



Jan Káš and Milena Roudná

NATIONAL BIOSAFETY FRAMERWORK FOR THE CZECH REPUBLIC



MINISTRY OF THE ENVIRONMENT
PRAGUE, MARCH 2004

**NATIONAL BIOSAFETY FRAMERWORK
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**Jan Káš and Milena Roudná
(Editors)**

**Ministry of the Environment
Prague, March 2004**

UNEP-GEF Project „Development of the National Biosafety Framework for the Czech Republic“

started in July 2002 and ended in March 2004.

National Executing Agency for the project was:

Ministry of the Environment,

Vršovická 65, 100 10 Prague 10

contact person:

Milena Roudná

Global Relations Department

Tel: + 420 267122769, Fax: + 420 267311949, e-mail: roudna@env.cz

National Project Coordinator was:

Prof. Jan Káš

Institute of Chemical Technology

Technická 3, 166 28 Prague 6

Tel: + 420 224353018, Fax: +420 233333726, e-mail: Jan.Kas@vscht.cz

National Coordination Committee consisted of 16 members, representing:

Ministry of the Environment, Ministry of Agriculture, Ministry of Health, Ministry of Industry and Trade, Ministry of Finance – Directorate General of Customs, Czech Environmental Inspection, universities and sectoral research institutes, private sector, non-governmental organizations and civil societies (Annex 1).

Report “National Biosafety Framework for the Czech Republic” was prepared within the Project UNEP/GEF.

Editors:

Milena Roudná, Jan Káš

Contributors:

Zuzana Doubková, Jaroslav Drobník, Ivan Branžovský, Tomáš Mařík, Martin Těhník, Martin Šindelář, Karel Říha, Miroslava Navrátilová, Radomír Belza, Josef Petráš, Jiří Ruprich, Milan Šmíd, Pavel Polák, Slavomír Rakouský, Miloš Němec, Jaroslava Ovesná, Kateřina Demnerová, Marie Čerovská and Josef Soukup, Miroslav Večeřa

Technical Assistance:

Karolína Pavlíčková

Consultations:

UNEP/GEF Biosafety Unit, Geneva (Christopher Briggs, Andrea Gondová / Liina Eek)

UNEP/GEF Biosafety Unit – Division of GEF Coordination, Nairobi (Lydia Eibl-Kamolleh)

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Acronyms and Abbreviations

UN	United Nations
UNEP	United Nations Environment Programme
GEF	Global Environment Facility
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
COP	Conference of the Parties
NFP	National Focal Point
CHM	Clearing House Mechanism
BCH	Biosafety Clearing House
LMO/LMOs	living modified organism/living modified organisms
GMO/GMOs	genetically modified organism/genetically modified organisms
NCC	National Coordinating Committee
NEA	National Executing Agency
NPC	National Project Coordinator
NGO/NGOs	non-governmental organization/non-governmental organizations
MoE	Ministry of the Environment
MoA	Ministry of Agriculture
MoH	Ministry of Health
MoIT	Ministry of Industry and Trade
CC GMOs	Czech Commission for the Use of Genetically Modified Organisms and Products
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
OECD	Organization for Economic Cooperation and Development
ECE	Economic Commission for Europe
FAO	Food and Agricultural Organization
WHO	World Health Organization
WTO	World Trade Organization
WIPO	World Intellectual Property Organization
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNCED	United Nations Conference on Environment and Development (Rio de Janeiro 1992)
WSSD	World Summit on Sustainable Development (Johannesburg 2002)

Important Websites

<http://www.biodiv.org/biosafety>

<http://bch.biodiv.org>

<http://www.unep.org>

<http://www.unep.ch/biosafety>

<http://gefweb.org>

<http://www.env.cz>

<http://gmo.vscht.cz>

<http://www.biotrin.cz>

Information on other websites in corresponding parts of the Report.

Foreword

More than ever before we are today aware of the widespread effects of human activities on our environment. Environmental changes acquired new global dimensions, which can be illustrated by climate change, depletion of the stratospheric ozone layer or loss of biodiversity. And this is why the topmost environmental meeting - World Summit on Sustainable Development - discussed the last global changes and set up priorities for actions, among them to achieve by 2010 a significant reduction in the current rate of loss of biological diversity.

An important part in biodiversity conservation represents efforts aiming at enhancement of biological safety and thus addressing novel and controversial issues. Adoption of the Cartagena Protocol on Biosafety in January 2000 was a great historic event and end of a very complicated negotiation period. At the same time it was a beginning – the beginning of an implementation process which will determine whether the results of complicated negotiations achieve the objective evoking originally the whole process. For this reason, the United Nations Environment Programme (UNEP) jointly with the Global Environment Facility (GEF) launched in June 2001 a new challenging project “Development of National Biosafety Framework”. Using a country-driven process, this project has been designed to help more than 100 countries all over the World to set up their national framework for management of living modified organisms and thus prepare conditions for the Cartagena Protocol ratification and consequent implementation. The UNEP thus proved its important role in global efforts to avoid a long-term environmental degradation.

I wish that activities initiated during the Project can be further developed to meet international commitments at national level and to promote regional and global cooperation without which the biosafety cannot be ensured. Closing of the Project coincides in the Czech Republic with the entry into force of a new Act on Genetically Modified Organisms and Products which prepares conditions for the Cartagena Protocol implementation as well as for a more intense regional cooperation, being compatible with the EU legislation in biosafety field.

Libor Ambrozek
Minister of the Environment

“Biotechnology could contribute significantly to the achievement of the objective of the Convention on Biological Diversity and the attainment of the Millennium Development Goals. However, it must be developed judiciously, and used with adequate and transparent safety measures.”

United Nations Secretary-General Kofi Annan

Information on the Project Development

The Czech Republic joined the UNEP/GEF Project “Development of the National Biosafety Framework” since July 1, 2002, with supposed duration of 18 months. The National Co-ordinating Committee was established, consisting of representatives of biosafety related sectors and institutions, Czech Commission for the Use of Genetically Modified Organisms and Products, non-governmental organisations and private sector. Prof. Jan Káš, Institute of Chemical Technology, was nominated National Project Co-ordinator. As the National Executing Agency was selected the Ministry of the Environment. Its Environmental Risks Department guaranteed technical aspects of activities (contact person Mrs. Zuzana Doubková), contact person of the Ministry of the Environment was Mrs. Milena Roudná, Global Relations Department.

The Czech Republic signed the Cartagena Protocol on Biosafety on May 24, 2000, during the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity in Nairobi, Kenya, when it was open for signature for the first time. The Czech Republic belongs to the first Parties to the Convention on Biological Diversity ratifying the Cartagena Protocol - on October 8, 2001, as the seventh country in this process. These acts were prerequisite for joining the UNEP/GEF Project.

The Project has been developed according to the UNEP/GEF rules as to its content and timing of actions, only the last part was extended due to certain administrative problems. A great attention was paid to elaboration of surveys in which experts from different spheres participated. Several workshops were organized for different groups of stakeholders - specialists, environmental inspectors and also public, in different country regions, including one Sub-regional Meeting of specialists in April 2003 in Prague.

Experts from the Commission for the Use of Genetically Modified Organisms and Products represent important partners in the Project implementation in the Czech Republic. The Commission was established as an advisory body at the Ministry of the Environment in January 2001. Its members are professionals representing administrative authorities, Academy of Sciences of the Czech Republic, universities and civil associations.

The Report on the Project is structured according to the UNEP/GEF proposed format into 5 main chapters:

1. Description of the national biosafety policy, its priorities, relations to sectoral policies and strategies, mainly State Environmental Policy. Information on status of ratification of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety by the Czech Republic.
2. Description of regulatory regime, principal acts related to biosafety and main decrees in force, institutions responsible for their implementation. Information on a new Act on Genetically Modified Organisms and Genetic Products.
3. System to handle notifications or requests for authorisation of certain activities, competent authorities.
4. Systems for enforcement and monitoring of impacts on the environment and human health, responsible institutions.

5. System and measures to enhance public education, awareness and participation, relation to national strategic documents, competent authorities. Basic information on the Biosafety Clearing-House, related websites. Future goals and mechanisms to achieve them.

We would like to thank all who contributed to the development of activities within the Project and their evaluation, as well as Czech authorities and institutions for their support, especially the Ministry of the Environment and the Institute of Chemical Technology. The Project could not be initiated and developed without valuable assistance of the UNEP/GEF Biosafety Unit in Geneva and UNEP/GEF specialists in Nairobi, whose consultations helped to overcome many procedural difficulties. Three UNEP/GEF regional meetings (Nitra, February 2002, Vilnius, May 2003, Antalya, December 2003) offered opportunity for meeting of national project coordinators and their collaborators and for mutual discussion on development of required activities. By closing the project we would like to remember kind understanding and collaboration of many individuals, mainly members of the National Coordinating Committee, Czech Commission for the Use of Genetically Modified Organisms and Products, collaborating experts and representatives of institutions involved in monitoring and control activities, universities (Palacký University Olomouc, Masaryk University Brno, South Bohemian University České Budějovice, Charles University Prague), research and governmental institutions (Research Institute of Crop Production, State Institute of Public Health, Institute of Agriculture and Food Information, etc.) as well as non-governmental and civil organisations (Biotrin, Czech Biotechnology Society, Society of Organic Farming, etc.). All these enthusiastic collaborators helped to collect valuable data and information, organize workshops and training courses at a low costs and to prepare publications. This joint effort enable to organize more public activities than originally intended.

The Project has helped to establish the basis for the Cartagena Protocol implementation in the Czech Republic on which further processes should be developed. The second – implementation phase of the Project, if recommended and adopted, would greatly support these activities.

Jan Káš and Milena Roudná

1. Biosafety Policy

In compliance with the Cartagena Protocol on Biosafety, the Czech Republic biosafety policy is based on precautionary principle and forms a part of wider policies and strategies, especially:

- **State Environmental Policy**
The last version of the Environmental Policy, so far in force, was adopted by the Government in 2001. An updated Environmental Policy is being prepared for adoption by the Government in 2004. The State Environmental Policy is a basic document which formulates policy principles in favour of the environment, not only in environmental, but also in other sectors, such as agriculture, energy, raw materials, transport, etc. It forms basis for more detailed programmes dealing with specific environmental issues. These programmes set up targets, responsibilities and deadlines. One of the main priority of the present period is to harmonize the environmental policy and its individual spheres with these of the EU. The Policy aims at: achieve improvement in the quality of the environment, implement principles of sustainable development, introduce economic aspects into environmental protection, enhance environmental education and public awareness.
- **Strategy of Sustainable Development of the Czech Republic**
Strategic, cross-sectoral document, which covers all three pillars of sustainable development, i.e. environmental, economic and social ones, as well as aspects of good governance. It reflects major international documents related to these three major spheres, including outcomes of the World Summit on Sustainable Development. It corresponds also to requirements at European level, especially EU Sustainable Development Strategy. The Strategy is presently under preparation.
- **State Nature Conservation and Landscape Protection Programme of the Czech Republic**
The Programme analysis the current status of nature and landscape, trends in its development and measures so far used. On the basis of this analysis it sets up the main aims and principles of nature conservation policy. The Programme was adopted by the Government of the Czech Republic in June 1998.
- **Strategy of Food Safety in the Czech Republic**
The Strategy was adopted by the Government of the Czech Republic in December 2001. It was elaborated on the basis of recommendation of the Food and Veterinary Office with the aim to improve mainly control management in this sphere. The Minister of Agriculture was charged by coordination of all activities regarding food safety, which refers to the sector of agriculture, health, the environment, industry and trade, interior, transport and communication, finance and State Office for Nuclear Safety. The Strategy has been harmonized with the White Book on Food Safety, Action Plan on Health and the Environment (adopted by the Government in 1998) and with the strategic document Health for the 21st Century. The Strategy set the following main tasks: to establish inter-sectoral coordination committee and to inform the Government on the system of food safety in the Czech Republic, including implementation of the respective legislation. The last 2003 report summarizes activities in the framework of the Strategy, including those related to biosafety.

Important tool to implement national biosafety policy represents national legislation. Until February 2004 it was especially the *Act 153/2000, on the Use of Genetically Modified*

Organisms and Products and Amendment of Some Related Acts, which entered into force on January 1, 2001. The new *Act 78/2004, on Genetically Modified Organisms and Genetic Products* transposing the provisions of the corresponding EU Directives and the provisions of the Cartagena Protocol not implemented by above mentioned Act was adopted at the beginning of 2004 and comes into force on February 25, 2004. Referring to food safety, principally the *Act 110/1997 on Food and Tobacco Products* defines conditions for labelling and distribution.

The principles applied on the basis of these strategic and legislative documents range the Czech Republic among relatively developed countries in this field. Research institutes, developing their activities since seventies of the twentieth century, and their experience serve as a good background for biosafety measures in the Czech Republic.

The main goals of the national biosafety policy of the Czech Republic can be defined as to:

- Develop National Biosafety Framework and all its components, i.e. legislation, administration, information sharing, education, public awareness and participation. Especially inspection and control represent parts of the system needed to be strengthened.
- Ensure a highest possible level of biosafety in transfer, handling and use of genetically modified organisms which may have adverse effects on conservation and sustainable use of biological diversity, taking into account risks to human health, on the basis of precautionary principle.

To these goals also the Czech Republic international cooperation and engagement contribute. The Czech Republic is a Party to the majority of international conventions and protocols related to biodiversity and biosafety, especially: Convention on Biological Diversity and Cartagena Protocol on Biosafety, Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), Convention on Wetlands of International Importance Especially as Waterfowl Habitat (Ramsar Convention), Convention on the Conservation of Migratory Species of Wild Animals (Bonn Convention), Convention on the Conservation of European Wildlife and Natural Habitat (Bern Convention), Convention concerning the Protection of the World Cultural and Natural Heritage, United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and / or Desertification, Particularly in Africa.

The Czech Republic ratified already the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade and the Stockholm Convention on Persistent Organic Pollutants.

The ratification process regarding the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the thirty-first Session of the FAO Conference in November 2001 was recently finished (approved by the Parliament) and the instrument of ratification will be deposited in a near future.

The Czech Republic cooperates very closely with UNEP, IUCN (State member), as well as Council of Europe, Economic Commission for Europe and OECD in environmental issues, especially those related to biodiversity. It is a member country of the FAO (succession in 1993 after splitting of the former Czechoslovakia) as well as of the WTO (since its establishment in January 1995). So far the Czech Republic has belonged to the group of CEE countries. Nevertheless, as an accession country, it follows the main principles of EU group of countries in international negotiations.

In the nearest forthcoming period the priorities of the national biosafety policy will consist in:

- Cooperation and involvement in activities of international organizations in the field of biosafety.
- Participation in development and implementation of the EU biosafety principles.
- Formulation of principles of safe handling and use of genetically modified organisms as a part of the State Environmental Policy.
- Information sharing and public awareness in the field of genetic modifications.

2. Regulatory Regime

The environmental legislation in general has been developed in the Czech Republic mainly since the beginning of the ninetieth of the twentieth century, after revolutionary changes in the former Czechoslovakia. Only after them the protection of the environment could get legal basis, connected with structural changes in industry and economy. At the same period the Czech Republic became the Party to major part of international environmental conventions, the implementation of which required again national legal basis.

Until February 2004 the main Act dealing explicitly with genetically modified organisms was: Act 153/2000, on the Use of Genetically Modified Organisms and Products and Amendment of Some Related Acts

Adopted on May 10, 2000, it entered into force on January 1, 2001, under jurisdiction of the Ministry of the Environment.

The Act described obligations of persons handling with and using genetically modified organisms, as well as competence of administrative authorities (issuing authorisation, inspection, control). It included also principles of information sharing, public awareness and participation. The Act was based on the precautionary principle in compliance with the EU regulations, international conventions and protocols and international organisations, with the aim to protect human and animal health, the environment and biological diversity.

The Act covered genetically modified organisms capable of replication and products thereof containing such organisms. The Act regulated:

Contained use (especially scientific research in medicine, biology and microbiology), introduction into the environment and placing on the market (field trials, selection/breeding of agricultural crops and seeds, cultivation, import and processing of agricultural commodities). On the basis of this Act the corresponding parts (referring to genetically modified organisms) of the following Acts were amended:

Act 219/2003, on Varieties, Seeds and Seedlings of Cultivated Plants

Act 79/1997, on Medicines, Amending and Supplementing Some Other Related Acts.

Consequently, after entry into force of the Act, the following legislation was amended:

Act 110/1997, on Food and Tobacco Products, Amending and Supplementing Some Other Related Acts

Act 91/1996, on Feed

Act 147/1996, on Phytosanitary Measures, Amending and Supplementing Some Other Related Acts.

The Act was also related to the Act 242/2000, on Organic Farming.

As a result of relatively rapid recent development in the field of genetic modifications and their regulations, as well as the Czech Republic approaching accession to the European Union and ratification of the Cartagena Protocol, the new **Act 78/2004, on Genetically Modified Organisms and Genetic Products** was adopted, which **entered into force on February 25, 2004**. In general, its scope is similar to this of the Act 153/2000. The changes regards the following procedures:

- Authorization for the use of genetically modified organisms
- Necessary steps in case of getting new information or changes in GMOs handling
- Public information and public participation
- Transport, import and export of GMOs
- Labelling and traceability
- Competence and cooperation among administrative authorities, especially as to control

- Liability and penalties
- Relation to existing legislation
- Communication with the European Commission
- Entry into force of certain regulations in relation to the CR accession to the EU.

The new Act prepares conditions for the Cartagena Protocol implementation in the Czech Republic. To be fully compatible with the recent EC legislation, an amendment of this Act has been proposed and is under process of negotiations.

Three Decrees of the Ministry of the Environment were related with the Act 153/2000:

- Decree 372/2000 – on technical conditions and methods for creation of GMOs
- Decree 373/2000 – on conditions for contained use
- Decree 374/2000 – on details in handling with GMOs and products (risk assessment, required documentation, formats for notifications).

Relating to adoption of the new Act 78/2004, only one Decree of the Ministry of the Environment will regulate detail conditions. Provisions of the existing Decree 372/2000 become part of Annexes to the new Act.

Other related Acts

Act 110/1997, on Food and Tobacco Products, Amending and Supplementing Some Other Related Acts

The Act is in force since 1997, under the jurisdiction of the Ministry of Agriculture.

The Act prescribes obligations of entrepreneurs in production of food and tobacco products and in their placing on the market, as well as supervision on compliance. During the last years the Act was amended several times, e.g. through the Act 306/2000 or Act 146/2002 (the Act on the State Agricultural and Food Inspection).

Several articles deals also with GMOs, especially with reference to food safety, packaging and labelling, and also conditions for placing on the market. The Act defines competences of the Ministry of Agriculture and Ministry of Health in this respect.

Decree of the Ministry of Agriculture 24/2001, which Amends Decree of the Ministry of Agriculture 324/1997, on Labelling of Food and Tobacco Products, on Tolerated Deviation of Product Quantity

Decree prescribes technical details regarding labelling (additives, aromatics, GMOs).

Act 146/2002, on State Agriculture and Food Inspection, Amending and Supplementing Some Other Related Acts

The Act was adopted in 2002 under the Ministry of Agriculture.

It establishes the State Agriculture and Food Inspection and defines its competence.

Act 91/1996, on Feed

The Act was adopted already in 1996, under the jurisdiction of the Ministry of Agriculture.

It regulates conditions for export, import, transport, use, packaging, labelling and placing on the market of feed. It defines also competence of control organs. Some articles refer to GMOs. The Act does not cover veterinary products and pharmaceuticals for humans.

The Act was amended through the Act 244/2000, Act 147/2002 and Act 320/2002.

A new amendment of this Act is under preparation.

Decree of the Ministry of Agriculture 451/2000, Implementing Act 91/1996, on Feed § 19 and §20 prescribe procedure of registration of producers, importers and distributors, and refer also to GMOs.

Act 219/2003, on Marketing of Seed and Planting Material of Cultivated Plants

Relatively recent Act of the Ministry of Agriculture, in force since September 2003.

It regulates marketing of seeds and plants for cultivations, registration of varieties and supervision on compliance. It does not refer to plants for research, selection of new varieties and conservation of biodiversity, and to forest species for reproduction. Some articles deal with genetically modified plants (crops).

Decree of the Ministry of Agriculture to this Act specifies technical details on labelling, field planting, registers and samplings.

Act 147/1996, on Phytosanitary Measures, Amending and Supplementing Some Other Related Acts

The Act in force since 1996, under the jurisdiction of the Ministry of Agriculture.

It prescribes conditions for the Czech Republic protection against pests, manipulation with herbicides and pesticides and it establishes control organs. Several articles refer also to GMOs.

Act 242/2000, on Organic Farming and Amendment of Act 368/1992, on Administrative Fees

Under jurisdiction of the Ministry of Agriculture, adopted in 2000.

Among others, the Act deals in its part 2, § 10 with restriction of negative impacts to organic farming. This regards also exclusion of GMOs cultivation and use of GMOs and products thereof (with exception of pharmaceuticals for humans as well as for veterinary purposes).

Act 166/1999, on Veterinary Care, Amending Related Acts (Veterinary Act)

The Act was adopted in 1999, under jurisdiction of the Ministry of Agriculture.

It sets up regulations in care for animals, their transfer, prevention and protection against infections, protection of the environment in relation to animal breeding. It sets up veterinary supervision.

Act 154/2000, on Breeding and Registration of Domestic Animals, Amending Some relating Acts (Breeding Act)

Act 246/1992, on Protection of Animals against Maltreating

Both Acts under jurisdiction of the Ministry of Agriculture.

They regulate keeping and breeding of domestic animals, including pets.

Act 79/1997, on Pharmaceuticals, Amending and Supplementing Some Other Related Acts

The Act adopted originally in 1997, under the jurisdiction of the Ministry of Health, later amended.

Several § of amended Act refer to GMOs and to the Act on GMOs.

Registration and placing on the market of pharmaceuticals containing GMOs are regulated through this Act, but only after approval by the Ministry of the Environment on the basis of the positive result of the risk assessment.

Government Regulation 178/2000, on Conditions for Health Protection of Employees

The Regulation defines risks for working processes, hygienic standards and measures for health protection.

Several articles refer to GMOs (§ 22 – Biological Factors, § 23 – Health Risk Assessment, § 24 Measures for Health Protection, § 25 and § 26 – Measures for health protection in specific working conditions).

Act 258/2000, on Protection of Health, and on Changes of Some Related Acts

The Act under the jurisdiction of the Ministry of Health defines rights and obligations in the sphere of health protection and nominates official authorities, their sphere of activity and competency.

The following articles are connected with GMOs handling:

§ 37 – Work Categories, § 41 – Use of biological material and asbestos.

Decree 89/2001, on Conditions for Work Categorization, Limit Indicators of Biological Exposition Tests and Reporting on Work with Asbestos and Biological Material

The Decree related to the preceding Act defines technical details for certain activities.

Several § relate to GMOs.

Act 206/2000, on Protection of Biotechnological Discoveries and on Amendment of Act 132/1989, on Protection of Rights on New Plant Varieties and Animal Breeds

Two articles are related to GMOs: § 2 – Biotechnological discoveries, § 3 – Patents.

More general Acts on protection of the environment and nature

Act 17/1992, on the Environment

Act in force since 1992 (one of the first environmental Acts adopted after revolutionary changes in the former Czechoslovakia), under jurisdiction of the Ministry of the Environment. The Act defines basic terms and determines basic principles of environmental protection, as well as basic obligations of citizens in the process of protecting and improving the environment and utilizing natural resources. It describes principles of evaluation of various activities, effects and consequences transcending national borders, responsibility for non-observance of obligations, sanctions and economic tools.

In the § 12 the acceptable level of environmental pollution is defined and according to this § “limit values must be determined with regard to the possible cumulative effects or synergetic effects of pollutants or polluting activities”.

According to § 14 everybody has the right to true and accurate information about the state and development of the environment.

On the basis of § 15 “everybody may approach the relevant authority and claim, in a prescribed manner, his or her legal rights stipulated by this Act and other Acts and regulations concerning the environment”.

In § 20-23 the Act regulates the environmental impact assessment, and in § 24-26 their transboundary consequences.

The Act also defines sanctions for damage to the environment (§ 28 and § 31 – Economic Tools).

Act 114/1992, on the Protection of Nature and Landscape

The Act defines the basic terms and basic obligations in nature conservation and landscape protection. It categorizes and defines protected areas and protected components of nature and sets basic conditions for their protection. The Act prescribes measures for the improvement of

the natural environment, describes participation of citizens and involvement of authorities and state administration in nature conservation, as well as their responsibilities.

Act 148/2003, on Conservation and Use of Genetic Resources of Plants and Microorganisms Important for Food and Agriculture

The Act regulates conditions and procedures for conservation and use of gene-pool of above mentioned group of organisms in order to conserve natural heritage. It covers both *in situ* and *ex situ* conservation. The Ministry of Agriculture adopted the National Programme (for 5 year period) aiming at implementation of this Act.

Public information and participation

Act 106/199, on Free Access to Information

The Act defines conditions for access to information and in providing information by governmental authorities and local administration, as well as by other public institutions. The information is provided on the basis of requirement or by publicizing it.

Act 123/1998, on Right to Environmental Information

The Act regulates right to information on the environment and natural resources, being at disposal at governmental authorities or local administration. The Act defines conditions and procedures how and in which terms to obtain required information.

Adoption of the Amendment of this Act is in progress (cf. Chapter 5).

International Biodiversity Related Conventions and their Reflection in National Legislation

The Czech Republic is a Party to the following biodiversity related conventions and protocols, which implementation is based on national Acts listed in corresponding sections.

Convention on Biological Diversity (CBD)

Due to a global character of the Convention, a relatively high number of Acts contributes to its implementation, first of all

Act 114/1992, on Protection of Nature and Landscape,
and further following Acts:

Act 289/1995, on Forests

Act 23/1962, on Game Management

Act 102/1963, on Fishery

Act 148/2003, on Conservation and Use of Genetic Resources of Plants and Microorganisms Important for Food and Agriculture

Act 154/2000, on Breeding and Registration of Domestic Animals (In § 14 Gene-pool of domestic animals listed)

Act 16/1997, on Import and Export of Endangered Species of Wild Fauna and Flora

Act 162/2003, on Management of Zoological Gardens

Act 246/1992, on Protection of Animals against Maltreatment

Act 219/2003, on Marketing of Seed and Planting Material of Cultivated Plants

Act 132/1989, on Protection of Rights to New Varieties of Plants and New Breeds of Animals

Act 252/1997, on Agriculture

Act 242/2000, on Organic Farming

Act 254/2001, on Waters

Act. 334/1992, on Protection of Agricultural Land Resources
Act 50/1976, on Territorial Planning and Construction Regulations
Act 100/2001, on Environmental Impacts Assessment
Act 244/1992, on Assessment of Environmental Impact of Development Conceptions and Programmes

Cartagena Protocol on Biosafety (CPB)

Act 78/2004, on Genetically Modified Organisms and Genetic Products

United Nations Framework Convention on Climate Change (UN FCCC)

Kyoto Protocol to the United Nations Framework Convention on Climate Change

Implementation covered mainly by the

Act 86/2002, on Protection of the Air

United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (UN CCD)

In the Central Europe the Convention main aim is to protect soil against degradation, which led to adoption of the special Annex V to the Convention. Czech legislation reflects this fact through the following Acts:

Act 334/1992, on Protection of Agricultural Land Resources

Act 50/1976, on Territorial Planning and Construction Regulations

Act 284/1991, on Land Management and Land Authorities

Act 252/1997, on Agriculture

Act 242/2000, on Organic Farming

Act 254/2001, on Waters

Act 289/1995, on Forests

Act 114/1992, on Protection of Nature and Landscape

Act 100/2001, on Environmental Impact Assessment

Act 244/1992, on Assessment of Environmental Impact of Development Conceptions and Programmes

Convention for the Protection of the Ozone Layer (Vienna Convention)

Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol)

and its Amendments:

London Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer

Copenhagen Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer

Montreal Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer

Implementation of this international Convention and its Protocol and Amendments is covered mainly by the

Act 86/2002, on Air Protection

and further by the

Act 76/2002, on Integrated Pollution Prevention.

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal

Amendment to the Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal

The most important instrument for national implementation is the

Act 185/2001, on Wastes

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

Amendment to the Article XI of the Convention on International Trade in Endangered Species of Wild Fauna and Flora

Amendment to the Article XXI of the Convention on International Trade in Endangered Species of Wild Fauna and Flora

A special Act was adopted for implementation:

Act 16/1997, on Import and Export of Endangered Species of Wild Fauna and Flora

An amendment of this Act will enter into force in 2004.

Further – completing Acts:

Act 114/1992, on Protection of Nature and Landscape

Act 162/2003, on Management of Zoological Gardens

Regional Seas Conventions

The Czech Republic as an inland country has no special legislation to protect seas, but legislation on protection of rivers (among them Labe and Odra are the most important, which flow into the sea) and waters in general:

Act 254/2001, on Waters.

3. System to Handle Notifications or Requests for Authorisation

3.1 Principles of GMO Act

Notifications (applications) are submitted to the Competent Authority - Ministry of the Environment.

Notification forms are prescribed by the implementing Decree (available also on the website: www.env.cz, link GMO).

A notification must include:

- data on the notifier,
- data on the GMO and product (where applicable),
- data on the facility / site (where applicable – contained use and field trials),
- data on the responsible expert (consultant),
- risk assessment,
- emergency response plan (for contained use and deliberate release),
- data on labelling, packaging and instructions for consumers (for placing on the market).

Administrative procedure - see the attached scheme (Annex 3).

Obligations of the notifier in case of contained use and deliberate release into the environment for other purposes than placing on the market:

- to appoint a responsible expert (consultant),
- to keep documentation, regularly inform the Ministry on the use of GMOs, including the final report,
- to provide a risk assessment and an emergency response plan as a part of the application and update them regularly,
- to ensure training of employees,
- to inform immediately the relevant Authorities in case of any accident,
- to provide assistance to Authorities during inspections, including providing samples.

Placing on the market:

Operators are obliged to label the presence of GMOs at all stages of placing on the market.

Farmers are obliged to inform MoE about the sites of growing GMOs authorised for cultivation.

Notifier is obliged to monitor effects of GMOs on health and the environment and report the results to MoE.

New information – safeguard clause

On the basis of new facts about risks related to the GMO the Ministry of the Environment may (after a consultation with MoH and MoA):

- terminate the consent to use the GMO
- change the conditions of the use of the GMO.

MoE is obliged to inform other Authorities about its decision.

Public information and public participation in the authorisation procedure

Notifications are published regularly on the MoE website (www.env.cz) and at the official desk of the Ministry of the Environment. In relation to a new Act the information will be also published in the region where the use of GMO is intended.

Public can send comments.

Received comments are discussed at public hearing, the results are taken into account in the final decision issued by the MoE.

Final decisions and the lists of authorised GMOs are published on the website of the MoE.

3.2. Procedures

All cases of handling with GMOs (LMOs), i.e. contained use, release into the environment and placing on the market, undergo the administrative procedure arising from the current legislation (see Part 2).

The administrative system is now well established and its principle is apparent from the attached scheme (Annex 3). All necessary information for notifiers are available at the mentioned websites of the Ministry of the Environment.

All individuals or organizations willing to use GMOs (notifiers) that have not been authorised for placing on the market have duty to submit a notification containing all prescribed data to the Ministry of the Environment (MoE) which is the competent Authority responsible for evaluation of the submitted notifications and decision-making. All applications are registered and sent for assessment to the Czech Commission for the Use of Genetically Modified Organisms and Products, to the Ministry of Health and Ministry of Agriculture.

The Ministry of Agriculture established already on December 9, 2000, Commission of the MoA on GMOs as an advisory body, consisting of 12 regular members and several ad hoc experts nominated according to the topic concerned. The activity of the Commission is regulated by the approved status and processing rules. The aim of the Commission is to prepare position to the submitted notifications for the MoE, to provide controlling activities in the institutions belonging to the competence of MoA, to monitor developments and research progress in the field of GMOs and it participates also in legislation developments. MoA ensures also monitoring of GMOs (see Part 4) by means of their specialized bodies and four controlling laboratories detecting GMOs in food, feeds and related raw materials and products (see also the Annex 4).

Presently the MoA is preparing principles of the coexistence of conventional, ecological and biotechnological types of agriculture in compliance with EU recommendation.

Since 2004 all notifications will be also available for the public (including nongovernmental organizations) by means of internet, at the MoE and at the municipal authority where the intended use is going to take place. The Commission, above mentioned Ministries (and also the public) send to the MoE their position and comment. On this base additional information is usually required from the notifier and consequently new assessment has to be done. After final evaluation the Ministry of the Environment takes decision. In case of approval the consent is given for limited period of time (usually 5 – 10 years). After this period a new application must be submitted.

After the accession of the Czech Republic to the European Union the MoE will also communicate with the European Commission when required by the EU legislation (mostly as regards the authorisation process for placing GMOs on the market.

All submitted notifications and the decisions of MoE are published on the official website <http://www.env.cz/gmo> and at the official MoE desk.

The system of inspections of the approved conditions of GMOs use is carried out by governmental Authorities determined by the law according to well established rules and procedures. The competence of controlling is related to the origin and purpose of the GMO use (see Part 4).

Risk assessment procedures include strict rules and they are carried out by experts appointed by the governmental institutions according to the Act on the use of GMOs and genetic products. The wide roaster (panel) of experts was carefully selected from the specialists from the Academy of Sciences of the Czech Republic, universities, research institutes, governmental bodies and professional nongovernmental organizations and it is permanently updated. In the frame of the UNEP-GEF project „Development of the National Biosafety Framework for the Czech Republic“ a detailed survey on the methodology of risk assessment has been worked out. The survey describes all possible risks of the use of GMOs and approaches how to evaluate them. Specialized seminars ensure experience exchange among the individual experts.

The review of the negotiated notifications and issued permits as of February 29, 2004 is presented in the Annex 5.

4. Monitoring and Enforcement

4.1 Description of systems for monitoring and enforcement

Compliance with legislation in force must be permanently and effectively controlled. Therefore in the Act 78/2004 (up to February 25, 2004 the Act 153/2000 was applied), on Genetically Modified Organisms and Genetic Products, the § 27 in part 6 designates competent control authorities. Along with the three ministries – Ministry of the Environment and its Commission for the Use of Genetically Modified Organisms and Products (List of members see Annex 2), Ministry of Health and Ministry of Agriculture – eight institutions are authorized to perform supervision and monitoring of the genetically modified organisms and the way of their use (see simplified scheme of monitoring system in Annex 4 and for the list of institutions involved see part 4.3). The detailed description of the duties and approaches in GMOs monitoring and inspections, worked out by the individual governmental institutions, is a part of the Survey on Monitoring (available only in Czech).

4.1.1 Czech Environmental Inspection

The main competent authority regarding supervision and control of GMOs designated by the Act 78/2004, on Genetically Modified Organisms and Genetic Products (up to February 25, 2004 by the Act 153/2000) is the **Czech Environmental Inspection** (<http://www.czpi.cz>).

The frame of this body competence is given mainly by the above mentioned Act. In the case, that any of Acts related to GMOs do not formulate special procedure the general Act 552/1991 on State Control is applied.

The competence of the environmental inspector for providing the control is proved by his/her professional ID card. The controls are usually planned (announced in advance), however, sudden controls are possible in case of necessity. The planned controls are carried out after careful preparation. This preparatory phase includes defined administrative steps, finding necessary information about the institution intended for control, studying the records of the already realized controls, examination of the possible suggestions of individuals or non-governmental and governmental organizations, finding and studying necessary professional documents (technology, standards, etc. in case of an industrial process), preparation of the necessary equipment (e.g. for sampling) and organization of intended collaboration (e.g. with customs officers, police, experts, etc.)

The announcement of controls planned in advance (usually 8 days beforehand, at least) contains besides the date, hour and place of the control beginning the subject of the control and the list of documents which should be available for inspection. The controlled institution/company (responsible personnel) are obliged to create conditions for control smooth development. In case of not keeping the prescribed duties the inspectors determine the

fine up to 50 000 Czech Crowns. The fine may be given repeatedly up to maximal amount of 200 000 Czech Crowns (according to the Act 71/1967).

In 2003 all field trials approved by the Ministry of the Environment were checked. The monitoring was performed during the experiments as well as after their termination. It regarded field test with the Bt maize, potatoes, flax and prune variety (virus resistant) Stanley. The 10 controls were focused on the observing of the conditions specified in the approval by the Ministry. No violations were found.

Another type of control is performed in facilities included in the register of places where the genetically modified organisms are used. All approved facilities were controlled in 2003. Only minor divergences from the required practice were found and corrected immediately. Only in one case the penalty procedure was started.

During the year 2003, 14 samples were randomly collected in areas of non-GMO planting in order to check possible transfer of transgenes. No transgenes were found in these samples.

The Czech Environmental Inspection organizes regular training courses for inspectors. In 2003 they were focused to the methods of laboratory processing of collected samples and methods of sampling. The courses were organized at the Institute of Chemical Technology and a certificate was issued to participants as a result. In addition, the inspectors take part in all workshops of the Commission for the Use of Genetically Modified Organisms and Products.

Permanent cooperation with laboratories performing the analysis of genetically modified organisms was established. It deals with methods of samplings, sample storage, biochemical analysis (e.g., ELISA or PCR). International contacts in corresponding fields were extended.

Regarding the origin and intended use of GMOs, the Czech Environmental Inspection collaborates with the following official bodies:

4.1.2 Czech Agricultural and Food Inspection Authority

Czech Agricultural and Food Inspection Authority (<http://www.szpi.gov.cz>) was established by the Act 146/2002 as a competent authority under the supervision of the Ministry of Agriculture and consists of the Central Authority and seven regional inspectorates.

The Inspection Authority performs the oversight of persons producing food and releasing it on the market as requested by the Act 110/1997, in the case of novel foods containing genetically modified organisms in the form of the Act 306/2000 and also by the Act 78/2004 (Act 153/2000 before February 25, 2004).

In connection with this activity the Inspection Authority controls all duties of producers and importers of novel foods who introduce them on the market. These controls are either centrally planned controls or controls initiated by regional inspectorates in the frame of regular every day controls.

The subjects of controls are food products and materials containing the substances from crops that might be potentially modified, e.g. maize or soy beans.

- ✓ Starting from January 1st of 2001 it is permitted to put on the market novel foods containing genetically modified organisms only with the approval of the Ministry of Health.
- ✓ Since May 1st of 2001 the user producing foods with the use of genetically modified organisms must be registered by the Ministry of the Environment and
- ✓ since January 1st of 2002 the labeling is compulsory even in case of foods not containing genetically modified organisms but produced with them.

The controls are conducted in own laboratory bearing accreditation by the Czech Accreditation Authority. It performs:

1. Detection of specific DNA in products containing maize or soy beans based on PCR screening for CaMV 35S promotor and NOS terminator.
2. Detection of specific DNA in foods of plant origin by Real-Time PCR screening for CaMV 35S promotor and NOS terminator.
3. Detection of specific DNA of Roundup Ready soy in soy products by PCR.
4. Detection of specific DNA of Bt-176 maize in maize products by PCR.
5. Detection of specific DNA of Roundup Ready soy in soy products by Real-Time PCR.

4.1.3 Central Institute for Supervising and Testing in Agriculture (CISTA)

The scope of the activity of the Central Institute for Supervising and Testing in Agriculture (<http://ukzuz.cz>) is given by the Act 147/2000 and in the field of GMOs by the Act 78/2004 (by the Act 153/2000 before February 2004). It is responsible for expert controlling in the following areas:

- a) Seed and planting materials of cultivated plants and cultivated plants for seeds production in accordance with the Act 357/1999. It examines plant cultivars for their registration and subsequently controls their planting after termination of the administrative registration process. In case of GMOs the process of registration may start only after obtained permission of their release into the environment. It means that the whole administrative process according to the Act 78/2000 (formerly according to the Act 153/2000) with the positive result is the necessary condition for the submission of the application for GM plant registration. The aim of the Department of cultivar examination is, along the biosafety testing of the plant cultivars released into the environment, to control the unregistered contamination of the tested cultivars during the field trials, including GM contamination.
- b) In relation to the Act 219/2003, the CISTA is providing control and testing of the use of seeds and planting material of agricultural plants. The Institute is also accredited centre and member of ISTA (International Association for Seed Testing) for testing of cultivar purity of the individual GMO ranks. The aim of these centres is to create uniform, comparable and reproducible results worldwide.

- c) CISTA carries out also the ad hoc controls of the registered and non registered genetically modified plants, seeds and plant components in feeds according to the Act 91/1996 and Act 78/2004 (formerly Act 153/2000).
- d) Further CISTA activity is concerned with permanent plant cultures in relation to several Acts, as Act.97/1996 (Protection of hops), Act 115/1995 (vineyards and wine making) and Act 219/2003 (release of seed materials and planting material into the environment) which covers planting material for fruit trees, presently mainly plum trees and other stone fruit trees.
- e) CISTA created own laboratory for GMOs testing which is oriented on the detection of wide scope of genetic modifications. However, it is equipped only for detection (i.e. qualitative assays). Quantitative assays are performed in other accredited laboratories (Research Institute of Crop Production, Prague, Institute of Chemical Technology, Prague and State Institute of Public Health, Brno).
- f) It is important to stress that CISTA is not accredited to provide administrative procedures and thus all findings passes to the Czech Environmental Inspection (for further administrative processing) and to the Ministry of the Environment.
- g) The results of inspections are regularly published on the institutional websites (for the address see above).

4.1.4 State Phytosanitary Administration

State Phytosanitary Administration (<http://tesnov.srs.cz>) is included in the Act 78/2004 for the state professional inspection of the use of genetically modified organisms and products and inspection of tests of genetically modified organisms in the frame of its mandate.

The registration of products for plant protection, their monitoring and control mechanisms are regulated by the Act 147/1996 on Phytosanitary Service. It is stated in the § 3 that the service includes registration of plant protection products (letter f), and monitoring their effectiveness as well as genetically modified organisms intended for the use in plant protection including their possible unintended effects (letter g).

Following the § 34 (d) products containing genetically modified organisms may be registered providing they meet the requirements of § 19 Chapter 1 and the applicant provided proof that these organisms are:

- a) accompanied by the risk assessment of handling with,
- b) included in the register of the Ministry of the Environment.

Products that are used and released for the market according to § 34 are subjected to the regular control from the criteria given in the § 19 Chapter 1 and in the § 26. The control is performed by the corresponding office of the State Phytosanitary Administration.

Phytosanitary supervision (§ 37a. letter b) consists of supervision over the use of genetically modified organisms and products according to specific decree, in the case when their presence or use is in connection with activities under § 3 letter b), c) and g).

Due to the practical absence of planting transgenic crops with toxic effects on pests, the State Phytosanitary Administration has not taken part in field controls till now.

4.1.5 State Veterinary Administration of the Czech Republic

State Veterinary Administration of the Czech Republic (<http://svscr.cz>) is a competent authority under the guidance of the Ministry of Agriculture in charge (along others) of:

- ✓ care and protection of the animal health,
- ✓ supervision over the safety of animal products and feed,
- ✓ protection of livestock from risks caused by polluted environment.

Therefore the task of the State Veterinary Administration is the oversight of the use of genetically modified organisms in animal feed and animal health care. In the latter case it cooperates with the **Institute for the State Control of Veterinary Biologicals and Medicaments** (<http://www.uskvbl.cz/>).

4.1.6 Institute for the State Control of Veterinary Biologicals and Medicaments

Institute for the State Control of Veterinary Biologicals and Medicaments (<http://www.uskvbl.cz/>) acts according to both national and EU legislations. The national Decree 79/1997 and related Acts on medicaments and Act 78/2004 on GMOs create the legal base for involvement of this institution into Czech administrative and monitoring system. The registration of veterinary medicaments, including GMOs, are now regulated by EU Directive 2001/82/EC and Decree 2309/93 and it is performed via European Agency EMEA. Institute is involved in decision making process via its representative in the GMO Commission of the Ministry of Agriculture which is preparing Ministry position for the Commission for GMOs and Products at the Ministry of the Environment and subsequently it participates in the controlling and monitoring activity in the field of veterinary biologicals and medicaments.

4.1.7 National Institute of Public Health

The Institute (<http://www.szu.cz>) executes the control of genetically modified organisms from the human health point of view. The Commission for the Use of Genetically Modified Organisms and Products adopted a rule that any organism, which as such or its part can be used as food or generally eaten, must be approved as food. This is the main role of the National Institute of Public Health that results from the §86 of the Act 258/2002, on the Protection of Public Health.

National Institute of Public Health established a group of experts for the assessment of problems connected with the health impact of the genetically modified organisms. These experts are representing:

- ✓ the hygiene of food chains,
- ✓ the hygiene of the environment,
- ✓ the hygiene of work and professional diseases,

✓ epidemiology and microbiology.

The expert group formulates its position on dossiers submitted by the Ministry of the Environment on the issues of genetically modified organisms. Based on the expert group opinion, the National Institute of Public Health submits its standpoint to the Ministry of the Environment. It is up to this Ministry to formulate final decision.

National Institute of Public Health also performs monitoring of the presence of food products that may contain traces of genetically modified organisms on the Czech market and refers on this situation to the Ministry of the Environment. The institute is independent from other monitoring and control bodies and it has not position of a governmental control body.

For the comparative studies the National Institute of Public Health stores the collection of reference samples of substances and products containing GM material that might be used as food and/or feed.

4.1.8 State Institute of Drug Control (SIDC)

The Institute (<http://www.sukl.cz>) is a governmental institution for supervision of the Act on Drugs 79/1997, § 67 and according to the Act 78/2004 (formerly Act 155/2000) it is included among the governmental bodies responsible for the use of GMOs and products.

Drug registration. Until the Czech Republic accession to EU (in accordance with both above mentioned Acts) the decision of the Ministry of the Environment is necessary prior to the application for genetically modified drug registration. This administration may be avoided in case that the evaluation has been already done by EU authorities (see Decree 473/2000). Since May 1, 2004 the majority of medicaments will be registered by a central system of EU (Decree 2309/93).

Clinical evaluation. Clinical evaluation of medicaments containing GMO needs written approval (Directive 2001/20/ES) which is given only when the conditions of the Act 78/2004 will be fulfilled. The documents needed for the application to provide clinical evaluation are given in the Decree 427/2000, § 13.

Specific health treatment programmes. The medicaments may be used and distributed only in accordance with the conditions of the Act 78/2004 (formerly Act 153/2000).

The use of medicaments containing GMO in the regime of unregistered use. The physician can not prescribe and use the medicament containing GMO for patient treatment. The § 5a of the Act 79/1997 is not applicable in the case of GMO presence in the medicament.

Supervision. If the medicament contains GMO then SIDC performs supervision in the frame of the Acts 79/1997 and Act 78/2004 (formerly Act 153/2000). It follows the conditions of production, distribution, application, use and liquidation. In case of breaking laws SIDC informs the Czech Environmental Inspection and the Ministry of the Environment.

Conclusions: SIDC has enough capacities to implement duties arising from above mentioned Acts. Up to now, no medicament containing GMO has been registered in the Czech Republic.

4.1.9 Customs Administration of the Czech Republic

Customs Administration (<http://www.cs.mfcr.cz>) belongs administratively to the Ministry of Finance. According to the Act 78/2004 Customs Administration takes part in controlling transboundary movement of GMOs.

Customs offices check all documents and certifications accompanying export and import of agricultural products and other organisms or products that might include genetically modified organisms. They take all measures to comply with the Act 78/2004 collaborating with other control bodies, mainly with the Czech Environment Inspection. Import, transit and export are controlled at particular transboundary traffic points. For instance, in 2003 five samples of soy beans and maize were analyzed during the non-stop control from March 3 to March 31 on different transboundary traffic points.

4.2 Laboratories for detection and assessment of GMOs

A quite large network of laboratories for detecting and assessment of GMOs has been created in the Czech Republic. It is advantageous that they are also well geographically distributed.

Four laboratories are working under the Ministry of Agriculture:

- Laboratory of the Czech Agricultural and Food Inspection Authority (Prague)
- Laboratory of the Central Institute for Supervising and Testing in Agriculture (Prague)
- Laboratory of the State Veterinary Administration of the Czech Republic (Jihlava)
- Laboratory of Molecular Genetics at the Research Institute of Plant Crops (Prague-Ruzyně). According to the decision of the Ministry of Agriculture this laboratory is accredited for methodological coordination of the other three laboratories and it also serves to the Czech Environmental Inspection.

Under the auspices of the Ministry of Health the laboratory of the National Institute of Public Health was established in Brno. This laboratory is specialized on foods and food products.

The network of laboratories testing samples with possible content of GMOs is completed by the university laboratory located at the Department of Biochemistry and Microbiology at the Institute of Chemical Technology in Prague. This laboratory serves also to the Czech Environmental Inspection.

The representatives of this laboratory and laboratory of the Research Institute of Plant Crops are involved as observers in activities of the European network ENGL (until accession of the Czech Republic to EU). In May 2004 an official collaboration between Czech Republic and ENGL will start.

4.2 List and addresses of Institutions responsible for above described actions

Ministry of the Environment

Department of Environmental Risks

Person responsible for GMOs : Zuzana Doubková

Address: 100 10 Praha 10, Vršovická 65

Phone: +420 267 122 922

Fax: +420 267 310 013

E-mail: doubkova@env.cz

Website: <http://www.env.cz>

Ministry of Agriculture

Person responsible for GMOs : Ivan Branžovský

Address: 117 05 Praha 1, Těšnov 17

Phone: +420 221 812 693

Fax: +420 224 812 989

E-mail: branzovsky@mze.cz

Website: <http://www.mze.cz>

Ministry of Health

(see **National Institute of Public Health**)

Czech Environmental Inspection

Persons responsible for GMOs: Tomáš Mařík and Martin Těhník

Address: 190 00 Praha 9, Na Břehu 267-1a

Phone: +420 222 860 330

Fax: +420 283 890 567

E-mail: marik@cipz.cz, tehnik@cipz.cz

Website: <http://www.czpi.cz>

Czech Agricultural and Food Inspection Authority

Person responsible for GMOs : Martin Šindelář

Address: 603 00 Brno, Květná 15

Phone: +420 543 540 237

E-mail: martin.sindelar@szpi.gov.cz

Website: <http://www.szpi.gov.cz>

Central Institute for Supervising and Testing in Agriculture

Person responsible for GMOs: Karel Říha

Address: 612 42 Brno, Hroznová 2

Phone: +420 543 548 239

Fax: +420 543 212 440

E-mail: karel.riha@ooz.zeus.cz

Website: <http://ukzuz.cz>

State Phytosanitary Administration

Plant Protection Product Division

Person responsible for GMOs: Miloslava Navrátilová

Address: 613 00 Brno, Zemědělská 1a

Phone: +420 545 137 045

Fax: +420 545 211 078

E-mail: Navratilova@srs.cz

Website: <http://tesnov.srs.cz>

State Veterinary Administration of the Czech Republic

Person responsible for GMOs: Radomír Belza

Address: 120 00 Praha 2, Slezská 7

Phone: +420 227 010 134

Fax: +420 221 812 979

E-mail: r.belza@svscr.cz

Website: <http://svscr.cz>

Institute for the State Control of Veterinary Biologicals and Medicaments

Person responsible for GMOs: Josef Petráš

Address: 621 00 Brno-Medlánky, Hudcova 56 a

Phone: +420 541 210 022 – 024

Fax: +420 541 210 026

E-mail: petras@uskvbl.cz, uskvbl@uskvbl.cz

Website: <http://www.uskvbl.cz/>

National Institute of Public Health

110 00 Praha 10, Šrobárova 48

Website: <http://www.szu.cz>

Person responsible for GMOs : Jiří Ruprich

Address: 612 42 Brno, Palackého 3a

Phone-Fax: +420 541 211 764
E-mail: secretariat@chpr.szu.cz
Website: <http://www.chpr.szu.cz>

State Institute of Drug Control

Person responsible for GMOs: Milan Šmíd
Address: 100 41 Praha 10, Šrobárova 48
Phone: +420 272 185 111
Fax: +420 271 732 372
E-mail: milan.smid@sukl.cz, sukl@sukl.cz
Website: <http://www.sukl.cz>

Customs Administration of the Czech Republic

Person responsible for GMOs: Pavel Polák
Address: 140 00 Praha 4, Budějovická 7
Phone: +420 261 332 332
E-mail: polak@cs.mfcr.cz
Website: <http://www.cs.mfcr.cz>

Laboratories accredited for assaying GMOs for the purpose of State administration on the basis of negotiation with the Ministry of the Environment

Research Institute of Crop Production

Contact person: Jaroslava Ovesná
Address: Drnovská 507, 161 06 Praha 6 – Ruzyně
Scope: Laboratory for identification of GMOs and fingerprinting

National Institute of Public Health

(Centre for the Hygiene of Food Chains in Brno)

Contact person: Jiří Ruprich
Address: Palackého 3A, 612 42 Brno
Scope: Detection of GMOs used in production of foods

Institute of Chemical Technology

Department of Biochemistry and Microbiology
Contact person: Kateřina Demnerová
Address: Technická 3, 166 28 Praha 6
Scope: Detection of GMOs, including microorganisms

Institute of Plant Molecular Biology, Academy of Sciences of the Czech Republic

Laboratory for detection of transgens in plants

Contact person: Jindřich Bříza

Address: Branišovská 31, 370 05 České Budějovice

Scope: Transgen detection during monitoring of genetically modified plants

(assaying of samples during GMO projects)

University of South Bohemia

Department of Genetics, Biological Faculty

Contact person: Miloš Ondřej

Address: Branišovská 31, 370 05 České Budějovice

Scope: Monitoring of rape seed spreading by pollen and grains

(Project of the Ministry of the Environment)

For the addresses of other laboratories see the corresponding Institution.

(Note: All responsible persons as well as the heads of GMO laboratories are highly qualified experts with university education, many of them with PhD degree, professors or associated professors.)

4.3 Future plans and needs

- To create the network of accredited laboratories involved in the European Network of the GMO laboratories (ENGL system).
- To organize regular roundtable discussions of the experts involved in risk assessment.
- To organize courses for personnel specialized in sampling and assessment of GMOs in order to improve the reliability of the controlling and monitoring processes.

5. Mechanisms for Promoting and Facilitating Public Awareness, Education and Participation

Right of the public to information belongs to the basic human rights according to the List of Basic Human Rights and Freedoms. With relation to the environment, the Rio Declaration – its Principle 10 recognizes three basic forms of public participation in environmental matters: the right of citizens to information, the right to participate in environmental decisions, access to mechanisms of redress and justice when the rights are violated. Recognition of these principles led to adoption of the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters in Aarhus, on June 25, 1998, during the fourth ECE Ministerial Conference “Environment for Europe”. In the framework of this Aarhus Convention, at the first meeting of the Parties in October 2002, Working Group on GMOs was established to explore the options for a legally binding approach to further development of the Convention in the field of GMOs, which negotiations still continue. The Cartagena Protocol on Biosafety, the principal international legally binding instrument in this sphere, recognizes the importance of public awareness and participation through its Article 23. It requires Parties to the Protocol to provide information on LMOs to the public, to ensure participation in LMOs related decision-making processes and to inform public about the access to the Biosafety Clearing-House.

In the sense of the above mentioned Article, public information should focus to three main areas: **public awareness, public education and public participation**. In the Czech Republic the environmental education and awareness have already certain tradition and in the last ten years have been developed correspondingly to principles of sustainable development and implementation of the Agenda 21. The Ministry of the Environment coordinates these activities as the supreme governmental body in environmental issues. The basic official documents for these activities are following:

State Programme on Environmental Education and Public Awareness, adopted in 2000

Action Plan of the State Programme for the period 2001-2003

Action Plan of the State Programme for the period 2004-2006

State Environmental Policy - version in force adopted in 2001

(the updated State Environmental Policy is under preparation and it is supposed to be adopted in 2004).

The environmental education is developed in cooperation with the Ministry of Education, Youth and Physical Training.

The National Network of centres for Environmental Education and Awareness spread throughout the whole country enables to develop activities at local level. The centres operates under auspices of different bodies, both governmental and non-governmental. Besides this, some local information centres, contributing to enhancement of public awareness, were established as a result of private initiative.

Access to information is based on two important acts, namely:

Act 123/1998, on Right to Environmental Information

Amendment of this Act was proposed. The Legislation Council of the Government deals with this Amendment, which will be passed to the Parliament approximately in April 2004. In comparison with the existing Act, the Amendment includes a shorter period for providing required information (15 days instead of 30 days according to existing Act).

Act 106/1999, on Free Access to Information (under State administration).

All information systems of the environmental sector will become part of so called Integrated Information System on the Environment, which is under development. This will include also libraries and information services and it will enable access to environmental information from different sources.

In relation to the biosafety issues, the main ways of public information so far used have been:

- Internet
- Ministry of the Environment Bulletin
- Open meetings of the Czech Commission for the Use of Genetically Modified Organisms and Products
- Workshops and specialized courses
- Publications, leaflets, CD-ROMs, etc.
- Radio and TV programmes.

The public participation and awareness was ensured mainly through the “*Act 153/2000, on the Use of Genetically Modified Organisms and Products and Amendment of Some Related Acts*” which came into effect on January 1, 2001. This Act, as mentioned in preceding chapters, together with three implementing Decrees covered the contained use, deliberate release of GMOs into the environment and placing on the market of GMOs as or in products, including the export and import thereof, as well as public involvement in the processes. In spite of the fact that this Act took into account legislation of the European Community and includes the main provisions of the Cartagena Protocol on Biosafety, it does not correspond fully to the recent development in this sphere.

Therefore the new *Act 78/2004, on Genetically Modified Organisms and Genetic Products* transposing the provisions of the EU *Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC* and the provisions of the Protocol not implemented by the above cited legislation was adopted by competent authorities and entered into force on February 25, 2004. The new Act on GMOs also reflects the experience with the implementation of GMOs legislation at national level. The Act defines rights and obligations of persons and competence of authorities in the use of genetically modified organisms and products thereof. In this new Act public information and participation were strengthened and are reflected mainly in the following Articles:

Article 5 – Granting Permission for Contained Use, Introduction into the Environment and Registration for Placing on the Market

The procedure includes public information and participation, public information on the content of application, possibility to send comments within 30 days from public announcement of the content of application, and in such a case obligation of public proceeding, obligation for the Ministry of the Environment to publicize the whole decision.

Article 6 – Public Proceeding

This is obligatory in case of some comments, as well as publicizing the result of public proceeding.

Article 10 – Public Information

The most important Article with respect to public, on the basis of which the Ministry of the Environment should publicize information:

1. on the official board of the Ministry, 2. through the Internet, 3. at local level - community and region, where the use of genetically modified organisms is taking place.

Article 11 – Labelling

Obligation to use label: “genetically modified organism” or “product containing genetically modified organism”.

Article 21 – Measures in Case of Accident

Among others obliged Ministry of the Environment to inform public about accident.

Article 22 – Register of Permitted Genetically Modified Organisms and Register of Users

Both registers available through the Internet.

Article 23 and 24 – Placing on the Market: Permit and Registration

Obligation to make public report on permits and to make available through the Internet the register.

Article 28 – Ministry of the Environment: Czech Commission and International Exchange of Information

Reports of the Czech Commission for the Use of Genetically Modified Organisms and Products are publicized, participation in its public meetings is possible.

International Exchange of Information as obligation of the Ministry of the Environment.

An amendment of this new Act reflecting the last EC legislation development has been proposed and is under process of negotiations.

The Czech Commission for the Use of Genetically Modified Organisms and Products was established in January 2001 as an advisory body at the Ministry of the Environment of the Czech Republic according to the Act 153/2000, on the Use of Genetically Modified Organisms and Products and Amendment of Some Related Acts. The Minister of Environment nominates the chair, secretary and members of the Commission, after consulting the Ministers of Health and Ministry of Agriculture, from amongst professionals representing the administrative authorities, Academy of Sciences of the Czech Republic, universities, sectoral research institutes and civil associations. The Secretariat of the Commission is at the Department of Environmental Risks of the Ministry of the Environment.

The Commission is authorised by the Ministry to:

- a) 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,
- b) control the information set forth in applications for the use of GMOs and to issue standpoints on these applications,
- c) carry out professional inspections of the workplaces of GMO users and sites of introduction into the environment, in cooperation with State administrative authorities,
- d) carry out professional inspections of documents kept by the GMO users, in cooperation with state administrative authorities,
- e) discuss the reports on the use of GMOs prepared by users,
- f) propose methods for testing of genetically modified organisms and propose equipment of workplaces for carrying out such testing.

In these activities the Commission co-operates with a number of external experts and consultants. Contact is maintained first of all through e-mail, even among members. The Commission meets approximately ten times a year. Certain meetings are organized as open meetings, enabling participation of interested public, mainly NGOs.

Biosafety Clearing House

National BCH was established at the Ministry of the Environment, Department of Environmental Risks. It collects data and enables exchange of information, publication of reports, etc. Website is a part of the Ministry of the Environment website: <http://www.env.cz> – link to GMO (part on GMOs so far only in Czech). The web contains:

- Definition of GMOs, on the basis of the Act 78/2004, on Genetically Modified Organisms and Genetic Products, and links to other important web-sites, both national as well as European and international (Centre for the Hygiene of Food Chain, Research Institute of Crop Production, Information from the European Union, including Plant Scientific Committee, Information from OECD countries, UNIDO, Biosafety Clearing-House of the Cartagena Protocol).
- Registers of GMOs, according to their use: placing on the market, introduction into the environment, contained use.
- Register of GMOs users.
- Expert reports of the Czech Commission for the Use of Genetically Modified Organisms and Products.

The Ministry website will be re-structured in a near future, which will enhance possibility of information sharing on GMOs and use of English version, as well as more inter-linkages.

The Czech BCH NFP was nominated as an integral part of international BCH network in close relation to already existing national GMO web and database. The main challenge for the efficient operability of the Czech NFP will be to create an effective link to a central portal of BCH and to make national BCH unit interoperable with BCH system (<http://bch.biodiv.org>). This will require further and more targeted capacity-building, tailored to national needs.

For the purpose of the UNEP/GEF Project a special website was established at the Institute of Chemical Technology: <http://gmo.vscht.cz>. This contains basic information on the Project and related activities, reports of the workshops and meetings, information on specialized publications, etc., both in Czech and English.

Workshops and courses

are organized as special actions or back to back with other events, such as special expositions, fares or conferences, under the auspices of ministries, universities, Academy of Sciences or their research institutes. In this respect e.g. cooperation with foreign embassies proved to be useful. Several such workshops were organized within the UNEP/GEF Project for various groups of stakeholders and in different country regions (see Annex 6). One Sub-Regional Meeting was held in Prague, on April 24 – 25, 2003, enabling exchange of experience among specialists representing the UNEP Biosafety Unit, Geneva, European Commission and four EU accession countries – Slovakia, Hungary, Croatia and the Czech Republic. Proceedings of the Meeting was edited and published in June 2003 by the Ministry of the Environment, Prague (see Annex 7). The outcomes of the negotiations show similarity as to main problems with the biosafety framework in all participated countries of Central and Eastern Europe. Especially Biosafety Clearing House mechanism has not been satisfactorily developed or even established, mainly as to compatibility and link to the central Biosafety Clearing House (CBD Secretariat). The presentations show that the Czech Republic has a relatively good experience in such areas as biosafety legislation, inspectors training or GMOs laboratory detection.

Publications

In spite of all technical progress and Internet more and more wide use, publications still remain an important source of knowledge and information, especially for education purposes and even research. With respect to a wide public, certain problem represents transformation of scientific style and terminology into commonly understandable language. In the Czech Republic, a number of publications have appeared on issues related with genetic modifications and biological safety, several of them have been prepared in the framework of UNEP/GEF Project (Annex 7).

Public perception

is influenced by many factors, such as geographical location, social and political culture of the region, level of education, accessibility of information. Even within Europe differences exist between Nordic countries, Western and Southern Europe and Eastern Europe. In the Czech Republic, similarly as in Western European countries, food safety and related regulatory procedures represent a wide concern. Even in general, there is not great deal of genetic modifications supporters (Cf. Čeřovská M, Soukup J.: Survey on Public Perception of GMOs. In: Proceedings, Sub-Regional Meeting on Biosafety Framework, Ministry of the Environment of the Czech Republic, June 2003, p. 33-35 - Annex 8). The public perception is inter-linked with the official Czech Republic policy, which follows the EU model.

Goals and Measures

Further development of public awareness and participation in biosafety sphere as a part of environmental education should correspond with the State policies of respective sectors, especially with the State Environmental Policy as the strategic document of the sector responsible for implementation of international biodiversity and biosafety related treaties.

The main measures for the nearest periods can be defined as to:

- Implement the State Programme on Environmental Education and Public Awareness and ensure its inter-linkage to other related programmes.
- Complete ratification process of the Aarhus Convention and ensure its subsequent implementation, including measures regarding GMOs.
- Enhance environmental education and awareness focused to different stakeholders groups.
- Focus to public education on preventive measures in the field of chemicals and GMOs.
- Ensure information sharing on risk substances, including GMOs.
- Through information sharing contribute to implementation of the Act 123/1998, on Right to Environmental Information and the Act 106/1999, on Free Access to Information.
- Develop an integrated information system on GMOs among Ministry of the Environment, Ministry of Agriculture, Ministry of Health and Ministry of Industry and Trade.
- Implement commitments of the Czech Republic as a Party to international environmental conventions and protocols.
- Cooperate with international organizations.

- Develop bilateral cooperation especially with respect to the EU priorities and at national level take measures reflecting European Commission recommendations in respective field.

Annexes

1. National Coordinating Committee
2. Czech Commission for the Use of Genetically Modified Organisms and Products
3. Administrative Procedure of Circulation and Assessment of the Notifications for the Use of GMOs
4. Simplified Scheme of GMOs Monitoring System
5. Overview of Authorisation Procedures for the Use of GMOs (29.2.2004)
6. Workshops (organized within the Project)
7. Publications (prepared within the Project)
8. Survey on Public Perception of GMOs

Annex 1

National Coordinating Committee

National Project Coordinator

Jan Káš

Institute of Chemical Technology

Technická 3, 166 28 Praha 6

tel.: 420 224 353 018, fax: 420 224 355 167, 420 233 333 726

Jan.Kas@vscht.cz

Ministry of the Environment – National Executing Agency

Vršovická 65

100 10 Praha 10

Milena Roudná

Global Relations Department

tel.: 420 26712 2769, fax: 420 26731 1949

roudna@env.cz

Zuzana Doubková

Environmental Risks Department

tel.: 420 26712 2922, fax: 420 26731 0013

doubkova@env.cz

Czech Commission for the Use of GMOs and Products

Slavomír Rakouský

Institute of Plant Molecular Biology

Academy of Sciences of the Czech Republic

Branišovská 31

370 05 České Budějovice

tel.+ fax: 420 387775537

ray@umbr.cas.cz

Czech Environmental Inspection

Tomáš Mařík

Na břehu 267

190 00 Praha 9

tel.: 420 283 890 568, mobile: 606 627 727

marik@cizp.cz

Research Institute of Crop Production

Jaroslava Ovesná

Drnovská 507

161 06 Praha 6 – Ruzyně

tel.: 420 233022424

ovesna@vurv.cz

Ministry of Agriculture

Těšnov 17

117 05 Praha 1

Zuzana Drašnarová

Plant Production Department

tel.: 420 22181 2103, fax: 420 234 432 989

drasnarova@mze.cz

Karel Jan Štolc

Department of Research, Education and Foundation Activities

tel.: 420 22181 2536, fax: 420 24810097

stolc@mze.cz

Ministry of Health

Lubomír Dobiáš

University of Ostrava

Medical-Social Faculty

Syllabova ul.

700 30 Ostrava - Zábřeh

tel.: 420 596 160 520, fax: 420 596 118 661

lubomir.dobias@osu.cz

Ministry of Finance – Directorate General of Customs

Petr Muroň

2nd Department

Budějovická 7

140 06 Praha 4

tel.: 420 26133 1111

muron@cs.mfcr.cz

Ministry of Industry and Trade

Viera Císařová

Na Františku 32

110 15 Praha 1

tel.: 420 22406 2696, fax: 420 22406 2418

cisarova@mpo.cz

Institute of Agriculture and Food Information

Olaf Deutsch

Slezská 7

120 56 Praha 2 – Vinohrady

tel.: 420 22701 0324, 420 22701 0249, fax: 22700 10114

deutsch@uzpi.cz

Private Sector

Jaroslav Maršálek

Spojovací 561

281 61 Kouřim

tel. 420 321 – 783 293

jaroslav.marsalek@volny.cz

Non-governmental Organizations and Civil Associations

Zelený kruh (Green Circle)

Jiří Urban

PRO-BIO (Organic Farmers Union)

Nemocniční 53

787 01 Šumperk

tel.: 420 649 21 66 09

jiri.urban@pro-bio.cz

Biotrin

Jaroslav Drobník

Viničná 5

128 44 Praha 2

tel.: 420 22195 3280

jaroslav.drobnik@atlas.cz

Czech Biotechnology Society

Tomáš Ruml

Institute of Chemical Technology

Technická 3

166 28 Praha 6

tel.: 420 22435 3022

Tomas.Ruml@vscht.cz

Annex 2

Czech Commission for the Use of Genetically Modified Organisms and Products

Chairman:

Mr. Miloš Ondřej, Department of Plant Transgenesis, Institute of Plant Molecular Biology, Academy of Sciences of the Czech Republic, České Budějovice
e-mail: ondrej@umbr.cas.cz

Secretary:

Mrs. Zuzana Doubková, Department of Environmental Risks, Ministry of the Environment, Prague
e-mail: doubkova@env.cz

Members:

Mrs. Monika Ambrozková, Department of Animal Physiology, Faculty of Science, Charles University, Prague,
nominated by the Czech Union of Nature Conservationists (NGO)
e-mail : mona@natur.cuni.cz

Mrs. Kateřina Demnerová, Department of Biochemistry and Microbiology, Institute of Chemical Technology, Prague
demnerok@vscht.cz

Mr. Jaroslav Drobník, Biotrend Civil Association, Prague,
former head of the Institute of Biotechnology, Charles University
e-mail: drobnik@mbox.cesnet.cz

Mr. Karel Jech, nominated by the Society for Sustainable Life (NGO)
e-mail : karel.jech@env.cz

Mr. Ivo Konopásek, Department of Microbiology and Genetics, Faculty of Natural Sciences, Charles University, Prague
e-mail: konop@mail.natur.cuni.cz

Mr. Tomáš Mařík, Department of Nature Protection, Czech Environmental Inspection
e-mail: marik@cizp.cz

Mr. Jaroslav Petr, Research Institute of Animal Production, Prague
e-mail: petr@vuzv.cz

Mr. Pavel Polák, Section Tariff Integrated, Directorate General of Customs, Ministry of Finance, Prague
e-mail: Polak@cs.mfcr.cz

Mr. Slavomír Rakouský, Department of Plant Transgenesis, Institute of Plant Molecular Biology, Academy of Sciences of the Czech Republic, České Budějovice
e-mail: ray@umbr.cas.cz

Mr. Jiří Ruprich, Head of the Centre for the Hygiene of Food Chains, National Institute of Public Health, Brno
e-mail: jruprich@chpr.szu.cz

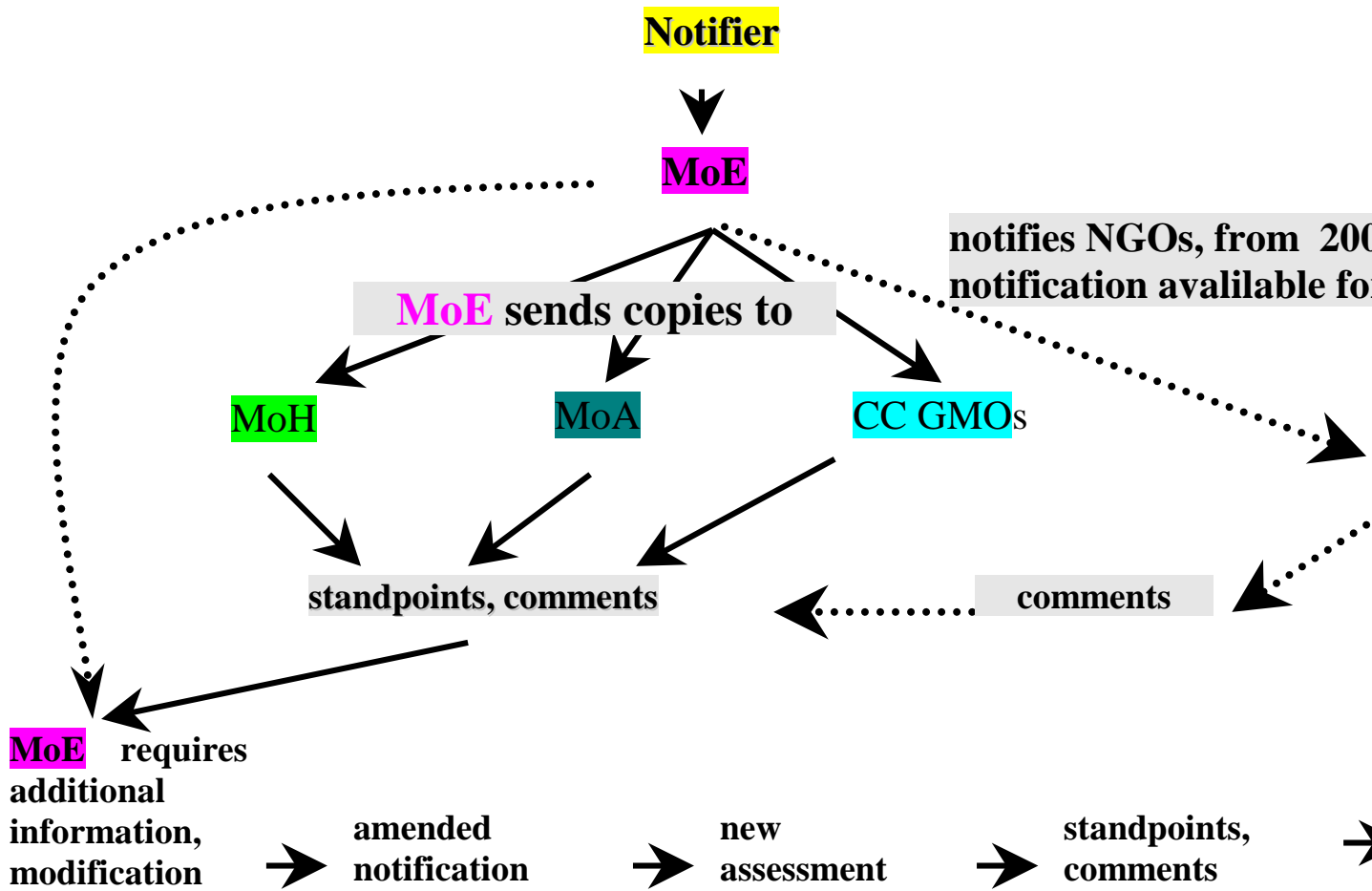
Mr. Karel Říha, Division of Plant Variety Testing, Central Institute for Supervising and Testing in Agriculture, Brno
e-mail: karel.riha@ooz.zeus.cz

Mr. Roman Rozsypal, representing organic farming and consumer associations, Brno
e-mail: roman.rozsypal@seznam.cz

Mr. Václav Routa, Department of Environmental Risks, Ministry of the Environment, Prague
e-mail: routa@env.cz

Annex 3

Administrative procedure of circulation and assessment of the notifications for the



Annex 4

Simplified Scheme of GMOs Monitoring System

Ministry of the Environment

Ministry of Health

Ministry of Agriculture

Ministry of Finance

National Institute of Public

Health (Prague/Brno)

Czech Environmental
Inspection

Institute of Drug

Control

■ Czech Agricultural & Food Inspection ■

Customs Administration

■ Central Institute for Supervising
& Testing in Agriculture

State Phytosanitary Administration

State

■ State Veterinary Administration
(laboratory in Jihlava)

Institute for the State Control of Veterinary
Biologicals and Medicaments

■ Research Institute of Plant Crops

Universities

Academy of Sciences of the Czech Republic

Institute of Plant Molecular Biology

■ Institute of Chemical Technology ■

■ *University of South Bohemia*

■ ■ ■ GMO laboratories

Annex 5

Overview of authorisation procedures for the use of GMOs (as of 29.2.2004)

	2001	2002	2003
Received notifications (start of the procedure)	47	20	11
Concluded procedures	31	29	8
Of that: issued authorisations	22	23	8
rejected notifications	6	3	0
suspended procedures	3	3	0
Requests for changes in the authorisation (mainly extension of the scope)	1	5	17
Approved changes in the authorisations	0	3	14
Subjects authorised for the contained use of GMOs	15	12	6
GMOs approved for the deliberate release for any other purpose than placing on the market (potato, Bt maize MON 810, RR maize NK 603, flax, oilseed rape MS8, oilseed rape MS8RF3, prunus var. Stanley)	4	3	0
Number of GMOs approved for placing on the market - (<i>Roundup Ready soybeans, for import and processing, Bt maize MON810, for cultivation, import and processing</i>)	1	0	1
Subjects authorised for the use of GMOs – total			
Pending notifications as of 29-02-2004			

Annex 6

Workshops (organized within the Project)

Research of Genetically Modified Organisms in the Czech Republic.
South Bohemian University, České Budějovice,
September 3-6, 2002, České Budějovice

Risk Assessment and Risk Management.
Institute of Chemical Technology, Prague,
February 13, 2003, Prague

Meeting of the Czech Commission for the Use of Genetically Modified Organisms and Products – meeting open to public.
Ministry of the Environment, March 11, 2003, Prague

Sub-regional Meeting on Biosafety Framework.
Ministry of the Environment and Institute of Chemical Technology, Prague,
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 Accession of the Czech Republic to the EU.
South Bohemian University, České Budějovice,
September 2, 2003, České Budějovice

Genetically Modified Organisms and the Cartagena Protocol.
Institute of Chemical Technology, Prague,
September 23, 2003, Prague

Course on Transgenesis.
South Bohemian University, České Budějovice,
October 6-10, 2003, České Budějovice

EMBO Workshop.
Institute of Chemical Technology, Prague,
October 26-29, 2003, Prague

Genetically Modified Organisms in Agriculture and Food Production.
Ministry of Agriculture, Institute of Chemical Technology and Institute of Crop Production,
Prague,
October 30, 2003, Prague

Ecological Impact of Genetically Modified Organisms.
IOBC/wprs Study Group,
November 26-29, 2003, Prague

Issues of Biosafety, Genetically Modified Organisms and International Commitments of the
Czech Republic.
Research Institute of Crop Production, Prague,
February 18, 2004, Prague

Genetically Modified Organisms and National Biosafety Framework for the Czech Republic.
Faculty of Sciences, Charles University, Prague (seminar for students)
February 25, 2004, Prague

Final Workshop – Presentation of the Project Results
Ministry of the Environment and Institute of Chemical Technology, Prague
March 23-24, 2004, Prague

Annex 7

Publications (prepared within the Project)

Drobník J., Ondřej M., Petr J.: Genetically Modified Organisms in Agriculture. Agriculture Information No. 4/2002, Institute of Agriculture and Food Information, Prague, 2002, 71 pp. (in Czech)

Roudná M. (Editor): Proceedings of the Sub-regional Meeting on Biosafety Framework (Prague, April 24-25, 2003). Ministry of the Environment of the Czech Republic, Prague, June 2003, 38 pp. (in English)

Doubková Z. (Editor): Genetically Modified Organisms – Issues Related with their Origin and Use. Ministry of the Environment, Prague, September 2003, 38 pp. (in Czech)

Drobník J., Ondřej M., Klouda Z.: Proceeding of the poster communications from exposition: Research of Genetically Modified Organisms in Czech Republic (September 2-9, 2002, České Budějovice). University of South Bohemia, České Budějovice, 2003, 23 pp. (in English and in Czech)

Drobník J., Ondřej M. (Editors): Proceedings of the Workshop „GMOs and Accession of the Czech Republic to the EU“ (September 1, 2003, České Budějovice). Attavena, o.p.s., České Budějovice, September 2003, 32 pp. (in Czech)

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

Roudná M.: Biological Diversity and Biosafety Related Issues. Ministry of the Environment, Prague, December 2003, 66 pp. (in Czech)

Ovesná J. (Editor): 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. (Editors): 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)

BIOPROSPECT, Bulletin of the Czech Biotechnology Society, Vol. 13, No. 1 – 4/ 2003, Prague, 28 pp. (Articles on genetic modifications, in Czech)

Káš J., Roudná M. (Editors): National Biosafety Framework for the Czech Republic. Ministry of the Environment, Prague, March 2004, 36 pp. (in English)

Annex 8

Survey on Public Perception of GMOs (Čeřovská M., Soukup J.)

