Ministry of Social Affairs and Health

N.B. Unofficial translation. Legally valid only in Finnish and Swedish

No. 928/2004

Government Decree on Gene Technology

Issued in Helsinki on 28 October 2004

Definitions

Section 1
Genetically modified organisms

Genetically modified organisms within the meaning of section 3(1) of the Gene Technology Act (377/1995) are organisms that have been obtained, inter alia, by the following techniques or methods:

1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

2) techniques involving the direct introduction into an organism of heritable material prepared or modified outside the organism, including micro-injection, macro-injection and micro-encapsulation; and

3) cell fusion or cell hybridisation techniques in which live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by methods that do not occur naturally.

Genetically modified organisms are not such organisms that have been produced by the following techniques or methods, if they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms referred to in paragraph 1:

1) mutagenesis; and

2) cell fusion, including protoplast fusion, of plant cells which yields an organism which can also be produced by traditional breeding methods.

In the contained use, genetically modified organisms are not, in addition to the organisms referred to in paragraph 2, such organisms that have been produced by such techniques or methods which do not involve the use of recombinant nucleic acid molecules or other than one or several of the following techniques or methods:

1) cell fusion, including protoplast fusion, of prokaryotic or eukaryotic species that exchange genetic material by known physiological processes;

2) fusion, including protoplast fusion, of any eukaryotic cells in cell culture, including production of hybridomas and plant cell fusions that could be considered to meet the conditions of the use under class 1 as laid down in section 13 of the Gene Technology Act; and

3) self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic

acid or its synthetic equivalent with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants; self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organism.

The following techniques or methods are not considered genetic modification unless they involve the use of recombinant nucleic acid molecules or genetically modified organisms referred to in paragraph 1:

1) *in vitro* fertilization;
2) conjugation, transduction, transformation or any other natural process;
3) polyploidy induction.

Commencing the contained use of genetically modified organisms

Section 2
Commencing the use under class 2

The contained use of genetically modified micro-organisms under class 2 may be commenced for the first time after 45 days from the date of submitting to the Board for Gene Technology the notification of premises referred to in section 14 of the Gene Technology Act and the notification of commencing the use referred to in section 14 a of the Act. Based on a decision of the Board the use may be commenced even before that.

When the operator has submitted to the Board for Gene Technology the notification of commencing the contained use of genetically modified micro-organisms referred to in section 14 a of the Gene Technology Act on premises that have previously been approved for use under class 2 or a higher class, the contained use under class 2 in question can be commenced immediately after submitting the notification.

The Board for Gene Technology shall make the decision referred to in section 14 c of the Gene Technology Act within 45 days from the date of submitting the request.

For the purpose of calculating the defined periods, the period of time under which the Board for Gene Technology is awaiting further information it has requested or consulting the public as laid down in section 36 b of the Gene Technology Act is not taken into account.

Section 3
Commencing the use under class 3 or 4

The contained use under class 3 or 4 may not be commenced without a written consent of the Board for Gene Technology. The Board shall make its decision on commencing the contained use of genetically modified micro-organisms under class 3 or 4 within 90 days from the date of submitting the application to the Board, if it is question of the contained use referred to in section 15 of the Gene Technology Act.

When the operator has submitted to the Board for Gene Technology the application for the contained use under class 3 or 4 referred to in section 14 b of the Gene Technology Act on premises that have been previously approved for use under a corresponding or a

higher class, the Board shall make its decision on the application within 45 days from the date of submitting the application.

For the purpose of calculating the defined period, the period of time under which the Board is awaiting further information it has requested from the applicant or consulting the public as laid down in section 36 a of the Gene Technology Act is not taken into account.

Assessment report on the application for placing on the market of products

Section 4
Content of the assessment report

The assessment report referred to in section 20 a of the Gene Technology Act shall include the following information:

1) a description of the qualities of the non-modified recipient organism which are relevant to the assessment of the genetically modified organism in question;

2) a description of the known risks caused by the deliberate release of the non-modified recipient organism to human and animal health and the environment;

3) a description of the result of the genetic modification in the modified organism;

4) an estimate if the genetic modification has been described sufficiently to enable assessment of potential risks to human and animal health and the environment;

5) a description of potential new risks that the release of the genetically modified organism may, based on the risk assessment referred to in the Gene Technology Act, cause to human and animal health and the environment compared to a release of corresponding non-modified organisms; and

6) the conclusion referred to in section 20 a (1) of the Gene Technology Act concerning whether and on which conditions the genetically modified organism in question may be placed on the market, or that it shall not be placed on the market; the conclusion shall clearly examine the planned use, risk management and the proposed monitoring plan, and the conclusion that the genetically modified organism shall not be placed on the market must be reasoned.

The Board for Gene Technology may, as necessary, state in its assessment report that it wants to consult the other Member States and the Commission of the European Communities on particular matters related to the risk assessment.

Advisory Board on Biotechnology

Section 5
Appointment of the Advisory Board on Biotechnology and its composition

The Government appoints the Advisory Board on Biotechnology upon the submission of the Ministry of Social Affairs and Health for a term of three years.

The Government appoints the chairman, vice-chairman and other members of the Advisory Board on Biotechnology, each with a personal deputy. The Advisory Board shall include representatives of at least the authorities most relevant to the control of gene technology, of the most representative organizations of trade, consumers and industry, as well as of research in the various fields of gene technology.

If a member or a deputy member resigns before the end of his/her term, the Ministry of Social Affairs and Health assigns a new member or deputy member to replace him/her for the remainder of the term upon the proposal of the same authority or organization as the member or deputy member concerned had been appointed.

Section 6
Duties of the Advisory Board on Biotechnology

The duties of the Advisory Board on Biotechnology in its capacity of an advisory body are as follows:

1) to promote the cooperation between authorities, research in the field and establishments in the field of biotechnology and in particular gene technology, as well as to organize information and training in the field;

2) to monitor and promote international cooperation on biotechnology;

3) to monitor in particular the developments and research in gene technology, as well as its health and environmental effects;

4) to promote the taking into account of ethical considerations in gene technology; and

5) to attend to other duties relating to biotechnology assigned to it by the relevant ministries.

Miscellaneous Provisions

Section 7
Remunerations payable to the Board for Gene Technology

The remunerations payable to the chairman, vice-chairman, members, deputy members, and experts of the Board for Gene Technology are established by the Ministry of Social Affairs and Health.

Section 8
Representation of the State

The Board for Gene Technology may sue and be sued on behalf of the State as well as represent the interests and rights of the State in courts of law and before other authorities in matters falling within its competence, unless otherwise provided by statute.

Provisions on entry into force

Section 9
Entry into force

This Decree enters into force on 3 November 2004.

This Decree repeals the Gene Technology Decree of 24 May 1995 (821/1995) with amendments.