UNOFFICIAL TRANSLATION
© Ministry of Social Affairs and Health

No. 377/1995

Gene Technology Act

Issued in Helsinki on 17 March 1995

Chapter 1
Aim of the Act, Scope of Application and Definitions

Section 1 (10.9.2004/847)
Aim of the Act

The aim of this Act is:

1) to promote the safe use and development of gene technology in accordance with the precautionary principle and in a way that is ethically acceptable; and

2) to protect human and animal health and the environment when carrying out the contained use or deliberate release into the environment of genetically modified organisms.

Section 2 (10.9.2004/847)
Scope of application of the Act

This Act shall apply to the contained use and deliberate release into the environment of genetically modified organisms. The Act shall also apply to the launch and operation of installations and premises intended for the handling of genetically modified organisms.

Notwithstanding the provisions of this Act, provisions elsewhere in legislation on the production and placing on the market of products and on health care, occupational safety and health, protection of animals and environmental protection shall apply. Chapters 4-6 of this Act shall not apply to the carriage of genetically modified organisms by road, rail, inland waterway, sea or air.

This Act shall not apply to organisms obtained through certain techniques of genetic modification which have long been used in a number of applications and have a long safety record. The provisions of this Act on genetically modified micro-organisms shall neither apply to organisms that have been established in accordance with generally accepted assessment criteria to be safe to human and animal health and to the environment. Further provisions on such safe micro-organisms and the criteria to be observed in the assessment of their safety are issued by decree of the Ministry of Social Affairs and Health as provided in the European Community legislation on gene technology.

Section 3 (10.9.2004/847)
Definitions

For the purposes of this Act:

1) *organism* means, with the exception of human beings, any biological entity capable of replication or of transferring genetic material;

2) *micro-organism* means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture and human cells and human tissues in culture;

3) *genetically modified organism* means an organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination;

4) *genetically modified micro-organism* means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination;

5) *contained use* means any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, transported, destroyed or disposed of or used in any other way and for which specific containment measures are used to limit their contact with the general population and the environment and to provide a high level of safety for the general population and the environment;

6) *deliberate release* means introduction into the environment of genetically modified organisms without using any specific containment measures to limit their contact with the general population and the environment or to provide a high level of safety for the general population and the environment;

7) *placing on the market* means making a product available to third parties either in return for payment or free of charge; as placing on the market is not considered supplying genetically modified organisms for contained use or their deliberate release into the environment for any other purpose than for placing on the market;

8) *operator* means any natural or legal person who is responsible for the contained use of genetically modified organisms or for the deliberate release into the environment of genetically modified and who is responsible for the content and correctness of the documents referred to in this Act and for submitting them to the competent authority;

9) *notification* means the submission of the documents referred to in this Act to the Board for Gene Technology regarding which the Board does not make a decision on granting consent;

10) *application* means the submission of the documents referred to in this Act to the Board for Gene Technology regarding which the Board makes a decision on granting consent;

11) *risk assessment* means evaluation of the risks that the use of genetically modified organisms may constitute to human and animal health and the environment, whether they are direct or indirect or immediate or delayed; and

12) *product* means a preparation placed on the market that consists of genetically modified organisms or a combination of them or that contains them.

Further provisions on the methods and techniques that are regarded as genetic modification referred to in paragraph 1 (3) and (4) are issued by Government decree.

Chapter 2
Competent Authorities

Section 4 (10.9.2004/847)
General steering and supervision

The Ministry of Social Affairs and Health shall guide compliance with this Act and any provisions issued in virtue of it as well as lead its supervision in general and in particular in respect of matters relating to human health.

The Ministry of the Environment shall guide compliance with this Act and the provisions issued in virtue of it as well as lead its supervision in regard to preventing and averting any harm to the environment caused by the use of genetically modified organisms.

Furthermore, the Ministry of Agriculture and Forestry shall guide compliance with this Act and the provisions issued in virtue of it as well as lead its supervision in matters relating to genetically modified organisms in the field of agriculture, forestry, fisheries and game husbandry.

Section 5 (10.9.2004/847)
Board for Gene Technology

The Government appoints the Board for Gene Technology upon the submission of the Ministry of Social Affairs and Health for carrying out the duties under this Act for a term of five years. The Government appoints the chairman and the vice-chairman of the Board. Furthermore, the Government appoints at the most five other members for the Board and a personal deputy member for each of them. The Board is linked to the Ministry of Social Affairs and Health.

The members of the Board shall represent at least the Ministry of Trade and Industry, the Ministry of Agriculture and Forestry, the Ministry of Social Affairs and Health and the Ministry of the Environment. Ethical expertise shall also be represented in the Board.

If a member or deputy member resigns or dies before the end of his/her term, the Ministry of Social Affairs and Health appoints upon the proposal of the same authority, organization or public institution as the member or deputy member was appointed a new member or deputy member to replace him/her for the remainder of the term.

Section 5 a (10.9.2004/847)
Duties of the Board for Gene Technology

The Board for Gene Technology leads and co-ordinates the supervision of compliance with this Act.

Besides the duties laid down for the Board for Gene Technology elsewhere in this Act, the Board shall:

1) act as the competent authority referred to in the Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms, hereinafter the Directive on contained use;

2) act as the competent authority referred to in the Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, hereinafter the Directive on deliberate release;

3) act as the competent authority referred to in the Regulation (EC) No. 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms and in the Cartagena Protocol on Biosafety; and

4) prepare opinions to be submitted to other national and international authorities.

Section 5 b (10.9.2004/847)
Presence of a quorum and handling matters within the Board

The Board for Gene Technology is convened by the chairman of the Board or, when the chairman is prevented, by the vice-chairman, or when both are prevented, by the general secretary of the Board.

The chairman of the meeting and at least three other members of the Board for Gene Technology constitute a quorum. A meeting is chaired by the chairman or vice-chairman of the Board.

The decision of the Board shall be the opinion that the majority has agreed with. If the votes are evenly divided, the chairman's opinion shall be decisive.

The decisions of the Board are signed by the chairman of the meeting and countersigned by the presenting official.

Section 5 c (10.9.2004/847)
Setting up sections

The Board for Gene Technology may set up sections. The Board appoints the chairman of each section from among its members. Also persons from outside the Board can be members of a section.

Section 5 d (10.9.2004/847)
Deciding on matters

The Board for Gene Technology decides on matters upon the submission of the general secretary of the Board or of the presenting official appointed by the Board. The Board may appoint as presenting officials for a defined period an adequate number of persons with a suitable higher university degree and good knowledge of gene technology.

Section 5 e (10.9.2004/847)
Criminal liability for public acts

When carrying out duties laid down in this Act the chairman, members, deputy members and presenting officials of the Board are subject to the provisions on criminal liability for public acts.

Section 5 f (10.9.2004/847)
Secretariat of the Board

The Board for Gene Technology has a full-time general secretary appointed by the Ministry of Social Affairs and Health for a period of five years at the most at a time. In addition, the Board has other personnel appointed by the Ministry of Social Affairs and Health.

The qualification requirement for the post of the general secretary is a suitable higher university degree, good knowledge of gene technology and familiarity with administrative tasks and the field of competence of the Board for Gene Technology.

Section 5 g (10.9.2004/847)
Supervisory authorities

The *supervisory authorities* referred to in this Act are the National Product Control Agency for Welfare and Health, the Finnish Environment Institute and the Plant Production Inspection Centre.

The supervision of compliance with this Act and the provisions and decisions issued in virtue of it is in charge of the inspectors of the supervisory authorities.

An inspector appointed by the supervisory authority shall have good knowledge of gene technology and the abilities and skills required to carry out the duties.

The actions of the inspectors are subject to what is provided by applicable statutes regarding the disqualification of authorities and arranging the interpretation and translation that is the responsibility of authorities in administrative matters. The provisions to be observed in respect of administrative matters on rectification of errors in decisions are applied to the rectification of errors in inspection records.

Further provisions on the inspection procedure and inspection record are issued by decree of the Ministry of Social Affairs and Health.

Section 5 h (10.9.2004/847)

Duties of the supervisory authorities

The National Product Control Agency for Welfare and Health keeps the gene technology register as laid down in this Act.

The National Product Control Agency for Welfare and Health supervises the contained use of and, in respect of health issues, the deliberate release into the environment of genetically modified organisms. The Finnish Environment Institute supervises the deliberate release into the environment of genetically modified organisms in respect of environmental issues. The Finnish Plant Production Inspection Centre supervises the deliberate release into the environment of genetically modified organisms in the field of agriculture and forestry.

Furthermore, the supervisory authorities:

1) are in charge of supervising, for their part, the use of genetically modified organisms in accordance with Chapters 7 and 8;

2) can, as necessary, request such further information from operators as is essential to the inspection; and

3) carry out other tasks as laid down by statute or ordered to be carried out by them.

If necessary, the Board for Gene Technology determines which supervisory authority is competent in a matter regarding the deliberate release into the environment of genetically modified organisms.

Section 6 (10.9.2004/847)

Expert authorities and institutions

Expert authorities and institutions in the field of gene technology are responsible for giving opinions to the Board for Gene Technology and acting even otherwise as experts in gene technology.

The expert authorities and institutions in the field of gene technology are, in their respective fields of competence: the National Food Agency, the National Veterinary and Food Research Institute, the National Public Health Institute, the Plant Production Inspection Centre, the National Agency for Medicines, Agrifood Research Finland, the Forest Research Institute, the Game and Fisheries Research Institute, the National Product Control Centre for Welfare and Health, the Finnish Environment Institute, the Institute of Occupational Health, and the Technical Research Centre (VTT).

The Board for Gene Technology may, as necessary, also turn to other expert institutions than those mentioned in paragraph 2.

Section 7

Section 7 has been repealed by Act 10.9.2004/847.

Chapter 3
General Duties (10.9.2004/847)

Section 8 (10.9.2004/847)
Risk assessment

The operator shall, when carrying out the contained use of genetically modified organisms and the deliberate release into the environment of genetically modified organisms, make a risk assessment with a view to preventing any adverse effects on health and the environment.

It has to be ensured in the risk assessment that potential adverse effects on human and animal health and the environment, which may occur directly or indirectly through gene transfer from genetically modified organisms to other organisms, are evaluated.

Paragraph 2 of section 8, which has been amended by Act 10.9.2004/847, enters into force in regard to products on 31 December 2004 and in regard to deliberate release into the environment for any other purpose than for placing on the market on 31 December 2008. The previous wording is:

The operator shall apply in the contained use of genetically modified organisms and in its risk assessment the newest scientific and technical knowledge concerning adverse effects on health and the environment and their control . Corresponding knowledge shall be applied in research and development experiments and in impact assessment regarding the placing on the market of products. (26.5.2000/490)

The use of antibiotic resistance marker genes which are harmful to human or animal health or the environment is prohibited when deliberately releasing genetically modified organisms into the environment.

Further provisions on the objectives of risk assessment and how it is carried out in practice and on the use of harmful antibiotic resistance gene markers are issued by decree of the Ministry of Social Affairs and Health.

Section 8 a (10.9.2004/847)
Obligation to show care

When using genetically modified organisms the carefulness and caution required by the organism or organisms in question shall be observed.

Section 9 (10.9.2004/847)
Duty to obtain information

The operator shall obtain any such information on the properties of genetically modified organisms and their effects on health and the environment as is reasonably accessible and adequate for fulfilling the obligations prescribed in this Act and in the provisions laid down in virtue of it.

Section 9 a (10.9.2004/847)

Duty to update documents

The operator shall inform the Board for Gene Technology of any changes relating to the contained use and deliberate release into the environment of genetically modified organisms that concern the operator's and responsible persons' personal or contact information. Furthermore, if the contained use is terminated in its entirety the Board for Gene Technology shall be notified thereof.

Section 10 (10.9.2004/847)
Duty to keep a record

The operator shall keep a record of the risk assessment and the contained use of genetically modified organisms. If requested, the information shall be submitted to the Board for Gene Technology.

Further provisions on the content of the duty to keep a record are laid down by decree of the Ministry of Social Affairs and Health.

Section 11 (10.9.2004/847)
Duty to monitor

When the consent for deliberate release into the environment has been granted the operator shall ensure that the monitoring and reporting will be carried out in accordance with the conditions specified in the consent. Provisions on the content of the consent are laid down in sections 18 and 21 a.

The duty to monitor is carried out by following the monitoring plan that has been drawn up. Further provisions on drawing up the monitoring plans are laid down by decree of the Ministry of Social Affairs and Health.

Section 12 (10.9.2004/847)

Section 12 has been repealed by Act 10.9.2004/847.

Chapter 4
Contained Use of Genetically Modified Organisms (10.9.2004/847)

Section 13 (10.9.2004/847)
Classification of use

The contained use of genetically modified micro-organisms is classified, using the risk assessment, in four classes. The classes of the use and the containment levels determined on the basis of them for the protection of human and animal health and the environment are as follows:

1) activities under *class 1* are linked with no or negligible risk, for which level 1 containment is sufficient;

2) activities under *class 2* are linked with a low risk, for which level 2 containment is sufficient;

3) activities under *class 3* are linked with a moderate risk, for which level 3 containment is sufficient; and

4) activities under *class 4* are linked with a high risk, for which level 4 containment is required.

The operator shall make the classification referred to in paragraph 1 (*classification of contained use*). The containment and other protective measures to be applied in the activity are determined according to the level of containment. Exception from the containment and other protective measures can be made in individual cases by consent of the Board for Gene Technology.

If there is doubt as to which class is appropriate for the intended contained use, more stringent containment and protective measures shall be used until the Board for Gene Technology has, based on sufficient evidence, approved the application of less stringent measures.

Further provisions on the classification of the contained use of genetically modified micro-organisms, levels of containment and related containment and protective measures as well an on rescue plans and safety measures to be applied are laid down by decree of the Ministry of Social Affairs and Health.

Further provisions on the classification of the contained use of genetically modified plants and animals as well as on the levels of containment and related containment and other protective measures are laid down by decree of the Ministry of Social Affairs and Health.

Section 14 (10.9.2004/847)

Notification of premises meant for the use of genetically modified organisms

The operator shall submit a notification to the Board for Gene Technology of the premises meant for the contained use of genetically modified organisms.

The notification shall contain information on the operator and the premises, the contained use of genetically modified organisms, the class of the contained use, the persons responsible for the supervision and safety of the contained use, and on waste management. The notification shall also include a summary of the risk assessment.

Further provisions on the content of the notification and on the notification procedure are laid down by decree of the Ministry of Social Affairs and Health.

Section 14 a (10.9.2004/847)

Notification of the use of genetically modified organisms

The operator shall notify the Board for Gene Technology of the planned commencing of the contained use of genetically modified organisms under class 2. As regards the use of genetically modified organisms under class 1 only the notification referred to in section 14 needs to be made.

The notification of the use of genetically modified micro-organisms shall include information on the operator and the date when the notification referred to in section 14 was submitted, the contained use of genetically modified micro-organisms, persons responsible for the supervision and safety, containment and protective measures, and on waste management. The notification shall also include a summary of the risk assessment. In addition, the notification shall contain information on the rescue plan as laid down by decree of the Ministry of Social Affairs and Health.

Notification of the use of genetically modified plants shall be made as far as the use comes under class 2. What is provided in paragraph 2 above regarding micro-organisms also applies to the notification of the first use.

Further provisions on the content of the notification and on the notification procedure are laid down by decree of the Ministry of Social Affairs and Health.

Section 14 b (10.9.2004/847)
Application for the use of genetically modified organisms

The operator shall submit an application to the Board for Gene Technology for the planned commencing of the contained use of genetically modified micro-organisms and plants under classes 3 – 4 as well as of genetically modified animals under class 2.

The application for the use of genetically modified micro-organisms shall include information on the operator, the premises and the date when the notification referred to in section 14 was submitted, the contained use of genetically modified micro-organisms, persons responsible for the supervision and safety, containment and protective measures and on waste management, as well as a copy of the risk assessment. In addition, the application shall contain information on the rescue plan as laid down by decree of the Ministry of Social Affairs and Health

What is provided in paragraph 2 above regarding micro-organisms also applies to the application for the use of genetically modified plants and animals.

Further provisions on the content of the application and on the application procedure are laid down by decree of the Ministry of Social Affairs and Health.

Section 14 c (10.9.2004/847)
Right of the operator to request decision of the Board for Gene Technology

An operator may request the Board for Gene Technology to give it the written decision referred to in section 16 a of this Act on the notification of the use under class 2.

Section 15 (10.9.2004/847)
Commencing the first use of genetically modified organisms

The contained use of genetically modified micro-organisms may be commenced as follows:

1) the contained use under class 1 when the notification of the premises has been submitted to the Board for Gene Technology;

2) the contained use under class 2 after the expiry of the period of time prescribed by Government Decree after the notification of commencing the use has been submitted to the Board for Gene Technology;

3) the contained use under class 3 or 4 after the expiry of the period of time prescribed by Government Decree after the notification of commencing the use has been submitted to the Board for Gene Technology and the Board has made its decision on approval of the application.

What is provided in paragraph 1 applies, as applicable, to commencing the contained use of genetically modified plants and animals.

Further provisions on the times of commencing the use and on the times of processing of applications are issued by Government decree.

Section 16 (10.9.2004/847)
Commencing the use of genetically modified organisms on premises notified of previously

The contained use of genetically modified micro-organisms other than that referred to in section 15 may be commenced on premises regarding which a notification of or application for the use has previously been submitted in regard to a corresponding or higher class of the contained use as follows:

1) the contained use under class 1 without a new notification provided that the operator keeps a record of the risk assessment;

2) the contained use under class 2 immediately after submitting a new notification of use, if the conditions for the approval of the notification of use on the same premises submitted previously are fulfilled;

3) the contained use under class 3 or 4 after a new application for the first use has been submitted to the Board for Gene Technology and the conditions for the approval of the previous application for the use on the same premises have been fulfilled and the Board for Gene Technology has made its decision on approval of the new application.

What is provided in paragraph 1 applies, as applicable, to the contained use of genetically modified plants and animals other than that referred to in section 15.

Further provisions on the times of commencing the use and on processing of applications are laid down by Government decree.

Section 16 a (10.9.2004/847)
Granting of consent

The Board for Gene Technology shall grant upon application a written consent for the contained use, if the contained use based on a risk assessment in accordance with section 8, taking account of the containment and other safety measures observed, does not cause harm to human or animal health or to the environment.

The Board for Gene Technology may include in the consent conditions related to risk management or achievement of sufficient containment and other protective measures.

Section 16 b (10.9.2004/847)
Notifying of new information

If the operator obtains relevant new information on risk assessment or if the operator modifies the contained use in a way which could have significant consequences with regard to the risk assessment, the Board for Gene Technology must without delay be informed thereof.

Once the Board has obtained the information it can, as appropriate, amend the conditions for its consent or undertake measures according to section 22.

Section 16 c (10.9.2004/847)
Notifying of accidents and hazardous situations

The operator shall without delay notify the Board for Gene Technology of any accident or hazardous situation which has or could have resulted in a release of a genetically modified organism from the contained use and which has or could have constituted a risk to human or animal health or the environment.

The Board for Gene Technology shall see to it that the states potentially affected by an accident and the Commission of the European Communities are immediately informed of it.

Chapter 5
Deliberate release into the environment for any other purpose than for placing on the market (10.9.2004/847)

Section 16 d (10.9.2004/847)
Scope of application

The provisions of this Chapter are not applied to medicinal substances and compounds for human use containing genetically modified organisms, if they have been authorized in virtue of other legislation and the risk assessment, monitoring plan, handling of new information, information to the public, information about the results of the release and the requirements for the exchange of information are in compliance with the requirements laid down in this Act.

Section 17 (10.9.2004/847)
Application

The operator shall apply for consent for the deliberate release of genetically modified organisms or a combination of them from the Board for Gene Technology, if the genetically modified organisms or a combination of them are intended to be released within the territory of the state of Finland.

In view of the risk assessment and identification of health and environmental effects the application shall contain the information referred to in Article 6 (2) of the Directive on deliberate release.

Further provisions on the content of the application and the application procedure are issued by decree of the Ministry of Social Affairs and Health

Section 18 (10.9.2004/847)
Granting of consent

The Board for Gene Technology shall acknowledge the date of arrival of the application and within 30 days of its arrival send a summary thereof to the Commission of the European Communities. When the Board for Gene Technology has considered the opinions possibly presented by other Member States it shall give the operator a written decision within 90 days from the date of receipt of the application.

The Board for Gene Technology shall grant consent for the release if no hazard for human or animal health or the environment is detected in the risk assessment according to section 8 and the technical dossiers have been drawn up as provided in section 17. No consent is granted if the requirements mentioned above are not fulfilled.

For the purpose of calculating the period of 90 days defined in paragraph 1, the period of time under which the Board is awaiting further information it may have requested from the operator or consulting the public as laid down in section 36 b is not taken into account.

If the Board for Gene Technology requests the operator to supply further information, it shall give its reasons for doing so.

The Board for Gene Technology may include in the consent such conditions related to the monitoring duty and risk management as are laid down in section 11.

The Board for Gene Technology may accept that a consent for releases of the same genetically modified organism or combination of genetically modified organisms on the

same site or on different sites for a defined period of time may be applied for in a single application if the purpose of the releases is the same.

Section 18 a (10.9.2004/847)
Differentiated procedures

If there is sufficient experience of releases of genetically modified organisms in certain ecosystems and the genetically modified organisms concerned comply with the provisions concerning them in the legislation of the European Community, exception from the procedure laid down in section 18 is allowed.

Further provisions on the genetically modified organisms referred to in paragraph 1 are issued by decree of the Ministry of Social Affairs and Health under observance what is provided in Article 7 of the Directive on deliberate release. Further provisions on the procedure to be observed and on the related technical dossiers and their detailed content are issued by decree of the Ministry of Social Affairs and Health.

Section 18 b (10.9.2004/847)
Commencing of operation

Any release of genetically modified organisms may be commenced only when the Board for Gene Technology has granted a written consent and in conformity with any conditions required in the consent.

Section 19 (10.9.2004/847)
Reporting on results

The operator shall inform the Board for Gene Technology of the results of a release in respect of any risk to human or animal health or to the environment and mention any products regarding which the operator intends to make an application at a later stage. The information shall be supplied after completion of the release and thereafter at the intervals laid down in the consent.

Further provisions on reporting on results and the detailed content of the documents related to the application procedure are issued by decree of the Ministry of Social Affairs and Health.

Section 19 a (10.9.2004/847)
Notifying of new information

If the release of a genetically modified organism or a combination of such organisms is altered or if it changes unintentionally in a way that can have consequences with regard to risks to human or animal health or the environment, or if new information becomes available on the risks under the processing of the application or after the Board for Gene Technology has granted its consent to the deliberate release, the operator shall immediately:

1) undertake the measures necessary to protect human and animal health and the environment;

2) inform the Board for Gene Technology of any changes planned in advance to the release or as soon as the unintended change has been observed or the new information is available; and

3) revise the measures specified in the application.

If the Board for Gene Technology obtains information referred to in paragraph 1 which could have significant consequences with regard to risks to human or animal health or the environment or which could significantly influence the circumstances described in the paragraph, the Board shall evaluate the information and make it available to the public. When the Board has obtained the information it can oblige the operator to modify the conditions of, defer the commencement of or terminate the deliberate release, if it is necessary to prevent or reduce significant health or environmental risks. The Board shall inform the public about the above-mentioned decision.

Chapter 6
Placing on the Market of Products (10.9.2004/847)

Section 19 b (10.9.2004/847)
Scope of application

Provisions of this Chapter are not applied to medicinal products for human or veterinary use or other such products containing genetically modified organisms which have been authorized on the basis of other legislation and in regard to which the risk assessment that has been carried out fulfils the requirements of this Act.

Section 20 (10.9.2004/847)
Authorization procedure

Before a genetically modified organism or a combination of such organisms as a product or contained in products is placed on the market in Finland the operator shall submit to the Board for Gene Technology an application for consent for it.

The Board for Gene Technology shall acknowledge the date of receipt of the application. The Board shall immediately send a summary of the application to the competent authorities of the other Member States and the Commission of the European Communities.

For the risk assessment and identification of health and environmental impacts the application shall contain the information referred to in article 13 (2) of the Directive on deliberate release. The Board for Gene Technology shall examine immediately if the application has been drawn up in accordance with this Act and, if necessary, request additional information from the operator.

If a genetically modified organism is intended to be used for a purpose other than that specified in the application, the operator shall make a separate application regarding it.

If the operator withdraws its application for consent, that does not hinder the operator from submitting an application at a later stage to the competent authority of another Member State of the European Communities.

Further provisions on the content of the application and the application procedure are issued by decree of the Ministry of Social Affairs and Health.

Section 20 a (10.9.2004/847)
Assessment report

When the Board for Gene Technology has received an application it will prepare an assessment report on it. It shall be stated in the assessment report if and under which conditions the genetically modified organism in question can be placed on the market or if it shall not be placed on the market.

If the Board for Gene Technology considers that that a genetically modified organism can be placed on the market, it shall within 90 days from the date of receipt of the application submit to the Commission of the European Communities its assessment report with additional information, as well as inform about its requests for further information stating its reasons for doing so. The assessment report shall also be sent to the operator.

If the Board for Gene Technology considers that a genetically modified organism cannot be placed on the market, it must within 90 days from the date of receipt of the application prepare an assessment report on it and send it to the operator. Thereafter the Board for Gene Technology shall no earlier than 15 days after sending its assessment report to the operator and no later than 105 days after receipt of the application send to the Commission of the European Communities its assessment report with additional information, as well as inform about its requests for further information stating its reasons for doing so.

A copy of the application shall be forwarded to the Commission of the European Communities together with the assessment report.

When calculating the defined periods no account is taken of the period of time during which the Board for Gene Technology is awaiting further information from the operator.

Further provisions on the content and the preparing of the assessment report are issued by decree of the Government.

Section 21

Placing on the market or its prohibition

The operator may commence the placing on the market only when it has received the written consent of the Board for Gene Technology and in conformity with the conditions laid down in the consent.

If the Board for Gene Technology has in its assessment report come to the conclusion that the product shall not be placed on the market, the application shall be rejected. The decision shall be reasoned.

If the Board for Gene Technology considers that the product can be placed on the market, the Board shall give a written consent to its placing on the market. The consent shall be granted if the risk assessment laid down in section 8 shows that the product does not pose a risk to human or animal health or to the environment and no Member State or the Commission of the European Communities has raised a reasoned objection to it and if there are no outstanding issues linked with it that have not been resolved between the Member States and the Commission of the European Communities.

The operator shall be informed of the decision on consent in writing and the decision shall be forwarded to the Member States and the Commission of the European Communities within 30 days from reaching the consensus referred to in paragraph 3.

A consent can be granted for a maximum period of ten years starting from the date on which it is issued.

If it is question of placing on the market of genetically modified seeds, the period of validity of the consent is calculated starting from the date on which the plant variety is

included on the official national list of varieties in accordance with the Seeds Trade Act (728/2000).

In regard to artificial forest regeneration material the period of validity of the consent is calculated starting from the date on which the basic material is accepted in the official national register in accordance with the Act on Trade in Forest Reproductive Material (241/2002).

Section 21 a (10.9.2004/847)
Content of the consent

The consent shall specify:

1) the scope of the consent, and the genetically modified organism or organisms and their specific identification;

2) the period of validity of the consent;

3) the conditions for the placing on the market of the product in respect of the use of the genetically modified organism or organisms, their handling and packaging, and for the protection of particular ecosystems, environments or geographical areas;

4) the obligation to supply, on request, control samples to the Board for Gene Technology as laid down in section 28;

5) the labelling requirements as laid down in section 21 c; and

6) the monitoring requirements as laid down in section 11, as well as the obligation to report to the Board for Gene Technology the results of monitoring in regard to the period of time covered by the monitoring plan and, as necessary, any obligations on the seller or user of the product.

Section 21 b (10.9.2004/847)
Handling of new information

If new information has become available regarding the risks posed by a genetically modified organism to human and animal health or the environment before the consent is granted, the operator shall immediately undertake the measures necessary to protect human and animal health and the environment and inform the Board for Gene Technology thereof. In addition, the operator shall in this respect reassess the information presented in the application.

If the Board for Gene Technology obtains information referred to in paragraph 1 after the consent has been granted, it shall immediately forward the information to the Commission and the competent authorities of the other Member States of the European Communities.

The Board for Gene Technology shall within 60 days after the receipt of the new information forward its assessment report to the Commission of the European Communities indicating if and how the conditions of the consent should be amended or if the consent should be terminated, since a genetically modified organism has been found to constitute a significant hazard to human and animal health and the environment.

In the absence of any reasoned objection from a Member State or the Commission of the European Communities or any outstanding issues that have not been resolved in regard to the conditions of the consent, the Board for Gene Technology shall amend the consent as proposed. The amended consent shall be sent to the operator, and the Member States and the Commission of the European Communities shall be informed thereof.

Section 21 c (10.9.2004/847)

Labelling

There shall be at all stages of the placing on the market of genetically modified organisms a mention on the labelling of the product or in the accompanying document that “This product contains genetically modified organisms”, unless otherwise provided elsewhere.

It has to be ensured, in addition, that the labelling and packaging of the genetically modified organisms as products or in products placed on the market comply at all stages of the placing on the market with the requirements specified in the written consent.

In regard to the products which contain minor amounts of authorized genetically modified organisms that are adventitious or technically unavoidable, a minimum threshold may be established by decree of the Ministry of Social Affairs and Health below which these products need not be labelled according to the provision in paragraph 1.

Section 21 d (10.9.2004/847)
Application for renewal of consent

The operator may apply for renewal of the consent from the Board for Gene Technology.

When the operator wishes to apply for renewal of the consent it shall submit to the Board for Gene Technology at the latest nine months before the period of validity of the consent expires an application containing the following:

1) a copy of the consent;

2) a report on the results of the monitoring;

3) any other information on such risks that the product may pose to human or animal health or the environment; and

4) as appropriate, a proposal for amending or complementing the conditions of the consent.

21 e (10.9.2004/847)
Procedure for renewal of consent

The Board for Gene Technology shall acknowledge the date of receipt of the application and without delay forward a copy of the application and its assessment report to the Commission of the European Communities.

The Board for Gene Technology shall without delay prepare the assessment report on the application for renewal of the consent referred to in section 20 a, as laid down in regard to it.

After the operator has submitted the application for renewal of the consent it may continue the placing on the market of the genetically modified organism in accordance with the conditions of the original consent until the decision on renewal of the consent is made.

21 f (10.9.2004/847)
Renewed consent

If the Board for Gene Technology has in its assessment report come to the conclusion that the product shall not be kept on the market, the Board shall forward its assessment report to the Commission of the European Communities. If the

Commission's opinion is in conformity with the Board's conclusion, the application shall be rejected. The decision shall be reasoned.

If the Board for Gene Technology considers that the product can be kept on the market, the Board shall grant a written consent to keeping the product on the market. The consent shall be granted if the risk assessment laid down in section 8 indicates that the product does not constitute a hazard to human or animal health or the environment, and no Member State or the Commission of the European Communities presents a reasoned objection and there are no outstanding issues related to it that have not been resolved between the Member States and the Commission.

The operator shall be informed of the decision on the consent in writing and the decision shall be forwarded to the Member States and the Commission of the European Communities within 30 days of reaching the consensus referred to in paragraph 2.

The maximum period of validity of the renewed consent is in general ten years, and it can be shortened or extended for particular reasons related to the protection of human and animal health and the environment.

Chapter 7
Prohibitions and Restrictions

Section 22 (10.9.2004/847)
Actions contrary to the provisions and restricting and prohibiting of use

If the operator violates this Act or provisions issued in virtue of it, the Board for Gene Technology or the supervisory authority may order the operator to fulfil the obligations laid down in the Act or in provisions issued in virtue of it.

If it is found after the submitting of a notification or an application in accordance with this Act that a genetically modified organism can cause considerable harm to human or animal health or to the environment, the Board for Gene Technology may on its own initiative or on the initiative of the supervisory authority:

1) restrict the taking into use of the installation or its part or the contained use of genetically modified organisms;

2) restrict the deliberate release for any other purpose than for placing on the market; or

3) prohibit the operator to continue a procedure violating the provisions, if the measures referred to in subparagraphs 1 and 2 do not result in a sufficiently high level of protection.

The operator shall be responsible for any expenses arising from the prohibition or restriction measures.

If the operator does not observe the order imposed by the supervisory authority in virtue of this provision, the supervisory authority may inform the Board for Gene Technology thereof, and the Board may undertake measures referred to in section 38 (2).

Section 23

Section 23 has been repealed by Act 10.9.2004/847.

Section 24 (10.9.2004/847)
Restricting and prohibiting the sale and use of a product

If the supervisory authority or the Board for Gene Technology finds out that a product may constitute a serious hazard to human or animal health or to the environment, it shall suspend the placing on the market of the product and inform the public thereof. The supervisory authority shall inform the Board for Gene Technology thereof. The Board shall inform the Ministry of Social Affairs and Health, which shall bring the matter to the plenary session of the Government for consideration.

The Government may provisionally restrict the use or sale of a genetically modified product, or prohibit its use or sale within the territory of Finland, if the supervisory authority or the Board for Gene Technology has after the granting of the consent obtained information that has significant consequences with regard to the risk assessment, or on the basis of which the Board for Gene Technology or the supervisory authority finds out that the product or a genetically modified organism in the product may constitute a serious hazard to human or animal health or to the environment.

The Board for Gene Technology shall immediately inform the Commission and the Member States of the European Communities of the measures in accordance with this section, at the same time giving its reasons for the decision, as well as forward to them its re-evaluation of risk assessment. It shall appear from the risk assessment if the conditions of the consent should be amended or if the consent should be cancelled. The new or complementary information that the decision is based on shall be supplied at the same time.

Section 24 a (10.9.2004/847)
Unauthorized products

The supervisory authority or the Board for Gene Technology shall undertake measures to prevent the placing on the market of a genetically modified product for which no authorization has been granted. At the same time remedial action to prevent damages must be initiated, if necessary, and the Board shall inform the public and the Commission and the Member States of the European Communities of the matter.

Section 25 (10.9.2004/847)
Enforcement functions

When imposing a prohibition or restriction referred to in section 24, the Government may at the same time assign the Board for Gene Technology duties relating to execution of the decision.

Chapter 8
Supervision and gene technology register (10.9.2004/847)

Section 26 (10.9.2004/847)
Gene technology register

The National Product Control Agency for Welfare and Health keeps the gene technology register. The Board for Gene Technology however decides on providing data from the register.

The following matters shall be entered into the gene technology register if they are not contained in some other register:

1) notifications and applications submitted to the Board for Gene Technology;
2) decisions made by authorities on account of applications;

3) inspection records;

4) release sites of genetically modified organisms released for any other purpose than for placing on the market;

5) sites of growing cultivated genetically modified organisms placed on the market;

6) reports on monitoring results concerning products containing or consisting of genetically modified organisms; and

7) other information considered essential by the supervisory authorities or the Board for Gene Technology, notwithstanding the personal data referred to in the Personal Data Act (523/1999).

If the information referred to above in paragraph 2 is contained in some other register, the name of the register and its keeper shall be given.

Section 26 a (10.9.2004/847)

Right to check data in the gene technology register and correction of errors

An operator has the right to check the information entered into the register regarding is operations.

It must be seen to it that any information that is in view of the use of the register incorrect, unnecessary, deficient or outdated will be corrected, removed or complemented without unnecessary delay (*correction of errors*). An error shall always be corrected on the operator's grounded request.

Section 26 b (10.9.2004/847)

Right to use the gene technology register

The Ministries referred to in section 4, the Board for Gene Technology and the supervisory authority have the right to use the gene technology register.

Section 27 (10.9.2004/847)

Access to information and right to inspect

The Board for Gene Technology and the supervisory authority have, notwithstanding the provisions on confidentiality, the right to obtain information for supervision of compliance with this Act and the provisions issued in virtue of it from those whom the obligations according to this Act and the provisions issued in virtue of it apply to.

The Board for Gene Technology and the supervisory authority have the right to make inspections on premises other than those protected by provisions on inviolability of domicile in order to supervise compliance with this Act and the provisions issued in virtue of it.

Section 28 (10.9.2004/847)

Right to receive samples and to carry out tests

The Board for Gene Technology or the supervisory authority have the right to make or commission free of charge the necessary measurements or tests and to receive sufficiently large samples to permit evaluation of the impact on health and the environment of genetically modified organisms.

The Board for Gene Technology may make or commission the necessary investigations considered reasonable in order to be able to determine whether the use of

genetically modified organisms causes harm to human or animal health or the environment.

Before action is taken, the operator shall be given a hearing, unless there is a particular reason for not doing so.

The operator shall have the access to the results of the measurements and other tests.

Section 29
Obtaining information from other authorities

Authorities carrying out the supervision of genetically modified organisms and related activities in virtue of this Act or other statutes have the right to obtain from each other any information necessary for the supervision and to use samples obtained by other authorities for the necessary tests. (10.9.2004/847)

The authority receiving the information shall maintain the same confidentiality as that imposed by section 32 on the authority supplying the information.

Section 30 (26.5.2000/490)
International exchange of information

The Board for Gene Technology may supply such information as is required by international agreements binding on Finland to the competent authorities, international organizations and states participating in co-operation. If personal data are supplied to foreign countries the provisions of the Personal Data Act (523/1999) shall apply.

Section 31 (10.9.2004/847)
Executive assistance

Police, border guard and customs authorities shall, if necessary, provide the Board for Gene Technology and the supervisory authority with executive assistance for the supervision of compliance with, and the enforcement of, this Act and the provisions issued in virtue of it.

Chapter 9
Miscellaneous Provisions

Section 32 (10.9.2004/847)
Publicity of information and confidentiality

Any documents received or drawn up when attending to duties prescribed in this Act are subject to the provisions on publicity and confidentiality of documents laid down in the Act on the Openness of Government Activities (621/1999).The following information is not considered confidential:

1) the date of the document;

2) the name and address of the operator;

3) general descriptions of genetically modified organisms;

4) information on the location of the use of genetically modified organisms as well as on the purpose and extent of the use and the planned use and monitoring;

5) class of the contained use and containment measures;

6) methods and plans for emergency situations;

7) risk assessment; or
8) authorization documents according to this Act.

The operator shall specify the information that it considers confidential. The operator shall state reasons for its opinion. When supplying information the Board for Gene Technology decides, after having heard the operator, which information must be kept confidential.

Section 33 (10.9.2004/847)
Supplying confidential information

In addition to what is provided in the Act on the Openness of Government Activities, information and documents produced in the context of the implementation of this Act may be provided:

1) to the authorities referred to in section 29 for implementation of this Act;
2) to experts employed by the Board for Gene Technology; and
3) to the prosecuting authorities, police, border guard or customs authorities for purposes of criminal investigation.

Section 34 (10.9.2004/847)
Referring to other applicants' information

In a notification or an application made in accordance with Chapters 4 - 6, the operator may refer to information or results provided in notifications or applications made by other operators, provided that they have given their written consent to such reference if the information is not public.

Section 35 (10.9.2004/847)
Charges

Provisions on the amount of charges for inspection and testing for the purposes of the supervision and of charges for the processing of notifications and applications collected under this Act are issued by Government decree in accordance with the Act on the Criteria for Charges Payable to the State (150/1992).

The supervisory authority and the Board for Gene Technology may, on application, for their part grant exceptions to collecting charges if a charge would be unreasonable in view of the restricted scope of the research on, or the use of genetically modified organisms, or for some other reason. Collection of the charge may be waived in part or in full.

Section 36 (10.9.2004/847)
Compensation for loss

Compensation for damage to the environment arising as a consequence of activities referred to in this Act is subject to the provisions of the Act on Compensation for Environmental Damage (737/1994).

Compensation for loss caused by a product containing genetically modified organisms to a person or to property intended for private use or consumption and used by the injured party mainly for such purpose is subject to the provisions of the Product Liability Act (694/1990).

Compensation for other loss caused by activities referred to in this Act is subject to the provisions of the Tort Liability Act (412/1974). The operator is liable to compensate for such loss, even if it was not caused wilfully or through carelessness.

The provisions of paragraphs 1 to 3 shall not restrict the right of the injured party to compensation on the basis of an agreement or by virtue of other acts than those referred to in paragraphs 1 to 3.

Section 36 a (10.9.2004/847)
Consulting the public in regard to contained use

The Board for Gene Technology may decide that the public must be consulted in regard to certain circumstances related to the proposed contained use.

The consulting and the supplying of documents are subject to the provisions on confidentiality laid down in section 32.

Section 36 b (10.9.2004/847)
Consulting the public in regard to the deliberate release into the environment for any other purpose than for placing on the market

The Board for Gene Technology shall consult the public in regard to a planned deliberate release into the environment for any other purpose than for placing on the market. The Board shall inform about having received the above-mentioned application at least in the Official Gazette (Virallinen lehti).

At least the following particulars shall be reported in the Official Gazette or other media:

1) the right of access of the public to documents regarding the deliberate release for any other purpose than for placing on the market;
2) at which agency and how the access to the documents is arranged;
3) possibility to obtain a copy of the application document;
4) to which authority written opinions shall be addressed; and
5) 60 days' time limit for consulting and when the time limit expires.

The consulting and the supplying of documents are subject to the provisions of section 32 on confidentiality.

Section 37 (10.9.2004/847)
Further provisions

Provisions on application and implementation of the legislation of the European Communities on gene technology can be issued by decree of the Ministry of Social Affairs and Health, as far as the competence does not fall under other authority or body.

Chapter 10
Sanctions and Appeal

Section 38 (10.9.2004/847)
Conditional fine, threat of performance at the defaulter's expense and threat of suspension

The Board for Gene Technology may oblige an operator which uses genetically modified organisms contrary to this Act or the provisions issued in virtue of it to make a notification or application under threat of a fine or of suspension of the operation or its part.

The Board for Gene Technology may reinforce a prohibition or order issued under this Act by imposing a conditional fine or with the threat that the measure that the neglected action concerns will be performed at the defaulter's expense.

Matters regarding conditional fines, threat of performance at the defaulter's expense and threat of suspension are subject to the provisions of the Act on Conditional Imposition of a Fine (1113/1990).

Sections 39 to 41

Sections 39 to 41 have been repealed by Act 24.5.2002/414.

Section 42 (24.5.2002/414)

Reference provisions concerning punishments

Punishment for jeopardizing health in contrary to this Act or provisions issued in virtue of it is prescribed in Chapter 34, section 4, of the Penal Code.

Punishment for gene technology offence contrary to this Act or provisions issued in virtue of it is prescribed in Chapter 44, section 4, of the Penal Code.

Punishment for damaging the environment in contrary to this Act is prescribed in Chapter 48, sections 1 to 4, of the Penal Code.

Punishment for breach of the confidentiality duty referred to in section 32 is imposed according to Chapter 38, 1 or 2 section, of the Penal Code, unless the act is punishable under Chapter 40, section 5, of the Penal Code or a more severe punishment is prescribed for it elsewhere in legislation.

Section 43

Section 43 has been repealed by Act 21.8.1995/1019.

Section 44 (10.9.2004/847)

Appeal

A decision issued by the Government or the Board for Gene Technology may be appealed as laid down in the Administrative Judicial Procedure Act (586/1996).

A decision concerning imposing a charge according to section 35 (1) may be appealed as laid down in section 11 b of the Act on the Criteria for Charges Payable to the State.

A decision concerning collection of a charge according to section 35 (2) may be appealed to an Administrative Court as laid down in the Administrative Judicial Procedure Act. The decision of the Administrative Court referred to in this paragraph is not subject to appeal.

Section 44 a (10.9.2004/847)

Claim for rectification of decision of the supervisory authority

Decisions of the supervisory authority are not subject to appeal. Rectification of a decision of the supervisory authority is applied for in writing from the Board for Gene

Technology within 30 days from the date of serving the decision. The provisions on service of notice in administrative matters are applied to the service of the decision.

The decision of the supervisory authority shall be furnished with instructions for how to bring it to the Board for Gene Technology for consideration. The claim for rectification shall include the name and contact information of the person who makes or draws up the claim for rectification as well specify in which respects rectification of the decision is demanded and the grounds for the claim for rectification.

Chapter 11
Implementing and Transitional Provisions

Section 45
Entry into force

This Act enters into force on 1 June 1995.

Measures necessary for the implementation of this Act may be undertaken before its entry into force.

Section 46
Transitional provision

The notifications referred to in Chapters 4-6 shall be made within twelve months from the entry into force of this Act.

Provisions on entry into force:
10.9.2004/847:

This Act enters into force on 15 September 2004.

Provisions of this Act are applied to the processing of applications referred to in Chapters 4 – 6 that are pending when this Act enters into force.

Sections 21 d, 21 e and 21 f of this Act are not applied to renewal of consents granted prior to 17 November 2002, if the renewal of the consent is applied for prior to 17 October 2006.

Paragraph 2 of section 8 enters into force in regard to products on 31 December 2004 and in regard to the deliberate release for any other purpose than for placing on the market on 31 December 2008.

Measures necessary for the implementation of this Act may be undertaken before its entry into force.