

THE NATIONAL BIOSAFETY FRAMEWORK OF CROATIA

Seminar for Parliamentarians¹, 16 December 2004, Zagreb, Croatia.

Summary report – draft 3 January 2005

Introductory presentations.

The seminar was opened by **M. Sc. Jadran Antolovic, State Secretary of the Ministry of Culture of Croatia**, who welcomed the Parliamentarians, the participants and the foreign resource persons, Mr. Drs. Piet van der Meer², prof. Julian Kinderlerer³ and Dr. Helmut Gaugitsch⁴. Mr Antolovic thanked the State Institute for Nature Protection for organising this timely seminar and pictured the importance of the seminar in the context of the ongoing discussions of Parliament on the draft GMO Act.

Mr. Drs. Piet van der Meer gave a brief overview of the historical and international context of national biosafety frameworks, their main components and practical implications. As a start, he described the different types of regulation that can apply to biotechnology, such as regulation addressing safety (e.g. environmental safety, food safety and worker protection), Product Regulation (e.g. seed registration, pharmaceuticals, pesticides) and generic issues (e.g. IPR, ethics, liability).

In focusing on biosafety regulations, he gave a historical overview touching upon the first rDNA applications in 1972, the OECD rDNA safety guidelines in 1986, the adoption of Agenda 21 and the Convention on Biological Diversity in 1992, the adoption of the Cartagena Protocol on Biosafety in 2000, the World Summit on Sustainable Development in 2002 and the first meeting of the parties to the Crthagena Protocol in 2004.

Referring to Article 8g of the CBD and Article 2 of the Biosafety Protocol, which oblige Parties to take the necessary and appropriate legal, administrative and other measures, he explained that National Biosafety Frameworks NBFs vary from country to country, but usually have a number of common components:

1. a policy on biotechnology and biosafety
2. a regulatory regime for biosafety
3. a system for handling requests for permits
4. a system of following up including enforcement and monitoring
5. public information and public participation

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In addressing policies for biosafety, he some discussed differences and commonalities in existing biosafety policies, including:

- Biosafety policies are almost always part of broader policies (biotechnology, agriculture, science, etc.)
- The process of preparing a biosafety policy builds consensus and integrates different goals into single national vision.
- A written policy can serve as guidance for future choices of stakeholders

Introducing the topic of regulatory regimes for biosafety, Mr. Van der Meer underlined that establishing an adequate level of biosafety is typically an ongoing, iterative process of developing a draft national biosafety framework, implementing the framework, and continuous evaluation and feedback. In addition to continuous evaluation by the Government, a review by a broadly composed panel of 'outside experts', can be very useful. He explained that a review of the biosafety regulation in the current Nature Protection Act was currently being carried out by experts from the CBD Secretariat, Governments, Academia, NGOs and the private sector, including the resource persons present in the seminar.

He announced that prof. Julian Kinderlerer would present later in the seminar the first, general results of that review.

Dr. Meira Bosnic of the State Institute for Nature Protection, and national coordinator of the UNEP-GEF project on Development of the National Biosafety Framework of Croatia presented the results of that project, which started on 7 February 2003

The main objective of the project is the preparation of a National Biosafety Framework in accordance with the relevant provisions of the Cartagena Protocol on Biosafety. The project was originally from 07th February 2003 until 07th August 2004, but was extended for another 5 months and the official end of the Project is on 7th January 2005.

She described the composition of the National Coordination Committee, as well as some challenges in the functioning of the NCC, which caused UNEP to urge the Croatian Government to address this issue.

The results of the project are:

- conducted the National survey of biotech institutions in Croatia
- A database was created from the results
- A survey on existing mechanisms for harmonisation of risk assessment/risk management, mutual acceptance of data and data validation had been conducted
- A survey on existing national biosafety frameworks in the countries of the sub-region
- A survey on the extent and impact of release of LMO's and commercial products had been conducted
- A review and assessment of existing legislation that may impact on the use of modern biotechnology
- Produced public awareness material and access to information for stakeholders

- six workshops were held
- Prepare 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)
- Attendance at regional or sub-regional workshops.

Following up on this introduction, **mr. sc. Krunoslav Capak, dr. med**, expanded on some key achievements in executing the “Development of a Framework for National Biosafety in Croatia”: an educational brochure, a web page, workshops and legislation.

Brochure

The brochure “Development of a Framework for National Biosafety in Croatia” was prepared by the National Committee on Project Coordination. It is intended for the public at large as an informational-educational material aimed at introducing the reader to the GMO problem area in the context of preserving Croatia’s biodiversity. The skeleton brochure consists of frequently asked questions about GMOs, why and how they came to be created, their influence on human health and the environment, the legal system etc. It is a publication based on a similar one published by WHO in 2003. Next, the brochure also includes original texts from the participants of the drafting of the Carthagena Protocol and execution of projects on the legal regulation of this area in Croatia, as well as on this country’s biodiversity.

Web page

Within the Project a web page has been designed the purpose of which is to offer Project information to the public on an electronic medium as well, as is done for all other topical information on the GMO problem area, such as for its legislation or domestic and foreign news about GMOs. Since the page also has an educational role, it includes a glossary with definitions from genetics and biotechnology, with an option to pose questions. Through links, this page is connected to web pages on other domestic and foreign projects and on the institutions concerned with similar problem areas. In the future, this web page should become a part of the wider information system run by the State Institute for Nature Conservation.

Workshops

As part of the Project, six Workshops were held with different target groups and on different subjects, with us also hosting many foreign lecturers:

- The **First Workshop** titled “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 Croatian Institute for Agricultural Counselling Service (CIACS). The members of CAEI are agronomists who work as consultants to farmers all over Croatia.

- The **Second Workshop** titled “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 gathering attended by primary and secondary school teachers of biology and related disciplines from all over Croatia.
- The **Third Workshop** named “Croatian Biosafety-Related Legislation” on 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 **Fourth Workshop** named “GMO problem area in Croatia and Europe” was designed for the NGOs concerned with nature conservancy, representatives of the scientific community and news reporters. The goal of this workshop was for them to exchange, thru the constructive discussion, their personal experiences and information about these topics.
- The **Fifth Workshop** named “**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, 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 Conservation Act (Official Journal of the Republic of Croatia, OJRC 162/03).
- The **sixth workshop**, which is the current workshop, is also the last. Its aim is 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 are defining the omissions and the work still ahead in achieving this objective.

Croatia’s regulation of GMOs

During a longstanding legal vacuum in the GMO area, a *de facto* moratorium was applied in the absence of any legal grounds. In 2003, two key pieces of legislation were enacted, regulating this area. All enumerated EU acts are implemented through these. They are Nature Conservation Act (Official Journal of the Republic of Croatia, OJRC 162/03) and Food Act (OJRC 117/03).

The Nature Conservation Act adopted at the 25 September 2003 Session of the Croatian Parliament 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 wastes. Whereas an authorisation for cross-boundary transport, transit, contained use, intentional introduction into environment, and placing of a GMO or GMO derivatives on the market is issued by the Ministry Competent for Nature

Conservation (MCNC) as the main executor of this regulation, invested with competence for issuing a marketing authorisation in conformity with the designed use of pharmaceuticals, cosmetics and food is the Ministry of Health. For feeds and uses in agriculture, forestry, and fisheries, the Ministry of Agriculture and Forestry issues the authorisations.

For the purpose of monitoring the status and development in the GMO area, providing technical assistance to competent state authorities in the execution of this regulation, Croatian government has set up an Appointed Committee and two Scientific Commissions, i.e.:

1. Appointed Committee on GMO (17 members)
2. Scientific Commission on Contained GMO Use (7 members)
3. Scientific Commission on GMO Introduction into Environment

Prescribed by law are also the application procedures authorising the intentional introduction of GMOs into the environment (food crops, food). With the consent of the Ministry of Agriculture and Forestry and an opinion of the Scientific Commission, the MCNC shall issue the authorisation. The key part of the procedure involves making a risk assessment with all elements of influence on health and environment, elaboration of remedial actions in the case of unforeseeable event, proposing a monitoring of influences on the environment etc. Restrictions have been laid down on the introduction of GMOs into environment in the protected areas, ecological network areas, areas designated for ecological agriculture and ecotourism. The sowing of GMO seeds is only allowed on the surfaces approved by the government on the proposal of the Ministry of Agriculture and Forestry.

For every GMO that one intends to introduce on the market for the first time, an authorisation must be applied for. The Act invests other state administrative bodies with the powers of enacting the regulations with which to regulate the issuing of authorisation for individual products, if they by their designed use pertain to their sphere of competence.

The Food Act regulates the areas of health safety and food safety surveillance. In compliance with the European practice, introduced into the Act for the first time has been a new category of foods, namely, novel foods. Novel food is either a food manufactured by using new technologies, or one that was not until now extensively used for nutrition. In consequence, novel foods come under special procedures for food assessment and for authorising their placing 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 their fulfilment of health safety requirements and of special marketing requirements, the law requires that a special authorisation by the Ministry of Health be issued for such products before their first appearance on the market. The Ministry of Agriculture and Forestry is competent to issue authorisations for such feeds. Any authorisation of such product is liable to a scientifically-based risk assessment to be carried out by the Scientific Commission (Commission on Novel GMO-containing Foods and Feeds) at the Croatian Food Agency. The labelling of foods derived from a GMO is mandatory. For GMO-containing animals, the law also introduces obligatory labelling.

The Food Act and the Nature Conservation Act constitute the legal framework for the legal order in the area of genetically modified organisms. However, for the system prescribed by them to start operating, implemental regulations (more than 20) need to be enacted. Expert Working Groups have written them as part of this Project. The application of the Nature Conservation Act will only begin when all implemental regulations have been passed, Appointed Committees and Scientific Commissions have been established and the laboratory made operational. The same obtains for the GMO-related provisions of the Food Act. In other words, the authorising of GMO food marketing may only be after the passage of the implemental regulation that shall elaborate the authorisation issuance procedure.

Based on Article 133 of the Nature Conservation Act, a decree was enacted in 2003 laying down allowances by individual product ingredients of the 15 GMO species allowed in the EU for accidental and technically unavoidable product contamination with 0.9%. A zero GMO tolerance was set for seeds, respectively plant reproduction material.

Another regulation passed stipulates the requirements to be fulfilled by the GMO detection laboratories.

Before putting the Nature Conservation Act provisions in application and before passing the implemental regulations, competence for nature conservancy was transferred to the Ministry of Culture. This was a consequence of a change in the state administration system. Thereby both the continuity of the implementation of this act and the enacting of implemental regulations were disrupted. After that, the Ministry of Culture decided to separate the GMO problem area from the Nature Conservation Act and pass a special umbrella act on GMO, 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 among the state law enforcement agencies. Instead of envisaging the drawing up of implemental regulations, it preferably incorporates implemental provisions into the law itself.

Prof. Julian Kinderlerer discussed some key considerations regarding the regulatory regime for biosafety in general and the existing regulatory regime of Croatia in particular.

In introducing the topic, he explained that in developing regulatory regimes a number of considerations are important:

- Objective ('Why')
- Scope ('What')
- Structure ('How')

He explained that the structure of a regulatory regime is usually a combination of:

- Enabling legislation (Act, Bill, Law), which requires Parliamentary involvement
- Implementing regulations (Regulation, Order, Ordinance, Decree, Rule), which are usually issued by the Government
- Guidelines, which are non legally binding.

In defining the structure of the regulatory regime, a number of key questions are important:

- Use existing regulatory (sectoral) regime or develop a new, comprehensive regime?
- One national competent authority, local competent authorities?
- - What is addressed on which level?, i.e. what is put in the enabling Act – in the Implementing regulations, and in Guidelines?

Focusing on this last point, he emphasised that while it is important to include fundamental aspects such as objective and scope in the enabling Act, technical and procedural details are best left to regulations and guidelines.

Focusing on the regulatory regime of Croatia, he presented the general conclusions of the reviewers on the overall framework and on the Nature Protection Act.

In Croatia, activities with GMOs are currently explicitly addressed in the Nature Protection Act, and the Food Act, which both came into force in 2003. In addition to the provisions of this chapter, there are two implementing regulations: The Regulation on the minimum threshold for GMO's in products below which the products placed on the market shall not have to be labelled as products containing GMO's, and The Ordinance on the conditions to be fulfilled by a laboratory for testing, control and monitoring of GMO's and products containing GMO's.⁵

As in every country, certain other legislation may also be relevant for activities with GMOs. The Croatian Government has listed some of that legislation on its website⁶, with a brief summary of each piece of legislation.

The reviewers are of the opinion that it is very commendable that the Croatian Government has listed this legislation on its website, as it provides transparency as well as service to applicants, who are often not aware of the types of legislation that may apply to their activities. However, the overview of the legislation also makes clear that there may be cases of duplication of regulation or perhaps even contradicting regulations. It is strongly advised that the Croatian Government reviews all these pieces of legislation and regulations, with a view to ensuring consistency and avoiding overlap or contradiction. Safety is not served with contradicting rules.

The regulatory system as laid down in the Nature Protection Act is to a large extent in line with similar legislation and regulations in many other countries, and offers a good basis for a transparent and workable system that is consistent with Croatia's (future) international obligations.

However, a number of aspects deserve closer attention to ensure that the resulting regulatory regime will indeed be transparent and workable.

1. the GMO related definitions in Part I divert in wording from related definitions in the Biosafety Protocol and the EU Directives on GMOs, and it is

⁵ Official Gazette No. 98/04

⁶ http://en.gmo.hr/index.php/zakonska_regulativa/hrvatski_zakoni.

advisable to take a close look at those definitions and stick as close to those as possible.

2. The Act contains in a number of articles very much technical detail. It is advised to revisit the Act and the regulations from the point of view to moving technical and procedural details as much as possible to regulations and guidelines.
3. In many articles reference is made that further (technical) details will be laid down in by-laws and rule books. Only two of those regulations are published on the Croatian web site to date. Since many of the others regulations and rule books are crucial for a proper functioning of the system, it is important that the other regulations be worked out in an integrated package, together with the guidelines.
4. A number of articles raise questions as to how this Act (and in particular the committee on Food and Feed) relates to the Food Act. Further clarification on the coordination is needed. The same applies to the bodies charged with enforcement.
5. A few articles are phrased in such a way that the resulting system would be very different from the 'standard' permit system as we find in most countries in the world with functioning biosafety systems.

This is particularly the situation with article 114.3 and article 140. Article 114 would result in an unqualified 'ban' on GMOs. Such as 'ban' is not in place in any other country inside or outside the EU, goes against the 'case by case' approach of the rest of the Act and goes against the EU Directives.

Dr. Helmut Gaugitsch presented a number of possibilities for Croatia to obtain technical and financial support in further developing and implementing its national biosafety framework, including:

- EU Projects
- International Projects
- Bilateral Projects

For the EU projects, he discussed:

- 1) Financing memorandum with the European Commission,
 - Phare
 - o Twinning
 - o Technical assistance
 - o Investment
 - Cards
- 2) TAIEX (Technical Assistance Information Exchange Service)
 - Short Expert Missions
 - Study Visits

He explained in more detail the EU Twinning projects and discussed the following aspects:

- Service oriented
- Assistance in implementing EU regulatory framework
- RTA expert on the spot

- Short term experts
- Longer duration (1 to 2 years)
- Twinning light (no RTA, 6 months)
- Practical
- Combination with Technical Assistance, Investment possible

As examples of international support projects, he highlighted:

- GEF – Biosafety projects, as implemented by UNDP, UNEP and World Bank, and which include the UNEP-GEF project on Development of National Biosafety Frameworks, the UNDP/UNEP/WB -GEF projects on Implementation of National Biosafety Frameworks and the UNEP-GEF BCH project.
- World Bank and FAO projects on biotechnology development which often also include biosafety components.

As examples of bilateral projects he mentioned that there are quite a number of bilateral projects on biosafety, such as the project "implementation of national biosafety frameworks in pre-accession countries in central and Eastern Europe", which was funded by the Dutch Government and coordinated by Piet van der Meer.

General Discussion

In response to the question what is Austria's view on new EU regulation on Food and Feed and the Moratorium, Dr. Gaugitsch explained that Austria makes a distinction between deliberate release (e.g. field trials) and placing on the market. In Austria very few notifications for releases have been handled thus far, and no releases have taken place to date, for several reasons, because 1) there are hardly any companies in Austria working with GMOs intended for deliberate release, 2) the political situation. Dr. Gaugitsch explained that there are many contained use applications in Austria and he underlined that there is no moratorium on field trials of GMOs in Austria. As regards placing on the market: Dr. Gaugitsch explained that there is no general ban, but Austria has prohibited three individual GM crops. Austria also supported the 'de facto' moratorium, which meant that some governments of EU member states had decided not to give a positive decision on market approvals as long as certain requirements are not fulfilled, such as traceability and regulations on co-existence. He also explained that the new Regulation (1829/2003/EC) is quite different, with – among others – the new European Food Safety Authority (EFSA) that has a key role in the assessment. Finally, Dr. Gaugitsch explained that Austria's position is strongly influenced by the organic farmers.

In response to a question how to deal with GMO enzymes, Prof. Kinderlerer explained that enzymes are not covered by the EU Directives on GMOs, but that they are covered by the Food and Feed regulation. He drew the attention to the fact that most feed contains GMOS, because much of it comes from US, Argentina or Brazil. He also explained that almost all vitamin C used in Europe in food production is transgenic; however foods using vitamin C do not have to be labelled.