Content

Summary report

The Finnish Environment Institute (SYKE) got funding from the Nordic Council of Ministers (Working Group of Nature, Outdoor Life and Cultural Environment) in order to make a survey of possible interest of co-operation of the Nordic biosafety authorities in environmental questions related to genetically modified organisms (GMOs), and in order to arrange a Nordic GMO-seminar. The aim of the seminar was to find out whether there is a need to have a permanent Nordic forum for discussing environmental GMO questions.

Preliminary survey of interest among Nordic GMO authorities had a very positive outcome, and it was suggested that the participation should be extended to the Baltic GMO authorities. In addition to strictly environmental issues, a few other topics were suggested to be added into the agenda. Due to the broad interest, participation in the GMO seminar in Helsinki had to be limited to 5 representatives from each Nordic country and 2 representatives from each Baltic country. Co-existence of conventional, organic and GMO crop cultivation was added in the meeting agenda, as this was suggested by several countries. Participants from all Nordic and Baltic countries attended the seminar held in Helsinki on 9th-10th December 2004.

The work in the meeting was arranged around three topics: co-existence, risk assessment and post-market monitoring of GMOs. The participants received and prepared working material beforehand. In the meeting, presentations were given on each subject, after which the participants were divided into working groups led by moderators. The results of the workshops were presented for all participants. The results of the meeting and possible future prospects were discussed in the end of the meeting. After the meeting, a preliminary meeting report was prepared and circulated among the participants for comments.

The results showed that even though there were differences in the policies and views in different countries, there was also a need to tighten the co-ordination between Nordic and Baltic GMO-authorities in certain issues. On the basis of the meeting, the following recommendations for Nordic/Baltic co-operation in GMO issues could be presented:

- Networking between authorities should be improved, as this would improve exchange of information and help discussions on the environmental risk assessments and other topics. One way to achieve this is to put links to the web-sites of different GMO authorities on the NMR internet pages, if possible.

- Future meetings were considered useful, but their frequency could be quite flexible. Annual meetings were considered sufficient. Possible future meetings should preferably focus on one current issue at a time, rather than have a general approach. Such current issues to be discussed would be e.g. the borderlines of directives 2001/18/EC and 2003/1829/EC, co-existence issues, and monitoring. Financiation of the meetings was, however, found problematic. NMR was identified as a possible source of funding for co-operation among Nordic countries. The possibility of financiation of Baltic countries by Baltic Environmental Forum was found unclear.
- It should be assessed if there is a basis for common positions which could then be promoted in the EU-meetings and decision making events.
- There is a need for sharing information on environmental risk assessments of both contained use and deliberate releases of GMOs. Further discussions on this issue are necessary, however, as there was no clear view on how this could be achieved.
- Common research projects should be inititiated on specific subjects. Such research should focus on new topics and topics where the Nordic/Baltic countries are sharing common interests and/or climatic conditions. No specific research subjects were agreed upon in the meeting, but future co-operation in farm-scale evaluations of GM-crops under Nordic/Baltic conditions was brought up as an interesting idea.

The general view of the participants was that one of the central achievements of the project was inititating and extending the networking between the Nordic and Baltic GMO authorities. The meeting itself, together with the materials provided, helped the authorities to know who is responsible of GMO issues in each country and in what context. This outcome, together with some future efforts proposed, should prove valuable when attempting to recognise common interests and be potentially helpful in taking a common stand in the decision making at the international level, when needed. Further meetings focussing on current topics were considered necessary. If financiation is found for them, they should be helpful in increasing the common background of knowledge and recognising common needs.

Introduction

Background

The Finnish Environment Institute (SYKE) got funding from the Nordic Council of Ministers (Working Group of Nature, Outdoor Life and Cultural Environment) in order to make a survey of possible interest of co-operation of the Nordic biosafety authorities in environmental GMO questions and in order to arrange a Nordic GMO-seminar. The aim of the seminar was to find out whether there is a need to have a permanent Nordic forum for discussing environmental GMO questions.

GMO-regulations

Testing, production and placing on market of genetically modified organisms (GMO's) have been regulated for over ten years in the European Union region. The release and marketing of GMO's was initially controlled in the EU under Council Directive 90/220/EEC, which required the Member States to ensure all appropriate measures to be taken to avoid adverse effects on human health and the environment that might arise from the release and marketing of GMO's. After that many procedural changes have been made to the Directive. In 1998, negotiations started on the amendment of the Directive 90/220/EEC. Until recently, no new GMO's were authorised for cultivation or import and processing in the EU during “de facto” moratorium. In April 2001 EU adopted a revised Deliberate Release 2001/18/EC directive, which provided for a more complete authorisation procedure for GMO's.

New regulations

Several new directives and regulations have been given quite recently. Examples of such regulations are:

- Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed that replaced the authorisation for GM foods and food ingredients previously covered by the Novel Food Regulation (EC) 258/97.
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending

Directive 2001/18/EC, since the Directive (2001/18/EC) did not itself provide the legal basis to ensure traceability of GMOs.
- Commission Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.
- The Cartagena Protocol

Present situation

Since the amendment (2001/18/EC) 23 new applications (two of which have been withdrawn) for placing on the EU market of GMO's have been sent to the EU Commission. This together with new regulations has created new challenges for authorities in EU. How should the directives and regulations be interpreted and applied in practise in the best possible manner?

Nordic perspectives

The Nordic countries have rather similar ideas, cultural values and traditions with regard to nature protection and conservation, as well as high public interest in environmental questions. The countries have different agricultural production structures, as well as a great deal of variation in their climate and geography. Nevertheless, they also have great resemblance in flora, fauna and ecology, especially when compared with the other EU countries. Cold winter and short summer are common phenomena to all Nordic countries. This, in turn, may have an effect on GM-production procedures and their environmental effects. Genetically modified plants that are designed to be cultivated in Central European conditions may not be cultivable in harsh Nordic conditions. Furthermore, GMO research results obtained in Central- or Southern Europe may not be applicable in Nordic countries due to their different ecological and climate conditions.

Although the Nordic countries have traditionally had close collaboration in many environmental issues, there has been no permanent Nordic forum for discussing the GMO questions since 1998, when the earlier Nordic co-operation project *NordRiskGen* ended.

The Baltic Countries Estonia, Latvia and Lithuania have joined EU in May 2004, which brings these countries under EU-legislation in GMO-matters. The Baltic countries have had earlier collaboration with the Nordic Countries in the *'Baltic Biosafety'* –project, which is lead by the Baltic Environmental Forum (BEF) and the Swedish Environmental Protection Agency (EPA). The Baltic-Nordic collaboration will continue in another NMR-funded project *(‘Is there any such thing as a sustainable GMO in Baltic-Nordic context?’)* dealing with environmental and social sustainability of GMO's and lead by Swedish EPA.

The goal of the seminar

The goal of this seminar was to identify common views and priorities in the Nordic and Baltic countries dealing with GMO issues, such as risk assessment, co-existence and monitoring practises. We wanted to explore possibilities to establish a permanent GMO co-operation under the Nordic Council of Ministers. The ultimate goal of the project is to strengthen Nordic and Baltic collaboration in GMO biosafety area, and thereby to facilitate Nordic influence on biosafety policy at EU and at global level.

Practical issues

There were short (approximately 15-20 min) presentations on each selected subject. After the presentations, all participants were divided into three groups. All groups had a moderator who lead the discussion, as well as a secretary who made notes about the discussion. Each group presented a short summary after the discussions. The following summary report is based on those discussions.

Discussion topics and group work

The participants acquainted themselves with the topics by getting the internet-material mentioned below:

Co-existence
Presentation by *Gitte Silberg Poulsen, Denmark*
Material about the subject (the new Danish coexistence law), see www-site: http://www.fvm.dk/file/co-extinse.pdf

Risk assessment
Presentations by *Esten Ødegaard (Norway), Liga Zala (Latvia), and Bettina Jensen (Denmark)*]
Material: see the Directive 2001/18/EC and Annex II (guidance; www-site: http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf), and the first report on the harmonisation of risk assessment procedures part 2: Appendices (www-site: http://europa.eu.int/comm/food/fs/sc/ssc/out84_en.pdf).

Monitoring and inspections
Presentation by *Marja Ruohonen-Lehto, Finland*
See the Directive 2001/18/EC and Annex VII (guidance; www-site: http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf).

Before the seminar, many other topics to be discussed were also suggested by the participants:

Legislative issues:

- Risk assessment of non-plant GMOs in relation to directive 2001/18/EC
- Interaction between legislative acts relevant to the administration of 2001/18/EC (e.g. 91/414/EEC, 1829/2003/EC and 726/2004/EC)
- Experiences with handling of different Directives
- Cartagena Biosafety Protocol
- Control of GM animals. Creating network for future cooperation
- Traceability
- Labelling
- Public participation
- Consumer acceptance of GMOs and biotechnology
- Registering GMO field trials in public registers
- Gene therapy

Scientific issues:

- Cooperation on GMO scientific matters
- Participation in EU research programmes which could benefit risk assessment
- How should admixtures of GM in non-GM crops be measured?

Other views or comments:

Before the seminar, a few other comments and views on different subjects were also presented in the messages from the participants:

- Common positions/views/practices are important aspects of a closer Nordic co-operation in the biosafety area
- What environmental conditions do the Nordic countries share and what environmental features distinguish the region from other MS?
- It would be interesting to further work out this question and find out if there is any ground to potentially include a joint Nordic condition in a decision for a market release. This condition could for instance exclude a GM-plant to be grown in the Nordic region due to special environmental features of the region or the reverse. The shared environmental features could for instance be wide areas of forest, large areas of non-cultivated land, short growing season, hardiness of plants, choice of cultivars, disease and pathogen pressure and possibly others.
- Should we have joint Nordic research projects to evaluate risks with GMOs?
- For instance the same field trial running at the same time in several places in the Nordic countries, i.e. to evaluate pollen spread or overwintering capacity of potato tubers.

- If we decide/propose to establish a permanent forum, new evolving GMO-related questions (e.g.regulation of DNA-vaccines) could also be topics for discussions and future workshops.
- Is there a need for a Nordic GMO authority web-site in case a permanent GMO-group will be founded?

Examples of environmental phenomena connecting the Nordic and Baltic countries

- Baltic sea (except Iceland and Norway)
- Boreal environment
- Gulf stream(Climate change, global warming)
- Cultivation/breeding procedures. Do they deviate in different countries?

Things to be taken into consideration in seminar group work:

- In which matters is co-operation especially needed?
- Do the different countries have similar views in the matters discussed?
- Practical issues?

Summary

The idea of the seminar was to explore whether there is a need for permanent co-operation in GMO-issues in the Nordic and Baltic Countries and to report recommendations (based on the seminar) to the Nordic Council of Ministers. We also wanted to find out whether the Baltic countries are willing to join in the collaboration body. There could be collaboration between e.g. the Nordic Council and the Baltic Biosafety Forum.

The aim of the workshop was to

- find out if there is a need for a permanent Nordic-Baltic forum
- discuss the most relevant topics in detail
- identify the forms of further work

1. Co-existence

Thu 9th December

13.30 - **The Danish co-existence initiatives**

Presentation by *Gitte Silberg Poulsen, Denmark*

Group discussions

Group 1:
Dorte Harning, Jussi Kauppila, Ulf Kjellström, Kai Korpela, Zinta Lâce, Fredrik Nordvall, Gitte Silberg Poulsen (moderator),
Marja Ruohonen-Lehto, Neringa Sarkauskiene, Jónína Stefánsdóttir, Esten Ødegaard

Are there guidelines (or legislation) concerning co-existence available in each country?

- what is meant by co-existence?
- used in EU for different purposes.
- what about contamination from seeds of different plant species?
- *Norway*: No legislation yet. Food safety authority has started preparative work. Discussion is more focused on whether GMOs are allowed to be grown or not. Legal protection of biodiversity extends to genetic resources, which may perhaps cause a potential problem.
- *Iceland*: There are neither guidelines nor legislation.
- *Latvia*: The Ministry of Agriculture has started to prepare regulations for co-existence.
- *Sweden*: Preparations for rules on co-existence are going on. Common markets may be problematic.
- *Finland*: Two expert groups have started preparations – legislation will follow.
- *Lithuania*: Working groups consisting of scientists and agriculture specialists have been formed – guidelines will follow.

What are the most problematic co-existence questions in each country?

- organic farming and GMOs are impossible to combine.
- structure of agriculture: big or small farms, amount of organic farming.
- who sets the standard for co-existence? What does the EU Commission intend to do?
- is the distance between conventional farms and organic sufficient to prevent contamination?

What is the share of organic farming in each country?

- in *Denmark* 7 %.
- in *Norway* the share was 3.7 % at the end of 2003. The official goal is 10 % by 2010.
- in *Latvia* 1.4 %

Liability issues? Are they solved?

- in *Denmark* new rules are set due to public pressure.
- in *Finland* there is a general scheme on environmental liability: economic losses may be compensated, if the causal link can be proved.
- how long will a field stay contaminated – two years, ten years?
- *Norway*: According to Section 23 of the Gene Technology Act the person responsible for deliberate release of GMO is liable for damage, inconvenience or loss, including economic loss, caused by the release, regardless of any fault on his part.

What is the public opinion in the co-existence questions in each country? Has there been any public discussion going on?

- *Latvia*: public opinion is negative, knowledge is poor.
- *Lithuania*: organisations and the public have a negative view.
- *Norway*: public hearings have been organised and different replies received; opinions were rather about allowing GMOs than about co-existence.
- *Denmark*: public opinion is very negative.
- *Iceland*: organic farmers are against GMOs (food import from USA); the consumer organization wants to have labelling rules.
- *Sweden*: public opinion is strongly against GM food.
- *Finland*: a public internet portal on gene technology will be published next week!

Is there need for Nordic-Baltic co-operation in co-existence questions?

- yes, experiences on Danish legislation are a good starting point .
- a Commission set task force on the exchange of opinions?

What are the most critical questions (e.g. legal questions, processes etc.)?

- Not discussed.

Group 2:

Beate Berglund Ekeberg, Árni Bragason, Claes Debourg, Bettina Helle Jensen (moderator), Katileena Lohtander-Buckbee, Tuula Pehu, Jyrki Pitkäjärvi, Lea Tummeleht, Karen Waagø, Liga Zala

Are there guidelines (or legislation) concerning co-existence available in each country?

- *Denmark*: Act on co-existence is in force, regulations are underway.
- *Norway*: No guidelines have been developed in Norway on co-exixtence. An open meeting for interested stakeholders about coexistence was held by the Biotechnology Advisory Board in April 04. The Norwegian Food Safety Authority has appointed one person who works with the co-existence issue with the aim to develop guidelines (merethe.aasmo@mattilsynet.no). In addition two groups are working in this area. The aim is to produce a first draft for regulation before May 1, 2005.
- *Sweden*: Co-existence is considered a technical and economic matter. Technical matters are taken care by the Board of Agriculture; safety distances are developed by the Ministry of Agriculture. Legal processes are underway, expected outcome is similar to DK. Entry into force is expected in the first half of 2005.
- *Finland*: Co-existence is rather an agricultural than environmental issue. Ministry of Agriculture and Forestry has established a group for legal matters as well as a sub-group for technical matters. Deadline of their report is in the end of 2005. No decision has been made yet on whether co-existence should be regulated by legislation or voluntary guidelines.
- *Iceland*: Legislation in force since 1996. Open: Minister for Environment can regulate on 15 matters and other issues necessary according to internal agreements signed by ICE. Legislative basis exists for co-existence. No discussion has taken place on the rules necessary, but on the other hand there is no urgent need for that.
- *Latvia*: Ministry of Agriculture is responsible for co-existence issues. Monitoring council for GMOs (composed of representatives from

ministries and experts) was asked one week ago for a report on co-existence by Feb 2005. The deadline was prolonged until April 2005.
- *Estonia*: Ministry of Agriculture is responsible. Discussions started in working groups, 2 meetings have taken place so far. Representations are from the Ministries of Agriculture and Environment and farmers. The deadline is not known.

Status of cultivation of GMO's?

- *Estonia*: No commercial cultivation or field trials of higher plants has yet taken place.
- *Latvia*: Similar situation.
- *Finland*: No commercial cultivation. Two field trials are currently going on: one with birch trees and another one with potatoes for industrial use (starch improvement).
- *Iceland*: No commercial cultivation. Currently there is a field trial with barley (testing models for producing medical proteins) in 2nd year tests.
- *Sweden*: No commercial cultivation. 15-20 field trials have taken place mainly with potatoes, sugar beet, and poplar.
- *Norway*: No commercial cultivation and no field trials presently. Greenhouse cultivation which is not totally contained is also considered as a release.
- *Denmark*: No commercial cultivation. No field trials are presently going on but have taken place earlier.
- [Commission: Spain is the largest commercial GMO grower in EU; but there has been no demand for co-existence issues because there have not been any practical problems.]

What are the most problematic co-existence questions in each country?

- *Sweden*: NGOs opinion: there is a need for common agreement between farmers' organisations and NGOs on rules before commercial cultivation can take place.
- *Finland*: Liability issues, as equal possibilities should be guaranteed for GMOs, conventional and organic farming.
- *Norway*: Too early to say, except that an emphasis is put on the freedom of choice.
- *Estonia*: Co-existence issues are mixed with pro/contra GM debate, especially by organic farmers.
- *Latvia*: As in Estonia. Nature protection areas are an issue as there is little place left over for GMO cultivation.
- *Iceland*: Discussions about effects to organic farming.Very limited knowledge.

Are there any countries considering declaring themselves GM-free or establishing GM-free zones?

- *Estonia*: No.
- *Latvia*: Political wish has been expressed but there are legal problems.
- *Norway*: No political desire has been expressed.
- *Finland*: Not officially. The possibility to achieve this e.g. on a voluntary basis has been discussed. Special product areas with a legal basis is one possible model.
- *Denmark*: Not officially.

What is the share of organic farming in each country?

- *Finland*: At least 10 %, but the demand is declining. Ministry of Agriculture is supporting organic farming due to consumer demand.
- *Denmark*: About 7 %.
- *Sweden*: About 10 %.
- *Norway*: At the end of 2003 the share was 3.7 %. The official goal is 10 % by 2010.
- *Iceland*: There is a growing interest.
- *Estonia*: Cannot give an exact figure, expected to be about the same as in other countries.
- *Latvia*: 1.4 %.

Liability issues? Are they solved?

Not for any countries. An EU Directive on environmental liability exists, but it is not clear whether it can be applied to GMO co-existence issues.

- *Denmark*: Liability regulation does not cover cultivated land. Some insurance companies are interested in selling insurances.
- *Sweden*: Not covered for economic loss.
- *Norway*: According to Section 23 of the Gene Technology Act the person responsible for deliberate release of GMO is liable for damage, inconvenience or loss, including economic loss, caused by the release, regardless of any fault on his part.

What is the public opinion in the co-existence questions in each country? Has there been any public discussion going on?

- *Finland*: Advisory Board for Biotechology has prepared a memorandum on co-existence measures, which was published in a public seminar of 100 participants some weeks ago. No strong opinions have been presented so far, but the situation might change after 2005 reports. Further education of farmers is needed due to changes in farming practices. Only few NGOs take part in the discussion, but they are quite active.

- *Sweden*: Little discussion. Co-existence GMO discussion NGO-led. UK field studies highly debated. Governmental policy is based on "case-by case" principle; if the product is safe, it is consumers' choice if they want to buy it or not.
- *Estonia*: An active NGO (Estonian Fund of Nature) doubts if co-existence could prevent contamination. Public opinion is that there is a huge lack of information.
- *Latvia*: Lack of knowledge in the public. Public seminars have been organised. Public is mainly interested in harmful effects.
- *Iceland*: Discussion in 2001. Public meetings have gained low interest. Iceland imports food & feed - knowledge is lacking about their GMO content.
- *Norway*: Little discussion as no GMO cultivation or field trials and a restrictive legislation and policy on GMO.
- *Denmark*: Law on co-existence ended the debate.

Is there need for Nordic-Baltic co-operation in co-existence questions?

- *Norway*: Norway is interested in evaluations in other Nordic countries, especially on legal issues and Commission reactions to the Danish Act on co-existence. Co-operation could support and expedite development measures in other countries.
- *Denmark*: Agrees with Norway, but stresses that national processes are necessary and important. Participant list of the meeting with a brief description of responsibilities would facilitate future contacts. Meeting once a year for discussing current issues would be useful.
- *Finland*: Information exchange would be useful.
- *Sweden*: Networking to exchange ideas when problems arise would be beneficial. Issues such as isolation distances (how to decide and defend them), GMO-fish, and forestry would be of interest.
- *Estonia*: Yes, as it comes to isolation distances.

Do the seminar participants from different countries have common views in the co-existence issues?

- Not discussed.

What are the most critical questions (e.g. legal questions, processes etc.)?

- Not discussed.

Is there a need for a Nordic-Baltic internet portal that deals with GMO-issues?

- Not discussed.

Group 3:

Trausti Baldursson, Gintare Blazauskiene, Meri Bäckman, Malin Carlsson, Stefan Källman (moderator), Andres Õunmaa, Irma Salovuori, Rikke Reumert Schaltz, Kirsi Törmäkangas, Birgitte Valen

Are there guidelines (or legislation) concerning co-existence available in each country?

- *Norway*: No, as GMOs are not grown yet and there is no interest neither from farmers nor from government. Norway has an anti-GMO public opinion. Board of Food and Feed has started to work on a draft on whether Norway should have legislation or guidelines on coexistence.
- *Denmark*: Yes, an act of growing etc. of GMO's was adapted before this summer, and will be enforced in spring 2005.
- *Estonia*: No. Work and discussion is going on, but the legislation will be ready earliest in the end of 2005.
- *Lithuania*: The Lithuanian Ministry of Agriculture has prepared a draft for an act on growing of GMOs, binding rules are also planned.
- *Finland*: There is no legislation yet, but two working groups are dealing with co-existence: the Advisory Board for Biotechnology (has recently presented recommendations) and Ministry of Agriculture (in the early state of planning of legislation). There will probably be no legislation for at least two years. Finnish guidelines will probably be based at least to some extent on Danish legislation.
- *Iceland*: There is legislation on GMOs, but not specifically concerning coexistence. There are no guidelines either, but Iceland has liability legislation on GMO growing.
- *Sweden*: Ministry of Agriculture will decide in the shift 2004/2005 if there will be guidelines or legislation (probably legislation). The regulations will be hopefully ready in spring 2005, before the next growing season.

What are the most problematic co-existence questions in each country?

- *Iceland*: There are so far no GM-plants adopted for Icelandic climate, but barley may become a GM-crop
- *Finland*: Isolation distances, volunteer issue (crop rotation and so forth), farm-produced seed, and liability issues. The plants in focus in Finland are oilseed rape, potato, and sugar beet.

- *Lithuania*: Isolation distances.
- *Estonia*: Isolation distances and farm-saved seed.
- *Denmark*: Compensation and liability issues and protection of organic farmers.
- *Norway*: Compensation and liability issues, isolation distances, and protection of the farmers right to choose the production form.
- *Sweden*: Liability issues and isolation distances.

What is the share of organic farming in each country?

- *Sweden*: c. 8-10 % of the area.
- *Norway*: At the end of 2003 the share was 3.7 %. The official goal is 10 % by 2010.
- *Denmark*: 7 % of the area.
- *Lithuania*: 1-2 % and increasing.
- *Finland*: 1-10 %.
- *Iceland*: ca. 2 %.
- EU average: ca. 5 %.

Liability issues? Are they solved?

See question 1.

- *Iceland*: These issues are solved since the GMO-liability legislation was put into force in 1996. Farmers are GMO-sceptical and therefore willingly accepted the strictness of the law.
- *Norway*: According to Section 23 of the Gene Technology Act the person responsible for deliberate release of GMO is liable for damage, inconvenience or loss, including economic loss, caused by the release, regardless of any fault on his part.
- *Denmark*: Solved.

What is the public opinion in the co-existence questions in each country? Has there been any public discussion going on?

- *Norway*: No public debate is taking place, but if discussed the public is sceptical to negative towards GMOs.
- *Denmark*: There has been an active debate, which has largely focussed on how the ecological growers will be able to continue if GM-crops are introduced.
- *Estonia*: There has not been proper debate, but the public is sceptical.
- *Lithuania*: There has been some debate. The government had a public opinion poll made: 50 % of consumers do not want GMO food; some farmers are sceptical.
- *Finland*: There has been little debate, mainly from NGOs concerning GM-food and GM-trees

- *Iceland*: Public opinion is sceptical towards GMO's, but currently there is not much debate going on in comparison with the situation some years ago.
- *Sweden*: Stakeholders discuss actively and some of this is reported to newspapers. Greenpeace is also active. The public seems to be slightly negative.

Is there need for Nordic-Baltic co-operation in co-existence questions?

- *Norway*: Yes, when working towards EU in questions where we have a common view.
- *Sweden*: The Nordic Ministers have made a common statement that cooperation should take place in this area. We have at the ministerial level (Ministry of Agriculture) recently established an informal cooperation between the EU-Nordic countries and the Baltic states. Norway and Iceland are also invited to join.
- *Denmark*: Yes, but the focus should be left open, and should not only be co-existence.
- *Finland*: Yes, and the working format that has been adopted in the Baltic-Nordic collaboration is favourable, with seminars focusing on one subject at a time. Scope of cooperation could also include contained use of plants, as it is not included in the EU legislation.

Do the seminar participants from different countries have common views in the co-existence issues?

- *Iceland*: Co-existence is an economical and environmental issue.
- *Finland*: Co-existence is mainly an economical issue but partly also environmental for some crops.
- *Estonia*: Co-existence is an economical issue.
- *Denmark*: Co-existence is an economical issue.
- *Norway*: Co-existence is an economical and environmental issue.
- *Lithuania*: Co-existence is an economical and environmental issue.
- *Sweden*: Co-existence is an economical issue.

What are the most critical questions (e.g. legal questions, processes etc.)?In what form should we cooperate?

- *Norway*: We need to have meetings that end in practical and usable results.
- *Denmark and Norway*: It is important to talk together to be prepared when we are approaching EU.

Is there a need for a Nordic-Baltic internet portal that deals with GMO-issues?

- No, but it is possible to put links to the different governmental GMO-websites on NMR's website.

2. Risk assessment

Fri 10th December

9.00 **Risk assessment**

Presentations by

- *Esten Ødegaard, Norway*
  Risk assessment of GM-plants.
- *Liga Zala, Latvia*
  Risk assessment in Latvia
- *Bettina Jensen, Denmark*
  Risk assessment of non-plant GMOs in relation to directive 2001/18

Discussions:

Group 1:

Dorte Harning, Jussi Kauppila, Ulf Kjellström, Zinta Lace, Fredrik Nordvall, Gitte Silberg Poulsen, Marja Ruohonen-Lehto, Neringa Sarkauskiene, Jónína Stefánsdóttir, Esten Ødegaard (moderator)

Nordic-Baltic conditions: effect on risk assessment?

- The people in Nordic and Baltic countries are fond of their nature and nature has a big importance. Our climate conditions are special and that might influence the colonisation of (at least some) plants. Due to the slower growth we will see some effects at a later point. There are different conditions within the Nordic and Baltic countries, but compared to the southern part of Europe we are quite alike. Forests cover 40 % (Latvia and Lithuania) to 70 % (Finland), but far less in Iceland and Denmark. The applicant has to take this into account – also according to the Directive 2001/18/EU.

What is nature? There are different definitions in different countries.

- Not discussed.

Risk assessment frameworks in Baltic and Nordic countries?

- *Sweden* has special risk assessment frameworks and guidance for each kind of GM (fish, plant e.g.).
- *Finland*: Finnish Environment Institute has published a guidance booklet about risk assessment to the applicants.
- *Iceland* has no guidelines.
- *Latvia* has no special guidelines, but a board is giving advice if needed.
- *Norway* has guidelines for all GMOs, but they need to be updated.
- *Lithuania* has a risk assessment order and two different Boards for GMOs.
- *Denmark* has guidelines dealing with risk assessment on contained use. Administrators ask for expert evaluations of the risk assessments on deliberate release.
- All countries have the possibility to get expert comments.

What kind of data is especially needed for risk assessment?

- The effects of GMOs on the special Nordic-Baltic conditions. This data is not always available, thus some special tests may be needed. Growth demands of the GMO covering the Nordic-Baltic area are sometimes relevant. Which wild relatives do the GM-plants have in our area? However, we have to focus on species that might have an effect (oilseed rape).
- "Data not relevant" is information on plants that are not able (or relevant) to grow in Nordic area.

How to handle lack of data or contradicting data? More studies?

- If data is lacking or contradicting, more information is requested from the applicant. We also try to get it ourselves from articles, experts, other countries etc. The directives cover all the risk assessment points, so we can ask the needed questions.

Public opinion (concerning risk assessment) in each country. Has there been any public discussion going on?

- *Lithuania*: Public participation is in legislation since 2003. The public can present opinions on field trials. Lithuanian government organized a meeting of representatives of Ministry of Environment, Ministry of Health, Ministry of Agriculture and State Food and Veterinary Service in May 2004 and they decided upon a need for a public interview. The Public Opinion Poll of 1007 respondents (representing different areas and social standings) was carried out in September 2004. The results show that 50 % of the public is against cultivation of GMOs and GM

food. On the other hand, ca. 40 % of the population do not know anything about GMOs. Main source of information is press-offices and radio (10 %). Wish for more information was expressed. 90 % considered labelling of GM-food important.

- *Denmark*: Some discussion from time to time. Public information is published in two national papers announcing the application (production and deliberate release) and telling where to get more information. Only few responses have been received so far.
- *Finland*: There has been discussions about the relevance of risk assessment. The public are very positive in general. A public hearing is held on field trials; the notification is announced in the official journal with 60 days response time.
- *Sweden*: Public opinion is divided about GMOs, but there has not really been a public discussion about risk assessment. There have been some seminars (but no public reactions on them). Mostly Greenpeace and the like are active. Public information is published like in Denmark.
- *Iceland*: Do not know.
- *Latvia*: Public opinion and discussion are needed before an approval is given, but this has not been tried yet. People may ask questions from the National Focal Point.
- *Norway*: There is a public hearing on field trials in the official journal. A lot of responses have been received.

Is there a need for Nordic-Baltic co-operation in risk assessment questions?

- Co-operation of experts would be needed. Co-operation is useful, if there are real issues to discuss. Co-operation is needed due to our special climate and land-use conditions. A network is needed, but meetings every month are not necessary. *Denmark* is working on a project (report) about risk assessment and decision-making – it will be sent to everybody. *Latvia* would like a checklist to be used in risk assessment.

Do the seminar participants from different countries have common views in the risk assessment issues?

- Not discussed.

What are the most critical questions in risk assessment?

- Not discussed.

Group 2:

Beate Berglund Ekeberg, Árni Bragason, Claes Debourg, Bettina Helle Jensen, Katileena Lohtander-Buckbee, Tuula Pehu, Jyrki Pitkäjärvi, Lea Tummeleht, Karen Waagø (moderator), Liga Zala

Nordic conditions: effect on risk assessment?

- Nordic conditions are similar although there are differences between countries. Certain crops are more relevant, such as oilseed rape and trees (future aspect).

What is nature? There are different definitions in different countries.

- What is the definition of environment? Environment includes fields. The directive uses the term "environment", which is also included in the discussion on biodiversity.

Risk assessment frameworks in Baltic and Nordic countries?

- EU guidelines are used. *Finnish* Environment Institute has published guidelines with more detailed instructions. *Norway* has looked especially at the antibiotic marker genes. *Norway* uses the directive together with their own law and is considering the possibilities of using the article 29 as the Gene Technology Act emphasizes ethical considerations in addition to environment and health considerations when assessing the consequences of deliberate release of a GMO. In the public hearing in *Norway and Denmark* a fact sheet and information about the GMO is published – answers are collected and summarized in a report assessing the consequences of deliberate release of the GMO. In *Norway* this report also includes a recommendation whether or not to allow the release. Universities and NGO's are also involved through the public hearing. In *Denmark* the parliament has to approve the response sent to EU.
- Monitoring was discussed and article 23 was considered important.

What kind of data is especially needed for risk assessment?

- The directive is sufficient as a base for the assessment, with the possible exception of long term effects, which should be included in the monitoring plan. In **Norway** the input received through public hearing often pointed out that Nordic conditions are not taken fully into account.
- Better standards are seen in the new applications – the applicants have learned.

How to handle lack of data or contradicting data? More studies?

- More information is asked and if it is not sufficient, it can be handled in the monitoring plan and as a condition for the final approval.

Public opinion (concerning risk assessment) in each country. Has there been any public discussion going on?

- Public discussion has been mostly led by NGOs with the same answers and arguments. There is not much general knowledge.

Is there a need for Nordic-Baltic co-operation in risk assessment questions?

- Not discussed.

Do the seminar participants from different countries have common views in the risk assessment issues?

- Not discussed.

What are the most critical questions in risk assessment?

- It is important to have a contact net to be aware who is doing what in the various countries. There are only few people working in the field.
- As there are different processes in the countries, it would be useful to share information on how things are done.
- Oilseed rape, sugar beets and the "cold climate questions" that are coming are important.
- Concerns were presented about the GM-fish question.

Group 3:

Trausti Baldursson, Gintare Blazauskiene, Meri Bäckman, Malin Carlsson (moderator), Andres Õunmaa, Rikke Reumert Schaltz, Kirsi Törmäkangas, Birgitte Valen

Nordic conditions: effect on risk assessment?

- Due to climate conditions spillage of e.g. maize will rarely cause (result in?) growing of maize. It would be nice to have a more detailed e.r.a. for cold climates. Development of GM salmon can be seen as a potential threat to biodiversity in Nordic/Baltic countries.
- *Iceland*: Biodiversity is very different throughout the country.
- *Lithuania*: Two varieties of *Brassica napus* are currently grown. There is a great worry about cross pollination from GMOs.

What is nature? There are different definitions in different countries.

- A difference is made between cultivated farmland and nature. Nature vs. environment is more tricky. Some argue that rivers, lakes, mountains are 'nature'. Maybe "environment" covers everything and nature is a part of the environment. The purpose of the directive 2001/18 is to protect environment - at least *Denmark* has implemented this in the form "to protect nature and the environment".

Risk assessment frameworks in Baltic and Nordic countries?

- In most Nordic/Baltic countries, evaluation of risk assessments in the notifications received by the EU is the responsibility of the Ministries of the Environment as well as the food authorities. Most countries also involve other ministries and agencies. *Finland* has taken steps to strengthen the e.r.a. Some countries have still not carried out any risk assessments. Some countries (*Sweden and Denmark*) involve the public and NGOs in the assessment of the notification and risk assessment (only deliberate releases).

What kind of data is especially needed for risk assessment?

- The annexes in the 2001/18 directive give the principles for e.r.a.. Some Nordic/Baltic countries put a specific weight on data on cold tolerance and non-target organisms and whether the GMO contains antibiotics.

How to handle lack of data or contradicting data? More studies?

- Sometimes lack of data or contradicting data is used to stall the authorisation process – i.e. used politically.
- Lack of data should be linked to the effort needed to provide this data combined with the estimated risks of not knowing the outcome of this new e.g. research. There is also a question of independence. Close dialogue is needed between the lead member state on a notification and the notifying company.

Public opinion (concerning risk assessment) in each country. Has there been any public discussion going on?

- In some countries there is no public debate specifically about the risk assessment and how assessments are carried out. In other countries comments have been made by organic farmers and NGOs, especially about confidentiality in the notifications/risk assessment and the independence of EFSA's experts.

3. Monitoring

Fri 10th December

13.15 - **Monitoring (and inspections)**

Presentation by *Marja Ruohonen-Lehto, Finland*

Group 1:
Beate Berglund Ekeberg, Dorte Harning, Jussi Kauppila, Ulf Kjellström, Zinta Lace (moderator), Katileena Lohtander-Buckbee, Fredrik Nordvall, Gitte Silberg Poulsen, Marja-Ruohonen-Lehto, Neringa Sarkauskiene, Jónína Stefánsdóttir, Lea Tummeleht, Liga Zâla, Esten Ødegaard

Case-specific monitoring and general surveillance

What kinds of networks do exist in each country? Are the networks explicit?

- *Latvia*: Existing systems cover e.g. wood disease and pest monitoring networks, seed registry, agricultural land registers and soil maps registers. There is also national environmental monitoring, nitrate and phosphorus monitoring, agricultural biodiversity and inland water biodiversity monitoring. There are links to other countries' monitoring systems. GMO monitoring is underway.
- *Norway*: An overview is lacking. Nature conservation monitoring for developments is under several existing programmes. Agricultural inspections are carried out by National Food Safety Authority.
- *Denmark*: Not very advanced, but there was theoretical work some years ago. Overview has been carried out; there are several existing networks. Agricultural monitoring focuses in GMO crops.
- *Sweden*: The Board of Agriculture monitors field trials. There is a network between different competent authorities.
- *Lithuania*: Food and veterinary services, Ministry of Environment and Environmental Protection Agency are involved in monitoring issues. A national environmental monitoring programme exists.
- *Estonia*: Discussions are at present going on about which authorities should be responsible for monitoring of GMOs.

Does the Nordic environment create a special challenge for monitoring (or vice versa)?

- *Denmark*: Time-span is an issue. Monitoring should be separated from inspections in the deliberate releases.
- *Latvia*: Monitoring by authorities is not excluded.
- *Norway*: When specific risks for specific parts of Europe are identified, the question of who should undertake monitoring might be a challenge for the Nordic countries. It is difficult to see specific Nordic challenges concerning general surveillance. In field releases, some type of monitoring should be carried out in order to gain experience for next steps: commercial release and its monitoring.
- *Sweden* and *Finland:* Distribution of costs is still an open question.
- *Sweden*: As Denmark mentioned; time-span is an issue.

How to make use of biodiversity- and agricultural monitoring in GM-monitoring?

- *Latvia*: Agricultural monitoring parameters are useful also for GMO monitoring. There may be need for additional special parameters due to specific characteristics of the GMO and the scale of the release, as well as target and non-target organisms. Biodiversity and agricultural monitoring is a good background.
- *Sweden*: They are a useful background, but specific monitoring is needed.
- *Norway*: Tests taken for other purposes may be used also for monitoring GMO contamination.

What kind of data is especially needed for monitoring?

- *Norway*: The amount and areas of GMO use. Cross-border contamination by different means makes co-operation between countries necessary.
- *Latvia*: Data from neighbouring countries may be needed (in Latvia e.g. from Russia). Data is also needed of organisms passing occasionally fields where GMOs are cultivated (bears from Estonia…) in order to check possible consequences.
- *Sweden*: Data is needed on how to detect the organism.
- *Denmark*: Data needed depends on the organism, the trait and its relevance in different areas. Oilseed rape monitoring in Denmark is different from that in Norway.

How the obtained (monitoring) data will be used?

- *Latvia*: When monitoring takes place and data are obtained they will be used to update monitoring plans as well as for databases and

reporting purposes.The data will be inspected and compared with results from monitoring in different countries.
- *Sweden*: Data will be used for the reduction of emerging effects and to obtain knowledge of large-scale releases.
- *Norway*: Reporting is critical and should be focused on.

Is there a need for case studies?

- *Latvia*: It is useful to take part in case studies.
- *Iceland*: Probably.
- *Estonia*: Yes.
- *Sweden & Finland*: Model-systems are also useful for GMO monitoring due to lower costs.
- *Denmark*: We prefer to await results of the ongoing case studies within the EU working group on monitoring before taking a standpoint on special Nordic-Baltic needs.

Is there a need for Nordic-Baltic co-operation in monitoring issues?Do the seminar participants from different countries have common views in the discussed issues?

- Not separately discussed.

What are the most critical questions in monitoring?

- *Latvia*: A standard checklist is under development in the EU working group on monitoring. Contact between scientists concerning field trials would be useful.
- *Estonia*: It is not clear if competence exists and if there is a need for co-operation.
- *Norway*: It is difficult to identify needs in addition to ongoing work in EU working group because monitoring is a new subject.
- *Denmark and Sweden*: Interactions between organisms make it difficult to assess whether GMOs are the causes of changes or whether other factors are involved.

Group 2:

As some participants had to leave early and this would have formed a very small group, members of this group joined in groups 1 and 3

Group 3:

Trausti Baldursson, Gintare Blazauskiene, Árni Bragason,
Meri Bäckman, Malin Carlsson, Bettina Helle Jensen, Andres Õunmaa,
Rikke Reumert Schaltz, Kirsi Törmäkangas, Karen Waagø,
Birgitte Valen (moderator)

Case-specific monitoring and general surveillance

What kinds of networks do exist in each country? Are the networks explicit?

- Some Nordic/Baltic countries have no monitoring plans, others have plans under development, but nothing specific yet.
- Some countries have existing monitoring programmes/networks, e.g. for environmentally friendly farming, biodiversity, health issues or for monitoring the environment in general, but these programmes are not always suitable for GMO monitoring. Several countries are uncertain how to add GMO monitoring to existing programmes/networks.
- Often several public institutions are involved in the monitoring and coordination is needed to bring together different plans/networks.

Does the Nordic environment create a special challenge for monitoring (or vice versa)?

- Maybe monitoring in Nordic/Baltic countries is easier than elsewhere? There are less species present, which also means that new species can easily win the 'monitoring competition'.
- Long term monitoring is necessary in order to know the baseline biodiversity in depth before the introduction of GM plants/trees.
- Monitoring of GM pine trees (and other trees) is foreseen a problem in *Sweden* and other Nordic/Baltic countries, because of the presence of wild relatives, but also since several Nordic/Baltic economies are dependent on forestry.
- *Finland* has sponsored a research project on herbicide breakdown; the results are to be published soon.
- Water related issues could be relevant as there are several rivers in Nordic/Baltic countries.
- *Sweden* has acknowledged that monitoring is probably much more comprehensive and potentially more expensive than first assumed. Some believe that it not enough to monitor in the field but the surrounding nature should also be monitored. It is important to communicate to the public that ambitious monitoring is very costly.

How to make use of biodiversity- and agricultural monitoring in GM-monitoring?

- It appears that there are lots of monitoring data available, but not concerning GM monitoring. These could be used as a baseline for developing plans and networks for GMO monitoring. Maybe these programmes should be extended to also cover GMOs?
- Agricultural monitoring and practices – are there any specific issues to consider in relation to Nordic/Baltic? – E.g. ability of seeds to survive longer, or sharing of machinery (for different crops and sharing between farmers).
- Existing programmes could be used to select the correct indicator species.
- How to handle spillage e.g. under transportation needs to be a part of the monitoring plan. Transportation measures are very different.

What kind of data is especially needed for monitoring?

- A wish was expressed for country-specific monitoring plans to be developed by the notifier.
- Country-specific handling, guidelines, rules and practices of the GMO could be demanded of the notifier. E.g. general terms about what should be monitored in such cases where GMOs are transported long distances (like in Norway), how the shipments are handled in the harbour etc. But also: what insects are feeding on a GMO-plant in a given country?
- Often the authorities could provide this information to the company and the company could subsequently include this information into the monitoring plan.

How the obtained (monitoring) data will be used?

- If the first monitoring report indicates a risk, the lead competent authority should ask for a revision of the monitoring plan.
- Access to a database containing the previous monitoring reports could be useful, both for companies and authorities. They should be available for the public (methods and conclusions). Maybe companies keep the rest confidential?

Is there a need for case studies?

- Not discussed.

Is there a need for Nordic-Baltic co-operation in monitoring issues?

Not separately discussed.

Do the seminar participants from different countries have common views in the discussed issues?

- Not separately discussed.

What are the most critical questions in monitoring?

- *Denmark*: Monitoring is taken care of by the EU Working Group – there is no great need for Nordic/Baltic cooperation.
- *Norway*: EU Working Group is useful, but after that there will be challenges in the 'real life' monitoring in which co-operation could be useful. And case studies are important. However, there is always the question of funding. Therefore it is important to find indicator species important for Nordic/Baltic countries.
- *Iceland*: Co-operation could take place in very specific issues as they "pop up" – in an *ad hoc* form.

4. Other issues

Fri 10th December

16.15 **Interaction between legislative acts relevant to the administration of 2001/18** (e.g. 91/414, 1829/2003 and the regulation on pharmaceuticals)

Presentation by *Rikke Reumert Schaltz, Denmark* - Risk assessment of non-plant GMOs in relation to directive 2001/18

- General discussion
  Is there need for Nordic-Baltic collaboration? If so, how?

5. Summary

The following needs for co-operation between Nordic and Baltic countries were recognised:

1) Co-existence:

Networking is crucial. Possible future meetings should focus on current issues and could take place once a year. Isolation distances are a central issue in the co-existence problematics and should be compared. Links from GMO-websites of different authorities could be placed on the NMR website.

The Swedish EPA has already launched a NMR-project (***'Is there any such thing as a sustainable GMO in Baltic-Nordic context?'***) dealing with environmental and social sustainability of GMO's.

2) Risk assessment:

Networking and co-operation is needed, but not regular meetings on a monthly basis. It seems that in addition to the guidelines of directive 2001/18/EC, specific risk assessment frameworks are not available. However, development work on frameworks is going on in Finland. It was agreed upon that check-lists would be needed. The following suggestions for Nordic/Baltic co-operation on environmental risk assessments were presented:

- Establish a network for exchange of information and discussions concerning e.r.a. and other topics
- Assess if there is a basis for common positions, and promote these in the EU-meetings and decision making events
- Share information on how the environmental risk assessment is carried out, and by which institutions, in the Baltic and Nordic countries
- Share also information on environmental risk assessment of contained use and discuss the borderlines of Directives 2001/18/EC and 98/18/EC
- Inititiate common research projects on specific subjects, e.g new topics and topics based on common interests and/or climatic conditions
- (Establish future cooperation in farm-scale evaluations focusing on the environmental effects of GM-crops under Nordic/Baltic conditions?)

3) Monitoring:

The issue is new and it was doubted if there is indeed enough expertise in this field. Contacts with scientists were considered important. Some countries found it better to wait until the EU working group on monitoring has finished its task before taking a stand on the need for co-operation, but it was anticipated that afterwards Nordic-Baltic co-operation might be needed. Case studies were considered useful. It might be possible to identify common indicator species suitable for monitoring. Co-operation could take place on a pop-up/ad hoc basis rather than by arranging meetings on a regular basis.

4) Other:

The general view of the participants was that one of the central achievements of the project was inititating and extending the networking between the Nordic and Baltic GMO authorities. The meeting and the materials provided helped the authorities to know who is responsible of GMO issues in each country and in what issues. Further meetings focussing on current topics were considered necessary. If financiation is found for them, they should be helpful in increasing the common background of knowledge and recognising common needs.

6. GMO-websites collected in the seminar

Denmark:

- www.biotik.dk (might change next year; news and regulation within biotechnology and gene technology)
- www.at.dk (regulation on contained use, also in English)
- www.skovognatur.dk/erhvogadm/biotek/ (The Danish Forest and Nature Agency)
- www.skovognatur.dk/biosafety/ (Danish Biosafety Clearinghouse under the Cartagena Protocol) – also in English

Estonia:

Finland:

- http://gmfoorumi.fi (only in Finnish so far)
- www.geenitekniikanlautakunta.fi (Board for Gene Technology, the Finnish competent authority; mostly in Finnish)
- www.honeybee.Helsinki.fi/esgemo (a research programme on environmental, societal and health effects of GMO's)
- Institutions responsible for GMO-inspections:
  - www.sttv.fi (Product Control Agency, GMO-pages under development)
  - www.ymparisto.fi (Finnish Environment Institute)
  - www.kttk.fi (Plant Production Inspection Centre)
  - www.biotekniikanneuvottelukunta.fi (Advisory Board for Biotechnology)

Iceland:

- www.ust.is (if you want information in English, contact jonina@ust.is)

Latvia:

- www.biosafety.lv (might be old data)
- www.lpc.gov.lv

Lithuania:

- http://gmo.am.lt

Norway:

- http://www.odin.no/md/engelsk/bn.html (The Ministry of Environment)
- http://www.dirnat.no (The Norwegian Directorate for Nature Management)
- http://www.mattilsynet.no (The Norwegian Food Safety Authority)
- http://www.bion.no (The Norwegian Biotechnology Advisory Board)http://www.odin.no/lmd/engelsk/bn.html (The Ministry of Agriculture and Food)
- http://www.odin.no/hod/engelsk/bn.html (The Ministry of Health and care Services)
- http://www.vetinst.no/inet_eng/index.asp?strUrl=1000335i&topExpand=&subExpand=(The Veterinary institute,)
- http://www.vetinst.no/inet_eng/index.asp?strUrl=1001126i&topExpand=&subExpand= (The Veterinary institute, analytical methods for GMO)

Sweden:

- www.gmo.nu (Swedish GMO- governmental org.)

7. Information about authorities in Baltic and Nordic countries

7.1 Denmark

GMO-authorities:

Ministry of the Environment
The Danish Forest and Nature Agency
Landbrugs- og Bioteknologikontoret
Haraldsgade 53
DK-2100 Copenhagen
Tel. +45-3947 2000
Fax +45-3927 9899
Constitutes the Competent Authority in Denmark for Directive 2001/18/EC.

The Danish Ministry of Employment
The Danish Working Environment Authority (WEA)
Landskronagade 33
DK-2100 Copenhagen
Tel. +45-7012 1288
Fax + 45-7012 1289
Constitutes the Competent Authority in Denmark for Directive 98/81/EC (contained use of GMOs).

Ministry of Family and Consumer Affairs
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
2860 Søborg
Phone +45-3395 6000
Constitutes the Competent Authority in Denmark for regulation 1829/2003 on GM food and feed.

Regulatory developments in biotechnology in Denmark

(from www-site: http://www.oecd.org/document/18/0,2340,en_2649_34393_2074962_1_1_1_1,00.html):

Relevant Laws/ Regulations/ Rules

- Consolidated Environment and Genetic Engineering Act
- Statutory Order from the Ministry of the Environment No. 687 of October 11, 1991, on Fees in Pursuance of Act on Environment and Genetic Engineering
- Statutory Order from the Ministry of the Environment No. 380 of May 17, 2000, on Transport and Import of Genetically Modified Organisms
- Statutory Order No. 830 of October 3, 2002, on the Approval of Production using Genetically Modified Micro-organisms
- Statutory Order No. 831 of October 3, 2002, on Deliberate Release into the Environment of Genetically Modified Organisms
- Statutory Order No. 829 of October 3, 2002, on the Approval of Production using Genetically Modified Plants and Animals
- Statutory Order No. 370 of May 17, 2000, on Approval of Exhibition and Information Provision.
- Statutory Order No. 642 of June 28, 2001, on Gene Technology and Working Environment
- Statutory Order No. 1153 of 10 November 2004 on transboundary movements of GMOs an on traceability and labelling of GMOs

Total number of summary notifications on deliberate releases circulated on 08/03/2004
Plant Environmental Release
Total number of applications to date: 39

Table 1.

Common Name	MainTrait	Notifier	Notification Number
fodder beet	tolerance to glyphosate	Danisco Seed	B/DK/96/02
fodder beet	tolerance to glyphosate	Danisco Seed	B/DK/97/08
fodder beet	tolerance to glyphosate	DLF-Trifolium Dansk Planteforæd-ling v. Vibeke Meyer	B/DK/99/02
fodder beet sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/95/02
fodder beet sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/95/03
fodder beet sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/96/01
fodder beet sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/98/01
fodder beet sugar beet	tolerance to glyphosate	Maribo Seed	B/DK/94/03
fodder beet sugar beet	tolerance to glyphosate	Maribo Seed	B/DK/94/05
maize	tolerance to glufosinate	Hoechst Schering AgrEvo A/S	B/DK/98/03
oilseed rape	restoration of male steril-ity/fertility	AgrEvo A/S	B/DK/99/04
oilseed rape	restoration of male steril-ity/fertility, tolerance to glufosinate	AgrEvo A/S	B/DK/98/04
potato	alteration of carbohydrate composition, alteration of starch biosynthesis	Danisco Biotechnology Danisco, Ingredients Danisco A/S	B/DK/98/02
potato	alteration of starch biosyn-	Danisco Biotechnology Danisco	B/DK/96/04

	thesis	Ingredients Danisco A/S	
potato	alteration of starch biosynthesis	Danisco Biotechnology Danisco Ingredients Danisco A/S	B/DK/99/03
potato	alteration of starch biosynthesis	Danisco Biotechnology Grindsted Products Danisco AS	B/DK/95/01
potato	alteration of starch biosynthesis, increased storage	Danisco Biotechnology Grindsted Products Danisco AS	B/DK/94/04
potato	downregulation of amylose synthesis, increased storage	Danisco Biotechnology Grindsted Products Danisco AS	B/DK/93/04-CON
potato	downregulation of amylose synthesis, increased storage	Maribo Seed in Danisco A/S	B/DK/93/01
potato	synthesis of oligogalacturonate lyase	Department of Physiology, Carlsberg Laboratory	B/DK/94/02
potato	virus resistance (potato mop-top virus), virus resistance (potato virus Y)	DLF-Trifolium A/S Dansk Planteforædling v/ Gorm Palmgren	B/DK/99/05
potato	virus resistance (potato virus Y)	Landbrugets Kartoffelfond Danish, Potato Breeding Foundation	B/DK/96/03
spring oilseed rape	restoration of male sterility/fertility, tolerance to glufosinate	Plant Genetic Systems NV The Royal Veterinary and Agricultural University	B/DK/92/03
spring oilseed rape	restoration of male sterility/fertility, tolerance to glufosinate	The Royal Veterinary and Agricultural University, Denmark	B/DK/94/01
sugar beet	resistance to fungi (not specified), tolerance to glufosinate, virus resistance	Maribo Seed	B/DK/93/03-CON
sugar beet	tolerance to frost, tolerance to glyphosate	Maribo Seed A/S	B/DK/92/01-CON
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/97/01
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/97/02
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/97/03
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/97/04
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/97/05
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/97/06
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/97/07
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/97/09
sugar beet	tolerance to glyphosate	Danisco Seed	B/DK/99/01
sugar beet	tolerance to glyphosate	Maribo Seed	B/DK/93/02-CON
sugar beet	tolerance to glyphosate	Maribo Seed A/S	B/DK/92/02-CON
sugar beet	tolerance to glyphosate	Maribo Seed in Danisco A/S	B/DK/91/01
sugar beet	virus resistance (rhizomania – beet, necrotic yellow vein virus)	Maribo Seed in Danisco A/S	B/DK/91/02

Other Organisms Environmental Release
Total number of applications to date: 1

Table 2.

Common Name	MainTrait	Notifier	Notification Number
Pseudomonas sp.	soil bioremediation	National Environmental Research Institute, (NERI) Dept. of Microbial Ecology and Biotechnology	B/DK/00/01

7.2 Estonia

GMO-authorities:
The Ministry of Social Affairs (Estonian competent authority)
Gonsiori 29
15027 Tallinn
Tel. +372-626 9301
Fax +372-699 2209

Regulatory Developments in Biotechnology in Estonia

In 1999, the Estonian Act on Deliberate Release into the Environment of Genetically Modified Organisms came into force. This act was replaced by a new version in 2004 (RTI, 27.04.2004, 30, 209). It is important to mention here that although there was no legal framework for the production and marketing of GMOs in Estonia until the adoption of the GMO act (1999), the Seed and Vegetative Propagation Material Act (RT I 1998,52,771) required labelling of the retail packaging of certified genetically modified seed and vegetative propagation and cultivation material with the letters "GMO".

In Estonia, until new GMO Act 2004 came into force, the task of monitoring the introduction of GMOs into the environment has been assigned to the Environmental Inspection and is regulated by the Environmental Control Act (RT I 1997,86,1460). From 1st of May 2004 the responsibilities are divided between the Environmental Inspection (general supervision over GMO carried into Environment) and the Plant Production Inspectorate (supervision over GMO varieties, seed, plant propagation material, fertiliser and plant protection products). The monitoring and inspection of GM food is the main responsibility of Veterinary and Food Board under Ministry of Agriculture.

A Committee of Gene Technology has been set up to issue licenses for the deliberate release of GMOs into the environment and the marketing of such entities. It is the responsibility of the Committee to make the application concerning the use/release of GM-containing entities available to the public, which then has the opportunity to make comments to it.

The Ministry of Environment handles requests for releases of GMOs. GM food and feed are the responsibility of the Ministry of Agriculture (GM Food - Veterinary and Food Board and GM Feed Plant Production Inspectorate). The Ministry of Agriculture is responsible for the implementation of "Regulation 1829/2003/EC on genetically modified food and feed" and "Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms". The Committee has been established by law to advise the Ministry during the novel food notification process and for the riskassessment. Various sec-

tors and disciplines related to biotechnology are represented in thecommittees for "GMO food".

Upon receiving applications and announcing the outcomes of the decisions for releases and placing on the market of GMOs the information is published in the official web-announcements page www.ametlikudteadaanded.ee. Information about possible new threats in connection with GMOs are published in a newspaper of nation-wide distribution. In addition, the Advisory Committee for Genetic Modification can publish any aspect it deems necessary. The Act contains provisions for the handling of confidential information. The Ministry of the Environment makes final decisions on requests for permits or authorizations.

The Ministry of Agriculture is also responsible for developing the elements for the best practices for co-existence of genetically modified, conventional and organic crops.

Total number of summary notifications circulated on 08/03/2004
Plant Environmental Release: 0
Total number of applications to date: 0

7.3 Finland

GMO-authorities:

The Board for Gene Technology, Ministry of Social Affairs and Health
P.O. Box 33, FIN-00023
Council of State
Tel. +358-9-16001
Fax. +358-9-160 73876

Ministry of Environment, (Kasarmikatu 25)
P.O. Box 35, FIN-00023 Government
Tel. +358-9-160 07
Fax: +358 9 1603 9545

Ministry of Agriculture and Forestry
P.O. Box 30
FIN-00023 Government
Tel. (exchange) +358-9-16001
Fax +358-9-160 54202.

Authorities supervising GMO use:

Finnish Environment Institute
Chemicals Division

P.O. Box 140
FIN-00251 Helsinki
Tel. + 358-9-403000
Fax: +358-94030 0190

Plant Product Inspection Centre
Seed Testing Department
P.O. Box 111
FIN-32201 Loimaa
Tel. +358-2-7605 6243
Fax +358-2-7605 6222

National Product Control Agency for Welfare and Health – STTV
Environmental Health Unit
P.O. Box 210
FIN-00531 Helsinki
Tel. +358-9-3967 2805
Fax +358-9-3967 2798

Parliamentary technology assessment on biotechnology in Finland according to Ramberg (2002).
- Parliament Committee on the future
- Board for Gene Technology (the national competent authority for directive 2001/18/EC)
- Other: National Advisory Board for Biotechnology

Regulatory Developments in Biotechnology in Finland

(from www-site: http://www.oecd.org/document/44/0,2340,en_2649_34393_2370284_1_1_1_1,00.html) . Updated 19 September 2000

Responsible Ministry/Agency

Functions under the Gene Technology Act are carried out by the Board for Gene Technology, appointed by the Council of State for a term of five years at a time. The Board is subordinate to the Ministry of Social Affairs and Health. The members of the Board shall represent the most important administrative sectors concerned with the use of gene technology as well as ethical expertise. The Board supervises the use of genetically modified organisms (GMOs) both for research and commercial purposes. The Board for Gene technology acts also as an expert authority when necessary.

The Board for Gene Technology acts in co-operation with:

- the Ministry of Social Affairs and Health,
- the Ministry of the Environment,
- the Ministry of Trade and Industry,
- the Ministry of Agriculture and Forestry,
- the National Advisory Board for Biotechnology, and
- national experts institutes and
- research centres.

Functions under the EC Novel Food Decree are carried out by the Novel Food Board which is working under the Ministry of Trade and Industry. National Food Agency is the national contact point referred to in the Novel Food Decree. The Novel Food Board consists of experts in the field of food sciences, nutrition, microbiology, medicine, toxicology and molecular biology. It is an expert body evaluating the safety of novel foods to be marketed. It also acts as an advisory body in issues relating to novel foods and gene technology in the food chain. The Board for Gene Technology is consulted in environmental safety issues.

Ministry of Social Affairs and Health is responsible for general supervision of the Gene Technology Act and particularly for the matters relating to human health. The Ministry of the Environment, in co-operation with the Finnish Environment Institute, is responsible for the prevention of any possible harm to the environment by the use of GMOs. The Ministry of Agriculture is responsible for GMO issues related to agriculture, forestry, game and fishery. The National Advisory Board for Biotechnology acts as an advisory committee especially in ethical questions.

Relevant Laws/ Regulations/ Rules

- The Gene Technology Act came into force on the 1 June 1995 and was amended in September 2004. The Act promotes the safe use and development of gene technology in an ethically acceptable way. The goal is to prevent and avert any possible harm to human health, animals, property or environment which may be caused by the use of genetically modified organisms. The EU Directives 90/219/EC and its amendment 98/81/EEC on the contained use of GMOs and 2001/18/EC on deliberate release of GMOs are implemented by the amended Act. Besides what is prescribed in these directives the Act covers the use of genetically modified plants and animals in contained use. The Novel Food Regulation (258/97/EC) came into force in 1997 and it was implemented in the Finnish legislation by the decision of the Ministry of Trade and Industry.
- Labelling provisions of GMO food is given in the Regulation 1137/98/EC and its amendment 49/2000/EC and labelling of GMO

additives used in foods in Regulation 50/2000/EC, and the placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs is governed by Regulation (EC) 1829/2003 on genetically modified food and feed. These regulations are all valid as such in Finland.

- The Ministry of Social Affairs and Health has also prepared regulations e.g. for the classification and use of genetically modified micro-organisms (GMMOs) and for the information requested in notifications. Several guidelines are also available e.g. for the classification of greenhouses, contained use of genetically modified animals, use and classification of virus vectors in contained use, and inspection procedure in contained use of GMOs. General information, legislation and regulations as well as the notification files are available at the website of the Board. The Finnish Environment Institute has published in 1998 Guidelines for the Assessment of Environmental effects of Genetically Modified Organisms (in Finnish).

Total number of summary notifications circulated on 08/03/2004
Plant Environmental Release
Total number of applications to date: 19

Table 3.

Common Name	MainTrait	Notifier	Notification Number
barley	marker system, monitoring transgene flow	Boreal Plant Breeding	B/FI/96/4MB
barley	marker system, monitoring transgene flow	Boreal Plant Breeding	B/FI/97/3MB
broccoli, cabbage, cauliflower, spring turnip rape	improvement of storage proteins, resistance to insects (Bt-derived), synthesis of lysine, testing of gene expression	Department of Plant Production, Applied plantbiotechnology group	B/FI/99/1MB
norway spruce, scotch pine, silver birch	marker system	The Finnish Forest Research Institute, Punkaharju Research Station	B/FI/96/1MB
norway spruce, scotch pine, silver birch	marker system	The Finnish Forest Research Institute, Punkaharju Research Station	B/FI/97/2MB
oilseed rape	increased stearate content	Mildola Oy	B/FI/96/2MB
oilseed rape	tolerance to glyphosate	Mildola Oy	B/FI/97/6MB
potato	alteration of starch biosynthesis, improvement of starch quality	Boreal Plant Breeding Ltd	B/FI/04/1MB
potato	resistance to fungi (*Phytophtora infestans*), virus resistance (potato virus Y)	University of Helsinki, Department of Plant Production	B/FI/97/1MB
potato	restoration of male sterility/fertility	Boreal Plant Breeding Ltd	B/FI/01/1MB
potato	virus resistance (potato virus X)	Kemira Agro Oy, Espoo Research Centre	B/FI/96/3MB
silver birch	resistance to fungi (not specified), resistance to insects (non-specified), synthesis of chitinase, synthesis of glucanase	University of Helsinki, Faculty of Agriculture and Forestry Department of Plant Biology	B/FI/00/2MB

silver birch	synthesis of nitrate reductase	The Finnish Forest Research Institute, Punkaharju Research Station	B/FI/00/1MB
sugar beet	tolerance to glufosinate	AgrEvo Nordic Finland, Hoechst Schering AgrEvo A/S	B/FI/98/1MB
sugar beet	tolerance to glyphosate	Agricultural Research Centre, Finnish Environment Institute, Sugar Beet Research Centre	B/FI/99/2MB
sugar beet	tolerance to glyphosate	Hilleshög AB	B/FI/96/5MB
sugar beet	tolerance to glyphosate	Novartis Seeds	B/FI/97/4MB
sugar beet	tolerance to glyphosate	Novartis Seeds	B/FI/97/5MB
tobacco	synthesis of arginine decarboxylase	Finnish Forest Research Institute,Parkano Research Station; University of Oulu, Department of Biology and Botanical Gardens	B/FI/99/3MB

Other Organisms Environmental Release
Total number of applications to date: 2

Table 4.

Common Name	MainTrait	Notifier	Notification Number
Rhizobium sp.	marker system	University of Helsinki, Department of Applied Chemistry and Microbiology, Division of Microbiology	B/FI/00/1MA
Streptococcus sp.	bioluminescence	Valio Ltd	B/FI/95/1M

7.4 Iceland

GMO authorities:

Ministry for the Environment
Skuggasund 1
IS-150 Reykjavík
Tel. +354-545 8600
Fax + 354-562 4566
E-mail: postur@environment.is

Environment and Food Agency of Iceland,
Suðurlandsbraut 24,
IS-108 Reykjavík
Tel: +354 591 2000
Fax: +354 591 2010

Ministry for the Environment /Municipal health and food control

The Ministry of Social Affairs/ Administration of Occupational Safety and Health in Iceland

Advisory Board on Genetically Modified Organisms

Regulatory Developments in Biotechnology in Iceland

Althingi (the Icelandic Parliament)
- responsible for the act on GMOs

Ministry of the Environment
- responsible for the regulations on GMOs

Environment and Food Agency of Iceland is competent authority
- supervises the function of the act on GMOs
- consents for contained use and deliberate release
- control

Advisory Board on Genetically Modified Organisms

- Advisory Board for Environment and Food Agency and Ministry for the Environment regarding notifications and enforcement of the act.
- Education on GMOs
- Opinions on new regulations
- The president, vice president and one member of the advisory board are without nomination. Other members of the Advisory board are nominated by Research Division of the Iceland Forest Service, University of Iceland - Center for ethics, University of Iceland - Institute of Biology, University of Iceland - Faculty of Medicine, Technological Institute of Iceland/ Agricultural university – research branch, The Icelandic Cancer Society, Icelandic Institute of Natural History.

Ministry of the Environment /Municipal health and food control
- Control of contained use of GM microorganisms: Solid waste and waste water.

The Ministry of Social Affairs/ Administration of Occupational Safety and Health in Iceland
- Control of contained use of GM microorganisms: Occupational safety, health and accommodation.

Relevant Laws/ Regulations/ Rules
- Act no. 18/1996 on genetically modified organisms Regulation no. 493/1997 on release or distribution and marketing of GMOs (based on 90/220/EEC)
- objective: protect nature, ecosystem, plants, human and animal health against harmful and undesirable effects from GMO and ensure that

production and use of GMO is ethically and socially responsible and in accordance with the principle on sustainable development.
- Regulation no. 275/2002 on contained use of genetically modified microorganisms, (based on 90/219/EEC and 98/81/EC)
- Regulation no. 276/2002 on contained use of genetically modified organisms, other than microorganisms
- Regulation no. 68/1998 on advisory board on genetically modified organisms.

No regulation to date in force on GM food and feed.
Total number of summary notifications circulated on 08/03/2004
Plant Environmental Release
Total number of applications to date: 1

Table 5.

Common name	Main trait	Notifier	Notification number
Barley	Marker gene	ORF Liftaekni hf	B/IS/04/01

Other Organisms Environmental Release
Total number of applications to date: 0

7.5 Latvia

GMO authorities:

The Ministry of Health:
Baznîcas Street 25, Riga,
LV-1010.
Tel. (+371) 7043755,
Fax (+371) 7043751,
email: vm@vm.gov.lv

Latvian Food Centre:
38 K Valdemara Street, Riga,
LV-1010, Latvia.
Tel. (+371) 70 217 28

The Ministry of Environment:
Peldu Street 25, Riga,
LV-1494, Latvia.
Tel. (+371) 70 26418,
Fax (+371) 7020442,
email: pasts@vidm.gov.lv

The State Environmental Service,
Rupniecibas Street 23, Riga,
LV-1045, Latvia.
Tel. (+371) 70 84200,
Fax (+371) 70 84212,
email: vvd@vvd.gov.lv

Parliamentary technology assessment on biotechnology in Latvia:

- Biomedical Research and Study Centre, University of Latvia
- Institute of Microbiology and Virology of Latvian Academy of Sciences
- Institute of Microbiology and Biotechnology, University of Latvia

Regulatory developments in biotechnology in Latvia

Responsible Ministry/Agency

- Monitoring Council of GMO and Novel Foods
- Latvian Food Centre (secretariat function; the National Focal Point)

Institutions insure the supervision and control of the legal acts according to its competence:

- Food and Veterinary Service; State Plant Protection Service (Ministry of Agriculture)
- Environmental State Inspectorate, Nature Protection Board (Ministry of Environment)

Relevant Laws/ Regulations/ Rules

- Law "Cartagena Protocol on Biosafety to the Convention on Biological Diversity" (11.02.2004)
- Regulation of Cabinet of Ministers No 333 "Regulation on the contained use and deliberate release into environment and placing into market and its monitoring (20.04.2004)
- Regulation of Cabinet of Ministers No 322 "Regulation on the Monitoring Council of GMO and Novel Foods" (15.10.2000)
- Regulation of Cabinet of Ministers No 295 "Procedures for Assessment of Novel Foods and Requirements for Classification, Labelling and Quality of Novel Foods (09.07.2002)

Total number of summary notifications circulated on 08/03/2004
Plant Environmental Release: 0
Total number of applications to date: 0

7.6 Lithuania

GMO authorities:

The Ministry of Environment,
4/9 A. Jaksto,
LT-01105 Vilnius,
Tel.: +370 5 2663661,
fax: +370 5 2663663,
e-mail: info@am.lt

Regulatory developments in biotechnology in Lithuania

Responsible Ministry/Agency
State management and control of the use of GMOs and GMPs according the functions and competence prescribed in the GMO Law is carried out by:

- the Ministry of Environment as the competent authority;
- the Ministry of Agriculture with is subordinated organizations – the State Plant Protection Service; the State Seeds and Grain Service;
- the Ministry of Health with its subordinated organizations;
- State Food and Veterinary Service with its subordinated organizations – the National Veterinary Laboratory.

The Ministry of the Environment is competent authority for State Management of the use of GMOs and GMPs.

Relevant Laws/ Regulations/ Rules
- The Law on Genetically Modified Organisms (GMOs) went into force December 31, 2002, amended in 2003. The law on GMO established the spheres of activities involving GMOs and GMPs, their state management and regulation, also the rights, duties and responsibilities of the users of the said orsganisms and products.
- Regulation of Risk Assessment of the GMOs to human health, the environment or agriculture adopted by the Order of the Ministers of Environment, Agriculture, Health and the Director of State Food and Veterinary Service in December 2002, amended in 2004.
- Order on Regulation on Public Information and Participation on issuing authorizations for use of GMOs came in force in 2003. The order was drafted taking into consideration the Aarhus Convention, Directive 98/81/EC GMMs and the Directive 2001/18/EC on the deliberate release of GMOs in the environment. According to this order the notifier has an obligation to organize the public information

via different mass media when intending to use GMOs or GMPs in Lithuania.

- Establishment of the Steering Committee on GMO Management came in force in December 18, 2001. The GMOs Steering Committee is a political advisory body for the development and enforcement of national regulatory system with respect to biosafety issues and giving advice in handling and request for the deliberate release into environment and placing on the market of GMOs in Lithuania. This Committee consist of stakeholders and members from the public and interested nongovernmental organisations.
- Establishment of GMO Expert Committee adopted by the Order of the Minister of Environment in April 2003. The main function is to advice on risk assessment.
- Regulation on deliberate release into environment, placing on the market came in force in April 2004.
- The Order on Regulation on GMO Data Base adopted by the Order No. D1-542 of the Minister of Environment in 18 October, 2004. The GMO database (it could be found via Internet address http://gmo.am.lt) is important to ensure the transparency of the operational management of the National Competent Authority, facilitates the implementation of better conditions for publci awareness raising, consultation and participation. In the GMO database there is the section for the direct public opinion presentation. This database will be further connected with the Biosafety Clearing House.
- Regulation on Genetically Modified Plants and their Products not intended to Use as Food and Feed, which are Phytosanitary Controlled, and Genetically Modified Seed adopted by the Order of the Minister of Agriculture in September 2004.

Total number of summary notifications circulated on 08/03/2004
Plant Environmental Releases: 0
Total number of applications to date: 0

7.7 Norway

GMO authorities:

The Ministry of Environment,
P.O. Box 8013 Dep,
0030 Oslo,
Tel: +47 22 24 90 90,
Fax: +47 22 24 95 60,
E-mail: postmottak@md.dep.no

Directorate for Nature Management,
Tungasletta 2,
7485 Trondheim,
Norway.
Tel: +47 73 58 05 00,
Fax: +47 73 58 05 01,
E-mail: postmottak@dirnat.no.

Parliamentary technology assessment on biotechnology in Norway according to Ramberg (2002).

- The Norwegian Biotechnology Advisory Board
- The Norwegian Board of Technology

Regulatory developments in Biotechnology in Norway

Responsible Ministry/Agency

In Norway the authority to act in relation to GMOs is shared between the Ministry of Environment (MD) and the Ministry of Health and Care services.

The Directorate for Nature Management (DN) administers and coordinates the assessment under directive 2001/18/EC, while the assessment under 1829/2003 is shared between DN and the Norwegian Food Safety Authority.

MD and DN manage matters related to deliberate release of GMOs while the health authorities are responsible for contained use.

MD and DN manage GMOs in close cooperation with other management authorities like the Ministry of Agriculture and Food, and independent institutions like the Norwegian Biotechnology Advisory Board and the Scientific Committee for Food Safety.

Relevant Laws/Regulations/Rules

The Norwegian Gene Technology Act came into force in 1993 and has undergone a couple of changes since then. It aims to ensure that development and use of clones is done in an ethical and sustainable way, and in accordance with the principle of sustainable development and without causing damage to health and environment. The law applies to manufacturing and use of GMOs. The Norwegian regulations on GMOs lies close to the ones found in the EU.

Regulation on contained use of GMOs.

Regulation on transport and import of GMOs.

The regulation on consequence investigation deals with the publics right to receive and comment upon information about the environment.

The Norwegian Food Law

Guidelines for the Health risk Assessment of Novel Food

Regulatory developments

The Norwegian Ministry of Environment is preparing for implementation of Directive 2001/18/EC in Norway by amendments to regulations pursuant to the Gene Technology Act.

New national legislation on GM food and feed will enter into force spring 2005. The legislation include authorisation, labelling and traceability and is based on the EC regulations 1829/2003 and 1830/2003. The national Regulations on transport and import of GMOs are under revision to include rules on traceability, labelling and export. The draft Regulations have been notified under the TBT and SPS Agreements under WTO (G/TBT/N/NOR/4 and G/SPS/N/NOR/11).The Ministry of Agriculture and Food have started to form a basis for a new national regulation on *co-existence*. Two groups conduct this, in addition to one person in the Norwegian Food Safety Authority who works on this full time. The first draft is expected by 1. may, 2005.

Environmental releases of transgenic plants

At the moment eleven applications for marketing of GMPs are under evaluation under the 2001/18/EC directive and 5 under regulation 1829/2003. Four commercial releases of GMP have so far been approved in Norway (one tobacco and three carnation).

Five notifications on plant products that are approved in the EU are not approved in Norway, due to that they contain antibiotic resistance marker genes (one mais, one sikori and three rape).

A product that is approved under the EU-agreement automatically is approved in Norway. All applications, which is received through the EU-system, is treated in the same way as a national application, but we have the possibility to forbid the product. In such cases we have to use the security clausal as it is adjusted through the EEA-agreement.

Field trials

We have not received any notifications for field trials in 2005.

The Biotechnology Advisory Board

The Norwegian Biotechnology Advisory Board is an independent body consisting of 24 members appointed by the Norwegian government. Each member has a background and/or education, which make him/her competent to discuss questions regarding modern biotechnology. Eight members

of the board represent different public organisations. The main tasks of the Norwegian Biotechnology Advisory Board are to evaluate the social and ethical consequences of modern biotechnology and to discuss usage, which promotes sustainable development.

The Norwegian Biotechnology Advisory Board has approximately ten regular board meetings and organises two to three public conferences annually.

The secretariat of the Norwegian Biotechnology Advisory Board has five employees assisting and coordinating the board.

The Norwegian Biotechnology Advisory Board publishes the free, quarterly journal "Genialt" in Norwegian. In addition it makes information pamphlets on various topics regarding modern biotechnology.

The Scientific Committee for Food Safety

The Scientific Committee for Food Safety consists of one main committee and 8 subgroups, among them a subgroup for GMOs. The main purpose with the committee is to ensure independent scientific risk assessment for the Food safety Authority. The members are appointed by the Ministry of Health and Care services.

Total number of summary notifications circulated on 08/03/2004
Plant Environmental Release
Total number of applications to date: 1

Table 6.

Common Name	MainTrait	Notifier	Notification Number
european aspen	synthesis of phytochrome A	Department of Biology University of Tromso	B/NO/99/01

Other Organisms Environmental Release
Total number to date: 0

7.8 Sweden

GMO authorities:

Ministry of Agriculture Food and Consumer Affairs
SE-103 33 Stockholm
Phone: +46(0)8-405 10 00

Ministry of Environment
SE-103 33 Stockholm
Phone: +46(0)8-405 10 00

Ministry of Sustainable Development
SE-103 33 Stockholm
Phone: +46(0)8-405 10 00

The Swedish Work Environment Authority
SE-171 84 Solna
Phone: +46(0)8-730 90 00

The National Board of Fisheries
Box 423
SE-401 26 Göteborg
Phone: +46(0)31-743 03 00

Swedish Gene Technology Advisory Board
Retzius väg 13 A
SE-71 77 Stockholm
Phone: +46(0)08-508 846 30

Swedish Board of Agriculture
SE-551 82 Jönköping
Phone: +46(0)36-15 50 00
e-mail: jordbruksverket@sjv.se

Swedish Environmental Protection Agency
SE-106 48 Stockholm
Phone: +46(0)8-698 10 00
e-mail: arbetsmiljoverket@av.se

The Swedish Chemicals Inspectorate
Box 2
SE-172 13 Sundbyberg
hone: +468-5191100

The National Food Administration
Box 622
SE-751 26 Uppsala
Phone: +46(0)18-17 55 00

The Medical Products Agency
Box 26
SE-751 03 Uppsala
Phone: +46(0)18-17 46 00

The Swedish Rescue Services Agency
SE-651 80 Karlstad
Phone: +46(0)54-13 50 00

The National Board of Forestry
SE-551 83 Jönköping
Phone: +46(0)36-15 56 00

The Swedish Seed Testing and Certification Institute
Onsjövägen
SE-268 81 Svalöv
Phone: +46(0)418-66 74 00

Regulatory developments in biotechnology in Sweden

Responsible Ministry/Agency
Where required, a notification or permit application must be submitted to the relevant sectoral authority. The various authorities have issued their own regulations stipulating what information is to be given in a notification or application. The requirements vary, according to the organism and the type of activity involved. As a rule, charges are payable by the notifier or applicant. The areas of responsibility of the different sectoral authorities, as laid down in the Ordinance on Supervision under the Environmental Code (SFS 1998:900), are as follows:

The Swedish Work Environment Authority
- Contained use of genetically modified micro-organisms.

The National Board of Fisheries
- Contained use of aquatic genetically modified organisms.
- Deliberate release of aquatic genetically modified organisms.
- Placing on the market of products containing or consisting of aquatic genetically modified organisms.

The Swedish Chemicals Inspectorate
- Deliberate release of genetically modified micro-organisms, nematodes, arachnids and insects.
- Placing on the market of products containing or consisting of genetically modified micro-organisms, nematodes, arachnids and insects.

The National Food Administration
- Placing on the market of foods consisting of or containing genetically modified organisms.

The Medical Products Agency
- Placing on the market of medicinal products containing or consisting of genetically modified organisms.

The National Board of Forestry
- Deliberate release of genetically modified forest trees intended for timber production.
- Placing on the market of genetically modified forest trees intended for timber production.

The Swedish Board of Agriculture
- Contained use of other genetically modified organisms, which are not aquatic organisms or micro-organisms.
- Deliberate release of other genetically modified organisms.
- Placing on the market of other genetically modified organisms and of animal feed containing genetically modified organisms.

The Swedish Rescue Services Agency
- Responsible for issues regarding for instance overland transport of genetically modified organisms that are classified as dangerous goods.

The Swedish Seed Testing and Certification Institute
- Responsible for control of adventitious presence of genetically modified seed in conventional seed.

The Swedish Gene Technology Advisory Board and the Swedish Environmental Protection Agency are the two authorities with overall, central responsibility for questions relating to genetic engineering. It is requried that the various sectoral authorities consult these two authorities when drawing up regulations and considering permit applications relating to the deliberate release in Sweden of new GMOs or of previously used GMOs under substantially new conditions. *The Swedish Environmental Protection Agency* is also to be informed of decisions on consents under Directive 2001/18/EC. The Agency is Swedens focal point for the clearing house mechanism placed under the Biosafety Protocol. Among other things, *the Swedish Gene Technology Advisory Board* monitors national and international developments in genetic engineering, reviews ethical issues arising in this field, and gives advice with a view to promoting ethically justifiable and safe use of genetic engineering, in order to protect human health and the environment.

Relevant Laws/ Regulations/ Rules

from www-site: http://www.gmo.nu/

The use of GMOs in Sweden is regulated in chapter 13 of

- the Environmental Code. Other provisions of this Code are also relevant to the use of GMOs, such as the general rules of consideration in chapter 2 and the provisions on biotechnical organisms in chapter 14. The purpose of the rules is to protect human health and the environment and to ensure that particular attention is paid to ethical concerns in connection with genetic engineering activities.
- The Environmental Code is supplemented by a number of ordinances and regulations.
- The Genetically Modified Organisms (Deliberate Release) Ordinance (SFS 2002:1086)
- and the Genetically Modified Organisms (Contained Use) Ordinance (SFS 2000:271) set out more detailed rules on when consents or notifications are required for genetic engineering activities.

Different authorities have a supervisory role in relation to different categories of organisms and different types of uses. Among other things, these authorities issue regulations laying down the requirements to be met by the activities concerned, examine the information submitted by users and inspect activities involving GMOs. The information to be supplied in a notification or application relating to contained use of GMOs is specified in the supervisory authorities' regulations, while the particulars to be provided in applications concerning deliberate releases and placing on the market are set out in SFS 2002:1086. The Swedish legislation on genetic engineering is based on two EC Directives: Directive 90/219/EEC, amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms, and Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. EC directives do not automatically apply in Sweden, but must first be transposed into Swedish law. Contained use of GMOs other than GMMOs is regulated by national legislation only. Other legislation dealing with GMOs includes Regulation (EC) No 1829/2003 (food and feed), Regulation (EC) No 1830/2003 (traceability and labelling) and Regulation (EC) No 726/2004 (medicinal products for human and veterinary use). The regulation on transboundary movements of genetically modified organisms (EC) No 1946/2003, implements the UN Biosafety Protocol in EC law. EC regulations are directly applicable, without prior incorporation into Swedish legislation.

Total number of summary notifications circulated on 08/03/2004
Plant Environmental Release
Total number of applications to date: 68

Table 7.

Common Name	MainTrait	Notifier	Notification Number
apple	improvement of the rooting ability, synthesis of rol gene product(s)	The Swedish University of Agricultural Sciences Department of Horticulture	B/SE/99/1644
beet	tolerance to glufosinate	Hilleshög AB	B/SE/96/6320
beet	tolerance to glyphosate	Hilleshög AB	B/SE/96/6319
oilseed rape	resistance to fungi (not specified), synthesis of chitinase, tolerance to glufosinate	Aventis CropScience Nordic A/S	B/SE/00/312-CON
oilseed rape	resistance to fungi (not specified), tolerance to glufosinate	Plant Genetic Systems NV	B/SE/99/6925-CON
oilseed rape	restoration of male sterility/fertility, tolerance to glufosinate	Malmöhus Hushållningssällskap Läns Plant Genetic Systems NV	B/SE/96/58
oilseed rape	restoration of male sterility/fertility, tolerance to glufosinate	Malmöhus Läns Hushållningssällskap, Plant Genetic Systems NV	B/SE/96/726
oilseed rape	restoration of male sterility/fertility, tolerance to glufosinate	Plant Genetic Systems NV	B/SE/95/3270-REV1
oilseed rape	restoration of male sterility/fertility, tolerance to glufosinate	Plant Genetic Systems NV	B/SE/95/3270-REV2
oilseed rape	restoration of male sterility/fertility, tolerance to glufosinate	Plant Genetic Systems NV	B/SE/97/4291
oilseed rape	tolerance to glufosinate	Plant Genetic Systems NV	B/SE/97/2776
oilseed rape	tolerance to glufosinate	Svalöf Weibull AB	B/SE/97/1772
oilseed rape	tolerance to glyphosate	Hushållningssällskapet i Östergötland Klostergården	B/SE/00/2834
oilseed rape	tolerance to glyphosate	Statens utsädeskontroll Onsjövägen	B/SE/00/2927
potato	alteration of carbohydrate composition, alteration of starch biosynthesis, downregulation of amylase synthesis	Amylogene HB	B/SE/00/1019
potato	alteration of starch biosynthesis	Amylogene HB	B/SE/00/1020
potato	alteration of starch biosynthesis	Amylogene HB	B/SE/95/30
potato	alteration of starch biosynthesis	Amylogene HB	B/SE/95/32
potato	alteration of starch biosynthesis	Amylogene HB	B/SE/96/531
potato	alteration of starch biosynthesis	Plant Science Sweden AB	B/SE/03/1946
potato	alteration of starch biosynthesis, downregulation of amylase synthesis	Amylogene HB	B/SE/98/1105
potato	alteration of starch biosynthesis, downregulation of granule bound starch synthase	Amylogene HB	B/SE/95/28
potato	alteration of starch biosynthesis down regulation of granule bound starch synthase,	Amylogene HB	B/SE/96/530
potato	alteration of starch biosy, synthesis of ADP glucose pyrophosphorylase	Amylogene HB	B/SE/97/1782
potato	alteration of starch biosynthesis, secretion of alpha-amylase, synthesis of	Tillämpad Biokemi	B/SE/96/492