from the same crop which is not genetically modified. More stringent rules exist in case of neighbouring organic crops;

The table gives the requested crop-specific minimum isolation distances.

Minimum isolation distance	Potatoes	Maize	Soybean
Between GM and non-GM (conventional) crop of the same species	3 m; 10 m – at the edge of the field where the machines rotate	70 m	10 m
Between GM and organic crop of the same species	20 m	200 m	20 m

In case of GM maize, the minimum isolation distance can be reduced by creating buffer strips, which are formed by conventional maize planted around GM maize (1 row of conventional maize buffer substitutes 2 m of the minimum isolation distance). Conventional maize from the buffer zone must be handled and labelled as genetically modified crop;

- After the harvest, label the final product of GM crop as "genetically modified organism" or "genetically modified maize/potatoes/soybean", incl. the unique identifier for the genetically modified crop, and provide this information to the buyer/user of the final product;
- Keep a record of basic data describing the handling of the GM crop from sowing till harvest on the farm for a period of at least five years.

The Ministry of Agriculture, in cooperation with its regional agricultural agencies and the State Phytosanitary Administration, controls every year whether farmers comply with the coexistence rules. In case of non-compliance, farmers can be penalized with a fine of up to Czech Crowns 250 000 (about EUR10 000).

The Ministry of the Environment and Ministry of Agriculture register the locations where MON 810 is grown through 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 the parcels used by them – access to the system is provided through an accredited password obtainable from the corresponding Regional Agricultural Agency. Thus the maps are available to the environmental and agricultural authorities and to the farmers. In addition to LPIS, the list of locations where GM crops are grown is published annually by the Ministry of the Environment at its website.

References

Act 78/2004 on the Use of Genetically Modified Organisms and Genetic Products (amended through the Act 346/2005)

Act 252/1997 on Agriculture (amended through Act 441/2005 and Act 291/2009)

Decree 89/2006 on Conditions for Cultivation Genetically Modified Crops (amended through Decree 58/2010)

Křístková M. (2010): Experience with Bt Maize Cultivation in the Czech Republic 2005 – 2009. Ministry of Agriculture, Prague, ISBN 978-80-7084-893-7, 44 pp.

IV. Monitoring and Enforcement

Jan Káš, Marie Křístková, Martin Těhník

The **Czech Environmental Inspectorate** is the main Competent Authority on state supervision of the use of genetically modified organisms, 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
- Customs Administration in charge of export and import
- Regional Agricultural Agencies of the Ministry of Agriculture in charge of field control of crop cultivation (compliance with coexistence rules).

Five authorized detection laboratories are available for these Authorities.

The activity of the Czech Environmental Inspectorate (CEI) in the field of genetically modified organisms is defined by the Act on the Use of Genetically Modified Organisms and Genetic Products in the following paragraphs: § 27 (Competent Authorities), § 31 (Competence of CEI), § 34 (Remedial measures in case of a breach of the law) and § 35 (Penalisations for offences). Regional Inspectorates of the CEI control the institutions using genetically modified organisms in the regime of contained use both for research and production, field trials and commercial GM crops cultivation in close collaboration with the Regional Agriculture Agencies, in case of placing on the market in close collaboration with the institutions of Ministry of Agriculture and Ministry of Health. CEI inspectors may enter the plots, premises and facilities used (or supposed to be used) for handling with genetically modified organisms or GM products in case of necessity, to take samples and to control the compliance with the rules, handling conditions and the documentation. Their competence is proved with a professional identification card. For the detection and quantification of the contents of genetically modified organisms, CEI is using contracted and certified laboratories. In the period 2006 - 2010 CEI made 359 controls and monitoring, evaluated 6 public initiatives, ordered 4 redresses and imposed 13 fines.

The Czech Agriculture and Food Inspection Authority (CAFIA), an institution of the Ministry of Agriculture, is in charge of food inspections and control. The inspectors of CAFIA take samples in a wide range of places where food products are sold (from small shops to hypermarkets). Until 2010 the samples were analyzed in CAFIA laboratory located in Brno. This certified laboratory, belonging to the Department of Molecular Genetics, analyzed food raw materials and products (e.g. soybeans, maize, and rice) for the presence of GM material in an amount of about 200 food samples per year. It was a member of the Czech network of GMO laboratories (CNGL) and European network of GMO laboratories (ENGL). The laboratory was closed at the end of 2010. The samples of GM food and feed are now analyzed in the National Reference Laboratory for GMOs Testing of the Crop Research Institute, Prague.

The Central Institute for Supervising and Testing in Agriculture (CISTA), an institution of the Ministry of Agriculture, is in charge of controlling seeds and feed. Its laboratory, a member of CNGL and ENGL, analyses about 150 samples per year of soybeans, maize, rapeseed, rice and potatoes.

The State Veterinary Administration, a supervision institution under the Ministry of Agriculture, is responsible for inspection of genetically modified organisms of animal origin. Its laboratory located in town of Jihlava, is a member of CNGL and ENGL. As no need has existed so far regarding testing of genetically modified organisms of animal origin, the laboratory has tested mainly GM plants used as feed for animals.

The State Institute for Drug Control, institution of the Ministry of Health, is charged by testing and controlling pharmaceutical products.

The Customs Administration, under the Ministry of Finance, is charged by control of transboundary movements of genetically modified organisms. Their obligations have been limited since the Czech Republic accession to the European Union and its inclusion into the Schengen area. These facts led to abolishing of regular customs controls at the border crossing points. The inspection as to genetically modified organisms is now focused on airports, mainly the international Prague airport. The taken samples are analyzed in the accredited laboratories collaborating directly with the Ministry of the Environment.

The Ministry of Agriculture, in cooperation with its Regional Agricultural Agencies and the State Phytosanitary Administration, controls commercial planting of GM crops, this means Bt-maize MON 810 (since 2005) and potatoes Amflora (only in 2010). The controls are focused on compliance with the coexistence rules. So far the authorities are not aware of any illegal cultivation of genetically modified crops in the Czech Republic.

Laboratories cooperating on the basis of contracts with the Ministry of the Environment

The National Institute of Public Health (belonging to the Ministry of Health) is the institution charged by monitoring genetically modified organisms in food and commodities. The laboratory of its Department for Food Safety and Nutrition in Brno, which is a member of CNGL and ENGL and serves as a reference laboratory of the Ministry of the Environment, is analyzing about 200 samples per year (e.g. soybeans and soy products, maize flour, rice, potatoes, tomatoes, papaya). The results are published in the journal Acta Alimentaria. The laboratory important function is to collect and keep reference standards (GMO bank) for the Czech Republic. This collection has now more than 150 samples. The laboratory participates in the international project Genomon focused on evaluation of health risks of genetically modified organisms used for food production.

The National Reference Laboratory for GMOs Testing and DNA Fingerprinting of the Crop Research Institute, Prague is focused on the detection and determination of genetic modification in plants and derived products. It prepares expert reports for the Ministry of Agriculture in the field of genetic modifications. The laboratory carries out national and international comparative tests and coordinates research related to genetically modified organisms testing. Among other activities, the laboratory elaborated a system of sampling *in situ*. The head of the laboratory represents the Czech GMO laboratories in the European Network of GMO Laboratories (ENGL).

The Controlling Laboratory of the Department of Biochemistry and Microbiology of the Institute of Chemical Technology, Prague is concentrated on detection and quantification of plant genetic modifications (e.g. maize, soybeans and products from them) and also on genetically modified microorganisms. It participates in various research projects (e.g. genetic modifications of microorganisms and plants for remediation) and in education at all three university levels (Bachelor, Master and Doctoral programmes). It closely cooperates with the National Reference Laboratory in joint research projects and in supervising diploma and PhD theses.

Common characteristics of the described GMO laboratories

All described laboratories are officially accredited and they regularly participate in inter-laboratory tests. Their equipment with modern technique enables use

of internationally recognized methods based on a classic and Real Time PCR, accompanied with other techniques, e.g. unified sampling and homogenization of samples before analysis. The implementation project of UNEP/GEF partly contributed to the unification of the procedures used and to improvement of laboratory equipment. The methods used are validated with official reference materials. All these laboratories are regular members of ENGL since the accession of the Czech Republic to the European Union (May 2004). Before that, some laboratories had the status of observers. They participate in the activities of ENGL either directly (e.g. in validation studies) or through their representatives.

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V. Public Awareness, Participation and Education

Milena Roudná

In the Czech Republic, the right to information in general is based on the Act 106/1999 on Free Access to Information (within State administration; later amended in 2006) and the Act 123/1998 on the Right to Environmental Information (later amended through the Act 132/2000 and Act 6/2005). The information can be requested through phone or in a written form through classical post or e-mail.

The Czech Republic is also a Party to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (signature on June 25, 1998 in Aarhus, ratification on July 6, 2004), as well as to its Amendment on Public Participation in Decisions on the Deliberate Release in the Environment and Placing on the Market of Genetically Modified Organisms (ratification – adoption on January 29, 2008).

As to environmental information the Act 123/1998 allows certain restriction due to protection of confidential data, personal data, intellectual property rights or commercial information. Report on the Environment, published each year, represents the regular source of updated environmental information of the Czech Republic. The Report presents information based on statistic data on important spheres of the environment, as air and water quality, waste management, nature conservation and landscape protection, environmental risks, including natural and man-made disasters.

The Act on the Right to Environmental Information includes also a special paragraph (§ 13) on the Environmental Education and Public Awareness. It charges State administration bodies to develop environmental education and awareness and to inform and educate their employees in environmental matters. The Ministry of the Environment and Ministry of Education, Youth and Physical Training in cooperation with other central offices, as well as regional and local administration centres are obliged to support environmental education and awareness based on sustainable development principles. The Ministry of the Environment prepares the State Programme on Environmental Education and Awareness (adopted by Government in 2000), the official document for environmental education in general. The actions are specified in more details and updated in the Action Plan (since 2001), originally regularly updated for a 2-year period, now for a 3-year period (last Action Plan adopted in 2009 for the period 2010 – 2012). The Ministry of the Environment as the main actor cooperates with the Ministry of Education in this field. The Ministry of Education has responsibility as to

integration of environmental education into basic official documents on education and as to support of teachers education in environmental matters. Regional authorities elaborate regional conceptions of environmental education on the basis of the State Programme and organize consultation on environmental matters. State authorities can establish special funds to support environmental awareness and education.

The commitments as to information on genetically modified organisms and their use are done by the Act 78/2004 on the Use of Genetically Modified Organisms and Genetic Products. 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 genetically modified organisms provided to the public correspond with the information required by EU 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 genetically modified organisms 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.

Ministry of Agriculture publishes on its website information regarding GM crops cultivation and food and feed products. The information on this website http://eagri.cz is available both in Czech and in English, in its sector Agriculture (co-existence principles and data) and Food Industry.

The information sharing and education in biosafety matters is to be considered as an integral part of environmental education in a broader sense. The reasons are purely logical but as well practical (especially at present period with restricted financial sources and cutting of the State budget). In this respect the cooperation with universities, schools, centres for environmental education and other similar institutions is an asset. Presentation by specialists, publications in language comprehensible for a target group of readers and other type of printed information, posters presented at conferences, workshops and public events are ways of a broader information sharing, enabling better contact with media as well.

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Project UNEP/GEF and its Importance in Enforcement of the National Biosafety Framework

Milena Roudná

UNEP/GEF projects played an important role in development of the National Biosafety Framework of the Czech Republic. This regards the following projects: Development of the National Biosafety Framework for the 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). Certain supporting activities were developed also within the project Access to Genetic Resources and Benefit-sharing, Conservation and Sustainable Use of Biodiversity (2004 - 2006).

In the period 2002 – 2004 the first project focused on assessment of the existing national capacity in development of Biosafety Framework 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).

During the implementation project (2006 – 2011), measures adopted in the preceding years were implemented and even enhanced. These cover the following **five spheres - 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 required processes were supervised by the Ministry of the Environment as the National Executing Agency. National Coordinating Committee (NCC) assisted in coordination of scheduled activities. It consisted 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, 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 was partly co-financed 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 (http://www.mzp.cz/biosafety), whereas Ministry of the Environment website (http://www.mzp.cz – Environmental Risks – GMOs) offers information in Czech language.

The UNEP/GEF Implementation Project principally aimed at and resulted in:

- Integration and regular updating of biosafety principles into relevant national strategies and policies in compliance with the Cartagena Protocol on Biosafety (CPB).
- Functional regulatory regime amended in line with the CPB processes, newest development, national needs and priorities.
- Functional administrative system for handling notifications, Environmental Risk Assessment, system for emergency response and mechanism for public involvement in decision-making process.
- Improvement of laboratory monitoring corresponding to scientific achievement, methodology and technical standards, enhanced collaboration with ENGL.
- Improvement of system for enforcement of compliance with biosafety regulations.
- Enhancement of system of public access to information, education and participation in decision-making process.

Numerous activities have been developed in the sphere of capacity building, education and public awareness, in the form of specially focused meetings, thematic workshops and trainings (list of workshops annexed). Publications with general information on biosafety issues as well as those focused on special topics, both in Czech (mostly with English summary) and some in English were edited (list of publications annexed).

Education and public awareness have been developed 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 were 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. During this meeting generally training for users of genetically modified organisms is organized on conditions for use, the most frequent inaccuracies in dossiers presented and on changes in adopted measures.

From above mentioned organizations, cooperation with the Centre for Environmental Education and Ethics was greatly enhanced. This Centre is a part of a broader network of environmental education centres (about 40 in total) working in different parts of the Czech Republic. With its headquarters in the East Bohemia and three affiliated centres, this institution focuses its activity on educational environmental programmes and ecological projects for primary and secondary schools, as well as on courses during weekends. For teachers and other educators it develops educational activities, courses and offers consultations, publications and other printed information. The Centre organizes special courses for other groups of society, such as farmers, officials etc. Different cultural actions and consultation on various local environmental problems are focused on public in general. On the other hand, the representatives of the Centre cooperates with higher administrative bodies such as ministries as members of committees and on the basis of their experience contribute to important environmental documents and to journals on environmental education.

In line with the world trend, also the Czech Republic prepares plans on network of modern visitors centres, so called Houses of Nature, to be constructed in Nature Protected Areas. Their construction need to respect low energy principles, with the use of local construction material. The main exposition will reflect local landscape development and influence of man activities. Also such centres can serve in future for dissemination of information on biosafety principles in cooperation with Protected Areas administration.

On the basis of experience gained in implementation of the UNEP/GEF projects, the following steps can be recommended to enhance public awareness and education at national level:

- Cooperation and coordination among authorities, institutions, civil society, NGOs, private sector – to promote synergies and networking at national level.
- Direct contact with schools and centres for environmental education – young people as a key target group.
- Publications tailored to target audiences and written in easy-to-understand language.

- Internet use.
- Government support as an important asset.
- Exchange of experience at regional and sub-regional levels.
- Cooperation with corresponding international organizations and institutions.

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Šoltysová L.: Public Information and Education – Integration into Nature Conservation Activities. Manuscript, 2011, 3 pp. (in Czech)

ANNEXES

I. Workshops organized within the UNEP/GEF Projects

2003

Risk Assessment and Risk Management
Institute of Chemical Technology, February 13, 2003, Prague
Sub-regional Meeting on Biosafety Framework
Ministry of the Environment and Institute of Chemical Technology,
April 24-25, 2003, Prague
Genetically Modified Organisms and Preparation of the National Biosafety Framework
Ministry of the Environment and Masaryk University, Brno, May 28, 2003, Brno
Genetically Modified Organisms and Preparation of the National Biosafety Framework
Ministry of the Environment and Palacký University, Olomouc, May 29, 2003, Olomouc
Genetically Modified Organisms and the Cartagena Protocol
Institute of Chemical Technology, September 23, 2003, Prague
Genetically Modified Organisms in Agriculture and Food Production
Ministry of Agriculture, Institute of Chemical Technology and Institute of Crop Production, October 30, 2003, Prague

2004

Issues of Biosafety, Genetically Modified Organisms and International Commitments of the Czech Republic
Research Institute of Crop Production, February 18, 2004, Prague
Genetically Modified Organisms and National Biosafety Framework for the Czech Republic
Faculty of Sciences, Charles University, February 25, 2004, Prague (seminar for students)
Final Workshop – Presentation of the Project Results
Ministry of the Environment and Institute of Chemical Technology,
March 23-24, 2004, Prague

2006

Joint UNEP/GEF Biosafety Inception Workshops – Czech and Slovak Republics
Ministry of the Environment, November 8-9, 2006, Prague

2007

Genetic Modifications and Biosafety Framework
Ministry of the Environment and Scientific-Technical Society, October 8, 2007, Prague

2008

Workshop for Teachers (training)
Centre for Environmental Education and Ethics, January 2008, Rýchory, Eastern Bohemia
News from Genetic Modifications Field
Institute of Chemical Technology and National Coordinating Committee (NCC), May 28, 2008, Prague
Project UNEP/GEF: Building Capacity for Effective Participation in the Biosafety Clearing-House - Final Workshop of the BCH Project
Ministry of the Environment., December 9, 2008, Prague

2009

News from Genetic Modifications Field
Institute of Organic Chemistry and Biochemistry, Institute of Chemical Technology and NCC, April 28, 2009, Prague,
Biotechnology in Forestry and Examples of its Use
Ministry of the Environment, May 7, 2009, Prague
Workshop for Educators
Centre for Environmental Education and Ethics, Krkonose, Eastern Bohemia, June 29 - July 3, 2009

2010

Use of Genetically Modified Organisms in the Czech Republic and Public Awareness
Ministry of the Environment in cooperation with Scientific-Technical Society January 28, 2010, , Prague
Workshop on activities of the Centre of Environmental Education and Ethics – cooperation with the UNEP/GEF Project and NCC Meeting
April 1-2, 2010, Krkonose, Eastern Bohemia,
News from Genetic Modifications Field
Institute of Chemical Technology and Biotechnological Society, May 15, 2010, Prague,
New Technology and Biodiversity Conservation
Within the Ministry of the Environment series of workshops organized on the occasion of the 2010 IYB, May 26, Prague

International Year of Biodiversity – UNEP, its Activities and Projects on Biodiversity and Biosafety
Meeting/Workshop for public, May 29, 2010, Jicin, Eastern Bohemia
Biotechnology in Forestry II.
Ministry of the Environment, June 2, 2010, Prague
Genetic Resources – Biosafety Principals and Risks of Genetic Erosion
In cooperation with Scientific-Technical Society, June 10, 2010, Prague,
International Year of Biodiversity – Related Projects and Programmes
In cooperation with Scientific-Technical Society, November 2, 2010, Prague
Genetically Modified Organisms and Biosafety Measures
In cooperation with University and Centre for Agricultural Research, November 3, 2010, Olomouc, Northern Moravia
Nature Diversity Conservation and Role of International Organizations
In cooperation with local organizations, November 26, 2010, Eastern Bohemia (workshop for public)
Nature Diversity Conservation and 2010 International year of Biodiversity
In cooperation with local authority, November 27, 2010, Northern Bohemia (workshop for public)
UNEP/GEF Project – Final Workshop
In cooperation with Scientific-Technical Society, November 30, 2010, Prague (workshop both for experts and a wider public)
Czech Commission on the Use of Genetically Modified Organisms and Genetic Products – Open Meeting + Instruction Meeting for Applicants on Request
In cooperation with Institute of Chemical Technology, December 2, 2010, Prague (meeting open to wider public)
Workshop on Food Safety
Organized by Centre for Environmental Education and Ethics, December 1, 2010, Trutnov, Eastern Bohemia. (Workshop for public)
Questions about Genetic Modifications
Workshop organized by Centre of Environmental Education and Ethics, December 13, 2010, Trutnov, Eastern Bohemia. (Workshop for public)
Questions about Genetic Modifications
Workshop organized by Centre for Environmental Education and Ethics, December 14, 2010, Hradec Králové, Eastern Bohemia. (Workshop for public)

2011

Possibilities of Genetic Modifications Use and Biosafety Measures
In cooperation with Scientific-Technical Society, March 24, 2011, Prague.

Outcomes and Experience of the UNEP/GEF Project on Biosafety Implementation
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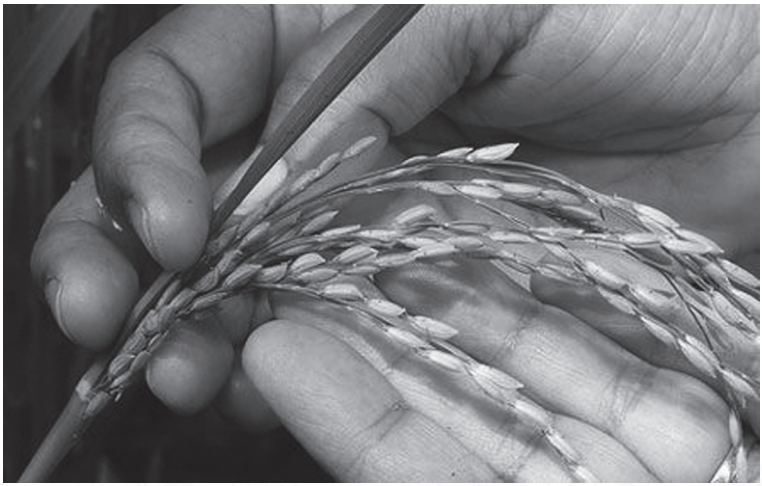

*As biotechnology techniques and approaches result in the creation of **genetically modified organisms** that can be potentially harmful to the environment and human health, the part of biotechnology that deals with genetically modified organisms is strictly regulated by biosafety laws and guidelines.* (FAO Biosafety Resource Book, 2011)

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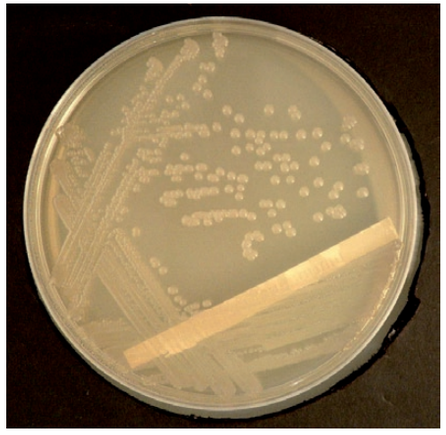


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