



United Nations
Environment Programme

UNEP-GEF Project on Development of National Biosafety Frameworks



Global Environment
Facility

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ESTONIA

FINAL DRAFT NATIONAL BIOSAFETY FRAMEWORK AS AT COMPLETION OF PROJECT

GENERAL INTRODUCTION

The UNEP-GEF project on the Development of the National Biosafety Framework of Estonia started in November 2001 and ended in June 2003.

The National Project Document was signed by *Mr Sulev Vare, Secretary General*.

The national executing agency for the UNEP-GEF project was the *Ministry of the Environment*, Toompuiestee 24, 15172 Tallinn, Estonia.

Contact person for NEA is Dr *Liina Eek-Piirsoo* (Tel.+ 372 6262 877, Fax:+ 372 6262 901, email leek@ekm.envir.ee).

The project coordinator was *Ms Epp Väli*.

The institutions and people represented in the *National Coordination Committee* are listed in annex 1.

DESCRIPTION OF THE NATIONAL BIOSAFETY FRAMEWORK

Biosafety policy

Estonia is Party to Convention on Biological Diversity since 1994. Estonia signed Cartagena Protocol on 6 September 2000 and it will be ratified by the end of November 2003.

There is no special national policy in biosafety in Estonia. As Estonia will join EU in 2004, the general policy is similar to this of EU. Estonia is currently harmonising its legislation so that EU directives and regulations regarding biosafety as well as Cartagena Protocol will come into force either in the end of 2003 or some secondary legislation also in 2004.

As there is no special policy in biosafety then we cannot also talk about any particular connections to other policies. However, biotechnology is one of the main priorities for Estonian Government. With its Human Genome Project, Estonia is one of the leading countries in the overall world, according to the amount of money spent per capita for biotechnology in the country.

While working out legislation for biosafety, it slowly becomes a natural part of agricultural policy and food and feed safety regulations. As the issue is quite new and there is no general agreement also inside of EU then there are currently several negotiations going on about organic farming and

GM farming, seed production, etc. The overall framework with all its details is not yet worked out, although the general frames and laws are in place.

The target to reach is pretty ambitious – to work out a system that is suitable to everybody – ie a system that allows people to use specific GMOs if they wish to, and at the same time to allow people to refuse specific GMOs if they so decide. Also, the problem with organic farming and GM farming still has to be solved. As we have seen in case of Austria then Estonia as an accession country to EU cannot take measures that are much more restrictive than those set by EU legislation (Austria wanted to restrict cultivating of GMOs in certain regions, but it was rejected by European Commission).

As Estonian Government has taken political decision to join EU and it was approved by referendum in September 2003, then we have to follow the policy of EU.

Regulatory regime

There are several acts dealing with GMOs and biosafety, directly or indirectly. Here are listed only main acts. The complete list of legal acts is attached as an **annex 2**.

Release into the environment and placing on the market of GMOs

1. The Estonian Act on Release into the Environment of Genetically Modified Organisms came into force on January 13, 1999 (Official Journal RT, I, 1999, 10, 151).

The objective of the Act is to protect human health and the environment from the consequences of the release into the environment of GMOs, to ensure the safe use of genetic modification techniques and the development of such techniques in an ethically acceptable manner. The Act also aims to implement EC Directive 2001/18/EC.

The Act covers the release of GMOs into the environment and placing on the marketing of GMOs.

The Act does not apply to: carriage of genetically modified organisms by rail, road, waterway, sea or air; modification of human genes by means of genetic modification techniques; and production of organisms through mutagenesis or cell fusion of plant cells where the resulting organisms can also be produced by traditional breeding methods.

The Act requires permits for the release into the environment and authorisation for the placing on the market of GMOs, and lays down general requirements for applications. Detailed requirements are given in Regulation No 32 of June 5, 2000. The competent authority is the Minister for the Environment.

Applications for permits must be submitted to: the Ministry of the Environment, attn of: Mrs. Liina Eek, Ministry of the Environment, Toompuiestee 24, Tallinn 15172, Estonia, Phone + 372 6262 877, Fax + 372 6262 901, e-mail: leek@ekm.envir.ee.

Formats for applications are available (see **annex 3**).

Upon receipt of an application, the Ministry of the Environment will send a copy to the Advisory Committee for Genetic Modification. The Committee is established by the Act and comprises of 9 members appointed by various ministries and institutions, with a request for advice. The advisory body is also involved in assessing the environmental aspects under the Novel Food regulations. The

advisory body advises also Ministry of Social Affairs in regard of contained use of genetically modified micro-organisms (GMMs) and Ministry of Agriculture in regard of GM animal tests.

Applications for releases and placing on the market of GMOs are published in a electronic newspaper as all the other public announcements. 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.

Final decisions on requests for permits or authorisations are made by the Ministry of the Environment.

This act will be amended according to new obligations under Cartagena Protocol (see **annex 4** for draft amended act).

2. Seed and Plant Propagation Material Act; entered into force 01.07.1998

Regulates the use of plant varieties, the production and packaging of the seed and propagating material of species of agricultural and horticultural plants and the cultivating material of forestry plants for marketing purposes; the marketing, import and export thereof; and state supervision and liability for violation of this Act or legislation established on the basis thereof.

According to this act all the GMOs have to be labelled as required under Act on Release into the Environment of Genetically Modified Organisms.

Responsible institution: Ministry of Agriculture, Estonian Control Centre of Plant Production, Teaduse 6, 75501, Saku, Harjumaa, e-mail info@tmkk.ee, fax +372 6729 149.

3. Feedstuffs Act; entered into force 01.07.2002

Sets the requirements for feedstuffs and for the manufacture and intermediation of feedstuffs, with the aim of ensuring their safety for human and animal health and for the environment and their favourable effect on animals and livestock products (hereinafter livestock products).

Responsible institution: Ministry of Agriculture.

4. Food Act; entered into force 01.01.2000

Regulates handling of food and raw material for food for marketing purposes and establishes self-checking by food business operators and state supervision to ensure food safety and the conformity of food to other requirements.

Secondary legislation:

1. Regulation No. 176 of 30 May 2000 of the Government of the Republic “*Special requirements for the labelling of food produced of genetically modified soybean or genetically modified maize and for presentation of information in any other manner*” (RT I 2000, 43, 275); entered into force 09.06.2000;
2. Regulation No. 446 of 30 December 1999 of the Government of the Republic “*Methods for assessment of the conformity of novel food to the requirements and the procedure for*

application for and issue of permits for the handling of novel food' (RT I 2000, 3, 18); entered into force 20.01.2000.

Responsible institution: Ministry of Agriculture, Veterinary and Food Board. Contact person: Ms Eveli Kaur, chief officer, Veterinary and Food Board, Väike-Paala 3, 11415, Tallinn, Estonia. Phone Number: +372 605 1718, Fax Number: +372 621 1441, Email address: eveli@vet.agri.ee

Contained use of genetically modified micro-organisms

On December 10, 2001, the *Act on the contained use of genetically modified micro-organisms (GMMs)* came into force (Official Journal RT I 2001, 97, 60).

The objective of the act is to regulate safe use of GMMs in contained use in order to protect human health and the environment. The Act also aims to implement Directive 90/219/EEC, as amended by Directive 98/187/EEC.

The Act requires permits for the contained use of GMMs. Detailed requirements for applications are given in the Regulation No 10 of 8 January, 2002. List of data to be included in a risk assessment and procedure for making risk assessment are given in the Regulation No 8 of 8 January, 2002. The Ministry primarily responsible for the implementation is the Ministry of Social Affairs.

Applications for permits for contained use of GMMs must be submitted to: Ms Silja Soon, Labour inspector, Labour Inspection, Teguri 37, 50107, Tartu, Estonia. Phone Number: +372 7366 191, Fax Number: +372 7366 188, Email address: silja.soon@ti.ee. Web site: www.ti.ee

System to handle notifications or requests for authorisations

The responsibility of regulating of use of GMOs is divided between three ministries in Estonia:

1. *Ministry of the Environment* is responsible for issuance of permits for deliberate release and marketing of GMOs or products containing of GMOs or consisting of GMOs;
2. *Ministry of Agriculture* is responsible for issuance of permits for handling and marketing of novel food (including genetically modified food), permits of use of seeds and plant propagation material, fertilizers, feed and permits for conducting of tests with animals;
3. *Ministry of Social Affairs* is responsible for issuance of permits for contained use of genetically modified micro-organisms (GMMs).

As a requirement of Cartagena Protocol, Estonia has nominated Ministry of the Environment, Ministry of Agriculture and Ministry of Social Affairs as Competent authorities, according to the abovementioned division of tasks (see <http://bch.biodiv.org/Pilot/SearchResults.aspx?SearchID=77629&Page=1&DocumentType=2>).

As Estonia is a small country, it was not considered to be necessary to create separate advisory bodies in every mentioned ministry. There are two advisory committees in Estonia responsible for making risk assessment for GMOs and products containing of GMOs or consisting of GMOs:

1. *Advisory Committee for Genetic Modification*,
2. *Novel Food Committee* (conducts also risk assessment for products that are obtained from GMOs but not containing GMOs).

Advisory Committee for Genetic Modification is composed as an advisory body at the Ministry of the Environment. Its staff is as follows:

Chair:

Liina Eek-Piirsoo, Ministry of the Environment, Department of Nature Protection

Vice-chair:

Ain Heinaru, Tartu University, Dean of Faculty of Biology and Geography

Members:

Helle Aruniit, Head of Consumers Protection Board
Mati Koppel, Head of Jõgeva Plant Breeding Institute
Jaanus Pikani, Estonian Genome Foundation, Chairman of the Supervisory Board
Erkki Truve, Professor in gene technology, Director of the Department of Gene Technology, Tallinn Technical University
Mart Ustav, Technology Institute of Tartu University, Director
Toomas Veidebaum, Estonian Institute of Experimental and Clinical Medicine, Director
Richard Villems, Academic of Estonian Academy of Science, Director of Estonian Biocentre

The task of **Advisory Committee for Genetic Modification** is to advise governmental institutions, namely Ministry of the Environment, Ministry of Agriculture and Ministry of Social Affairs, in issues concerning genetic modification:

1. in issues concerning releasing GMOs (including genetically modified novel food, genetically modified seeds, fertilizers and feed) into the environment;
2. in issues concerning marketing of products containing of GMOs or consisting of GMOs (including genetically modified novel food, genetically modified seeds, fertilizers and feed);
3. in issues concerning conduction experiments with genetically modified test animals;
4. in issues concerning using of GMMs in contained environment.

Novel Food Committee is composed as an advisory body at the Veterinary and Food Board of Ministry of Agriculture. Its staff is as follows:

Chair:

Raimond Strastin, Head of Department of Food Hygiene, Veterinary and Food Board

Members:

Helle Aruniit, Head of Consumers Protection Board
Liina Eek, Ministry of the Environment, Department of Nature Protection, senior officer
Ain Heinaru, Tartu University, Dean of Faculty of Biology and Geography
Jüri Kann, Professor of food chemistry, Tallinn Technical University, Director of Tallinn Technical University Institute of Chemistry
Aadu Kolk, Head of Food Hygiene Laboratory of The Faculty of Veterinary Medicine, Estonian Agricultural University
Heino Lutsoja, Councillor of Health Protection Inspectorate
Marika Mikelsaar, professor of medical microbiology and virology of Tartu University, Head of Institute of Microbiology of Tartu University
Märt Nõges, Adviser of Plant Material Control Centre

Toomas Paalme, Professor of food technology of Tallinn Technical University, senior scientist of National Institute of Chemical Physics and Biophysics

Kairi Ringo, Head of the Bureau of Food Safety of the Department of Veterinary and Food, Ministry of Agriculture

Erkki Truve, Professor of gene technology of Tallinn Technical University, head of Estonian Genome Foundation, senior scientist of National Institute of Chemical Physics and Biophysics

Raivo Vokk, Professor of food science of Tallinn Technical University, Head of Food Institute

Mihkel Zilmer, Professor of medical biochemistry of Tartu University, Head of Institute of Biochemistry

The task of this committee is, according to the documents submitted to the Veterinary and Food Board, decide upon the compliance of the novel food to the established requirements; also decisions will be made on the intended labelling and the issuance or refusal of permit for handling of the novel food.

Risk assessment requirements are regulated by following legal acts:

For GMOs intended for deliberate release into the environment or marketing:

“The list of data submitted in the application for the permit for release into the environment and the distribution of GMOs and the forms of permits thereof” (RTL 2000, 64, 1010), in force since 19.06.2000

For novel food:

“Assessment methods of the conformity of novel foods to requirements and the procedure of application for and issuing of novel food handling permits” (RT I, 2000, 3, 18) in force since January 1, 2000.

For genetically modified test animals (other than GMMs):

“Requirements for risk assessment for conducting experiments with genetically modified test animals and the list of data to be submitted with the risk assessment” (RTI, 13.12.2002, 101, 595). In force since 10 December 2002.

For GMMs in the contained use:

“Requirements applicable to the risk classes of contained environment” (RTL 2002, 14, 179); in force since 28.01.2002

“List of data to be included in a risk assessment and procedure for making a risk assessment” (RTL 2002, 10, 103); in force since 21.01.2002

“Requirements for work hygiene and work safety for working environment affected by biological risk factors” (RT I, 01.01.2000, 234); in force since 01.06.2002.

The description for applying for permits together with timeframes are attached as annex 5.

Formats for applications are attached as annex 3, 6 and 7 (only for deliberate release of GMOs and contained use of GMMs).

Monitoring and enforcement

Similarly to the system of handling requests, also the monitoring and enforcement are divided between three ministries in Estonia:

1. *Environmental Inspectorate under Ministry of the Environment* is responsible for surveillance of deliberate release and marketing of GMOs or products containing of GMOs or consisting of GMOs;
2. *Veterinary and Food Board under Ministry of Agriculture and Health Protection Inspectorate* is responsible for surveillance of novel food (including genetically modified food),
3. *Plant Production Inspectorate under Ministry of Agriculture* is responsible for surveillance of use of seeds and plant propagation material,
4. *Veterinary and Food Board, Environmental Inspectorate and Policy Board* are responsible for surveillance of conducting tests with animals;
5. *Labour Inspectorate under Ministry of Social Affairs* is responsible for surveillance of contained use of genetically modified micro-organisms (GMMs).
6. *Consumer Protection Board* is responsible for checking the proper labelling of the products at retail level.

There is no functional environmental monitoring system in place yet, as so far, no permits for deliberate release of GMOs and GMO products have been issued by the Ministry of Environment.

There are 2 different laboratories in Estonia that are able to carry out GMO analysis: National Institute of Chemical Physics and Biophysics in Tallinn; Institute of Molecular and Cell Biology, Tartu University. The above-mentioned laboratories use Polymerase Chain Reaction (PCR) method.

None of the laboratories have received accreditation for GM food analyses. The Laboratory of Molecular Genetics of the National Institute of Chemical Physics and Biophysics is currently in the process to receive the accreditation in 2002. Since 2000 the laboratory has participated in proficiency testing of GM maize and GM soya analyses provided by FAPAS (UK). The results have proved good and hence, the results of the analyses are considered to be reliable.

The Veterinary and Food Board in cooperation with the Ministry of Agriculture has introduced programs for monitoring of presence of genetically modified soya and maize in food. First monitoring of GM soya and GM maize was carried out during May-November 2001. The monitoring focused on the products that potentially could contain GM soya or maize. The aim of the monitoring program was to get an overview what kind of and how many food products which are produced from genetically modified soya or maize are on the Estonian market. 61 samples containing soya ingredient and 81 samples containing maize ingredient were taken from state border and wholesalers. The variety of foodstuffs from which the samples were taken was quite wide. For example, samples were taken from soy flour, maize starch, soy sauces, cornflakes, meat products, biscuits etc. The samples were analysed in the National Institute of Chemical Physics and Biophysics using a polymerase chain reaction (PCR) method. A commercial kit was used allowing the detection of Maximizer Bt 176, Bt 11, Liberty Link and Yield Gard corn and Roundup Ready soybean. 49 samples out of 142 did not give a result. No samples containing GM maize were detected. However, 8 samples containing soybean ingredient found to be genetically modified.

Public information and public participation

In Estonia everybody has access to information regarding GMOs and right to participate in decision making process.

Main legal act is **Act on Release into the Environment of Genetically Modified Organisms** (Official Journal RT, I ,1999, 10, 151)

This act contains provisions on active and passive information to the public and public participation in decision making.

Upon receipt of an application, the Ministry of the Environment will send a copy to the Advisory Committee for Genetic Modification (ACGM). The advisory body is established by the Act and comprises of 9 members appointed by various ministries and institutions, with a request for advice.

Final decisions are taken by the Ministry of the Environment.

Applications for releases and placing on the market of GMOs are published in an electronic newspaper, indicating inter alia:

- 1) the place where it is possible to familiarise oneself with the content of the application (ie the address of Ministry of the Environment);
- 2) the time period during which it is possible to express opinions about the planned release of GMO into the environment. This time period is not longer than 30 working days.

ACGM have to answer in written form in 14 days to these comments and explain whether these comments have been taken into account in decision making process or not and if no, then why. The questions and answers are not published, but it is considered as public information so that every interested person could request to see them. All the documents except confidential information are available in Ministry of the Environment.

In addition, the Advisory Committee for Genetic Modification can publish any aspect it deems necessary (except confidential information).

ACGM notifies the appropriate local municipality about the location of the site of release into the environment envisaged in the application.

According to this act all the GMO products must be marked and labelled so that every consumer could have relevant information about this product.

Additionally, there is also a general act on access to information - **Public Information Act** (entered into force 01.01.2001). The purpose of this Act is to ensure that the public and every individual has access to information intended for public use, based on the principles of a democratic and social rule of law and an open society, and to create possibilities for the public to monitor the performance of public duties.

According to **Act on contained use of GMM-s** it is not obligatory to publish information about GMM-s in contained use, but competent authority (Ministry of Social Affairs) could do it accordingly to **Public Information Act**.

Data on GMOs both in the environment, on the market and in contained use (name of GMO, site of use, purpose of use etc, except confidential information) will be available in the **public GMO register**. Due to reconstruction of this database it is currently not available electronically.

Estonia has also ratified the UNECE **Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention)** on 2 August 2001.

Information in Estonian about GMOs (legislation, outcome of survey of public opinion in regard of GM agricultural products, contact persons, popular information about novel food and GM agriculture, translated materials about GMOs etc) are available in the website of Ministry of the Environment (<http://www.envir.ee/looduskaitse/geneetiliselt.html>).

Experience of Estonia

Three permits for scientific purposes have been issued by Labour Inspectorate for contained use of GMMs from 1. and 2. risk classes. No public concern has been shown in regard of them.

So far, only one application has been submitted to Ministry of the Environment for marketing maize MON810. After receiving this application Ministry organised a press conference and the event was widely reflected in mass media (TV, newspapers, radio). Only one journalist came to Ministry to read the application, and no comments were submitted to the Advisory Body. After the Advisory Body expressed their opinion to Minister and advised him to issue the permit, a public letter was sent to Minister by several NGOs and other organisations, asking Minister to refuse to permit GMOs in Estonia. Although the official commenting time was over, Minister still took this letter into account, met with applicant and as a result the application was withdrawn for further discussions and analyses with lawyers.