3rd Baltic Biosafety Workshop:
Deliberate release of genetically modified plants in the EU

REPORT

TIME: 24-25 March, 2004
PLACE: Riga, hotel "Maritim", Latvia
PARTICIPANTS: Representatives from the Ministries of Environment, Agriculture and their subordinated institutions (e.g., Food and Veterinary as well as Plant Protection Services, Environmental and other inspectorates), Universities and Research institutes, Laboratories and the relevant Projects from Estonia, Latvia and Lithuania. There were also experts from the Swedish Environmental Protection Agency, Swedish Board of Agriculture and Finnish Environment Institute. In total 44 participants.

THE GOAL OF THE WORKSHOP:

- To exchange the information and knowledge on deliberate release and placing on the market of genetically modified plants in agriculture and forestry i.e. applicable rules and procedures, responsibilities, monitoring and control.

PROCEEDINGS:

Wednesday, 24 March

Welcome and introduction

Ms. Kristina Veidemane, Baltic Environmental Forum (BEF), opened the workshop and welcomed the participants. She introduced to the Baltic Environmental Forum, its activities and previous events on genetically modified organisms (GMO) organised in cooperation with Swedish Environmental Protection Agency within the frame of the Baltic Biosafety project. She introduced to the goals and the agenda of the current workshop.

Ms. Mette Svejgaard, Swedish Environmental Protection Agency (Swedish EPA), outlined that the Swedish EPA advises other authorities on matters like deliberate release or placing on the market as well as on designing of relevant regulations in the country. Swedish EPA will also host the Biosafety Clearing House (BCH).

Ms. Svejgaard gave a brief overview on GMO legislative framework – EC directives and regulations. She explained that mostly due to consumers concerns and concern for the environment first legislative acts at the EU level were elaborated in 1990 (Directive 90/220/EEC). The recent legislative acts are the following:

- Directive 2001/18/EC on deliberate release of GMOs into the environment;
- Regulation 1946/2003 on transboundary movements of GMOs;
- Regulation 1829/2003 on genetically modified food and feed and
- Regulation 1830/2003 on traceability and labelling of GMOs. The latter two Regulations shall be applied from 18 April 2004.

Ms. Jenny Andersson, Swedish Board of Agriculture introduced to the requirements of the Directive 2001/18/EC and the Regulation 1829/2003. The Directive requires handling notifications for deliberate release (Part B) and placing on market (Part C) of GMOs as well as control and monitoring. Ms. Andersson explained the related obligations of:

- notifier (e.g., to submit information on GMOs, monitoring plan, SNIF (Summary Notification Information Format), to carry out environmental risk assessment and to report);
- competent authorities (e.g., to evaluate notifications, to forward SNIF to Joint Research Centre, to ensure publicity, inspection).

Ms. Andersson explained that decision on contained use of GM plants (e.g., cultivation in greenhouses and other indoor facilities having high level of security) as well as on release into the environment for every

other reason than placing on the market shall be made at the national level. While the decision for placing on market of GM plants shall be taken at the EU level.

She gave an overview on the related decision process under Directive 2001/18/EC and Regulation 1829/2003. The process is quite time consuming and it could take up to 1 year until the decision is made. So far no products have been approved under these 2 legislation acts. The previous permits issued according to the Directive 90/220/EEC will be reviewed. New permits will be reviewed every 10 years. Currently 23 new notifications for placing on market are under assessment. All SNIFs and assessment reports (in English) can be found at http://gmoinfo.jrc.it.

Ms. Andersson admitted that accession of 10 new Member States will cause additional challenges for the coordination of the process. Communication among the countries is essential for the decision making process (e.g., voting in committees)

During the discussions it was clarified that countries have different practices with regard to covering the costs for notification procedure. In most countries (except e.g., Holland) notifier shall cover the notification costs. Also there are different penalties for deliberate release without notification. For example, in Sweden it is up to 2 years in a prison.

Legislative framework and responsible authorities for releases of GM-plants in the Baltic States were presented by:

- Ms. Lilika Käis, Ministry of the Environment, Estonia;
- Mr. Janis Ancans, UNEP/GEF Project "Development of Infrastructure for National Biosafety in Latvia", Latvia;
- Ms. Neringa Sarkauskiene, Ministry of Environment, Lithuania.

In all three Baltic States the transposition of the Directive 2001/18/EC is currently in the adoption stage. More information about the existing legislation acts and the competent authorities is presented in the **Annex I.**

There has been only one application for deliberate release of GM plant (maize MON810) submitted to the Ministry of the Environment in Estonia. Application was withdrawn. Also Lithuanian experts could not comment about rumours on GM rape grown in Lithuania. There is no official information about such case, no notification submitted; however particular investigations have not been done so far.

During the discussions participants clarified approaches concerning the detailness of information that shall be given to public e.g., disclosure of the actual site of field release. In Estonia the exact location of the site shall be given to public, while in Latvia and Lithuania it has not been decided yet.

Handling of GM plants in Finland and Sweden

Ms. Kirsi Törmäkangas, Finnish Environment Institute (SYKE) introduced to the Finnish environmental administration and the structure of SYKE. She informed that GMO issues are handled by the Expert Services department, Chemicals division at SYKE. Ms. Törmäkangas outlined that the Gene technology Act (1995) has been updated to transpose the requirements of the Directive 2001/18/EC and will be enforced in autumn 2004. The Board of Gene Technology consisting of representative from several ministries (Trade and Industry; Agriculture and Forestry; Social affairs and Health; Environment) and ethical experts is the Finnish competent authority on GMO issues and issues permits for genetically modified (GM) plants. Notification for deliberate release has to be submitted to the Board well before commencing the field trial of GM-plants. If necessary, additional experts are involved in supporting the decision making for permit issuing.

So far 2 inspectors nominated by the Board are carrying out inspections. Field releases are usually controlled twice a year. From 2004 inspection under supervision of the Board will be performed by the Plant Production Inspection Centre, National Product Control Agency for Welfare and Health, and Finnish Environment Institute.

Ms. Törmäkangas stated that since 1996 twenty notifications have been handled in Finland. As positive aspects of the Finnish notification system she mentioned relatively low bureaucracy and openness to the public. Negative sides are related to involvement of part-time advisors and the narrow base of decision making, for example, the advisory Board for Biotechnology represents large expertise, but it is not directly involved in the decision making process.

Mr. Staffan Eklöf, Swedish Board of Agriculture informed that the requirements of Directive 2001/18/EC are transposed in Sweden. Notifications have to be submitted to the Swedish Board of Agriculture (SBA). It also compiles all comments and carries out the risk assessment (4 persons involved), if necessary inviting external experts for advise. SBA issues permit for deliberate release in Sweden. Since 1989, 98 of 100 submitted notifications for deliberate release have been approved. Also for placing on market SBA makes the first decision, but the Government gives the official standpoint.

Mr. Eklöf pointed out, that it has to be carefully assessed cases by case if there is a real need to collect additional data by making field studies. In certain situations it can be very important but sometimes it would mean just waste of resources, especially if field releases are small in scale and time.

Answering the questions, Mr. Eklöf explained that in Sweden notifier has to submit annual reports about the field trial. Besides, in case any unexpected results (e.g., in behaviour of the crop) are discovered, this information has to be submitted immediately. With regard to control of sites Mr. Eklöf admitted that there is no overall guidance for controlling field trials. Control is performed in each case individually; however, samples for analyses have not been taken so far.

Concerning transparency to public, much information (in Swedish) about deliberate releases or placing on market is available at www.sjv.se. All information can be requested by the public. Little is found confidential. Mr. Eklöf pointed out that all SNIFs are put on Internet and within 30 days people can submit their comments or questions. Information is also sent to various organisations. The notifier is obliged to make an announcement about field release in the local press. Reaction of society varies. Usually general concerns about GMOs release to environment are expressed, but not on exact cases.

Working group session I. ”How to judge risk assessments and make conditions for approval”? (Annex II)

During national working groups experts analysed three real-life cases on:

1) Deliberate release of thale cress *(Arabidopsis thaliana);*
2) Deliberate release of silver birch *(Betula pendula);*
3) Placing on the market of Bt11-maize *(Zea maize).*

Participants had to analyse the given SNIF information. They had to make risk identification and to elaborate under which conditions the permit would be given in their country and how the control and monitoring will be performed later on. Afterwards experts from Finland and Sweden reflected on the risk assessment and notification conditions for the respective cases in their countries.

Summarising the procedures of decision making for placing of GM plants on the market, Mr. Eklöf drew attention to some particular phases of the decision making process. He pointed out that Member States have to raise their concerns about placing on market of GM plants during the so called “objection phase”. If any of Member State has posed objection for notification, the process enters into the “agreement phase” where no new objections can be raised, but there are discussions with the applicant and assessment of new information submitted. If agreement cannot be reached at this stage, it is put on voting in the Committee. Each Member State has certain amount of voices. If less than 62 votes of 87 are in favour, voting for making decision will be done in the Council. If a Member State is abstain or no attend its votes are assumed as against. If no decision is made in 3 months, further the Commission will take the decision.

Mr. Eklöf pointed out that after the accession of 10 new Member States the decision making process will become even more complicated. He advised Baltic States to submit their opinions in a written form and seek for other Member States sharing their point of view before the decision making.

Thursday, 25 March

Monitoring, reporting and control after deliberate release and placing on the market of GM plants

Ms. Mette Svejgaard, Swedish EPA stressed the necessity to assign responsibilities for risk management, monitoring and control. Next important topics will be related to the traceability requirements as laid down in the EC Regulation 1830/2003. Currently there are many discussions ongoing with regard to coexistence of conventional and genetically modified plants. As there is no common EU legislation established, there shall be clear national rules setting also the liability in case of infringements.

Ms. Jenny Andersson, Swedish Board of Agriculture explained in details the **EU legislation requirements** for control, monitoring and reporting set by the Directive 2001/18/EC.

She outlined that concerning deliberate release (part B):

- The purpose of monitoring is to identify effects of the GMOs on human health or the environment. Notifier has to submit the monitoring plan. Usually it causes many disputes and can be among the reasons for objection;
- Notifier has to report on the results of release - describe the monitoring methods and the observed effects (both expected and unexpected);
- Control shall be organised at the national level. Competent authorities have to organise inspections and other appropriate measures to ensure compliance with the Directive.

For example, in Sweden inspection is organised 1 per year on a field trial to ensure that the notifier follows the prescribed conditions e.g., if wild relatives of the GM plant are taken away in the vicinity, if area is maintained appropriately.

Concerning placing on market (Part C):

- Monitoring shall be carried out to confirm assumption in the risk assessment and identify unexpected adverse effects. Member States have to appoint who shall perform monitoring, how often and how it should be compiled;
- There is a need to establish the period and frequency of reporting. It should be set out in the monitoring plan as a part of the notification. Reports may result in amendment of the monitoring plan.
- Member States shall ensure that the conditions of the consent are followed

During discussions it was clarified that if the same GM plants are grown in several Member States and at several sites, still the monitoring has to be carried out in each site as specific site conditions can differ a lot. In such cases, only the monitoring plans can be adapted between each other. However, Ms. Andersson also pointed out that it is not possible to monitor everything. Monitoring plan shall be designed case by case to identify the potential effects. The monitoring effort must be proportionate to the value of the information that may come out.

Ms. Mette Svejgaard, Swedish EPA explained in details the **principles how commercial growing of GM plants should be monitored.** The legal frame for monitoring is set by the Annex VII of the Directive 2001/18/EC. Monitoring has to be done after consent for placing on the market has been given. The results of the monitoring should be evaluated with regard to other conditions or activities.

Ms. Svejgaard admitted that it is difficult to judge when the effect is adverse to the environment or to human health. In the draft EC Directive on Environmental liability it is written that: *"damage is a measurable adverse change in a natural resource and/or a measurable impairment of a natural resource service which may occur directly or indirectly"*.

Monitoring will not help to achieve biosafety, nor prevent damage, nor retrieve alien gene constructs. Before setting the plan and carry out monitoring it is necessary to gather the baseline data from the site. During the monitoring there are several environmental values to consider - ecological interactions, biodiversity, soil functions, sustainable agricultural practices and plant health. However, prioritisation of monitoring elements is necessary in order to reduce the overall costs.

Working group session II. "How monitoring of GM plants should be dealt with in practice?" (Annex III)

During national working groups experts analysed control and monitoring of deliberate release of the following GM plants:

1) Virus resistant sugar-beet
2) BT-maize
3) Herbicidtolerant oilseed rape
4) GM potato

Participants discussed what items would be controlled, how the control will be carried out and by which institution in their countries. The main conclusion from the working groups was that still responsibilities for inspection and control of GMOs have not been strictly divided in the Baltic States.

Mechanisms for public awareness, information and participation in decision-making

Mr. Gintaras Jodinskas, UNEP/GEF Project "Development of national Biosafety System for Lithuania" emphasized that information to public shall be submitted taking into consideration that there are different audiences. Thus the information given has to be targeted. There are various tools for public information and raising awareness also on GMOs related issues – seminars, mass media, printed materials and websites.

Mr. Jodinskas gave a brief overview on the requirements for public participation laid down in the Cartagena Protocol on Biosafety and the Directive 2001/18/EC. He also informed that in Lithuania the relevant Order of the Ministry of Environment on "Public Information and Participation upon issuing the authorizations to use the GMOs" came in force on 1 January, 2004. According to this Order, notifier has to present information about the application for the deliberate release to the relevant municipalities. Competent authority has to submit information to the public within 10 days after the decision. Mr. Jodinskas explained the draft scheme of the involved stakeholders and the information flow in Lithuania. The Ministry of Environment has the overall responsibility to ensure that non confidential data on GMOs are available to public.

Unintentional releases. Lessons learned from the Hyola-case

Mr. Staffan Eklöf, Swedish Board of Agriculture described an example of an unintentional release of GM oil seed rape in Sweden. Oil seed rape seeds were imported from Canada in 1999 - 2000 and sold to farmers. In 2000 it was discovered that the seeds contained a small amount (0,4%) of glyphosate tolerance. Analyses showed that also the previous year seeds were contaminated. The contamination has happened because of crosspollination even within a distance of 10 km. The seed was condemned as illegal and the manager of the company was prosecuted. In Sweden the decision was made to destroy the crops and to burn them for heating. Fortunately the contaminated plants were male-sterile; the spread of pollen would be very little. The farmers were compensated by the company. In other countries it was allowed to set seed and use for industrial purposes.

Mr. Eklöf stressed the importance in such situations to give the correct and immediate information to public thus avoiding rumours and the negative reaction from the society.

Unintentional transboundary movements of GMOs

Ms. Mette Svejgaard, Swedish EPA explained that unintentional transboundary movements (UTM) of GMOs can be the result, for example, of accidental release, failure of risk management measures after deliberate release into the environment. According to the Cartagena Protocol on Biosafety and the EC Regulation 1946/2003 the party of origin of the UTM is obliged to consult affected or potentially affected States, including non-parties of the Protocol. According to the obligations of general international Environmental Law also non-parties have to notify affected states when UTM are anticipated.

Ms. Svejgaard stressed the importance for setting clear responsibilities for the institutions in case of UTM. She informed that if the UTM would be caused by a Swedish actor, the competent authority for the specific GMO will take the required actions. The national focal point for the BCH will inform the BCH central

portal. In case the UTM is affecting Sweden, the national contact point to receive this information is still to be established.

CONCLUSIONS AND RECOMMENDATIONS

- Responsible authorities in the Baltic States have the necessary competence to judge upon the risk assessment with regard to deliberate release or placing on market of GMOs.
- All communications in the future will go through the European Union – if not done already, the responsible bodies for the discussions at the EU level has to be identified in the countries.
- For further process it would be helpful to finalize the national legislation in the Baltic States and also to assign responsibility for enforcing requirements.
- Baltic States should actively participate in the discussions on how to handle the post-marketing situation with regard to GMOs.

NEXT STEPS

- Next workshop on "Traceability, labelling and approval of GM food and feed" would be held in Latvia in autumn 2004. Countries are welcome to send their proposals for particular discussion topics to kristina.veidemane@bef.lv or to mette.svejgaard@naturvardsverket.se.

Report by Daina Indriksone, BEF

Annex 1

Legislative framework and responsible authorities for releases of GM-plants in the Baltic States

	Estonia	**Latvia**	**Lithuania**
Transposition of 2001/18/EC	In adoption process	In adoption process	In adoption process
Legislation	- new Act on GMOs (2004) - Regulation on list of data submitted in the application for the permit for release into environment and distribution of GMOs and the form of permits thereof - Several related acts	- Law on Environment - CM Regulations 322 "Monitoring Council of GMOs and novel food" (2000) - CM Regulations 323 "Procedure for the use and distribution of GMOs" (amendments in 2004)	- Law on GMO (2002) - Order on procedures for notification and permitting the placement of GMOs or their products on the market, deliberate release into environment - Orders on Regulation: ▪ Risk assessment of GMOs ▪ GMOs classification and labelling ▪ Public information and participation in issuing permits for the use of GMOs
Submission of notifications	Ministry of Environment (having 2 advisory bodies)	Monitoring Council of GMOs and novel foods	Ministry of Environment (having 2 advisory bodies)
Permitting authority	- Ministry of Environment (deliberate release and placing on market) - Ministry of Agriculture (use of seeds, handling and marketing of novel food)	- Ministry of Environment (deliberate release into environment) - Ministry of Health (placing on market)	Ministry of Environment
Control and monitoring for placing on the market	- Environmental Inspectorate - Plant Protection Inspectorate	- State Plant Protection service	- State Food and Veterinary Service - State Plant protection service - State Seed and Grain service
Control and monitoring for deliberate release	- Environmental Inspectorate - Plant Protection Inspectorate	- State Environmental Inspectorate	- Ministry of Environment - Forest Seed and Planting stock Quality Inspectorate
Cartagena Protocol	Ratified (2004)	Ratified (2004)	Ratified (2003)
National Focal Point	Ministry of Environment	Latvian Food Centre	???

Annex II

Results of the working group session I.
"How to judge risk assessments and make conditions for approval"?

Risks identified			
Deliberate release of silver birch (Betula pendula); (Estonian wgr)	***Placing on the market of Bt11-maize (Zea maize);*** (Latvian wgr)	***Placing on the market of Bt11-maize (Zea maize);*** (Lithuanian wgr)	***Deliberate release of thale cress (Arabidopsis thaliana);*** (Latvian wgr)
- Cross- pollination - Vegetative reproduction - Development of GM resistant insects - Fungal pests - Might damage natural mycorisa - New allergies or higher allergy levels	<u>Environmental Risks:</u> - Disbalancing of ecosystem (risks regarding non targeted organisms) - Development of resistance of target organisms - Soil contamination with toxins - Coexistence (organic farming, conventional crops) <u>Health risks</u> - Allergic effect - Mutagenic effect <u>Socio –economic risks</u> - Coexistence - Public perception	- Toxic to animals and plants (?) - Influencing dynamics of population (?) - Transferring antibiotics	Gene spread: - Crosspollination with wild plants - Distribution of seeds by insectivores, small rodents - Surveillance (integrity of protective measures)
Conditions			
<u>During the trial:</u> 1. Secure distance 2. Particular fence 3. Weekly monitoring and reporting 4. Proper maintaining of surrounding area (cutting hay, etc.) <u>After the trial:</u> 1. Cutting down and burning of plants 2. Treatment with herbicides 3. Collecting roots 4. Monitoring	Due to lack of the case specific information, further investigations will be necessary to identify the conditions	Due to the risk to human health and animals the permit shall not be issued	1. Location – away from wild relatives 2. Protective margin – several metres around the field 3. appropriate physical barrier above and below ground level 4. Appropriate monitoring and control (5 years)

Annex III

Results of the working group session II.
"How monitoring GM-plants should be dealt with in practice?"

What items to be controlled and monitored?			
GM potatoes (for industrial use) (Latvian wgr)	**BT-maize** (Latvian wgr)	**Virus resistant sugar-beet** (Estonian wgr)	**Herbicidtolerant oildseed rape** (Lithuanian wgr)
- Impact on food chain - Non-targeted organisms (invertebrates, vertebrates) - Soil microorganisms - Production chain	- Bt specific insects - Non-targeted organisms - Gene flow to the neighbouring field of unmodified corn	- Possible impact on wild relatives due to crosspollination - Stability of resistance in the plant	- Impact of rape to wild flora in the neighbouring fields - Non-targeted organisms
How the inspection would be carried out?			
Field inspections (e.g., at boarder areas), sampling, analyses		Visual inspection at least once during the field trial and once afterwards All field shall be inspected Sampling to identify crosspollination	Field inspections, sampling, analyses
Which institutions will perform the inspection?			
- State Plant Protection service, - State Environmental Inspectorate In cooperation with laboratories, scientific institutions	- State Plant Protection Service - Environmental State Inspectorate in cooperation with academic and research facilities, laboratories, entomologists	- Environmental Inspectorate - Plant Protection Inspectorate	- State Plant protection service - State Seed and Grain service Analyses would be done at GMO laboratory in Lithuania