*Unauthorised translation of statutory order no. 370, 17 May 2000.*

Ministry of Environment and Energy, Denmark

# Statutory order on the approval of display of genetically modified organisms and dissemination of information involving genetically modified organisms

In pursuance of 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.** This order concerns the use of genetically modified organisms for display or other types of information dissemination, with the exception of the use of genetically modified organisms for teaching purposes.

**Article 2.** Genetically modified organisms are plants, animals, microorganisms including cell cultures and viruses in which the genetic material has been altered in a way that does not occur naturally (see Annex 1).

Part 2

*Approval, etc*

**Article 3.** Exhibitions or other types of information dissemination in which genetically modified organisms are used must not take place without approval by the National Forest and Nature Agency.

**Article 4.** Applications for approval shall be in writing and shall include the following information:

1) the address of the venue of the exhibition or the information dissemination, a description of the conditions under which the activity is to take place, the time for the beginning of the activity and the duration of the activity;
2) the name of the person or persons responsible for the exhibition or the dissemination of information, including the names of people in charge of control, monitoring and safety and details of their education, training and qualifications;
3) the purpose of the exhibition or the dissemination of information;
4) the quantity of genetically modified organisms to be displayed;
5) a description of safety and containment measures;
6) a description of donor, recipient and possibly parental organisms, a description of the genetically modified organisms, and information about the potential impact of the organisms on public health and the environment (see Annex 2); and

7) an assessment of the genetically modified organisms as regards the potential impact of the activity on human health and the environment. The risk assessment shall include an assessment of the chances of the genetically modified organisms of surviving, reproducing, establishing themselves, passing on genetic material and affecting public health and the environment.

**Article 5(1).** The National Forest and Nature Agency may require additional information to any extent deemed necessary for the processing of the application.

*(2)* The National Forest and Nature Agency may fix a deadline for submission of this information and may also state that the application will lapse if the information has not been submitted on or before the deadline date.

**Article 6(1).** Approvals shall include information about the layout and execution of the exhibition and the dissemination of information, as well as a description of the genetically modified organisms and a summary of the risk assessment.

*(2)* In its approval, the National Forest and Nature Agency shall state conditions concerning layout and display, protective measures and monitoring, as well as a time limit for the approval.

## Part 3

*Supervision and complaints*

**Article 7(1).** County councils shall supervise that the provisions in this statutory order are observed, that orders and injunctions issued in pursuance of the act are observed, and that conditions stipulated in relation to approvals are observed.

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

**Article 8.** It shall not be possible to file complaints about decisions made in pursuance of this statutory order with any other administrative authority.

## Part 4

*Penalties*

**Article 9(1).** Unless a higher penalty applies under other legislation, a fine will be imposed on persons who:

1) fail to obtain prior approval as stated in Article 3 hereof;
2) disregard conditions on which an approval is based;
3) fail to comply with orders or injunctions.

*(2)* The penalty may increase to simple detention or imprisonment for a period of up to two years if the conditions stated in Section 36(2) of the Environment and Genetic Engineering Act apply.

*(3)* Companies and others may incur criminal liability under Part 5 of the Danish Criminal Code.

## Part 5

*Entry into force and transitional provisions*

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

*(2)* On the same day, statutory order no 691 of 15 October 1991 concerning approval of research, large-scale experiments, exhibition, dissemination of information, etc in pursuance of the Environment and Genetic Engineering Act shall be repealed.

*(3)* Decisions made in pursuance of the statutory order mentioned in paragraph (2) hereof shall remain valid until the expiry of the period stated for them or until a new decision is made in accordance with the provisions of this statutory order. Non-compliance with decisions made in pursuance of the statutory order mentioned in paragraph (2) hereof shall be punishable in accordance with the provisions previously in force.

*(4)* Pending cases concerning approval which have not been finally concluded by the date on which this order comes into force shall be concluded in accordance with the provisions of this order.

# Annex 1

## 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 or 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) polypoloidy induction.

The Statutory order does not apply to organisms 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 prokaryotic species that exchange genetic material by known physiological processes.
3) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.

## Annex 2

### 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);
- ability to form survival structures (such as spores or sclerotia).

**B. Characteristics of the modified 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 organism;
- stability of the organism in terms of genetic traits;
- frequency of mobilisation of inserted vector and/or genetic transfer capability;
- activity of the expressed protein.

**B. Health considerations**

- toxic or allergenic effects;
- products hazards;
- comparison of the modified organisms to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
- capacity for colonisation;
- if the organism 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.