Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms, etc. (Gene Technology Act)

This transaltion is based on the norwegian text with latest amendments of 17 june 2005.

Translation for information use only.

Chapter 1 General provisions

§ 1 Purpose of the Act

The purpose of this Act is to ensure that the production and use of genetically modified organisms and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment.

§ 2 Substantive scope of the Act

The Act applies to the production and use of genetically modified organisms. The Act also applies to the production of cloned vertebrates and crustaceans. The provisions of the Act relating to genetically modified organisms also apply to substances and products that consist of or contain genetically modified organisms.

Unless genetically modified organisms are used as parental organisms, the Act does not apply to the production of the following by means of cell technology:

a. genetically modified plant cells where the same result can be obtained by means of traditional breeding methods, or
b. animal cells in culture where the cell material has been obtained from different individuals of the same species and the cells could have been produced by natural reproduction,

or the use of such plant or animal cells.

Unless the purpose is to produce a cloned individual, the Act does not apply to cloning of genes, cells and tissues.

The Act does not apply to the production of cloned animals that are not genetically modified and that could also arise through natural biological processes.

§ 3 The territorial scope of the Act

The Act applies within the realm, including Svalbard and Jan Mayen. The Act also applies to the Norwegian dependencies in Antarctica, within Norway's economic zone and on the Norwegian part of the continental shelf.

§ 3a Duty to submit notification when establishing gene technology activities abroad

The King may issue regulations relating to a duty for persons or companies under Norwegian jurisdiction that establish gene technology activities abroad to submit notification of this. Gene technology activities means any activities that come within the substantive scope of the Act, cf section 2.

§ 4 Definitions

For the purposes of this Act, the following terms shall have the following meanings:

a. microorganism: any microbiological entity, cellular or non-cellular, that is capable of replication or of transferring genetic material
b. genetically modified organism: a microorganism, plant or animal in which the genetic material has been altered by means of gene or cell technology
c. gene technology: techniques that involve the isolation, characterisation and modification of heritable material and its introduction into living cells or viruses
d. cell technology: techniques for the production of living cells with new combinations of genetic material by the fusion of two or more cells
e. cloned animal: an animal that is genetically identical or almost identical to another animal
f. animal cloning: any technique for producing animals with identical or almost identical genetic material.

Chapter 2 Contained use of genetically modified organisms

§ 5 Definition

The term "contained use" means any operation in which genetically modified organisms are produced, cultured, stored, destroyed or used in some other way in a closed system in which physical barriers are employed, either alone or together with other special containment measures, to limit their contact with humans and the environment, in order to ensure a high level of safety for the latter.

§ 6 Safety measures in contained use

Contained use shall take place in laboratories and installations that are approved pursuant to the second paragraph, and in accordance with good microbiological practice. The user shall ensure that the necessary safety measures are taken to prevent adverse effects on health and the environment, including measures to limit the adverse effects of any unintended release of genetically modified organisms. Records shall be kept of all contained use of genetically modified organisms.

Laboratories and other installations for contained use of genetically modified organisms shall be approved by the King.

The King may issue regulations relating to safety measures for contained use and laying down further details concerning the duty to keep records.

The King may by regulations grant exemptions from the provisions of this section for specified types of teaching activity.

§ 7 Duty to submit notification or to obtain approval

The contained use of genetically modified organisms shall be notified or approved in accordance with regulations issued by the King. Such regulations may provide for exemptions to be granted for specified types of teaching activity.

Irrespective of any regulations issued pursuant to the first paragraph, approval is required for the following forms of contained use:

a. genetic modification of vertebrates resulting in heritable genetic alterations, except for experiments that are approved pursuant to section 21, first paragraph, of the Prevention of Cruelty to Animals Act
b. the transfer of human genetic material to animals, plants or microorganisms if this is not carried out as part of research or experiments for the purpose of identifying the structure, characteristics and functions of heritable material
c. the production and use of genetically modified organisms for placing on the market or other commercial use.

The King may by regulations decide that for specific types or quantities of genetically modified organisms, production such as is mentioned in litra c shall instead be subject to the duty to submit notification.

The provisions concerning the duty to submit notification and the requirement for approval pursuant to this section do not apply to the production and use of hybrid animal cells for the production of monoclonal antibodies or to the isolation of chromosomes and chromosome fragments.

§ 8 Impact assessment for contained use

The King may require that any person that applies for approval for contained use shall ensure that an impact assessment is carried out to elucidate the impacts of any unintended release of genetically modified organisms. Section 11, first paragraph, second sentence, and second paragraph, apply correspondingly.

Chapter 3 Deliberate release of genetically modified organisms

§ 9 Definition

The term "deliberate release" means any production and use of genetically modified organisms that is not considered to be contained use pursuant to section 5.

The following are among the activities that are considered to be deliberate release under the Act:

a) deliberate release of genetically modified organisms for research purposes (field experiments)

b) deliberate release of genetically modified organisms for commercial purposes, for remedial purposes and the like

c) use of genetically modified organisms in greenhouses, aquaculture facilities, animal accommodation and the like, unless the facility in question is approved for contained use as part of an approved laboratory or other installation

d) routine release of genetically modified organisms from contained use

e) disposal of waste containing living genetically modified organisms

f) placing on the market of a product consisting of or containing genetically modified organisms

g) import of genetically modified organisms

h) transport of genetically modified organisms

i) export.

§ 10 Requirements relating to approval

The deliberate release of genetically modified organisms may only take place with the approval of the King. Deliberate release such as is mentioned in section 9, litrae a, b, c and f, shall as a general rule only take place according to a step-by-step procedure. A product may not be approved for placing on the market until it has been subject to satisfactory field testing in natural environments that will be affected by the intended use. Approval is not required for other deliberate release of a product that has been approved for placing on the market pursuant to this provision.

The deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on health or the environment. In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development.

The King may by regulations decide that deliberate release pursuant to section 9, litrae g and h, may take place without prior approval if further conditions, including requirements for special packaging and labelling of the products, have been fulfilled. It may be decided that such release shall instead be subject to the duty to submit notification.

Neither approval nor notification is required for export, unless otherwise provided by regulations issued by the King.

The King may by regulations provide that specific types of genetically modified organisms may be released into certain specified environments without approval pursuant to the first sentence of the first paragraph. Such release shall instead be subject to the duty to submit notification.

Approval is not required for the placing on the market of a product that has been approved for placing on the market in another EEA state pursuant to the rules laid down in Annex XX, paragraph 25, of the EEA Agreement (Council Directive 90/220/EEC). The competent authorities under the present Act may nevertheless prohibit or limit such placing on the market if in their view it involves a risk to health or the environment or if placing on the market is otherwise in conflict with the purpose of this Act.

§ 11 Impact assessment

Applications for the approval of deliberate release pursuant to section 10 shall include an impact assessment setting out the risk of adverse effects on health and the environment and other consequences of the release. The King may by regulations lay down provisions concerning inter alia the content of the assessment and exemptions from the duty to submit an assessment.

The King may also require further information and investigations in addition to the impact assessment before a decision is made on an application.

Chapter 3a. Cloning

§ 11a. Prohibition against the cloning of animals

It is prohibited to clone vertebrates and crustaceans.

§ 11b. Exemptions

The Ministry or the instance designated by the Ministry may on application grant exemptions from the prohibition of section 11a for cloning as part of basic biological and medical research or for medical purposes. It is a condition for granting exemptions for cloning for medical purposes that the objective is to find treatment methods and prophylactic measures for people and animals, and that there is a sound balance between considerations of animal ethics and the expected benefits.

The power to grant exemptions does not apply to cloning of primates.

Applications for exemptions shall weigh up the benefits of the project against the animal stress or suffering caused, including considerations of animal integrity, instincts and welfare. Any person who applies to produce cloned animals shall review existing alternative methods and give an account of these in the application.

The King may issue regulations laying down further details concerning the content of applications for exemption.

§ 11c. Requirements relating to cloning activities

Records shall be kept of all activities carried out in accordance with exemptions granted pursuant to section 11b, first paragraph. The authorities may require the disclosure of information on cloning carried out in accordance with exemptions granted pursuant to section 11b, first paragraph, for use in public registers of cloning activities.

Premises that are used for cloning carried out in accordance with exemptions granted pursuant to section 11b, first paragraph, shall be suitable for the purpose and equipped for the functions they are to carry out.

The King may by regulations lay down further requirements concerning such activities, further requirements concerning the duty to keep records and requirements concerning the information to be disclosed to the authorities for use in registers of cloning activities.

Chapter 4 Implementation of the Act. Enforcement provisions

§ 12 Relationship to the Freedom of Information Act

The Freedom of Information Act applies to cases that are dealt with under the present Act. Notwithstanding the duty of secrecy, the following information shall, however, always be public, unless it comes within the scope of section 6, subsection 1, of the Freedom of Information Act:

a. the description of the genetically modified organism, the user's name and address, the purpose of the use and the location of use
b. methods and plans for monitoring and emergency response
c. assessments of foreseeable effects.

§ 13 Public consultation

In cases where approval is required under the present Act, the competent authority may decide that a public consultation is to be held. The processing of applications for the deliberate release of genetically modified organisms shall always include public consultation. The public consultation shall be held well before a decision is made. It must be carried out in a way that ensures that the general public, and particularly interest groups who will be affected, are given access to relevant information and a real opportunity to make their opinions known. A decision to hold a public consultation shall be published.

§ 14 Labelling requirement

The King may issue regulations relating to the labelling of products that consist of or contain genetically modified organisms or products from cloned animals.

§ 15 Conditions laid down in approval

Conditions may be laid down in approval granted pursuant to sections 6, second paragraph, 7, or 10, or in an exemption granted pursuant to section 11b. These may include conditions relating to the choice of the technical procedures and other factor inputs that are best on the basis of health and environmental considerations, a duty to take out insurance or provide security for liability pursuant to sections 21 and 23, and measures for preventing and limiting possible adverse effects. Approval may be granted for a limited period of time.

§ 16 Alteration and withdrawal of approval

The conditions attached to an approval may be altered by the King, and if necessary the approval may be withdrawn if:

a. the risk to health or the environment posed by the use in question proves to be greater than was foreseen when the use was approved, or
b. new technology makes it possible to reduce the risk of adverse effects on health or the environment, or
c. this otherwise follows from the rules for reversing decisions that are currently in force.

§ 17 Control and internal control systems

The King will decide which instance shall be responsible for ensuring compliance with this Act and any decisions made pursuant thereto.

The King may issue regulations relating to internal control and internal control systems to ensure compliance with requirements laid down in or pursuant to this Act.

§ 18 Right of inspection

The supervisory authority may inspect any place where activities that come within the scope of this Act are being carried out.. The supervisory authority may require documents and other material that may be of importance for the exercise of its duties pursuant to this Act to be submitted for its inspection.

§ 19 Duty to provide information

Any person that carries out activities that come within the scope of this Act has a duty on orders from the supervisory authority and notwithstanding any duty of secrecy, to provide the supervisory authority with any necessary information to enable it to carry out its duties pursuant to this Act. Information may also be required from other public authorities, notwithstanding any duty of secrecy that otherwise applies.

The supervisory authority shall be notified immediately in the event of an accident or other unforeseen circumstances that arise during the production and use of genetically modified organisms.

§ 20 Order to stop activities

The supervisory authority may give orders for any activity that is in conflict with the Act or any decision made pursuant thereto to be stopped immediately. The same applies if the production and use of genetically modified organisms pursuant to the Act or decisions made pursuant thereto prove to pose a risk of adverse effects on health or the environment. If necessary, an order to stop an activity may be implemented with the assistance of the police.

§ 21 Duty to avoid or limit damage

If genetically modified organisms have entered the environment in conflict with the Act or decisions pursuant thereto, the person responsible for the activity shall take reasonable measures to avoid or limit damage and nuisance. The same applies if the genetically modified organisms have been deliberately released into the environment in accordance with decisions pursuant to this Act, and their use proves to involve a greater risk to health or the environment than foreseen when the use was approved. The supervisory authority may order the person responsible to retrieve or take other measures to control the organisms within a specified time limit, including measures to restore the environment to its initial state as far as possible. Measures pursuant to this provision may also be implemented on another person's property.

If orders given pursuant to the first paragraph are not carried out within the time limit specified, the supervisory authority may arrange for the measures to be implemented at the expense of the person responsible. The same applies if giving an order pursuant to the first paragraph may mean that implementation of the necessary measures is delayed. The expenses incurred by the supervisory authority are enforceable by execution proceedings.

§ 22 Fees

The King may issue regulations relating to fees for processing applications for approval pursuant to this Act or regulations laid down pursuant thereto, and relating to supervisory measures implemented to ensure compliance with the Act or decisions pursuant thereto. Fees are enforceable by execution proceedings.

§ 23 Compensation

Any person responsible for activities pursuant to the present Act is liable to pay compensation regardless of any fault on his part if his activities cause damage, nuisance or loss through the deliberate or unintended release of genetically modified organisms into the environment.

Moreover, the provisions of Chapter 8 of the Pollution Control Act concerning compensation for pollution damage apply insofar as they are appropriate. The supervisory authority pursuant to the present Act takes the place of the pollution control authority pursuant to section 58 of the Pollution Control Act. The instance authorised to grant approval pursuant to the present Act takes the place of the pollution control authority pursuant to section 63, second and third paragraphs, of the Pollution Control Act.

§ 24 Coercive fines

In the event of contravention of conditions, orders or prohibitions issued pursuant to this Act, the King may impose a coercive fine that continues to be effective for as long as the contravention continues. A coercive fine is enforceable by execution proceedings.

§ 25 Penal measures

Any person who wilfully or through negligence contravenes provisions set out in or issued pursuant to this Act or decisions made pursuant to the said provisions is liable to fines or imprisonment for a term not exceeding one year.

If there are especially aggravating circumstances, imprisonment for a term not exceeding four years may be imposed.

An attempt to commit such an offences or aiding and abetting therein are subject to a penalty. Contravention of the first paragraph is considered to be a misdemeanour.

Chapter 5 The Norwegian Biotechnology Advisory Board

§ 26 The Norwegian Biotechnology Advisory Board

The King will appoint a board that on request or on its own initiative shall give opinions on matters that come within the scope of this Act and other questions relating to biotechnology. The opinions of the board are public unless otherwise required by the statutory duty of secrecy. Section 12 of this Act applies correspondingly to the opinions of the board.

Chapter 6 Final provisions

§ 27 Entry into force

This Act enters into force on the date decided by the King. It may be decided that different parts of the Act enter into force at different times.

§ 28 Transitional provisions

§ 29 Amendments to other Acts

External link: Text of the law (in Norwegian)