MINISTRY OF THE ENVIRONMENT

DANISH ENVIRONMENTAL PROTECTION AGENCY

Translation LK

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STATUTORY ORDER NO. 1098 OF DECEMBER 11, 1992 ON THE APPROVAL OF EXPERIMENTAL RELEASE AND OF MARKETING OF GENETICALLY MODIFIED ORGANISMS<1>

Pursuant to section 13(1), 20(2), 25(1 and 2), and 27(1) of Act No. 356 of June 6, 1991, on Environment and Genetic Engineering, the following provisions are laid down:

PART 1

Scope of the Order

1.-(1) This Order applies to:

1) deliberate release of genetically modified organisms (hereinafter called GMOS) into the environment for the purpose of research and development and any other purpose other than marketing (experimental release), cf. section 9(1) of the Act, and

2) marketing of GMOs intended for deliberate release (marketing), cf. section 9(2) of the Act.

2.-(1) Genetically modified organisms means plants, animals, microorganisms, cell cultures and viruses in which the genetic material has been restructured in a way that does not occur naturally, cf. Annex 1 of this Order.

(2) Deliberate release of GMOs means any intentional introduction into the environment of such organisms without provisions for containment used to limit their contact with the general population and the environment.

(3) Placing on the market means supplying or making available to third parties, save where the GMOs are transferred by mutual agreement solely for the purpose of research or experiments.

PART 2

Authorities

3.-(1) Decisions on the approval of experimental release and marketing of GMOs are made by the Minister for the Environment.

(2) Application for approval shall be lodged with the Danish EPA which prepares the basis for the Minister's decision.

(3) The Danish EPA consults authorities and organizations on the subject of approval of GMOs for experimental release or marketing.

(4) Where applications concern food, food ingredients and additives, including technical adjuvants, the application shall also be submitted to the Minister for Health, who will as regards health and nutritional aspects decide on the approval of production, use, import or sale thereof, cf. section 11 of the Act.

PART 3

Content of the Application

4.-(1) Applications for approval of experimental release shall be in writing and present the information required - and supported by relevant documentation - for consideration of the application, including:

1) particulars specified in Annex 2 to this Order, accompanied with reports on the tests made to evaluate the risks which the GMO(s) or combination of GMOs may present to the environment, nature and health, together with the methods used and available literature,

2) an evaluation of the risks posed by the GMOs to the environment, nature and health from the uses envisaged, and

3) information on results from releases in Denmark and other countries of the same GMOs or a the same combination of GMOs previously or currently carried out by the applicant.

(2) Where the applicant does not find all the particulars required in Annex 2 relevant to the consideration of the case, or where it is not technically possible to supply all such information, the information may be left out, cf., however, section 6 below. Omission of information shall be motivated.

(3) The application shall be accompanied with a summary dossier form duly filled in. The form can be obtained from the Danish EPA and must be completed in Danish and English.

(4) Where the applicant wishes to change the release experiment or the GMOs or the combination of GMOs, or where during review of the case new information is supplied on the possible risks to the environment, nature and health, such information shall immediately be supplied to the Danish EPA.

5.-(1) Applications for approval of marketing shall be in writing and present the information required - and supported by relevant documentation - for consideration of the application, including:

1) the particulars specified in Annex 2, accompanied with reports on the tests made to evaluate the risks which the GMO(s) or combination of GMOs may present to the environment, nature and health of the ecosystems which may be affected by application, together with the methods used and available literature,

2) an evaluation of the risks posed by the GMOs to the environment, nature and health, together with the results obtained during tests on the impact of the release on the environment, nature and health,

3) information on where and for which purposes the GMO(s) or a combination of GMOs will be marketed, together with detailed directions for use and proposed labelling and packaging fulfilling the requirements specified in Annex 3 to this Order, and

4) information on results from releases in Denmark and other countries of the same GMOs or the same combination of GMOs previously or currently carried out by the applicant.

(2) In the application suggestions may be made for one or several derogations from the requirements of Annex 3,

point B, where on the basis of experience with an experimental release or other scientific results it is documented that marketing does not present risks to the environment, nature and health.

(3) The application shall be accompanied with a summary dossier duly filled in. The form can be obtained from the Danish EPA and must be completed in Danish and English.

(4) Where during review of the case new information is supplied on the possible risks to the environment, nature and health, such information shall immediately be supplied by the applicant to the Danish EPA.

6.-(1) The Danish EPA can require further information deemed necessary to consider the case. Where the particulars given in the application are insufficient, the Danish EPA can refuse to review the application.

(2) The Danish EPA can fix a time limit for submission of additional information and state that the application shall be considered lapsed if information is not submitted before expiry of the time limit.

7.-(1) Information submitted in connection with applications for approval cannot form part of the review of applications from other applicants, unless the latter have obtained a written consent from the party submitting such information.

8.-(1) A fee is to be paid for consideration of the application, to be fixed in accordance with the provisions of Statutory Order from the Ministry of the Environment on Fees in Pursuance of Act on Environment and Genetic Engineering.

PART 4

Content etc. of the Application

9.-(1) Decisions on approval of experimental release or marketing are made within the time limits specified in Annex 4 to this Order.

(2) An approval shall contain an account and an evaluation of the information given in the application, including:

1) a description of the GMO(s), the name and address of the applicant, purpose and location of the intended release,

2) methods and plans for monitoring of the GMO(s) and for emergency response,

3) assessment by the Minister for the Environment of the possible risks to the environment, nature and health presented by the GMO(s) or the combination of GMOs.

(3) The approval shall also contain the terms fixed for the experimental release or marketing, cf. section 16 of the Act.

10.-(1) Where after the approval was granted new information becomes available on the possible risks to the environment, nature and health, the holder of the approval shall immediately notify the Danish EPA.

(2) The holder of the approval shall at the same time take all measures required to protect the environment, nature and health.

PART 5

Supervision

11.-(1) The Danish EPA is in charge of the enforcement of sections 9 and 14 of the Act and of the approval terms laid down for marketing.

(2) The regional council is in charge of the enforcement of terms laid down for experimental releases. In the Copenhagen and Frederiksberg area supervision is discharged by the local council.

(3) The Minister for the Environment may decide and state in the approval of experimental releases that the supervision discharged by the regional council shall be carried out in specified periods of the release experiment.

(4) In case of irregular activities the regional council shall immediately notify the Danish EPA.

(5) Supervision and enforcement is otherwise covered by the provisions of Parts 3 and 4 of the Act.

PART 6

Entry into Force

12.-(1) This Order enters into force on January 1, 1993.

Ministry of the Environment

December 11, 1992

Per Stig Møller

/Hans Jürgen Stehr

ANNEX 1

SCOPE OF THE ORDER

For the purpose of Act on Environment and Genetic Engineering which is an incorporation in Danish law of Council Directive on the contained use of genetically modified micro-organisms (90/219/EEC) and Council Directive on the deliberate release into the environment of genetically modified organisms (90/220/EEC), a genetically modified organism and the scope of the Statutory Order are as follows:

'Organism' shall mean any microbiological entity capable of replication or of transferring genetic material.

'Genetically modified micro-organism' (GMO) shall mean a micro-organism 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 whereby is understood formation of genetic material by introduction of nucleic acid molecules which have somehow been produced outside the cell in a virus, in bacterial plasmid or in another vector system so that they may be incorporated in a host organism where they do not occur naturally, but where they can still mate.

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 hybridization 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 they do not involve

the use of recombinant-DNA molecules or GMOs:

1) in vitro fertilization;

2) conjugation, transduction, transformation or any other natural process;

3) polyploidy induction.

The Act on Environment and Genetic Engineering shall not apply to micro-organisms which are produced by the use of the following techniques of genetic modification, on 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 from plants which can be produced by traditional breeding methods.

ANNEX 2

INFORMATION REQUIRED FOR THE APPLICATION

I. GENERAL INFORMATION

A. Name and address of applicant

B. Information on personnel and training

1. Name of person(s) responsible for planning and carrying out the release, including those responsible for supervision, monitoring and safety, in particular, name and qualifications of the responsible scientists,

2. Information on training and qualifications of personnel involved in carrying out the release.

II. INFORMATION RELATING TO THE GMO

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

1. Scientific name

2. Taxonomy

3. Other names (usual name, strain name, cultivar name etc.).

4. Phenotypic and genetic markers

5. Degree of relatedness between donor and recipient or between parental organisms

6. Description of identification and detection techniques

7. Sensitivity, reliability (in quantitative terms) and specificity of detention and identification techniques

8. Description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts

9. Potential for genetic transfer and exchange with other organisms

10. Verification of the genetic stability of the organisms and factors affecting it

11. Pathological, ecological and physiological traits:

(a) Classification of hazard according to existing Community rules concerning the protection of human health and/or environment

(b) Generation time in natural ecosystems, sexual and asexual reproductive cycle

(c) Information on survival, including seasonability and the ability to form survival structures e.g.: seeds, spores or sclerotia

(d) Pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms

(e) Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy

(f) Involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

(a) Sequence

(b) Frequency of mobilization

(c) Specificity

(d) Presence of genes which confer resistance

13. History of previous genetic modifications

B. Characteristics of the vector

1. Nature and source of the vector

2. Sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO

3. Frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination

4. Information on the degree to which the vector is limited to the DNA required to perform the intended function

C. Characteristics of the modified organism

1. Information relating to the genetic modification:

(a) Methods used for the modification

(b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence

(c) Description of the insert and/or vector construction

(d) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function

(e) Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question which particular reference to any known harmful sequence

2. Information on the final GMO:

(a) Description of genetic trait(s) of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed

(b) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism

(c) Stability of the organism in terms of genetic traits.

(d) Rate and level of expression of the new genetic material. Method and sensitivity of measurement

(e) Activity of the expressed protein(s)

(f) Description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector

(g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques

(h) History of previous releases or uses of the GMO

(i) Health considerations:

i) toxic or allergenic effects of the non-viable GMOs and/or their metabolic products

ii) Product hazards

iii) Comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity.

iv) Capacity for colonization

v) If the organism is pathogenic to humans who are immunocompetent

- diseases caused and mechanism of pathogenicity including invasiveness and virulence,

- communicability,

- infective dose,

- host range, possibility of alteration,

- possibility of survival outside of human

- presence of vectors or means of dissemination,

- biological stability

- antibiotic-resistance patterns,

- allergenicity,

- availability of appropriate therapies.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release

1. Description of the proposed deliberate release, including the purpose(s) and foreseen products

2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases

3. Preparation of the site previous to the release

4. Size of the site

5. Method(s) to be used for the release

6. Quantities of GMOs to be released

7. Disturbance on the site (type and method of cultivation, mining, irrigation, or other activities)

8. Worker protection measures taken during the release

9. Post-release treatment of the site

10. Techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment

11. Information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems

B. Information of the environment (both on the site and in the wider environment)

1. Geographical location and grid reference of the site(s) (in case of notifications under Part C the site(s) of release will be the foreseen areas of use of the product)

2. Physical or biological proximity to humans and other significant biota

3. Proximity to significant biotopes or protected areas

4. Size of local population

5. Economic activities of local populations which are based on the natural resources of the area

6. Distance to closest areas protected for drinking water and/or environmental purpose

7. Climatic characteristics of the region(s) likely to be affected

8. Geographical, geological and pedological characteristics

9. Flora and fauna, including crops, livestock and migratory species

10. Description of target and non-target ecosystems likely to be affected

11. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release

12. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. Biological features which affect survival, multiplication and dispersal

2. Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.)

3. Sensitivity to specific agents

B. Interactions with the environment

1. Predicted habitat of the GMOs

2. Studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses

3. Genetic transfer capability:

(a) post-release transfer of genetic material from GMOs into organisms in affected ecosystems

(b) post-release transfer of genetic material from indigenous organisms to the GMOs

4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism

5. Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal or genetic material. Methods to verify stability

6. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.

7. Description of ecosystems to which the GMOs could be disseminated

C. Potential environmental impact

1. Potential for excessive population increase in the environment

2. Competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s)

3. Identification and description of the target organisms

4. Anticipated mechanism and result of interaction between the released GMOs and the target organism

5. Identification and description of non-target organisms which may be affected unwittingly

6. Likelihood of post-release shifts in biological or in host range

7. Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens

8. Known or predicted involvement in biogeochemical processes

9. Other potentially significant interactions with the environment

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring techniques

1. Methods for tracing the GMOs, and for monitoring their effects

2. Specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques

3. Techniques for detecting transfer of the donated genetic material to other organisms

4. Duration and frequency of the monitoring

B. Control of the release

1. Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of release or the designated area for use

2. Methods and procedures to protect the site from intrusion by unauthorized individuals

3. Methods and procedures to prevent other organisms from entering the site

C. Waste treatment

1. Type of waste generated

2. Expected amount of waste

3. Possible risks

4. Description of treatment envisaged

D. Emergency response plan

1. Methods and procedures for controlling the GMOs in case of unexpected spread

2. Methods for decontamination of the areas affected, e.g. eradication of the GMOs

3. Methods for disposal or sanitation of plants, animals, soils, etc. that were exposed during or after the spread

4. Methods for the isolation of the area affected by the spread

5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect

ANNEX 3

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET

A. The following information shall be provided in the notification for placing on the market of products, in addition to that of Annex 2:

1. Name of the product and names of GMOs contained therein.

2. Name of the manufacturer or distributor and his address in the Community.

3. Specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited.

4. Type of expected use: industry, agriculture and skilled trades, consumer use by public at large.

B. The following information shall be provided, when relevant, in addition to that of point A:

1. Measures to take in case of unintended release or misuse.

2. Specific instructions or recommendations for storage and handling.

3. Estimated production in and/or imports to the Community.

4. Proposed packaging. This must be appropriate so as to avoid unintended release of the GMOs during storage, or at a later stage.

5. Proposed labelling. This must include, at least in summarized form, the information referred to in points A.1, A.2, A.3, B.1 and B.2.

ANNEX 4

Council Directive of April 23, 1990, on the deliberate release into the environment of genetically modified organisms (90/220/EEC<2>, lays down the following provisions on time limits to the authorities' review of cases:

I. Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Article 6

2. The competent authority, having considered, where appropriate, any comments by other Member States made in accordance with Article 9, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed, or

(b) indicating that the release does not fulfil the conditions of this Directive and the notification is therefore rejected.

3. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority:

- is awaiting further information which it may have requested from the notifier, or

- is carrying out a public inquiry or consultation in accordance with Article 7

shall not be taken into account.

Article 7

Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on any aspect of the proposed deliberate release.

II. Placing on the market of products containing GMOs

Article 12

2. At the latest 90 days after receipt of the notification, the competent authority shall either:

(a) forward the dossier to the Commission with a favourable opinion, or

(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

3. In the case referred to in paragraph 2(a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority propose to consent to the placing on the market of the product.

4. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account.

Article 13

1. On receipt of the dossier referred to in Article 12(3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.

2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

3. In cases where the competent authority of another Member State raises an objection - for which the reasons must be stated - and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.

4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.

Article 21

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

1 This Order lays down provisions implementing Council Directive 90/220/EEC published in OJ 1990, L 117, p. 15.

2 The Council Directive is printed in its entirety in OJ 1990 L 117, p. 15.