

Unauthorised translation of statutory order no. 369, 17 May 2000.

Ministry of Environment and Energy, Denmark

Statutory order on the approval of production using genetically modified plants and animals

In pursuance of Sections 13(1), 19, 20(2) and 31(5) of Act no 356 of 6 June 1991 concerning the environment and genetic engineering the following provisions are laid down:

Part 1

Scope

Article 1(1). This order concerns approval in pursuance of Section 8 of the Environment and Genetic Engineering Act in cases where a genetically modified plant or a genetically modified animal is used in contained conditions (see Section 8 of the act).

(2) A genetically modified plant or a genetically modified animal is a plant or an animal in which the composition of genetic material has been altered a way which does not occur naturally (see Annex 1).

Part 2

Authorities

Article 2(1). Decisions concerning approval shall be made by the relevant country council. However, in cases where the environment and energy minister has required the cases in pursuance of Section 28(1) of the act, decisions shall be made by the National Forest and Nature Agency.

(2) Applications for approval shall be sent to the county council in the county where the enterprise is located. At the same time the applicant shall send a copy of the application to the local town or city council.

(3) In cases where the minister for the environment has required the cases in pursuance of Section 28(1) of the act, applications shall be sent to the Natural Forest and Nature Agency. At the same time the applicant shall send a copy of the application to the county council and the local town or city council. The county council shall send the Natural Forest and Nature Agency an assessment of whether special circumstances apply in relation to the case in question which may have an impact on the assessment of potential hazards.

(4) In the City of Copenhagen and in Frederiksberg Municipality the city council and municipal council respectively shall carry out the tasks which are to be carried out by county councils according to the provisions of this order.

Part 3

Content of applications

Article 3. A genetically modified plant or a genetically modified animal must not be used for production without prior approval.

Article 4(1). Applications for approval shall be in writing and shall contain all documented information which is necessary for the processing of the application, including:

- 1) the location of the installation and information about environmental conditions, for example the location of the enterprise in the area, discharge of waste water, etc;
- 2) the name of the person(s) in charge of production, including persons responsible for production control, supervision and safety, and information about their education, training and qualifications;
- 3) a description of production process and scope of production;
- 4) the purpose of production;
- 5) a description of the production plant and production conditions, including discharge-limiting measures and the treatment and disposal of waste water and refuse;
- 6) a description of detection and identification procedures and possibilities of environmental monitoring;
- 7) a description of measures taken to avoid breakdowns and accidents; and
- 8) possible emergency response plans in the event of accidents.

(2) Applications shall contain the following information about genetically modified production organisms:

- 1) a description of donor, recipient or possibly parental organisms, a description of the genetically modified production organism and information about the production organism's potential impact on public health and the environment (see Annex 2); and
- 2) an assessment of hazards in relation to public health and the environment that may result from the use of the plants or animals in production. The risk assessment shall include an assessment of the chances of genetically modified plants and animals of surviving, reproducing, establishing themselves, passing on genetic material and affecting public health and the environment.

Article 5(1). The competent authority may request further information to any extent deemed necessary for the processing of the application.

(2). The competent authority may fix a deadline for the submission of further information and may also state that the application will lapse if the information has not been submitted on or before the deadline date.

Part 4

Decisions concerning approval

Article 6(1). Approvals shall contain information about the location, layout and operation of the production plant, including information concerning discharge-limiting measures and emergency measures in the case of accidents. In addition approvals shall include a description of the genetically modified plant or the genetically modified animal, as well as a summary of the risk assessment.

(2) As stated in Section 16 of the act, the approval given by the competent authority shall include stipulations concerning:

- 1) the layout and operation of the enterprise and discharge conditions;

- 2) limitations in the release of genetically modified production organisms to the surrounding environment;
- 3) measures taken to prevent and avoid undesirable impact on public health and the environment; and
- 4) the enterprise's own control, supervision, limitations in use and submission of information to the supervisory authority.

(3) The competent authority may limit the approval in time (see Section 16 of the act).

(4) The approval may, if necessary, contain conditions as to the preparation of an emergency response plan containing information about measures to be taken to delimit the impact on public health and the environment in the event of accidents.

Article 7. The competent authority may decide that the approval may not be used until the period set aside for complaints has expired and that, in the event of a complaint, the approval must not be used until the complaint authority has made a decision. Grounds shall be given for such decisions.

Part 5

Charges

Article 8(1). At the submission of an application for approval under Article 3 hereof the competent authority shall fix a charge to be paid.

(2) This charge shall cover actual costs incurred in relation to the processing of the application. The charge may never exceed a sum of DKK150,000.

(3) Decisions concerning charges made by a county council or by the Copenhagen City Council or the municipal council in Frederiksberg may be appealed to the National Forest and Nature Agency.

Part 6

Supervision

Article 9(1). County councils shall supervise that:

- 1) Section 8 of the act and the provisions of this statutory order are observed;
- 2) conditions laid down in approvals issued in pursuance of Section 8 of the act and
- 3) orders and injunctions are observed.

(2) The rules in Part 3 and Part 4 of the act shall otherwise apply to supervision and enforcement.

Part 7

Entry into force and transitional provisions

Article 10(1). This statutory order shall enter into force on 5 June 2000.

(2) Pending cases concerning approval which are not finally concluded on the day on which this statutory order enters into force shall be concluded in accordance with the provisions of this statutory order.

Scope of application of the statutory order

An organism is any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses and viroids and animal and plant cells in culture.

A genetically modified organism is a microorganism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Within the terms of this definition, genetic modification occurs at least through the use of:

- 1) Recombinant DNA-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, bacterial 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 a micro-organism of heritable material prepared outside the micro-organism including micro-injection, macro-injection and micro-encapsulation;
- 3) Cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

The following techniques are not considered to result in genetic modification, on condition that that they do not involve the use of recombinant DNA molecules or GMOs:

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

The Statutory order does not apply to plants and animals produced by application of the following techniques for genetic modification on the condition that they do not involve the use of GMOs as recipient or parental organisms:

- 1) mutagenesis;
- 2) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.

Information about the genetically modified production organism

Applications shall contain the information listed below. Any omission of information shall be explained.

A. Characteristics of the donor, recipient or (where appropriate) parental organism(s)

- names and designation;
- sources of the organism(s);
- information on reproductive cycles (sexual/asexual) of the parental organism(s) or, where applicable, of the recipient micro-organism;
- history of prior genetic manipulations;
- stability of the parental or of recipient organism in terms of relevant genetic traits;
- nature of pathogenicity and virulence, infectivity, toxicity and vectors of disease transmission;
- nature of indigenous vectors:
 - sequence
 - frequency of mobilisation
 - specificity
 - presence of genes which confer resistance;
- host range;
- other potentially significant physiological traits;
- stability of these traits;
- natural habitat and geographic distribution; climatic characteristics of original habitats;
- significant involvement in environmental processes (such as nitrogen fixation or pH-regulation);
- interaction with, and effects on, other organisms in the environment (including likely competitive or symbiotic properties);

B. Characteristics of the modified production organism

- origin of the genetic material involved in the genetic engineering operations and the intended functions of that material;
- description of the modification including the method for introducing the vector-insert into the recipient organism or the method used for achieving the genetic modification involved;
- the function of the genetic manipulation and/or of the new nucleic acid;
- nature and source of the vector;
- structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified micro-organism;
- stability of the micro-organism in terms of genetic traits;
- frequency of mobilisation of inserted vector and/or genetic transfer capability;

- rate and level of expression of the new genetic material; method and sensitivity of measurement;
- activity of the expressed protein.

B. Health considerations

- toxic or allergenic effects of non-viable organisms and/or their metabolic products;
- products hazards;
- comparison of the modified microorganisms to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
- capacity for colonisation;
- if the microorganism is pathogenic to humans who are immunocompetent;
 - a) diseases caused and mechanism of pathogenicity including invasiveness and virulence;
 - b) communicability;
 - c) infective dose;
 - d) host range, possibility of alteration;
 - e) possibility of survival outside of human hosts;
 - f) presence of vectors or means of dissemination;
 - g) biological stability,
 - h) antibiotic-resistance patterns;
 - i) allergenicity;
 - j) availability of appropriate therapies.

B. Environmental considerations

- factors affecting survival, multiplication and dissemination of the modified organism in the environment;
- available techniques for detection, identification and monitoring of the modified organism;
- available techniques for detecting transfer of the new genetic material to other organisms;
- known and predicted habitats of the modified organism;
- description of ecosystems to which the organism could be accidentally disseminated;
- anticipated mechanism and result of interaction between the modified organism and the organisms or microorganisms which might be exposed in case of release into the environment;
- known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, vector or pathogen, allergenicity, colonisation;
- known or predicted involvement in biogeochemical processes;
- availability of methods for decontamination of the area in case of release to the environment.