

# **Sub-Regional Meeting on Biosafety Framework**

**Prague, April 24. – 25, 2003**

## **Proceedings**

**Milena Roudná (Editor)**

**Ministry of the Environment of the Czech Republic, June 2003**

## Foreword

Natural sciences represented in the Czech science always a strong and important position. Many scientists contributed remarkably to the mankind progress in nature understanding. Speaking about biotechnology and especially about living modified microorganisms we can not forget at least two world known Czech scientists, i.e. Jan Evangelista Purkyně and Johann Gregor Mendl.

J. E. Purkyně (1787-1869) discovered cell nucleus in bird egg (1825) and elucidated the role of cell as a basic and structural unit of all plant and animal organisms. He also first described a lot of various cell structures and several of them bear his name up to now.

Johann Gregor Mendl (1822-1884), living in Moravian city Brno, is recognized as a founder of genetics. He formulated three basic genetic laws which are named after him. They contributed to the development of plant breeding, medicine and in the advancement of genetics in general.

Czech scientists played an important role also in the later developments of biotechnology. I would like to remember at least Czech microbiologist Ivan Málek (1909-1994) who was the first who investigated continuous microbial fermentation.

These few historical remarks should evoke impression that there is tradition in this country and permanent interest in examination and recognition of natural phenomena, including practical biotechnological applications. Thus it is easy to understand that Czech scientists expressed their interest in examination of genetically modified organisms some twenty years ago. The first attempts corresponded both with Mendel tradition and world trends and included, of course, plants. The scientific responsibility and the requirement of mutual discussions among all interested specialists lead to the creation of a voluntary Czech Commission on Transgenic Plants which became, later on (since 1989 to 2000), an advisory board of the Czech Ministry of the Environment. Experience of this Commission was utilized in drafting the first Czech Act on Genetically Modified Organisms (No. 153/2000). This Act recognized the Ministry of the Environment as a central body for approval of GMOs use. The Czech Commission for the Use of Genetically Modified Organisms and Products was established on the basis of this Act as an advisory body of independent specialists.

The described approach of the Czech official authorities in the field of genetically modified organisms is fully in agreement with the Cartagena Protocol on Biosafety which enabled the Czech Republic to ratify the Protocol among the first countries and participate in the UNEP/GEF Project Development of the National Biosafety Framework. At present, we are in the second phase of the project and certain national biosafety measures have been already adopted. A new updated Act on GMOs will form backbone of the National Biosafety Framework. Its new version will be discussed with stakeholders in the third phase of our project.

We are in the important phase of the development of the National Biosafety Framework when all comments and suggestions have the highest value. I am convinced that our sub-regional meeting was organized in proper time and was inspiring for all participants, both from abroad and the Czech Republic. The Proceedings you are receiving now will surely remember you fruitful discussions in Prague. I am also sure that the established contacts and started friendships will continue to the benefits of all participating countries.

With thank for active participation and wish of a full success in the development of your National Biosafety Frameworks,

*Professor Jan Káš*  
*Czech National Project Coordinator*

## **Summary and Further Development in Biosafety Regulation**

The workshop was organized in the framework of the UNEP/GEF Project “Development of the National Biosafety Frameworks” by the Ministry of the Environment of the Czech Republic and the University of Chemical Technology Prague. It took place in the University Congress Centre Sázava, Prague 4 – Chodov. The main aim of the workshop was to enable exchange of information and experience among countries of the Central and Eastern Europe with similar conditions as to biosafety measures. The representatives of the UNEP Biosafety Unit, European Commission and the following countries participated in the workshop: Slovakia, Hungary, Croatia and the Czech Republic. Information from Slovenia was also presented (poster). The representatives of this country as well as of Poland apologized in the last moment. The total number of foreign participants was 11. From the Czech Republic, 30 experts and officials participated, representing the University of Chemical Technology, Ministry of the Environment, Ministry of Industry and Trade, Ministry of Agriculture, The Netherlands Embassy, Academy of Sciences and other research institutions, as well as private sector.

The workshop was opened by the Deputy Minister – Director of International Relations Section of the Ministry of the Environment Mr Tomáš Novotný and by the representative of the UNEP/GEF Ms Andrea Gondová. The Deputy Minister underlined the fact that this is the first sub-regional CEE countries meeting within the Project, remembered lengthy and difficult negotiations preceding adoption of the Cartagena Protocol on Biosafety, as well as the undergoing process of its ratification, and expressed hope that shared experience will be helpful and be successfully implemented in national conditions of participated countries.

Two presentations of Ms Andrea Gondová as representative of the UNEP/GEF Biosafety Unit and presentation of Mr Julien Mousnier from the European Commission, DG Environment – Biotechnology represented main general information forming the basis for further discussion. Ms Gondova informed on the history and development of the UNEP/GEF Project on Biosafety Framework and on the Biosafety Clearing House situation and development at European level on the basis of the Questionnaire prepared by the UNEP-GEF Biosafety Team in cooperation with the CBD Secretariat. Mr Mousnier informed about European Commission strategy and legal instrument in relation to the Cartagena Protocol on Biosafety and its implementation. Representatives of participating countries gave general information on biosafety measures and policy in respective countries and following aspects were further discussed: risk assessment, enhancement of biosafety measures, including role of inspection and training of its staff, monitoring of genetically modified organisms, laboratory activities related to GMOs detection and risk assessment. The information on the biosafety database on GMOs use was presented by Slovakia. Members of the Czech Commission for the Use of Genetically Modified Organisms and Products informed about activities and experience of this Commission. General reflection on information systems in the field of GMOs was

presented and discussed. The Czech Republic National Project Coordinator Prof. Jan Káš informed about development of the UNEP/GEF Project in the hosting country.

The Workshop was closed by Ms Zuzana Doubková on behalf of the Ministry of Environment of the Czech Republic and Ms Andrea Gondová as UNEP representative.

The posters themes regarded biosafety system in Slovenia, activities of the Czech Commission for the Use of Genetically Modified Organisms and Products, as well as of the Department of Environmental Risks Assessment of the Ministry of the Environment – Division for GMOs, activity of the BIOTRIN Association, demonstration of plant growth support via depletion of plant ethylene levels, and results of GMOs public perception study (comparison between the Czech Republic and Germany).

Outcomes of the Workshops and results of discussions show similarity of main problems with biosafety framework in all participated countries of Central and Eastern Europe. Especially Biosafety Clearing House mechanism has not been satisfactorily developed or even established, especially as to compatibility and link to the central Biosafety Clearing House (CBD Secretariat). The Czech Republic proved a relatively good experience in such areas as biosafety legislation, inspectors training or GMOs laboratory detection. Participating countries with more developed biosafety framework would welcome possibility to participate in the second – implementation phase of the UNEP/GEF Project which would represent a valuable support in fulfilment of requirements resulting from the Cartagena Protocol ratification.

One month later, on May 27-30, 2003, the CEECCA Sub-Regional Workshop was held in Vilnius, Lithuania on Risk Assessment and Management and Public Awareness and Participation, within the UNEP/GEF Project on the Development of National Biosafety Frameworks. The workshop themes represent two of four main components of the national biosafety framework, apart from legislation and administration systems.

And again shortly after the Vilnius Workshop, on June 13, 2003, the Cartagena Protocol on Biosafety reached its 50 ratifications by States and will enter into force on September 11, 2003. This is a very challenging event, especially for the CEE and Central Asia countries, as this region reached the lowest number of ratifications among five basic UNEP geographic regions. As of June 13, 2003 the number of ratifications in the UN regional groups is as follows: Africa – 13, Asia and Pacific – 10, GRULAC (Latin America and the Caribbean) – 11, WEOG (Western Europe and Others Group) – 10, CEE – 7.

On June 13, 2003 the EU Environment Ministers formally adopted the Regulation on the transboundary movement of genetically modified organisms, which confirms the commitment of the European Union to the objectives of the Cartagena Protocol on Biosafety.

*Milena Roudná*

*UNEP/GEF Project National Executing Agency contact person*

## Programme of the Workshop

**April 23, 2003 Wednesday: Arrival of Participants, Accommodation at Hostel Volha**

<b>April 24, 2003 Thursday</b>	
08.00 – 09.00	<b>Registration</b> in „Congress Centre Sázava“
09.00	<b>Official opening:</b> Tomáš Novotný, Deputy Minister, Ministry of the Environment of the Czech Republic, Andrea Gondová, UNEP
09.30 – 13.00	<b>Morning session:</b> Chairing: Jan Káš and Andrea Gondová
09.30	Brief Information on UNEP-GEF Project and Issues for Discussion during the Regional CEE/Central Asia Workshop (May 2003, Lithuania) Speaker: Andrea Gondová, UNEP-GEF Biosafety Unit, Geneva Remarks of country representatives. Discussion
11.00 – 11.30	Coffee break
11.30 – 13.00	<b>Morning session (Continuation)</b>
	Development of the EU Policy and Legislation on GMOs in accordance with the Cartagena Protocol on Biosafety Speaker: Julien Mousnier, European Commission Gabor Nechay: Implementation of the Hungarian Legislation. Discussion
13.00 – 14.00	Lunch
14.00 – 17.00	<b>Afternoon session</b> Chairing: Igor Ferenčík and Milena Roudná
14.00 – 15.30	Development of Biosafety Clearing House Mechanism with Special Attention to Activities at European Level Speakers: Andrea Gondová, UNEP-GEF Biosafety Unit, Geneva and countries representatives Discussion
15.30 – 16.00	Coffee break
16.00 – 17.30	Information Systems in the Field of GMOs Introduction: Jaroslav Šilhánek, Institute of Chemical Technology, Prague Countries Experience Martin Chovan: Slovak Database Software.
18.00	Dinner
<b>April 25, 2003 Friday</b>	
09.30 – 11.00	<b>Morning session:</b> Chairing: Meira Bosnić and Jaroslav Drobník
	Mechanism of Evaluation of Applications of GMOs Use and Risk Assessment, Examples Speakers: Countries representatives

	<p>Jan Turna: Risk Assessment – Experience and Examples from Slovakia.</p> <p>Jaroslav Drobník, Jaroslav Petr: Activities and Experience of the Czech Commission for the Use of GMOs and Products.</p>
11.00 – 11.30	Coffee break
11.30 – 13.00	<p><b>Morning session (Continuation):</b>  Experience with Enforcement of Biosafety Regulations  Speakers: Countries representatives  Kateřina Demnerová: Experience with GMOs Monitoring and Training of Inspectors in the Czech Republic.  Janka Schwarzová: Experience with GMOs Inspection in Slovakia.</p>
13.00 – 14.00	Lunch
14.00 – 16.00	<p><b>Afternoon session</b>  Chairing: Gábor Nechay and Miloš Ondřej  Igor Ferencík: Experience with Enforcement of Biosafety Regulations in Slovakia.  Jaroslava Ovesná : Experience of the Czech Laboratories with GMOs Detection and Assessment.  Discussion  Summary: Jan Káš, NPC  Closing: Zuzana Doubková, Environmental Risks Assessment, Ministry of the Environment of the Czech Republic</p>

**April 26, 2003 Saturday – Departure of Participants**

## Opening of the Workshop

Ladies and Gentlemen,

It is a great pleasure for me to welcome you in Prague as participants of the first sub-regional workshop within the Central and East European countries dealing with one of the most important issues of our era - safe use of modern biotechnology and adoption of corresponding biosafety measures at national level.

This workshop was convened to enable exchange of information and experience among state with similar conditions as to the development of biosafety framework. It is organized in connection with the UNEP/GEF project which was launched to prepare countries for implementation of the Cartagena Protocol on Biosafety after its entry into force. In practice it means carrying out surveys, preparing inventories and establishment of the institutional and management structures.

Many of you were witnesses of several year long and difficult negotiations preceding adoption of the Cartagena Protocol on Biosafety in January 2000. For me, as the Deputy Minister responsible for international cooperation within the Ministry of the Environment of the Czech Republic, the Cartagena Protocol represents one of the most important international treaties, adopted as a first environmental treaty of the twenty first century. The Czech Republic was among countries signing the Protocol at the first occasion - in May 2001 in Nairobi, during the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity, and one of the first countries ratifying it, on October 8, 2002.

We are still waiting for remaining three ratifications enabling the Protocol entry into force, which hopefully will not take too much time. Therefore, implementation measures have become more urgent than any moment before and from this point of view this workshop is taking place in a right time. It is a great honour for me to welcome here representatives of UNEP as a leading body of the Biosafety Project, and of European Union, as an important Protocol negotiator. Their experience will be an essential enrichment of the programme and I strongly believe that their participation will contribute to the success of this meeting.

Ladies and gentlemen,

allow me to wish you fruitful discussions on all Agenda issues, especially on implementation and main problems of the National Biosafety Framework, EU policy and legislation on genetically modified organisms with respect to the Cartage Protocol, information systems, use of genetically modified organisms and risk assessment, and enforcement of biosafety regulations. I wish you a pleasant stay in Prague and successful implementation of gained experience at corresponding national levels.

*Tomáš Novotný, Deputy Minister – Director of International Relations Section,  
Ministry of the Environment of the Czech Republic*

## UNEP-GEF PROJECT ON “DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORKS”

The Conference of the Parties to the Convention on Biological Diversity adopted on 29 January 2000 a supplementary agreement to the Convention, known as the Cartagena Protocol on Biosafety. The Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol contains reference to a precautionary approach and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a Biosafety Clearing House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

**The UNEP-GEF global project on the “Development of National Biosafety Frameworks” started in June 2001. Using a country-driven process, the global project has been designed to help up to 100 participating countries to set up their national framework for the management of living modified organisms (LMOs), allowing them to meet the requirements of the Cartagena Protocol.**

For each country, the process of developing their national biosafety framework would consist of four phases: setting up the required project management structures, gathering of baseline information, analysis of that information in consultation with stakeholders, and preparation of the draft national biosafety frameworks (NBF). Whilst allowing for country specific situations, needs, and priorities, each NBF will consist of four common elements:

- a. A regulatory system
- b. An administrative system
- c. A decision making system that includes risk assessment and management
- d. A mechanism for public awareness and participation

### **Capacity building for development of NBF**

Under the UNEP-GEF Biosafety project, the development of the NBF is country-driven and each NBF is developed through a process of “learning by doing”. The UNEP-GEF biosafety team provides each country with support and advice as needed; these include:

- **A modular toolkit** – this provides a practical “how-to” guide for countries to develop their NBF. The toolkit is being prepared in a flexible manner tailored to meet the diverse needs of different countries, and allows countries to select those tools and ideas that are most useful to them. Two modules of the toolkit have been distributed so far, dealing with Phase 0 (Starting The Project) and Phase 1 (Taking stock).
- **Regional activities** – these have been designed to promote regional and sub-regional collaboration and exchange of experience on issues of relevance to NBFs. The first round of regional workshops in support of this aim focussed on improving understanding of the

issues involved in developing national biosafety frameworks amongst countries in the regions. These workshops have been carried out in cooperation with the CBD Secretariat, which has held back-to-back workshops on the Biosafety Clearing House.

- **Sub regional Training workshops** – these are based on the results of the first round of awareness raising workshops at the regional level, the UNEP-GEF Biosafety project is planning two further rounds of training workshops. These workshops started in November 2002 and are focussing on building capacity in participating countries on key issues related to the development of National Biosafety Frameworks such as risk assessment and management, public participation, as well as administrative and regulatory systems.

### Dissemination of information

The project team is working to encourage countries to disseminate their relevant information through the BCH. The project also recognises the important role of information dissemination in biosafety capacity building and is carrying out a number of activities to promote this aim:

- The project website provides information on the current status of the project and on important relevant documents and links on: <http://www.unep.ch/biosafety>
- A mailing list server provides project updates for all relevant contacts and enables the dissemination of relevant information to stakeholders.
- A Newsletter is produced for the provision of project related information. The first Newsletter was mailed out in December 2001, the second in May 2002 and the third in August 2002.
- Reports of Regional workshop have been circulated to all participants in the workshops. A synthesis of the results of the regional workshops has been distributed and is available on the project web site.
- Brochures on the project as well as on capacity building activities in biosafety have also been widely distributed.

### National Projects

As of 29<sup>th</sup> April 2003, 116 countries are currently participating in the project, and 112 of these have already prepared their draft National Project Document (NPD). 101 national projects have been approved and 75 have already started under the guidance of the relevant regional coordinators.

Africa		Asia - Pacific		Central and Eastern Europe		Latin America and Caribbean	
1.	Algeria	1.	Bangladesh	1.	Albania	1.	Antigua and Barbuda
2.	Benin	2.	Bhutan	2.	Armenia	2.	Argentina
3.	Botswana	3.	Cambodia	3.	Belarus	3.	Bahamas
4.	Burkina Faso	4.	Cook Islands	4.	Croatia	4.	Barbados
5.	Burundi	5.	Fiji	5.	Czech Republic	5.	Belize
6.	Central African Republic	6.	Indonesia	6.	Estonia	6.	Chile
7.	Comoros	7.	Iran, Islamic Republic of	7.	Georgia	7.	Costa Rica
8.	Congo	8.	Jordan	8.	Latvia	8.	Dominica
9.	Congo, Democratic Republic of	9.	Kazakhstan	9.	Lithuania	9.	Dominican Republic
10.	Côte d'Ivoire	10.	Kiribati	10.	Macedonia, The former Yugoslav Republic of	10.	Ecuador
11.	Djibouti	11.	Korea, Democratic People's Republic of	11.	Malta	11.	El Salvador

12. Gabon	12. Korea, Republic of	12. Republic of Moldova	12. Grenada
13. Gambia	13. Kyrgyzstan	13. Romania	13. Guatemala
14. Ghana	14. Lao PDR	14. Slovakia	14. Guyana
15. Guinea	15. Lebanon	15. Slovenia	15. Haiti
16. Guinea Bissau	16. Maldives	16. Turkey	16. Honduras
17. Ethiopia	17. Marshall Islands,	17. Ukraine	17. Jamaica
18. Lesotho	Republic of		18. Nicaragua
19. Liberia	18. Micronesia, Federated		19. Panama
20. Libyan Arab	States of		20. Paraguay
Jamahiriya	19. Mongolia		21. Peru
21. Madagascar	20. Myanmar		22. St. Kitts and
22. Mali	21. Nauru		Nevis
23. Morocco	22. Nepal		23. St. Lucia
24. Mozambique	23. Niue		24. St. Vincent and
25. Niger	24. Palau		the Grenadines
26. Nigeria	25. Papua New Guinea		25. Suriname
27. Rwanda	26. Philippines		26. Trinidad and
28. Senegal	27. Samoa		Tobago
29. Seychelles	28. Solomon Islands		27. Uruguay
30. Sierra Leone	29. Sri Lanka		28. Venezuela
31. South Africa	30. Syrian Arab Republic		
32. Sudan	31. Tajikistan		
33. Swaziland	32. Tonga		
34. Tanzania, United	33. Vanuatu		
Republic of	34. Viet Nam		
35. Togo	35. Yemen		
36. Zimbabwe			

*Presented by Andrea Gondová, UNEP – GEF Biosafety Unit*

**Questionnaire** on the resources and the expertise available in countries for the exchange of information with the Biosafety Clearing-House of the Cartagena Protocol

Preliminary summary of results as of April 10, 2003

The **Questionnaire** was prepared by the UNEP-GEF Biosafety Team in cooperation with the CBD Secretariat and sent with an explanatory letter to the 186 Parties of the CBD. Main referents were the ICCP, Cartagena Protocol, BCH and CBD focal points. For information purposes, the same documents were also sent, when relevant, to the 113 National Executing Agencies currently involved in the UNEP-GEF Project on Development of National Biosafety Frameworks.

A copy of the Questionnaire is available on the UNEP-GEF project web site at: <http://www.unep.ch/biosafety/BCHquestionnaire.pdf>

The Questionnaire explicitly requested that the person/s who fill(s) in the questionnaire will actually be responsible for entering/registering the data on the Biosafety Clearing House (BCH). The purpose of the questionnaire was to find out what each country is currently capable of doing according to the current design of the Biosafety Clearing House.

UNEP/GEF Biosafety Unit has received as of April 10, 2003, 74 replies from 65 countries (Africa 21.6%, Asia and Pacific 18.9%, CEE 23.0%, GRULAC 25.7%, Not Developing Countries 10.8%) to our questionnaire. Some of the answers are roughly summarized below.

**Data storage and Biosafety:** database: almost half of the users are familiar with data management or database software (54.8%) and with GMO related databases (42.5%). A third of the users indicate that there are GMO databases existing in their country (31.5%), half of which are available through the Internet (45.5%).

The majority of the users are aware of existing procedures to make information available to the BCH (56%) and a considerable group is aware of existing protocols for interoperability of national biosafety database with the BCH (43.5%). The majority of the users indicate that their country plans to use the central BCH database located at the Secretariat to store their data (57.1%) while a considerable group does not know yet (31.4%).

**Biosafety Clearing-House:** the majority of the users indicate that they are “familiar” with the BCH (75%), have been involved in the ICCP process (58.1%), are the official BCH National Focal Point (57.5%), or have retrieved information from the BCH website (52%). A vast majority finds the information easy to retrieve (79.5%) and did not experience problems while browsing the BCH (76.3%). Only a small fraction has inserted data into the BCH on behalf of their government (13.5%).

**Needs for assistance:** A relevant group (67.6%) indicated what kind of assistance they would like to receive in order to improve their use of the BCH. Among other things the following were indicated: training in use of the BCH (68%), training in information management (52%), hardware (28%), financial support (22%), software (22%), technical support (16%), and better Internet connection (12%).

Additional information on the results of questionnaire is available at the UNEP/GEF Secretariat.

*UNEP-GEF Biosafety Unit (presented by Andrea Gondová)*

## **The implementation of the Cartagena Protocol on Biosafety into European Community legislation**

### Objective of the Protocol

#### Preliminary remarks

- The EU already has an extensive legal framework in the field of biotechnology
- The “disconnection clause” contained in Art. 14 of the protocol offers the possibility to EU legislation for movements of GMOs into the EU and imports to the EU

#### Implementation strategy

- Develop new legislation for exporter obligations
- Use the existing framework to address importer obligations
- Stick to the wording of the Protocol as far as possible but upgrade to the level of protection of EC legislation where feasible
- Keep some margin of maneuver for upcoming international discussions

#### Legal instruments

- For exports: uniform procedures contained in a Proposal for a Regulation on the transboundary movements of GMOs
- For imports and movements between MS: existing EC legislation, mainly Directive 2001/18/EC
- Future legislation on biotech

#### Transboundary movements of GMOs. Objective and scope

- Set up common export rules for GMOs
- Establish information and reaction mechanisms for unintentional transboundary movements of GMOs
- Establish a common system of information sharing for transboundary movements of GMOs

#### Definitions

- Technical definitions from the Community legislation are consistent with the one from the Protocol and have therefore been used
- Other definitions (import, export...) are taken over from existing Community implementing legislation

#### Exporter obligations - GMOs intended for deliberate release

- Obligations for the exporter, NOT the Party of export
- Mandatory requirements to notify, in writing to the Party of Import prior to the first intentional transboundary movement and to ensure the accuracy of the information contained in the notification
- The notification shall contain as a minimum the information specified in Annex I CPB.

#### Cases of non reply by PoI

- The original proposal only impose a reminder in the absence of a reply by the Party of Import
- Council and Parliament have developed specific provisions imposing the explicit consent prior to a first transboundary movement of a GMO
- These were not accepted by the Commission

#### Notifications to non Parties

Notifications and procedures for non-Parties are almost systematically similar to those for Parties to the Protocol.

#### Exporter obligations - GMOs FFP

- Procedure for notification to the BCH and export of GMOs intended for food/feed/processing
- System of notification MS-COM-BCH
- Procedures introduced in codecision for the respect of relevant PoI procedures

#### Identification

- Direct transposition of Art. 18 CPB, adapted to certain requirements of EC legislation (notably for GMO-FFPs)
- Do not prejudice the upcoming EC legislation (i.e. Traceability) and international legislation (i.e. negotiation on Art 18 CPB)

#### Unintentional transboundary movements

- Ensure that necessary measures are taken to terminate the release, to initiate remedial action if necessary;
- Inform its public, the Commission, other Member States, affected or potentially affected states, the BCH, and where appropriate relevant international organisations

#### Common provisions

- Repartition of notification procedures between EU and MS
- Nomination of the relevant authorities for the implementation of the Protocol at national and EU level
- Monitoring and reporting
- Confidentiality

#### Illegal movements

- A standard penalty clause puts an obligation on the MS to guarantee the enforcement of the Protocol

#### Import of GMOs

- Directive 2001/18/EC on the deliberate release of GMOs into the environment
- “Vertical” legislation on biotechnology
- Upcoming legislation (i.e. Labelling and traceability and “food-feed”)

#### Directive 2001/18/EC on the deliberate release of GMOs into the environment

- Equivalent definitions
- Comparable to the AIA procedures
- Contains risk assessment procedures as requested by the Protocol
- Contains provision on public participation

#### Research authorisation (Part B)

- Notification to a Member State
- Authorisation delivered by the national authorities of Member States
- Summary of notifications accessible to all Member States

Placing on the market (Part C)  
DECISION

Legal Framework on Biotechnology  
Directive 2001/18/EC  
Directives 90/219/EEC and 98/81/EC

Future relevant legislation

- Proposal for a Regulation on labelling and traceability of GMOs - COM (2001) 182 final
- Proposal for a Regulation on GM food and feed - COM (2001) 425 final
- Proposal for a Directive on environmental liability with regard to the prevention and remedying of environmental damage - COM(2002) 17 final

Further Information available on the Commission web page  
[www.europa.eu.int](http://www.europa.eu.int)

*Julien Mousnier, European Commission, DG ENV – Biotechnology*

## **Implementation of the Hungarian legislation on GMOs**

One of the problems of implementation of the Convention on Biological Diversity (CBD) is the question of genetically modified organisms (GMOs). Hungary has a rather strict regulation on potentially harmful substances and in the middle of 1990s the need for appropriate rules on production and use of GMOs arose, both in the administration and in society. Hungarian representatives participated also in negotiations on international legal instruments on GMOs such as the UNEP Guidelines and a protocol of the CBD. All these resulted in a moratorium on GMOs with potential impacts on biological diversity, as the first legal measure, with the adoption of the Act No. LIII. of 1996, a new law on Nature Conservation.

Art. 9 (6): production of GMOs which influence biodiversity, experiments carried out with them, their breeding, distribution, exportation and importation shall be exercised by the conditions and methods laid down in a separate provision of law and in compliance with the provisions of this law.

Consequently a separate Act on Gene-Technology have been enacted in 1998, which took also into account existing EU legislation at that time, and entered into force in 1 January, 1999. The Act have been amended recently in accordance with new EU directives on GMOs. Selected provisions of the Act are summarised in Table 1.

Table 1. Certain provisions of the Act No XXVII of 1998 on Gene Technology Activities amended by the Act LXVII of 2002 according to Directives 98/81/EC and 2001/18/EC

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*Scope:*

Art 1 (1). ...modification of natural organisms with genetic engineering technics, their „ contained use, release into the environment, marketing, import, export and transportation” and products thereof.

(2) Human genes (as set forth in Health care Act),

(3) wild living organisms (as set forth in Nature Conservation Act) and

(4) protected organisms

shall not be modified.

Art 2 New definitions (according to 2001/18/EC), such as:

microorganism and microorganism modified by gene-technology (GM microorganism),

contained system and its type A and B,

release/marketing (transfer for any use),

GM product,

environmental risk assessment.

Gene technology authorities:

Art 4 and 5 establishes the Gene Technology Advisory Committee (GTAC) and authorities.

5 Members of GTAC are delegated by the Hungarian Academy of Sciences (HAS),

5 by relevant Ministers: Minister of Agriculture, Minister of Industry and Trade, Minister of Environment and Waters, Minister of Health, Minister of Education),

7 by NGOs including 4 environmental, 1 biotechnological, 1 consumerism and 1 health care NGO.

Veto authorities (Art 26): which in pursuance of Art 4 of the Act shall mutually participate as special agencies in official procedures on GMOs

Minister of Agriculture (FVM),

Minister of Industry and Trade,

Minister of Environment and Waters (MEW),

Minister of Health.

*Licences:*

Art 7 licences for 10 years but they shall be renewed yearly (detailed provisions and fees prescribed by separate law).

Art 16 Establishment of GM Laboratories should also be licensed based on opinion of the GTAC (registered laboratories at 7 institutes at present).

Art 8,9,10,11,15,18,34 closed system, inspection (classes, methods, inspectors by separate law), users in research/production (university /MSc/ degree

required).

*Labelling: obligatory*

Art 12 details which GMO or products prepared from GMO or material thereof (methods of labelling and exceptions detailed by separate law: No.1/1999(I.14.) FVM – its amendment is in preparation).

*Accidents: new Art 21/A obligatory information on and plan to avoid accidents.*

*Withdrawal of licences:*

Art 23, 24 *ex officio* or upon recommendation of agencies participating in registration immediate termination of GM activity or GMO if provisions of the Act or separate laws and related licences violated, especially in case of threats to the environment and human health.

*Responsibility for damage:*

Art 27 governed by provisions of the Civil Code.

*Waste management:*

Art 17 biological impact assessment may be required, waste materials shall be marked and managed according to the license and according to separate law.

*Important further acts and implementing law:*

Act No. LXXXI of 2001 on ratification of the Aarhus Convention (25 June, 1998).

Ministerial Decree No. 1/1999 (I.14.) FVM on GT activity in the field of agriculture and food industry (e.g. provisions on genetic isolation zone according to opinion of the GTAC and to the license including environmental and nature conservation considerations, on GT register (information centre) which is the Agricultural Biotechnology Centre (ABC), Godollo.

Annex 1 conditions for performing GM

Annex 2 terms of reference to the GTAC

Annex 3 information needed to application on GM or use of GMOs in closed system (microorganisms, plants, animals)

Annex 4 *ibid* for licence on release and marketing

Annex 5 list of official institutions authorised for identification GMOs (5 at present)

Annex 6 markings for labelling

Annex 7 determination of transportability

Ministerial Decree No. 20/2000. (VIII.25) KöM

on assignment of its authority participating as veto authority in legal procedures according to Art.4 (1)-(4) of the Act No XXVII of 1998 – General Inspectorate on Environment and Nature Conservation (GIENC)

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Considering potential ecological impacts, most important are GMOs released into the environment, at present especially plants for agricultural production. Since the establishment of legislation demonstrated above, agricultural application of GMOs are in accordance with regulation but there are no GM plants registered for production up to the present. Licences have been given out only for experimental releases in isolated areas of institutions registered according to the Gene-technology Act (see: [Table 2](#)).

Table 2. Number of GM plants (varieties) and their features released into the Environment since 1999

Notices: 1. release in isolated experimental plots only 2. + column in table means plants with both, gluphosinate tolerance and insect resistance (res.)

		<i>gluphosinate tolerance</i>	+	<i>insect res.</i>	<i>virus res.</i>	<i>other res.</i>
Maize	26		4	37	-	-
Wheat	2		-	-	-	4 (gluten)
Sugar beet	8		-	-	-	-
Potato	-		-	-	8	-
Tobacco	-		-	-	-	9
Turnip	1		-	-	-	1 (male sterility +gluphosinate tol.)

## Problems of implementation

As a consequence of lack in capacities inspection and enforcement system and activities are insufficient and they should be improved.

Capacities of existing competent authorities, especially their staff need to be strengthened.

Implementing law on environmental release and contained use of GMOs shall be amended according to certain detailed rules of new EU directives.

Implementing laws and competent authorities in the field of health-care and human pharmaceuticals and cosmetics as well as in the field of industrial use still need to be prepared and designated.

Greater care must be placed on potential environmental impacts of GMOs intended for environmental release. There are hardly any exact observations on ecological hazards of such GMOs. (One survey on impacts of Bt-maize on soil organisms and non-target species has been started in Hungary in 2001).

*Gabor Nechay, Ministry of Environment and Waters, Hungary*

## **Biosafety Situation in the Slovak Republic**

Act No. 151/2002 Coll. on the use of genetic technologies and genetically modified organisms (thereinafter “Act on GMOs”) came in-to force as of April 1<sup>st</sup> 2002 and Implementing regulation No. 252/2002 Coll. of the Act on GMOs as of June 1<sup>st</sup> 2002. Both documents were prepared by the Ministry of the Environment of the Slovak Republic as the competent authority in the biosafety field. In accordance with mentioned Act some relative acts were amended: the Act on seeds, the Act on food, the Act on feed, the Act on public health ...

In the MoE Biosafety Department was established and currently is in the process of development and organisational strengthening. By the Act on GMO a new Biosafety Inspection department was created on the Slovak Environmental Inspection and it is also in the process of development.

In accordance with the Act on GMOs the Slovak Biosafety Committee (SBC) has been established as an advisory body to the MoE. Members of the SBC are representatives from Ministries of Agriculture, Health and Education, but also scientists, representatives of NGOs, and business sector.

At present the first application has been in licensing process. It is Monsanto corn line MON 810 with Cry1A(b) gene for import of food, feed and use in processing. The SBC has recommended for grant permission. In the licensing process is 13 applications for contained use also. No permitted field trials have been carried out yet.

On October 2002 PHARE - Twinning Biosafety Project on biosafety legislative preparing was finished. In present time we are contend with next one focussed on GMO laboratory control system building. MoE have not such as control laboratories in agency and the control tests are made in cooperation with Slovak Academy of Sciences.

The UNEP-GEF "Project on Development of National Biosafety Frameworks" start in January 2003.

Ratification process of the Cartagena Protocol is expected at the end of the year 2003.

The text of the Act on GMOs and of Regulation is available in English on the website: [www.enviro.gov.sk](http://www.enviro.gov.sk). Current news on biotechnology in the Slovak Republic is available on the web site [www.biosafety-cee.org](http://www.biosafety-cee.org).

*Igor Ferenčík, Ministry of the Environment, Slovak Republic*

## **BIOSAFETY SYSTEM IN SLOVENIA**

A) Due to the fact that Slovenia is in the process of acquiring biotechnology products in result of release and commercialisation of GMOs, it needs a workable and an effective biosafety system at national level that facilitate the implementation of EU regulatory framework to reconcile the respective needs of use of GMOs on the one hand and the environment protection on the other, with respect to biotechnology.

B) In the light of this situation Slovenia adopted Management of GMOs Act in 2002 (OJ 67/2002) which provides horizontal type of legislation on the use of GMOs and their products, and intermediate other existing legislative frameworks in the areas of agriculture and health care. The Act does not include novel foods and medical products for the human and veterinary. In principle, the Ministry of the Environment, Spatial Planning and Energy (in addition Ministry) is responsible of carrying out the necessary task to comply with the requirements. Therewith, the Ministry is responsible to carry out administrative/decision making-risk assessment procedure of receipts/permits/approvals for contained use and/or deliberate release of GMOs into the environment and placing on the market. This also includes the establishment of public registers for the location of the Part B and C releases of GMOs according to the EU directives. According to the implementation plan, several decrees based on the Act should be transposed and implement in a first quarter 2004.

C) According to survey, the Ministry expect 21 notification for contained use-mainly for class I and II. Namely, currently work with GMOs is being conducted in 21 closed systems, most of them (12) at Universities, 5 at public Institutes and 4 units within Companies. In 19 cases GMMs are being used, in 5 cases transgenic plants, in 5 cases transgenic animals and the remaining 3 closed systems are dealing with genetically modified cell cultures, human and animal cell cultures and embryo cells.

To strengthen all activities on the field of biotechnology the Ministry established Biotechnology Sector (three staff are employed and have 3rd level degrees from University) in order to provide co-ordinates issues and task to the above. Inspections and two Scientific Committees (contained

use and deliberate release) which will carry out the evaluation of the notifications and especially the risk assessment therein and to prepare their assessment opinion for the Ministry are in place.

D) No figures are available for deliberate release, and the Ministry does not expect a lot of activity in this field mainly due to the relatively limited areas with agricultural production in Slovenia. Regarding to above, several activities has been done within the Sector of Biotechnology. In collaboration with the Biotechnical Faculty University of Ljubljana and with the Ministry of Education, Science and Sport the project Deliberate release of Bt corn and its assessment for the purpose of evaluating potential risk to human health and the environment was done. In order to establish an national referable laboratory for assessing of GMOs in plant, seed and feed, the project Quantitative assessing of GMOs was completed by National Institute of Biology which is currently trying to be accredited for GMOs testing and it is already involved in EU lab-network.

E) No controls have yet been put in place for the import of GMOs, although given data on imports of two main types of agricultural products (Soya and Maize) by origin of import it can be concluded as highly probable that GMOs are present.

G) Biotechnology Sector supports and maintains good co-operation with the NGOs and remains stakeholders in Slovenia, and within these co-operation organised several Workshops and Conference in 2002 such as; "Towards Effective and Harmonised Biosafety Framework and Procedures" (July 2002), Conference "GMOs - Risk and Challenge" (October 2002), "Simulation of Biosafety Regulation in Slovenia" (December 2002), in closely co-operation by the TAIEX, French Government and UNEP/GEF.

"As the result of activities within the UNEP/GEF project in 2003, the Workshop "Introduction to Risk Assessment and Case Study" (UNEP/GEF), organised in April 16 to 18, has been tailor-made workshop for members of Scientific Committees and Inspectors. Moreover the National Biosafety Clearing House is in place; <http://www.bch.bf.uni-lj.si>."

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## **STATUS OF BIOSAFETY IN CROATIA WITH BRIEF REPORT ON PROGRESS OF NBF PROJECT**

Up to now Croatia has not regulated, neither by law nor other regulation, the issues related to the import/export, marketing, use and production of genetically modified organisms and products (GMOs). Croatia has signed the Cartagena protocol on September 8, 2001 and Croatian National Parliament has ratified the Cartagena Protocol on May 24, 2002.

Although at present no regulation on GMO is effective, there has been a very intensive legislative activity in this field, under the cooperation of four Ministries (Ministry of Environmental Protection and Physical Planning-MEPPP, Ministry of Health-MH, Ministry of Agriculture and Forestry-MAF, and Ministry of Science and Technology-MST), and under active participation of non-governmental organizations and the wider public.

By agreement between the above indicated Ministries it was determined that Croatia would not govern this matter by a separate law, but that it would be integrated into other two laws instead: the ***Law on Nature Protection*** (MEPPP), which will cover the area of biological safety (provisions of the Cartagena Protocol - release of LMOs into the environment, impact on biological diversity, contained use), and the ***Food Law*** (MH and MAF), which will govern the field of food made of GMOs, the obligation to label such food, monitoring, etc.

Republic of Croatia sees its future as a member of EU and is undergoing the process of accession. As a part of that process, Croatia has the obligation to adjust its legislative framework according to European standards and that also refers to all regulations regarding GMOs. Integration of provisions of relevant EU Council Directives and Council Regulations into national legislation is already under way.

Provisions of the Cartagena Protocol on biosafety together with provisions of relevant EU Directives have already been adequately integrated into the *Draft Law on Nature Protection* and *Draft Food Law*. Both of these laws are in expedited parliamentary discussion as Croatia is undergoing the process of accession in EU.

Through public participation in passing the *Law on Nature Protection*, numerous comments and suggestions were collected and integrated into the new Draft, and they refer to a significant extent also to the field of GMOs. In this way this law should govern issues related to the import, marketing, use and production of genetically modified organisms, biological safety measures, ways of innocuous clearance of waste from LMOs, as well as monitoring and inspection. Deliberate release of LMOs into the environment or marketing thereof is permitted only under conditions prescribed by Law, in a way by which hazard with regard to biological diversity is prevented or minimised, and taking into consideration human health hazards. Detailed procedures for obtaining import permits based on previous notification, the hazard assessment procedure, conditions of limited use for laboratories, etc. will be regulated by decrees.

One of the basic elements for the implementation of future regulations is also the establishment of a *laboratory for GMO detection*, which would be used in monitoring and inspection. The establishment of an adequate laboratory has already been initiated within the Public Health Institute of the Republic of Croatia, while the necessary funds were allocated in the central budget for 2001, within the relative positions of the Ministry of Health, the Public Health Institute, the Ministry of Environmental Protection and Physical Planning, and the Ministry of Agriculture and Forestry.

The Ministry of Environmental Protection and Physical Planning has on February 07, 2003 signed with UNEP-GEF project of Development of the National Biosafety Framework for Republic of Croatia. For this Project the Ministry is National Executing Agency appointed by UNEP-GEF. The Ministry has chosen National Project Coordinator that started its work on March 12, 2003 and is situated inside the Ministry.

At the moment Croatia is still in the Phase One of the national project, which consists of preparatory activities and the gathering of the necessary information.

On May 20, 2003 the first meeting of National Co-ordinating Committee (NCC) was held. NCC was established by the National Executing Agency (NEA) to advise and guide the preparation of a National Biosafety Framework. This committee has 16 members and consists of representatives of most government agencies and public. Members of NCC are representatives from Ministry of Environmental Protection and Physical Planning, Ministry of Economy, Ministry of Agriculture and Forestry, Public Health Institute of the Republic of Croatia, Faculty of Agriculture, Faculty of Biological and Mathematical sciences; Institute "Ruđer Bošković", Institute of Social Science "Ivo Pilar", industry, four NGO-s and one political party.

On the first NCC meeting it was decided that the members will first get familiar with Protocol, proposed Croatian Laws and EU Directives related to biotechnology/biosafety. At the same time it will be done preliminary investigation on current use of modern biotechnology in Croatia, experts and programs.

On the second NCC meeting we plane to have the representatives from Slovenia that will present there experience and overview of NBF Project in Slovenia.

*Meira Bosnić, National Project Coordinator, Croatia*

## **Biosafety Measures in the Czech Republic**

### **Legislative Framework**

The "Act 153/2000 Coll., on the Use of Genetically Modified Organisms and Products and Amendment of Some Related Acts" came into effect on January 1, 2001. The Act together with three implementing Decrees covers 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. The Act is harmonised with the legislation of the European Community and includes the main provisions of the Cartagena Protocol on Biosafety.

A new Act on GMOs 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 current legislation is at present discussed by the Parliament of the Czech Republic. It will come into force on January 1<sup>st</sup> 2004 at the latest. The new Act on GMOs will also reflect the experience with the implementation of GMO legislation.

The Czech Republic ratified the Cartagena Protocol on Biosafety in October 2001.

### **State Administration**

The Ministry of the Environment is the Competent Authority handling the notifications and regulating the use of GMOs and Biosafety in the Czech Republic. It co-operates with the Ministry of Health in respect of risks for human health and with the Ministry of Agriculture as the agricultural risk, animal health, crops and feeds are concerned. The

Czech Commission for the Use of GMOs and Products is the Advisory body to the Ministry of the Environment. Members of the Commission are representatives of administrative authorities, scientists and representatives of NGOs.

The Czech Environmental Inspectorate is the Competent Authority on state supervision of the use of GMOs. It co-operates with other state supervisory bodies in fulfilling this task.

### **Approvals**

The Ministry of the Environment as the Competent Authority on the use of GMOs and on Biosafety in the Czech Republic has up to now received about 70 notifications of the use of GMOs, mostly for the contained use. No GM crops are grown commercially in the Czech Republic. The Ministry of the Environment has issued approvals for small-scale field testing of the oilseed rape, potato, flax and virus-resistant plum tree for scientific and breeding purposes. Field trials at four sites with Monsanto Bt maize MON 810 were approved last year. The purpose of these trials is agricultural and entomological research studying the possible environmental impact on non-target organisms and comparison of GM, chemical and organic technologies of crop protection. Limited field trials with Monsanto Roundup Ready maize NK 603 have been approved as well. The field trials with GM oilseed rape notified by Aventis were terminated. The number of field trials in the Czech Republic has decreased significantly since the legislation concerning GMOs came into effect.

As placing on the market of GMO is concerned, only one approval has been issued: For the import and processing of Monsanto Roundup Ready soybeans. This approval corresponds with European Commission Decision 96/281/EC.

The notification for placing on the market of Monsanto Bt maize MON810 has been submitted to the Ministry of Environment at the end of 2002. The Ministry has issued an approval for field trials for the registration of varieties, but not for import and processing of the maize. Monsanto appealed against the restrictive conditions of the approval. The other side, Greenpeace, appealed against the approval as such and requires a re-assessment of the environmental risks of Bt-maize. Until the appeals are resolved, the placing on the market of the maize is not possible.

The list of the authorised users and the lists of approved GMOs together with the relevant legislative measures and other information are made available to the public and updated on the website of the Ministry of the Environment, at the address: [www.env.cz](http://www.env.cz), GMO link.

The English version will be available on the Czech UNEP/GEF Biosafety Project website.

*Zuzana Doubková, Ministry of the Environment of the Czech Republic*

## **Czech Commission for the Use of Genetically Modified Organisms and Products**

The Czech Commission for the Use of Genetically Modified Organisms and Products was established in January 2001 by the Ministry of The Environment of the Czech Republic according to the Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amendment of some related Acts. According to the Act, the activities of the Commission cover the contained use, deliberate release into the environment and placing on the market of GMOs and products containing or consisting of GMOs, including the export and import thereof.

The Commission is an administrative part of the Ministry, the Secretariat of the Commission is at the Department of Environmental Risks. The Minister of Environment names and recalls the chair, secretary and members of the Commission, after consulting the Ministers of Health and Agriculture, from amongst professionals nominated by the administrative authorities, the Academy of Sciences of the Czech Republic and by civic associations. The statute and the rules of procedure of the Commission have been issued by the Ministry.

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 (GMOs) 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 the users,
- f) propose methods for testing of genetically modified organisms and propose equipment of workplaces for carrying out such testing

The Commission co-operates with a number of external experts and consultants.

The sessions of the Commission take place approx. 10 times a year, most of the work is done by e-mail correspondence.

The Commission has assessed over 70 notifications for the use of GMO.

*Zuzana Doubková, Ministry of the Environment of the Czech Republic  
Jaroslav Drobník, BIOTRIN, Prague*

## **Genetically Modified Animals**

### **Experience from the Czech Republic**

According to the Czech Act on Genetically Modified Organisms (GMOs), vertebrates and invertebrates as well as cell lines derived from these beings are considered as “organism” and their contained use, release into the environment or placing on the market are regulated by this Act. The genetic modification of man (e.g. gene therapy) is excluded from the regulation by Act on GMOs.

At present, there are no GM animals released into the environment or placed on the market in the Czech Republic. All GM animals are in contained use. They are mainly kept for the research purposes. There are barriers protecting animals from outside and these barriers prevent very efficiently the escape of GM organisms from places determined for contained use. There was no escape of GM animals from contained use in the Czech Republic.

Three species of invertebrate GM animals exist - worm *Caenorhabditis elegans*, silk moth *Bombyx mori* and fruit fly *Drosophila melanogaster*, as well as several genetically modified vertebrate species - claw frog, rat, mouse, chicken and rabbit. There is no GM fish in the Czech Republic, but we have experts in fish biology which are able to produce GM fish. The Czech commission for the Use of Genetically Modified Organisms and Products is fully aware of all problems connected with contained use of aquatic organisms and their possible impact on the environment. The keeping of genetically modified claw frog *Xenopus laevis* is not accompanied by risks for the environment, because this species is not native in our latitudes and cannot survive during the winter. Based on these data, the use of GM animals seems to be clearly defined and easily managed. However, some questions remained unresolved. The DNA-vaccines can be mentioned as a very illustrative example, especially when the acute danger of epizooties (e.g. foot and mouth disease) is taken into account. The principle of DNA-vaccine is very simple. The DNA sequence from virus or bacteria is directly injected into the tissue of live animal and the expressed protein induces immune response. The DNA-vaccinated animal is surely GM-animal. What about clinical trials of DNA-vaccines? Is it contained use of GM animal or release of these animals into the environment? Has to be DNA-vaccination of farm animals on farms considered as placing of GM animal on the market? Many similar examples can be introduced and they all indicate that the problems connected with GM animals could be quite complicated and have to be considered very carefully.

*Jaroslav Petr, Czech Commission for the the Use of Genetically Modified Organisms and Products*

## Experience with GMOs Monitoring and Training Inspectors in the Czech Republic

Three topics were discussed in the presentation:

- 1) **training courses**, which were organised in the frame of two TEMPUS projects for public administrators and courses for inspectors by ICTP and RICP
- 2) **monitoring of GMO samples 2002** organised by Czech Inspectorate of Environment and by individual GMO control laboratories in the Czech republic
- 3) **ENGL- JRC Ispra**: the involvement of Czech laboratories in the European network

ad1) Training courses:

Since 1996 czech participants (4 Universities, two Ministeries, Biotrend a.s.) of two TEMPUS projects together with participants from different European countries (Austria, Spain, Italy, UK, Portugal) organised several GMO training courses for universities and public administrators

TEMPUS project (1996 – 1998), JEP No. 09768-95 “Implementation of EU directives in Curricula of Biology and Chemistry“

TEMPUS project (1998 – 2000), JEP No. 13292 - 98 “Modern biotechnology courses for public administrators“

Outputs of TEMPUS project (1998-2000):

- \*12 courses for public administrators (basic and advanced)

- \* 3 text books for courses participants

- \* Text book on CD

Training courses (2001-2003):

- \*organized by Ministry of Environment together with Czech Commission for the Use of GMOs and Products

- \* courses for inspectors of the Czech Inspectorate of the Environment

- \* 2003-2004 Transformation project of Ministry of Education - training of the state administrators

The aim of the first course for inspectors was to give them more information about GMO, their origin, usage and to explain how elaborative is GMO estimation and the role of the sampling for it.

Programme included following lectures:

- \*What are GMO? Basic principles of their preparation and testing

- \*Legislative aspects of handling GMOs controls

- \*Different kinds of GMO

- \*Basic principles of GMO estimation

- \*Quantitative estimation of transgenic DNA

- \*Sampling

- \*Video – Detection procedure of GMO

Another course focused only on the sampling of material for GMO detection was organised by 2 THETA ASE Ltd.

ad 2) Monitoring of GMO samples in the year 2002

During the year 2002 the Czech Inspectorate of Environment (CIE) has controlled 37 institutions handling with GMO. There did not find any serious faults.

In the Table 1 the summary of samples analysed for GMO detection is presented.

* CIE Prague	36 (9)
* ICT Prague	55 (7)
* RICP Prague	58 (8)
* SHI Brno	192 (24/96/24)
* RVI Jihlava	108 (10)
-----	
<b>Summary</b>	<b>449 (58) 12.9%</b>

The classification of samples took and analysed by different bodies and laboratories:

**Czech Inspectorate of Environment**

green plants of maize : 26 (3)\*

soya beans: 6 (6)\*

maize: 4 (2)\* #

analyses done by :\* RIC, # ICTP

**Institute of Chemical Technology Prague**

soya beans: 27 (5)

maize: 10 (2)

potatoes: 3 (0)

wheat: 3 (0)

aromatic essences 12 (0)

**Research Institute of Crop Production – Ruzyně**

soya beans: 1 (0)

soya oil: 1 (0)

maize: 1 (0)

hops: 2 (0)

rape seeds: 5 (3)

food: 44 (4)

raw material: 4 (1)

**State Health Institute Brno**

soya products: 48 (18/22/8)\*

soya beans : 48 (6/36/6)

maize flour: 48 (0/0/0)

tomatoes: 48 (0/38/10)

\*positive/negative/inconclusive

**Research Veterinary Institute Jihlava**

soya beans and products: 108 (10)

ad3) ENGL- JRC Ispra

European Network of GMO Laboratories was officially established in December of 2002 in Brussels. Non-EU member states have a status of observers: **Czech Republic**, Slovakia, Slovenia, Hungary, Poland, Estonia, Romania, Bulgaria

The first meeting ENGL spread work in the different sub-groups:

\*2001/art.31 (Molecular Register), \*Thresholds interpretation, \*Quantitation methods, \*Communication, \*Sampling, \*Screening methods, \*Reference material, \*Business plan, \*Tools improvement, \*Validation 'Lab' requirement

In the minutes of the 2nd of ENGL meeting (April 3 - 4. 2003, Ispra) is recommendation to set-up national GMO Networks which will be closely associated with ENGL. Such a network is already working in Germany and includes 40 different laboratories. It has confidentiality rules. In UK wide network of GMO was established too, but without confidentiality rules.

ENGL is organising programme **KeLDA- Kernels Lot Distribution Assessment** which has a three main tasks

\*Assess the distribution of GMO in kernel lots imported within the EU member States  
\*Evaluate currently used sampling strategies for the detection of GMO material in lots of bulk raw materials  
\*Provide recommendations for implementing sampling strategies.

Czech Republic is included in this programme together with other nine European countries.

*Kateřina Demnerov, Jarmila Pazlarov, Institute of Chemical Technology –  
Department of Biochemistry and Microbiology, Prague*

## **EXPERIENCE OF THE CZECH LABORATORIES WITH GMOs DETECTION AND RISK ASSESSMENT**

### **Introduction:**

Czech Ministry of the Environment (ME) is the responsible body, which regulate GMOs (Genetically Modified Organism) handling. ME is the central administrative authority in the area of assessing the impact of genetically modified organisms and products on the environment and on the biological diversity. ME execute supreme state supervision in the area of the use of genetically modified organisms and products from the standpoint of protection of the environment and biological diversity and lay down procedures for risk assessment in the use of genetically modified organisms and products.

ME regulates and controls (1) contained use of GMO, (2) introduction of GMOs into the environment and (3) the placing on the market of genetically modified organisms. ME consults GMO issues with Czech Ministry of Health and Czech Ministry of Agriculture. ME established its advisory body – Commission for Use of Genetically Modified

Organisms and Products. ME does monitoring of GMOs by means of Czech environmental inspectorate (Inspection) and by the contractual laboratories listed below. The Inspection controls how legal persons and natural persons comply with the provisions of the legal regulations and with the conditions laid down by the decisions of the Ministry related to the use of genetically modified organisms and products, from the standpoint of the environment, and cooperate with the customs authorities. Inspectorate can impose on legal persons and natural persons remedial measures and penalties for infringement against obligations pursuant to Act 153/2000. Inspection carries out inspections on its own or in cooperation with the administrative authorities.

### **GMO detection:**

A set of laboratories is authorised to run GMO analysis and environmental studies:

GMO laboratory

Institute for Chemical Technology, Department of Biochemistry and Microbiology  
Prague – Dejvice, [www.vscht.cz](http://www.vscht.cz)

### **GMO laboratory**

The National Institute of Public Health, The Centre for the Hygiene of Food Chains Brno,  
[www.chpr.czu.cz](http://www.chpr.czu.cz)

### **Reference laboratory for GMO identification and DNA fingerprinting**

Research Institute of Crop Production, Prague 6-Ruzyně, Department of Molecular  
Biology, [www.vurv.cz](http://www.vurv.cz)

Laboratories participate in control and enforcement procedures in the field of GMOs use and biosafety. They are involved in GMO identifications and biosafety framework.

### **GMO identification**

In reflection of the current state of the art detection methods insisted on DNA-based approaches, in particular those involving PCR (polymerase chain reaction). This has various reasons. DNA can be purified and multiplied in billions of copies in just a few hours with the PCR technique. However, many obstacles have to be overcome to develop reliable, reproducible and robust methods.

#### • sampling

The first step is the sampling of the material to be analysed and preparing of the laboratory sample. Sampling strategies are based on some rather complex statistics. It is necessary to use strategies suitable for detection of GMOs in huge lots of mixtures of different grains or thousands of plants in the fields.

RICP and ICT laboratories participated in KeLDA project organised by EC JRC in Ispra, Italy (sampling of grains). Based on ISO/CEN recommendations RICP laboratory propose sampling procedures, which is currently used by Inspectorate.

#### • preparation of test portion from laboratory sample

Samples have to be ground and homogenised. Analytical sample has to be prepared. Sizes of particles in the analytical sample should be monitored. Again sampling strategies and statistics are involved. The ratio of target (transgene) to non-target analyte in the test portion shall be representative of laboratory sample. How homogeneous must the sample be? What is the optimal particle size? How much material do we need?

#### • matrices from which DNA/protein are extracted (analyte extraction)

The third step the isolation/purification of DNA is. The quality, purity and amount/concentration of the DNA is the most critical factors determining the detection and quantification limits of the analyses. Different matrices required modified purification procedures and potential problems connected with specific effects are important.

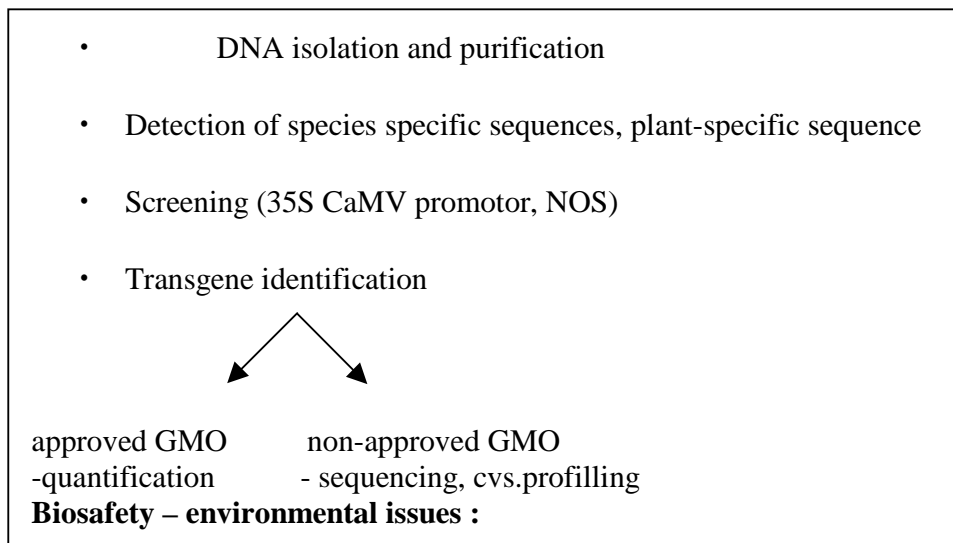
#### Acceptable performance of selected methods for GMO detection

A range of alternative methods are available, with differences in their ability to discriminate between derivatives of different GMOs, and their reliability with respect to avoid false positive and negative results. The latter is very important. A method may not be capable of detecting the presence of GMO-derivatives although such are present in the sample (false negatives). Similarly, a method may report the presence of GMO-derivatives although such are NOT present in the sample (false positives). That fore methods validations accross tens of laboratories are required and organised by EC JRC Ispro. RICP and ITC laboratories are involved.

#### Acceptable performance of selected methods for GMO quantification

Similar aspects are considered as in the case of GMO detection. However, advanced techniques e.g. real-time PCR are used. Sophisticated machines are usually used.

#### **Fig. 1 A brief chart of GMO detection procedure**



The Conference of the Parties to the Convention on Biological Diversity adopted a supplementary agreement to the Convention known as the [Cartagena Protocol on Biosafety](#) on 29 January 2000. The Protocol seeks to protect biological diversity from the potential risks posed by [living modified organisms](#) resulting from modern biotechnology. It establishes an [advance informed agreement \(AIA\)](#) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory.

Czech Republic should gather and provide information on

- the sites at which the genetically modified organism will be introduced into the environment and the location thereof
- the amounts of genetically modified organisms that are to be used and the area over

which the genetically modified organisms will be introduced into the environment  
- measures that are intended to prevent the spreading of the genetically modified organisms during the introduction into the environment and the occurrence and spreading thereof at the given site after termination of the introduction into the environment  
- information on possible interactions between the genetically modified organism and the environment.

Several projects have been supported by the Ministry of Agriculture (National Agency of Agricultural Research) and Ministry of Environment to develop data which make risk assessment more reliable. Gene flows within and between species are recorded, weedy and newly introduced species spreading is estimated, possible effect of GM cultivars upon agricultural practises is studied. Also monitoring of the incidence of insects in different agro-ecosystems is running. Experiments are mostly focused on plant species, which genetically modified forms have been released into the environment in Czech Republic – wheat and rapeseed (already withdrawn), potatoes, flax, pea and corn.

In case of wheat the most comprehensive investigation have been began. Pollen flow between wheat cultivars is studied in field experiment. Red hulled wheat (100m<sup>2</sup>) is used as a donor of morphological marker genes and commonly used cultivars (surrounding the central square) are used as acceptors of the genes. Range of flight of the pollen can be thus estimated. Annual bread-wheat related species, which occur in the territory of Czech Republic are also included. Special studied have been run to estimate the possibility of hybridisation between bread wheat and *Agropyron* ssp. *Agropyron intermedium* spreading was investigated and new stands were found. Diversity of different populations was evaluated by storage protein analysis. Double haploid lines of *Agropyron repens* were developed. The lines were pollinated by wheat pollen and vice versa. Caryopses developments were studied. In case of flax and pea studies revealing survival of seeds after waste disposal (e.g. composting).

Competent authorities in Czech Republic possess tools, which make efficient control of GMOs possible and which provide information on individual aspect connected with biosafety.

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## **EXPERIENCE WITH GMOS INPECTION IN SLOVAKIA**

**Slovak Act on Use of Genetic Technologies and Genetically Modified Organisms No 151/2002Coll. came into force on 1<sup>st</sup> April 2002. Transition period related to the enforcement of this act ended on April 1<sup>st</sup> this year.**

The main government body in Slovak Republic that regulates use of GMOs is Slovak Ministry of the Environment.

Biosafety Commission and Board of Experts represent main advisory bodies.

The body of state supervision over use of genetic technologies and GMOs is the Slovak Inspectorate of the Environment.

Organisationally, the Slovak Inspectorate of the Environment consists of: the Headquarters and the subordinate inspectorates. The Headquarters - located in Bratislava, manages the activity of individual inspectorates and plays a role of the second grade appeal body in the administrative proceeding in regard to the penalties imposed by local inspectorates for infringement. It secures guidelines and other expert support as well as communication with the Ministry of the Environment.

The SIE is mainly responsible for the inspection of contained use of GMOs taking part in both research and diagnostic laboratories as well as on experimental plots. Each producer and first ever-national importer of GMO must first obtain permission from the Ministry of the Environment. Once approved and permitted, GMO handling responsibilities are transferred to relevant ministries and state administration bodies.

SIE may impose a fine of up to 5 million SKK (about 120 000 euro ) for:

- ◆ GMO handling without notification,
- ◆ GMO handling in contained facility, which is not recorded in the register of facilities,
- ◆ GMO handling in facility without establishing the safety committee or biosafety officer,
- ◆ GMO handling GMOs without a permit,
- ◆ import or placing the GM products on the market without permit.

*Janka Swarzová, Slovak Inspectorate of the Environment - Department of Biosafety Inspection, Bratislava*

## **Survey on public perception of GMOs**

### **Comparison between Czech and German respondents**

#### **Introduction**

The survey on public perception of GMOs based on questionnaire was carried out in 2001. The respondents were Czech and German university students with different skills (the main three groups involved students of agro-economics, medicine, and students with **other** skills). The survey was based on a sample of 400 respondents, 200 of them in each country, equalised between men and women. A statistical analysis was made by means of statistical software SAS.

The main aim of this survey was to show attitudes of Czech consumers about GMOs and compare them to German ones. The key question was: "Are you a supporter or an opponent of GM crops?" With this question correlate the other questions that investigate the information rate

about GMOs, influence of public media, interests and preferences of the consumers. Based on these preferences, conclusions for GMOs marketing strategies could be drawn..

## Survey results

### ➤ **Minority of GMOs supporters**

The key question (Are you a supporter or an opponent of GM crops? – q.Nr.6) have answered in positive way 23% of the Czech men and 18% of the German men and only 9% of the Czech and 7% of the German women. The most sceptical about GMOs were German women. I think that the low percentage of positive answers in women group is caused by women status as a mother who feels the responsibility for the family and keeps the preliminary caution. In Germany, the negative attitude to the GMOs could be reinforced by the state promotion of organic farming and fear of this system about GMOs impact. This opinion support the higher percentage of Bio fans (q.Nr.18) and higher request for the ban on field trials with GMOs (q.Nr.15) by German students.

### ➤ **Less fear by the Czech consumer**

The question Nr.14: “Are you afraid of the consumption of GMO products?” refers to consumer’s fear of GMOs consumption. In Germany, almost a half of those asked (47%) are afraid of the GMO’s consumption. In Czech Republic, fewer respondents reject the GMO products – 37%. In women group there was observed higher fear (CR-42%, Germany-52%) than by men (CR-31%, Germany-40%) in both countries. The lowest aversion to GMO’s consumption showed the students with technical and biological skills. These students showed also higher rate of information about GMOs (q.Nr.14). In opposite, students, who did not achieve high information level, showed bigger fear of GMO’s consumption. The highest aversion was found by German students of agro-economics (women-63%).

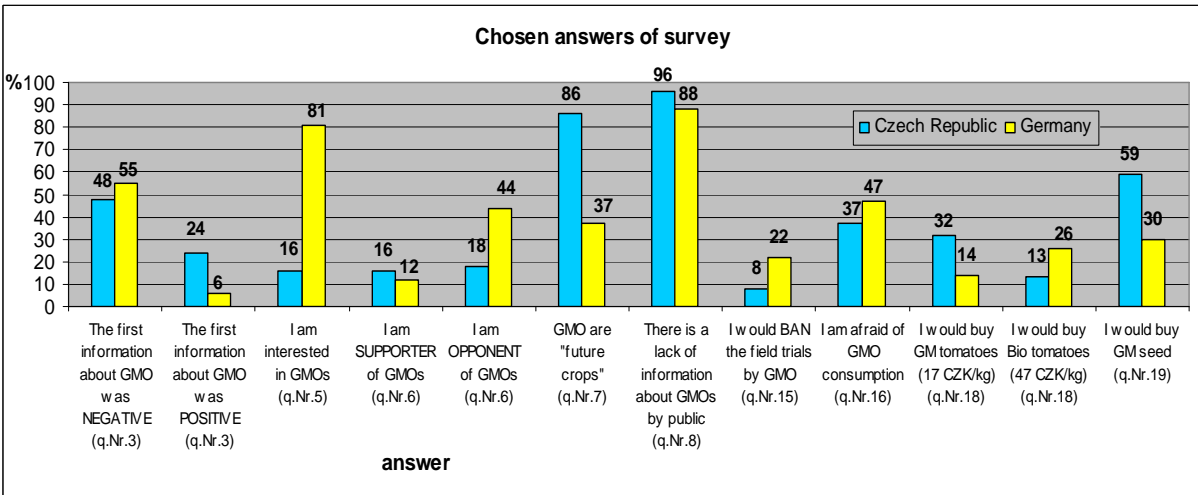
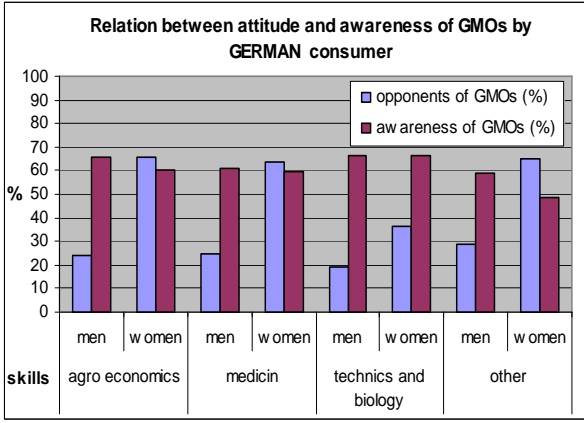
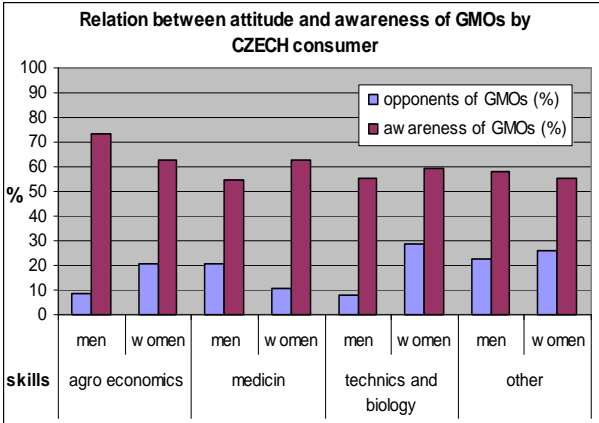
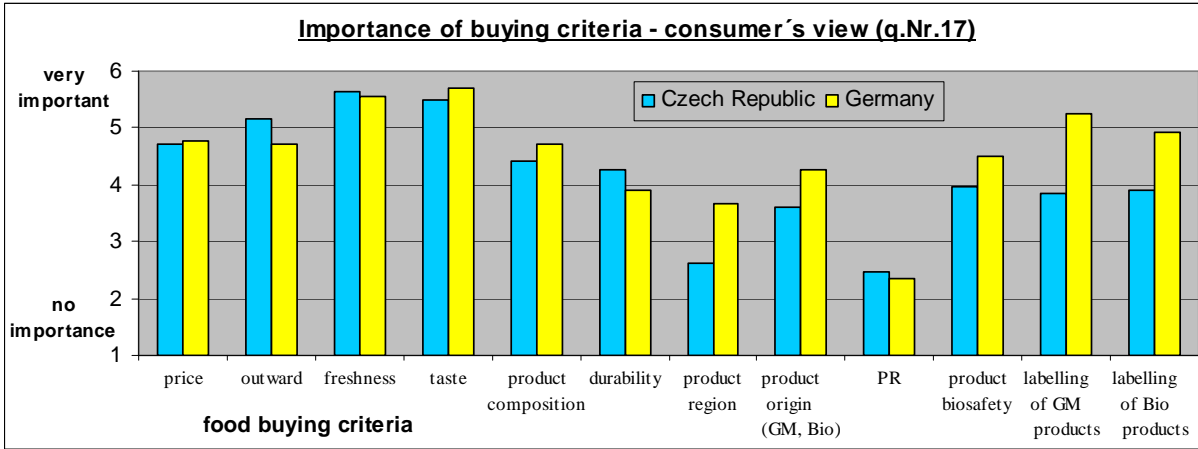
### ➤ **Lack of information about GMOs, negative information**

In summary we could say that there is quite a good awareness of GMOs (q.Nr.4) by students. But they mean that the public has not enough information about GMOs. This lack of information was observed in both countries – CR 96%(!), Germany 88% (q.Nr.8). The lack of information was related as a risk of GMO release or as a cause of fear of the GMO consumption. The survey reveals that in both country respondents have heard more frequently those who oppose GM crops (q.Nr.3), while only 24% Czech and 6% German have heard more frequently those who support them.

### ➤ **Average awareness of GMOs – 60%**

Average information level of GMOs ranges about 60% (equal to 3-4 right answers of total 6 – q.Nr.14). The higher information level show students of agro-economics and men. The other groups did not achieve the average rate of 60%. Students of agro-economics manifested statistically significant higher level than the students with other skills (with the exception of students of medicine). The lowest information rate was found by students of humanity studies. These students showed also the highest aversion against GMOs.

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