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NATIONAL BIOSAFETY FRAMEWORK

FOR SLOVENIA

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FOREWORD

Modern biotechnology raises different types of issues which should be addressed at the appropriate time and level in accordance with the subsidiary principle. Strengthening and/or developing adequate mechanisms and authorities concerns should base on sound scientific data and clear correct facts. Such biosafety framework has also to be capable of safeguarding the environment, biodiversity, the multifuctionality of our agriculture, and allowing consumer to choose if they wish between the products of genetically modified organisms (GMOs), conventional or organic agriculture. It should enables our industry to seize the opportunity that these technology offers, for the ultimate benefit as society at large.

Potential risk assessment of GMOs involves technical and regulatory procedures to work best with public involvement and dissemination of information, and with respect to the legislation of GMOs and their products. Consequently, the establishment of a national biosafety system is a common need. It is important that each element of it presents unique management challenges and resources requirements, which should be review during the national case studies, and working group exercises. We should not transfer biosafety schemes from others without being critical. From a global perspective, the implementation of such system can also be mutually supportive and should provide a sound international framework in order to promote the safe development of modern biotechnology, its acceptability and its use in Slovenia.

The Government has defined modern biotechnology as one of the priority area of research and technological development, where Slovenia has comparative advantage and critical mass of knowledge and strengthening is given to the importance of the investment in national research, in order to create conditions for scientists to work effectively and transfer skills to industry where necessary.

In view of the above, the support in form of the UNEP/GEF project "Development of National Biosafety Framework for Slovenia" was extremely valuable to ensure effective and efficient system with respect to the adopted legislation.

This document serves as a basic guide to the implementation of the biosafety system. The involvement of different ministries and several stakeholders in the preparation of this document ensures that different views were taken into account when developing effective and efficient system to enable safe use of GMOs in Slovenia.

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TABLE OF CONTENS

FOREWORD 1
TABLE OF CONTENS 2
ABREVATIONS 4

1. INTRODUCTION TO BIOSAFETY 5

2. BIOSAFETY POLICY 6

3. REGULATORY SYSTEM 8

3.1. CURRENT SITUATION OF THE BIOSAFETY REGULATORY SYSTEM 8
3.2. FUTURE PLANS AND NEEDS 9
OPERATIONALIZATION OF GMO ACT 9
Commission for GMO management 9
Scientific committees 9
Deliberate release of GMOs into the environment 10
Placing a product on the market 10
Import /Export 11
GMO register 11
TRANSPORT, PACKAGING AND IDENTIFICATION 11
CUSTOMS 11

4. ADMINISTRATIVE SYSTEM 12

4.1. CURRENT SITUATION – COMPETENT AUTHORITIES 12
COMPETENT MINISTRIES 12
Contained use of GMOs 12
Deliberate release of GMOs into the environment 12
Placing a GMOs as or in a product on the market 12
COMMISSION FOR GMO MANAGEMENT 13
SCIENTIFIC COMMITTEES 13
INSPECTION 14
CUSTOMS 15
OTHER AVAILABLE INFRASTRUCTURE 15
4.2. FUTURE PLANS AND NEEDS 16
COMPETENT MINISTRIES 16
COMMISSION FOR GMO MANAGEMENT 16
SCIENTIFIC COMMITTEES 16
INSPECTION 17
MONITORING 17
CUSTOMS 18
OTHER AVAILABLE INFRASTRUCTURE 18

5. DECISION MAKING SYSTEM THAT INCLUDES RISK ASSESSMENT AND MANAGEMENT 19

5.1. CURRENT SITUATION 19

CONTAINED USE 19
DELIBERATE RELEASE OF A GMO INTO THE ENVIRONMENT 20
PLACING A PRODUCT ON THE MARKET 20
5.2. FUTURE PLANS AND NEEDS **21**

6. MECHANISMS FOR PUBLIC PARTICIPATION AND INFORMATION 22

6.1. CURRENT SITUATION - PUBLIC AND THE GMO ACT **23**
CONSULTATION OF AND INFORMATION TO THE PUBLIC - CONTAINED USE & DELIBERATE RELEASE OF GMOS INTO THE ENVIRONMENT 23
CONSULTATION OF AND INFORMATION TO THE PUBLIC - PLACING A PRODUCT ON THE MARKET 24
GMO REGISTER 25
6.2. VIEW ON PUBLIC PARTICIPATION FROM COALITION OF NGOS **25**
6.3. FUTURE PLANS AND NEEDS **26**
6.4. SLOVENIAN BCH **26**
CHALLENGES FOR SLOVENIAN BCH IN THE FUTURE: 27

7. UNEP-GEF PROJECT 'NATIONAL BIOSAFETY FRAMEWORK FOR SLOVENIA' 29

7.1. STAKEHOLDERS **30**
7.2. INVENTORIES **30**
7.3. SLOVENIAN BIOSAFETY CLEARING HOUSE (BCH) **32**
7.4. WORKSHOPS **32**
7.5. DRAFT GUIDELINES **35**
7.6. PRINTED MATERIAL **35**
7.7. MEDIA COVERAGE OF THE PROJECT **36**
7.8. INTERNATIONAL AND REGIONAL ACTIVITIES **36**
7.9. CONCLUSION **38**
ACKNOWLEDGMENT **39**
Personal remarks of National Project Coordinator 39

ABREVATIONS

BCH	Biosafety Clearing House
EU	European Union
GEF	Global Environmental Facility
GMO	Genetically Modified Organism
GMO Act	Management of Genetically Modified Organisms Act
LMO	Living Modified Organism
NBF	National Biosafety Framework
NCC	National Coordinating Committee
NGO	Nongovernmental Organisation
UNEP	United Nations Environmental Programme

1. INTRODUCTION TO BIOSAFETY

The objective of biosafety framework is two fold: firstly to ensure that human health and the environment are protected at a high level from possible adverse effects of the products of modern biotechnology, and secondly to provide a basis for public confidence and for legal certainty for research organizations and industry.

The need to achieve an agreed equilibrium between research, development, production and sustainable development of the environment is nowhere more important than in the field of modern biotechnology. Here, the potential benefits and broad implications for individuals, society and the environment have rightly generated intense public debate. In an area such as the development and use of genetically modified organisms in the environment and in foodstuffs, it is obligatory to take a rational precautionary approach.

Response to all this issues takes the form of a national biosafety framework that enforces the principle of a precautionary response. Such a response must be based on an informed public opinion, which brings an intuitive understanding of the ethical considerations that underpin the welfare of society, coupled with science and technology based knowledge and internationally approved risk assessment procedures. Therefore a framework must include access to and exchange of information at international and national levels.

Slovenia has ratified international protocol on biosafety, namely the Cartagena Protocol on Biosafety, which is mainly concerned with transboundary movements of living modified organisms (LMOs), and establishes the international procedures that have to be followed by Parties to the Protocol in such cases. The Protocol is a supplementary agreement to the Convention on Biological Diversity which recognises biosafety as one of the important issues in the conservation of biodiversity.

2. BIOSAFETY POLICY

Slovenia recognizes the importance of developing a national biosafety framework to support effective national and international biosafety system.

Slovenia also recognizes the **Cartagena Protocol** as an international platform for biosafety associated with LMOs, and ratified the Cartagena Protocol on Biosafety in October 2002 (OJ 89/02). Slovenia is also using all available mechanisms within the Protocol in order to build up the national biosafety framework.

It is very important to stress that the Slovenian biosafety policy is based on measures for preventing and reducing possible adverse effects on environment, especially related to preservation of biological diversity and human health in order to ensure safe application of modern biotechnology. Several ministries are engaged in biosafety policy; Ministry of the Environment, Spatial Planning and Energy, Ministry of Health, Ministry of Agriculture, Forestry and Food, Ministry of Science, Education and Sport, Ministry of Economy, Ministry of Finance and Ministry of Internal Affairs. In view of the above, the most important goal in biosafety policy in Slovenia is to implement the consensus-building process which would result in the efficient biosafety policy involving all competent authorities and a wide spectrum of stakeholders.

In this regard, emphasis is given to the institutional capacities, human expertise as well as adequate mechanisms for supply and exchange of information in order to implement the provisions of national mechanisms on biosafety.

Namely, to have a strong technical infrastructure to carry out risk assessment and risk management of biotechnology products so that field trials and commercialisation of biotechnology products can proceed successfully without compromising safety is a common end sustained by sectorals (ministries) arrangements. In addition, main infrastructure requirements include the development of national research institutions, genetic repositories and operational means for scientific committees, industry, private companies and others. All this issues are addressed in biosafety policy in Slovenia.

At the national level, expertise to undertake the process of risk assessment and risk management are promoted with technical, scientific, managerial and legislative training of all stakeholders. This should be done also in the future through long-term educational and research programmes and through short-term regional training workshops, as well.

The Government has defined biotechnology as one of the priority areas of research and technological development, where Slovenia has comparative advantage and critical mass of knowledge, to benefit from increased investments from EU founds (Structural Funds). In this regard, strengthening is given to the importance of the Government investment in national (biotechnology) research, in order to create conditions for scientists to work effectively and transfer skills to industry where necessary.

In the light of this situation and according to the survey, currently work with GMOs is being conducted in 21 closed systems, most of them (12) at university faculties, 5 at public institutes and 4 units within companies. No figures are available for deliberate release and no controls have yet been put in place for the transboudary movements of GMOs, although taken into

account data on imports of two main types of agricultural products (Soya and Maize) by origin of import can be concluded as highly probable that GMOs are present.

The support in form of the UNEP-GEF project 'Development of National Biosafety Framework (NBF) for Slovenia' was extremely valuable and have speeded up many of the activities towards functional and efficient NBF, therefore we rise our hopes high for the future support, possible in the form of UNEP-GEF implementation of National Biosafety framework project which would definitely accelerate the implementation of biosafety framework in Slovenia.

Slovenia is in the process of completing its legal and administrative biosafety framework with intention to put in place an enabling mechanism for making decisions on the safe transfer, handling and use of genetically modified organisms (GMOs).

The main elements of the national biosafety framework (NBF) are:

- Regulatory system
- Administrative system
- Decision making system that includes risk assessment and management
- Mechanisms for public participation and information including public consultation in decision making processes regarding GMOs

3. REGULATORY SYSTEM

3.1. CURRENT SITUATION OF THE BIOSAFETY REGULATORY SYSTEM

Slovenian legislation related to GMOs transposes and/or enforces EC legislation and the Cartagena Protocol on Biosafety.

The Management of Genetically Modified Organisms Act (GMO Act) adopted in July 2002 (OJ 67/2002) provides a horizontal type of legislation on the use of GMOs and their products, and intermediate other existing legislation in the areas of agriculture and health care. The Act regulates contained use of GMOs, the deliberate release of GMOs into the environment, and placing on the market, importing and exporting GMOs or products containing GMOs or consisting of them or their combinations. The Act includes provisions of the Directive 90/219/EEC and 98/81/EC, Directive 2002/18/EC and some provisions from Cartagena Protocol on Biosafety, which was ratified in Slovenia in 2002 (OJ 89/02). The GMO Act is not jet fully operational, since derived regulations are not jet in place.

The provisions of the Management of Genetically Modified Organisms Act that refer to placing products on the market and to the import and export of GMOs and products, are not applying to:

- Pharmaceuticals containing GMOs or consisting of them or their combinations for use in human and veterinary medicine, which are regulated with the Medicinal Products and Medical Devices Act (OJ 101/1999). The authority competent for medicinal products and medical devices for use in human medicine is the Agency for Medicinal Products and Medical Devices under the Ministry of Health.
- Foodstuffs for use in human food containing GMOs or consisting of them or their combinations, the placing on the market and import and export of which are regulated by the Health and Hygiene Safety of Foods, and of Materials and Articles Intended to Come into Contact with Foods Act which was amended in 2002 (OJ 42/2002), with articles about novel foods covering also GMOs. The authority competent for foodstuffs for use in human food is the Ministry of Health.
  The Act defining among others that the procedures for obtaining permit for use food containing GMOs or consisting of them or their combinations have to be defined and implemented, as well as the register of food containing GMOs or consisting of them or their combinations have to be established.
- Transport
  Currently there are no specific regulations available in Slovenia for safe transport of GMOs. Partly this is covered in the Transport of dangerous goods Act, which implements also European agreement on transport of dangerous goods on roads (ADR).

The Ministry of Agriculture, Forestry and Food is enforcing laws ('Forest reproductive material Act', 'Agricultural seeds and propagating material Act', 'Protection of new varieties of plants Act' and the 'Act on feeding stuffs') with provisions on GMOs which demand compliance with the Management of Genetically Modified Organisms Act. The Ministry for Agriculture has also ratified International Plant Protection Convention (IPPC) and adopted all phytosanitary standards (ISPM) that are derived for the convention.
The Ministry of Economy is enforcing Regulation on legal protection of biotechnological invention (OJ 81/003) in order to harmonies protection of invention with EU directive

98/44/EC and to maintain and encourage investment in the field of biotechnology (genetic engineering, biological material, biological processes for the production of plants and animals, methods of cultivation, etc) in Slovenia.

Slovenia has signed following agreements with the World Trade Organisation, that relate to GMOs:

- Agreement on the application of sanitary and phytosanitary measures
- Agreement on technical barriers to trade
- Agreement on Agriculture.
- Agreement on Trade –Related aspects of Intellectual Property Rights (TRIPS Agreement)

Based on the GMO Act the Ministry of the Environment and particularly the Biotechnology Sector supports and maintains fruitful co-operation among ministries (authorities). So far, the efficiency and effectiveness of decision-making process within the framework of biosafety system should be vital to create widespread confidence in the end result through the close sectoral co-operation and different stakeholders, too. In this relation, good lesson of the above from the past reflect an important implementation aspect of biosafety framework in the future.

For more detail information and full text of laws and regulations please visit Slovenian Biosafety Clearing House (www.bch.bf.uni-lj.si.) sub-pages: Laws and regulations and National legislation.

3.2. FUTURE PLANS AND NEEDS

Operationalization of GMO Act

Most important is to make the GMO Act operational as soon as possible with adoption of derived regulations.

Currently it is possible to regulate GMO and GMO products in Slovenia only on the basis of labeling, but it is not yet possible to perform decision-making procedure (including risk assessment) based on the GMO Act. In following section the activities and regulations that are necessary in this respect are described, and their status explained as follows:

Commission for GMO management

- The Minister for Environment, Spatial Planning and Energy shall provide the procedure for determining the proposal of representatives of non-government organisations as members of the commission

Scientific committees

- The Government shall provide the form of providing expert opinions in procedures according to the Act, the manner and form of reporting of the committees and procedures

for ensuring the exclusion of interest and protection of data which are confidential in accordance with this Act, in the work of the committees.

Contained use

Draft proposals of four regulations are on track;

- Regulation specify the criteria to classify each contained use of GMO into a specific class, containment and other safety measures, rules of management and other conditions for individual class shall be specified in a separate regulation.
- Regulation specifying detailed contents of the notification of premise for contained use and notification of contained use.
- Regulation specifying the elements and the extent of the risk assessment for contained use and the methodology for its production.
- Regulation specifying detailed contents and the extent of the emergency plan in relation to the class of the work, the methodology of its preparation, examining and supplementing and the manner and extent of informing and warning competent bodies, services and the general population in the event of an accident.

Deliberate release of GMOs into the environment

Draft proposal of three regulations are on track;

- Regulation specifying the methodology, the elements, and extent of the assessment of risk of the deliberate release of the GMO into the environment.
- Regulation specifying detailed contents of the notification for deliberate release of GMOs into the environment.
- Regulation specifying the extent and content of the report on the results of the deliberate release of the GMO into the environment.

Placing a product on the market

Following regulations have to be prepared:

- Regulation specifying elements and the extent of the assessment of the risk of placing a product on the market and the methodology of its production.
- Regulation specifying contents of the notification for placing a product on the market and data which shall not be part of the notification shall be specified in a separate regulation in agreement with the minister responsible for agriculture, forestry and food.
- Regulation specifying the extent and elements of the assessment report shall be specified in a separate regulation.
- Regulation specifying contents and extent of the programme of monitoring and the manner and extent of reporting shall be specified in a separate regulation in agreement with the minister responsible for health and the minister responsible for agriculture, forestry and food.
- Regulation specifying the extent of data on the packaging or in the declaration of the product and requirements for packaging the product shall be specified in a separate

regulation in agreement with the minister responsible for health and the minister responsible for agriculture, forestry and food.

Import /Export

- Transposition of the EU Regulation on transboundary movements of Genetically Modified Organisms.

GMO register

- The form and manner of keeping the register and the manner of determining the material costs of communicating data shall be specified in a separate regulation.

Transport, packaging and identification

Transport of GMO is also only partly covered in Slovenia and will have to be addressed more fully at nationally or even internationally in the future.

- It would be very useful to have at least some unofficial guidelines on transport and packaging of GMO in Slovenia, which can in the absence of formal regulation, give advice to users.

- In the international context we would support the guideline on handling, transport, packaging and identification of LMO (under Article 18), which would put additional safety net on the international biosafety system promoted by Cartagena protocol.

- In the international context we would support the guideline on liability and redress for damage resulting from transboudary movements of LMO (Art.27) in order to establish standard of liability in closely connected with the scope and nature of the defences available to the person to whom liability has been channeled.

Customs

- The agreement on cooperation in the field of GMO between the Ministry for the Environment, Spatial Planning end Energy and Customs was signed in September 2003.
- Customs in Slovenia need clear and simple guidelines on the procedures and documentation needed under the Protocol concerning GMO import/export.
- It is also necessary to formally designate only selected border crossings, for import/export of GMOs. Only border crossing which also have inspection services are suitable for that, since the inspection services check the compliance of the GMO goods, with accompanying documents.
- There is a person/s at customs dedicated to also follow the Parties to the Protocol list, and update border crossings on that and other new developments in this area.
- In this respect it would be also worth to organize simulation of border procedures for import/export of GMOs for customs and inspection services.

4. ADMINISTRATIVE SYSTEM

4.1. CURRENT SITUATION – COMPETENT AUTHORITIES

Competent Ministries

In Slovenia, different authorities have responsibilities in the field of genetically modified organisms (GMOs), depending on the subject and intended use of the GMO. However, risk assessment for the environment and human health is the key element in all decisions on GMOs, irrespective of the authority responsible for the decision.

The horizontal Act, Management of genetically modified organisms Act adopted in July 2002 defines the authorities that have responsibilities in the field of GMOs.

Contained use of GMOs

The Ministry for the Environment, Spatial Planning and Energy is responsible for contained use of GMOs. It issues permits for contained use of GMOs and approves the premises for working with them.

Deliberate release of GMOs into the environment

For deliberate release, the notifier has to obtain a permit from the Ministry for the Environment, Spatial Planning and Energy. The Ministry shall issue such a permit with agreement of the Ministry of Agriculture, Forestry and Food.

Placing a GMOs as or in a product on the market

For placing GMOs as or in a product on the market for the first time, the notifier has to obtain approval from the Ministry for the Environment, Spatial Planning and Energy. The approval shall be issued in agreement with the Ministry of Health, and the Ministry of Agriculture, Forestry and Food.

- The Ministry of Health is responsible for pharmaceuticals for use in human and veterinary medicine and foodstuffs for use in human food containing GMOs or consisting of them or their combinations. Risk assessment for the environment is still approved by the Ministry for the Environment, Spatial Planning and Energy. Pharmaceuticals which contain GMOs for use in human and veterinary medicine, or consist of them or their combinations, are regulated under the 'Medicinal products and medical devices Act', and foodstuffs containing GMOs or consisting of them or their combinations for use in human food are regulated under the 'Health and Hygiene Safety of Foods, and of Materials and Articles Intended to Come into Contact with Foods Act'.

    - In the field of food safety (including animal feed and water) Slovenian government have issued Regulation on coordination of the Ministries and their bodies in the field

of food safety and risk assessment evaluation process (OJ 56/003) which have competencies in the process of risk assessment evaluation and risk communication . Competent ministries being Ministry of Health, and the Ministry of Agriculture, Forestry and Food and Ministry for the Environment, Spatial Planning and Energy. Integration of Slovenia in EU and other international associations demands also harmonisation of regulatory system, informing about accepted regulation different international organisations (ex. EU, European Council, WHO, FAO, WTO, OECD, …), collaborating in preparation and Implementation of internationally accepted standards (Codex Alimentarius) and others.

- With entering of Slovenia into EU the competent body for risk assessment for food (and feed) will become most probably EFSA (European Food Safety Agency) and for notification EU Commission (DG SANCO or appropriate Standing Committee). New EU Regulations on 1) traceability and labeling of GMOs and traceability of food and feed produced from GMOs and 2) GM Food and Feed are expected at the end of this year.

Commission for GMO Management

13. members of the Commission for GMO management among 17. of them were nominated and nomination of NGO's member is under procedure. Namely, according to the Management GMOs Act the commission shall consist of seventeen members, who shall represent social, humanist, natural, medical and veterinary sciences, scientific committees, non-governmental organisations from the sphere of environmental protection, consumer protection and health safety and Chamber of Commerce and Industry of Slovenia. The commission shall be fully operational in next few months.

The commission shall be independent and sovereign in its work, and its work shall be public.
The duties of the commission are:

- monitoring conditions and development in the field of the use of genetic technologies and GMO management,
- adopting positions and providing opinions and initiatives in connection with the use of gene technologies and GMO management and in relation to social, ethical, technical and technological, scientific and other aspects of GMO management,
- advising to the government in connection with use of gene technology and GMO management,
- enlightening and informing the general public about conditions and developments in the field of the use of genetic technologies and GMO management, about their positions and opinions and about their work, and
- exchange data and experiences with related institutions abroad and cooperation with them.

Scientific Committees

In order to provide professional assistance to ministries responsible for deciding on GMO management the government recently adopted Regulation on Scientific Committees (OJ 66/03). Consequently, the government found two scientific committees; scientific committee for work with GMOs in contained use and scientific committee for the deliberate release of GMOs into the environment and placing products on the market. The committee for contained use consists of seven members, experts from the field of microbiology, genetics, medicine,

biochemistry and molecular biology, pharmacy, biotechnology and safety at work. The committee for deliberate release of GMOs and placing on the market also consists of seven members, experts from the field of genetics, biology, agriculture, veterinary science, biochemistry and molecular biology, microbiology and medicine. Both committees have the possibility to invite to the discussion other experts from fields relevant to the discussion of the notification and preparation of an expert opinion.

The two committees are established to:

- provide expert opinions on GMO management in administrative procedures ,
- provide opinions and proposals in the preparation of regulations on GMO management,
- provide opinions and proposals in other matters in connection with GMO management requested by competent ministries, and
- cooperate with related institutions abroad.

Inspection

Inspection supervision of the implementation of the provisions GMO Act and regulations issued on its basis shall be performed by the Inspectorate of the Republic of Slovenia for the Environment and Spatial Planning, the Health Inspectorate of the Republic of Slovenia, the Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Hunting and Fishing, the Inspectorate of the Republic of Slovenia for Quality Control of Agricultural Products and Foodstuffs, the Office for Inspection Supervision within the Veterinary Administration of the Republic of Slovenia, the Inspectorate of the Republic of Slovenia for Safety at Work and the Market Inspectorate of the Republic of Slovenia, each in accordance with its competencies. Competences for the inspection supervision will be specified in permits or approvals.

If an inspector during the performance of his work or on the basis of a notification establishes that because of unfulfilled required conditions and requirements, the environment or human health are at risk because of possible adverse effects, he may order the following measures:

- prohibit contained use, deliberate release of a GMO into the environment or placing a product on the market,
- order the temporary suspension of contained use, the deliberate release of GMOs into the environment or placing a product on the market,
- order the rectifying of established irregularities within a time limit that he specifies, and
- order remediation and other measures for rectifying or reducing the consequences of adverse effect that have occurred because of GMO management.

- Monitoring of GMO presence in 2003 for Slovenia

According to survey done in 2002, currently work with GMOs is being conducted in 21 closed systems, most of them (12) at university faculties, 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.

In June 2003 the Ministry for the Environment, Spatial Planning and Energy started with the project on monitoring of GMO presence which based on the methodology of sampling as the

Health Inspectorate of the Republic of Slovenia, the Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Hunting and Fishing and the Inspectorate of the Republic of Slovenia for Quality Control of Agricultural Products and Foodstuffs are providing. The monitoring results of previously mentioned inspectorates will be presented at the end of the year 2003.

- EU GMO inspectors network

In 2003 two Slovenian inspectors from Inspectorate of the Republic of Slovenia for the Environment and Spatial Planning joined the EU GMO inspectors' network.

Customs

Customs in Slovenia is part of Ministry of Finance.

In the absence of the specific regulation for GMO import and export, customs can act on the basis of Article 44.b. of the Customs Act, stating among other also that in specific circumstances Government can on the basis of protection of health and lives of humans, animals and plants or protection of environment ban or limit certain customs goods.

With entry into force of Cartagena protocol, customs will also check for Decisions of the parties to the Protocol on import/export of LMOs (AIA procedure). In order to ensure such procedure the agreement between the Ministry for the Environment, Spatial Planning and Energy and Customs was signed in September 2003.

Other available infrastructure

Laboratories for GMO detection

In Slovenia there are more laboratories working on detection of GMOs, but none was appointed jet by Slovenian government as an official institution within the biosafety framework:

- National Institute of Biology, Department of Plant Physiology and Biotechnology was accredited by Slovenian accreditation Body for qualitative and quantitave detection of GMOs under No L-051. The accreditation was given for detection of GMOs on following materials: genetically modified organisms and matrices: seeds, grains, plants, raw material, food and feed. This laboratory is providing services to Slovenian companies for two years and in this year also to inspection services.
- At the Agricultural Institute they prepare themselves to have qualitative and semi quantitative detection on seeds in the frame of seed laboratory accredited according to ISTA rules.
- At the Institute for Public Health in Ljubljana and Maribor they started to introduce methods for qualitative analysis of food samples.

The first two laboratories are also members of European Network of GMO Laboratories (ENGL).

4.2. FUTURE PLANS AND NEEDS

Competent Ministries

All the competent ministries have appointed the responsible person/s for preparation of regulatory framework. But for the administrative procedures for handling requests for permits and approvals of different GMO use/premises additional support will be needed.

Coordination of the Ministry for the Environment, Spatial Planning and Energy, Ministry of Health and the Ministry of Agriculture, Forestry and Food and Ministries and their bodies which have competencies in administrative procedures for handling requests for permits and approvals including inspection and customs as controlling bodies has to be tested. The problem might present the complex system of decision making, involving different steps and competent authorities as well as general public together with tight time limits for every administrative step and somewhat unpredictable number of notifications at the time when GMO Act will become operational.

- The manual for administrative handling of request will be needed as soon as all regulations are in place. It has to contain also the system to track dossiers and guard procedural steps.
- A user friendly manual for administrative handling of request should be also provided for notifiers.
- A system for the protection of confidential information has to be defined.
- Forms used within administrative procedures for handling of requests should be prepared (ex. Acknowledgment of Receipt, Acknowledgment of completeness of the notification, form requesting additional information, etc.).

Commission for GMO Management

In the Commission for GMO Management 13 members (from 17) accept 4 NGO members have been nominated. In order to nominate NGO members the draft regulation on procedure for their determination is under procedure.

Scientific Committees

The members and deputies of the two scientific committees (Scientific committee for contained use and Scientific committee for deliberate release and placing on the market) were nominated and The Order on Scientific Committees, describing internal rules of procedures, was adopted this year, so they are operational.

From the experiences of other countries it might be the case that we will have to rearrange the division of the Scientific committees on the basis of the use of GMO to organism related division of expertise ex. Scientific committees for GM plants, GM animals, GM micro organisms and gene therapy. That would make more sense with the limited number of experts from different areas and will also provide the continuity of the scientific committees through the phases of uses of GMO from contained use towards placing on the market.

- The manuals for risk assessment would be needed as tools to be used by notifiers and Scientific committees.

- Access to relevant databases such as BCH, Gene Files, Botanical Files, GeneBank, SwissProt, etc. should be provided.

Inspection

The GMO Act is appointing seven different competent bodies to perform the inspection, based on their competences.
It might be that the system as it is formed now with flexibility to appoint different competent inspectorates on the case by case basis will work, on the other hand most of the competent bodies are used to work on more formal grounds, so it might be the case, that more strict separation of the competences will have to be formalized for GMO use.

All inspectors that were appointed so far, lack strong scientific background. At different workshops they repeatedly expressed the concern, that they do not fell that they are competent enough to be sure to pose the right questions in the area of scientific risk assessment. During the training activities it seems that the biggest problem will arise in contained use and some cases of deliberate release.

Therefore it seems necessary to provide them with the scientific support through enabling them to use external experts (ex. the members of the scientific committees) or to involve at least one to two new people within inspectorates with scientific background and experiences that will be educated in inspection procedures.

- Saying all the above, it would be worth carrying out a survey to established the inspection capacities required for GMO area.
- The continuous training should be provided to GMO inspectors.
- The manuals and guidelines for all different types of GMO inspection should be provided.
- Forms used by GMO inspectors should be prepared (ex. Prohibition notice, Investigation report, etc.).

Monitoring

In the GMO Act, plans for monitoring are part of notification. Monitoring can consist of general surveillance and, depending on the results of the risk assessment, case specific monitoring. A notifier who places a product on the market should ensure implementation of monitoring of the effects of the product and its use on the environment and human health in accordance with its programme and regularly report to the Ministry for Environment, Spatial Planning and Energy on the results of monitoring.

- The guidelines on different approaches for monitoring should be provided for Scientific committees and notifires.

Traceability and transparency

There is a strong need especially from the side of food industry for clear rules on traceability and for transparency of all processes (industrial and administrative), since that would restrain their costs for GMO analyses. They propose that in addition to the regulations (or guidelines or codex) for transport also storehouse management, acceptance of harvest and other supporting activities of the industry should be performed in accordance to good practice rules and guidelines provided where applicable so there would be no mixing of raw stuffs. Food

industry can label their products appropriately only if all processes in the production chain are done in accordance with good practice rules.

New EU Regulations on traceability and labeling of GMOs , on GM food and feed and on transboundary movement of GMOs are expected at the end of this year.

Customs

In order to ensure effective import/export procedure for GMO (including AIA procedure) the agreement between the Ministry for the Environment, Spatial Planning end Energy and Customs was signed in September 2003. This agreement defines that both parties will established procedures to for import/export of GMO, as well as cooperate in training and information sharing in the GMO field.

The other partners for customs at the border are Inspectorates that can control the goods coming in the country (Phytosanitary inspectorate, Veterinary inspectorate …). There is a need, that also they are involved in this coordination at the border, in a form of training or/and formalization of procedures or/and information sharing.

Next year with entering of Slovenia into EU, there are only six border crossings planed on Schengen border where also inspection services will be present. It is therefore necessary to formalize these border crossings as obligatory also for GMOs and their products. A special attention should put on the Port –Luka Koper, where the majority of the GMO goods are expected.

The survey of the available infrastructure at the border crossings should be performed, to identify what is still needed for effective inspection control at the borders.

Other available infrastructure

Laboratories for GMO detection

Some infrastructure support is still needed, as well as resources to be able to introduce and develop methods for GMO detection, which are constantly under development for two reasons: first, the standards are not yet available for all products on EU market, second, new products are expected, and products, that are not permitted in EU, but are produced in other countries might enter illegally/unintentionally to Slovenia.
Also an official formalization of the status of different GMO detection laboratories in the country is expected.

5. DECISION MAKING SYSTEM THAT INCLUDES RISK ASSESSMENT AND MANAGEMENT

5.1. CURRENT SITUATION

The decision making system is defined in GMO Act in general terms, but some regulations are still needed to precisely define this procedures.

Contained use

Classification of the contained use

Contained use should be classified into one of four classes, where class 1 suit the work in which the risk is negligible and class 4 where the work in which the risk is high.

Notification of premise

Before the premise is used for the first time for contained use the notifier should submit a notification to the Ministry for the Environment, Spatial Planning and Energy. For every class there are specified required containment measures and other safety measures and required provisions. Contained use may only be performed in a premise in which the required conditions for the class into which the intended work is classified are fulfilled. The committee for contained use writes an opinion on notification to the Ministry.

Permit for work in contained use

Class 1 contained use may be commenced without notification to the ministry. For class 2 work the committee for contained use should communicate to the ministry a written opinion and notifier can start the work within 45 days if it is not decided otherwise by the Minister. For classes 3 and 4 the ministry shall verify the compliance of the notification with the required provisions and after obtaining the opinion of the committee for contained use shall decide on the permit.

Risk assessment

A notifier, prior to the commencement of contained use work, should ensure an assessment of the risks of the intended work. In the risk assessment it is necessary on the basis of analysis of the characteristics of the GMO and the intended work with it and the environment which could be exposed to risk, to ascertain and evaluate in particular possible adverse effects, the level of risk and necessary containment and other safety measures. In particular, it is necessary to determine measures for waste management and effluent disposal from the premise. On the basis of the risk assessment, the notifier shall classify the contained use into one of the classes (one to four). During implementation of the contained use, the notifier should review the risk assessment at least once a year, and supplement it as necessary, especially from the point of view of the suitability of the containment and other measures in relation to the class and new scientific understandings, and inform the ministry of supplements if this concerns work with a GMO referred to in the second, third or fourth class.

A notifier, prior to the commencement of contained use should ensure an emergency plan in the event of an accident.

Deliberate release of a GMO into the environment

Permit for the deliberate release of a GMO into the environment

A notifier should obtain a permit from the Ministry for the Environment, Spatial planning and Energy for the deliberate release of a GMO into the environment. The Ministry shall issue such a permit with the agreement of the Ministry responsible for agriculture, forestry and food.
The Ministry shall verify compliance of the notification with required provisions and after obtaining the opinion of the committee for releasing GMOs, with the agreement of the Ministry responsible for agriculture, forestry and food, shall decide on a permit for the deliberate release of a GMO into the environment.

Risk assessment

A notifier, prior to submitting a notification for obtaining a permit for the deliberate release of a GMO into the environment, should ensure an assessment of the risk that the intended deliberate release represents. In the risk assessment it is necessary on the basis of an analysis of the characteristics of the GMO and its intended deliberate release and the environment which could be exposed to risk, ascertain and evaluate, in particular, possible adverse effects and their possible consequences, the level of risk and measures required for their control.
A notifier, prior to the commencement of the deliberate release of a GMO into the environment, should ensure an emergency plan in the event of an unanticipated spread of the GMO in the environment occurred.

Placing a product on the market

Permit for placing a product on the market

A notifier should obtain a permit from the Ministry for the Environment, Spatial planning and Energy for placing a product on the market if it is a product that is being placed on the market for the first time. The permit shall be issued in agreement with the Ministry responsible for health, and the Ministry responsible for agriculture, forestry and food.

Risk assessment

Prior to submitting a notification for a permit for placing a product on the market, the notifier should assure an assessment of the risk which the intended placing of the product on the market represents. In the risk assessment it is necessary, on the basis of an analysis of the characteristics of the GMO, the product and its use and the environment in which the product will be used, to ascertain and evaluate in particular possible adverse effects on the environment and human health, the possible consequences of these effects, the level of risk and necessary measures for its control.

The Ministry for the Environment, Spatial planning end Energy shall verify compliance of the notification with required provisions and, after obtaining the opinion of the committee for releasing GMOs, in cooperation with the ministry responsible for health, and the ministry responsible for agriculture, forestry and food shall decide on the permit for placing a product on the market within 105 days after receiving the notification. The notifier may only place the product on the market in the way and under the conditions that are required and specified in the permit.

Labeling

A notifier may only place on the market a product that states on the packaging or in the declaration data that it contains or consists of a GMO, and other required data in connection with the product and its use.

5.2. FUTURE PLANS AND NEEDS

As described in above, the regulations that will enable the risk assessment are in preparation. Some training on risk assessment and management was already provided to the members of the scientific committees and they seem to be relatively competent in the scientific assessment of risk.

Because of he limited number of experts or lack of specific national experts in some scientific fields the international support in the form of rosters of experts, lists of species with risk assessments or any other formal or informal form will be of the most interest to small countries like Slovenia.

6. MECHANISMS FOR PUBLIC PARTICIPATION AND INFORMATION

As stated at the beginning the objective of biosafety framework is two-fold: firstly to ensure that human health and the environment are protected at a high level from possible adverse effects of the products of modern biotechnology, and secondly to provide a basis for public confidence and for legal certainty for research organizations and industry.

Slovenia has in the past experienced lively public debate on a wide range of issues related to environment and, use and release of GMOs in a dialogue among NGO's, citizens, consumers, the media, competent authorities and scientists. Divergent opinions and public debates demonstrated the complexity of the issues facing modern society and cultural legitimacy of different views. Moreover, in the past, debate on environment and GMOs coincided with growing public awareness of wider societal issues such as safety and policy development. This reflects in the fact that very important aspect in implementation of the government policies should be credibility for all parties involved, including general public. This is only possible if the public is involved in the decision making process. Prerequisites for that is transparency of rules in decision making process as well as access to information.

In that respect e.g. both Environmental Protection Act and Act on Management of GMOs involve all stakeholders, NGO's and interesting public in the decision making process through consultation. In addition the Access to public sector information Act which entered into force on the 22nd of March this year provides a legal instrument that allows the carrying out of the constitutional provided freedom of information in practice. It also promotes the use of internet for presentation of public information.

The Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) provides the horizontal legislation on public information and public participation. Slovenia is in the process of ratification of the Convention. The Convention requires its Parties to involve the public in decision-making on specific activities, listed in article 6 where GMOs are not included. The Party may, according to national legislation, apply the provisions also to GMOs. Slovenia is member of working group which was established to explore the legally binding options approach to further developing the application of the Convention in the field of GMOs.

Particularly Act on Management of GMOs provides formalization of extensive consultation with public. Public awareness and public participation is also explicitly mentioned in Article 23 of the Protocol stating that parties should promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. Parties should further endeavor to ensure that public awareness and education encompassing access to information on living modified organisms identified in accordance with this Protocol that may be imported and consult the public in the decision-making process regarding LMOs and shall make the results of such decisions available to the public.

6.1. CURRENT SITUATION - PUBLIC AND THE GMO ACT

Public Principle

One of the principles of the act is the public principle which states: the public has the right to be informed about GMO management, and to be involved in the procedure of issuing permission. Data on contained use, the deliberate release of GMOs into the environment and placing products on the market, and data on procedures and activities of ministries responsible for GMO management, shall be public in compliance with regulations in the field of environmental protection.

Public principle is incorporated into the act in different manners and provisions.

Commission for GMO Management

One of the mechanisms to implement this principle the Government of the Republic of Slovenia has set up the Commission for GMO management, which members represent different stakeholders in Slovenia.

Scientific Committees

In order to provide professional assistance to ministries two scientific committees were nominated. The Ministry should provide public with perusal of committee's opinion in a procedure for issuing a permit for contained use class 3 and 4, for deliberate release of GMO and for placing GMO or products on the market. The committees shall issue annual reports on their work in the past year, and publish these in such a manner that they are accessible to the general public.

Consultation of and Information to the Public - Contained Use & Deliberate Release of GMOs into the Environment

In a procedure for issuing a permit for contained use class 3 and 4 and for deliberate release of GMOs into the environment, the Ministry should provide the general public with perusal of the notification and risk assessment, with the opinion of the committee, and with public hearing. A public announcement containing a statement of the place and time for perusal and public hearing and the manner of providing opinions and comments, shall be published in public media. The time limit for the perusal and the possibility of giving opinions and comments is defined. The Ministry should also include a standpoint to the opinions and comments of the general public in the reasoning of the decision on a permit.

New information

In case of new information which could change the risk or classification in contained use, a new notification or request should be submitted. Through new notification again public is involved.
In case of new information for deliberate release the ministry should inform the general public about new data and changes that have occurred after the issue of a permit and about decisions in connection with it.

Emergency plan
A notifier, prior to the commencement of contained use or deliberate release, should ensure an emergency plan in the event of an accident which among other requirements should contain the manner and extent of providing information and warning competent bodies, services and the general population in the case of an accident or unintended release.

Accident or unintended release

The Ministry should prepare a report on the accident or unintended release and measures taken and their efficiency, which the Government shall adopt and acquaint the public without delay.

Consultation of and information to the public - Placing a product on the market

Consultation to the public

Whenever it is evident from the assessment report that the product is suitable for placing on the market, the Ministry should in the procedure of issuing the permit for placing a product on the market or its extension, guarantee the general public perusal of the notification, the opinion of the committee for releasing GMOs and the assessment report. The public announcement, with a statement of the time and place for perusal and on the way of providing opinions and comments, shall be published in the public media. The time limit in which the ministry shall provide perusal and the opportunity to provide opinions and comments is defined in the Act. The Ministry should also include a standpoint to opinions and comments given by the general public in the reasoning of its decision referred to in the previous paragraph.

Informing the public

The Ministry should immediately inform the general public through the Ministry responsible for consumer protection about the issue of a permit for placing a product on the market or its extension, or that the issue or extension of a permit has been refused. In the information about the issuing or extension of a permit should be stated which GMOs or their combination the product contains or from which it is composed and for what use the product is intended.

New information

In case of new information in connection with the risk the product could represent, the procedure of issuing a permit or its annulment is used and involvement of public is demanded.

Monitoring

A notifier who places a product on the market should ensure implementation of monitoring of the effects of the product and its use on the environment and human health in accordance with its programme and regularly report to the ministry on the results of monitoring. Data from the report on the results of monitoring shall be public in accordance with regulations on environmental protection.

Labeling products and GMOs
A notifier may only place on the market a product that states on the packaging or in the declaration data that it contains or consists of a GMO. The labeling on packaging or in the declaration should contain in a visible place the words: »This product contains a genetically modified organism«.

GMOs that are made available to third persons for contained use or for deliberate release should also be labeled even when making available in such a way is not considered placing on the market.

GMO Register

The documents, issued in the administrative procedures will be part of the register. The GMO register shall consist of records of premise, contained use, deliberate releases of GMOs into the environment and placing of products on the market. Records referred to in the previous paragraph shall contain in particular data on:

1. business names and registered offices or addresses of notifiers for:
    - contained use,
    - deliberate release of GMOs into the environment, or
    - placing a product on the market,
2. addresses and properties of the premise
3. contained use and its classification,
4. deliberate releases of GMOs into the environment, including an exact description of the location of release, and
5. products and their placement on the market, including a description of the site in which the product is placed on the market.

An integral part of the register shall be receipts and permits issued for premises, contained use, deliberate release into the environment and for placing products on the market.

The GMO register shall be kept by the Ministry as a public document.

Anyone shall have the right to peruse the data from the GMO register and request and obtain an extract from the GMO register against payment of the costs, which may not exceed the material costs of communicating the data.

The Register will be part of the Slovenian Biosafety Server and will be accessible through the internet. The Register will be built gradually. In the first phase the Register for premises and contained use will be established and will be available by May 2004.

6.2. VIEW ON PUBLIC PARTICIPATION FROM COALITION OF NGOS

(Coalition of NGOs for GMO free Slovenia includes 16 NGOs and individuals.)
The fact is that representatives of NGOs did not manage to get its representative in the either of two scientific committees which will be giving their opinion on the applications for approval of GMOs. The concrete experiences of public participation in the approval process are still absent as the Act on GMOs is not yet operational. In general it could be said that the representatives of NGOs face at least two problems, when it comes to public participation in

decision making process. First one is related to the small physical capacity of organized NGOs, which is becoming more obvious and problematic due to the »opening of the decision making processes« and at the same time due to the increasingly complex legislation governing the environmental field. The other problem is actually a frustration originating in actual (in)ability of public when it comes to really changing something (the navigation route of the tanker) as too often the public participation is carried out for its own sake and the true interest for it is still absent in our society. Maybe because the opinion and standpoints of public are of a lesser weight than those of other (expert) public, also because they only represent the interests of public goods (environment, public health).

6.3. FUTURE PLANS AND NEEDS

- To ensure a very generous flows of information related to GMO, among different stakeholders, as it is required by GMO Act and the Cartagena protocol, the GMO register should be provided as soon as possible and designed in a way to make all the above requirements possible including interoperability with the central portal of BCH.

- A substantial amount of biosafety awareness work should be targeted to specific target groups (consumers, schools, farmers, private sector …) through appropriate form (manuals, brochures, leaflets, workshops, internet...).

- A special care should be given in the development of relations with media (through press releases, workshops…).

- Brochures describing goal and provisions of the Cartagena and GMO Act should be published, explaining also benefits and risks of modern biotechnology.

- The seria of brochures that we started within this project (read below) should be continued with: GMO food, GMO in medicine, GMO procedures in deliberate release and GMO procedures in market release.

6.4. SLOVENIAN BCH

Slovenian Biosafety Clearing-House (BCH) is an integral part of the Biosafety Clearing House mechanism which was established under Cartagena Protocol (Article 20) in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and to assist Parties to implement the Protocol.
The system of BCH was design as decentralized system with national BCHs components organized by the parties of the protocol and central portal (run by CBD Secretariat) to support and organise the information flows from national BCH (See also the Proceeding of the CBD Secretariat in this publication.).

In Slovenia the trend towards information society is very strong, and web based government services are seen as very important in the future (The Access to public sector information Act). Accessibility to computers and internet is also comparable with the EU, and in this respect it is worth to publish biosafety information for Slovenes in Slovene language (the Slovenian BCH page is bilingual en/si).

In year 2002 when we started to think about the Slovenian BCH (http://www.bch.bf.uni-lj.si/) we first faced the challenge that all countries face – gathering information in efficient, organized and impartial manner. The decision was made to gather and present all obligatory information and as much of non obligatory information on Slovenian biosafety system as possible, since there was no other page in Slovenia dedicated specially to biosafety area or even to biotechnology. This way one could use Slovenian BCH as on stop shopping point for biosafety field in Slovenia.

We chose the format of the Slovenian BCH to be web based but not interlinked or interoperable with central portal. The reason was that Slovenia is just in the process of building up the Slovenian Biosafety Server, which will contain the data that are obligatory to be publicly available by Slovenian regulation (see above). We see the Slovenian BCH in the future as an integral part of this Server, which will also, automatically fed the data into Slovenian BCH and central portal. That means, that we plan that the simple web based BCH will evolve through time to interlinked and interoperable national BCH.

The decision was also made on the design and format (menus, appearance …) of Slovenian BCH, that it would be most convenient to mimic the central portal, for a simple reason, that we expected that visitors will jump from our site to the portal or other way around when searching for information, so it would be convenient for them to find the same topics in the same place. For that reason we also provide links from our sub pages to the corresponding sub pages of the central portal (e.g. decisions, competent authorities …) in this way coming a little bit closer to the interlinked format.

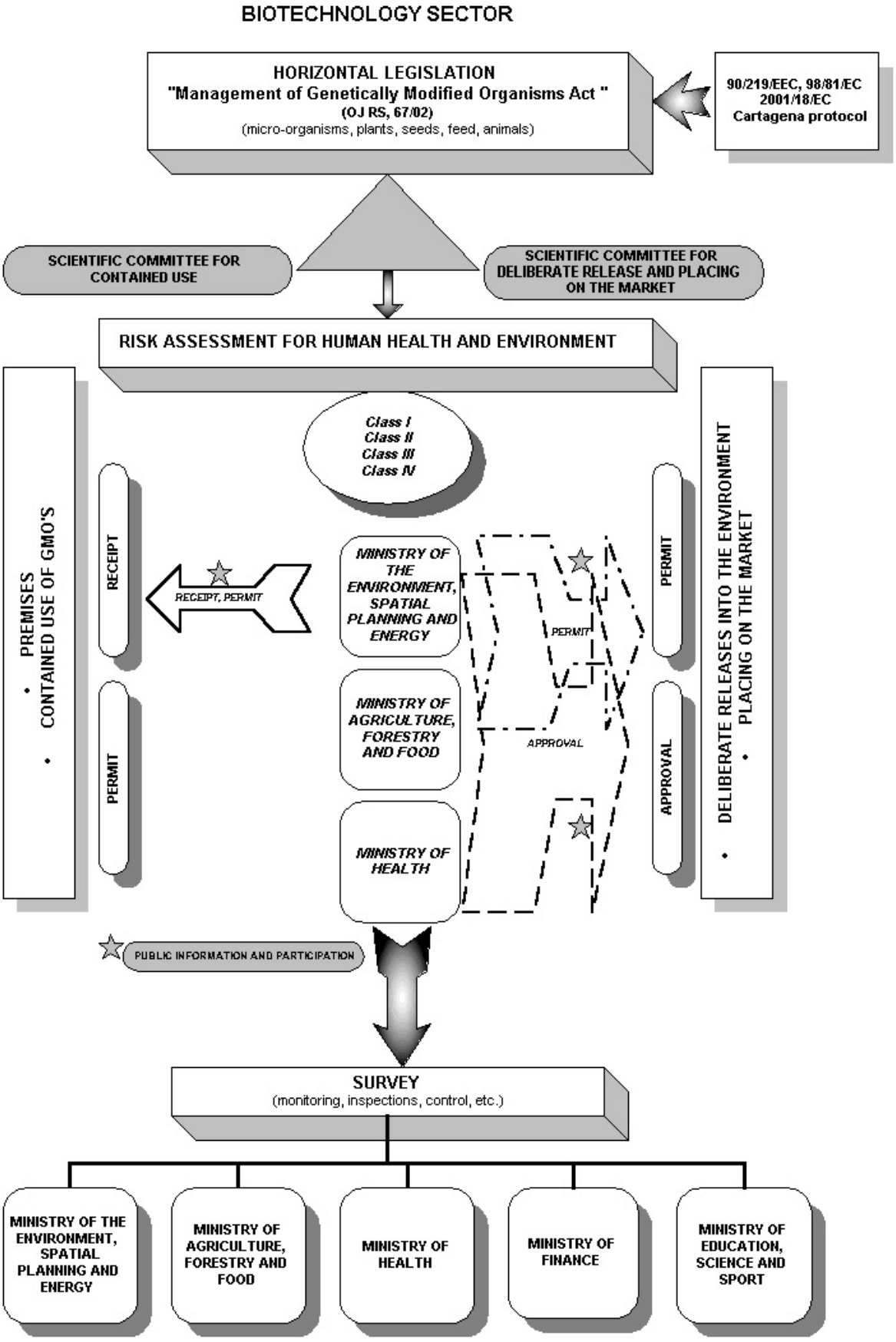
Challenges for Slovenian BCH in the future:

Making sure that interested people can find Slovenian BCH easily

It is clear that people involved in administrative procedures for GMO in the Parties to the Cartagena protocol will be aware of where to look for national BCH sites on the central portal without special announcement. But by our opinion the site is also very useful for other stakeholders as well as for interested general public. We are announcing the site on every event that we organize and this way we can reach some groups of stakeholders. To reach general public (at least the one that has the internet access) we would have to publish link to our page on as many as possible bio-related national sites. That remains the very difficult task for the future.

Development of the existing page to interoperable national BCH

As discussed in previous paragraphs we plan to evolve the Slovenian BCH to the interlinked/interrelated national BCH in the future.



Picture 1: Schematic presentation of the of Slovenian Biosafety Framework

7. UNEP-GEF PROJECT 'NATIONAL BIOSAFETY FRAMEWORK FOR SLOVENIA'

The draft of National Biosfety Framework for Slovenia was prepared during the UNEP-GEF project 'National Biosafety Framework for Slovenia', which is part of the UNEP-GEF Global Project aimed to assist countries (currently supporting 119 countries) in implementing the Cartagena Protocol on Biosafety through the development and implementation of their NBFs.

Implementation: National Institute of Biology (NIB) (Večna pot 111, POB 141, 1001 Ljubljana, Tel: +386 1 423 33 88) in cooperation with the Ministry of Environment, Spatial Planning and Energy (MESP) (Dunajska cesta 48, 1000 Ljubljana, Tel.: +386 1 478 74 00)

Duration: 12 months (Commencing: September 2002; Completion: September 2003)

Cost of National Project:

- Cost to the GEF Trust Fund 100,000 US$
- Co-financing (in-kind/in-cash
- Government contribution 50,000 US$

Total Cost of the Sub-project: 150,000 US$

Main Phases of the project:

Phase 1: Survey phase

Aim of the first phase was to make the survey of the situation of biosafety framework in Slovenia and to identify key stakeholders. So during the first phase following surveys were made: surveys of modern biotechnology, biosafety expert list, expert list to support risk assessment, survey of legislation and competent authorities in the country and survey of international regulation, survey of capacity building projects, related web sites and survey of GSO media coverage (See below for detailed information on availability of the data collected.).
The final output of the Fist phase of the project was establishment of internet page of **Slovenian Biosafety Clearing House**, where most important data on biosafety were made publicly available on: www.bch.bf.uni-lj.si.

Phase 2: Analysis and Consultation phase

During this phase workshops were organized to review findings from the Survey stage, identify gaps and needs and to decide priorities for Slovenian NBF. Series of training workshops was aimed at different administrative steps (inspectors, risk assessment, ministries …) in the regulation of GMO (See below for detailed list of the workshops and other activities under the project.).

Phase 3: Preparation of draft of National Biosafety Framework for Slovenia

The product of this phase is this document, which was discussed with the stakeholders identified in previous phases of the project and accepted by NCC.

7.1. STAKEHOLDERS

In the beginning of the project we identified some stakeholders in biosafety area and include them in the National Coordinating Committee (NCC), whose function was to advise and guide the activities of the project and preparation of NBF. NCC members were:

- representative of Ministry of Environment, Spatial Planning and Energy
- representative of Ministry for Health
- representative of Ministry for Agriculture, Forestry and Food
- representative of Custom (Ministry for Finance)
- representative of Ministry of Education, Science and Sport
- representative of NGO
- representative of NEA (National Institute of Biology)
- representative of Chamber of Commerce and Industry of Slovenia
- representative of Biotechnical Faculty
- representative of Krka d.d. (pharmaceutical company)

During the lifetime of the project the additional important stakeholders were involved in different activities.

- Chamber of Agriculture
- Institute for Education
- Inspectorates of different Ministries
- Media
- Biosafety Focal point

In the implementation phase of the project we predict, that we would have to address or include also:

- Consumers
- Farmers
- Ministry of the Economy
- Private sector (production and trade)

NGOs with interest in GMO have organized themselves in Coalition of NGOs for GMO free Slovenia which includes 16 NGOs and individuals. The aim of the Coalition is to ban GMO field trials and market release of GMOs. They will strive for development of and implementation of strict regulative for this field. Especially for implementation of labeling system on a principle 'from field to fork', monitoring and control systems and to assure public participation in decision making system in a way that public opinion will be considered. In the period till regulation of this field will be accepted, they will strive to ban any import GMO field product, seeds and food as well as for control over this restriction.

During the lifetime of this project the coalition made the communication with NGOs easier, since the NGO representative had the possibility to inform other members of the coalition, and sometimes also stated their common positions.

7.2. INVENTORIES

- **The inventory of the existing national legislation** was made. The matrix of the laws and regulation was explained in Slovenian BCH sub-page Laws and regulations. A special page under this sub-page was established for searching the National legislation. One can

search the laws and regulations by intended use - Search the legislation by usage (contained use of GMO, deliberate release of GMO to the environment) or placing on the market product consisting of or containing GMO) or by subject - Search the legislation by subject (agriculture, food safety, feed safety, medicinal products for human or veterinary use, protection of workers, human, transport, trans-boundary movement, explicit prohibitions and restriction of use of GMOs). All full texts of laws are available in Slovenian version of BCH; in English version almost all full text laws are available in official or un-official translations. In Slovenian version of the BCH one can also chose between reading the full text of the laws or only read articles addressing the GMOs, which is the step towards making the complex biosafety legislation system more user friendly.
The information is also available in requested formats on central BCH.

- **The inventory of the National competent authorities** for different areas was derived from the regulative. How the competences are divided or/and shared was explained in Slovenian BCH sub-page: Competent national authorities. The information is also available in requested formats on central BCH.

- **Surveys in biosafety experts/expertise**

    - *List of biosafety experts* was officially processed by Ministry of environment, spatial planning and energy and is available on Slovenian BCH sub-page Roster of expertsand is also available in requested formats on central BCH.
    - *Lists of experts* can be used on case by case basis to evaluate *risk assessment* within the decisions-making process (ex. Botany, entomology, immunology, molecular biology…) by committees as needed. The list is available only in paper and is not official.

- **Surveys in biotechnology and related experts/expertise**

    - *List of research organisations/departments working in biotechnology, genetic or molecular biology*
      The list is available at Slovenian BCH sub-page Institutions and resarch groups (, and the links to their web pages or to their basic information are provided, where possible.
    - *List of Biotechnology standards* that were accepted in Slovenia is available on Slovenian BCH sub-page Standards.

- **Conventional safety and related experts/expertise** was not explored in detail and it is only listing the organizations that have competences in this area in Slovenia (also links to their web pages are available).

The list of Regional and international agreements related to biosafety is available on Slovenian BCH sub-page Regional and international agreements

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- **The list of capacity building project** carried out in Slovenia in recent past is available on Slovenian BCH sub-page Capacity building. The Capacity Building needs and Priorities are defined in the Central BCH.

- **List of related web sites addressing biosafety issues is available on** Slovenian BCH sub-page Related web sites.

- **Media coverage of GMO related issues for year 2002-2003** was done in cooperation with public relation office of MOPE and is covering the most popular media coverage (main newspapers, radios and TV). The photocopies of the publications are available only in paper; the list of media coverage and other printed publications is available in Excel file.

- **Survey of presence of GMOs and GMO products on Slovenian market** was done in cooperation of Ministry for the Environment, Spatial Planning and Energy, Ministry for Health and Ministry for Agriculture, Forestry and Food. Partially this activity was supported also through this project. The monitoring results of previously mentioned inspectorates will be presented at the end of the year 2003.

- **Survey of the coverage of the modern biotechnology in Secondary schools curricula** was done and the learning programs are available in file (only in Slovene).

7.3. SLOVENIAN BIOSAFETY CLEARING HOUSE (BCH)

Slovenian BCH is available on: www.bch.bf.uni-lj.si. For the explanation on development of this page please read above.

The topics covered on the Slovenian BCH are mostly related to biosafety except the part on Biotechnology in Slovenia is added:

- Introduction to biosafety and BCH
- Cartagena Protocol
- Slovenian Biosafety server
- National contacts
- National Laws and Regulations
- Regional and international agreements
- National decision information (under Cartagena Protocol)
- Capacity building
- Roster of experts
- Related web pages
- Frequently asked questions
- Management, common formats

The Slovenian BCH is also hosting the Internet forum for CEE region National Project Coordinators, which is intended for exchange of experiences among the countries in development of NBF and administration of the project.

7.4. WORKSHOPS

- Workshop **Simulation of biosafety regulation in Slovenia** was organized by the end of survey phase of the project (December 16-17. 2002). All identified stakeholders were invited to the workshop. During two days workshop participants were very involved posing 11 pages of questions to foreign experts and representatives from competent

authorities in Slovenia. From the questions and from self evaluation forms was clear that the biggest gaps are:

- Understanding of which competent authority will be responsible for what in practice and related to this the need that in future workshop we provide a lot of practical examples and a need to provide a clear matrix of the GMO administrative processes.
- Need of different competent authorities for more specific education (inspection, customs, GMO-food, risk assessment, etc.)

Available materials in paper and/or files (some material for this workshop is also available on Slovenian BCH sub-page Capacity building, Projects):

- Programme
- Ppt. presentations and other materials used by speakers
- List of participants
- Questions and Answers
- Self evaluation summary

- Workshop **Risk Assessment and Management** was organized (April 16-18. 2003) for members of scientific committees, their deputies and GMO inspectors. Also selected members of other stakeholders were invited.

  Available materials in paper and/or files (files are subjected to authors approval for further use):

  - Programme
  - Ppt. presentations and other materials used by speakers
  - List of participants
  - **Road map** for risk assessment of deliberate release and placing on the market (what are the things that should be considered when setting up a system for this)
  - Self evaluation summary

- Awareness workshop **Biosafety in Agriculture** for agriculture advisers organized in cooperation with Chamber of agriculture and forestry and Chamber of Commerce (June 5. 2003). The programme was prepared on the requests from Chamber of agriculture and forestry.

  Available materials in paper and/or files in Slovene only (files are subjected to author's approval for further use):

  - Programme
  - Ppt. presentations and other materials used by speakers
  - List of participants

- Lecture **Transgenic plants – social and biological risks** was organized in cooperation with Agricultural Institute (two hours, turned to three hours lecture with discussion, mailing went to 1600 addresses, also through NGO – Umanotera mailing lists), 6. June 2003.

  Available materials in paper and/or files (files are subjected to author's approval for further use):

  - Ppt. presentations and other materials used by speakers

- List of participants
- Programme

- **Working group of GMO inspectors – deliberate release** (two days activity; simulation of deliberate release of GMO inspection and preparations of guidelines for deliberate release inspection), 19.-20. June 2003

  Available materials in paper and/or files (files are subjected to authors approval for further use):
  - Programme
  - Ppt. presentations and other materials used by speakers
  - **General procedures for inspections of deliberate releases** (Part B), **Logbook** and draft **check lists** were discussed and agreed and after the workshop translated to Slovene and distributed to the inspectors.

- Workshop **Detection of GMO and administrative procedure from sampling to decision of competent body** was organized for representatives of all laboratories in Slovenia involved in GMO detection and representatives of competent ministries and inspectorates (July 1-2. 2003).

  Available materials in paper and/or files (files are subjected to authors approval for further use):
  - Programme
  - Ppt. presentations and other materials used by speakers
  - List of participants
  - Questions and Answers
  - Self evaluation summary

- Working group **Inspection of contained use of GMO and preparation of guidelines for inspection of CU was** organised for GMO inspectors and representatives of the biggest organisations working with GMO in CU (September, 22.-23. 2003).

  Available materials in paper and/or files (files are subjected to authors approval for further use):
  - Programme
  - Ppt. presentations and other materials used by speakers
  - List of participants
  - Check lists for different type of Contained use inspection
  - Questions and Answers

- Workshop **Public Awareness, Public Information & Public Participation in National Biosafety System** was organized in cooperation with Chamber of Commerce for all stakeholders (governmental, scientific, NGO, private sector, media, etc.). Mailing went also through public relation office of the Ministry of Environment, Spatial Planning and Energy (media), Chamber of Commerce (industry) and NGO Umanotera) Also representatives from Czech Republic, Macedonia and Croatia (Moldova and CBD Secretariat participated with the paper on their situation, which was included in Workshop book) were attending and sharing their experiences in a Tour de table **National Biosafety Systems in CEE Region** (September 11.-12. 2003).

Available materials in paper and/or files (files are subjected to authors' approval for further use):

- Programme
- Ppt. presentations used by speakers
- **Workshop book** was printed (Proceedings) and is also available on Slovenian BCH
- List of participants
- Questions and Answers

7.5. DRAFT GUIDELINES

During different workshops organized within the scope of the project following draft guidelines were prepared:

- Road map for risk assessment of deliberate release and placing on the market (what are the things that should be considered when setting up a system for this) was prepared during workshop 'Risk assessment and Management'.
- General procedures for inspections of deliberate releases (Part B), Logbook and draft check lists were prepared during working group Simulation of DR inspection.
- Check lists for different type of Contained use inspection were prepared during working group **Inspection of contained use of GMO and preparation of guidelines for inspection of CU**

7.6. PRINTED MATERIAL

Following printed material (It is also available on Slovenian BCH.) was produced during the project:

- National Biosafety Framework for Slovenia (ISBN 961-90363-4-4, October 2003; English; 200 copies)
- Workshop book of the workshop Public Awareness, Public Information & Public Participation in National Biosafety System (ISBN 961-90363-3-6; September 2003; English with Slovene summaries; 200 copies)
- Brochure Genetically Modified Organisms aimed at the age group 12-16 years in cooperation with Institute of Education and designed to be attractive for this target group. (October 2003;ISBN 961-6392-11-5; Slovene; 4000 copies, ISBN ??? English 1000 copies)
- Brochure Cricket Skater - Contained Use of Genetically Modified Organisms, describing the administrative procedure for obtaining permit for Contained use of GMO and designed to be attractive for younger generations and providing better understanding what is National Biosafety Framework all about. (November 2003; ISBN 961-6392-16-6; Slovene, 1000 copies; ISBN 961-6392-18-2; English; 1000 copies)
- Ex-situ gene banks in Slovenia describes their current situation, legal management instruments with the comment of their future development and co-operation and the list of institutions and contact-points, too (Brochure will be printed in cooperation with MESP by the end of 2003.).

- GMO: risks and challenges – influence on environment, health and economy; Proceedings from the conference are available in Slovene with English summaries and in French (ISBN 961-6392-06-9; October 2002)

7.7. MEDIA COVERAGE OF THE PROJECT

- Interview in largest daily newspaper Delo 13.9.2003 (Saturday supplement – Sobotna priloga) with Jana Žel (representative of NEA in NCC) on GMO and Biosafety in general. Title: Half of soy is already genetically modified
- Interview in largest daily newspaper Delo (12.9.2003) with Julian Kinderlerer on public participation in biosafety and on Cartagena Protocol. Title: Genetically Modified Organisms; Who should destroy weed, women or herbicides?
- Resume from workshop Public Awareness, Public Information & Public Participation in National Biosafety System in AgraFood Biotech (15.9.2003) from Chaterine Williams. Title: Involving the public while protecting science
- Short resume of the workshop Public Awareness, Public Information & Public Participation in National Biosafety System and presentation of Cartagena protocol in Kmečki Glas (17.9.2003). Title The Cartagena protocol is in force – The access to information is important.
- The project Development of National Biosafety Framework fro Slovenia was presented on Bulletin of Ministry for Environment, Spatial Planning and Energy (February 2003). Title: UNEP/GEF project Development of National Biosafety Framework fro Slovenia (http://www.gov.si/mop/en/publikacije/bilteni/b2_03.pdf)
- Cartagena Protocol on Biological Safety-International Agreement on Trade of GMO of Bulletin of the Ministry for Environment, Spatial Planning and Energy (July, August 2003) (http://www.gov.si/mop/en/publikacije/bilteni/b7_8_03.pdf)
- Cartagena Protocol on Biosafety is in force (11. September 2003, interview on RGL radio station with Biserka Strel)
- Article in largest daily newspaper Delo 17.11.2003 (Supplement Science – Znanost), at the conffering the accreditation document for the qualitative and quantitative detection of GMO to one of the detection laboratories in Slovenia. Title: Detection of GMO – We have excellent national knowledge (Jana Žel, Maja Ravnikar).
- Short presentation of the project, NBF document, Slovenian BCH and GMO brochure for schools in largest daily newspaper Delo 17.11.2003 (Supplement Science – Znanost). Title: National Biosafety System (Darja Stanič Racman, NPC).
- Interview on the largest radio in Slovenia on Saturday broadcast for younger audience about the GMO in general and the two brochures that we have published for schools 29.11.2003 (Radio Slovenia – Sobotna raglja) (Darja Stanič Racman, NPC).

7.8. INTERNATIONAL AND REGIONAL ACTIVITIES

- Within the workshop **Public Awareness, Public Information & Public Participation in National Biosafety System** also Tour de table on **National Biosafety Systems in CEE Region** was organized where representatives from Czech Republic, Macedonia and Croatia (Moldova participated with the paper on their situation, which was included in Workshop book) were attending and sharing their experiences (September 11.-12. 2003).
    - List of participants
    - Questions and answers

- The Slovenian BCH is hosting the Internet forum for CEE region National Project Coordinators (http://www.bch.bf.uni-lj.si/bchprivate/), which is intended for exchange of experiences among the countries in development of NBF and administration of the project. The feedback from the NPCs is limited since only 9 NPCs from 20 have replied. The most probable reason is that the forum is not user friendly enough, since all of them are stating that the information on the forum is very useful, but are using only mail to contact me and not the forum. We think that normal internet page with restricted access (password), which would be managed actively by someone, would be better solution.

- On 14. – 15. May 2003 we were invited to participate meetings with Austrian delegation (Gaugitch Helmut, Dietmar Vibiral, and Alice Schmatzberger) to discuss and compare biosafety information systems, including BCH and public participation in GMO decision making system. The visit was organized in the framework of Twinning light project "Development of information and reporting systems" between Austria and Slovenia. NPC presented Slovenian BCH, and also plans for Slovenian Biosafety Server were presented.
    - Ppt. presentations are available

- NPC attended the Liaison Group meeting of technical experts on the Biosafety Clearing-House in Montreal (10-11th of April 2003), where the Slovenian BCH (http://www.bch.bf.uni-lj.si) was presented 'on line' and also recommendation given from our experience, was very well supported by other participating experts.
    - Ppt. presentation is available

- President of NCC (Biserka Strel), member of scientific committee (Borut Bohanec), person responsible for public participation in GSO regulatory framework from MESP (Martin Batič), and NPC participated CEECCA Sub-Regional Workshops "Risk Assessment & Management" **a**nd "Public Awareness & Participation"**, (**Vilnius, Lithuania, 27-30 May 2003**)**.

- BCH Focal Point and NPC attended the Technical Meeting: Implementation of the Biosafety Clearing House (BCH) in industrialized countries. Experiences and future development (29-30 September 2003), which was organized by the Swiss Agency for Environment, Forests and Landscape with the support of the Geneva Environment Network. At the meeting the Slovenian BCH (http://www.bch.bf.uni-lj.si) was presented 'on line' and also recommendation given from our experience.
    - Ppt. presentation is available

- NPC attended the second meeting of NCC of the project Development of National Biosafety framework for Croatia in Zagreb, where she presented the Slovenian experience with the project.
    - Ppt. presentation is available

- The activities of the project have also facilitated the involvement of two environmental inspectors to the European Enforcement Groups of GMO inspectors (http://eep-mon.iitb.fhg.de/) and supported the involvement of two GMO detection laboratories to European Network of GMO Laboratories (http://engl.jrc.it/).

- At Sub-Regional Meeting on Biosafety Framework in Prague (24.-25.4.2003) Slovenia participated with poster: Biosafety System in Slovenia where current activities and situation in biosafety system in Slovenia was presented.

- poster

7.9. CONCLUSION

The activities performed within this project and were described in previous sections correlate with suggested work plan and have even excided the expectations.

The most important output of the project is that stakeholders in NBF now recognize their roles much better and are regularly coordinating activities among themselves. We were also very pleased by the responses on our activities (Self evaluation forms, Questions and answer) and have been asked frequently about the possibility of extended cooperation. Having said this, we see the continuity of this scope of activities that facilitated the building of NBF as a problem in the future, since whole national biosafety system has to compete for the resources (people and money) in the national budget every year. This makes stable financial and personal support somewhat unsure. In Slovenia because of the limited resources in the country the support in form of the UNEP-GEF project 'Development of National Biosafety Framework (NBF) for Slovenia' and other projects financed form abroad was extremely valuable and have speeded up many of the activities towards functional and efficient NBF. We hope that Slovenia will also be part of the Implementation of National Boisafety Framework project, since during the development phase we have established connections and mechanisms among most of the stakeholders in the biosafety area on different levels and the greatest loss now, when we spend huge amount of time, effort and money for that, would be that we would stop with this scope of activities in biosafety area before we achieve the efficient working system.

ACKNOWLEDGMENT

We would like to thank some organisations and individuals for their valuable contribution to the project Development of National Biosafety Framework (NBF) for Slovenia.
First of all we appreciate the UNEP-GEF financial and administrative support. We would like to stress out here that these projects were extremely user friendly offering prepared templates for reports and prepared Toolkits, which took a load of work of the executive team. Special thanks go to UNEP/GEF team in Geneva, Andrea Gondova, Christopher Briggs and Liina Eek for their quick and effective consultation.

Thanks also to Secretariat of CBD, especially to Kristy Mclean and Marina Ocampo, for their support in building Slovenian BCH.

Thanks also to organizations in Slovenia, which have been our partners in the project activities and have donated their resources (people, knowledge, premises and equipment, mailing lists…): Chamber of Commerce, Chamber of agriculture and forestry, NGO Umanotera, Institute of Education and Institute of Agriculture.

Personal remarks of National Project Coordinator

In Slovenia the project, as it was organised, worked extremely well. The Ministry of Environment, Spatial Planning and Energy (MOPE) have signed the contract with the UNEP/GEF and had also supervisory role. National Institute of Biology was executive agency (NEA) and National Coordinating Committee (NCC) had advisory and supervisory role. All this institutions have performed excellent, since the people involved took this project and the importance of biosafety very seriously. That is why I would like to thank them that made all the activities of the project possible. The core executive team of project that were daily involved in the project were employees of Sector for Biotechnology (MOPE) Biserka Strel, Martin Batič and Julijana Lebez-Lozej, the responsible person in NEA, Jana Žel and administrative personnel of NEA who handled the specificity of the UNEP/GEF project. NCC had five meetings on which they proposed and addressed six new activities in the project that they identified as urgent to deal with in Slovenia. Members of the NCC were also supporting individually the activities of the project in their areas and have contributed to the draft NBF. Therefore I would like to thanks members of the NCC: Biserka Strel, Maruša Pavčič, Mira Zupanc-Kos, Marjana Dermelj, Jana Žel, Tatjana Zagorc, Aleš Gasparič, Peter Dovč, Stojan Pečlin, Monika Logar and Vojko Otovič.