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THE DRAFT NATIONAL BIOSAFETY FRAMEWORK FOR CROATIA

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Abbreviations

AMPMD = Agency for Medicinal Products and Medical Devices
BCH = Biosafety Clearing House
CARDS = Community Assistance for Reconstruction, Development and Stabilization
CEA = Croatian Environment Agency
CFA = Croatian Food Agency
CNIPH = Croatian National Institute for Public Health
CVI = Croatian Veterinary Institute
DG SANCO = Directorate General for Health and Consumer Protection
DUS testing = Distinct, Uniformity and Stability testing
EFSA = The European Food Safety Authority
EU = European Union
FAO = Food and Agricultural Organization
GEF = Global Environment Facility
GMO = Genetically modified organisms
HACCP = Hazard Analysis and Critical Control Point
ISO = International Organization for standardisation
MAFWM = Ministry of Agriculture, Forestry & Water Management;
MC = Ministry of Culture
MEPPPC = Ministry of Environmental Protection, Physical Planning & Construction
MHSW = Ministry of Health & Social Welfare
MSES = Ministry of Science, Education and Sports
MSTTD = Ministry of the Sea, Tourism, Transport and Development
NBF = National Biosafety Framework
NCC = National Coordination Committee
NEA = National Executing Agency
NPC = National Project Coordinator
RASFF = Rapid Alert System for Food and Feed
SIDA = Swedish International Development Cooperation Agency
SINP = State Institute for Nature Protection
SWEDAC = Swedish Board for Accreditation and Conformity Assessment
TWINNING projects = Pre accession assistance for institution building (EU)
UNEP = United Nations Environment Program
VCU testing = Value for Cultivation and Use
WHO = The World Health Organisation

Foreword

This publication is result of the Project "Development of the National Biosafety Framework in Croatia". The Project is designed, supervised and financially supported by the United Nations Environment Program (UNEP) & Global Environment Facility (GEF) and the executing agency for this Project in Croatia was the State Institute for Nature Protection.

The term “Biosafety” used here considers the protection of biodiversity, nature & human health from possible adverse effects of genetically modified organisms (GMOs). The aim of this Project was to propose an adequate Draft National Biosafety Framework (NBF) for the Republic of Croatia. The idea of the draft NBF was to review existing biosafety legislative, administrative, enforcement and other systems, then to identify gaps and/or overlaps within them and on the basis of these findings propose improvements in order to establish an effective legislative, monitoring & enforcement system for biosafety in Croatia.

Because GMOs are widely used in scientific research in Croatia, production of medicines and food, and at the same time may possibly pose a threat to biodiversity and human health there is urgent need to regulate and implement systems for safely dealing with following issues of cross-boundary transport, transit, contained use, intentional introduction into the environment, placing of a GMO or GMO derivatives on the market, GMO handling, transportation and packing, as well as the disposal of GMO waste.

The publication is reviewing the existing situation in Croatia regarding biosafety. It is especially over viewing the legislation dealing with biosafety, analysing the system to handle notification or requests for authorization for contained use, intentional introduction into environment and the placing of GMOs on the market. It assesses the systems to monitor and enforce existing or proposed legislation as well as mechanisms for public participation, information and education. By reviewing the existing situation in Croatia, various gaps were found which could cause problems with undesirable consequences in future. Therefore, there are proposed improvements in order to form a strong system for everybody to benefit from. The idea of this publication was to propose an NBF and plans and actions that have to be undertaken to enable successful implementation of the NBF in practice in accordance with Croatian political stand towards the GMO issue.

Davorin Marković

The head of the State Institute for Nature Protection

1. INTRODUCTION TO BIOSAFETY

The production of genetically modified organisms (GMOs), in the farming and food sectors and the controversy surrounding them, has grown in the last ten years. Opinions differ between developed and developing countries and amongst farmers, scientists and consumers. Some advocate less restricted distribution while others favour the precautionary principle or full restriction. Others who claim that there are at least allergy risks counter claims that GMOs carry no health risk. Potential ecological risks are recognized by all stakeholders, as well as economic risk related to the coexistence of GMO and conventional and/or organic crops.

Question marks remain, over the development of GM crops, scientific research in this area, coexistence with traditional crops, effects on biodiversity, consumers' freedom of choice, free competition, International trade, patents, the needs of developing countries, proper public information (including-through compulsory labelling), the animal feed chain, the precautionary principle and the notion of sustainability.

Croatia is one of the countries that have ratified the Cartagena Protocol, which deals with biosafety. This International agreement tries to find compromises between conflicting interests. This concept referees the needs for the protection of human health and the environment from possible adverse effects of products of modern biotechnology. At the same time, modern biotechnology is recognized as having great potential for the promotion of human well being, particularly in meeting critical needs for food, agriculture and health care.

The Total surface area of Croatia is 87 661 km², from which 56 594 km² is land surface. Forests cover 43. 5% and National Parks & other protected areas cover 9. 9%. There is more than 24.6 % of agricultural land in Croatia (of the total land surface), of which over 77.4 % is private farm holdings with an average size of 3.5 ha. Every year, one million ‘ha’ of arable land is cultivated. Croatia has a tradition of seed production of maize & wheat, for which some is used for export.

Croatia has a high biological diversity and is promoting itself as a tourist destination in Europe where biodiversity is preserved as well as a rural way of life. Therefore, eco-tourism and ecological agriculture can be considered priorities. From the 21 counties in the Republic of Croatia, eight have declared or are in process of declaration themselves as "GMO free zones".

Croatian pharmaceutical and food industries, as well as scientific institutions, use biotechnological methods in the research and production of pharmaceuticals and of food. Various groups, focused mainly around the Universities and Institutes, have been using DNA technology for their basic research, as well as for biotechnological purposes.

Croatia does not have its own Biosafety policy. In 2003, two key pieces of legislation were enacted, which are the Nature Protection Act and the Food Act. Within them, the topics regarding GMOs and biosafety have been regulated. They are based on the Cartagena protocol (ratified in 2002) and on European legislation that Croatia must implement as a requirement of predecessor countries to the European Union (EU).

The implemental regulations, which are stipulations for implementation and enforcement of these two Acts, although most of them were drafted during the UNEP/GEF project entitled

"Development of the National Biosafety Framework for Croatia" (later referring as the Project), haven't been accepted as yet. Therefore, the system to handle notification or requests and for authorization of approvals /registrations, as well as other procedures, activities and bodies that are prescribed under these two Acts, is not in place.

The laboratory used for the detection of GMOs is functional and enables 'inspection' to monitor and control food, feed and seeds.

From the time these two Acts were enacted, the legislation involved hadn't been fully implemented and the government administrative system has been changed. The jurisdiction over Nature Protection had been transferred from the Ministry of Environmental Protection & Physical Planning to the Ministry of Culture (MC). This had disrupted jurisdiction over implementation of the Nature Protection Act, as prescribed by it. A decision was made to separate and remove the 'GMO' section from the Nature Protection Act. Then as independent umbrella legislation on GMOs, take it in due process of law in Parliament, which resulted in a delay of the whole implementation process.

This Project had managed to fulfil all of its goals in spite of an undefined Biosafety policy in Croatia and an increase in negative sensitivity to the subject by the media and the public. So far, the Project has held six educational workshops for various stakeholders. The National database has been established on the use of biotechnology, capacities for its implementation, experts in this field from which the members of scientific committees were proposed. The Project had communicated with and informed the public about the workshops with written material, media and its web site. The implemental regulations for the Nature protection Act have been drafted as well as the Draft National Biosafety Framework (NBF). The most important achievement of this Project has been the fulfilment of the basic requirements for further implementation of the Cartagena Protocol and NBF.

There is still a lot to do before the NBF for Croatia can be fully established and implemented. To achieve this goal the fulfilment of requirements that have been described in detail within this report would be needed.

2. BI0SAFETY POLICY

2.1. Current situation

Croatia does not have a specific policy on biosafety as mentioned above. Biosafety in Croatia is only part of more general policies on biodiversity conservation, biotechnology, science and technology, food production, food safety, environment protection, sustainable development etc. These policies are in the competence of different governmental bodies and are not mutually coordinated; therefore, some of these policies are contradictory.

As mentioned before:
a) Croatia has a high biological diversity.
b) Croatian biodiversity is preserved as well as a rural way of life.
c) Eco-tourism and ecological agriculture can be considered priorities.

But as yet, on all levels there are no coordinated systematic, economical and financial programs with the goal of practical support relating to all aspects of biosafety. A defined coexistence of various types of research, industries and agricultural practices is not in place. There are also, no clearly defined priorities and targets for the country as a whole in relation to biosafety.

Listed here are some of the National policies that cover biosafety regulations in Croatia as well as International agreements, which regulate biosafety and which Croatia has ratified.

1. The basic National legislative framework for the conservation and sustainable use of biological diversity is the *Constitution of the Republic of Croatia* (1992), which promotes the preservation of the natural environment as the highest priority of the State.

2. The Republic of Croatia had signed in 1992 and ratified in 1996, the *Convention on Biological Diversity* (Rio de Janeiro, 1992) – (Official Gazette – International Treaties, No. 1/6/1996).

3. In March 1993, the Government of the Republic of Croatia initiated and then endorsed *Agenda 21*.

4. *The National Strategy and Action Plans for the Protection of Biological and Landscape Diversity* (NSAP) - was adopted by Croatian National Parliament (Official Gazette No. 81/1999 dated 3 August 1999). It also represents the first National Report for the Conference of Parties to the Convention on Biological Diversity, which includes an overview of the state of the landscape and biological diversity of Croatia, with protection strategy and action plans. GMOs are recognised in the NSAP as a potential risk to biodiversity, so the systematic control of their release into the environment is a priority. The NSAP is currently in the process of revision, which will be completed till the end of 2005. It is expected that in the updated and revised NSAP more consideration will be given to the GMO use.

5. The Republic of Croatia became a member of the *World Trade Organisation (WTO)* by accession to the Marrakesh Agreement on Establishing the World Trade Organisation (Geneva, 2000) – Law on Ratification of the Protocol on Accession of the Republic of Croatia to the Marrakesh Agreement on Establishing the World Trade Organisation (Official Gazette – International Treaties, No. 13/2000) and concluded with the WTO the following agreements related to GMOs:
a) Agreement on Implementation of Sanitary and Phytosanitary Measures.
b) Agreement on Technical Barriers to Trade.
c) Agreement on Agriculture.

6. On 19 July 2001, the Croatian Government adopted the Decision on Measures in the Procedure of Approximation of Legislation of the Republic of Croatia to the *Acquis Communautaire*, which was enforced on 1 December 2001.

7. In *the National Environmental Strategy* adopted by the Croatian Parliament during its session of 25 January 2002 (Official Gazette No. 46 of 29 April 2002), environmental subjects of strategic importance are defined. In this strategy it is stated that Croatia's main goals are the sustainable development with protection and preservation of existing biological diversity. Therefore, under this National Strategy, priority is given to the preservation of existing biological diversity by harmonising legislation, administration and other actions. GMOs are listed amongst secondary priorities, which mean that more time will be needed to regulate and implement laws in this field by the government.

8. During July 2003, Croatian Parliament had adopted *the National Strategy for Forestry* (Official Gazette No. 120/2003). It states, the goal of this strategy is for the preservation and protection of biodiversity and sustainable management of forestry resources in Croatia. The protection of forestry resources can be achieved by implementation of ecologically and economically acceptable technologies. The Republic of Croatia has obtained a certificate from the Forest Stewardship Council (FSC-a) for 2 million of 'ha' listed under forest, until 2007. This certificate is given for the management of forestry resources under strict ecological, social and economical conditions, and explicitly forbids the use of GMOs in forestry.

9. On 29 August 2002, the Republic of Croatia had signed and ratified *the Cartagena Protocol* (with the Convention on Biological Diversity) (Official Gazette, International Agreements No. 7/2002), which came into force on 11 September 2003.

National policies, which are indirectly connected with biosafety, are listed in **Annex 1.**

More International agreements, which Croatia is a member of, can be found on the web page of this Project (www.gmo.hr).

2.2. Future plans and needs

In the forthcoming period, the priorities of Croatia regarding the biosafety policy are to:
a) Construct a National biosafety policy that would be harmonized with other National strategies. In order to ensure their quicker implementation there is need to specify economical and financial programs which would in practice support all aspects of adopted biosafety policy and other related National strategies.

b) Update all of the National Strategies, harmonize them between themselves and with EU legislation.
c) Ensure the inclusion of principles for the safe handling and use of GMOs within biosafety policy.
d) Construct a National Strategy for Food Safety.
e) Co-operate and become involved in activities with International organizations in the field of biosafety.
f) Participate in the development and implementation of the EU biosafety principles.

3. REGULATORY SYSTEM

3.1. Current situation

In 2003, two key pieces of legislation were enacted regulating this area during a longstanding legal vacuum in the GMO area, a *de facto* moratorium was applied in the absence of any legal grounds. They are the Nature Protection Act (Official Gazette No. 162/2003) and the Food Act (Official Gazette No. 117/2003).

Nature Protection Act (Official Gazette No.162/2003)
The Nature Protection Act came into force on 23 October 2003. Regulated by its provisions are the issues of cross-boundary transport, transit, contained use, intentional introduction into the environment, placing of a certain GMO or GMO derivatives on the market, GMO handling, transportation and packing, as well as the disposal of GMO waste. The central government authority empowered for implementation of this Act is the Ministry of Culture (MC) - The Nature Protection Department. The provisions of this Act do not apply to import, transit, placing on the market, use and production of medicines containing GMOs, unless otherwise determined by a special regulation.

The transport, transit and handling of living modified organisms shall be governed by the provisions of special regulations relating to transport, transit and handling of hazardous substances, unless determined otherwise by this Act or a regulation issued on the basis thereof.

The applicant or a legal or natural person using GMOs shall dispose of and permanently and harmlessly destroy the waste containing GMOs, in a manner that ensures that the GMO is no longer capable of transmission or reproduction of genetic material and that its genetic material cannot be transferred to other organisms.

The contained use of GMOs shall be classified into one of the four groups according to the level of hazard. The closed systems for the contained use of GMOs must fulfil all the conditions laid down for the level of hazard into which the planned use has been classified and must be registered in the GMO register. Authorization is issued by the MC for closed systems and the use of GMO within them.

The application procedures authorizing the intentional introduction of GMOs into the environment (experimental and commercial crops) are also prescribed by this Act. With the consent of the Ministry of Agriculture, Forestry & Water Management (MAFWM) and an opinion of the Scientific Commission, the MC shall issue the decision. The key part of the procedure involves making a risk assessment with all elements of influence on health and the environment, elaboration of remedial actions in the case of unforeseeable events, proposed monitoring of influences on the environment etc. It is not allowed to release GMOs in protected areas, ecological network areas, areas intended for ecological (organic) agriculture and ecological forms of tourism in Croatia. To clearly determine those areas and buffer zones it is essential to define and map them. A ‘Protected areas’ database is currently in the process of revision and digitalization. The first draft of the National ecological network as well as the Croatian section of the Natura 2000 network, constructed as a part of the Life III project "Croatian National Ecological Network (CRO-NEN)", which started in 2003, and is planned to be finalized by June 2005. The State Institute for Nature Protection (SINP) is the NEA for

this project. Defining and mapping of areas intended for ecological (organic) agriculture and ecological forms of tourism is in the competency of the MAFWM and Ministry of the Sea, Tourism, Transport and Development (MSTTD).

For every GMO that one intends to introduce on the market for the first time, an authorization permit must be applied for. The Ministry of Health & Social Welfare (MHSW) is invested with competence for issuing a marketing authorization in conformity with the designed use of pharmaceuticals, cosmetics and food. The (MAFWM) issues the authorization for feeds and use in agriculture, forestry, and fisheries. For placing of a GMO or GMO derivatives on the market for any other designed use the competent authority is MC. In Article 133, there are labelling requirements for every GMO that one intends to place on the market. The product must have a visible label on the packaging and in its accompanying documents should state that the product is a GMO or contains a GMO, including other data as may be prescribed that relate to the product and its use. The label must clearly specify "the genetically modified organism" or contain the sentence "this product contains genetically modified organisms".

The Regulation on the minimum threshold for GMOs in products below which the products placed on the market shall not have to be labelled as products containing GMOs (Official Gazette No. 34/2004)
Pursuant to Article 133, paragraph 3 of the Nature Protection Act, the Government of the Republic of Croatia at its session held on 12 March 2003 passed this regulation. This Regulation lays down the minimum threshold for genetically modified organisms in products below which the products placed on the market shall not have to be labelled as products containing GMOs. It has imposed a limit of 0.9% per individual ingredient of a product as the level of random or technologically unavoidable contamination for the 15 types of GMO allowed in the EU. In addition, plant reproductive material containing GMOs in any amount must be labelled in accordance with a special regulation.
In spring 2004 the GMO laboratory had detected 0.5-0.7% of GM seeds amongst a sample of conventional corn seed. Under this Regulation the MAFWM decided to plug down all the corn plants, which were owned by farmers and agriculture companies. There was no authorization of GMO, risk analysis had not been done and it was concluded that danger of GMO genes spreading to conventional corn, due to no existing barriers between them, could have been realised. The farmers were paid cca. 1.000 Euro per hectare, while the Government had officially accused the company that had imported the seed without authorization.

The Ordinance on the conditions to be fulfilled by a laboratory for testing, control and monitoring of GMOs and products containing GMOs (Official Gazette No. 98/2004)
Pursuant to Article 138, paragraph 4 of the Nature Protection Act this Ordinance has been passed. This Ordinance establishes the conditions related to the premises, equipment and employees qualifications, to be fulfilled by laboratories for testing, control and monitoring of GMOs and products containing GMOs. In August 2004, the Minister for Health & Social Welfare (MHSW) had granted authorization for testing, control and monitoring of GMOs and products containing GMOs to the laboratory, which was set up in the Croatian National Institute for Public Health (CNIPH), Zagreb, in September 2003.

For full operational commencement of the system prescribed by the Nature Protection Act, all implemental regulations (more than 20) need to be enacted. Expert Working Groups have written them as part of this Project and they can be found in **Annex 2.**

In summer 2004, the MC decided to separate the 'GMO' topic from the Nature Protection Act and pass a special umbrella act on GMOs, which is currently in due process of law in the Parliament. The proposed new law is largely a transcript of the existing provisions, except for a change in distributional responsibility amongst the state law enforcement agencies. An Unofficial translation of the proposed GMO Act can be found on web pages of the Project (www.gmo.hr).

***Food Act** (Official Gazette No. 117/2003)*
The Food Act regulates the problem areas of health safety and food safety surveillance. In compliance with European practice, a new category of foods, namely 'Novel foods', has been introduced into the Act for the first time. The term 'Novel food' relates to either a food manufactured by using new technologies, or one that was not until now extensively used for nutrition in Croatia.
Therefore, Novel food could have a potential hazardous effect, which must not be overlooked or completely excluded. Consequently, Novel foods come under special procedures for food risk assessment and for authorization of their placement on the market. Belonging to this category are GMO foods or GMO-containing foods that have been manufactured from a GMO whatever the degree of processing involved.
In addition to the fulfilment of health safety requirements and of special marketing requirements, the law requires that a special authorization by the MHSW be issued for such food products before their first appearance on the market. The MAFWM is competent to issue authorization for such feeds.

Other related Acts
Mentioned here, are other Acts that regulate various areas from waist, transport, and agricultural production to science. Some of them clearly state their connection with the GMO issue but in others it is not so. Also not clearly stated, is the relation to these Acts neither in the "Umbrella law" as it is the Nature Protection Act or the new proposed GMO Act. At base level, this has created confusion with regulators on the subject of 'the holding of ultimate responsibility' for regulating in various different fields. For the purpose of stressing the fact that there is a need for clarification of inter-relations, listed here are all these Acts, although some of them are connected to GMOs but only indirectly.

A. *The Water Management Act (Official Gazette No. 107/1995)*
This Act regulates the legal status of water and water estate, the methods and conditions of water management (water use, water protection, regulation of watercourses and other water bodies, and protection from adverse effects of water), the method of organizing and performing water management tasks and functions, basic conditions for carrying out of water management activities; powers and duties of Government administration and other Government bodies, local authorities and other legal subjects, and other issues of importance to water management.
The Act also establishes "Croatian Waters" - the legal entity in charge of water management tasks. Under the conditions of this Act, water permits can be or are issued. Water permits are issued under certain conditions for some of the dangerous substances in water. These substances are defined under the *Regulation on Dangerous Substances in Water* (Official Gazette No. 78/1998). Sometimes different biological agents, which can consist of or are GMOs, are used in the *water treatment facilities*. The following Articles: 70, 72, 76 and 128-

134 refer to these subjects. The Department of water management (MAFWM) is responsible for implementation of this Act.
The Regulation on Dangerous Substances in Water (Official Gazette No. 78/1998)
This Regulation on Dangerous Substances in water defines substances and their quantities in accordance with Article 70 of The Water Management Act that are considered dangerous substances in a water environment.

B. *The Ecological Production of Agricultural and Food Products Act (Official Gazette No. 12/2001)*

The Ecological Production of Agricultural and Food Products Act came into force on 22 February 2001. This Act governs ecological production of agricultural and food products, processing in ecological production, trade in ecological products, unprocessed vegetable and animal products, products fully or partly consisting of such products, marking in ecological production, performance of expert and inspection control and other issues relevant for the implementation of a unique system of ecological production. In article 15 of this Act, it is specifically stated that the use of GMOs and all products that consist of or are produced from GMOs are "banned" in ecological production. It is also prohibited to use GMOs as reproduction material, secondary raw material, additives and secondary substances or as packaging. The MAFWM is responsible of implementation of this Act.

C. *The Minor Offences Act (Official Gazette No. 88/2002)*
The Minor Offences Act came into force on 1 October 2002. Article 30, directly specifies which type of fine will be issued for offences committed, during import, transit, contained use, placing on the market and release into environment of GMOs. The Ministry of Justice is responsible for implementation of this Act.

D. *Consumer protection Act (Official Gazette No. 96/2003)*
The Consumer Protection Act came into force on 18 June 2003. This Act covers general law on consumer protection. In Article 17, product content declarations are described. Amongst other label declarations, a statement by the manufacturer on the existence of any modified features of products including organisms, ingredients, parts & additives should be included, plus the type of modification, if any, should be in line with special regulations. It also states that other by-laws will define specific declaration for specific products. The Ministry of Economy, Labour and Entrepreneurship is in charge of implementation of this Act.

E. *The Medicinal Products and Medical Devices Act (Official Gazette No.121/2003)*
The Medicinal Products and Medical Devices Act came into force on 6 August 2003. This Act defines testing within marketing procedures, production, marking, classification, trade, monitoring of side effects, advertising & information, control over medicines and medical products, also with quality checks for medicines and assessment of conformity for medical products, requirements and type of marketing & control of homeopathic products. The Act also defines the term *"substance"*, which, inter alia, can also be GMOs. Prior consent from the MHSW is required, inter alia, for clinical research of a ready medicine intended for gene therapy, treatment with somatic cells, including xenogenetic cells, and treatment with medicines containing GMOs. The Articles that refer to this issue are: 2, 7,121-138. The MHSW has established the *"Agency for Medicinal Products and Medical Devices"*, which is responsible of implementation of this Act in October 2003. The MHSW is monitoring the legal activities of the Agency. The web address of the Agency is: www.almp.hr. The Agency controls production & issuing permits for placing on the market of medicinal products and homeopathic products, permits for research, etc. Under this Act the National Medical

Bioethical Committee has to be established. This Committee is advising the Government on ethical and law issues regarding development and implementation of biomedical research on humans, and is giving recommendations to Government to change existing or to adopt new legislation in this field.

F. *The Decision Promulgating the Science and Higher Education Act (Official Gazette No. 123/2003)*
The Decision Promulgating the Science and Higher Education Act, which came into force on 16 August 2003, also regulates the system of scientific activities (scientific and development research). Croatian Parliament, upon proposals by the Government, will appoint the *"Committee for Ethics in Science and Higher Education"*. The task of the Committee is the promotion of ethical principles and values in science and higher education, in business relations and in relations to the public, also, application of current technologies as well as in the protection of the environment. The Committee shall adopt the "Code of Ethics". More details about this Committee can be found in Article 112. Under this Act the National Scientific Council has to be appointed. This Council, will have an expert and advisory function and is in charge of the development of overall scientific activities in the Republic of Croatia. The members of this Council had been nominated at the end of last year (Official Gazette No. 174/2004). The MSES is responsible for the implementation of this Act.

G. *The Amendments Act to the Transport of Dangerous Substances Act (Official Gazette No. 151/2003)*
This Act came into force on 2 October 2003 and regulates transport of dangerous substances-type of transport & cargo, the duties of personnel involved in the transportation, conditions for packaging & for transportation and governmental bodies responsibilities for inspections in transport.
Regulations on the transportation of dangerous substances:
a) The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) applies to roads.
b) The Ordinance on International Carriage of Dangerous Goods by Railway (RID) applies to railways.
c) The European Agreement concerning the International Carriage of Dangerous Goods by Inland
d) Waterways (ADN) apply to rivers & lakes within the country.
e) The International codex of dangerous cargo (IMDG Code) applies to sea transport.
f) The Convention on International civil air transport, Annex 18, applies to air transportation.
The packaging of the products that contain or are made from GMOs is prepared in accordance with this Act. The MSTTD is responsible for its implementation.

H. *The Waste Act (Official Gazette No. 151/2003)*
The Waste Act came into force on 1 January 2004. This Act regulates rights, obligations and responsibilities of institutions and persons dealing with waste and wastage. The MEPPPC is responsible for implementation of this Act.
The Ordinance on Classification of Waste (Official Gazette No. 27/1996)
This Ordinance is to define the different types of waste; how they should be managed; which type of documentation is needed; methods of testing the physical and chemical attributes of hazardous waste; sampling of waste and charges implemented for non appliance with this Ordinance. Under this Ordinance, the characteristics of hazardous waste are specified. If the waste that consists of GMOs has the characteristics of hazardous waste under this Ordinance, it has to be managed by *The Regulation on conditions on the handling of hazardous waste*

(Official Gazette No. 32/1998). This Regulation regulates the safety & technological conditions for area; buildings or equipment used for storage, processing or the depositing of hazardous waste and qualifications needed for personnel handling hazardous waste.

I. *The Seeds, Plant Material and Registration of Varieties of Agricultural Plants Act (Consolidated text, Official Gazette No. 137/2004)*
The Government of the Republic of Croatia at its session held on 21 September 2004 passed the 'Consolidated' text of this Act. It regulates production and trade of agricultural seeds, seedlings, mycelium of edible and medicinal fungi, agricultural seed material, recognition of varieties of agricultural plants and other topics, which are important for establishing a unique system for agricultural seeds and seedlings. Production and trade of *genetically modified* agricultural seeds, seedlings, mycelium of edible and medicinal fungi, agricultural seed material, and registration of varieties of *genetically modified plants,* are also governed by provisions of a special law (Article 1). The MAFWM is responsible for implementation of this Act.

All these translated legislations are available on the web site of the Project: www.gmo.hr.

3. 2. Future plans and needs

Implementation of biosafety regulations
The Croatian primary goal is to harmonize National legislation, in every area, with EU legislation. This process had started on 1 December 2001 and it has intensified, especially now, since Croatia became an accession country to the EU.

Presently, there are many areas that still haven't been fully harmonized. Amongst them, is legislation for GMOs and biosafety. Furthermore, as it can be seen from the review of current legislation, various different Ministries are now responsible for various different parts of GMO legislation. To be able to achieve the goal, of covering the whole very complex biosafety and GMO issue, there is serious need for involved ministries to transparently communicate and coordinate their actions in drafting needed legislation and harmonising it with the EU.

Identified during the Project was that Croatia has a lack of lawyers with any specialisation in environmental law, especially in regards to International legislation. This is causing many operational problems, because it is almost impossible to get professional and reliable advice in this field. It would be advisable for such specialised lawyers to be employed by all Ministries dealing with the Environment (the MEPPPC, the MC and the MAFWM) and also by the Ministry for European Integrations and the Ministry of Justice. Another option would be to set up an independent consulting organization, which would employ such specialised lawyer's who could give advice to all interested parties. It should be advisable that Croatia considers as priority educating lawyers in this area. Taking such a position would enable Croatia to professionally represent and if need be defend its stand within the International community.

The Food Act and the Nature Protection Act constitute the legal framework for the legal order in the area of GMOs in Croatia. The Nature Protection Act and new proposed GMO Act are designed as the umbrella law on GMOs in Croatia. The first requirement to make the NBF system in Croatia clear and operable is for its harmonization with other Acts that are

previously listed under "Other related Acts" to this Act. Through guidelines, it should/must clearly state ‘when and which’ competent authority should hold responsibility in specific cases.

Under this *new proposed GMO Act,* it no longer states that the implementation of this Act will only begin when all by-laws come into force as it was stated under the Nature Protection Act. This was legally unusual and was blocking the implementation of framework law before all by-laws are adopted. As soon as the Croatian Government passes this new proposed Act, all the necessary actions for implementation of this Act will have to begin (appointment of the Committee and Scientific Commissions, as well as drafting and passing implemental regulations).

In the new proposed GMO Act it states that in transportation, transit and in handling, the regulations on the transportation, transit and handling of hazardous substances apply to *only the live modified organisms that are posing hazards to the environment.*

The treatment of waste containing GMOs under both Acts should be clarified and specified in bylaws or guidance's, in order to avoid any confusion. This is of special importance in cases of the release of GMO into the environment and the placing of them onto the market, as now in practice it requires every farmer to incinerate all of the material of the GMO crops he/she has grown.

Within the new proposed GMO Act, genetically modified reproductive plant material may be introduced into environment only on plots of land to be allocated by decree by the government of the Republic of Croatia on the proposal of the MAFWM with the consent of the state administrative body for nature protection. According to the opinion of several International experts the ‘hidden ban’ remains.
Therefore, it should be sensible:
1. To exclude this sentence from the Act and take a case-by-case approach.
2. To fully implement Article 23 of Directive 2001/18/EC.
3. To also include seed & seedling production areas and protected zones of influence around them, when naming the areas of the environment where the introduction of GMO is banned.

It could also be beneficial to give an option that some GMOs could be released into the environment under the simplified procedure in the new GMO Act and then thru the by-laws regulate all details of such procedures. Such an approach would give Croatia an opportunity, based on National experience to draft much needed by-laws and would also relate calm to the public who are presently cautious and see that such provision in the Act as "opening doors" to GMO in Croatia.

The new proposed GMO Act must make improvements in this area, as it states that the MAFWM is competent and responsible for product marketing for reproduction material in agriculture, forestry, and veterinary medicine, and for veterinary drugs and plant protection products. Therefore, this Act will now cover the control and testing in this area, which wasn't covered under previous regulations. But horticultural seeds & seedlings are still not covered within existing and proposed legislation. There is no mention either in the Act who will control feed for animals that are not use for human consumption. Therefore, there is serious need to regulate the responsibility for the control and testing on GMOs in these areas as well. Unfortunately in the new proposed Act (Article 3) there are no longer any more general references to other GMOs or

products containing GMOs that require permits for the placing on the market, as required under the Nature Protection Act (Article 129, Chapter 5). Since there are other examples of products, which don't fall under ones mentioned in Article 3 of the new proposed Act, a "safety net" is needed, to declare which minister is responsible for such products.

Also under the new proposed GMO Act, the definition of products has been broadened and is now more in line with new EU legislation. Products are now defined as a GMO or GMO containing/made/derived products. The labels of such products must clearly state, "genetically modified organism" or contain one of the two sentences: "This product contains genetically modified organisms", respectively," This product derives from genetically modified organisms**".** Within by-laws the clear distinction between which provisions of this Act will apply to "GMOs & products containing GMOs" and which to "products made/derived from GMOs", have yet to be clarified in order to make this Act workable in practice.

Under *the Food Act,* during December 2004 the CFA had been established. The CFA has become fully operational with appointed Committees and Scientific Commissions. The Agency shall together with the MAFWM and the MHSW, coordinate development and formation of regulations in the field of food and feed. All needed implemental regulations within the Food Act shall be drafted by responsible Ministries and approved by scientific panels, within three years from the adoption of the Food Act (until the end of 2006). Each one of them has to undergo a revision by independent scientists and this brings new highlights to this issue. The Agency shall also develop guidebooks for good production practices, guidebooks for the application of the HACCP system and guidebooks for good laboratory practice.

At EU level, the 'Novel food' regulation no longer applies to GM food and feed. The GMO food and feed is regulated as such under 1829/2003/EC. Therefore, harmonization of the Food Act accordingly to this new EU Directive is needed.

4. SYSTEM TO HANDLE NOTIFICATION OR REQUESTS FOR AUTHORIZATION

4.1. Current situation

Presently in Croatia, the system to handle notification or requests for authorization for activities, such as release of GMOs into the environment, placing on the market or contained use, has not been set up as yet. The process of implementation of Acts regulating the GMO issue have began only under the Food Act.

A*. Under the Nature Protection Act (Official Gazette No.162/2003)* the authorization for import, transit, contained use, deliberate release into the environment and placing of GMOs or products containing GMOs on the market shall be granted by the Ministry of Culture (MC) - The Nature Protection Department.

In (Annex 3) - the flow charts of the system to handle notification or requests under the *Nature Protection Act* are detailed.
In (Annex 4) - the flow charts of the system to handle notification or requests under the proposed *new proposed GMO Act* are detailed.

For the purpose of monitoring state and developments in the field of GMO handling and provision of technical assistance to competent government authorities, the Government shall set up a Commission for Genetically Modified Organisms (the Commission for GMOs), a Scientific Committee for Contained Use of Genetically Modified Organisms (the Committee for Contained Use of GMOs), a Scientific Committee for the Release of Genetically Modified Organisms into the Environment (the Committee for the Release of GMOs into the Environment) and a Committee for Novel Food and Animal Feed Containing Genetically Modified Organisms (the Committee for Novel Food and Animal Feed Containing GMOs). The composition, scope of activities and methodology of work of the Committee for Novel Food and Animal Feed containing GMOs shall be laid down by a special regulation.
In (Annex 3) - there is the flow chart of the composition and responsibilities of the Commission and Scientific Committees.
The process of selecting and appointing members of the Scientific Committee for Contained Use of GMOs & the Scientific Committee for the Release of GMOs into the Environment had started in spring 2004, but has come to a halt.

Under the Nature Protection Act applicants shall submit an application ***for contained use of GMOs*** to the MC - The Nature Protection Department. This Ministry shall examine whether the application complies with the conditions laid down in this Act and after obtaining an expert opinion from the Committee for Contained Use, the Ministry may issue a decision. The contained use of GMOs shall take place in a closed system that fulfils all the conditions laid down for the level of hazard in which the planned use has been classified.
Classification of the contained use should be placed into one of four classes, where class 1 describes the work in which the risk is negligible and class 4 where the work is of high risk. For every class there are required specified containment measures, other safety measures and required provisions. Contained use may only be conducted in the premise in which the required conditions are fulfilled for the class into which the intended work is classified.

The purpose of the risk assessment for contained use of GMOs is, 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 evaluate, in particular possible adverse effects, the level of risk and necessary containment and other safety measures.
The MC shall examine whether the application complies with the conditions laid down. After obtaining an expert opinion of the Committee for Contained Use (within **30 days from** receipt of the copy of an application) every closed system, regardless of its grade of containment, shall be entered into the GMO register. The Ministry shall issue a statement to the applicant confirming the entry of the system into the GMO register **within 60 days** from receipt of the application.
In (**Annex 3.1.a) - a** flow chart of the procedure to enter the system into the GMO register is detailed.
In (**Annex 3.1.b) - a** flow chart of the procedure to start with the contained use is detailed.
The contained use of GMOs classified under the *first level of hazard* may commence without notification to the Ministry if it takes place in a closed system for which a permit has been granted.
If the applicant applies for the use of GMOs that are classified under the *second, third and forth level* of hazard in a closed system for which the permit has been granted (for the same level of hazard that he is applying now) the **Ministry** shall make a decision on the application within **45 days** and after obtaining the opinion of the **Committee** for Contained Use of GMOs (comment to be made within **21 days**). The applicant for the use of GMOs that are classified under the *second level* of hazard may commence using the GMOs 45 days from submission of notification or before that time only on the basis of the application with the consent of the Ministry.
If the applicant applies for the use of GMOs that are classified under a *third and forth level* of hazard in a closed system for which he doesn't have a permit the **Ministry** shall make a decision on the application within **90 days** and after obtaining the opinion of **the Committee** for Contained Use of GMOs (comment to be made **within 45 days)**.
The Ministry will make public the applications for the use of GMOs that are classified under a *third and forth level* of hazard. The public can comment on them within **30 days**. This period of time shall not be included in the time limit for granting the decision.

An application ***for a deliberate release of GMOs into the environment*** is to be submitted to the MC - The Nature Protection Department. This Ministry, after obtaining opinions by the Committee for Release of GMOs into the Environment and the opinion of the Ministry of Agriculture, Forestry & Water Management (MAFWM) shall issue a decision.
In (**Annex 3.2) - a** flow chart of the procedure for deliberate release of the GMO into environment is detailed.
Prior to the submission of the application for a permit for a deliberate release of GMOs into the environment, the applicant shall through a competent legal person deliver *a risk assessment* for the deliberate release. On the basis of an analysis of the features of a GMO and its planned release into the environment, of the ecosystem into which the GMO would be released and the biodiversity that might be exposed to risk, the risk assessment shall evaluate possible negative impacts and their possible consequences, the level of hazard and control measures required, taking also into account the impact on human health.
Before undertaking a deliberate release of GMOs into the environment the applicant shall draw up an *emergency response plan* containing measures to be taken in the case of an uncontrolled spread of GMOs into the environment. The emergency response plan for elimination of risks of uncontrolled spread of GMOs into the environment (the emergency response plan) is a document describing actions and measures to be taken in the case of an

accident so as to mitigate possible negative effects on biodiversity, the environment and human health.
In addition to this case, the applicant shall submit an emergency response plan in the following cases:
a) Upon expiry of five years from the date of the last submission of a plan for elimination of risks.
b) Within thirty days after any change in conditions and status that might seriously affect the measures prescribed for the case of an accident.

The Ministry shall issue a decision for a deliberate release of GMOs into the environment with the consent of the MAFWM not later than **90 days** from receipt of the application, if all the conditions prescribed are met and the opinion of the Committee for Release of GMOs into the Environment has been obtained. When the Ministry considers it appropriate, it may require *additional information* from the applicant and shall issue a request in that regard. Any period of time during which the applicant is bound to furnish extra information requested *shall not be included in the time limit* for granting the decision.
The Ministry shall forward without delay, duplicates of applications to the Committee for Release of GMOs into the Environment. Should the **Committee** find it impossible to clearly evaluate the impacts of a deliberate release of GMOs on human health, the environment and biodiversity from the information contained in the application, it may require the Ministry to demand from the applicant *additional information* on the effects of the intended release of GMOs into the environment. The Committee for Release of GMOs into the *Environment shall deliver its opinion* within **45 days** from receipt of an application.
A decision for a deliberate release of GMOs into the environment may also be issued using a *simplified procedure,* if sufficient information and experience in a deliberate release of a specific GMO into specific ecosystems are available and if the GMO satisfies the conditions prescribed, especially in regards to the elimination of a possible hazard. **The Ministry** shall make a decision on the application with the consent of the MAFWM not later than **30 days** from receipt of the application and issue a permit, if all the conditions prescribed are met and the opinion of the Committee for Release of GMOs into the Environment has been obtained.
The Committee for Release of GMOs into the Environment shall deliver its opinion in writing to the Ministry within **15 days** from the submission of the application duplicate.
In stating the reasons for the issue of the decision the Ministry shall give its viewpoints on public opinion and comments submitted.
In the event of any modification or unplanned change in the deliberate release of GMOs into the environment which could have adverse impacts on biodiversity, the environment or human health, or if any new information has become available after the submission of the application or after the issue of a decision for a deliberate release of GMOs into the environment, the applicant shall immediately:
a) Take measures necessary to protect biodiversity, the environment and human health.
b) Inform the Ministry.
In the event referred to above the Minister may, with the consent of the MAFWM, require the applicant to modify the conditions of the deliberate release of GMOs into the environment or temporarily or permanently prohibit the deliberate release of GMOs into the environment. In such an event, the Ministry shall inform the public accordingly upon completion of the risk assessment.
The applicant shall submit to the Ministry **the report on the results of the deliberate release** of GMOs into the environment, no later than **60 days** from expiry of the time limit for which the permit, issued by the Ministry, for the deliberate release of GMOs into the environment. If the applicant intends to place on the market any material derived from the

GMO, which was the subject matter of the deliberate release into the environment, he/she shall include any such information in the report.
In the event of an unintentional release of a GMO into the environment the applicant shall take the emergency response measures and inform the Ministry. The Ministry shall, in cooperation with competent government authorities, adopt and implement a programme for the elimination of the consequences of an unintentional release of GMOs into the environment, which shall be enacted by the Government. In this programme, the persons to perform the activities, conditions and measures for mitigation or elimination of consequences and for the prevention of any further uncontrolled spread of the GMO, the method of covering the costs and all restrictions or prohibitions in connection with any further release of GMOs into the environment by trading or use, shall be determined on the basis of the risk assessment.
The Ministry shall inform the Government and the public of any event of an unintentional release of a GMO into the environment and of the preparation and implementation of the programme.
In the event of an unplanned spread of a GMO into the environment which could have considerable negative effects on the biodiversity, the environment and human health the Ministry shall inform any endangered or potentially endangered states and, when necessary, corresponding International organizations, and make available to them any information necessary for determination of appropriate measures.
It is obvious that official attitude toward a deliberate release of GMOs into the environment is based on a strong precautionary level, taking in account the impact on the ecosystem into which the GMO would be released, on the biodiversity that might be exposed, on human health and the possible consequences of such release.

A decision for the ***placing on the market*** of GMOs or products containing GMOs shall be granted by the competent government authority after examining its compliance with the conditions prescribed, after obtaining the opinions of the Committee for Release of GMOs into the Environment and/or the competent Committee for Novel Food and Feed Containing GMOs and after completion of a public hearing within **105 days** from receipt of the application. (Article 129)
In (**Annex 3.3) - a** flow chart of the procedure for placing on the market of GMOs & products containing GMOs is detailed.

In the event that the placing on the market of a GMO includes its deliberate release or a possibility of an unintentional release into the environment, the government body responsible for granting a permit shall submit a duplicate of the application to the *Committee for Release of GMOs into the Environment.* In the event of placing on the market of the food and feed containing GMOs, the competent authority shall also submit a duplicate of the application to the *Committee for Novel Food and Feed Containing GMOs.*
A permit for the placing on the market of GMOs or products containing GMOs that is used in:
a) *Cosmetics, pharmacy and human healthcare* - shall be granted by the minister of the MHSW.
b) *Agriculture, veterinary medicine, forestry and fisheries* - shall be granted by the minister of MAFWM with the consent of the MC and Ministry of Environmental Protection, Physical Planning & Construction (MEPPPC).
c) Placing on the market *of foodstuffs and products that are used in food processing industry or are a product thereof* - shall be granted by the minister of the MHSW, with the consent of the MAFWM.

d) Placing on the market of GMOs or products containing GMOs *that are not included under **a, b** and **c*** - shall be granted by the MC and MEPPPC.
Issues relating to the production, sanitary fitness, labelling and marking of food and feed and placing on the market of the food and feed containing GMOs or their ingredients shall also be governed by the provisions of this Act and special regulations.
The applicant will have to obtain a decision for each GMO or product containing a GMO that he intends to put on the market for the first time. Prior to the submission of application for a decision for placing on the market of GMOs or products containing GMOs the applicant shall carry out an *assessment of the risk* that could be caused by a deliberate placing on the market. On the basis of the analysis of the properties of a GMO and products containing a GMO and its use, the risk assessment shall include an evaluation of possible adverse effects and the consequences on biodiversity, the environment and human health, the level of hazard and necessary control measures.

For each intended use of a GMO or products containing GMOs differing from the one permitted, the applicant shall submit to the competent government authority a separate application for a permit for placing on the market.

The Committee for Release of GMOs into the Environment and the Committee for Novel Food and Animal Feed Containing GMOs shall deliver to the competent government authority a written opinion of the intended placing on the market of GMOs and products containing GMOs not later than **60 days** from receipt of the application duplicate. The opinion shall be delivered on the basis of a comprehensive analysis of the product and its impacts on biodiversity, environment and human health.

The applicant may place GMOs and products containing GMOs on the market in the manner and under the terms and conditions required by the decision. The permit for the placing on the market shall be granted for a period of time not exceeding **5 years**, but with the possibility of extending the permit. The EU has a maximum of 10 years. On this issue Croatia has taken a more cautious approach than the EU as result of public pressure, which mainly has a negative stand towards GMO food.
The decision, with the exception of information prescribed and indicated as confidential, and the assessment of risks to biodiversity, environment and human health, must be made available to the public in compliance with the present Act and other regulations.

An *applicant* intending *to apply for the extension of the decision* for the placing on the market of GMOs or products containing GMOs must submit the application to the competent government authority not later **than 9 months** prior to the expiry of the decision validity. The application shall include new information on risks posed by the product to biodiversity, environment and human health and a proposal for the amendment of conditions for the placing on the market contained in the previous permit, especially those relating to monitoring and the time limit of the permit validity, if necessary.
Having examined the compliance of the application with the conditions prescribed and having obtained the opinion of the Committee for Release of GMOs into the Environment and/or the competent Committee for Novel Food and Animal Feed Containing GMOs, **the competent government authority** will with the consent of any other competent government authority, extend the decision for a specific period of time **within 90 days** from receipt of the application.
The period of time for which the decision is extended must be **less than 10 years.**

If new information relating to the risks of GMOs or products containing GMOs to biodiversity, the environment and human health becomes available after the issue of the decision, the applicant shall immediately take the measures necessary to protect biodiversity, the environment and human health and inform correspondingly the Ministry and the competent government authority that issued the permit. If new information with regard to the risks of a GMO or a product containing the GMO or its use becomes available to the competent government body either before or after the procedure of issuing the decision, this information must be taken into account when making the decision on placing on the market of the GMO or a product containing the GMO. If new information becomes available to the competent government authority after the permit has become legally valid, this authority shall inform the Committee for Release of GMOs into the Environment and/or Placing on the Market and the Committee for Novel Food and Animal Feed Containing GMOs accordingly, and take a new decision to amend or annul the valid permit within **90 days.**

The person placing on the market a GMO or products containing a GMO shall provide evidence to the competent government authority that all measures necessary to avoid the adventitious or technically unavoidable contamination by an authorised GMO have been taken.
Persons placing on the market GMOs or products containing GMOs shall keep a database and ensure a procedure to allow the identification of the person by whom and the person to whom GMOs or products containing GMOs have been made available, except for end users, for a period of **5 years** from each placing on the market.

Import of GMOs or products containing GMOs is authorised if prior to the import a permit has been granted for a contained use of GMOs or products that are the subject matter of the import, for the deliberate release or placing on the market of GMOs or products containing GMOs in compliance with the provisions of this Act and special regulations.

In accordance with ***the PrecautionaryPrinciple*** the Government may in a by-law prescribe more stringent measures than those provided for the present Act, including the prohibition of the use of GMOs. The Government may, on the proposal of the competent government authority and on the basis of the opinion delivered by the Committee for Release of GMOs into the Environment, or the Committee for Novel Food and Animal Feed Containing GMOs, temporarily or permanently restrict or prohibit the import, if there is a lack of available scientific information and knowledge relating to the possible extent of impacts on biodiversity, the environment and human health, or if new or additional scientifically established information has become available about the risks of the product to biodiversity, the environment and human health.

B. *Under the Food Act (Official Gazette No. 117/2003)* the authorization for placing of GMO foods or GMO-containing foods that have been manufactured from a GMO, whatever the degree of processing involved, shall be granted by the MHSW. The MAFWM is competent to issue authorization for feeds. Any authorization of such products is subject to a risk assessment to be carried out by the Scientific Commission (Panel on Novel GMO-containing Foods and Feeds) at the Croatian Food Agency (CFA).
The labelling of foods derived from a GMO is mandatory. For GMO-containing animals, the law also introduces obligatory labelling. If the random inspection sampling discovers a product which has not been labelled correctly then such a product will be harmlessly removed

and destroyed. Such an incident had occurred in spring of 2004, when the GMO laboratory found GM Soya in a meat product (sausages), which resulted in the product being destroyed.

If someone is willing to place GM foods on the market for the first time in the Republic of Croatia, he/she has to obtain a decision according to the provisions of the Food Act. The Minister of Health in accordance with the Minister of AFWM, shall provide the conditions and the procedures for issuing the approval. Under this Act the conditions and the procedures for issuing such an approval are not specified. Data is collected in The Register Book on Issued Approvals for Placing Novel Food on the Market. The MHSW keeps the Register Book on the approvals issued. The Minister of Health provides the content, form and way of keeping the Register Book. Detailed procedures on how this Register Book will be accessible have not been provided under this Act.

The Precautionary Principle in this Act is defined as follows:
In special circumstances, where following an assessment of all available information, the possibility of harmful effects of a food on human health is identified, but scientific uncertainty persists the competent authorities may take provisional measures of risk management, much-needed for ensuring the highest possible level of human health protection to until further scientifically founded information necessary for the overall assessment of the risk is acquired. The measures taken must be adequate and not restrict trade more than is necessary to achieve high level of human health protection, taking in to account their technical and economical feasibility and the established state of the facts. The undertaken measures must be reconsidered within a reasonable period of time, depending on the nature of the identified risk for human health and life, and the type of scientific information needed to clarify the scientific uncertainty, and to conduct the overall risk assessment.

It is obvious that official attitude toward foods containing GMOs is based on a strong precautionary level. The adoption of such a strong precautionary principle was the result of public pressure from consumer groups that are mainly anti-GMO orientated.

The CFA is foreseen as a leading link to all the institutions in Croatia, which deal with food in the matter of food safety. The structure of the Agency is in **Annex 5.** The structure and organization of the scientific panels are comparable to EFSA (European Food Safety Authority) panels.

The Agency shall conduct risk analysis regarding food and feed safety and monitoring of risks. Within the framework of risk management, the Agency shall together with the other competent bodies, coordinate activities regarding the official control of food and feed safety.

Risk analysis planned to be the process consisting of three interconnected components; risk assessment, risk management and risk communication.
1. In order to achieve the main objective, which is a high level of protection of human life and health, the measures, which are implemented pursuant to food regulations, shall be based on risk assessment. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner, which should be conducted by the Agency through its scientific panels. Risk assessment shall mean a scientifically based process consisting of four stages: hazard identification, hazard characterization, exposure assessment and risk characterization.
2. Risk management shall mean a process by which different reactions of competent authorities, relating to risk are compared, in cooperation with interested parties, taking into

account risk assessment and other relevant factors, and, if necessary, the procedure of selecting appropriate prevention and control measures. In the risk management the Agency is involved as an advisory body. It was first planned to combine all the food & feed inspections from the responsible ministries with the Agency. However, this proposal was not accepted.
3. Risk communication shall mean an interactive exchange of information and opinions during the whole process of risk analysis, in regards to hazards and risks, risk-related factors and risk perceptions, amongst risk assessors (competent authorities, consumers, food and feed producers, academic community and other interested parties), including an explanation of findings during risk assessment and the basis for making decisions during risk management. Transparency of risk communication is seen as the main tool for gaining the publics attention and confidence.

4.2. Future plans and needs

The new proposed GMO Act has incorporated the following improvements regarding the old Nature Protection Act. It clearly states the following general provisions:
1. The use of GMOs shall be made in such a way that the hazard to biodiversity is either prevented or reduced to the minimum by taking into account the possible hazardous level to people and the environment.
2. In order to prevent a negative influence on the conservation and sustainable exploitation of biodiversity, and taking account of hazards to human health and the environment, appropriate measures shall be secured and implemented to ensure the safe use of GMOs.
3. The head of the competent authority shall prescribe by ordinance the content details and the method of submitting the application, as well as a method for protecting the confidentiality of the data provided in the application, as well as the procedure for issuing authorization.
The system to handle notification or requests for authorization for activities, such as release of GMOs into the environment, placing on the market or contained use, has yet to be set up and a similar situation resides in both of these Acts.

One way of making this system immediately more operable is to appoint a **central administrative body** that would in sense deal with every application. This central body would receive the application first and then forward it to the appropriate competent government authority. The main responsibility of this body would be to keep track on its whereabouts, inform on its progress to the applicant, the competent government authority, and the competent scientific committee and to the public. It is of special importance when the application for the placing on the market of a GMO includes its deliberate release or the possibility of an unintentional release into the environment, as in this case has to be submitted also to the Committee for Release of GMOs into the Environment. The necessity for such a body is obvious, with the existing strict timetables and no expedites governmental administration. This body could also keep a central GMO register and central database for the BCH. It could be situated either in the State Institute for Nature Protection (SINP) where the GMO department would be formed or within the MHSW.
If this central body were to be situated within the SINP, it would have the following advantages:
a) The benefit of the education received from the people (NPC and administrative personnel) that were working on the Project who are currently situated there.
b) The benefits of good National & International relations with professional contacts and stakeholders established during the Project.

c) The Project web site has been established as one of the focal points for GMO information in Croatia and has been a starting block for the Croatian BCH.
d) The equipment used during the Project could be used as the basis for the setting up of the GMO department.
The Ministry that will keep the central GMO Register is the MHSW who is appointed as such by the Food Act, the new proposed GMO Act and The Medicinal Products & Medical Devices Act. At the same time, this Ministry is the competent authority for placing GMO food on the market, cosmetics, pharmaceuticals and human healthcare. Under the newly proposed GMO Act the MHSF should ensure funds for the operation of the Committees and execution of technical-administrative activities Therefore, this central body could also be placed within this Ministry.

Competent Ministries
All competent ministries have to appoint and educate responsible person/s for the administrative procedures for handling requests for permits and approvals of different GMO use/premises. These appointed people and their contact details have to be clearly announced to all stakeholders.
The education of appointed administrative personnel can be achieved through International projects which are add-on projects of this Project for example "Project on Implementation of National Biosafety Framework" and "Building Capacity for Effective Participation in the Biosafety Clearing-House (BCH)" or projects from EU as CARDS and TWINNING projects.
Coordination of the MC - The Nature Protection Department; the MHSW; the MAFWM; the MEPPPC; the MSES, 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 present problem is the complex system of decision making, involving different steps, between competent authorities as well as the general public. Also, there are time limitations for every administrative step taken.
The following manuals and systems will be needed as soon as all regulations are in place:
a) Manual for administrative handling of request, that must contain a system to track dossiers and guard procedural steps.
b) A user-friendly manual for administrative handling of request should be provided for notifiers.
c) A clearly defined system for the protection of confidential information.
d) Forms used within administrative procedures for handling of requests.

Committees and Scientific Commissions
Under the Nature Protection Act the Government shall set up a Commission for Genetically Modified Organisms (GMOs), a Scientific Committee for Contained Use of GMOs, and a Scientific Committee for the Release of GMOs into the Environment and a Committee for Novel Food and Animal Feed Containing GMOs. In the Food Act, it is stated, that The Croatian Food Agency shall appoint the Scientific Committee and Scientific Panels, as expert bodies for determining scientific opinions within the scope of the Agency.
Therefore, it is not clearly defined if the Committee for Novel Food and Animal Feed containing GMOs under the Nature Protection Act is one of the scientific bodies that have to be set up by the Food Agency under the Food Act.
The following differences regarding these technical-scientific law enforcement bodies in the new proposed GMO Act are:
1. There are now only two Committees for the Contained Use of GMOs and on GMO Introduction into Environment.

2. Presently, the Committee for the Contained Use of GMOs has 11 members (only 7 previously). The new added professions the members of this Committee should have are agriculture, forestry, veterinary medicine, nature conservancy, and environmental protection. No longer is there any mention of the Committee for Novel Food and Animal Feed Containing GMOs. In place of it, the Food Agency is directly mentioned, so possible overlapping of responsibilities and duties between the Committee for Novel Food and Animal Feed Containing GMOs and the Agency is avoided. There is a need to clearly define and nominate the Committee and/or Committees that will give opinions to the competent authorities for products marketed as:
a) Reproduction material in agriculture, forestry, and veterinary medicine.
b) Veterinary drugs & plant protection products.
c) Cosmetics, pharmaceuticals and human health care
has still to be done.
Manuals for risk assessment would be needed as tools to be used by notifiers and scientific committees.

Contained Use
There are a few improvements regarding the contained use under the new proposed GMO Act and there are Additional requirements, on data that had to be provided by the notifier for entering the system in the GMO Register as: all data about the applicant, the closed system and the level of hazard entailed by the activities designed to take place in the closed system, namely, user name, inclusive of the names of persons in charge of inspection and security; data on the training and other qualifications of the persons responsible for surveillance and security; details of all professional bodies; address and general description of the facility and surrounding space; description of the nature of job that will be carried out; level of hazard posed by the contained use of the GMO.
Before starting with the contained use the applicant has to provide the competent authority with a plan of the Measures in Case of an Accident, a summary of the risk estimate for the intended use of the GMO that shall be the base to determine the measures for managing the waste and wastewaters from the closed system.
Also in this new proposed Act, for new use of a GMO that belongs to the first level of hazard, in the system that has permission for such use, the user is obliged to report this use to the competent authority in writing.
Care for laboratory and biosafety in them was, and still is, largely left to the responsibility of involved researchers and group leaders. Good laboratory practices are mostly left to the knowledge and consciousness of senior scientists and are passed to co-workers in practical examples, largely in an unwritten fashion. Systematic education about risks, hazards, and methods of storage and containment of introduced and/or generated recombinant organisms is not carried out (with the exception of pharmaceutical company, Pliva).
To make the whole system of 'Contained use' operable under the Nature Protection Act and the new proposed GMO Act, the following pre requirements have to be fulfilled:
1. It has to be clearly stated that the applicant can at the same time make an application for the system and for the use of the GMO. The use of the GMO will not commence until the permit for the system has been granted.
2. The current state and conditions of Croatian laboratory sites are not appropriate. It will be necessary to upgrade the infrastructure by investing in renovation work, as well as in new equipment.
3. It is imperative that in every laboratory the principles of good laboratory practice are applied.

4. It will be necessary to set biosafety standards within every institution. The institutions should employ and educate at least one individual for the supervision of biosafety – the Biosafety Officer. The appointed Officer is responsible to inspectors for implementation of safe biosafety procedures within their individual institutions. The Biosafety Officer must have previous practical working experience in a laboratory and have additional education in biosafety. Part of his/her duties would also be to organise and /or to educate all employees on biosafety issues.
5. Personnel working with GMOs should keep records about each created plasmid construct and the institution should keep records of all research with GMOs.
6. It will be necessary to develop a system for labelling of laboratories according to the class of possible risk. These labels should be clearly visible at the entrance of laboratories.
7. The notifier, usually the group leader, working with GMOs in contained use, should have at least three years experience working with recombinant DNA techniques. Additional education in the form of courses or scientific specialization and practical experience with microorganisms, plants, or animals is highly desirable. The obligation of each group leader would be to ensure the regulations within his/her group.
8. Courses on working with GMOs in contained use should be organized and such seminars should be conducted once a year. Educational material should be developed. A simplified written set of unified regulations should be supplied to all group leaders working with GMOs.

Deliberate release of GMOs into the environment
The risk assessment and monitoring should be conducted at the highest possible level for safety for the environment and human health. The precautionary principle should be observed and regional ecological considerations and issues of nature protection taken into account in the appropriate manner. To be able to achieve these goals there is great need for many more improvements to be put in place. It should be advisable before including previously mentioned improvements in the bay laws of the new proposed GMO Act, to clearly state that a permit is required for each GMO or product containing GMO that is intended to be release into environment for the first time.

The *Plan of Relief Measures against an Unintentional Release of GMOs into the Environment* (the "Plan of Measures") has more definition within the new proposed GMO Act. It states that this Plan of Measures is a document describing the actions and measures to be taken in the case of an accident with which to relieve the negative impact on biodiversity, the environment and human health. It is subject by approval of the competent authority by issuing the authorization. The head of the competent authority with the consent of the minister of the environment shall lay down the particulars of a Plan of Measures and the method of its implementation.

The content and scope of an assessment of the risk of intentional introduction of the GMO into environment, risk estimate methodology and conditions to be fulfilled by the legal person in order to make the risk estimate under this Act shall be prescribed by an ordinance by minister of MC with consent of MAFWM and MHSW.

Some new very important points, for an application for the authorization of intentional introduction of a GMO into environment, are included in the new proposed GMO Act. They are as follows:
1. A plan for the monitoring of GMO impact on the environment, biodiversity and human health.
2. Data to be gathered on waste management, i.e., the type of waste produced, anticipated amount of waste, description of the envisaged processing method.

3. Envisaged techniques for the removal or deactivation of the GMO at the end of all experiments.
These new improvements should be precisely defined in by-laws or in guidance's and instructions and education should be provided for the personnel who would implement them. This is very important, as a release into environment is a very sensitive and complex subject.

The Placing of products on the Market
This procedure has been altered in the new proposed GMO Act. The alterations mainly consist of differences in the time frames of the whole process. The whole system and new time frames are easier to understand from the flow chart in **Annex 4.3.a.** As mentioned before, the precise conditions and the procedures for issuing the approval and who will be issuing it, for different type of products has also to be defined. There is also a need to define the time period for public hearings as well as rechecking all other time limits in this procedure.

The Precautionary Principle
In the new proposed GMO Act (Article 13) an almost identical definition of the Precautionary Principle as in the Nature Protection Act (Article 137), can be found. The Precautionary Principle needs two points to be clarified: the potential threat aspect and lack of knowledge about this particular threat aspect, in order to be in line with the Cartagena Protocol. Therefore, it would be desirable to harmonize these definitions with definitions in the Protocol.

5. MONITORING AND ENFORCEMENT

5.1. Current situation

Mechanisms for harmonization of risk assessment/risk management, for data validation, are planned but are not yet operational.
From 1997 until 1999, the Scientific Committee appointed by the Ministry of Agriculture & Forestry approved several field trials of GMO maize on selected locations in Croatia. All trials were for research purposes only. Since 1999, not a single permit has been issued for field trials or commercial growth of GMOs.

Under existing National legislation, the following government bodies regulate the controlling, monitoring, and issuing of permits for the following:

1. *For human medical products* – the *Agency for Medicinal Products and Medical Devices* (AMPMD) is controlling production & issuing permits for placing on the market of medicinal products and homeopathic products, permits for research, etc. under the Medicinal Products and Medical Devices Act. The Ministry of Health & Social Welfare (MHSW) is monitoring the legal activities of the Agency. Inspections that are conducted through this Agency are the Pharmaceutical inspectors.

2. F*or food that is mainly of animal origin, for feed and for veterinary medicine* - the Croatian Veterinary Institute (CVI), perform the tests. The main responsible body for the issuing of permits for feed is the Croatian Food Agency (CFA). The ministry responsible is the Ministry of Agriculture, Forestry & Water Management (MAFWM). Border inspection is conducted by border veterinary inspection and inside Croatia by veterinary inspection and the State Inspectorate.

3. *For food of other origin* - The Croatian National Institute of Public Health (CNIPH) perform the tests. The CFA is the main responsible body for the issuing of permits. The ministries responsible are the MHSW and MAFWM. Border inspection is conducted by border sanitary inspection and inside Croatia by sanitary inspection and the State Inspectorate.

4. *For agronomy seeds and seedlings* - the Croatian Institute for Plant protection. This Institute performs phytosanitary testing and checks declarations of seeds and seedlings under the Seeds, Plant Material and Registration of Varieties of Agricultural Plants Act. The Institute for Seed and Seedlings perform tests (VCU and DUS testing) on new varieties of agricultural plant material and seeds from the applicant, who would in turn like them to be included in the "Croatian Agricultural Varieties of plant material and seeds" list. They also perform tests to check whether the seed for seed production belong to a particular declared variety, as well as performing random post control. The ministry responsible is the MAFWM. The border inspection is conducted by phytosanitary inspection and within Croatia by agronomy inspection and the State Inspectorate.

5. *For plant protection products* - the Croatian Institute for Plant protection is controlling and issuing permits. The ministry responsible is the MAFWM. Phytosanitary inspections perform inspections at the border crossings and the State Inspectorate within Croatia.

6. *For forestry seeds & seedlings and horticulture*-The Forestry Research Institute perform the tests. The ministry responsible is the MAFWM. Phytosanitary inspections perform inspections at the border crossings, the State Inspectorate within Croatia and by forestry inspection within forestry. The jurisdiction over horticulture is not clearly defined.

7. *Research conducted in scientific institutions and universities* is regulated by The Decision Promulgating the Science and Higher Education Act. The Committee for Ethics in Science & Higher Education is the body, which approves the research activities. The Ministry of Science, Education & Sports (MSES) is responsible for the implementation of this Act.

8. *For dangerous substances in water* - The CNIPH perform the tests. The Regulation on Dangerous Substances in Water Act regulates these substances. The ministry responsible is the MAFWM.

9. *For transport of dangerous substances* - The packaging and transportation of the products that contain or are made from GMOs is prepared in accordance with the Transport of Dangerous Substances Act. The Ministry of Sea, Tourism, Transport & Development (MSTTD) is responsible of its implementation. Different inspections from different government institutions are responsible for enforcement of this Act.

10. *For Environment Protection* - The Ministry of Environmental Protection, Physical Planning & Construction (MEPPC) is responsible for implementation and enforcement of environment protection, and rely upon their environmental inspection. Amongst other duties this Ministry collects, integrates and processes environmental data on inland water, sea, air, soil, biodiversity and waist through the Croatian Environment Agency (CEA). For the European Environment Agency (EEA) and it's European Environment Information and Observation Network (EIONET), this Agency is the NEA for Croatia. The Croatian Environment Agency is responsible for monitoring, collecting and integrating data on:
a) Endangered species and habitats in Croatia.
b) The state and trends in water quantity, quality and impact of Croatian inland waters.
c) The state of the sea, coastal area, mariculture and fisheries on Croatian territory.
d) Air emissions. The collected and processed data is used by the Agency to prepare reports and guidelines for the air quality and environmental protection strategy.
e) Soil. The CEA has the task to integrate all data needed for the evaluation and monitoring of the state of soil. Such a database is needed as a guideline for the Croatian soil protection policy.
f) Collection of data and information on waste to maintain the waste information system and prepares waste monitoring indicators.

11. *For Nature Protection* - The Ministry of Culture (MC) - the Nature Protection Department is responsible for implementation of the Nature Protection Act and enforcement relies upon nature protection inspection. The State Institute for Nature Protection (SINP) that has been established under this Act shall perform expert nature protection work relating to:
a) Collection and processing of data, collected in connection with nature protection.
b) Development of appropriate databases on plant, fungus and animal species, types of habitat, ecosystems and landscapes.
c) Monitoring of the level of conservation of biological and landscape diversity and proposing measures for the protection thereof.
d) Preparation of expert background documents for the protection and conservation of parts of nature or those of natural value.

e) Development of expert background documents for the purpose of applying nature protection conditions, the management of protected areas and the use of natural resources.
f) Conducting statistical analyses, integration of results and preparation of reports on the state of the natural environment and nature protection.
g) Expertise in work connected with the assessment of the acceptability of an activity to nature.
h) Competent authorities and relevant institutions shall submit to the Institute all information on the state of nature collected in compliance with this Act.

Most of these institutions and inspections rely on declarations upon the products. The majority of samples collected for random testing on GMOs have been collected by sanitary and veterinary inspection.
Not one of the inspectors from all of these competent government bodies have been appointed to deal 'exclusively' with GMOs or have been educated for it. The very important point that has to be stressed is that the cost of any random tests has to be paid from the government budget if the results of the tests are negative. This limits the number of sample testing because of the limited budgets of the government institutions involved.

A. *Under the Nature Protection Act (Official Gazette No.162/2003)*
Every applicant applying for a permit for contained use of a GMO should in the application include a risk assessment for the planned use of the GMO and an emergency response plan. In application for a permit for the release of a GMO into the environment and/or for placing a GMO onto the market the applicant should also include risk assessment and an emergency response plan. They should also include the plan of monitoring the impact of the GMOs and its use on biodiversity, the environment and human health, including the period of time in which the monitoring plan will be implemented. The applicant should also inform the competent authority of any new information on risks posed by the specific GMO to biodiversity, environment and human health. The competent authority will then assess the application based on the new information received.

Administrative supervision over the enforcement of this Act, in the section relating to GMOs, shall be exercised by the MC the MHSW, the MAFWM & the MSES, each within their respective scope of activities.

The inspection control of the enforcement of this Act shall be carried out by nature protection inspectors, sanitary inspectors, veterinary inspectors, agricultural inspectors, plant protection inspectors, water management inspectors, forestry and hunting inspectors and inspectors of the State Inspectorate, each within the scope of their competencies and in compliance with this Act and special regulations.

Within Croatia, only one laboratory for the detection of GMOs is accredited. The laboratory was set up in the CNIPH. This laboratory provides services for inspections, companies and private households in Croatia. It provides qualitative and quantitative detection analyses of GMOs obtained from different samples: seeds, grains, plants, raw material, food and feed.
The laboratory provides the following analyses:
1. Detection of specific DNA in products containing maize or soybeans based on PCR screening for CaMV 35S promoter and NOS terminator.
2. Detection of specific DNA in foods of plant origin by Real-Time PCR screening for CaMV 35S promoter and NOS terminator.
3. Detection of specific DNA of Roundup Ready soy in soy products by PCR.

4. Detection of specific DNA of five maize modifications (Bt-11, Bt-176, Mon 810, Star Link, Liberty Link) in maize products by PCR.
5. Detection of specific DNA of Roundup Ready soy in soy products by Real-Time PCR.
6. ELISA specific analyses of Roundup Ready soy proteins in soy products.

During last year, 1270 samples of food and feed were tested on their GMO content. From this amount of samples, 60-70 % came from the Inspection institutions, and 30-40 % came from the companies themselves. All results are reported monthly to the MHSW.

B. *Under Food Act (Official Gazette No. 117/2003)*
Within their respective scope of activities, the MAFWM and the MHSW conduct administrative supervision over the enforcement of this Act.
The CFA in cooperation with the CNIPH and the CVI and other authorised legal persons will perform monitoring of food and feed safety.
The type of food and inspectors in charge for its control are listed in the Annex of this Act.
Dividing food control into three groups of inspection; has caused a division of responsibility. Activities sometimes overlap in the present system and become unclear as to who is ultimately responsible for which service.

5.2. Future plans and needs

The "Nature Protection Act" is designed as the umbrella law on GMOs in Croatia. Its first requirement is to make the whole system of monitoring and enforcement clear and operable under this Act and harmonise it with other Acts that partly regulate the GMO issue and where listed under paragraph "Regulatory regime".
A gap is apparent, in control of plants in the field concerning the matter of food safety. Under the Food Act the term “food” shall not include plants before harvesting, picking, or collecting of fruits. Therefore, the term “from the field to the table” is hard to realise.
This grey area has been covered under the new proposed GMO Act that is now in Parliamentary procedure. In Article 3 of this Act, it states, for product marketing as reproduction material in agriculture, forestry, and veterinary medicine and product marketing as veterinary drugs and plant protection products that the MAFWM shall supervise and give administrative supervision.

Monitoring
In the Nature Protection Act, plans for monitoring are part of notification. The guidelines on different approaches for monitoring should be provided for scientific committees, the notifiers and institutions appointed to perform monitoring. Annex VII of EU Directive 2001/18/EC and the Guidance Notes on monitoring could be used as references for such guidelines.
Monitoring should be stressed more in legislation, as one of the main tools to assess the impact of GMOs on the environment, biodiversity and human health.
The responsibility of the SINP is to "generally" collect and process data in connection with nature protection. The CNIPH is collecting data on human health. For contained use, the MSES is responsible for the implementation of this Act. There is a need for these institutions to be specifically empowered to monitor GMOs, each within their own area of impact. Therefore, it would be advisable that the SINP is appointed as a main body that will be responsible to monitor the impact of the GMOs and their use on biodiversity and the environment, in collaboration with other institutions. The CNIPH shall monitor the impact of the GMOs and their use on and human health. It is clearly stated in the Food Act that the

monitoring of food and feed safety would be done by the CFA in cooperation with the CNIPH and the CVI.
Each contained system should appoint a biosafety officer. This officer should be responsible for monitoring and applying biosafety standards in his/her system. The MSES should nominate the body and/or inspectors that would be responsible for the monitoring of all contained systems via the elected biosafety officers.

Inspection
There are several competent bodies appointed to perform the inspection, based on their competences. Therefore, stricter separation and clearly defined competences will have to be formalized for GMO inspection.
So far, no specific inspectors with the correct training in GMO field have been appointed in Croatia. All current inspectors lack a scientific background in this area and during different workshops they had repeatedly expressed their concern about their own lack of training. It appears necessary to provide them with scientific support through enabling them to use external experts or to involve new people who will be specifically trained in GMO inspection procedures. GMO inspectors should have, at least, the basic knowledge in one of the following fields: microbiology, cell biology, molecular biology, virology, biotechnology, hygiene, worker's safety and other biological processes. Additional education in the form of courses or scientific specialization and practical experience with microorganisms, plants, or animals is highly desirable. Courses on working with GMOs should be organized throughout Croatia and Educational material should be developed and unified.
Regarding all above:
a) Clarification of inspectors responsible to control deliberate release of GMOs is essential. Under provisions of the Nature Protection Act there are nine different inspectors empowered, each within the scope of their competencies. The same situation exists in the newly proposed GMO Act. Guidelines should be printed for such inspectors with a clearly stated area of their authority as well as how to perform inspection.
b) Continuous training should be provided to GMO inspectors.
c) Manuals and guidelines for all types of GMO inspection should be provided.
d) Ensure responsibility of all inspections regarding the GMO subject.
e) Enforce the responsibility of inspections, according to the basic rules of monitoring, in order to, check the reliability of gained data and satisfy requirements for correct declarations and test results.
f) The inspection should include and cover all raw food material, components, half-products and final products that contain GMO or are made of GMO – sampling and analyses.
g) Checking of content, declaration and written documents.
h) Enforce control of imported GMO.
i) Organize educational courses for the appropriate sampling, which is a crucial step in GMO detection and control.
If the results of any test prove negative under existing legislation, the Croatian government bare the cost, presently limiting the number of samples tested. Therefore, it would be sensible to set up a financial fund from which the cost of negative test results could be bared. The proposed fund could be financed from the every application fee. It would be beneficial that every applicant shall advance a set amount (undetermined) as a ‘Refundable Deposit’ on expiry of their permit on the condition of safe use and handling of the GMO involved during the time period of the permit. This proposed ‘Refundable Deposit’ will become a safeguard for any potential misuse or accidents concerning the GMO used and will hopefully encourage safer practices during the time period of the permit by the applicant. In the case of an accident and/ or an unauthorized release of a GMO into the environment and/or an unintentional

release into the environment, this proposed Deposit will be used to rectify any damage or harm endured, ensuring a quick response system concerning funds available for such an occurrence.

At the moment in Croatia various Ministries are applying for different 'CARDS' programs which will hopefully improve the capabilities of the plant protection, the veterinary health system and following inspections: phytosanitary, sanitary and border veterinary inspection. Hopefully, education of inspectors within the GMO area will be included in these 'CARDS' projects. Similar education for inspectors exists under EU-PHARE through the Twinning projects. Keeping in mind that all areas of the control have to be included and special attention should be given to the education for the control of deliberate release of GMOs, as this is the most complicated area.

Traceability and Transparency
There is a strong need for clear rules, especially from the side of the food industry on traceability and transparency of all processes (industrial and administrative), since this would restrain costs on their GMO analyses. The food industry can label their products appropriately only if all processes in the production chain are done in accordance with good practice rules. Therefore there is pressing need to begin implementation of good production practices, the HACCP system and good laboratory practice, in order to put into practice the traceability system (from the field to the table).

The Croatian Food Agency
The initial structure was made just to start up the Agency. For a better definition of the concept of the Agency, the Agency has been involved with the SIDA/SWEDAC/Swedish National Food Administration project. The existing module of the Agency has to be improved especially in regards to risk management. The Agency now has become more of an advisory and scientific body instead of actively participating in risk management. The consequence of this approach is the difficulty of putting risk management into practice.

Laboratories for GMO Detection
The following recommendations can be provided:
a) Creation of a network of accredited Croatian laboratories involved in the European Network of GMO laboratories (ENGL system).
b) Organized regular roundtable discussions with experts involved in risk assessment.
c) Organized courses for specialized personnel in sampling and assessment of GMOs in order to improve the reliability of the controlling and monitoring processes.
d) The GMO laboratory still needs extra support for future development because methodology for GMOs detection is at a dynamic stage. The reasons for further development are: lack of standards for all products on the EU market, new products expected, also the possibilities of unintentional/illegal entrance of products.
e) Beside accredited laboratories there is need to establish reference laboratories.
f) In a process of accrediting of reference laboratories an independent institution should give confirmation that the laboratory conditions fulfil requirements by defined standards.

Protection of Environment and Nature
Presently, the jurisdiction over enforcement and monitoring of the Environment and Nature protection is divided by two Ministries (MEPPPC and the MC-The Nature Protection Department). There are therefore two inspections, one for nature protection and one for environment protection. The CEA is collecting, integrating and processing environmental data

on inland water, sea, air, soil, biodiversity and waist. The SINP performs expert nature protection work and on a ground level and is involved in monitoring of biodiversity and nature.
The division of these interconnected areas is the cause of many operational problems; therefore, there is a need to combine them or to establish better cooperation between them. The written guidelines that would clearly define duties and responsibilities of employees from each Ministry would be very helpful. This is especially needed for nature protection inspectors and environmental inspectors.

6. MECHANISMS FOR PUBLIC PARTICIPATION AND INFORMATION

Until 2003, Croatia suffered from a long legal gap during which a de facto moratorium on the import or production of GMOs was in place. During this period certain public voices, from green NGOs, the general public and some scientist questioned GM food safety and even the need for basic research projects involving GMOs. This can be partly explained because terms such as “Food safety and Healthy Food” are used for conventional food, therefore the public had associated GMO food mainly with health hazards or even with contamination. Polemics in the media had a very strong impact on public opinion that has resulted in an irrational fear with the subject in more than 80% of the population. As a result of this, from the 21 counties in the Republic of Croatia, eight have declared or are in the process of declaration themselves as "GMO free zones".

6.1. Current situation

Croatian public systems for public awareness, education and participation
Education about the basic principles of genetic engineering is already organized in primary schools. According to the newly compiled Catalogue of Knowledge, GMO issues are covered in the eighth grade. Special attention is given to the potential risks to the biodiversity of Croatia. However, potential benefits of new foods as well as risks in other areas are not particularly well covered and education about them is left to the will of teachers. On the other side, several aspects of genetic engineering and genetics in general are essential parts of the teaching program at the second level of education (gymnasium).
During all organized workshops it became obvious that there is need for scientifically based education in this field. The brochure that was published as part of the Project and distributed through daily papers had a very good acceptance by the public.
The public in general, are not well informed on how they can participate in the decision making process. Opening of Internet sites by different government bodies’ also had a very positive effect. Croatian government institutions, research institutions, big industry and NGO's have their own individual web sites, on which much information can be found. All main web addresses can also be found on the Projects web site.

A. *Under the Nature Protection Act*, information on the contained use of GMOs, the deliberate release of GMOs in the environment, placing of GMOs and products containing GMOs on the market and information on the actions within the scope of activities of the Ministry for Culture and other government authorities responsible for the use of GMOs under this Act, shall be public in compliance with this Act and other regulations. The Commission for GMOs shall inform the public about the state and developments in the field of genetic technology application and the use of GMOs and about its viewpoints and opinions. The task of this Commission is also to advise the Government and competent government bodies in matters related to the use of GMOs and genetic technology.

For the contained use of GMOs:
1. The applicant shall submit data about their emergency response plan to the Ministry of Culture (MC), the Ministry of Health & Social Welfare (MHSW), the Ministry of Agriculture, Forestry & Water Management (MAFWM), the Ministry of Science, Education & Sports

(MSES), the Ministry of Interior and competent authorities of the regional and local self-government units. This information shall be accessible to the public.
2. In the procedure of granting a permit for a contained use of GMOs classified under the third and fourth levels of hazard, the MC shall make the applications contents, the risk assessment and the opinion delivered by the Committee for Contained Use of GMOs available to the public.
3. A public announcement of the duration and time period for preparation of documents (under No 2) publicly available, including the way of delivering opinions and making comments, shall be made by mass media.
4. The time limit granted by the Ministry for the preparation of the documents (under No 2) availability and for the delivery of opinions and making comments thereon shall not exceed **30 days**.
5. In its statement of reasons for the decision on the permit the Ministry shall include its view on its comments and on public opinion.

For deliberate release of GMOs into the environment:
1. Article 120 states:
a) In the procedure of issuing a permit the contents of the notification (the technical dossier and risk assessment) and the opinion of the Committee for Release of GMOs into the Environment must be made available to the public.
b) Public invitation, specifying the place and time of providing access to the documents as referred to under a), including the method of delivering the opinion and giving comments to the same shall be announced by the mass media.
c) The time period in which access to the documents, the delivery of opinion and commenting, will be provided by the Ministry and shall not exceed **30 days.**
d) In stating the reasons for the issue of the permit the Ministry shall give its viewpoints about public opinion and comments submitted.
e) In the event of any modification and unplanned changes in the deliberate release into the environment, the Ministry shall inform the public accordingly upon completion of the risk assessment.
2. Article 123 states that in the event of an unplanned spread of a GMO into the environment the Ministry shall inform the Government and the public of the event and of the preparation and implementation of the emergency response programme.

For placing on the market GMOs:
1. Article 129 states: a permit for the placing on the market of GMOs or products containing GMOs shall be granted by the competent government authority after fulfilling other requirements and also after the completion of the public hearing within **105 days** upon receipt of the application.
2. Article 130 states: the permit for the placing on the market of GMOs and products containing GMOs, with the exception of information prescribed and indicated as confidential, and the assessment of risks to biodiversity, environment and human health must be made available to the public in compliance with this Act and other regulations.

The Register of GMOs
In Article 139 states:
a) A register of GMOs, shall be kept by the Ministry and other competent government authorities, each within the scope of its competencies.

b) In the register of GMO closed systems, certificates and authorization granted for a contained use of GMOs, the deliberate release of GMOs into the environment and placing on the market of GMOs or products containing GMOs, shall be recorded.
c) Anybody shall have the right to be given access to information contained in the register of GMOs and to require and obtain copies of GMO register entries against payment of a fee that shall not exceed actual costs of issuing copies.
d) Information treated as confidential in compliance with this Act or privileging from special protection on the basis of a special regulation shall not be entered into the register of GMOs.
The Minister in an ordinance shall prescribe the form and method of keeping a register of GMOs and a method of fixing a fee for the issue of copies. Competent ministers shall also prescribe the form and method of keeping a register of GMOs, each within his scope of competences.

On a more general basis this Act in Article 236 states that the Ministry, the SINP, nature protection institutions of the counties and the City of Zagreb, offices of government bodies, competent bodies of local and district (regional) self-government units and public institutions managing protected natural values shall make public the information on the state and protection of nature, unless classified confidential by a special act or a document of a competent authority. The competent bodies and legal entities mentioned previously shall keep records of data relating to the state and protection of nature, and in case of nature degradation they shall immediately inform the public thereof and give instructions for the procedure aimed at nature protection and conservation. In case of any immediate threat to nature and human health the public shall be informed about necessary measures and actions to be taken with the aim to prevent or mitigate the damage that might arise from such a threat.
Article 239 states that public participation shall be ensured in the course of preparing regulations or documents on designation of protected natural values, physical planning documents, protected area management plans and plans for utilization of natural resources, including generally applicable and legally binding regulations and documents in the field of nature protection. In the course of procedures as referred to previously the public shall be informed by a public notification or individually about the act or activity that might affect the state of nature. Professional and other associations have the right to participate in nature protection. These general rules of informing public were based on the Aarhus Convention but are unfortunately no longer included in the new proposed GMO Act.

B. *Under the Food Act* the Croatian Food Agency (CFA) has established its own web site as a central information system for the exchange of information on food safety. This web site (www.hah.hr) offers scientific opinion regarding human nutrition, feed and also issues regarding animal health and welfare and plant health.
The Agency is also planning to establish a rapid alert system that will accept and forward all information regarding food hazards. The Croatian National Institute for Public Health (CNIPH) was for a few months during 2004, unofficially connected to the RASFF by following alerts and information and by forwarding this to responsible institutions and laboratories. This was the period of testing on how the other institutions would react to alerts and information received. The main obstacle in the correct functioning of the system was no prescribed obligations of other institutions on reaction or forwarding information to others in the chain. Therefore, the CFA has decided to form an information system within the country as a first step. This would be the basis for an efficient connection to the DG SANCO office in Bruxelles.
The CFA, directly or through authorized representatives of consumers or other interested groups, during preparation, evaluation and revision of the risk management measures, must

carry out open and transparent public consultation, except when the urgency does not permit it. If there is a justified doubt that food or feed could represent a risk for human or animal health, depending upon the nature, seriousness and extent of that risk, the Agency shall take measures to inform the public about the nature of the health risk. Risk communication shall be conducted by the Agency in order to provide timely, reliable, objective and understandable information about the food and feed related hazards and risks. If the Advising committee, which also involves consumer's representatives, has an opinion that a particular kind of food or feed can represent certain risks to health, it can advise the director of the Agency to request a scientific opinion. This opinion should be published on the Agency web site. Furthermore, the plan is to open a "consumer's web forum".

6.2. Future plans and needs

Croatia has signed the Aarhus Convention but it hasn't as yet ratified it. Therefore, it would be desirable to begin as soon as possible with ratification and implementation of this Convention, which is one of preconditions for better public participation and information in Croatia.

Croatian scientists have participated partially in the development of the legal framework regulating GMO issues. There is intense need for more involvement from scientists and professionals in drafting legislations, in general within Croatia. It is essential to educate the general public in the method of active involvement in the decision-making processes and their rights and obligations as citizens.

There is also requirement for more educational public discussions with the goal of explaining to the public in simple terms, the science and to inform them where they can find more information if needed.

Considering the presence of the GMO issue in primary and secondary schools, the lack of systematic scientifically based education of teachers is evident. The experience obtained in the workshop for teachers organized under the Project, led to the conclusion that there is a necessity for similar workshops on an annual basis in order to present essential information about the state of the art in the field.

Within the new proposed GMO Act, the main improvement is to secure the central GMO Register. The MHSW keeps a Central GMO Registry and the other competent government authorities keep special Registries within their scopes of activity. The form and method of running the GMO Registry, and the method of calculating the cost of reprints shall be prescribed by the head of the state administrative body for nature conservation through an ordinance with the consent of heads of other competent authorities. The detailed procedures on accessibility to the Register Book have yet to be provided. This registry will/would be the basis for the Croatian BCH.

Public information and participation in the newly proposed GMO Act is the same as in the Nature Protection Act. Therefore it would be sensible to:
a) Write the guidelines that would precisely prescribe how and when the Commission for GMOs would inform the public and when it would be the Government, as it is unusual for the Commission to directly inform the public.

b) Write in the guidelines the precise procedure on informing public for deliberate release of GMOs into the environment and for the placing of a GMO on the market, as now it is not clarified in which way the public will be informed.

In November 2004, the web site of the Project became operational. The Project web page has been designed with the purpose of offering Project information to the public on a worldwide scale as well as all other topical information on the GMO problem area. Through links, the web page is connected to web pages on other domestic and foreign projects and to institutions concerned with similar problem areas. During this period, various stakeholders in Croatia and International have acknowledged the web site. It would be advisable to maintain this web site as independent. By doing so, all necessary information required, especially taking into account that this web site was designed as base for the Croatian BCH, would be much more accessible. The address of the web site is: www.gmo.hr

Although various systems for the exchange of information and alert systems are prescribed, by existing legislation, they should firstly be coordinated between them to ensure that no overlapping is involved. Then the responsible institutions should nominate specific persons for such duties as providing and exchanging information within known timeframes. The chosen candidates and their contact details must be known and forwarded to all stakeholders.

This process of education, organizing workshops, publishing and conducting media discussions must continue. More informative web sites and the availability of government institutions to the public will improve public participation and understanding of information.

7. UNEP-GEF PROJECT "DEVELOPMENT OF THE NATIONAL BIOSAFETY FRAMEWORK FOR CROATIA"

The draft of National Biosafety Framework for Croatia was prepared during the UNEP-GEF project "Development of the National Biosafety Framework (NBF)", which is part of the UNEP-GEF Global Project aimed to assist countries in implementing the Cartagena Protocol on Biosafety through the development and implementation of their NBFs.

Duration of the Project: This project started on 7 February 2003. It was originally designed to run for 18 months but because of unexpected operational delays, the project was extended for another 5 months. The official end of the Project is now on 7 January 2005.

National Executing Agency:
1. *Ministry of Environmental Protection and Physical Planning (MEPPP)*; Ul. Republike Austrije 20, 10000 Zagreb; Contact person: Jasminka Radović, BSc, Head of the Biodiversity and Landscape Conservation Department
2. Due to a change in government of Croatia's institutional set up, and the fact that MEPPP & Construction was no longer responsible for Nature Protection, the Government of Croatia has decided to appoint the new National Executing Agency (NEA) for the project Development of the NBF for Republic of Croatia (Project No: GF/2716-01-4319, Sub Project Number: GF/2716-02-4593). From 2 April 2004 the new Project's NEA is the *State Institute for Nature Protection (SINP)*. Contact person: Davorin Marković BSc., Head of State Institute, Bogovićeva 1A, 10 000 Zagreb, Croatia; (Tel: + 3851 4812 545; Fax: + 3851 4828 283; E-mail: davorin.markovi@dzzp.hr).

The National Project Coordinator (NPC): Meira Bosnić BSc. (Vet. Med.); State Institute for Nature Protection; Bogovićeva 1A; 10 000 Zagreb; Croatia; (Tel.: + 3851 4828 282 or + 385 91 6060 272 (mobile); Fax. + 3851 4828 283; E-mail: meira.bosnic@dzzp.hr or meira.bosnic@zg.htnet.hr; web: www.gmo.hr

The National Coordination Committee (NCC) has 16 members, representatives of institutions as follows:
* = Institutions and representatives that have been nominated in NCC until April 2004.

1. Croatian National Institute of Public Health
   Krunoslav Capak- president of NCC
   Sanela Ljubenko Mihelj - deputy
2. Control station for organic-biological production
   Davor Šamota - deputy president of NCC
   Berislav Vrkljan - deputy
3. Ministry of Agriculture, Forestry and Water Management
   Miljenko Rakić
   Višnja Ljubetić - deputy
   Božica Rukavina*
   Jadranka Mička - deputy*
4. Ministry of Economy, Labour and Entrepreneurship
   Ankica Čižmek
   Katarina Kališnik - deputy
5. Faculty of Science, University of Zagreb
   Jasenka Topić

Srećko Jelenić - deputy

6. Faculty of Agriculture, University of Zagreb

Vinko Kozumplik

Sanja Sikora - deputy

7. Faculty of Food Technology and Biotechnology, University of Zagreb

Zoran Zgaga

Duška Ćurić - deputy

Damir Karlović*

8. College of Agriculture at Križevci

Marijan Jošt

Vesna Samobor - deputy

Institute "Ruđer Bošković"

Nikola Ljubešić

Hrvoje Fulgosi - deputy

Institute of Social Sciences "Ivo Pilar"

Vladimir Lay

Dražen Šimleša - deputy

Pliva d.d. (Pharmaceutical company)

Marija Čepo

Liljana Palinkaš - deputy

Croatian Association of Genetical Engineers

Vladimir Delić

Petar Mitrikeski - deputy

Green Action, Friends of the Earth Croatia

Jagoda Munić

Rođena M. Kuhar - deputy

Association for Organic Husbandry, Environment Protection and Health Improvement of Croatia

Miodrag Hitrec

Zora Maštrović - deputy

Croatian Peasants Association

Darko Grivičić

Marijana Petir - deputy

Ivan Kolar*

16. State Institute for Nature Protection

Andreja Ribarić

Irina Zupan - deputy

Ministry of Environmental Protection and Physical Planning*

Vinko Mladineo*

Andreja Markovinović*

Representatives from the following organisations were present at each NCC meeting: Institute "Ruđer Bošković"; Pliva d.d. (Pharmaceutical company); Control station for organic-biological production; Croatian Association of Genetical Engineers and Association for Organic Husbandry, Environment Protection & Health Improvement of Croatia.
Representatives from the following organisations have attended only half of the meetings: the Ministry of Agriculture, Forestry & Water Management, Croatian Peasants Association and Green Action (Friends of the Earth Croatia).

Cost of the Project:
• Cost to the GEF US$136 800, 00
• Government contribution US$68 500, 00
Total Cost of the Sub-project: US$205 300, 00

7.1. Stakeholders

At the beginning of the project the NEA had identified various stakeholders in the biosafety area and had included them in the NCC.
The goal of the NCC was to guide and give advice during the activities of the project. During the lifetime of the Project and from conducted surveys it became obvious that some main stakeholders hadn't been included directly in this Project. Therefore, the Project invited the rest of the identified stakeholders on organized workshops and had included them in the drafting of secondary legislation needed for implementation of the Nature Protection Act. Although fruitful communication amongst the NCC members was sometimes hard to achieve, as most of the members were divided in two groups: "pro" and "contra" GMOs, the Project had managed to fulfil its goals.

7.2. Inventories

A. The NPC with help from NCC members had conducted *the National survey of:*

1. *Existing uses of biotechnology and the arrangements for safe use of biotechnology.*
At the beginning of August 2003, after research, a questionnaire was constructed and was sent to 280 institutions in Croatia (Universities, Pharmaceutical companies, Food industry and Research institutions). A database was then created detailing relevant outputs of the National surveys. The questionnaire response was 64% from the institutions approached. In addition the Project has also used other sources for the required information. By doing so, data was gathered from 220 institutions with 518 laboratories. From this number of laboratories, only 6% out of the 13% that were using biotechnology, and had acknowledged that they had worked with GMO's. In the questionnaire they were asked to list their arrangements for the safe use of biotechnology in their labs. From received answers, only 13% of laboratories had some kind of safety system in place and only 5% were implementing principles of Good Laboratory Practice. An extra 2% of laboratories had acknowledged that they are in the process of implementing ISO 14000 or ISO 17025. The laboratories that have some kind of control system/quality standards are mainly comprised from Pharmaceutical companies and the Food industry. More detailed findings of this National survey can be found in **Annex 6.**

2. *National experts in fields related to biotechnology and biosafety, as well as in fields relevant to risk assessment and risk management of GMO's and on existing National, bilateral and multilateral co-operative programmes in capacity building, Research & Development and application of biotechnology.*
A list of 50 National experts in fields related to biotechnology & biosafety, and fields relevant to risk assessment & risk management of LMO's, in consultation with NCC members had been finalised during this survey.
During this survey the Project had tried to find existing National, bilateral and multilateral co-operative programmes in capacity building, Research & Development and application of biotechnology. The Ministry for Science, Education & Sports (MSES) is the only one that

keeps records and finances different research and technological projects in Croatia. There are also other projects financed by private companies, or from abroad and International organisations. Data on these projects is not stored and people who are working within them do not like to disclose such information. The only information that could be gathered was on the CARDS and TWINNING projects.
To find out how much Croatia is actually investing in biotechnology the Project had asked the MSES about the projects they had financed in 2003. Here are the results:
a) All together, they had financed 1 768 scientific projects with an amount of 125 238 000 KN. Only a rough estimate of figures of expenditure could be obtained on biology / biotechnology projects because of different classification of projects made by the Ministry. Collected data has shown that 38% of all scientific projects have been in the before mentioned category and they were financed with 44% of the total budget. In the National survey, from 567 project summaries only 12% have connections with biotechnology.
b) The following information was gathered to obtain details on the interests of Croatian students for the study of such topics and also to find out what is Croatia's expert capacity in this field. During the year 2002, 14 % of students had enrolled in faculties that have biotechnology as a subject and 11% had graduated from such faculties (around 100 people per year). Only 40 % of them have found employment related to this profession.

B. *A survey on existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation*
This survey had been conducted in April 2004 under existing legislation. Under current legislations mentioned above, mechanisms are planned but they haven't been structured as yet. The new proposed GMO Act, which has passed its first reading in Parliament, will be changing the administrative procedures for the setting up of these mechanisms.

C. *A survey on existing National biosafety frameworks in the countries of the sub-region* had been conducted in April 2004.

D. *A survey on the extent and impact of release of LMO's and commercial products*
This survey had been conducted in April 2004. From 1997 until 1999, there were approved field trials of GM maize in Croatia. The Ministry for Agriculture and Forestry had appointed the Scientific Committee. This Committee was responsible for receiving applications, for risk assessment, for giving approval, for monitoring and giving expert opinion on trials. From 1999 until now, not one 'official' permit has been issued for field trials or the commercial growth of GM plants. The Ministry of Health had issued an Order banning the import of GM food products in the same year, which in effect meant a ban on import into or production of GM food products in Croatia. The border sanitary inspections would ban import of GM food products that had been declared as such and they would random sample test other imports. No un-declared GM food products had been found during that period.
From the beginning of 2004, the GMO laboratory began sampling & testing. In this period two GMO incidences have happened in Croatia. One incident involved a meat product (sausages), which contained GM Soya, and the second involved maize seeds, which had already been planted.

E. *The survey of existing National legislation or legal instruments related to biotechnology /biosafety*
During the projects lifetime, this survey was conducted four times. The list of National legislation can be found on the project web pages (www.gmo.hr; Legislation, Croatian legislation) with translated Acts.

F. *The list of the bilateral, regional and multilateral agreements that Croatia is member of or has ratified and are relevant for establishment of NBF* is also on the project web pages (www.gmo.hr ; Legislation, Bilateral, regional and multilateral agreements) with PDF format of relevant Agreement. There is also a web link to the EU legislation web page.

G. *Preparation of a National Biosafety Framework,* including procedures for the safe application of biotechnology in accordance with the Cartagena Protocol on Biosafety (administrative, legislative, risk assessment and public participation systems). In June 2004 the MC had given authorization to the Project, to assemble a team of experts (more than 30), who will draft all the required by-laws (more than 20) needed for implementation of the Nature Protection Act. This has been achieved and all drafts of the bylaws had been delivered to the Ministry in September 2004. They are in **Annex 2.**

7.3. Workshops

Six workshops held during this Project:

A. *The First Workshop,* entitled "*Genetically Modified Plants in Agricultural Production and New Legislation*", was held at Stubičke Toplice on 16 December 2003. It encompassed technical lectures for the meeting of department heads and managers of the Croatian Institute for Agricultural Counselling Service (CIACS). Thirty-three representatives from all the Croatian counties had attended. At regional conferences, the department heads have communicated the presented lectures to their agronomic counsellors in those counties, these in turn communicating them to the farmers in the areas covered by their counselling services.

B. *The Second Workshop* entitled "*Genetic engineering, GMO and Croatian legislation*", was organised on 9 January 2004 in Zagreb in collaboration with the Institute of Education of the Republic of Croatia (IERC). It was a scientific-educational based gathering attended by primary and secondary school teachers of biology and related disciplines. More than 200 teachers attended this workshop and they expressed the need for more similar workshops.

C. *The Third Workshop* entitled "*Croatian Biosafety-Related Legislation*", concerning legislation and inspection was held on 13-14 May 2004 in Zagreb. Its aim was to introduce conferees (staff from ministries and working groups to draw up by-laws and redefine the inspection) to the problems faced by EU professionals and search for the best solution in conjunction with lecturers from the EU, Austria, Netherlands and Slovenia. The Workshop heard presentations on the topics of Croatian, Slovenian, Austrian and EU legislation. There was also a workshop dealing with examples of processing the applications for contained use of GMO organisms. Invited were 62 institutions (Ministries, Industry, State laboratories, Research institutes and NGO-s) or 175 representatives. From the people invited, 47% had attended the workshop.

D. *The Fourth Workshop* entitled "*GMO problem area in Croatia and Europe*", was designed for the NGOs concerned with nature conservancy, representatives of the scientific community and journalists. This was organised in Topusko on 28-29 September 2004 in collaboration with the European Molecular Biology Organisation (EMBO). The Workshop objective was to explain the system of information for the public and their participation in the decision-making process under the Nature Protection Act. The Workshop reviewed the GMO problem area, biodiversity, sociological, economic and ethical problems within these fields through the

lectures presented by Croatian experts. In addition, the Workshop was also intended to pinpoint the communication problems between scientists, journalists and governmental authorities and to suggest a method for avoidance of such problems in future. Over 66 participants situated in 40 institutions were invited, from which were 31 scientists, 21 journalists and 14 NGO-s. On the day of the workshop, 27 of the invited guests had attended, (41%) from 21 institutions (52.5%). The majority of the people who attended the workshop were scientists (61%) then NGO's (29%) and the lowest attendance we had from journalists (19%).

E. *The Fifth Workshop* entitled "*Treatment of Genetically Modified Organisms*" took place in Zagreb on 22 October 2004. It was designed for inspectors (sanitary, agricultural, phytosanitary, marketing, environment, and nature), representatives of different ministries, the State Inspectorate, GMO detection laboratory, Institute for seeding and nursery-gardening, scientific commission members (for contained use of GMO and their introduction into environment) under the Nature Protection Act. The purpose of the Workshop was to inform the employees and professionals who will participate directly in the decision-making on GMO applications and in their processing on the same applications in the EU. Over 154 participants situated in 50 institutions were invited, comprised of 38 people in charge of laboratories, 64 representatives of Ministries and 16 inspectors. On the day of the workshop, 68 of the invited guests had attended (44.1%) from 30 institutions (60%). The majority of the people who attended the workshop were people in charge of laboratories (57.9%) then inspectors (43.7%) and the lowest attendance we had from representatives of the Ministries (34.3%).

F. *The Sixth Workshop* entitled "*GMOs - The National Biosafety Frameworks of Croatia*", took place in Zagreb on 16 December 2004. Its aim was to evaluate not only what has already been completed on this project, but also the achievements in the overall creation of a biosafety system. Other aims were to define the omissions and the work still ahead of Croatia in achieving this objective and establishing a regional cooperation. The first part was held in Croatian Parliament. To this seminar invited were Parliamentarians, Government officials from all involved ministries, NCC members and media journalists. From 250 people invited only 48 (18 %) had attended the seminar.
On December 17 2004 in Zagreb, the second part of this workshop had been held. For which, the members of National Coordination Committee in this Project, members of scientific committee's under the Law of Nature Protection, representatives of Ministries and representatives from neighbouring countries from Slovenia, Bosnia & Herzegovina, Serbia & Montenegro, Macedonia, Hungary and Bulgaria had been invited. Overall, 217 participants had been invited (23 inspectors, 66 representatives of government institutions, 15 industry representatives, 32 NCC members, 17 representatives of NGO's), and from this number 60 participant's had attended (27. 6%). Mostly, from industry (40%), followed by representatives from NCC (37.5%), then by representatives from universities and institutions (31.8%) and the lowest attendance, was by representatives from government institutions (21.8%).

Detailed Workshop Timetables, reports and presentations can be found on the web site of the Project: www.gmo.hr (About the project; Workshops).

The attendance of NCC members to the workshops was calculated.
The following NCC members, the representatives from the following institutions: the Croatian National Institute of Public Health, the Control station for organic-biological production and the Faculty of Science were present at all of the workshops.

The following NCC members who had not attended any of the workshops are representatives from following institutions: the Ministry of Agriculture, Forestry & Water Management, the Green Action, Friends of the Earth Croatia and the Croatian Peasants Association.

During the workshops, not only did participants gain the latest knowledge about different subjects and practices, which was very valuable, furthermore they had the opportunity to personally meet with different stakeholders in Croatia and exchange their opinions with them. This had helped in establishing professional and personal contacts between different governmental and nongovernmental institutions from within a still very rigid administrative and hierarchy system in Croatia. Also, participants had the opportunity to meet with professionals from neighbouring countries and establish personal contacts with them. This is very important, for establishing a broader, coordinated and professional cooperation which is essential to all involved, when one keeps in mind, that we are small countries (regarding size and capacity building capabilities). This is true, in the fact that establishing and implementing workable biosafety systems can be very costly and demanding. This statement is especially true for small countries, which on top of having very limited financial resources, also lack in experts and experience to deal with this complex biosafety area.

Last but not least, the Project team and NCC had a great opportunity to establish personal and professional contacts with lecturers from important European institutions. We would like to take this opportunity to show our gratitude to all lecturers from abroad that had attended our workshops and had helped in making them successful. We are listing them here in alphabetical order, but not in order of importance or preference:
1. Andrew Moore, PhD; Science & Society Programme Manager, the European Molecular Biology Organization; Germany.
2. Dr. Bernard Dixon; Freelance Journalist; United Kingdom.
3. M.Sc. Darja Stanič –Racman; the Ministry for the Environment & Spatial Planning; Slovenia.
4. M.Sc.Dietmar Vybiral; the Federal Ministry of Health & Women; Austria.
5. Dr. Harry A. Kuiper; RIKILT - Institute of Food Safety; Wageningen University & Research Centre; The Netherlands; also chairman of European Food Safety Authority (EFSA) - GMO panel.
6. Dr. Helmut Gaugitsch; Federal Environment Agency Ltd; Austria.
7. Prof. Julian Kinderlerer; Sheffield Institute of Biotechnological Law & Ethics; United Kingdom.
8. Dr. Maddalena Querci; Joint Research Centre; Institute for Health and Consumer Protection; Italy.
9. Dr. Michael Eckerstorfer; Zentrum für Lebensmittel und Konsum; Austria.
10. Mr. Piet van der Meer; Horizons sprl; Belgium.
11. Piet de Wildt, the Environment inspectorate; The Netherlands.

We would like to thank them for their understanding of the financial situation within the Project. Their acknowledgement of the importance of this subject has been an insight and benefit to the Project and Croatia as a whole.

7.4. Printed material

For each of the six workshops held, the Project had provided either printed material or had handed out CD's containing presentations.

The "Glossary" of commonly used terminology in this field was published.
A booklet entitled "Development of National Biosafety Framework in Republic of Croatia" was published in 70 000 copies. It was distributed through "Nacional" (weekly paper) and "Priroda" monthly journal for popularisation of Natural Sciences and Ecology. All these publications are also on the web site of the Project: www.gmo.hr.

7.5. Web page of the project

In November 2004, the web site of the Project became operational. The Project web page has been designed with the purpose of offering Project information to the public on a worldwide scale as well as all other topical information on the GMO problem area, such as its legislation or domestic and foreign news about GMOs. Since the web page also has an educational role, it includes a glossary with definitions from genetics and biotechnology, with an option to pose questions. Through links, the web page is connected to web pages on other domestic and foreign projects and to institutions concerned with similar problem areas. The Web Site of this project has listed relevant biosafety legislations, findings of National surveys, presentations and reports from all organised workshops, publications and useful links to other web sites. The address of the web site is: www.gmo.hr

7.6. International and regional activities

The NPC and numerous other members of the National Executing agencies, or NCC or other Ministries have attended in total 7 UNEP-GEF workshops. Not only did we receive valuable information, on particular topics, but we also had a great opportunity to exchange our own experiences with other participants.
Attendance at regional or sub-regional workshops:
1. UNEP-GEF Sub-regional Workshop on "Biosafety Framework" (Prague, 23 April - 25 April 2003).
2. UNEP-GEF - CEECCA Sub-regional Workshops: "Risk Assessment & Management" and Public Awareness & Participation" (Vilnius, 26 May - 2 June 2003).
3. UNEP-GEF regional Workshop on "Public Awareness, Information and Participation in National Biosafety System" (Ljubljana, 11 September - 12 September 2003).
4. UNEP-GEF Biosafety Sub-Regional Workshop on developing a Regulatory Regime and administrative Systems for National Biosafety Framework (Antalya, 9 - 12 December 2003).
5. UNEP-GEF - BCH workshop (Kuala Lumpur, 24 - 26 February 2004).
6. International workshop in Croatia at Plitvica Lakes on "GMO laws, inspection and labelling of food" (April 21 - 23 2004).
7. "World of Food 2004" (Istarske Toplice, 28 May 2004).
8. International two-week workshop "Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms" (Tromsø)
9. International Biotechnology Information Conference in United States (October 11 - 15 2004).
10. UNEP-GEF regional workshop for "Implementation of National Biosafety Framework" project (Prague, 10 - 11 November 2004).

ACKNOWLEDGMENT

The Project Team would like to thank everybody for his or her valuable contributions to the project of "Development of National Biosafety framework for Croatia".
First of all we would like to thank to UNEP-GEF team in Geneva (Andrea Gondova, Christopher Briggs and Liina Eek) for their financial and administrative support.
Thanks also to the organisations in Croatia, which have been our partners in the Project activities and have donated their resources and support (people, knowledge, premises, equipment etc) the Croatian Parliament, the Faculty of Food Technology and Biotechnology, University of Zagreb, the Croatian Institute for Agricultural Counselling Service & the Institute of Education of the Republic of Croatia.

Personal remarks of the National Project Coordinator
On this occasion, the Project Coordinator would like to express her gratitude to the many people and organisations, which had helped her & the team during the Project. Being so many, it is very hard to list all of them and/or to list them in order of their contribution or importance or preference. Therefore, she will list just the ones that the team had collaborated with the longest and/or the closest in alphabetical order, first from abroad and then from Croatia. Special thanks to:
1. Dr Liina Eek; Assistant Regional Coordinator for CEE (UNEP - GEF), for here quick, professional & personal advice and support during this Project, which had helped give guidance to the team thru hard times.
2. Dr. Helmut Gaugitsch who had reviewed the Croatian NBF and given the team valuable advice and support.
3. Mr. Piet van der Meer for his professional and personal contribution and support outside the scope of his contract.
4. All the lecturers from abroad listed in Chapter 7.3 for their understanding of the financial situation within the Project and their professional support.
5. To the team of Reviewers& Authors who had worked directly on NBF.
6. MD, M.Sc. Krunoslav Capak- president of NCC who had wisely coordinated the actions of the Project.
7. Special thanks go out to all NCC members for their contribution to all outputs of the Project.
8. The core executive team who were involved in the Project on a daily basis.

Annex 1

The National policies, which are indirectly connected with biosafety are:

1. On 11 July 2002, Croatian Parliament had adopted *the National Strategy for Agriculture and Fishery* (Official Gazette No. 89/2002). It covers agriculture, fisheries and the food industry. This strategy states that the government supports competitiveness within the agricultural sector, but the imperative is to maintain sustainable development of the rural sector. Therefore, the aim of this strategy is to preserve the rural sector, support research towards "clean" agricultural practices, which promote sustainable and ecological agriculture (which are using less chemicals or different substances that promote plant or animal growth). The benefit of such an approach is the creation of Croatian produce, nature protection and preservation and at the same time insuring healthier and safer food products. The only precise references towards GMOs in this Strategy are towards food safety where it is stated that "the goal is to minimize possible risks from GMO" by implementation of legislation in this area. It also states that one of the goals is to "increase the area under ecological production". The general policy of this Strategy could be interpreted as to restrict and regulate the use of GMOs in Croatian Agriculture and food.

2. On 26 June 2003, Croatian Parliament had adopted the *National Development Strategy for Science (*Official Gazette No. 108/2003). This strategy generally supports development and investment in science. The National Scientific Council has to decide which fields in science have priority in Croatia. This Council, which is to be established, is also pursuant to the Law on Scientific Activities and University Education (Official Gazette No. 123/03), which will have an expert and advisory function and will be in charge of the overall development of scientific activities in the Republic of Croatia. The members of this Council had been nominated at the end of last year (Official Gazette No. 174/2004), but haven't decided as yet on the National priorities in science and research.

3. In a Declaration from Croatian Parliament (Official Gazette12/2005) regarding the basic principles in negotiations with the European Union (EU), the following was declared by Parliament. Although the Croatian primary goal is to harmonize National legislation with the EU, the Croatian Parliament will support the initiative for exemptions or/and prolongation of terms for harmonization in agriculture and in the nature protection area amongst other fields. No specific exemptions are referred to in this declaration.

4. Specific institutions are currently working on the *National Strategy for Food Safety*. The Croatian Public Health Institute (CPHI) is leading the project and is preparing a draft framework. The Croatian Food Agency (CFA), Ministry of Agriculture, Forestry & Water Management (MAFWM) and other institutions are involved through 'workshops' in order to introduce National policy to food strategy. It is likely that the Strategy will be finalised by the end of 2005. Explanation: with the exception of the *National Environmental Strategy* (Official Gazette No. 46 of 29 April 2002) and *the National Strategy for Agriculture and Fishery* (Official Gazette No. 89/2002), there is still no strategy that would be appointed exclusively on food and National attitude toward food safety and food production. The fact, there is presently major public concern toward food safety and competitiveness in the food market, brings the obligation to the responsible institutions to define National priorities, especially, from the time when Croatia had officially become a member country for joining EU (2004). Because the food-producing sector is mainly supported by primary production, the concern is, how efficient will those producers be in competition with EU producers in the process of

joining EU. The Government is now directing land policy into increasing and enforcing these small family business. Because it would be hard to compete with strong EU farmers with quantity of food products, the policy is to preserve sustainable agriculture as much as possible, as products coming from such properties are foreseen as much more welcome on the EU market.

Annex 2

The list of Expert Working Groups with accompanying implemental regulations that have been drafted for the Nature Protection Act:

A. Contained Use of GMOs

Article 101

(3) Criteria for classification of the contained use into levels of hazard, standards for facilities in closed systems, prevention and other precautionary measures, the method of handling and other conditions for a specific level of hazard shall be laid down by a by-law passed by the Government.

Article 102

(7) Standards of facilities for a contained use of GMOs within a closed system with respect to the level of hazard shall be established in a rulebook issued by the minister responsible for science and technology, with the approval of the minister responsible for the protection of nature and environment, the minister responsible for health and the minister responsible for agriculture and forestry.

Article 103

(6) The contents and scope of the risk assessment for the contained use of GMOs and the methodology of its preparation shall be determined by the Minister in a rulebook.

Article 108

(9) The contents of the application for the contained use at the second level of hazard shall be prescribed in detail by the Minister in a rulebook.

Article 109

(7) The contents of the application for a permit to use GMOs at the third and fourth level of hazard shall be laid down by the Minister in a rulebook.

Members of working group

Institution	First name	Last name
State Institute for Nature Protection	Andreja	Ribarić
Ministry of Agriculture, Forestry and Water Management	Vesna	Kubiček
Ministry of Environmental Protection, Physical Planning and Construction	Hrvoje	Buljan
Croatian National Institute of Public Health	Jelena	Žafran Novak
Ministry of Science, Education and Sport	Andreja	Jakovac
Institute "Ruđer Bošković"	Hrvoje	Fulgosi
School of Public Health	Jadranka	Mustajbegović
Croatian Institute for Brain Research	Srećko	Gajović
"Pliva"- Pharmaceutical Industry	Damir	Janić
Institute "Ruđer Bošković"	Duška	Vujaklija

B. Deliberate Release of GMOs into the Environment

Article 113

(3) Conditions to be met by GMOs and other conditions that are to be met in order to issue a permit using summary procedure shall be prescribed by the Government in a rulebook.

Article 114

(3) It is not permitted to release the reproductive plant material containing GMOs deliberately into the environment, except for areas of land that shall be determined by a by-law of the Government, on the proposal of the ministry responsible for agriculture and forestry and the minister responsible for environmental protection.

Article 115

(4) The contents and scope of a risk assessment for a deliberate release of a GMO into the environment, the methodology of assessment preparation and legal persons authorized for preparation of the assessment shall be prescribed by the Minister in a rulebook, with the consent of the minister responsible for agriculture and forestry.

Article 116

(5) Contents of Emergency Response Plan and the ways how it should be implemented shall be prescribed by the Government in the Regulation.

Article 117

(4)The method of submitting an application and its contents shall be laid down by the Minister in a rulebook, with the consent of the minister responsible for agriculture and forestry.

Article 119

(6)The method of submission and the contents of the application shall be determined by the rulebook under Article 117, paragraph 4 of the present Act.

Article 123

(2) The Ministry shall, in co-operation with competent government authorities, adopt and implement a programme for elimination of consequences of an unplanned spread of GMOs into the environment, which shall be enacted by the Government.

(5) In the event of an unplanned spread of a GMO into the environment which could have considerable negative effects on the biodiversity, environment and human health the Ministry shall inform the endangered or potentially endangered states and, when necessary, corresponding International organizations, and make available to them any information necessary for determination of adequate measures.

(6) The method of providing information under paragraph 5 of the present Article shall be prescribed by the Government in a rulebook.

Members of working group

Institution	First name	Last name
State Institute for Nature Protection	Irina	Zupan
Ministry of Agriculture, Forestry and Water Management	Irena	Lješević
Ministry of Environmental Protection, Physical Planning and Construction	Hrvoje	Buljan
Croatian National Institute of Public Health	Krunoslav	Capak
Faculty of Science, University of Zagreb	Srećko	Jelenić
Faculty of Science, University of Zagreb	Željko	Kućan
Faculty of Agriculture, University of Zagreb	Snježana	Kereša
BC Institute	Ivica	Buhiniček
Forestry Institute "Jastrebarsko"	Danko	Slade
Institute "Ruđer Bošković"	Duška	Vujaklija

C. Placing on the Market of GMOs and Products Containing GMOs

Article 125

(3) The contents and scope of a risk assessment for placing on the market of a GMO or products containing a GMO and the methodology of carrying out the risk assessment shall be prescribed by the Minister in a rulebook, with the consent of the minister responsible for agriculture and forestry and the minister responsible for health.

Article 127

(6) The contents of the application and the technical dossier for the placing on the market of GMOs or products containing GMOs, the conditions for monitoring, labelling and packaging of products shall be laid down by the Minister in a rulebook, with the consent of the minister responsible for health and the minister responsible for agriculture and forestry.

Article 129

(5) Permits for the placing on the market of GMOs or products containing GMOs that are not included in paragraphs 2, 3 and 4 of the present Article shall be granted by the Ministry.

(8) Enforcement regulations governing the procedures of granting the permit in compliance with the paragraph 2 of the present Article shall be issued by the minister responsible for health; for the procedures under paragraph 3 of the present Article the minister responsible for agriculture and forestry, with the consent of the minister responsible for the protection of nature and environment; for the procedures laid down by paragraph 4 of the present Article the minister responsible for health, with the consent of the minister responsible for agriculture and forestry, and for the procedures laid down by paragraph 5 of the present Article the minister responsible for the protection of nature and environment.

Article 135

(2) Standards relating to handling, packaging and transport of GMOs shall be laid down by the Minister in a rulebook, taking into account International regulations and the practice.

Members of working group:

Institution	**First name**	**Last name**
State Institute for Nature Protection	Irina	Zupan
Ministry of Agriculture, Forestry and Water Management	Miljenko	Rakić
Ministry of Agriculture, Forestry and Water Management	Božica	Rukavina
Ministry of Agriculture, Forestry and Water Management	Anđelko	Gašpar
Ministry of the Sea, Tourism, Transport and Development	Vjekoslav	Bolanča
Croatian National Institute of Public Health	Zrinka	Petrović
Croatian Chamber of Economy	Božica	Marković
State Inspectorate	Danica	Ledecki
"Pliva" – Pharmaceutical industry	Vlasta	Vidmar
"Podravka" – Food industry	Nada	Knežević

D. GROUP

Genetically Modified Organisms

Article 93

(2) The methodology and safety measures in transboundary movement, transit, contained use, deliberate release into the environment and placing of GMOs and products containing GMOs on the market, the techniques and genetic modifications permitted, measures for elimination of harmful consequences of the uncontrolled use of GMOs and the method of a harmless destruction of GMOs and wastes containing GMOs shall be prescribed by a by-law to be passed by the Government.

Import of GMOs and Products Containing GMOs

Article 136

(3) The method of handling and other conditions for the import of GMOs or products containing GMOs shall be determined by a by-law passed by the Government.

Register of GMOs

Article 139

(7) The form and method of keeping the register of GMOs and the method of fixing a fee for the issue of copies shall be prescribed by the Minister in a rulebook.

(8) The register of GMOs shall also be kept by competent government authorities responsible for granting authorizations for the use or placing on the market of GMOs or

products containing GMOs pursuant to the present Act and a special regulation. The form and method of keeping a register of GMOs shall be prescribed by competent ministers, each within his scope of competencies.

Management of Waste Generated by the Use of GMOs
Article 140

(2) The method of disposal and harmless destruction of wastes containing GMOs shall be prescribed by the Government in a by-law as referred to in Article 93, paragraph 2 of the present Act.

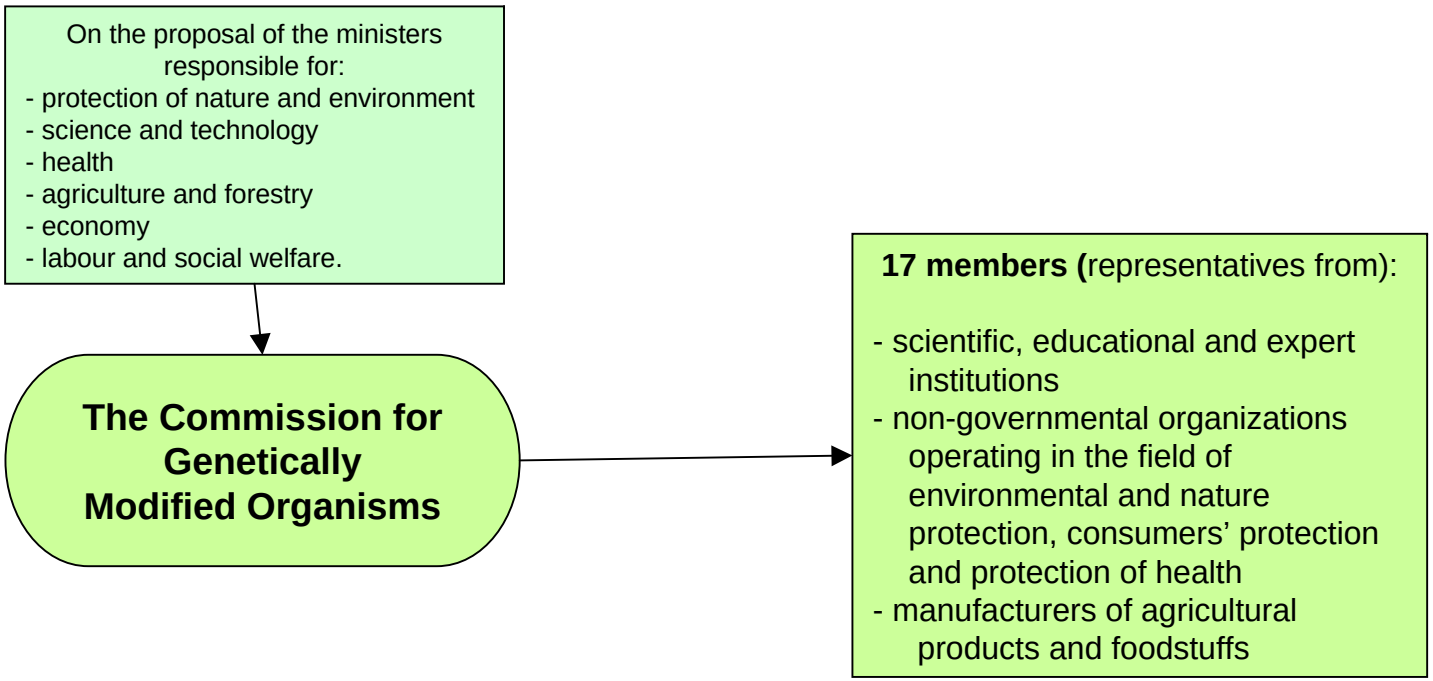
Members of working group:

Institution	**First name**	**Last name**
State Institute for Nature Protection	Andreja	Ribarić
Ministry of Agriculture, Forestry and Water Management	Vesna	Kubiček
Ministry of Environmental Protection, Physical Planning and Construction	Hrvoje	Buljan
Ministry of Health and Social Welfare	Nera	Belamarić
Ministry of Science, Education and Sports	Andrea	Jakovac
Ministry for European Integration	Maja	Kušt

Annex 3. systems under the Nature Protection Act (Official Gazette 162/2003)

ANNEX 3. | **THE STRUCTURE OF THE COMMISSION AND THE COMMITTEES**

NOTE: For the purpose of monitoring state and developments in the field of GMO handling and provision of technical assisstance to competent government authorities, the Government shall set up the Commission and the Committees for a period of **four years.**



The duties of the Commission are:

- monitoring the state and development in the field of genetic technology application and the use of GMOs;
- following scientific achievements and give opinions and incentives in relation to genetic technology application and the use of GMOs;
- delivering its opinion on social, ethical, technical and technological, scientific and other conditions of the use of GMOs;
- advising the Government and competent government bodies in matters related to the use of GMOs and genetic technology;
- informing th epublic about the state and development in the field of genetic technology application and the use of GMOs and on its viewpoints and opinions;
- co-operating with similar foreign authorities and exchanging data and experiences.

ANNEX 3. THE STRUCTURE OF THE COMMISSION AND THE COMMITTEES

NOTE: The chairmen and deputy chairmen of the Committee for Contained Use of GMOs, the Committee for the Release of GMOs into the Environment and the Committee for Novel Food and Animal Feed Containing GMOs are members of the Commission for GMOs.
The Government shall set up the Committees for a period of **four years** on the proposal of the ministers.

Scientific Committee for Contained Use of GMOs

- on the proposal of the **minister responsible for science and technology**, with the consent of the ministers responsible for protection of nature and environment, health, agriculture and forestry, economy, labour and social welfare.
7 members - scientists and experts in the field of microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, biotechnology, safety at work.

Scientific Committee for the Release of GMOs into the Environment

- on the proposal of the **minister responsible for protection of nature and environment**, with the consent of the ministers responsible for science and technology, health, agriculture and forestry.
9 members - scientists and experts in the field of genetics, ecology, nature protection, agriculture, forestry, veterinary medicine, biochemistry and molecular biology, microbiology and medicine.

Committee for Novel Food and Animal Feed Containing GMOs

The composition, scope of activities and methodology of work of the Committee shall be laid down by a special regulation.

The duties of the Committes are to:
- deliver expert opinions about the use of GMOs in administrative and other procedures in compliance with the present Act;
- deliver opinions and proposals in the process of drafting regulations on the use of GMOs;
- deliver opinions and give proposals to competent government authorities in the matter of using the GMOs;
- submit to the Government annual reports on their activities, which shall be published in a manner accessible to the public.

ANNEX 3.1 – (a)

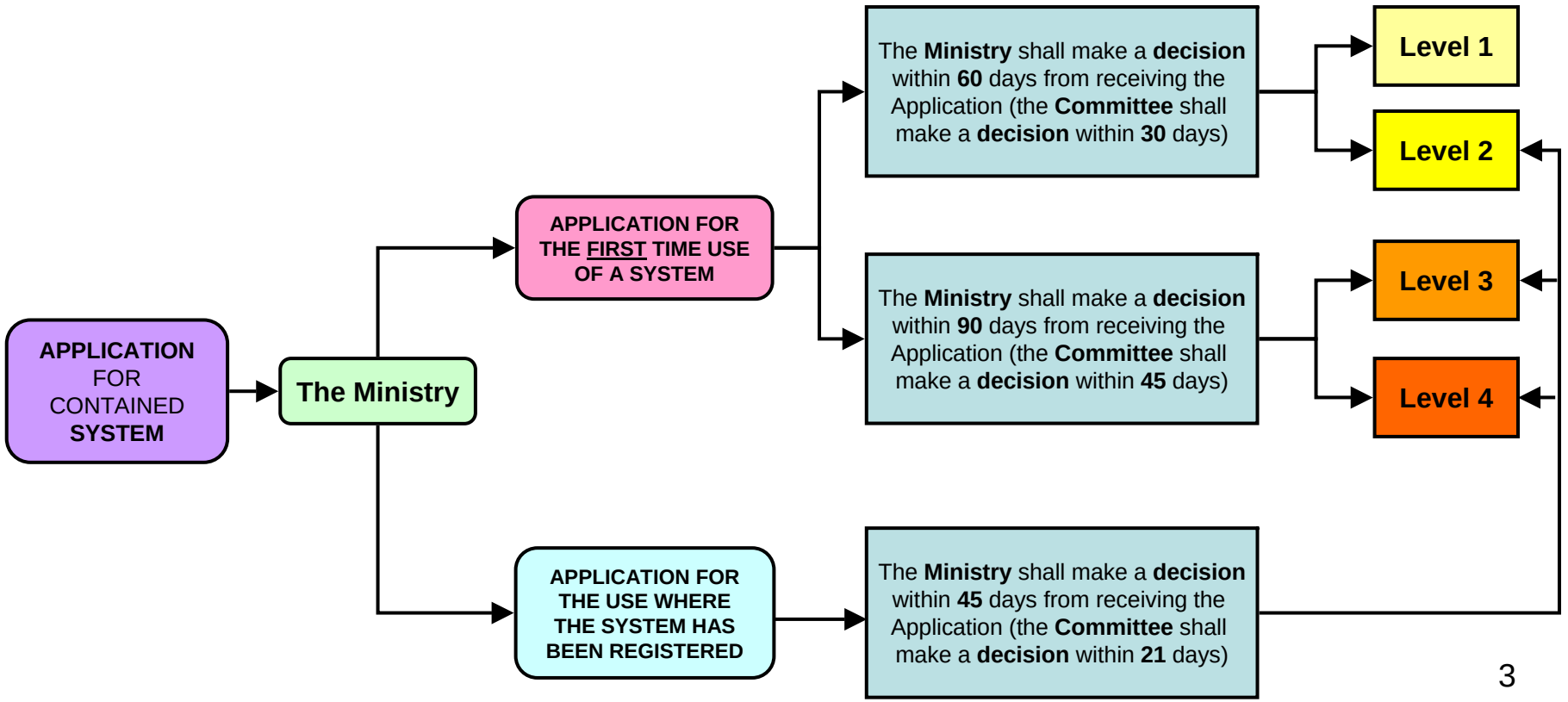
APPLICATION FOR THE ENTRY OF THE CLOSED SYSTEM INTO THE GMO REGISTRY

The Ministry = The Ministry of Culture (The Nature Protection Department)

The Committee = The Committee for Contained Use of GMOs

Time Limit of Decision = By the Ministry from opinion of the Committee

NOTE: Before the first use of GMO in containment - the system has to be approved for its entry into the GMO registry

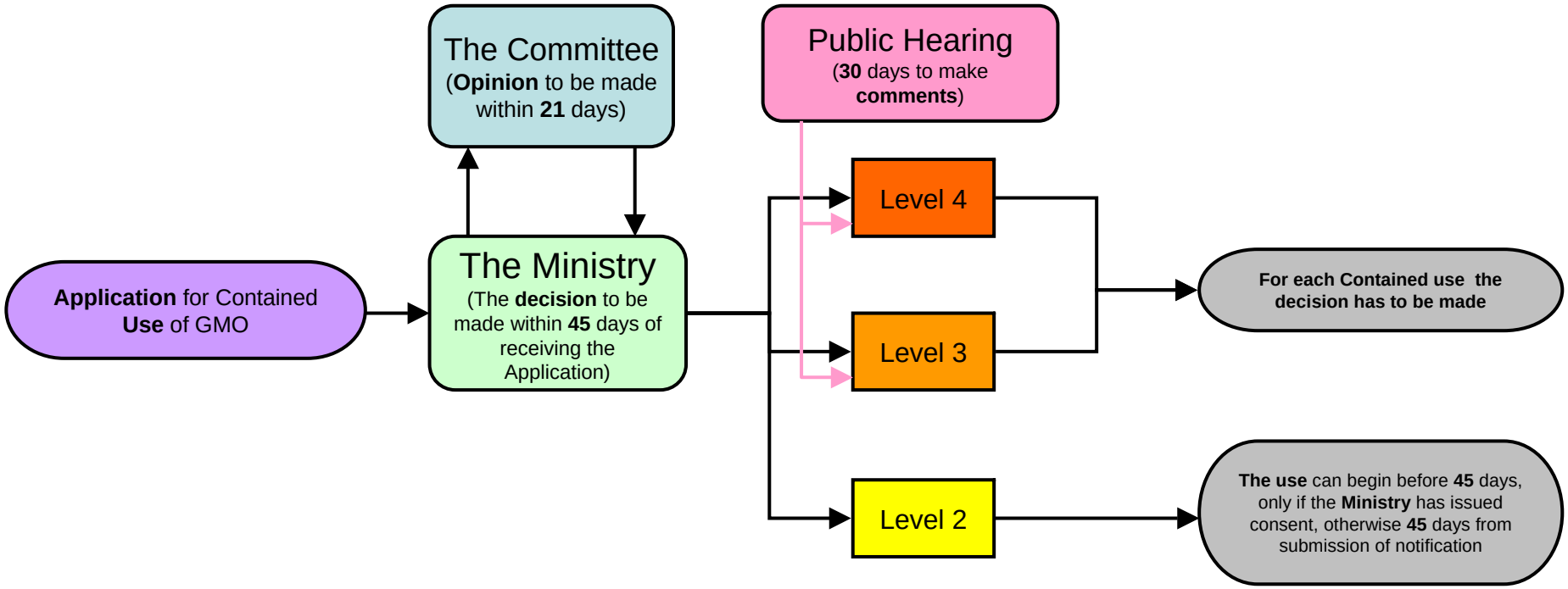


ANNEX 3.1 – (b)	APPLICATION FOR THE CONTAINED USE OF GMO

The Ministry = The Ministry of Culture (The Nature Protection Department)

The Committee = The Committee for Contained Use of GMOs

NOTE: Level 1 Use – Can commence without notification to the Ministry only if the Ministry had previously issued the decision for entering the specific system into the GMO registry



ANNEX 3.2 – (a)

APPLICATION FOR DELIBERATE RELEASE OF THE GMO INTO THE ENVIRONMENT (THE NORMAL PROCEDURE)

The Ministry = The Ministry of Culture (Nature Protection Department)

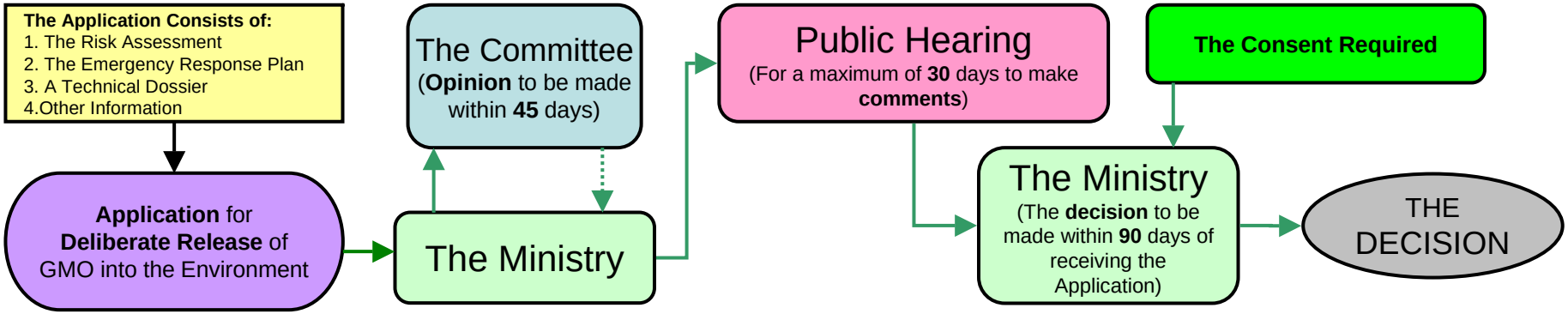
The Committee = The Committee for Release of GMOs into the Environment

The Consent Required = By the Ministry of Agriculture, Forestry & Water Management

Deliberate release into the Environment is **NOT PERMITTED** for reproductive plant material, **except** for areas of land determined by a by-law of the government (on the proposal of the Ministry of Agriculture, Forestry & Water Management and the Ministry of Environmental Protection, Physical Planning & Construction)!

NOTE: If extra information is required by the Ministry and/or the Committee for the decision to be made – the clock stops

A. The **Normal** Procedure for the Deliberate Release of GMO



NOTE: In the event of any new information and/or of any modification or unplanned change of deliberate release of GMO into the environment, which could have adverse impact on biodiversity, the environment or human health, the minister may require the applicant to modify the conditions of the deliberate release or temporarily/permanently prohibit the deliberate release of the specific GMO

ANNEX 3.2 – (b)

APPLICATION FOR DELIBERATE RELEASE OF THE GMO INTO THE ENVIRONMENT (THE SHORTENED PROCEDURE)

The Ministry = The Ministry of Culture (Nature Protection Department)

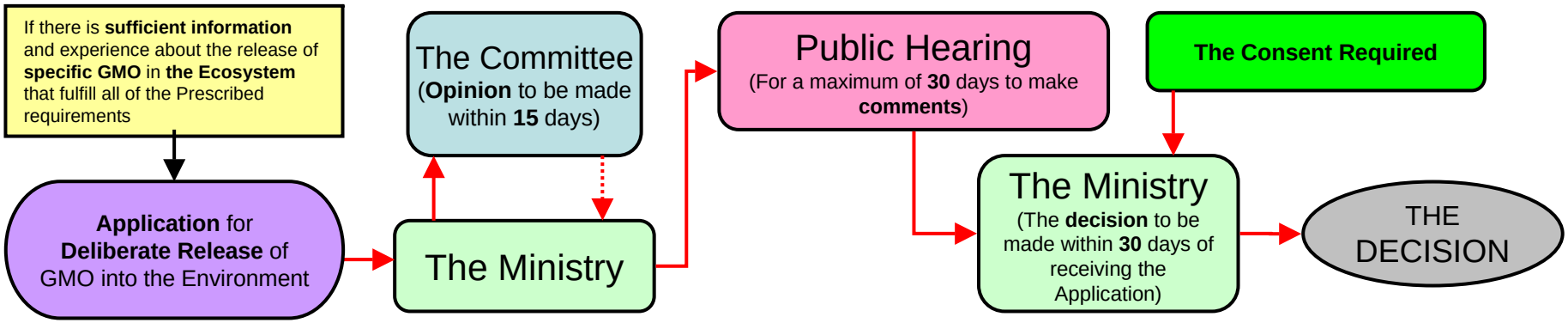
The Committee = The Committee for Release of GMOs into the Environment

The Consent Required = By the Ministry of Agriculture, Forestry & Water Management

Deliberate release into the Environment is **NOT PERMITTED** for reproductive plant material, **except** for areas of land determined by a by-law of the government (on the proposal of the Ministry of Agriculture, Forestry & Water Management and the Ministry of Environmental Protection, Physical Planning & Construction)!

NOTE: If extra information is required by the Ministry and/or the Committee for the decision to be made – the clock stops

B. The **Shortened** Procedure for the Deliberate Release of GMO



NOTE: In the event of any new information and/or of any modification or unplanned change of deliberate release of GMO into the environment, which could have adverse impact on biodiversity, the environment or human health, the minister may require the applicant to modify the conditions of the deliberate release or temporarily/permanently prohibit the deliberate release of the specific GMO

ANNEX 3.3	APPLICATION FOR PLACING THE GMO ON THE MARKET

The Ministry of Culture = **MC**; The Ministry of Health & Social Affaires = **MHSA;** The Ministry of Agriculture, Forestry & Water Management = **MAFWM**

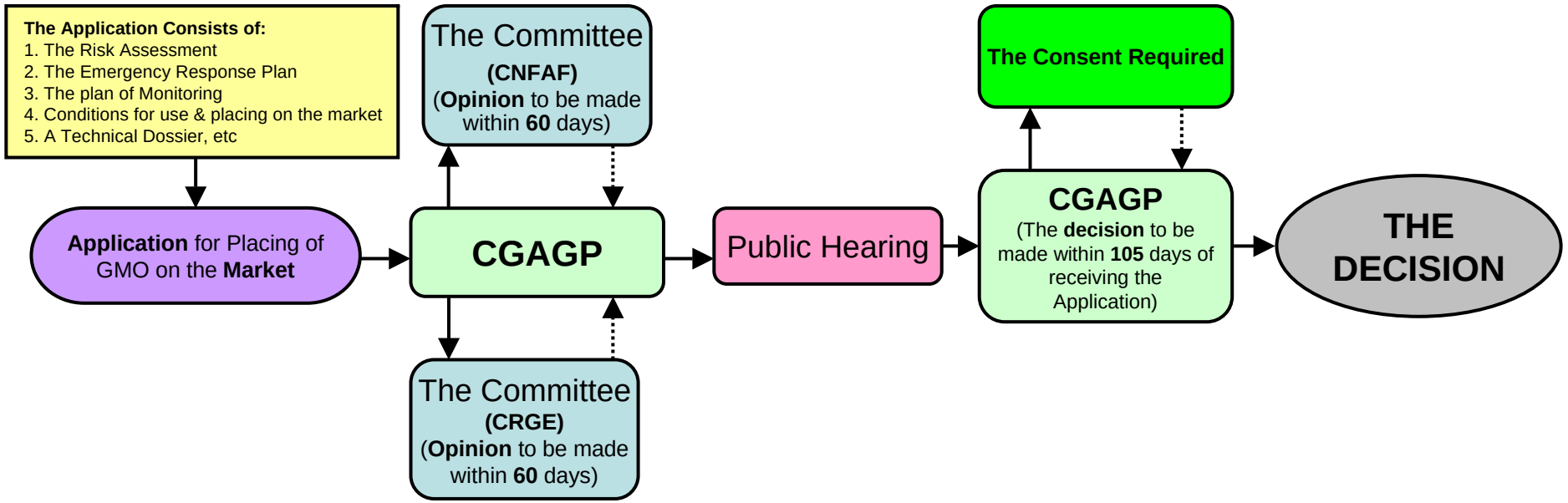
The competent government authority granting the permit (CGAGP) for the placing GMO or products containing GMO that are used in:

1. Cosmetics, pharmacy and human health care = The **MHSA**
2. Agriculture, veterinary medicine, forestry & fisheries = The **MAFWM** (with the consent of the **MC**)
3. Of food stuff and the products used in the food processing industry = The **MHSA** (with the consent of the **MAFWM**)
4. All other GMO and/or GMO products not included in the above = The **MC**

The Committee (CNFAF) = The Committee for Novel food & animal feed

The Committee (CRGE) = The Committee for Release of GMOs into the Environment

NOTE: The applicant shall obtain a permit for each GMO or product containing a GMO that is intended to be placed on the market for the **first** time. The provisions of this Act do **not** apply to **Import, Transit, Placing on the Market, Use & Production of Medicines** containing GMO

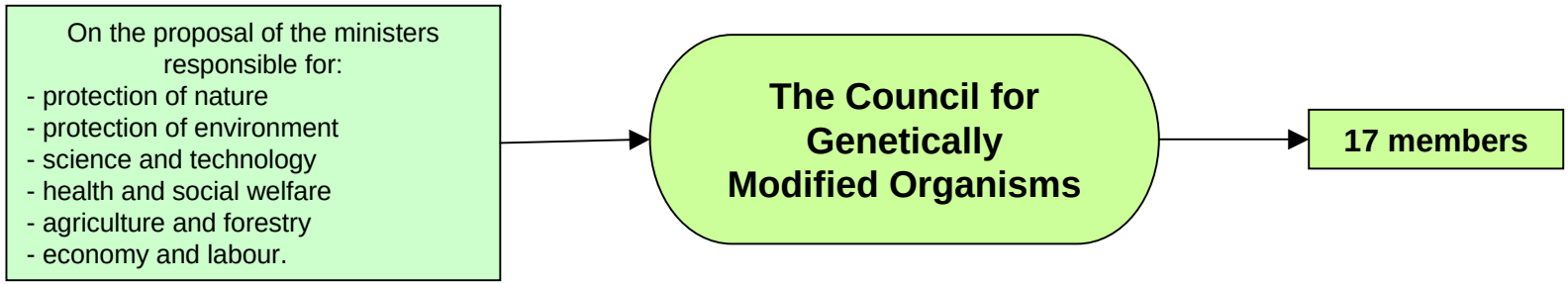


NOTE: The **decision** is granted **for a maximum** of **5 years**
If new information becomes available to the applicant and/or CGAGP a new **decision** will be taken to amend or annul the valid permit within **90 days.** The applicant has to submit an application for **extension** of the permit within **9 months** prior to **expiry** of the permit. The CGAGP has to make a **decision** within **90 days** and if the **extension** is granted, it cannot run for more than **10 years**

Annex 4. systems under the new proposed GMO Act

ANNEX 4.	THE STRUCTURE OF THE COMMISSION AND THE COMMITTEES

NOTE: For the purpose of monitoring state and developments in the field of GMO handling and provision of technical assisstance to competent government authorities, the Government shall set up the Council for GMOs for a period of **four years.**



The duties of the Council are:

- monitoring the state and development in the field of genetic technology application and the use of GMOs;
- following scientific achievements and give opinions and incentives in relation to genetic technology application and the use of GMOs;
- delivering its opinion on social, ethical, technical and technological, scientific and other conditions of the use of GMOs;
- advising the competent government bodies in matters related to the use of GMOs and genetic technology;
- informing th epublic about the state and development in the field of genetic technology application and the use of GMOs and on its viewpoints and opinions.

ANNEX 4.

THE STRUCTURE OF THE COMMISSION AND THE COMMITTEES

NOTE: On the proposal of competent government authorities the Council nominates the Committees for a four-year term.

Scientific Committee for Contained Use of GMOs

11 members - scientists and experts in the field of microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, biotechnology, agriculture, forestry and veterinary medicine, safety at work, nature conservancy, environmental protection.

Scientific Committee for the Release of GMOs into the Environment

9 members - scientists and experts in the field of genetics, ecology, environmental protection, nature conservancy, agriculture, forestry, veterinary medicine, biochemistry and molecular biology, microbiology and medicine.

The duties of the Committes are to:

- deliver expert opinions about the use of GMOs in administrative and other procedures in compliance with the present Act;
- deliver opinions and proposals in the process of drafting regulations on the use of GMOs;
- deliver opinions and give proposals to competent government authorities in the matter of using the GMOs;
- carry out such other activities as may be prescribed by th epresent Act and regulations;
- submit to the Government annual reports on their activities, which shall be published in a manner accessible to the public.

ANNEX 4.1 | **a) APPLICATION FOR THE ENTRY OF THE CLOSED SYSTEM INTO THE GMO REGISTRY**

NOTE: In this Act, **the Ministry** is the **Ministry of Science and Technology**

ANNEX 4.1 | **b) APPLICATION FOR THE CONTAINED USE OF GMO**

NOTE: In this Act, **the Ministry** is the **Ministry of Science and Technology**

NOTE: Level 1 Use – Can commence **only with a written notification** to the Ministry if the Ministry had previously issued the decision for entering the specific system into the GMO registry

ANNEX 4.2 — APPLICATION FOR DELIBERATE RELEASE OF THE GMO INTO THE ENVIRONMENT

NOTE: In this Act, genetically modified reproductive plant material **may be introduced into environment only on the plots of land** to be allocated by decree by the government of the Republic of Croatia on the proposal of the Ministry of Agriculture and Forestry **with the consent of the state administrative body for nature conservation.**

The Application Consists of:
1. The Risk Assessment
2. The Emergency Response Plan
3. A Technical Dossier
4. **Plan for monitoring the GMOs impact**
5. **Data on Waste Management**
6. **Techniques for the removal of the GMOs**
7. Other Information

ANNEX 4.2 – (a) — APPLICATION FOR DELIBERATE RELEASE OF THE GMO INTO THE ENVIRONMENT (THE STANDARD PROCEDURE)

The competent authority shall submit a summary of the application to the European Commission within 30 days of receiving the application. The competent authority is obliged to take account of the comments received from the competent authorities of the EU Member States when deciding on the application to authorise the intentional introduction of a GMO into environment. European Commission shall be informed by competent authority of the authorisations it has granted for intentional introduction of GMOs into environment, reasons for refusing to issue authorisations, and of the results of intentional introduction of GMOs into environment.

ANNEX 4.2 – (b) — APPLICATION FOR DELIBERATE RELEASE OF THE GMO INTO THE ENVIRONMENT (THE SHORTENED PROCEDURE)

NOTE: An authorisation for intentional introduction of a GMO into environment may be issued using the shorter procedure if there is **sufficient information** and experience about the release of **specific GMO** in **the Ecosystem** that fulfill all of the Prescribed requirements. **The shorter procedure may be used if the European Commission has made a decision to apply such procedure to a certain GMO, and in compliance with that decision.**

The competent authority informs the European Commission in advance of applying the shorter procedure for intentional introduction of a GMO into environment. If it estimates that all legal requirements have been met, the competent authority may propose to the European Commission to authorise the implementation of the shortened procedure for intentional introduction of a certain GMO into environment.

ANNEX 4.3 – (a)

APPLICATION FOR PLACING THE GMO AND/OR GMO CONTAINING AND/OR MADE/DERIVED PRODUCTS ON THE MARKET

The Ministry of Culture = **MC**; The Ministry of Health & Social Affaires = **MHSA;** The Ministry of Agriculture, Forestry & Water Management = **MAFWM**

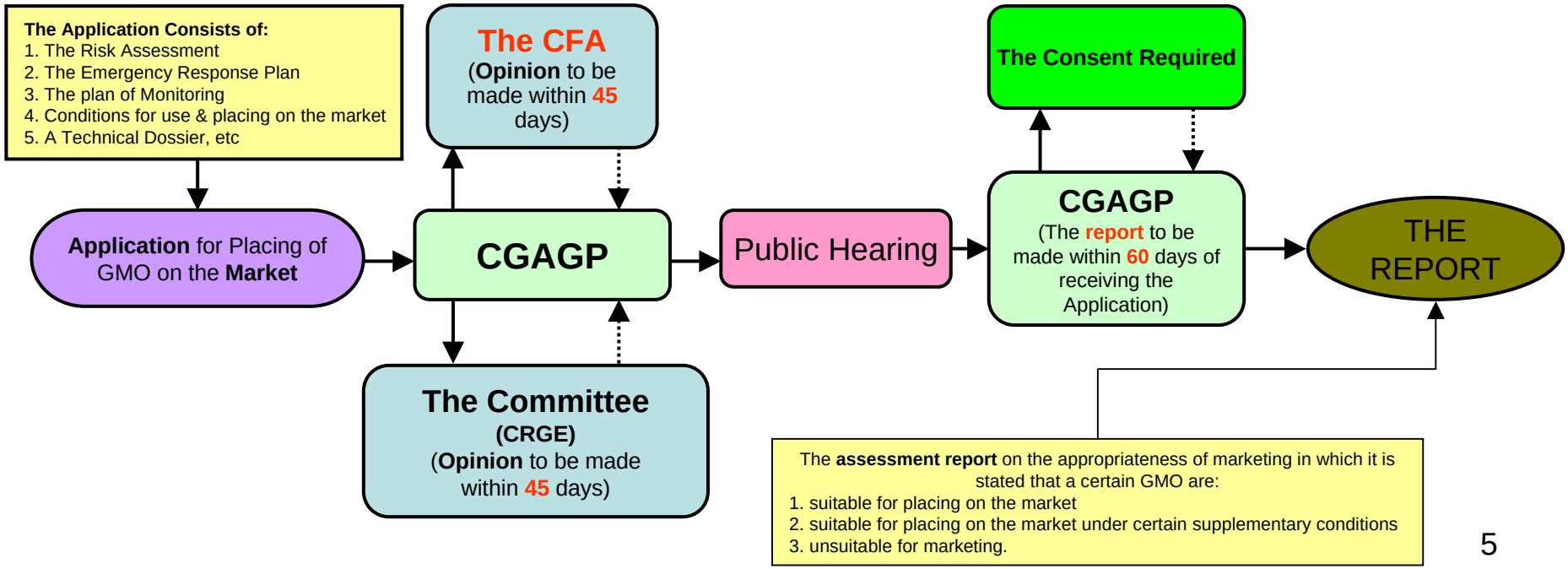
The competent government authority granting the permit (CGAGP) for the placing GMO and/or GMO containing and/or made/derived products:

1. as food = The **MHSA**
2. as feed = The **MAFWM** (with the consent of the **MHSA**)
3. as reproduction material in agriculture, forestry, and veterinary medicine = The **MAFWM** (with the consent of the **MHSA**)
4. as veterinary drugs and plant protection products = The **MAFWM** (with the consent of the **MHSA**)
5. in cosmetics, pharmaceutical industry and human health care = The **MHSA**

The CFA = The Croatian Food Agency; **The Committee (CRGE) =** The Committee for Release of GMOs into the Environment

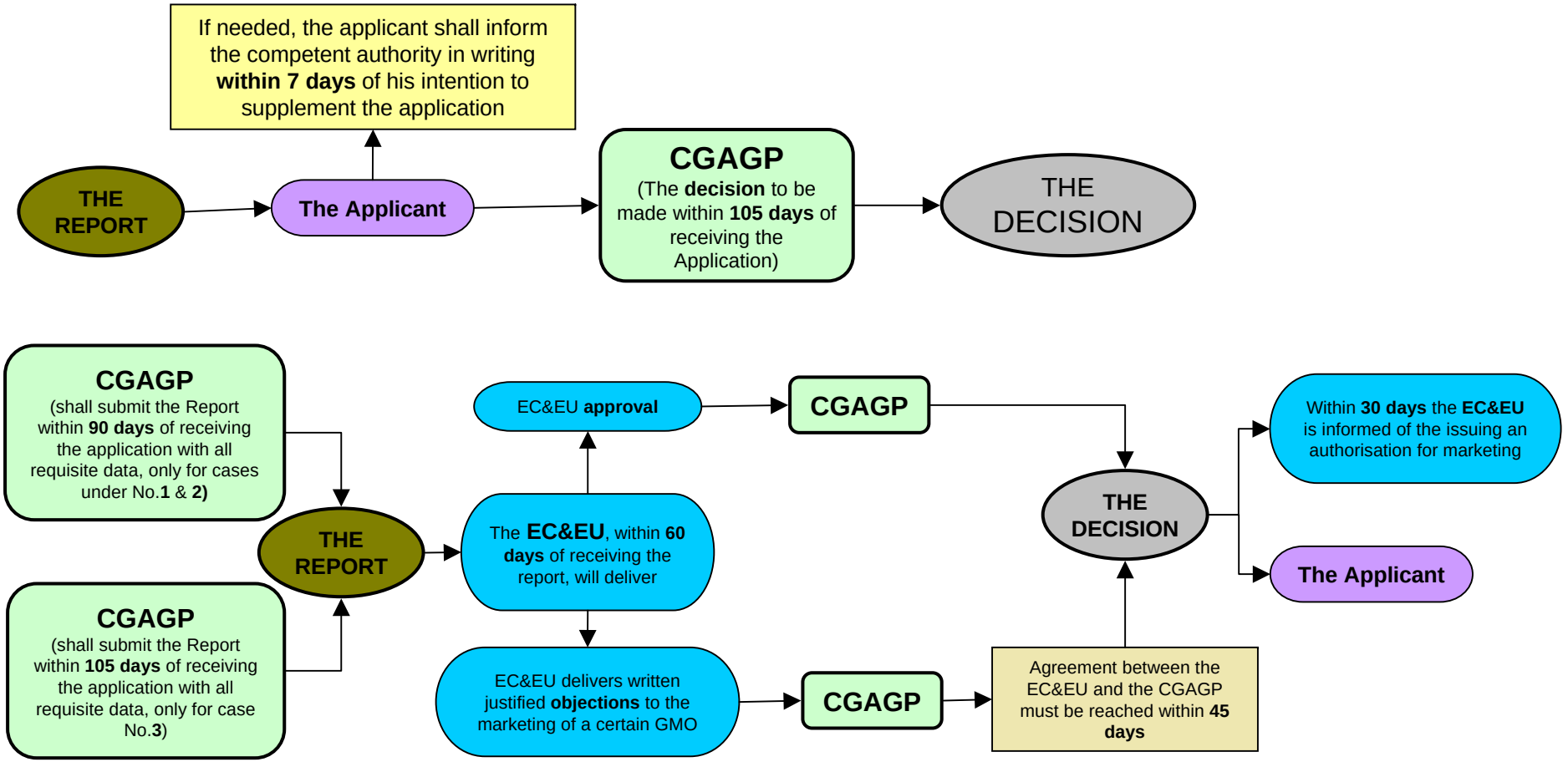
The European Commission and competent bodies of the European Union = EC&EU

NOTE: The applicant shall obtain a permit for each GMO or product containing a GMO that is intended to be placed on the market for the **first** time. The provisions of this Act do **not** apply to **Import, Transit, Placing on the Market, Use & Production of Medicines** containing GMO.



ANNEX 4.3 – (b)

APPLICATION FOR PLACING THE GMO AND/OR GMO CONTAINING AND/OR MADE/DERIVED PRODUCTS ON THE MARKET

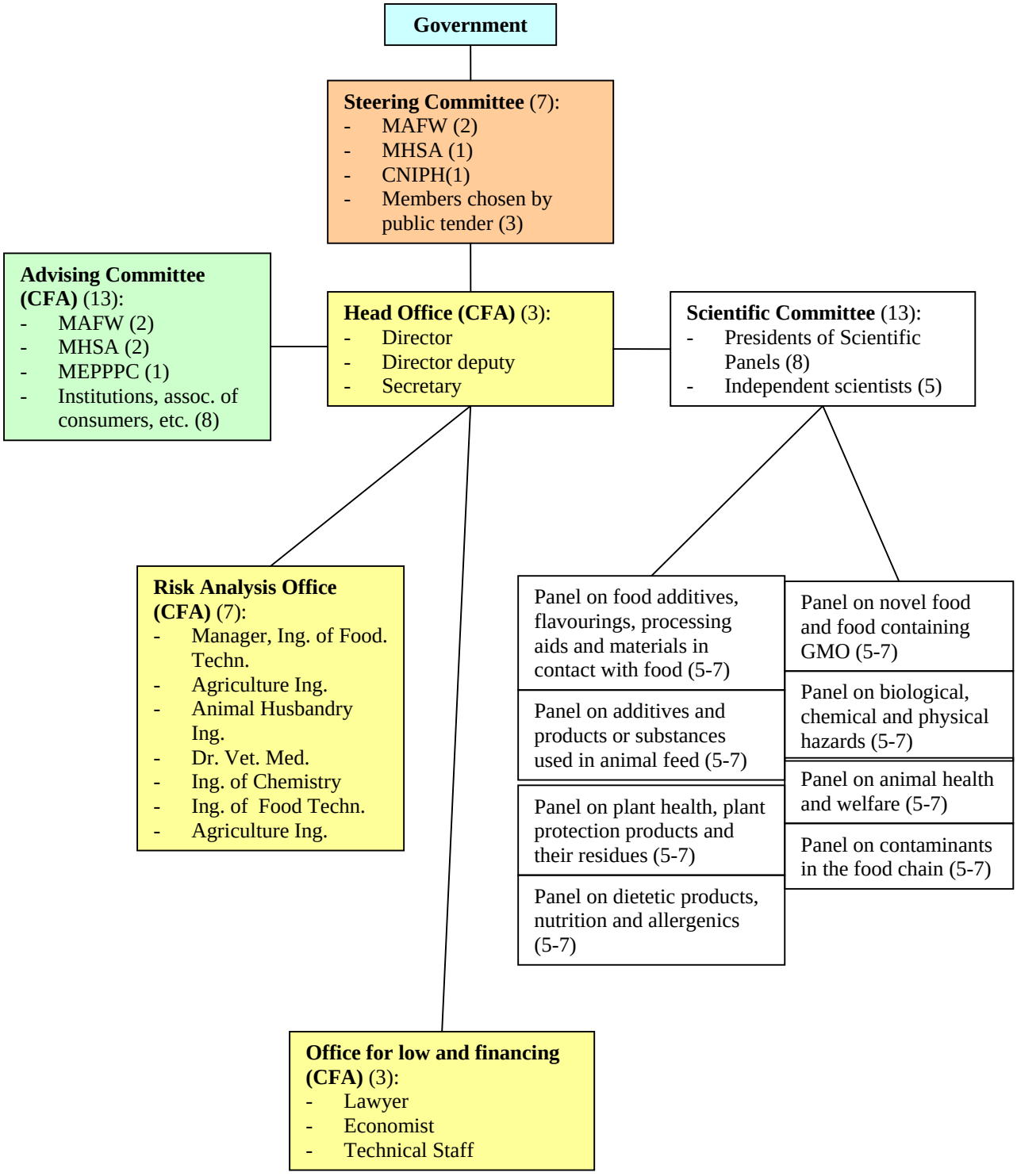


NOTE: The **decision** is granted **for a maximum** of **5 years**
If new information becomes available to the applicant and/or CGAGP a new **decision** will be taken to amend or annul the valid permit.
The applicant has to submit an application for **extension** of the permit within **9 months** prior to **expiry** of the permit. The CGAGP has to make a **decision** and if the **extension** is granted, it cannot run for more than **5 years.**

ANNEX 5.

The Structure of the Croatian Food Agency (CFA)

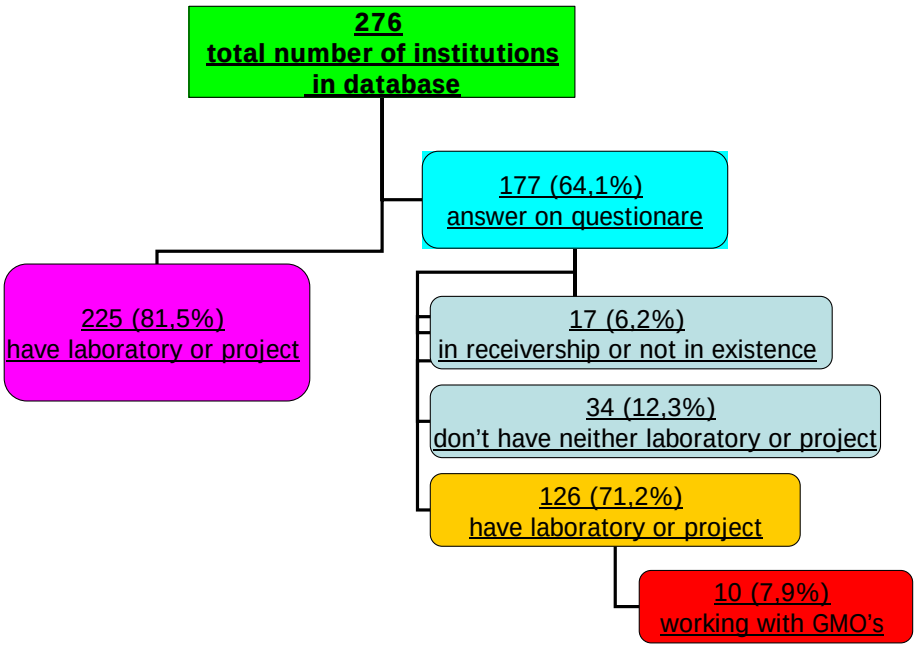
MAFW = Ministry of Agriculture, Forestry and Water Management;
MHSA = Ministry of Health and Social Affairs
CNIPH = Croatian National Institute for Public Health
MEPPPC = Ministry of Environmental Protection, Physical, Planning and Construction



ANNEX 6.

Report on National Questionary (February 5th, 2004)

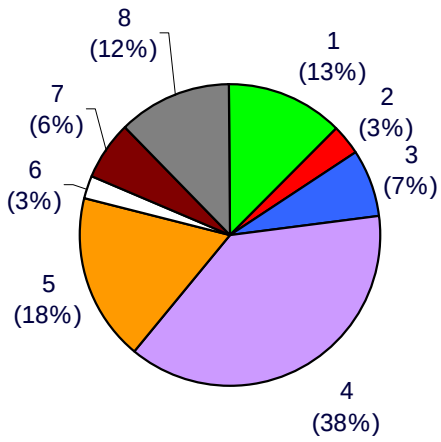
INFORMATIONS ABOUT INSTITUTIONS



INSTITUTIONS REPRESENTED BY CATEGORIES

Category	Of total number	Of answers
1. Scientific and research institutions	35 (15,6%)	32 (25,4%)
1a) medicine and health	6 (2,7%)	5 (4,0%)
1b) veterinary and agronomy	13 (5,8%)	12 (9,5%)
1c) other	16 (7,1%)	15 (11,9%)
2. Institutions with research activity and manufacturing	9 (4,0%)	5 (4,0%)
3. Institutions with laboratories for control and scientific research	20 (8,9%)	15 (11,9%)
3a) medicine and health	16 (7,1%)	11 (8,7%)
3b) veterinary and agronomy	2 (0,9%)	2 (1,6%)
3c) water management	2 (0,9%)	2 (1,6%)
4. Industry	104 (46,2%)	47 (37,3 %)
4a) food and agriculture	75 (33,3%)	36 (28,6%)
4b) pharmaceutical industry	10 (4,4%)	6 (4,8%)
4c) chemical industry	19 (8,4%)	5 (4,0%)
5. Institutions with routine control	50 (22,2%)	27 (21,4%)
5a) medicine and health	23 (10,2%)	9 (7,1%)
5b) veterinary and agronomy	13 (5,8%)	9 (7,1%)
5c) water management	6 (2,7%)	3 (2,4%)
5d) other	8 (3,6%)	6 (4,8%)
6. Other	7 (3,1%)	-
∑	**225 (100,0%)**	**126 (100,0%)**

INSTITUTIONS REPRESENTED BY CATEGORIES



1. Scientific and research institutions

2. Institutions with research activity and manufacturing

3. Institutions with laboratories for control and scientific research

4. Industry

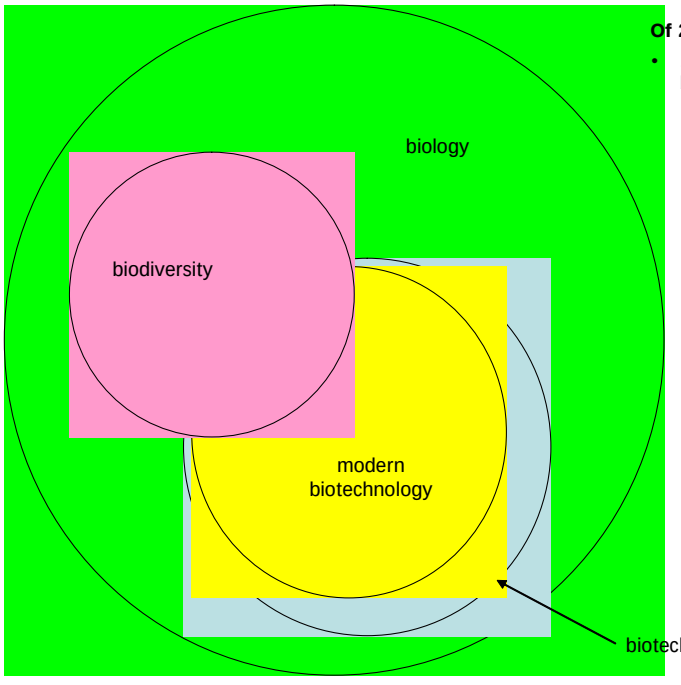
5. Institutions with routine control

6. Other

7. Institutions in receivership or not in existence

8. Institutions with no laboratories or projects

INSTITUTIONS DEALING WITH BIOLOGY



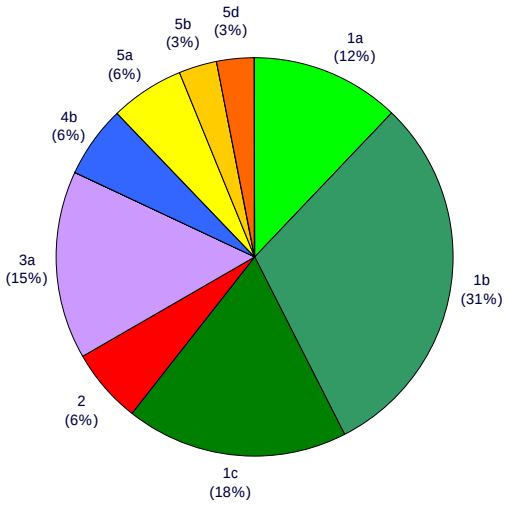
Of 225 institutions:

- 125 (55,6%) are dealing with biology:
  - 33 (26,4%) are dealing with bitechnology
  - 28 (22,4%) are dealing with modern biotechnology
  - 20 (17,6%) are dealing with biodiversity, and 9 of them are dealing with biotechnology and modern biotechnology also

INSTITUTIONS DEALING WITH BIOTECHNOLOGY

Category	Of total number	Dealing with biotechnology	%
1. Scientific and research institutions	35 (15,6%)	20	57,1
1a) medicine and health	6 (2,7%)	4	66,7
1b) veterinary and agronomy	13 (5,8%)	10	76,9
1c) other	16 (7,1%)	6	37,5
2. Institutions with research activity and manufacturing	9 (4,0%)	2	22,2
3. Institutions with laboratories for control and scientific research	20 (8,9%)	5	25,0
3a) medicine and health	16 (7,1%)	5	31,3
3b) veterinary and agronomy	2 (0,9%)	-	-
3c) water management	2 (0,9%)	-	-
4. Industry	104 (46,2%)	2	1,9
4a) food and agriculture	75 (33,3%)	-	-
4b) pharmaceutical industry	10 (4,4%)	2	20,0
4c) chemical industry	19 (8,4%)	-	-
5. Institutions with routine control	50 (22,2%)	4	8,0
5a) medicine and health	23 (10,2%)	2	8,7
5b) veterinary and agronomy	13 (5,8%)	1	7,7
5c) water management	6 (2,7%)	-	-
5d) other	8 (3,6%)	1	12,5
6. Other	7 (3,1%)	-	-
∑	**225 (100,0%)**	**33**	**14,7**

INSTITUTIONS DEALING WITH BIOTECHNOLOGY



1. Scientific and research institutions
- 1a) medicine and health
- 1b) veterinary and agronomy
- 1c) other

2. Institutions with research activity and manufacturing

3. Institutions with laboratories for control and scientific research
- 3a) medicine and health
- 3b) veterinary and agronomy
- 3c) water management

4. Industry
- 4a) food and agriculture
- 4b) pharmaceutical industry
- 4c) chemical industry

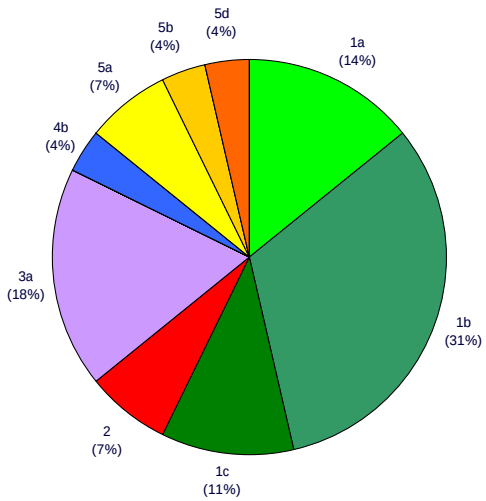
5. Institutions with routine control
- 5a) medicine and health
- 5b) veterinary and agronomy
- 5c) water management
- 5d) other

6. Other

INSTITUTIONS DEALING WITH MODERN BIOTECHNOLOGY

Category	Of total number	Dealing with modern biotechnology	%
1. Scientific and research institutions	35 (15,6%)	16	45,7
1a) medicine and health	6 (2,7%)	4	66,7
1b) veterinary and agronomy	13 (5,8%)	9	69,2
1c) other	16 (7,1%)	3	18,8
2. Institutions with research activity and manufacturing	9 (4,0%)	2	22,2
3. Institutions with laboratories for control and scientific research	20 (8,9%)	5	25,0
3a) medicine and health	16 (7,1%)	5	31,3
3b) veterinary and agronomy	2 (0,9%)	-	-
3c) water management	2 (0,9%)	-	-
4. Industry	104 (46,2%)	1	1,0
4a) food and agriculture	75 (33,3%)	-	-
4b) pharmaceutical industry	10 (4,4%)	1	10,0
4c) chemical industry	19 (8,4%)	-	-
5. Institutions with routine control	50 (22,2%)	4	8,0
5a) medicine and health	23 (10,2%)	2	8,7
5b) veterinary and agronomy	13 (5,8%)	1	7,7
5c) water management	6 (2,7%)	-	-
5d) other	8 (3,6%)	1	12,5
6. Other	7 (3,1%)	-	-
∑	**225 (100,0%)**	**28**	**12,4**

INSTITUTIONS DEALING WITH MODERN BIOTECHNOLOGY



1. Scientific and research institutions
1a) medicine and health
1b) veterinary and agronomy
1c) other

2. Institutions with research activity and manufacturing

3. Institutions with laboratories for control and scientific research
3a) medicine and health
3b) veterinary and agronomy
3c) water management

4. Industry
4a) food and agriculture
4b) pharmaceutical industry
4c) chemical industry

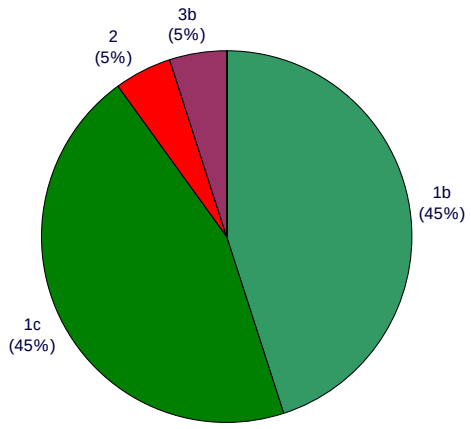
5. Institutions with routine control
5a) medicine and health
5b) veterinary and agronomy
5c) water management
5d) other

6. Other

INSTITUTIONS DEALING WITH BIODIVERSITY

Category	Of total number	Dealing with biodiversity	%
1. Scientific and research institutions	35 (15,6%)	18	51,4
1a) medicine and health	6 (2,7%)	-	-
1b) veterinary and agronomy	13 (5,8%)	9	69,2
1c) other	16 (7,1%)	9	56,3
2. Institutions with research activity and manufacturing	9 (4,0%)	1	1,1
3. Institutions with laboratories for control and scientific research	20 (8,9%)	1	5,0
3a) medicine and health	16 (7,1%)	-	-
3b) veterinary and agronomy	2 (0,9%)	1	50,0
3c) water management	2 (0,9%)	-	-
4. Industry	104 (46,2%)	-	-
4a) food and agriculture	75 (33,3%)	-	-
4b) pharmaceutical industry	10 (4,4%)	-	-
4c) chemical industry	19 (8,4%)	-	-
5. Institutions with routine control	50 (22,2%)	-	-
5a) medicine and health	23 (10,2%)	-	-
5b) veterinary and agronomy	13 (5,8%)	-	-
5c) water management	6 (2,7%)	-	-
5d) other	8 (3,6%)	-	-
6. Other	7 (3,1%)	-	-
∑	**225 (100,0%)**	**20**	**8,9**

INSTITUTIONS DEALING WITH BIODIVERSITY



1. Scientific and research institutions
1a) medicine and health
1b) veterinary and agronomy
1c) other

2. Institutions with research activity and manufacturing

3. Institutions with laboratories for control and scientific research
3a) medicine and health
3b) veterinary and agronomy
3c) water management

4. Industry
4a) food and agriculture
4b) pharmaceutical industry
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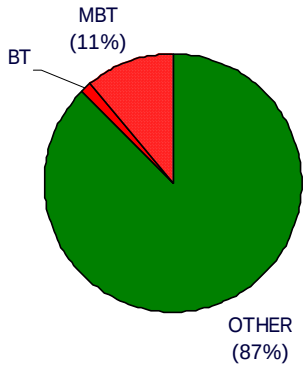
5. Institutions with routine control
5a) medicine and health
5b) veterinary and agronomy
5c) water management
5d) other

6. Other

LABORATORIES DEALING WITH BIOTECHNOLOGY AND MODERN BIOTECHNOLOGY



Total of 518 laboratories:

- 65 (12,5%) are dealing with biotechnology(BT)
- 57 (11%) are dealing with modern biotechnology (MBT)

LABORATORIES DEALING WITH BIOTECHNOLOGY AND MODERN BIOTECHNOLOGY

	Of total number in database	Received answers
Total number of laboratories	518	407
Dealing with biotechnology	65	59
Dealing with modern biotechnology	57	54

QUALITY SYSTEMS AND STANDARDS

From total informations in database

- total of 518 laboratories within 220 institutions
- 69 laboratories (13,3%) within 21 institutions (9,5%) have quality systems and standards

From received answers

- total of 407 laboratorija within 121 institutions
- 50 laboratories(12,3%) within 19 institutions (15,7%) have quality systems and standards

NUMBER OF INSTITUTIONS WITH QUALITY SYSTEMS AND STANDARDS

Category	Total number of institutions	Number of institutions with quality systems and standards	%
1. Scientific and research institutions	35	5	14,3
1a) medicine and health	6	2	33,3
1b) veterinary and agronomy	13	2	15,4
1c) other	16	1	6,3
2. Institutions with research activity and manufacturing	9	1	11,1
3. Institutions with laboratories for control and scientific research	20	1	5,0
3a) medicine and health	16	1	6,3
3b) veterinary and agronomy	2	-	-
3c) water management	2	-	-
4. Industry	104	9	8,7
4a) food and agriculture	75	6	8,0
4b) pharmaceutical industry	10	2	20,0
4c) chemical industry	19	1	5,3
5. Institutions with routine control	50	5	10,0
5a) medicine and health	23	4	17,4
5b) veterinary and agronomy	13	1	7,7
5c) water management	6	-	-
5d) other	8	-	-
6. Other	7	-	-
$\sum$	225	21	9,3

NUMBER OF INSTITUTIONS AND LABORATORIES WITH QUALITY SYSTEMS AND STANDARDS

Category	laboratories	% of 518	institutions	% of 220
1. Scientific and research institutions	16	3,1	5	2,3
1a) medicine and health	13	2,5	2	0,9
1b) veterinary and agronomy	2	0,4	2	0,9
1c) other	1	0,2	1	0,5
2. Institutions with research activity and manufacturing	2	0,4	1	0,5
3. Institutions with laboratories for control and scientific research	12	2,3	1	0,5
3a) medicine and health	12	2,3	1	0,5
3b) veterinary and agronomy	-	-	-	-
3c) water management	-	-	-	-
4. Industry	28	5,4	9	4,1
4a) food and agriculture	14	2,7	6	2,7
4b) pharmaceutical industry	4	0,7	2	0,9
4c) chemical industry	10	1,9	1	0,5
5. Institutions with routine control	11	2,1	5	2,3
5a) medicine and health	10	1,9	4	1,8
5b) veterinary and agronomy	1	0,2	1	0,5
5c) water management	-	-	-	-
5d) other	-	-	-	-
6. Other	-	-	-	-
∑	69	13,3	21	9,5

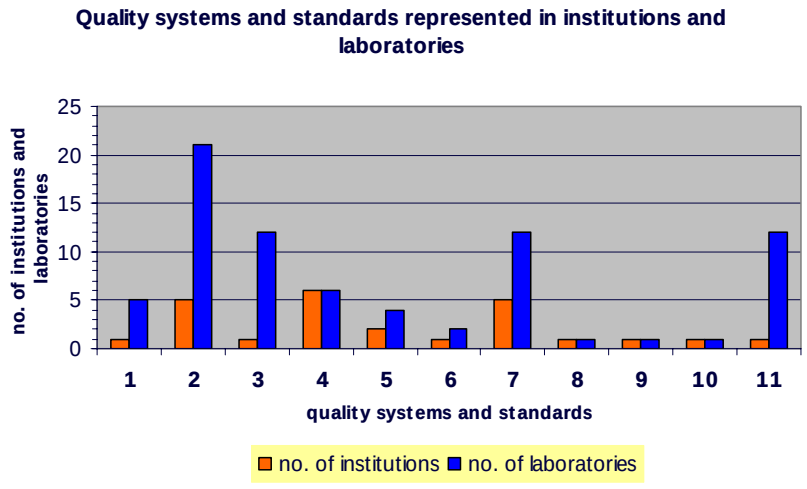
Institutions and laboratories in process of imposition quality systems and standards

- 10 (1,9%) laboratories within 8 (3,6%) institutions are in process of imposition quality systems and standards

- **Scientific and research institutions:**
  - medicine and health: 1 laboratory impositioning ISO 17025
  - other: 1 laboratory impositioning ISO 17025

- **Industry:**
  - food and agriculture: 7 laboratories within 5 institutions imposition quality systems and standards;
    2 laboratories impositioning ISO 17025
    3 laboratories impositioning HACCP
    2 laboratories impositioning ISO 14000

- **Institutions with routine controle:**
  - veterinary and agronomy: 1 laboratory impositioning ISO 17025



1. ISO 14000 **2**. ISO 17025 **3**. ISO 15189 **4**. GLP **5**. GMP
6. Ordinance on seed quality, declarations and packaging **7**. HACCP
8. WHO **9**. SOP **10**. SSOP **11**. QA/QC