Legislation

The Act relating to the production and use of genetically modified organisms

(Gene Technology Act)

Act No. 38 of 2 April 1993

Miljøverndepartementet
Ministry of Environment

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Chapter 1
General provisions

Section 1 Purpose of the Act

The purpose of this Act is to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment.

Section 2 Technical area of application of the Act

The Act applies to the production and use of genetically modified organisms. 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 the genetically modified organisms are used as parent organisms, the Act does not apply to the production with the aid of cell technology of

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

and the use of such plant or animal cells.

Section 3 The territorial area of application of the Act

The Act applies in 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.

Section 4 Definitions

In this Act the following terms mean:

a) microorganisms: any cellular or non-cellular microbiological entity that is able to reproduce or transfer genetic material
b) genetically modified organisms: microorganisms, plants and animals in which the genetic material has been altered by means of gene or cell technology
c) gene technology: techniques that involve the isolation, characterization, modification and introduction into living cells or viruses of DNA
d) cell technology: techniques for the production of living cells with new combinations of genetic material by the fusion of two or more cells.

Chapter 2
Contained use

Section 5 Definition

The term "contained use" means any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a closed system in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to limit contact between the organism on the one hand and humans and the environment on the other.

Section 6 Safety precautions 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 precautions are taken to prevent adverse effects on health and the environment, including

measures to limit the detrimental effects of the unintentional release of genetically modified organisms. Records shall be kept of all contained use of genetically modified organisms.

Laboratories and other installations for contained use shall be approved by the King.

The King may issue regulations concerning safety precautions for contained use and specifying the material details of the duty to keep records.

The King may issue regulations granting exemptions from the provisions in this section for specified forms of teaching activities.

Section 7 Duty to report or to obtain approval

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

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

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

The King may issue regulations prescribing that the production mentioned in litra c shall instead be subject to the duty to report in the case of specified types or amounts of genetically modified organisms.

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

Section 8 Impact assessment for contained use

The King may decide that a person or company applying for approval for contained use shall submit an impact assessment setting out the consequences of the unintentional release of genetically modified organisms. Section 11, second sentence of the first paragraph, and second paragraph, apply correspondingly.

Chapter 3
Deliberate release

Section 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.

Section 10 Approval

Deliberate relase of genetically modified organisms may only occur subject to approval by the King. Deliberate release pursuant to section 9 litrae a, b, c and f shall as a rule only be carried out step by step. A product may not be approved for placing on the market until it has been satisfactorily tested in natural environments that will be affected by the intended use. Approval is not required for other deliberate release of a product that is approved for placing on the market pursuant to this provision.

Deliberate release of genetically modified organisms may only be approved when there is no risk of detrimental effects on health or the environment. In deciding whether or not to grant the application, significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.

The King may issue regulations providing that deliberate release pursuant to section 9, litrae g and h, may take place without prior approval if certain specified conditions, including requirements for special packaging and marking of the products, have been fulfilled. The duty to report may be imposed instead.

The King may issue regulations providing that specified types of genetically modified organisms may be released in certain specified environments without approval pursuant to the first sentence of the first paragraph. Such release shall be subject to the duty to report instead.

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

Section 11 Impact assessment

Applications for approval of deliberate release pursuant to section 10 shall contain an impact assessment setting out the risk of detrimental effects on health and the environment and other consequences of the release. The King may issue regulations 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 the application.

Chapter 4
Implementation of the Act. Enforcement provisions

Section 12 Relation to the Freedom of Information Act

The Freedom of Information Act applies to cases that are dealt with under the present Act. The following information shall, however, always be public, regardless of the duty of secrecy, unless it comes under 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 the foreseeable consequences.

Section 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 carried out. Such consultation shall take place in good time before the decision on the case is made. The decision to carry out a public consultation shall be publicly announced.

Section 14 Marking requirement

The King may issue regulations concerning the marking of products that consist of or contain genetically modified organisms.

Section 15 Conditions of approval

Approval granted pursuant to section 6, second paragraph, section 7 or section 10 may be conditional. Conditions that may be stipulated are inter alia the choice of the best technical procedure and other means of production from the point of view of health and the environment, a duty to take out insurance or provide security for liability pursuant to sections 21 and 23 or measures for preventing and limiting possible detrimental effects. The approval may be granted for a limited time.

Section 16 Alteration and revocation of approval

The conditions of approval may be altered by the King, and if necessary the approval may be revoked if:

a) it turns out that the use concerned involves a greater risk to health and the environment than predicted when the use was approved, or
b) new technology makes it possible to reduce the risk of detrimental effects on health or the environment, or
c) such revocation follows from other existing rules relating to revocation.

Section 17 Supervision

The King decides who shall exercise supervision over the implementation of this Act and any decisions made pursuant thereto.

Section 18 Right of inspection

The supervisory authority may inspect any place where the production and use of genetically modified organisms is being carried out. The supervisory authority may require to be shown

documents and other material that may be pertinent to the performance of its function under the Act.

Section 19 Duty to provide information

Any person who produces and uses genetically modified organisms is obliged, at the request of the supervisory authority and regardless of the duty of secrecy, to provide the information necessary for the carrying out of the tasks of the supervisory authority under the Act. Information may also be required from other public authorities regardless of any existing duty of secrecy.

The supervisory authority shall be notified immediately in the event of accident or other unforeseen circumstances occurring in connection with the production and use of genetically modified organisms.

Section 20 Order to cease activity

The supervisory authority may give orders for the immediate cessation of any activity that is in conflict with the Act or any decisions made pursuant thereto. The same applies if the production and use of genetically modified organisms in accordance with the Act or decisions made pursuant thereto are shown to involve the risk of detrimental effects on health or the environment. If necessary the order to cease activity may be implemented with the aid of the police.

Section 21 Duty to prevent and limit damage

When 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 prevent or limit damage and inconvenience. The same applies if the genetically modified organisms have been deliberately released into the environment in accordance with decisions pursuant to the Act, after which the use is shown 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 combat the organisms within a specified time, including measures to restore the environment to its previous state as far as possible. The implementation of measures pursuant to this provision may also take place on another person's property.

If the orders given pursuant to the first paragraph are not carried out within the specified time, the supervisory authority may have the measures implemented at the expense of the person responsible. The same applies if the giving of the order pursuant to the first paragraph may mean that the implementation of the required measures is delayed. The expenses incurred by the supervisory authority are enforceable grounds for attachment of property.

Section 22 Fees

The King may issue regulations concerning fees for the treatment of applications for approval pursuant to this Act or appurtenant regulations, and concerning supervisory measures implemented to ensure that the Act or decisions pursuant thereto are being complied with. Fees are enforceable grounds for attachment of property.

Section 23 Compensation

The person responsible for an activity pursuant to the present Act has liability for damages regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release or emission 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 authorities pursuant to the present Act take the place of the pollution authorities in section 58 of the Pollution Control Act. The person authorized to grant approval pursuant to the present Act takes the place of

the pollution authority in section 63, second and third paragraphs, of the Pollution Control.

Section 24 Coercive fine

In the event of contravention of conditions, orders or prohibitions issued pursuant to this Act, the King may impose a coercive fine that accrues as long as the contravention is taking place. The coercive fine constitutes enforceable grounds for attachment of property.

Section 25 Penalties

Any person who intentionally or negligently contravenes the provisions prescribed in or pursuant to this Act or decisions taken pursuant to these provisions shall be liable to fines or imprisonment for a term not exceeding one year.

In the event of especially aggravating circumstances, imprisonment for a term not exceeding four years may be imposed.

Attempts and complicity are a criminal offence. Contravention of the first paragraph is considered a misdemeanour.

Chapter 5
The Norwegian Biotechnology Advisory Board

Section 26 The Norwegian Biotechnology Advisory Board

The King shall appoint a board that shall express its views on matters covered by this Act and on other questions concerning biotechnology, on request or ex officio. The board's opinions are public unless otherwise required by the statutory duty of secrecy. Section 12 of this Act applies correspondingly to the board's opinions.

Chapter 6
Concluding provisions

Section 27 Entry into force

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

Section 28 Transitional provisions

For activities to which the present Act applies, which are already in progress when the Act enters into force, a report or application for approval pursuant to sections 6, 7 or 10 shall be submitted within a time limit determined by the King. Provided that the report or application has been submitted within this time limit, the activity may continue until the authorities have dealt with the report or the application according to the provisions prescribed in or pursuant to the Act.

Section 29 Amendments in other Acts

From the date decided by the King, the following amendments in other Acts will enter into force:

I

Act No. 10 of 22 May 1902, the General Civil Penal Code, shall be amended as follows:

Section 153 a, first paragraph, shall read:

Imprisonment for a period term not exceeding 10 years may be imposed upon any person who manufactures, produces, stores or in other way obtains or keeps:

1. bacteriological or other biological substances, *genetically modified organisms*, or toxins, irrespective of their origin or method of production, of such a type or in such quantities

that they cannot legitimately be used for preventive, protective or other peaceful purposes; or

2. weapons, equipment or means of transport that are made for using substances, *organisms* or toxins as mentioned in subsection 1 for hostile purposes or in armed conflict.

II

Act No. 73 of 20 December 1974 relating to the protection of animals shall be amended as follows:

The title of section 5 shall read:
Breeding, supervision and care.

Section 5, new first paragraph, shall read:
It is prohibited to alter the genetic material of an animal with the aid of gene technology methods or by traditional breeding methods if

1. *this makes the animal unable to carry out normal behaviour or affects physiological functions in an undesirable way*
2. *the animal is made to undergo unnecessary suffering*
3. *the alterations provoke general ethical reactions.*

The present first paragraph becomes the new second paragraph.

Section 21, first paragraph, shall read:

No one may carry out biological experiments with animals without special permission. Permission may be granted if the purpose is to find out what kind of disease animals or humans are suffering from or *if the purpose is to prevent or eliminate disease. Permission may also be given* when the purpose is related to research, manufacture or testing of drugs, medications, preparations, toxins or the like for the use of humans, animals or plants.

III

Act No. 79 of 11 June 1976 relating to product control shall be amended as follows:

Section 1 shall read:

Section 1. The scope of the Act

This Act is intended to prevent products from bringing about injuries to health or disturbances of the environment in the form of *disturbances in ecosystems*, pollution, waste or noise or the like.

Section 2, first paragraph, shall read:

This Act applies to the manufacture, *including testing*, import, placing on the market, use and other treatment of the product.

IV

Act No. 4 of 4 February 1977 relating to worker protection and working environment shall be amended as follows:

Section 7, subsection 3 b, shall read:

b) the undertaking shall obtain permission for the carrying out of hazardous work, *including work with biological factors in the working environment.*

Section 8, subsection 1 d, shall read:

d) that pollution in the form of dust, smoke, gas, vapours, unpleasant odours, *effects of biological factors* and radiation is avoided unless it is known that the pollution cannot lead to undesirable effects upon employees.

In sections 11 and 18, the words "hazardous substances" and "hazardous substance" shall be amended to "hazardous substances, including toxic or hazardous biological material" and "hazardous substance, including toxic or hazardous biological material", respectively.

V

Act No. 5 of 6 March 1981 relating to protection against pollution and relating to waste (the Pollution Control Act) shall be amended as follows:

Section 3, first paragraph, shall read:

The Act applies to pollution and waste in the external

environment. *As regards the deliberate release of genetically modified microorganisms and the disposal of same as waste in the environment, the Gene Technology Act applies.*

VI

Act No. 66 of 19 November 1982 relating to the municipal health service shall be amended as follows:

Section 1-4, third paragraph, fourth item, shall read:

If the health service becomes aware of matters relating to the Working Environment Act, the Product Control Act, the Pollution Control Act *or the Gene Technology Act*, the health service shall inform the authorities concerned so that they may make a decision.