

# **NATIONAL BIOSAFETY FRAMEWORK**

## **FOR THE SLOVAK REPUBLIC**

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**(Editors)**

**DRAFT**

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**Ministry of the Environment SR**

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## **Foreword**

The active protection of the environment has become a part of economic process, political and social life. There are regularly organized international sessions of local, regional and global importance. The goals of these sessions are to exchange information relevant to the state of components of ecosystems, to gain the experience with conservation of biological species and abiotic elements of the environment, prepare proposals of regional and global legislation, and the experience with using these legislation.

The conservation of the biological diversity remains significant element of the environmental protection. Several important decisions, which encourage the Parties to improve the conservation of biological diversity, were adopted at the COP 7 (COP = Conference of the Parties) in Kuala Lumpur. Another important meeting was the First meeting of the Parties of the Cartagena Protocol to the Convention on Biological Diversity - COP/MOP1. Even though it was the first meeting of the Parties, it contributed to strengthening position of Protocol in international context.

As the President of the COP4, which took place in Bratislava, Slovakia, I have good memories of the period between the years 1998 – 2000. The most intensive discussion about the text of the Protocol was held in different parts of the world within agenda of COP4. The final text of the Protocol was adopted at the Secretariat of the Protocol in Montreal in January 2000.

I gladly recall all discussions about the final version of the text of the Protocol until it was negotiated and acceptable for all negotiating groups very well. It was inspiring despite the fact that debate lasted until late nights or many times until early mornings.

After adopting the Protocol we started with preparation of the national legislation in Slovakia. We exploited the experience of colleagues from different European countries, but the “real impulse” for intensive international cooperation was the Project UNEP/GEF. It allowed not only

concluding the legislative framework for GMOs use and at the same time to join international cooperation in the field of biotechnology. In 2002 Slovakia organized a workshop, where the Secretariat CBD launched the important part of Cartagena Protocol- Biosafety Clearing House. National Council of the Slovak Republic adopted our first Act on GMOs at the same year.

In the scope of implementation of the Project “Developing of National Biosafety Dept. Biosafety MoESR Framework”, we prepared the amendment of our Act, that include the provisions of Cartagena Protocol, we improved administrative and information structures and we arranged a lot of seminars and workshops for different target groups.

We took advantage of the experience from the Project for successful ratification of Cartagena Protocol. Slovakia ratified the Cartagena protocol in November 2003, so we had already become the Party to the Protocol at COP/MOP1.

The cooperation in the field of Biosafety as the member of the bureau of Convention and Cartagena Protocol is ongoing.

Our next steps will point toward improvements of the regional cooperation with European countries and at creation of structures for monitoring of GMOs in the environment.

Henceforth we will keep all friendly and collegiate relations that we gained during the cooperation in the field of biotechnologies up to now.

László Miklós  
Minister of Environment  
Of the Slovak Republic

## **Information on the Project**

UNEP-GEF– GEF Project Number GF/2716-02-4573 (PMS:GF/6010-01-3A) Project

„Development of the National Biosafety Framework for the Slovak Republic“ started in January 2002 and was prolonged till October 2004.

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**National Coordination Committee** consisted of 9 members, representing:

Ministry of the Environment, Ministry of Agriculture, Ministry of Health, Comenius University, Slovak Academy of Sciences, Scientific Press VEDA, private sector, nongovernmental organizations and civil societies (Annex 1).

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## **Abbreviations**

BCH Biosafety Clearing House

CCTIA Central Control and Testing Institute of Agriculture

EU European Union

GEF Global Environment Facility

GMO Genetically Modified Organism

GMOs Genetically Modified Organisms

LMO Living Modified Organism

MoE SR Ministry of Environment Slovak Republic

MoA SR Ministry of Agriculture Slovak Republic

NBF National Biosafety Framework

NCC National Coordinating Committee

NGO Non-governmental Organisation

PHA Public Health Authority

SEI Slovak Environmental Inspection

SVFA State Veterinary and Food Agency

UNEP United Nations Environmental Programme

## **1. Biosafety Policy**

Slovak Republic has adopted system of legislative norms for protection of biological diversity, safe use of biotechnology and GMOs with their application in the environment and agriculture. The legislative norms adopted allow exploitation of genetically modified organisms under strictly defined conditions. These include releases to the environment, contained use and marketing of GMOs including genetically modified foods and feeds. Slovak Republic ratified the Convention on Biodiversity and Cartagena protocol on Biosafety in November 2003. To strengthen the system on biosafety Slovak Republic joined several international projects. The UNEP/GEF project is aimed on the development of the mechanisms for Biosafety Clearing House and implementation of the Cartagena protocol. The PHARE projects are oriented to the adoption EU environmental legislation and to cover gaps in Biosafety system in governmental control and inspection. Slovak scientific priorities have been stated in 2000 where bioscience plays prominent role. Priorities are consonant to EU priorities with biosafety, food safety, biotechnology and informatics on the first place.

The Environmental Policy reflects the needs of protection and conservation of Slovak environment, improvement of the health of people, economical growth including agriculture, industry and transportation. It is based on the prevention principle, principle of sustainable development, with endeavour to enhance environmental education and public participation.

The prominent role of Cartagena Protocol in shaping legal framework for biosafety was recognized and implemented to Slovak legal system (Notification of ministry of Foreign Affairs 82/2004 Coll.) in February 2004. Important tool for implementation of national biosafety policy is Act on GMOs and Decree to the Act. Act No. 151/2002 Coll. on the use of genetic technologies and genetically modified organisms (Act on GMOs) is in force as of April 1<sup>st</sup> 2002 and implementing regulation Decree No. 252/2002 Coll. of the Act on GMOs as of June 1<sup>st</sup> 2002. The law is first instance legislation for GMOs. It regulate releases, marketing, contained use of genetically modified micro-organisms, higher plants, and animals. Approval for any use of GMO must be granted under this Act. Based on this approval the specific uses further require approvals granted by different central institutions.

Other laws that are listed later in the text cover safety aspects for the human health, food and feed safety and agricultural applications. The responsibility for human health is at Ministry of Health, which also share the responsibility for food with Ministry of Agriculture, which has responsibility for regulation of seeds, feed and other agricultural application of GMOs.

## 2. Regulatory regime

In the last decade the environmental legislation in Slovak Republic was developed with the vision of membership to EU. The harmonization processes of Slovak legislation to EU legislation lead to high complementarities of both systems. During that time Slovak Republic became the party to international conventions with adopting legal system accordingly.

Regulatory regime for biosafety consists of binding international treaties and EU and national legislation.

The provisions of international treaties, EU directives and other EU legislative acts that are not directly applicable are implemented into the national legislation. As EU regulations are directly valid in member countries national legislation does not cover some aspects of GMOs and biosafety issues.

International treaties

**Convention on Biological Diversity** was ratified November 2003 and entered into force in February 2004.

The following EU directives establish a regulatory framework concerning GMOs and biosafety in the EU. The requirements of these directives have been implemented in the national legislation.

**Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.**

The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

- Carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,
- Placing on the market genetically modified organisms as or in products within the Community.

**Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified**

**micro-organisms; Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.**

The Directive lays down common measures for the contained use of genetically modified microorganisms with a view to protect human health and the environment. In accordance with the Directive, Member States have to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment that might arise from the contained use of GMMs.

*The directly applicable EU legislative acts concerning GMOs and biosafety.*

**Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms**

Regulation:

- Establishes a common system of notification and information for transboundary movements of genetically modified organisms (GMOs);
- Ensures a coherent implementation of the provisions of the Cartagena Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of the GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health.

The Regulation establishes the procedures that are in compliance with Cartagena Protocol in respect to exports of GMOs to third countries (which are not member states of the EU).

There are different procedures for:

- GMOs intended for deliberate release into the environment and
- GMOs intended for direct use as food and feed, or for processing.

**In SR the competent body for CPB and for relevant EU directives is Department of Biological safety of MoE SR. Ministry of Agriculture is national competent body for food and feed in respect of communication with European Commission.**

**Regulation (EC) 1829/2003 of the European Parliament and Council of 22 September 2003 on genetically modified food and feed**

In accordance with the general principles laid down in Regulation (EC) No 178/2002 this

Regulation:

- Provides the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring effective functioning of the internal market;
- Lays down Community procedures for the authorization and supervision of genetically modified food and feed;
- Lays down detailed provisions for the labelling of genetically modified food and feed.

The Regulation establishes detailed procedures for the authorization and supervision of genetically modified food and feed.

The Regulation requires labelling of the food and feed, which are to be delivered as such to the final consumer or mass caterers in the Community and which:

- (a) Contain or consist of GMOs; or
- (b) Are produced from or contain ingredients produced from GMOs.

The Regulation states also that labelling of foods containing a material which contains, consists of or is produced from GMOs is not required in the case when GMOs proportion is not higher than 0.9% of the food ingredients considered individually or for food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable. 0.9% limit is for GMOs that are approved for marketing, and 0.5% for GMOs having positive opinion of scientific assessment of EFSA and approved by EFSA and 0% non-approved GMOs.

The institutions responsible for the implementation of this Regulation are basically the EU authorities – the Commission, Food Safety Authority and the Council, making decisions on the use of genetically modified food and feed in the territory of the EU.

**Ministry of Agriculture SR is national competent body for food and feed in respect of approval of GM food and for communication with European Commission.**

According to the last amendment to the Food law (Act No. **546/2004 Coll**). The responsibility is for:

- Acknowledging of receipts of applications;
- Informing and making the applications, and for any supplementary information supplied by the applicants available to the European Food Safety Authority.

**Commission Regulation 641/2004 of 6 April 2004** establishes detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

**Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety**

The Regulation

- Lays down the general principles governing food and feed in general, and food and feed safety, in particular, at the Community and the national level;
- Establishes the European Food Safety Authority;
- Lays down procedures for matters with a direct or indirect impact on food and feed safety in order to provide the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account, in particular, the diversity in the supply of food, including traditional products;
- Establish common principles and responsibilities, the means to provide a strong scientific base, efficient organizational arrangements, and procedures to underpin decision-making in matters of food and feed safety.

**Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.**

The Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products from circulation.

This Regulation applies, at all stages of placing the product on the market, to:

- Products consisting of, or containing GMOs placed on the market in accordance with Community legislation;
- Food and feed produced from GMOs placed on the market in accordance with Community legislation.

Regulation establishes detailed requirements for:

- Traceability and labelling of products consisting of or containing GMOs,
  - Traceability of products intended only for direct use as food, feed or for processing (requirements for labelling of these products are established by Regulation (EC) 1829/2003).
- Compliance with these requirements has to be ensured by the operators.

### **Traceability and labelling requirements for products consisting of or containing GMOs**

At all stages of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators have to ensure that the following information is transmitted in writing to the operator receiving the product:

- (a) That it contains or consists of GMOs;
- (b) The unique identifier(s) assigned to those GMOs in accordance with Article 8 of the Regulation.

For products consisting of or containing GMOs, operators have to ensure that:

- (a) For pre-packaged products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ appear on a label;
- (b) For non-pre-packaged products offered to the final consumer the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ must appear on, or in connection with, the display of the product.

### **Traceability requirements for products for food and feed produced from GMOs**

In the event of placing on the market of products for food and feed produced from GMOs, the Regulation states that operators have to ensure that the following information is transmitted in writing to the operator receiving the product:

- (a) An indication of each of the food ingredients produced from GMOs;
- (b) An indication of each of the feed materials or additives produced from GMOs;

(c) In the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

The institution responsible for the implementation of this Regulation is Ministry of Agriculture of SR together with national control institutions – the State Veterinary and Food Administration, the Central Control and Testing Agricultural Institute.

### **Biosafety related legislation Slovak Republic**

The relevant legislation covering wide range of application of GMO is as follows:

#### *Food legislation*

Act No 23/2003 Coll. that amends Act 159/1995 Coll. on food. Giving the option to use GMOs in food; require approval of Ministry of Health SR.

Under current amendment (as from 1<sup>st</sup> of January 2005), the Genetically Modified Foods can be put on the market under the condition approved by European Commission.

Food Codex, decree 1865/2001-100, §142a on obligatory labelling foods containing GMO is in line with EU legislation. Responsible institution is Ministry of Health SR, Ministry of Agriculture SR.

#### *Seed and plant variation legislation*

Act No 470/2002 Coll. that amends Act no. 291/1996 Coll. on varieties and seeds. Responsible institution - Ministry of Agriculture SR. The amended Act regulates the rights and obligations of natural and legal persons in the registration and testing of plant varieties and in the production, recognition and placing on the market of planting stock and plant varieties. It harmonises the registration and testing of plant varieties and the production, recognition and placing on the market of planting stock and plant varieties. It is necessary to obtain permit for deliberate release issued by MoE for field trials and for testing of GM varieties according to this act. Then the procedure of adopting of new variety is administrated in the European Committee. The last step of adoption is registration to the Common European register of approved varieties.

### *Feedstuffs legislation*

Act No 184/93 Coll. on feedstuffs (with three ordinances from January 2002; on ingredients used; on technical equipment and special nutritional value indicators; on use of additives). Responsible institution is Ministry of Agriculture SR. With effect from 1 March 2002; the Act amends three Ordinances of the Ministry of Agriculture.

1. Ordinance of 31 January 2002 No. 39/1/2002-100, which amends MoA Ordinance of 7 October 1997 No. 1497/1/1997-100 on the ingredients used in the production of compound feeds and farm feedingstuffs;
2. Ordinance of 31 January 2002 No. 39/2/2002-100, which amends MoA Ordinance of 7 October 1997 No. 1497/2/1997-100 that lays down the requirements for technological equipment and technological processes employed in the production of compound feeds and specifies the indicators of nutritional value and the use of compound feeds;
3. Ordinance of 31 January 2002 No. 39/3/2002-100, which amends MoA Ordinance of 7 October 1997 No. 1497/3/1997-100 that lays down conditions for use of additives and their putting into circulation.

### *Related legislation*

- Act No 11/1992 Coll. on the environment is the basic law to protect environment.
- Act No 543/2002 Coll. on the nature and country protection.
- Act No 237/2002 Coll. on the trade with wild animals and plants (CITES).
- Act No 215/2001 Coll. on the protection on genetic resources of plants aimed for the nutrition and agriculture.
- Act No 415/2002 Coll., which amends Act No 224/98 Coll. on organic farming. The policy of this Act for organic farming is the same as in EU countries. The Act determines the governmental body responsible for register, inventory, control and overall management of the organic food production. According the § 7 article 4b it is forbidden to use GMOs in bioproducts.
- Act No 415/2002 Coll. 471/2001, which amends Act No 285/95 Coll. on phytosanitary care.
- Act No 23/2003 Coll., which amends Act 159/1995 Coll. on food.

- Food Codex, decree 1865/2001-100, §142a on obligatory labelling foods containing GMO with line with EU legislation.
- Act No 514/ 2002 Coll., which amends Act No 272/1994 Coll. on the protection of human health.
- Act No 367/2001 Coll. on the safety and protection of human health at the workplace.
- Governmental Decree No 47/2002 Coll. on the health protection while working with biological factors.

### **Future plans and needs**

- The Act No. 151/2002 Coll. on the use of genetic technologies and genetically modified organisms as well as the Decree No. 252 of the MoE SR on the same topic is prepared for amendments to meet current EU legislation on GMOs.
- The bottleneck of Slovak Biosafety system is trained laboratory staff and equipment for GMO detection in the environment and food chain. The Phare project on the GMOs detection system in Slovakia “**Biosafety Monitoring System**“ for Slovakia will start in autumn 2004 to fulfil the EU standards.
- The rules on the “Co-existence” of traditional, organic and GM varieties farming needs to be prepared by MoA SR in future.

### **3. System to Handle Notifications or Consent for Use of GMOs.**

#### **Principles of GMO Act**

Competent authority for handling matters on the Genetic technology and GMOs is Ministry of the Environment SR (MoE SR).

The manipulation with GMOs in contained conditions and use of GMO in the case of its introduction to the environment requires, under Slovak legal system, approval by competent authority. The competent authority, MoE SR, after receiving request from applicant, publish it and then submit it for the assessment to the Commission for Biosafety, an advisory body of MoE SR. The commission was established by the minister of MoE SR as an advisory body consisting of twelve members (Details are in Annex 1). The members are:

- representatives from involved ministries: agriculture, health, education and defence,
- scientists, working in institutes of Slovak Academy of Sciences and in universities,
- representatives of public: consumer and environmental NGOs.

For strengthening of the expert level of committee there is an board of experts having 15 members, scientists from different expert areas: environment, human and veterinary medicine, food and feed production, plant and animal breeding, micro organisms. For the actual cause they are also serving as a member of committee in its meeting.

More details are in Annex2.

Forms for applications are prescribed by the implementing Decree (available also on the website: [www.enviro.gov.sk](http://www.enviro.gov.sk), part GMO).

All cases of handling GMOs, either their contained use or releases to the environment, are submitted to the approval process. It means that every legal entity or a person intending exploit GMOs has to receive approval in advance. User of genetic techniques and GMOs is legal entity or a person using GMOs not the final user of it on the market - consumer.

Procedural framework for use of GMOs is different for contained use and for introduction into the environment.

#### **Contained Use**

The operator of a facility has an obligation to be registered with MoE SR. The facility may be entered into the facility register only if complying with construction and technical equipment requirements and requirements concerning its location, internal operational arrangements,

laboratory procedures and system of work in contained rooms and the waste handling and waste water treatment.

The user is obliged to:

- establish a safety committee for contained use at each facility,
- appoint a head of the project for each use of genetic technologies and genetically modified organisms

The head of the project should have to have professional qualification that means university education in relevant field, at least three-year experience in genetic engineering and modern biotechnology and regular participation in professional education.

The member of the safety committee should be person with integrity; university education in relevant field and three year experience in using of genetic technologies and genetically modified organisms.

A user should assure the implementation of following principles as regards the occupational safety and health protection and good microbiological practice in facilities.

Prior to the beginning of any contained use the user have to:

- to execute measures for averting of possible harmful effects to humans and environment, that may be resulting from such use, to assess the risk arising from planned contained use, in particular as regards the possible harmful effects to humans and environment, on the basis of result of the risk assessment to assign the prepared use of genetic technology to a risk class,
- to provide the level of protection corresponding to the risk class and its relevant requirements on contained use and particular protective measures,
- to draw up the emergency response plan and make it available via internet, or in other appropriate manner,
- to provide the substantial information on the content of the emergency response plan to persons likely to be affected in case of accident,
- to submit a notification or submit an application for consent with contained use.

The user has to identify the following possible harmful effects in risk assessment:

- allergenic and toxic effects of genetically modified organisms to humans,
- effects of genetically modified organisms to animal and plant health,

- effects causing resistance to antibiotics used in human and veterinary medicine,
- effects deleterious for providing of effective prophylaxis
- effects due to the natural transfer of inserted genetic material to other organisms.

The user has to assign any planned contained use to one of the following risk class:

- risk class 1 – activities of no or negligible risk, for which level 1 containment is appropriate,
- risk class 2 – activities of low risk, for which level 2 containment is appropriate,
- risk class 3 – activities of moderate risk, for which level 3 containment is appropriate
- risk class 4 – activities of high risk, for which level 4 containment is appropriate.

In case of doubt the higher risk class shall be applied to the proposed use, unless the reason for applying lower risk class is justified.

The notifier has to notify Ministry on:

- The data on the head of the project and on members of the safety committee, as well as the changes in these data,
- The commencement of the activity assigned to risk class 1 in facility, for which first consent for contained use has been issued,
- The commencement of the activity assigned to risk class 2 in facility, for which the consent for contained use in activities assigned to classes 2 to 4 has been already issued and for which all requirements of this consent have been met,
- The finding out of new information concerning the activities that may have significant impact on risk.

### **Deliberate Release**

Deliberate release is any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms or their placing on the market, for which no containment measures have been used to limit their contact with population and environment with the aim to provide high level of safety.

Introduction or release into environment is every use of genetically modified organisms in environment, particularly seeding, planting, farming and release into wild nature.

Placing on the market is every accessing of the products to third persons on the market with the exception of accessing of the genetically modified organisms including culture collections for contained use or release into the environment.

Prior to beginning of every deliberate release the user have to:

- describe up the emergency response plan and make it available via the Internet, or, if appropriate in other manner.
- provide substantial information on the content of emergency response plan to the persons that are likely to be affected in case of an accident,
- to carry out measures for prevention of possible adverse effects on humans and environment, which could be caused by the deliberate release,
- assess the risk arising from planned deliberate release, in particular to identify and evaluate direct and indirect, immediate and delayed effects of genetically modified organisms on humans and environment,
- perform the analysis of cumulative long term effects of genetically modified organisms on humans and environment,
- decide on the need for risk management and on the use of the most suitable genetic method,
- assess every case of possible adverse effects arising from direct or indirect transfer of genes from genetically modified organisms to other organisms,
- to apply for a consent and comply with the requirements laid down in the Act on GMOs.

Consent of the Ministry for introduction into the environment is required for:

- first and every other release of a genetically modified organism or a combination of genetically modified organisms into the environment, which means on the market and/or field releases
- change of the purpose of introduction of a genetically modified organism, several genetically modified organisms and a combination of genetically modified organisms, which could have significant effect on humans or environment or which could give rise to new knowledge of such effects,
- import of genetically modified organisms designed for the introduction into the environment.

One consent for introduction into the environment may be issued for the introduction of the same genetically modified organism or the same combination of genetically modified organisms to the same place or to various places but for the same purpose at the same time.

### **Withdrawal or alteration of the consent to the use – safeguard clause**

The MoE SR, on the basis of new evidence regarding risk involved to the use of GMO, may alter or withdraw the consent for use of it. In the case when the GMO is introduced to the common market of EU and, there is good reason to believe that it represent risk for human health or to the environment, the member state can stop the use of it in its territory.

### **Future plans and needs**

The system for handling notifications and permissions for use of GMOs is well established according to EU standards in Slovakia.

The system of presenting Slovak position in the EU Commission by two different ministries (MoE and MoA SR) needs to be co-ordinated, as they often present not consistent opinions.

## **4. Monitoring and Enforcement**

### **Descriptions of system for monitoring**

The national system for monitoring of safe use of GMO depends upon the provisions of the Act No. 151/2002 Coll. (in force since April 1st, 2002), on Use of Genetic technologies and Genetically Modified Organisms, relevant secondary legislation to this act and, of course on the relevant EU directives. The competencies for monitoring of the compliance with legislative requirements are devoted to the Slovak Environmental Inspection (SEI), an inspection body of the Ministry of Environment. SEI is competent for control of using of GMOs in contained use and field trials. It is responsible for inspection of the labeling of those special products on the market, which are not in competency of other authorities.

Other authorities responsible for monitoring are Ministry of the Environment, Ministry of Agriculture and Ministry of Health. Besides of SEI, the specialized control bodies of these ministries are:

- The State Veterinary and Food Agency – competent for control of food and veterinary products
- The Central Control and Testing Institute of Agriculture – competent for control of feed and seed products
- The Public Health Authority – competent for control food in public catering enterprises.

### **Slovak Environmental Inspection, biosafety department (SEI)**

SEI is the main competent authority regarding supervision and control of GMOs designated by the Act No. 151/2002 Coll. The general Act on State Control No. 10/1996 Coll. is applied by the SEI, too.

The Slovak Environmental Inspectorate is an authority providing state supervision and imposing fines on the matters concerning environment protection. The competences of SEI increased substantially in regards to the transposition of the EU legislation into Slovak legal framework. As a result of it a new Biosafety department for supervision on the use of genetic technologies and genetically modified organisms has been established in 2003.

The main task of SEI is to control the performance of the Act in the process of utilisation of GMOs in contained use. At the same time SEI controls the conditions for the labs use, affirmed by MoESR in approval. There are currently registered 19 GMOs users in contained use with

more than 200 labs in the Slovak Republic currently. These are mainly institutions of the Slovak Academy of Sciences and of the Universities. Three of users are private companies.

No serious faults were observed till now, so there was no need to restrict or cease their activities or inflict a fine in line with the “Gene” Act. While controlling GMO releases to the environment, the compliance with the conditions established by MoE SR are being checked up. No GM crops trial has been approved and put into practice in the Slovak Republic so far. The process of the market releases of GM commodities are controled, as well as the adherence of their labeling and conditions of their exploitation, which were set up by MoE SR during approval procedure.

Since 1<sup>st</sup> May 2004, when the Slovak Republic has become the member state of the European Union, the conditions for approval of GMOs and its placing on the market have been guided by European Commission. SEI controls the conformity with EU legislation.

#### **The State Veterinary and Food Agency (SVFA)**

SVFA executs control of food products on the market, particularly food safety aspects and also the correctness of labelling. The competency of SVFA are given by the Act No. 159/1995 Coll. as ammended by No. 23/2003 Coll. on Food and Decree No.1865/2001-100 of Food Codex.

When examining the presence of GM food products on the market SVFA found a few goods, which contents was inferior, some products contained higher amount of GMO than limit established by EU.

Since 1<sup>st</sup> of May 2004, goods approved by European Commission can be sold in the Slovak Republic, too. These goods must comply with EU conditions (labelling, content of GM component, etc.), which factuality is also controled by SVFA.

#### **The Central Control and Testing Institute of Agriculture (CCTIA)**

CCTIA, one of the oldest control bodies in Slovak Republic, established in 1951 on the bases of Kings Hungarian Seeds Control Institute (founded in 1884).

Acts (later ammended) gives the scope of the activity of the CCTIA ([www.uksup.sk](http://www.uksup.sk)) on the feeds (Act. No. 184/93 Coll.), Varieties and seeds (Act. No. 291/1996 Coll.), fertilizers (Act. No. 136/2000 Coll.), state phytosanitary service (Act. No. 291/1996 Coll.).

It is responsible for expert controlling in the above-mentioned areas. Besides this it is responsible for GMO monitoring in the seed and feed materials. For this purpose CCTIA created its own laboratory, which is in the process of accreditation by national authority – Slovak National

Accreditation Service. Their task is to monitor the presence of GM components mostly in feeds as the GM seeds are not used in Slovakia.

The CCTIA is responsible to register and control the organic farmers, in line with Act No. 224/1998 Coll. on Organic Farming.

### **The Public Health Authority (PHA)**

The responsibility of PHA is given by the Act on Food No. 159/1995 Coll. as amended by No. 23/2003 Coll. The Novel Foods including GM foods have to be approved by PHA before putting them on the market. PHA assess the safety of novel foods for human consumption and performs the monitoring of the presence of food products that may contain traces of genetically modified organisms on the market and exchanges this information with the Ministry of the Environment. The institute is independent from other monitoring and control bodies.

### **Laboratories for detection and assessment of GMOs**

SEI and PHA do not perform laboratory examinations and tests for GMOs. For control purposes they utilize the installation of the others inspections.

SVFA possess two labs, one of them is based in Dolný Kubín. This lab is accredited for detection of quality and quantity of GM Food.

CCTIA has got very good equipped lab in Bratislava, and is in the final phase of accreditation process for detection GMOs in plants and feed materials.

The Institute of Molecular Biology Slovak Academy of Sciences (IMB SAS Laboratory) dedicated to the method development and focused on the detection of unique GMOs produced for research purposes is being created. The institute will also serve as the reference laboratory, once accredited.

All introduced labs are the members of the european DNA labs network ENGL of EU Joint Research Centrum, based in Ispra, Italy and are also cooperating with the others worldwide organisations (e.g. ICGEB).

### **Adresses of institutions responsible for above described actions**

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Slovak Academy of Sciences  
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### **Future plans and needs**

- To create better links between Slovak accredited laboratories involved in the European Network of the GMO laboratories – ENGL.
- To held regular discussions of the experts involved in risk assessment and risk management.
- To provide support to the GMO control institution via organization of workshops, seminars and courses especially in sampling GMOs in order to improve the controlling and monitoring processes.

## **5. Public participation and public information in the decision making process**

The right of public to be informed, the freedom of speech, the right to freely spread information and ideas is anchored in the Slovak Constitution and further broadened by Act No. 23/1991 on the List of Basic Human Rights and Freedoms.

Within the environmental context there are following international obligations:

**Aarhus convention** on the access to information, public participation in decision making and access to justice in environmental matters from June 1998.

Status: Not ratified.

**Cartagena Protocol on Biosafety** to the Convention of Biological Diversity is another international legally binding instrument which recognizes the importance of public awareness and participation (Article 23). The Parties to the Protocol should provide information to the public by means of the Biosafety Clearing-House.

Status: Ratified November 2003

### **European legislation**

#### **Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC**

This Directive is based on the principles anchored in the Aarhus Convention that is transposed to European Community legal system.

The objectives of Directive 2003/4/EC are:

- a) to guarantee the right of access to environmental information held by or for public authorities and to set out the basic terms and conditions of, and practical arrangements for, its exercise; and
- b) to ensure that environmental information is progressively made available and disseminated to the public in order to achieve the widest possible systematic availability and dissemination of environmental information to the public.

The Directive regulates access to environmental information, access to justice, dissemination of environmental information, the quality of environmental information and the review procedure of the Directive based on the experience gained by the Member States.

### **National legislation**

National legislation supports public information and public participation in decision-making processes. General conditions, procedures and scope of the right of public to free access to information is given by the Act 211/2000 Coll.

As regards particularly GMOs the **Act on use of genetic technologies and genetically modified organisms 151/2002 Coll.** has implemented the obligation of the MoE SR to inform public. The Act contains provision transposed from EU legislation (Directives 90/219/EHS, 98/81/ES, 2001/18/ES) and the crucial ideas of Cartagena Protocol and Aarhus Convention.

Department of biological safety of the MoE SR as national competent authority for handling requests for GMO endorsement has the obligation of providing:

**General information via:**

- publication on the Internet
- publication in the official journal
- publication in the means of mass communication – news papers, leaflets, brochures,
- TV, radio
- Providing seminars, courses

**Information on requests:**

- Orally, or on telephone request
- Assist in the sending information by post, electronic post or by fax
- assist in the making a copy of request

MoE SR has the obligation to inform public on:

- beginning of the authorization
- a summary the content of requests
- reports on the results of introduction of GMOs into the environment
- activity reports on the results of the Biosafety Committee
- evaluation report for the EU

There are several other paragraphs dealing with obligation to provide information in the case of trans boundary movement of GMOs, accidents and measures for their removal etc. One of them is the requirement to label genetically modified products on the market.

The Act (Article 27) establishes Commission for Biosafety and its board of experts as an advisory body to the Minister of Environment. The task of the Commission is:

- a) to deal with the state of the scientific and technologic development in the field of genetic technologies in particular to gather the results of any contained use and deliberate release obtained from notifier's reports and notifications, to generalize it and compare to scientifically proved facts obtained on the international level,
- b) to analyze, review and assess the content of submitted notifications and applications for issue of notifications from the point of view of science and available knowledge on genetic methods, genetic techniques and on risks arising from the use of genetically modified organisms,
- c) to work out the recommendations as the professional basis for Ministry issuing the consents (Article 13, 17 and 21),
- d) to analyze and assess the content of received comments from public,
- e) to work out recommendations needed for determination of technical and organizational requirements on facilities, good laboratory practice, monitoring and evaluation of the use of genetic technologies,
- f) to assess the proposals for entering the register of used genetic techniques, genetic methods and used modified genes.

The Commission meets regularly every month and on important issues if necessary.

The board of experts scientifically supports the work of Commission.

The rules for decision making process contain mechanism for public involvement. Besides representation of governmental institutions the participant may be non governmental organisations and civic associations. The summaries of the notifications are published on the web page of MoE SR ([www.enviro.gov.sk](http://www.enviro.gov.sk)). The public can send comments while the decision process is not finished. After the sending the notification to the EC, the information of the notification is summarised and published together with link of the SNIF website on the MoE SR web site.

### **Biosafety Clearing House**

In the CBD Secretariat server the Slovak BCH site was created, which contains the basic information on Slovak legislative acts, competent authorities and decision made to date. The national BCH is placed in the Ministry of the Environment website: <http://www.enviro.gov.sk>

site. It collects data and enables exchange of information, publication of reports, etc. In the meantime the basic information is on the same web site, without interoperability possibility.

The web contains:

- Slovak and English text of the Act 151/2000 Coll. on use of genetic technologies and genetically modified organisms, and Decree 252/2002 Coll. to the Act 151/2002
- 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 Slovak Biosafety Commission
- Information on received applications and issued permits
- The news

Links to the web sites, in which is possible to find present applications send and proceeded in European Committee

- links to the web sites, to where is possible to send comments by public

It is necessary to underline that there is endeavor in EC to establish EU BCH as a contact point to the BCH Secretariat.

### **Workshops and courses**

During the life span of the UNEP/GEF Project there were several workshops and seminars for general public, consumer association, primary and secondary school teachers, environmental inspectors, researchers, toxicologist and scientists. Slovak Republic invited lecturers from Czech Republic for Slovak Inspectors training. The reason was that Slovak Inspectorate was just established and our Czech partners are experienced in the field.

Members of the National Coordinating Committee participated in Regional and Sub Regional Meetings on the topic.

## **Publications**

The paper form of publications play an important role in dissemination of information as the Internet access is still limited as regards of the age, language and social factors. As the information accessible to general public comes from “tabloid” newspapers and several “green” organizations it is still necessary to provide stakeholders with scientifically based facts. Several such publications have been prepared in the framework of UNEP/GEF Project (Annex 7).

## **Public perception**

As a part to the project, the public perception survey has been done in Slovak Republic. It is not surprising that the public perception is similar to other similar reports. More than half of the Slovaks who responded to the survey think biotechnology and genetically modified organisms (GMOs) are “useful” or “rather useful” in agriculture, medicine and ecology. They remain negative about using biotechnology in the food. More than 40% of the respondents still think that there is only limited information available on biotech products. Almost 21% responded that they never heard of GMOs. 35% of the respondents believe they knew the meaning of the term “genetically modified organism”, and three quarters 27% of these knew the correct meaning. Less than 25% of the respondents were aware that there are already existing laws and regulations for biotech products in Slovakia. Almost 42% of the respondents were not interested in biotechnology or think “it’s not their problem”, while 37% of respondents is interested (2.4% actively). So it is not true that majority of consumers are highly involved in the issue. In general, Slovaks trust that scientific institutions, medical associations and non governmental environmental organizations protect their interests and rights. However, consumers are susceptible to the influences of non-governmental environmental organizations that try to scare consumers by providing one-sided or partial information.. Small portion of consumers (10%) search Internet for GMOs, majority “receive” information from newspapers, TV and radio. In general, Slovakia still lacks enough information on biotech products even though the situation improved in the last couple of years.

The results of the survey were published as articles in journals and as reports on meetings and also summarized on the web page of MoE SR and US embassy in Vienna.

## **Goals and Measures**

Further development of public awareness and participation in biosafety appears to be crucial for public understanding and possibly acceptance of biotechnological products including GMOs.

The improvement of primary and secondary school education in bio sciences of young generation together with education of stakeholders should increase acceptance of modern biotechnology.

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

- Start ratification process of the Aarhus Convention together with its implementation,
- Raise environmental awareness focused to different stakeholders groups
- Deliver information on dangerous substances in the environment in comparison to the GMOs
- Develop bilateral cooperation especially with respect to the EU priorities and at national level take measures reflecting European Commission recommendations in respective field.

Annex 1

## SLOVAK BIOSAFETY COMMITTEE

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