

GMOs

THE NATIONAL BIOSAFETY FRAMEWORK OF CROATIA

Workshop 16 – 17 December 2004, Zagreb, Croatia¹

The workshop was opened by **Dr. Marina Mlakar**, Deputy Minister of the Department for Nature Protection, who welcomed the participants and the foreign guests, which included resource persons from EU countries and observers from Bosnia and Herzegovina, Bulgaria, Hungary, Macedonia, Romania, Serbia and Slovenia.

Dr. Mlakar explained that this workshop builds on a seminar that was held earlier that day for Parliamentarians, and that the main aim of the workshop is to take stock of the biosafety system in Croatia and to identify what needs still to be done to make the system operational.

1. National Biosafety Frameworks, policies and regulations.

Mr. Drs. Piet van der Meer introduced the main components and practical implications of national biosafety frameworks.

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

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,

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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.

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')

In defining the objective of a regulatory regime, it is important to look at the national policies on biosafety and biotechnology as well as at international obligations such as the CBD, the Biosafety Protocol, the WTO and the Codex Alimentarius.

The scope of a regulatory regime is determined by 2 elements:

1. Which activities are covered?, e.g.:
 - Contained use,
 - Introduction into the environment,
 - Placing on the market,
 - transboundary movement.
2. With what? e.g:
 - LMOs/GMOs
 - Organisms with novel traits

The structure of 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.²

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 website³, 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

² Official Gazette No. 98/04

³ 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. 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.

Dr. Darja Stanič-Racman, the Coordinator of UNEP-GEF Biosafety project for Slovenia from Ministry for the Environment and Spatial Planning, introduced the current regime for biosafety in Slovenia.

She explained that the Management of GMO Act covers: Contained use, deliberate release, placing on the market, Export, transit of GMOs. Excluded are: Feed, Food and Transport.

Involved in the procedures of the GMO Act are the Ministry of the environment, spatial planning and energy, the Ministry of agriculture, forestry and food, and the Ministry of health, as well as a Scientific committee Contained use and a Scientific committee Deliberate release and Placing on the market.

Next, she discussed which regulations are in force and which are in draft.

For the functioning of the committees are in force rules that the government shall provide the method of operation of the two committees, the manner and form of providing expert opinions in procedures according to this Act, the manner and form of reporting of the committees and procedures for ensuring the exclusion of interest and protection of data which are confidential in accordance with this Act, in the work of the committees. In draft are Procedures for selection of representatives of NGOs for the GMO commission and Regulation on GMO register .

For contained use are in force

- Regulation on the criteria to classify each contained use of GMO into a specific class, containment and other safety measures, rules of management and other conditions for individual class shall be specified in a separate regulation.
- Regulation on the detailed contents of the notification
- Regulation on the elements and the extent of the risk assessment for contained use and the methodology for its production

In Draft are: Detailed contents and the extent of the emergency plan in relation to the class of the work, the methodology of its preparation, examining and supplementing and the manner and extent of informing and warning competent bodies, services and the general population in the event of an accident.

For deliberate release are in draft:

- Regulation on methodology, the elements, and extent of the assessment of risk of the deliberate release of the GMO into the environment
- Regulation on contents of the notification
- Regulation on report on the results of the deliberate release of the GMO into the environment

For placing on the market have not yet been drafted:

- Regulation on elements and the extent of the assessment of the risk of placing a product on the market and the methodology of its production.
- Regulation on the contents of the notification
- Regulation on the extent and elements of the assessment report
- Regulation on the contents and extent of the programme of monitoring and the manner and extent of reporting

Lessons learned for contained use are:

- SI is in the process of testing the notification system with four real notifiers.
- Guidelines for notification procedure for administrators and notifiers are drafted.
- Simulations of CU inspection and joined inspections (AT, NL) were already organized. Guidelines and check lists are already prepared.
- Information system for handling notification for CU is running. Guidelines for administrators and notifiers are drafted.

There were no deliberate releases of GMO in SI yet.

SI is involved in the EU procedure for placing on the market since 1.5. 2004.

SI has not yet been lead CA. The first conclusion is that the system as set up in GMO Act is workable.

The Most difficult point is intersectoral coordination. Rules for reaching decisions should be determined and arguments should be scientifically based. Government of SI has provided the Rules on procedures for preparing SI position in EU, which address this matter.

Ms. Katya Trichkova of the Ministry of the Environment of Bulgaria elaborated on the biosafety framework of Bulgaria.

She explained that no specific policy paper on biosafety has been elaborated yet.

The current regulatory regime for biosafety consists of a 1996 - Regulation for release of GM higher plants, created by recombinant DNA.

The main principles of that regulation are:

- Permit regime for release of GMHP for research or commercial purposes
- Notification to the Council for Safe Use of GMHP

The competent authority is the Council for safe use of GMHP
Chairman – Minister of Agriculture and Forestry

Scientific Secretary – distinguished scientist
5 Permanent Members – Ministry of Environment and Waters, Ministry of Agriculture and forestry, Ministry of Health, Scientific organisations.
External experts may be drawn in the Council's activities

The Council allows or reject the release of GMHP in the territory of Bulgaria,
Evaluates the risk assessment and safety measures, proposed by the applicant
Keeps records and Controls the releases approved.

Permits for field trials only were issued on: maize, potato, sunflower and tobacco.

Over the years a number of large scale field trials were carried out:

1999 – 13 000 ha
2000 – 19 000 ha
2001 – 6 400 ha
2002 – 2 200 ha
2003 – 2 119,5 ha
2004 – 0,5 ha

Special conditions of field trials include:

- Contracts between the company and the farmers that will undertake the large the large-scale field experiments must be signed.
- GM crop to be kept at a distance of 50 m minimum;
- Large-scale field trials to be carried out under the supervision of the representative of the applicant.
- All of the remaining seed quantities other than planting should be returned to the applicant;
- The farmers must not use the seeds for other purposes;
- Farmers are obliged to harvest separately the GM plants from non- GM and to store them also separately in special storehouses with respective designation;
- The production should be bought by a company, which is going to export it out of Bulgaria and EU member's countries; In case that the production is not bought out it must be destroyed and plant residues should be buried during the autumn soil tillage;
- Farmers who are supposed to test the hybrids should receive full explanations by the representatives of the company: how the hybrids were developed, practical instructions how to carry on the technology trials, etc.

The next step in developing the regulatory regime for GMOs is the development of a New Draft Law on GMOs – in accordance with the EU Directives 90/219/EEC and 2001/18/EC, Requirements of Cartagena Protocol and the Aarhus Convention.

The scope of that New Law covers:

- Contained use
- Deliberate release
- Placing on the market
- Transboundary movements

The competent authorities are:

- Minister of Environment and Water for contained use and deliberate release
- Minister of Agriculture and Forestry for placing on the market of GMOs.

A consultative Scientific Committee on GMOs will also be established.

The main principles of the new Act include:

- Permit regime for all activities
- Advanced Informed Agreement for transboundary movements
- Environmental risk assessment
- Public hearings (for deliberate releases and placing on the market)
- Post-release/post-marketing monitoring
- Labelling and traceability requirements

2. National Biosafety frameworks - Handling requests for permits.

Mr. Drs. Piet van der Meer introduced the topic of handling requests for permits and explained that handling requests for permits typically follow three steps:

1. administrative processing
2. risk assessment
3. decision making

Administrative processing involves: registering of requests, checking for completeness, storing in databases and forwarding to involved institutions. He discussed some of the practicalities that are involved in these steps.

He underlined that for risk assessment it is very important to have a proper understanding the science and practice of the genetic modification.

He explained that the principles of risk assessment can be found in many internationally agreed documents, such as the 1986 OECD Guidelines, the 1995 UNEP Technical Guidelines, the Cartagena Protocol on Biosafety and the EU Directives.

All these documents reflect the extensive international practice of conducting risk assessment in a number of steps:

1. Identify potential adverse effects
2. Estimate likelihood
3. Evaluate identified risks
4. Consider management strategies
5. Assess overall impact

In following these steps, the risk assessment takes into account:

- The Host organism
- The Inserted genes / sequences

- The Characteristics of the GMO
- The Intended use (e.g. field trial or placing on the market)
- Receiving environment (e.g. presence of wild relatives)
- Existing situation (e.g. current agricultural practice).

He illustrated each of these steps and points, and underlined that for a transparent and scientifically sound risk assessment, it is imperative to be very systematic.

A risk assessment typically starts with a brief description (often on a cover note) of the host organism involved (e.g. maize), the inserted genes/sequences, as well as of the intended activity (e.g. field trial, size, duration).

Next follows an evaluation of the potential risk, if any, of each of the inserted genes/sequences, followed by an evaluation of all the inserted genes/sequences together addressing the question of synergetic effects, taking also into account results of earlier tests with the GMO, if available. Next, the risk assessment addresses the question whether any potential risks identified are manageable, and in a last step the question is addressed whether any remaining risks are acceptable, taking into account the potential risks of the non modified host.

He presented some formats (cover notes and tables) for risk assessment which are often used as tools to ensure a systematic approach.

Prof. Julian Kinderlerer took the discussion to the next step, i.e. the 'decision making', in which he also addressed the application of the Precautionary Approach.

He explained that in many countries part of the step of decision making is a round of 'public participation', which will be discussed later in the program.

For now he focused on the question of how to place the results of a risk assessment in a broader context for decision making. He explained that it depends on a country's regulatory system what finally can be taken into account in decision making.

He gave several examples of how the results of risk assessment and other considerations can be taken into account in decision making.

He also explained that one of the aspects that is very important in this is the issue of risk perception, and he illustrated that risk perception can vary strongly from one person to the other and from one country to the other. The fact that 200 million Americans have eaten GM food for many years and that no adverse effects have been reported does not seem to impress the average European consumer.

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3. Monitoring and Enforcement.

Dr. Helmut Gaugitsch of the Austrian Federal Environment Agency Ltd, introduced the topics of monitoring and enforcement.

He explained that these topics are often discussed together as 'follow up' activities, but that they refer to different things. Monitoring looks at possible effects in the environment, while enforcement looks at compliance.

Focusing on monitoring, Dr. Gaugitsch addressed the following topics:

- Monitoring according to Directive 2001/18
- Case-specific monitoring
- Requirements for General Surveillance
- Existing environmental networks
- Recommendations

The EU Directive 2001/18/EC lays down requirements for

- Field releases in Annex III (information requirements)
- Placing on the market in Annex VII plus Guidance notes

This is not a formalized procedure, the notifier has to develop monitoring programme.

The role of the Authorities is:

- Evaluation of monitoring plan (additional requests)
- On-site inspections
- Probably perform monitoring in co-operation with company and research institutions at field releases
- Monitoring and inspection concerning placing on the market

Monitoring requires an interdisciplinary approach covering effects on the environment and human health.

An important distinction is between 1) case - specific Monitoring (based on the risk assessment) and 2) General Surveillance

The Legal requirement for general surveillance is Based on Annex VII and the Guidance Notes

- What are the questions to be answered? (hypothesis, checklist)
- Scientifically valid design:
- Parameters and methods
 - o Time frame
 - o Sampling and statistics
 - o Baseline
 - o Reference areas
 - o Is the programme able to answer the questions in a scientific way?

Gaugitsch explained that there are several grey areas, in which answers have to be found for questions such as:

- There is no Monitoring without hypothesis
- What is a hypothesis?
- Indicators for testing
- Distinction between CS-monitoring and GS?
- More important:
 - o Which kind of monitoring is necessary?
 - o Arguments for not performing certain tasks
 - o Interpretation of results
 - o Compilation of results (regional, national and EU-wide)
 - o Responsibilities of notifiers?

He illustrated the Austrian study „Biodiversity hotspots in agro-ecosystems as a basis for risk assessment and monitoring of GMOs“, available end of 2005.

In ending, he gave the following general recommendations:

- Specific development and implementation of General Surveillance
- Use experience from Biodiversity and FFH Monitoring
- Develop concept (list of questions) for GS
- General Surveillance is the answer, but what is the question?
- Grey area between CS-Monitoring and GS:
- Further work on baseline, indicators, reference areas
- Regional basis, EU wide compilation

Mr. Drs Piet van der Meer introduced the topic of Enforcement.

Important aspects of a meaningful enforcement system require:

- Clear legal basis for inspection
- Train inspectors
- Prioritize inspections
- Record keeping
- Evaluate performance of system
- Maintain transparency

The legal basis should include the authority for inspectors to:

- Enter premises
- Take written statements
- Issue notices (correction, abatement)
- Give testimony for prosecutions

Training of inspector should include:

- Technical knowledge
- Legal training
- Interpersonal skills

In cases where large numbers of GMO activities need to be inspected, a prioritization needs to be made.

Relevant elements for the prioritisation are:

- Level of risk:
- Assessment made at application
- Assessment made at previous inspection
- Time since last inspection
- Past performance of applicant
- Other factors: Public opinion, politics

Key to efficient and effective enforcement is adequate record keeping.

Records need to be systematic and records should be accessible to: Inspectors and reviewers. Confidential information needs to be secured.

In the discussion following these presentations, the need for including effects on human health in the monitoring programs were discussed.

4. Public information and public participation

Dr. Helmut Gaugitsch introduced the topic of public information, in which he discussed the following topics:

- Public Information as a prerequisite for Public Participation
- EU Directive 2001/18/EC
- Example: Austrian GMO Regulations
- UN-ECE Aarhus Convention

He discussed public information under the Cartagena Protocol, under EU Directive 2001/18/EC – Part B, and under EU Directive 2001/18 – Part C.

He explained that under the EU Directive, registers are an important component of public information.

Taking the Austrian approach as an example, he illustrated the practicalities of public information. Components of the Austrian approach for public information about Deliberate release of GMOs for research and development (part B) are:

- Notification in newspapers
- public: 3 weeks to take a look and make comments
- public hearing
- right to appeal: notifier, owner of the plot, neighbours, Federal State

Turning to the Aarhus Convention, he discussed first the Guidelines on Access to Information, public Participation and Access to Justice with Respect to GMOs.

Important elements are:

- Voluntary, non-legally binding
- Guidance to the practical implementation of the Aarhus Convention with respect to GMOs
- Chapters
 - o Public Information
 - o Public Participation

- Access to Justice
- Implementation, Annexes

The characteristics of the chapter of the Guidelines on public information are:

- Broad Scope
- Collection and dissemination of information by public authorities
- lists, registers, files
- Information on Products such as labelling and accompanying documentation, other fora

As regards GMOs, the Aarhus convention leaves much to the member states. Gaugitsch explained the current debate under the Aarhus Convention, so far undertaken in the GMO Working Group, in which options for legally binding approaches are being discussed. The second meeting of the Parties to the Aarhus Convention (Almaty/Kazakhstan, May 2005) will take a decision on that issue.

Gaugitsch ended with a number of recommendations:

- Information sharing through several means
- Transparency
- Define stakeholders - Who should be involved? What are their interests?
- Where in a decision making process should stakeholders be involved?
- To what extent? Through which means?
- Regard to history, experiences with administrative and political system so far, resources
- Responsibility for the process.

Prof. Kinderlerer discussed the topic of public participation, underlining the complexity of the issue.

Showing a number of examples of labelling of GMOs, he discussed a number of studies about public perception and public participation.

One study found that " For reasons that are not entirely clear, but which involve fear of new technology, concern over food safety, concern at the possible environmental impact, concern at globalisation and the concentration of power in too few hands, there is considerable fear at the use of modern biotechnology for food....".

According to the Euro-barometer, the feeling of danger varies only slightly according to the level of studies or knowledge of the persons questioned.

Public Perceptions of Agricultural Biotechnologies in Europe - the PABE Report - provides a set of questions relating to the perception by 'stakeholders' of the public understanding of science.....(Published December 2001).

Next, professor Kinderlerer discussed a number of 'myths or truths?':

- The primordial cause of the problem is that lay people are ignorant about scientific facts - if only they understood the science better, they would be reassured and would accept GMOs.
- People are either 'for' or 'against' GMOs

- Consumers accept medical GMOs but refuse GMOs used in food and agriculture
- European consumers are behaving selfishly towards the poor in the Third World
- Consumers want labelling in order to exercise their freedom of choice
- The public thinks – ‘wrongly’ - that GMOs are unnatural
- It's the fault of the BSE crisis: since then, citizens no longer trust regulatory institutions
- The public demands "zero risk" - and this is not reasonable
- Public opposition to GMOs is due to "other" - ethical or political – factors
- The public is a malleable victim of distorting sensationalist media

In ending his presentation, he discussed the public debate in England, which included Meetings, Citizen’s juries and Public opinion surveys.

Discussion

In the discussion following these morning presentations, a number of questions were addressed to the resources persons and observers from neighbouring countries.

One recurring theme was the need to help 'translating' between scientists and the general public.

In response to a question from the consumer organisation how to launch big information programs, Piet van der Meer illustrated the work of the NGO 'Consumer and Biotechnology' (<http://www.consubiotech.nl/>) which is an NGO specialised in translating science for the public.

5. Sub regional collaboration on biosafety between Bosnia and Herzegovina, Croatia, Hungary, Macedonia, Romania, Serbia, Slovenia

In a session moderated by Helmut Gaugitsch, the participants discussed possible topics and possible ways for subregional collaboration.

The following possible topics for subregional collaboration were mentioned:

- Inspections
- Methods
- Database
- Cross border issues (customs collaboration)
- Detection labs (e.g. ENGL network)
- Risk assessment
- Specific topics, e.g. coexistence
- Regulatory frameworks
- International conventions
- Links to EU

The following ways of accomplishing sub-regional collaboration were suggested:

- Need to prioritise the topics, taking into account existing initiatives, e.g. BCH or ENGL
- Information exchange,
- start with making use of an existing web site (e.g. www.biosafety-CEE.org) –
- internet forum (e.g: Slovenia initiative)
- Databases
- contact persons for different topics e.g. border control
- Joint workshops with sufficient time for real exchange of experiences and information
- Sub regional steering committee
- Need for volunteers in each country as well as a 'dedicated person'
- Need for funds (e.g. EU or individual country or organisation).
- Mutual attendance in the various national workshops.

It was agreed that the host of the meeting, Dr. Meira Bosnic, would follow up with the European Commission and bilateral contacts to seek support for this kind of activities.

6. General Discussion.

The General Discussion moderated by Helmut Gaugitsch touched upon a variety of issues related to the topic, varying from fundamental religious questions to very practical questions about the availability of web sites relevant to risk assessment.

Much of the discussion focussed on the need for and appropriateness of a 'ban'.

In response to a number of questions, Dr. Gaugitsch explained that there is no general ban in Austria, but that Austria used the existing articles to limit the use of a number of products. National ban (article 23 procedures under Directive 2001/18/EC, former Art 16 of Directive 90/220/EEC): 3 maize products; Scientific reasons: a) the scientific basis for toxicology and allergenicity assessment – in general - is questionable, b) Bt plants: indirect effects to the food web are not well addressed as well as resistance development. These arguments were not shared by the Scientific Committee of Plants.

7. Next steps for the further development and implementation of the National Biosafety Framework of Croatia

As a last session of the workshop, Dr. Meira Bosnic invited the Croatian participants and the foreign colleagues to brainstorm about the 'next steps' that are needed for Croatia in further developing and implementing its national biosafety framework. The session was moderated by Helmut Gaugitsch.

Looking at the different main components, the following suggestions were made:

1. Policy on Biotechnology and Biosafety

Should be within a national strategy - Identification of existing policies/strategies, e.g. agricultural production

2. Regulatory regime for biosafety

- Ensure clarity and coordination between the different acts as well as ensure communication between different government bodies, e.g. with regard to waste management;
- Taking into account the comments of the international panel of experts and finalise GMO Act
- Finalise the implementing by laws (regulations, rule books, etc)

3. Handling requests for permits

- Identify who should/will do what on the basis of the legislation
- Adequate training of the involved bodies (using list of experts)
- Additional guidance for applicants
- Internal manuals for governmental officials
- Modus operandi for the risk assessment body
- Development of notification formats
- Contained use
- Import/export
- Releases
- Marketing

It was noted that these topics needed to be prioritised.

4. Monitoring and Enforcement

Monitoring:

- Identify who will/can do what
- Training
- Collect existing monitoring practices for case specific monitoring and general surveillance

Enforcement

- Identify who will do what
- Training – sharing experience
- Sub regional collaboration (e.g. border control)

5. Public information and public participation.

- Should be more interactive and continuous,
- someone / organisation who is always available to answer questions (e.g. specialised NGOs in other EU countries)
- distinguish clearly between biotechnology and biosafety
- involving TV programs
- special information sessions / training for journalists
- training scientists how to deal with the media and how to communicate

The resource persons underlined that addressing these issues requires the input of sufficient manpower, and at least the full time involvement of a lawyer on environment-international law and a team of inspectors from different back grounds (sanitary, agricultural, veterinary and environmental).

In the closing session of the workshop, the observers and resource persons thanked the organisers for their invitation and their warm hospitality.

Dr. Meira Bosnic thanked the participants and in particular the observers and resource persons for their contributions and closed the workshop.