2nd Baltic Biosafety Workshop – the Biosafety Protocol

Report

TIME: 23-24 October, 2003
PLACE: Tallinn, hotel "Peoleo", Estonia
PARTICIPANTS: Representatives from the Ministries of Environment, Agriculture, Food and veterinary institutions, Universities and Research institutes, relevant projects from Estonia, Latvia and Lithuania as well as experts from Sweden, Finland, Denmark, and Norway. Altogether 32 participants.

GOALS:

- To give a sound idea of the goals and thoughts behind the Biosafety Protocol;
- To help clarify what steps need to be taken to implement the Protocol in the Baltic States.

PROCEEDINGS:

Thursday, 23 October

Welcome and introduction
Ms. Kai Klein, Baltic Environmental Forum (BEF), opened the workshop, gave a short overview about BEF and the events related to genetically modified organisms (GMOs) and biosafety organised so far. She introduced to the main goals, and the target group of the current workshop.

Ms. Mette Svejgaard, Swedish Environmental Protection Agency (Swedish EPA), pointed out that this workshop is organised within the frame of the Baltic Biosafety project. The project aims at capacity building of Baltic administration in Biosafety[*] legislative framework particularly focusing on contained use of genetically modified microorganisms (GMMs), transboundary movements of living modified organisms (LMOs) and release of genetically modified (GM) plants. It is a Baltic – Swedish co-operation project having contributing parts from competent authorities in Estonia, Latvia and Lithuania, BEF and Swedish EPA. Ms. Svejgaard informed that the next workshop on "Risk assessment and monitoring of GM plants" is planned in spring 2004.

Why a Biosafety Protocol? An introduction
Mr. Veit Koester, former chairman of the Open-ended Ad Hoc Biosafety Working Group, Denmark, gave an overview on the development process of the Biosafety Protocol (7 phases). He pointed out that scientific discussions as well as society concerns on potential harms of GMOs raised already at late 1970s. Nevertheless, only at the beginning of 1990s during the negotiations of Biodiversity Convention establishment of a particular Biosafety Protocol was proposed. Quite many countries at the beginning were not in favour towards this proposal. However, in 1995 a mandate for development of the Protocol was given and content negotiations between countries started. Finally the agreement on the Protocol was reached in 2000. Presently more than 100 countries have signed and about 60 have ratified the Protocol.

Mr. Koester informed that meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) will be held in Kuala Lumpur in February 2004 where the following main decisions according to specific provisions of the Protocol must be taken on:

- appropriate procedures and mechanisms to facilitate decision making by Parties on import;
- developing standards with regard to identification, handling, packaging and transport;
- modalities of operation of the Biosafety Clearing House, including reporting on its activities;
- appropriate rules and procedures with regard to liability and redress for damage resulting from transboundary movements of LMOs;

[*] Biosafety – a term used to describe the need to protect human health and the environment from possible adverse effects of modern biotechnology

- cooperative procedures and institutional mechanisms to promote compliance with the provisions of the Protocol and to address cases of non-compliance.

But many other decisions are needed in order to put the Protocol on track.

Discussion:

- at the beginning only few EU Member States were in favour to the Protocol and it was difficult to find a common position. Changes in governments as well as society pressure stimulated the positive opinion.
- European Court of Justice has decided that EC Treaty Articles on Environment have to be considered as legal bases for ratification of the Protocol within the European Community.
- in order to become a Party and to participate in the first meeting, a country has to ratify the Protocol until 26 November 2003. From the three Baltic States currently only Lithuania is considering the participation in this event.
- experts from all three Baltic States pointed out the necessity to increase the institutional capacity (particularly legislative expertise) for development of secondary legislation in order to implement the Protocol.

Ratification process and state of implementation in European Community and EU Member States.

Mr. Urban Boije, Ministry of Environment, Sweden, informed that the European Community ratified the Protocol in 27 August 2002. Several of EU Member States (MS) have ratified it as well (e.g., Austria, Denmark, France, Sweden, the Netherlands).

Mr. Boije gave an overview to the main EC legislation implementing the Biosafety Protocol:

- Directive on deliberate release of GMO (2001/18/EC). Only a few MS have transposed it into the national legislation.
- Regulation on transboundary movements of GMO *(adopted in June 2003 but not published yet in the Official Journal)* will be the most important legislation act for implementation the Biosafety Protocol. It focuses on export of GMOs and products containing GMOs from EU, unintentional transboundary movements, information sharing, reporting, penalties and monitoring. It has a broader scope and more detailed rules than the Protocol.
- Regulation concerning the traceability and labelling (EC Reg. No 1830/2003) of products consisting or containing GMOs (e.g., tomatoes, GM bread, vegetable oil, sugar). It sets threshold levels of unintentional presence of GMOs.
- Regulation on GM food and feed (EC Reg. No. 1829/2003) defines notification and approval requirements of GM food and feed, labelling, provisional rules on prevention of adverse effects, etc.
- Directive on environmental liability *(not adopted yet)*

Discussion and additional information:

- the relevant EC legislation is quite complicated. Clear legislative requirements are elaborated for import of GMOs but not yet for export;
- EC Guidelines on GMO and conventional products has to be developed;
- an Explanatory Guide to the Protocol on Biosafety is prepared by the IUCN Environmental Law Centre and is available on Internet: www.iucn.org/themes/law/pdfdocuments/Biosafety-guide.pdf.

National Biosafety framework in the Baltic States, Sweden and Finland

Estonia

Ms. Lilika Käis, Ministry of the Environment informed that several legislative acts are setting provisions with regard to GMOs in Estonia. The most important ones are the "Act on release of GMOs into environment and placing on market"; "Act on Contained use of GMMs" and "Act on Food". Responsible authorities for implementation and information exchange are:

- Ministry of Environment – issuing permits for deliberate release and marketing of GMOs or products, control of use of permits;
- Ministry of Social Affairs – issuing permits of contained use of GMMs;

- Ministry of Agriculture – handling and marketing of GM novel food, use and treatment of GM feeds, seeds and plant protection materials, conducting tests with animals.

Two advisory bodies are established to consult the competent authorities. Several institutions (e.g., Environmental Inspectorate, Veterinary and Food Board, etc.) are responsible for monitoring and enforcement of requirements.

Ms. Käis pointed out that Estonia has signed the Biosafety Protocol and ratification is presently in the process. Legislation will be changed in order to fulfil the requirements. Currently the provisions do not fully cover import, export and transport of GMOs in Estonia. The national focal point for the Biosafety Protocol and Biosafety Clearing House is Ms. Liina Eek-Piirsoo, Nature Protection Department under the Ministry of the Environment.

Latvia

Mr. Janis Ancans, National Project Coordinator of the UNEP/GEF project "On the Development of the National Biosafety Framework" gave a brief overview to the Cabinet of Ministers Regulations on:

- Monitoring council of GMOs and novel food;
- Use and distribution of GMOs;
- Procedure for assessment of novel foods and requirements for classification, labelling and quality of novel foods.

He also introduced to the procedure of authorisation for GMOs and novel foods in Latvia. The Monitoring council of GMOs and novel food is responsible for risk assessment and recommendations (proposals) on permits. The council consists of experts from Ministries of Environment, Agriculture, Health, Economy and their subordinated institutions as well as scientific institutes.

Mr. Ancans pointed out that also in Latvia the ratification of the Biosafety Protocol is currently in the process. It is foreseen to nominate the Latvian Food Centre as the national focal point by the "Law on the Cartagena Protocol on Biosafety which is incorporated to Convention on Biological Diversity". At present the draft of this normative document was accepted in the Cabinet of Ministers of the4 Republic of Latvia on 21st of October, 2003. The ministries of Health and Environment are responsible for implementation of requirements.

Discussion:

Participants discussed the practical possibilities to influence allowance or prohibition of GMOs within the countries. It was commented that detailed national legislation has to be elaborated to properly regulate placing on market and transboundary movements of GMOs or GM products. For example, particular rules can be laid down for growing different crops, etc.

Lithuania

Mr. Gintaras Jodinskas, National Project Coordinator of the UNEP/GEF project "Development of the National Biosafety Framework" informed that on 18 September 2003 Lithuania have ratified the Cartagena Protocol on Biosafety. It is envisaged that it will enter into force at the beginning of 2004. The basic law "GMO Act" has been adopted already in 2002. Responsible for implementation will be the Ministries of Environment, Health, Agriculture and their subordinated institutions as well as the State Food and Veterinary Service. The Ministry of Environment as the main competent authority shall receive and assess notifications and issue permits for the use of GMOs/GMPs. Ministry of Environment (GMO division) will have to gather and manage data in the national BCH data base, organise risk assessment for human health, the environment and agriculture as well as organise monitoring and national traceability system as well as to execute the state control.

Discussion:

Current national legislation on export of GMOs. In Lithuania currently a Ministerial Order on export, import and transport of GMOs/GMPs is under preparation. Participants from EU Member States advised Baltic States in order to avoid double work, to wait with developing new legislation until the new EC Regulation on transboundary movements is entering into force.

Sweden
Ms. Mette Svejgaard, Swedish EPA, pointed out that in Sweden responsibility for different gene technology activities under the Environmental Code is shared between several authorities. In order to coordinate activities joint meetings are held twice a year.

Ms. Svejgaard explained how export of GMOs to the third countries (i.e., non EU countries) is regulated in Sweden. According to the legislation the exporter itself has to be responsible for notification to the importer country. The competent authority e.g., Swedish Agricultural Board will assure if this is done in a correct way. The Agricultural Board is also responsible for labelling GMO feed and seed, but the National Food administration - for labelling of food containing or produced from GMOs. The Swedish Environmental Protection Agency is the national focal point for the Biosafety Clearing House. More information about authorities involved and relevant legislation in Sweden can be obtained on Internet www.gmo.nu.

Discussion:
Participants discussed pros and cons with regard to sharing the roles and competences between different authorities. Separation of competences according to GMO types increase the necessity of coordination of activities but at the same time ensures broader expertise.

Finland
Mr. Jyrki Pitkäjärvi, Finnish Environment Institute, explained that Finland has not yet ratified the Biosafety Protocol. Governmental proposals to approve the Protocol and amend the current legislation will be submitted to Parliament in spring 2004. Thus Finland will participate only as an observer in the first Meeting of Parties in February. It is envisaged that the national focal points will be:

- Department of Environmental Protection (Ministry of Environment) – for Biosafety Protocol;
- Board of Gene technology (Ministry of Social Affairs and Health) – for BCH.

Mr. Pitkäjärvi informed that a national GMO data base is currently under construction. It will be available on Internet. Main users of the data base will be the relevant competent authorities, expert institutes and inspectorates. Non-confidential data will be available for public as well.

Working in groups: Real and Hypothetical examples about Biosafety, and how to handle them
Participants in national groups discussed several examples on deliberate release, placing on market, export, unintentional transboundary movements of GMOs. The application of Biosafety Protocol, legal frames, different roles and necessary actions to be taken by responsible authorities was discussed in each case separately.

Friday, 24 October
Coexistence of GM crops growing with conventional crops
Mr. Urban Boije, Ministry of Environment, Sweden informed that countries had long negotiations on necessary legislation which would regulate coexistence of GM crops growing with conventional crops. Many MS considered the necessity of a common legislation at the EU level. The position of the European Commission is that the MS have to make national legislation relevant to local agricultural circumstances. EC shall issue only guidelines supporting countries. Decision on common legislative frame at the EU level might be considered later.

Mr. Boije also informed that the Swedish Agricultural Board has compiled information about field trials for rape, sugar beets, corn etc. in Sweden. The reports are available on Internet www.sjv.se.

Discussion on open questions:
1. GM free zones.
Participants shared opinions and discussed different approaches of the countries. The common opinion was that GM free zones shall be established. Nevertheless, there are many uncertainties:

- Setting legislative frame for GM free zones at EU or national level;
- What shall be the contamination limits and how to differentiate between different crops;
- Size of GM free zones – the whole country or certain counties. For example, in UK and also in USA there are counties defined as GM free zones;

- Strict rules or voluntary agreements.

In Estonia currently discussions are ongoing on establishment of GM free zones and contamination limits. A particular working group will be developed soon.

2. Limit of GM contamination in conventional organic

It was discussed that the EC threshold level of contamination in food is 0.9%. If the level is exceeded than the product has to be labelled. In Lithuania according to the draft legislation on sustainable farming GM limit for seeds or feed has to be "0". Other participants commented that none of materials are 100% free of GMOs. Approval of such rules would harm organic framing.

3. Legislation on liability

Different opinions were discussed on setting legislation for liability for activities with GMOs:

- EU Framework legislation defining general mechanisms and later national legislation which shall be more specific e.g., setting compensation amounts, etc.;
- More countries were supporting establishment of the relevant national legislative requirements as development of EU law takes much more time, but problems have to be solved already now.

Demonstration of the Biosafety Clearing House (BCH).

Mr. Jan Husby, BCH focal point, Norway explained the role of BCH. BCH is the information and communication centre under the Biosafety Protocol having to:

- facilitate the exchange of scientific, technical, environmental and legal information on, and experiences with LMOs;
- assist parties to implement the Protocol, taking into account the special needs of developing country Parties.

Further on Mr. Husby introduced to a Users Guide to a simple National Biosafety Clearing House Application. The guide explains how to build up the system, how and in which way to put information into data base and how data have to be transferred to the main data base in Montreal. The Guide on CD is available at the Biosafety Secretariat upon request.

He also informed that Nature Department of the Ministry of Environment will be the focal point for the BCH in Norway. More information on national BCH is available at http://bch.dirnat.no. Presently most of information put on Internet is in Norwegian. Serving more local needs, only selected materials are translated in English. Currently 2 persons are involved in compiling the necessary information in the national data base.

Discussion:

- Translation of materials is an important topic for discussions and will be brought up during the first Meeting of Parties.
- Establishment of national BCH in Baltic States. Only Lithuania is planning to establish the national BCH (until March 2004).

CONCLUSIONS

- Sweden, Denmark, Norway and also Lithuania have already ratified the Biosafety Protocol. Ratification of the Protocol currently is in the process in Finland, Estonia and Latvia.
- The first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) will be held in Kuala Lumpur on 23-27th February 2004 where several important decisions will be taken. In order to participate as a Party in this meeting ratification of the Protocol has to be done until 26 November 2003. In other case a country can participate as an observer. Countries can seek for financial support for participation at the Biosafety Secretariat in Montreal.
- The Biosafety Protocol regulates the transboundary movements of LMOs (GMOs) intended for introduction into the environment as well as LMOs for food, feed and processing, but does not cover LMOs used in pharmaceuticals for human beings.
- The relevant EU legislation (Directive 2001/18/EC) is already adopted setting requirements on import of LMOs into the EU.

- Concerning export a new EC Regulation will be published soon. It will require that, for example, when exporting seeds the advance informed agreement procedure shall apply to both Parties and Non Parties alike.
- Unintentional transboundary movements will be also regulated.
- Biosafety Clearing House (BCH) is an essential tool for implementation of the Protocol, especially with regard to LMOs for food, feed and processing.
- Accession countries shall avoid elaborating legislation, which soon will become unnecessary due to new EU Regulations coming into force.
- Next workshop on "Risk assessment and monitoring of GM plants" is planned in spring 2004. Time and the topic for the further workshop are not identified yet. Countries are welcome to send their proposals to kai.klein@ekm.envir.ee or to mette.svejgaard@naturvardsverket.se.

Report by Daina Indriksone, BEF