Translation from Finnish
Legally binding only in Finnish and Swedish
Ministry of Social Affairs and Health, Finland

Gene Technology Act

(377/1995, amendments up to 39/2023 included)

By decision of Parliament, the following is enacted:

Chapter 1
Objective of the Act, scope of application and definitions

Section 1 (847/2004)
Objective of the Act

The objective 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 (847/2004)
Scope of application of the Act

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

Notwithstanding the provisions of this Act, provisions laid down in other acts 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 do not apply to the carriage of genetically modified organisms by road, rail, inland waterway, sea or air.

This Act does 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. Neither do the provisions of this Act on genetically modified micro-organisms 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 (847/2004)
Definitions

In 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; supplying genetically modified organisms for contained use or their deliberate release into the environment for any other purpose than for placing on the market is not considered 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 organisms 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 documents referred to in this Act that are to be submitted to the Board for Gene Technology regarding which the Board does not make a decision on granting consent;

10) *application* means the documents referred to in this Act that are to be submitted 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 subsection 1, paragraphs 3 and 4 are issued by government decree.

Chapter 2
Competent authorities

Section 4 (847/2004)
General guidance and supervision

The Ministry of Social Affairs and Health guides and leads the supervision of compliance with this Act and any provisions issued under it in general and in respect of matters relating to human health in particular.

The Ministry of the Environment guides and leads the supervision of compliance with this Act and any provisions issued under it in respect of preventing and averting any harm to the environment caused by the use of genetically modified organisms.

Furthermore, the Ministry of Agriculture and Forestry guides and leads the supervision of compliance with this Act and any provisions issued under it in respect of matters relating to genetically modified organisms in the field of agriculture, forestry, fisheries and game husbandry.

Section 5 (144/2015)
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 chair and the vice-chair of the Board. Furthermore, the Government appoints a maximum of five other members for the Board and a personal deputy member for each of them. The Board operates in conjunction with the Ministry of Social Affairs and Health.

The chair and vice-chair of the Board shall be sufficiently well versed in the field of gene technology and public sector decision-making and have proven leadership skills.

Members of the Board shall represent the Ministry of Social Affairs and Health, the Ministry of the Environment, the Ministry of Agriculture and Forestry, the Ministry of Economic Affairs and Employment, the Ministry of Education and Culture or the administration subordinate to these ministries. Sufficient gene technology sector expertise and other scientific and ethical expertise

among the Board members shall be ensured. If the representatives of the ministries do not have such expertise, the Government may appoint a maximum of three experts in these sectors to the Board as permanent experts.

If a member or deputy member resigns or dies before the end of the term, the Ministry of Social Affairs and Health shall appoint a new member or deputy member to replace the member for the remainder of the term upon the proposal of the same authority, organisation or public institution that had proposed the appointment of the original member or deputy member.

Section 5a (847/2004)
Duties of the Board for Gene Technology

The Board for Gene Technology leads and coordinates the supervision of compliance with this Act.

Besides the duties specified 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 5b (847/2004)
Quorum and consideration of matters within the Board

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

The Board for Gene Technology is quorate when the chair and at least three of the other members participate in a meeting. Members of the Board and other persons who have the right to attend and speak at meetings of the Board may also participate in the meetings by means of telephone or video conferencing or some other suitable technical data transmission method. A meeting is chaired by the chair or vice-chair of the Board. (144/2015)

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

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

The Board for Gene Technology shall confirm rules of procedure, which provide more detailed instructions on organising the Board's administration and operations and dealing with and deciding on matters. (144/2015)

Section 5c (847/2004)
Setting up sections

The Board for Gene Technology may set up sections. The Board appoints the chair of each section from among its members. Persons from outside the Board can also be members of a section.

Section 5d (144/2015)
Deciding on matters

The Board for Gene Technology decides on matters upon the submission of the secretary general of the Board or of the presenting official appointed by the Board. The Board for Gene Technology can appoint as presenting officials for a fixed period the required number of people who have a suitable Master's degree and good expertise in the gene technology sector, or other qualification

as required by the matters dealt with by the Board. In those matters which are not decided on by the Board, a presenting official may be the one to decide on a matter.

The Board may use a written procedure for deciding on urgent routine matters, unless any of the members separately requests that the matter be considered at a meeting.

Section 5e (144/2015)
Criminal liability for acts in office

When carrying out duties laid down in this Act, the chair, members, deputy members, presenting officials and permanent experts of the Board are governed by the provisions on criminal liability for acts in office.

Section 5f (1002/2009)
Secretariat of the Board

The Board for Gene Technology has a secretary general and other secretarial personnel appointed by the Ministry of Social Affairs and Health.

Section 5g (847/2004)
Supervisory authorities

The supervisory authorities referred to in this Act are the Finnish Medicines Agency Fimea, the Finnish Environment Institute and the Finnish Food Authority. (1488/2019)

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

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 governed by separate provisions on the disqualification of authorities and on 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 5h (847/2004)
Duties of the supervisory authorities

The Finnish Medicines Agency Fimea shall maintain a gene technology register as provided in this Act. (1488/2019)

The Finnish Medicines Agency Fimea supervises the contained use 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 Food Authority supervises the deliberate release into the environment of genetically modified organisms in the field of agriculture and forestry. (1488/2019)

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

3) carry out any other tasks provided by law 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 (847/2004)
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 also otherwise as experts in gene technology.

The expert authorities and institutions in the field of gene technology operating in their own fields of expertise are the Finnish Food Authority, the Finnish Institute for Health and Welfare, the Finnish Medicines Agency Fimea, the Natural Resources Institute Finland, the Finnish Environment Institute, the Finnish Institute of Occupational Health and VTT Technical Research Centre of Finland Ltd. (1488/2019)

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

Section 7 (847/2004)

Section 7 was repealed by Act 847/2004.

Chapter 3
General duties (847/2004)

Section 8 (1847/2004)
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 shall 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.

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 8a (847/2004)
Duty of care

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

Section 9 (847/2004)
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 laid down in this Act and the provisions issued under it.

Section 9a (847/2004)
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 of this.

Section 10 (847/2004)
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 (847/2004)
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 21a.

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 issued by decree of the Ministry of Social Affairs and Health.

Section 12 (847/2004)

Section 12 was repealed by Act 847/2004.

Chapter 4
Contained use of genetically modified organisms (847/2004)

Section 13 (847/2004)
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 subsection 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 as on emergency plans and safety measures to be applied are issued 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 issued by decree of the Ministry of Social Affairs and Health.

Section 14 (847/2004)
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 issued by decree of the Ministry of Social Affairs and Health.

Section 14a (847/2004)
Notification of the use of genetically modified organisms

The operator shall submit a notification to 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 emergency plan as provided 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 subsection 2 above regarding micro-organisms also applies to the notification of commencing the use for the first time.

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

Section 14b (847/2004)
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 emergency plan as provided by decree of the Ministry of Social Affairs and Health.

What is provided in subsection 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 the application procedure are issued by decree of the Ministry of Social Affairs and Health.

Section 14c (847/2004)
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 16a of this Act on the notification of the use under class 2.

Section 15 (847/2004)
Commencing the use of genetically modified organisms for the first time

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 application for 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 subsection 1 applies, as appropriate, to commencing the contained use of genetically modified plants and animals.

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

Section 16 (847/2004)
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 respect of 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 commencing the 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 subsection 1 applies, as appropriate, 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 issued by government decree.

Section 16a (847/2004)
Granting of consent

The Board for Gene Technology shall, upon application, grant 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 16b (847/2004)
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 shall be informed of this without delay.

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

Section 16c (847/2004)
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 ensure that the states potentially affected by an accident and the Commission of the European Communities are immediately informed of it.

Section 16d (1488/2019)
Clinical trials

Before starting a clinical trial, the operator shall provide the Board for Gene Technology with a risk assessment referred to in section 8 if the trial is carried out on contained use premises previously notified in accordance with section 16, subsection 1, paragraph 1.

Chapter 5
Deliberate release into the environment for any other purpose than for placing on the market (847/2004)

Section 16e (1488/2019)
Scope of application

The provisions of this chapter do not apply to medicinal substances and compounds for human use containing genetically modified organisms, if they have been authorised under other legislation and the risk assessment, monitoring plan, handling of new information, information to the public, informing 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 (847/2004)
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.

The application shall be submitted in the standard data format approved in accordance with Article 39f of the Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, hereinafter the *General Food Law Regulation*. (481/2021)

Subsection 3 as added by Act 481/2020 enters into force on a date to be specified by decree.

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 (847/2004)
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 of it 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 subsection 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 36b 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 18a (847/2004)
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 subsection 1 are issued by decree of the Ministry of Social Affairs and Health in compliance with 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 18b (847/2004)
Commencement of operations

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 (847/2004)
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 19a (847/2004)
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 subsection 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 subsection, 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 (847/2004)

Section 19b (847/2004)
Scope of application

Provisions of this chapter do not apply to medicinal products for human or veterinary use or other such products containing genetically modified organisms which have been authorised under other legislation and in respect of which the risk assessment that has been carried out fulfils the requirements of this Act.

Section 20 (847/2004)
Authorisation 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 application shall be submitted in the standard data format approved in accordance with Article 39f of the General Food Law Regulation using an information system maintained by the European Commission. 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. (481/2021)

Subsection 3 as amended by Act 481/2021 enters into force on a date to be specified by decree.

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 20a (847/2004)
Assessment report

When the Board for Gene Technology has received an application, it prepares 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 shall, 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 government decree.

Section 21 (847/2004)
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 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 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 subsection 3.

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

If the case concerns 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).

With 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).

Seeds Trade Act 728/2000 was repealed by Seed Act 600/2019.

Section 21a (847/2004)
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 provided in section 28;

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

6) the monitoring requirements as provided in section 11, as well as the obligation to report to the Board for Gene Technology the results of monitoring with 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 21b (847/2004)
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 of this. 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 subsection 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 regarding 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 of the matter.

Section 21c (847/2004)
Labelling

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

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

In respect of the products which contain minor amounts of authorised genetically modified organisms that are adventitious or technically unavoidable, a minimum threshold below which these products need not be labelled in accordance with subsection 1 may be established by decree of the Ministry of Social Affairs and Health.

Section 21d (847/2004)
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.

Section 21e (847/2004)
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 an assessment report to the Commission of the European Communities.

The Board for Gene Technology shall without delay prepare an assessment report referred to in section 20a on the application for renewal of the consent in the manner provided.

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.

Section 21f (847/2004)
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 subsection 2.

As a rule, the period of validity of the renewed consent is at most ten years, and it can be shortened or extended for special reasons related to the protection of human and animal health and the environment.

Chapter 7
Prohibitions, restrictions and orders (387/2009)

Section 22 (847/2004)
Actions contrary to provisions, and restriction and prohibition of use

If the operator violates this Act or provisions issued under it, the Board for Gene Technology or the supervisory authority may order the operator to fulfil the obligations laid down in this Act or in the provisions issued under 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 paragraphs 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 by virtue of this provision, the supervisory authority may inform the Board for Gene Technology of this, and the Board may undertake measures referred to in section 38, subsection 2.

Section 23 (387/2009)
Order for the prevention and remediation of substantial environmental damage

If substantial pollution of a water body referred to in section 176 of the Environmental Protection Act (527/2014) or damage to nature referred to in section 3, paragraph 7 of the Nature Conservation Act (9/2023) occurs or threatens to occur in consequence of an action contrary to provisions referred to in section 22, subsection 1, the Board for Gene Technology shall, in addition to what is provided in section 22 of this Act, order the operator causing the damage or its threat to take the necessary measures to prevent the damage or limit it to a minimum or to take remedial measures referred to in the Act on the Remediation of Certain Environmental Damages (383/2009). The procedure laid down in section 22 of this Act shall be followed when issuing the order. (39/2023)

The Board for Gene Technology shall request the opinions needed to decide the matter referred to in subsection 1.

Section 24 (847/2004)
Restriction and prohibition of 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 of this. The supervisory authority shall inform the Board for Gene Technology of the matter. 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 affects 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 and how 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, as necessary.

Section 24a (446/2019)
Unauthorised products

The supervisory authority or the Board for Gene Technology shall take action to prevent the placing on the market of a genetically modified product for which no consent has been granted, notwithstanding the provisions of the Act Restricting the Cultivation of Genetically Modified Organisms (445/2019). At the same time, remedial action to prevent damages shall be initiated, if necessary, and the Board shall inform the public and the European Commission and the Member States of the European Communities of the matter.

Section 25 (847/2004)
Execution duties

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 (847/2004)

Section 26 (1002/2009)
Gene technology register

The Finnish Medicines Agency Fimea maintains a gene technology register. However, decisions on the disclosure of data from the register are made by the Board for Gene Technology. (1488/2019)

The following data 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; however, no other personal data referred to in the Personal Data Act (523/1999) than the name, date of birth and contact information of the natural person acting as operator and of the person in charge appointed by the operator.

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

Section 26a (847/2004)
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 its operations.

It shall be ensured 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 26b (1002/2009)
Right to use the gene technology register

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

Section 27 (847/2004)
Access to information and right to inspect

The Board for Gene Technology and the supervisory authority have, notwithstanding non-disclosure provisions, the right to obtain information necessary for the supervision of compliance with this Act and provisions issued under it from those whom the obligations laid down in this Act and provisions issued under it apply to.

The Board for Gene Technology and the supervisory authority have the right to make inspections on premises other than those covered by the right to domestic privacy in order to supervise compliance with this Act and the provisions issued under it.

Section 28 (847/2004)
Right to receive samples and to carry out tests

The Board for Gene Technology or the supervisory authority has 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 an opportunity to be heard, unless there is a particular reason for not doing so.

The operator shall have 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 by 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. (847/2004)

The authority receiving the information is subject to the same non-disclosure obligation as the authority supplying the information under section 32.

Section 30 (490/2000)
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 organisations and states participating in cooperation. When disclosing personal data abroad, the provisions of the Personal Data Act (523/1999) shall be complied with.

Section 31 (847/2004)
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 under it.

Chapter 9
Miscellaneous provisions

Section 32 (481/2021)
Publicity of information and non-disclosure

The following information is not considered non-disclosable:

1) the date of a 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;

8) consent documents in accordance with this Act.

The operator shall specify the information that it considers non-disclosable. The operator shall state reasons for its opinion. When disclosing information, the Board for Gene Technology shall decide, after consulting the operator, which information shall be designated as non-disclosable.

Unless otherwise provided in this Act, the provisions of the Act on the Openness of Government Activities (621/1999) shall otherwise be applied to the publicity and non-disclosure of the documents received and prepared when performing the duties provided in this Act.

Section 32a (481/2021)
Non-disclosure of applications concerning deliberate release into the environment

By way of derogation from the provisions on business secrets laid down in section 24, subsection 1, paragraph 20 of the Act on the Openness of Government Activities (621/1999), the Board for Gene Technology may, at the operator's request, designate the following items of information included in the applications referred to in sections 17 and 20 of this Act as non-disclosable:

1) the production and manufacturing process, including the method and its innovative aspects and other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;

2) the commercial links between a producer or importer and the operator or the consent holder;

3) commercial information revealing sourcing, market shares or business strategy of the operator;

4) DNA sequence information, except for the sequences used in the methods of detection, identification and quantification for the transformation event;

5) breeding patterns and strategies.

The prerequisite for the non-disclosure referred to in subsection 1 is that the disclosure of such information is demonstrated by the operator to potentially harm its interests to a significant degree.

Furthermore, in scientific outputs, the names and addresses of the natural persons involved in testing on vertebrate animals or in obtaining toxicological information may be designated as non-disclosable in order to protect the privacy and integrity of these persons.

The decision of the Board for Gene Technology referred to in subsections 1 and 3 shall be made before the public consultation referred to in section 36b, and the operator shall be notified of the decision.

By way of derogation from the provisions of subsection 3, the application procedures referred to in sections 17 and 20 of this Act shall comply with section 24, subsection 1, paragraph 31 of the Act on the Openness of Government Activities, provided that the Board for Gene Technology shall publish the following personal data in respect of the related scientific outputs:

1) the name and address of the operator;

2) the names of the authors of the published or publicly available studies supporting the request;

3) the names of people participating in scientific outputs, the scientific committee and panel meetings and the meetings of their working groups and other ad hoc working groups dealing with the matter and those attending these as an observer.

By way of derogation from the provisions of subsection 1, the Board for Gene Technology may publish the information referred to in subsection 1, if this is necessary to protect human health, animal health or the environment. Information that forms part of the conclusions of scientific outputs presented by a scientific committee or the conclusions of assessment reports and that are related to predictable impacts affecting human health, animal health or the environment shall in any case be published.

In addition to the provisions laid down in the Act on the Openness of Government Activities, the Board for Gene Technology shall ensure the non-disclosure of information irrespective of whether there has been time to process the operator's request for non-disclosure, if the operator cancels the notification or application which contains information that the operator has requested to be treated as non-disclosable.

Section 33 (847/2004)
Disclosure of non-disclosable information

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

1) to the authorities referred to in section 29 for the implementation of this Act;

2) to experts employed by the Board for Gene Technology; and

3) to the prosecution, police, border guard or customs authorities for the purposes of criminal investigation.

Section 34 (847/2004)
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 (1488/2019)
Charges

The supervisory authority has the right to collect charges for inspections carried out under this Act. The provisions of the Act on Criteria for Charges Payable to the State (150/1992) on charges for a performance under public law apply to charges collected for inspections. Further provisions on the inspection charges and their amount may be issued by government decree.

Provisions on charges and their amount other than those referred to in subsection 1 collected by the Board for Gene Technology and those referred to in section 6 collected by the supervisory authorities for performances are laid down by government decree pursuant to the Act on Criteria for Charges Payable to the State.

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 (847/2004)
Damages

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

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

Compensation for other damage caused by activities referred to in this Act is governed by the provisions of the Damages Act (412/1974). The operator is liable to compensate for such damage, even if it was not caused intentionally or through negligence.

The provisions of subsections 1–3 shall not restrict the right of the party suffering damage to compensation on the basis of an agreement or under other acts than those referred to in subsections 1–3.

Section 36a (847/2004)
Consulting the public regarding contained use

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

The provisions on the non-disclosure obligation laid down in section 32 shall be observed in the consultation and disclosure of documents.

Section 36b (481/2021)
Consulting the public regarding 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 regarding the planned deliberate release into the environment for any other purpose than for placing on the market in compliance with the provisions of sections 62a and 62b of the Administrative Procedure Act (434/2003) on service by publication, unless otherwise provided in this Act.

The consultation period is 30 days. However, the consultation may be waived in the case of an urgent medical procedure, research or treatment with the purpose of safeguarding the life or health of a person or if such consultation is likely to endanger the privacy protection of the person who is subject to the procedure.

Provisions on the non-disclosure obligation are laid down in sections 32 and 32a.

Section 36c (387/2009)
Right of institution of proceedings

A matter referred to in section 23 may be instituted in writing

1) by a person whose right or benefit it may concern;

2) by a registered association or foundation whose object is the promotion of nature conservation or environmental protection and whose rules cover the field of activities where the environmental effects in question are manifested.

Section 37 (847/2004)
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 request for review

Section 38 (847/2004)
Conditional fine, conditional enforcement of performance and conditional enforcement of suspension

The Board for Gene Technology may oblige an operator that uses genetically modified organisms in violation of the provisions of this Act or the provisions issued under it to make a notification or application under threat of a fine or of suspension of the operations either in full or in part.

The Board for Gene Technology may reinforce a prohibition or order issued under this Act by imposing a conditional fine or issuing a notice that the neglected measure will be performed at the expense of the negligent party.

Matters concerning conditional fines, conditional enforcement of performance and conditional enforcement of suspension are governed by the provisions of the Act on Conditional Fines (1113/1990).

Section 39

Section 39 was repealed by Act 414/2002.

Section 40

Section 40 was repealed by Act 414/2002.

Section 41

Section 41 was repealed by Act 414/2002.

Section 42 (414/2002)
Reference provisions concerning punishments

Provisions on the punishment for endangerment of health in violation of this Act or provisions issued under it are laid down in chapter 34, section 4 of the Criminal Code.

Provisions on the punishment for a gene technology offence in violation of this Act or provisions issued under it are laid down in chapter 44, section 9 of the Criminal Code.

Provisions on the punishment for degradation of the environment in violation of this Act are laid down in chapter 48, sections 1–4 of the Criminal Code.

A punishment for a violation of the non-disclosure obligation laid down in section 32 is imposed in accordance with chapter 38, section 1 or 2 of the Criminal Code, unless the act is punishable under chapter 40, section 5 of the Criminal Code or unless a more severe punishment for the act is provided elsewhere by law.

Section 43 (1019/1995)

Section 43 was repealed by Act 1019/1995.

Section 44 (1488/2019)
Request for review

An administrative review may be requested of a decision issued by the Board for Gene Technology and a supervisory authority with the exception of decisions referred to in chapter 7 and section 38. Provisions on requesting an administrative review are laid down in the Administrative Procedure

Act (434/2003). An administrative review of a decision made by a supervisory authority other than a decision made under section 35, subsection 3 of this Act shall, however, be requested from the Board for Gene Technology.

Provisions on requesting a judicial review by an administrative court are laid down in the Administrative Judicial Procedure Act (808/2019). An administrative court decision in a matter referred to in section 35, subsection 3 is ineligible for review by appeal.

Such a registered association or foundation also has the right of appeal in a matter referred to in section 23 whose purpose is the promotion of nature conservation and/or environmental protection and whose rules cover the field of activities where the environmental effects in question are manifested.

Provisions on requesting a review of a decision concerning the setting of a charge are laid down in the Act on Criteria for Charges Payable to the State (150/1992).

Section 44a (1026/2015)

Section 44a was repealed by Act 1026/2015.

Chapter 11
Entry into force 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 provisions

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