MINISTRY OF THE ENVIRONMENT

DANISH ENVIRONMENTAL PROTECTION AGENCY

Translation

March 1995

STATUTORY ORDER NO. 800 OF SEPTEMBER 1, 1994 AMENDING STATUTORY ORDER CONCERNING APPROVAL OF EXPERIMENTAL RELEASE AND MARKETING OF GENETICALLY MODIFIED ORGANISMS<1>)

1.-(1) In Statutory Order no. 1098 of 11 December 1992 concerning approval of experimental release and marketing of genetically modified micro-organisms, the following amendments shall be made:

1. *In section 4(1), no. 1, section 4(2) and section 5(1), no. 1,* "Annex II" shall be replaced by "Annex II A" or Annex II B, cf. Annex II".

2. Annex II shall be amended and an Annex II A and an Annex II B shall be inserted. Those Annexes shall read as follows:

Annex II

Information required in the notification

The notification for a deliberate release referred to in Article 5 and of the placing on the market referred to in Article 11 is to include, as appropriate, the information set out in Annex II A and Annex II B.

Not all points included will apply to every case. It is to be expected that individual notifications will address only the particular subset of considerations which is appropriate to individual situations.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and scale of the proposed release.

Annex II A applies to releases of all types of genetically modified organisms other than higher plants. Annex II B applies to releases of genetically modified higher plants.

The term "higher plants" means plants which belong to the taxonomic groups (*gymnospermae* and *angiospermae)*.

Annex II A

Information required in notifications concerning releases of genetically modified organisms other than higher plants

I. GENERAL INFORMATION

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of the responsible scientist(s).

C. Title of the project.

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, 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 detection 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, symbiont 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 the 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 or 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's 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 with particular reference to any known harmful sequence.

2. Information on the final GMO:

(a) description of genetic trait(s) or 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 or 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 host,

- 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 on 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.)

2. sensitivity to specific agents.

B. Interactions with the environment:

1. predicted habitat of the GMOs;

2. studies of the behaviour and characteristics of the GMO's 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 of genetic material. Methods to verify genetic 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 interactions or in the host range;

7. known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbiont, 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 plans:

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, 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 II B

Information required in notifications concerning release of genetically modified higher plants (GMHPs) (gymnospermae and angiospermae)

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute)

2. Name, qualifications and experience of the responsible scientist(s)

3. Title of the project

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:

(a) family name;

(b) genus;

(c) species;

(d) subspecies;

(e) cultivat/breeding line;

(f) common name.

2. (a) Information concerning reproduction:

(i) mode(s) of reproduction;

(ii) specific factors affecting reproduction, if any;

(iii) generation time.

(b) Sexual compatibility with other cultivated or wild plant species.

3. Survivability:

(a) ability to form structures for survival or dormancy;

(b) specific factors affecting survivability, if any.

4. Dissemination:

(a) ways and extent of dissemination;

(b) specific factors affecting dissemination, if any.

5. Geographical distribution of the plant.

6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbiont.

7. Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.

2. Nature and source of the vector used.

3. Size, source (name of donor organism(s)) and intended function of each constituent fragment of the region intended for insertion.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted/deleted:

(a) size and structure of the insert and methods used for its characterization, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;

(b) in case of deletion, size and function of the deleted region(s);

(c) location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination;

(d) copy number of the insert.

3. Information on the expression of the insert:

(a) information on the expression of the insert and methods used for its characterization;

(b) parts of the plant where the inserts is expressed (e.g. roots, stem, pollen etc.)

4. Information on how the genetically modified plant differs from the recipient plant in:

(a) mode(s) and/or rate of reproduction;

(b) dissemination;

(c) survivability;

5. Genetic stability of the insert.

6. Potential for transfer of genetic material from the genetically modified plants to other organisms.

7. Information on any toxic or harmful effects on human health and the environment, arising from the genetic modification.

8. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

9. Potentially significant interactions with non-target organisms.

10. Description of detection and identification techniques for the genetically modified plant.

11. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 5)

1. Location and size of the release (site(s).

2. Description of the release site ecosystem, including climate, flora and fauna.

3. Presence of sexually compatible wild relatives or cultivated plant species.

4. Proximity to officially recognized biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 5)

1. Purpose of the release.

2. Foreseen date(s) and duration of the release.

3. Method by which the genetically modified plants will be released.

4. Method for preparing and managing the release site, prior to, during and post-release, including cultivation practices and harvesting methods.

5. Approximate number of plants (or plants per m^2)

G. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 5)

1. Any precautions taken:

(a) distance(s) from sexually compatible plant species;

(b) any measures to minimize/prevent pollen or seed dispersal.

2. Description of methods for post-release treatment of the site.

3. Description of post-release treatment methods for the genetically modified plant material including wastes.

4. Description of monitoring plans and techniques.

5. Description of any emergency plans.

H. INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE

GENETICALLY MODIFIED PLANTS

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to other sexually compatible plants species, which may result from genetic transfer from the genetically modified plant.

3. Potential environmental impact on the interaction between the genetically modified plant and target organisms (if applicable).

4. Possible environmental impact resulting from potential interactions with non-target organisms.

Section 2. - This Statutory Order shall come into force on 12 September 1994.

Ministry of the Environment

September 1, 1994

SVEN AUKEN

/Leo Larsen

1) The Statutory Order contains provisions implementing Council Directive No. 94/15, Official Journal of the European Communities 1994 No L 103, p 20