Regulations relating to the labelling, transport, import and export of genetically modified organisms

Laid down by Royal Decree on xx.xx.xxxx pursuant to section 10, third and fourth paragraphs, and section 14 of Act No. 38 of 2 April 1993 relating to the production and use of genetically modified organisms (the Gene Technology Act). Submitted by the Ministry of the Environment.

Chapter 1. General rules

Section 1. *Object*
The object of these Regulations is to

a. establish conditions enabling the transport and import of genetically modified organisms without the general approval required by section 10, first paragraph, of the Gene Technology Act and
b. issue rules for giving notification of/obtaining consent prior to export and to
c. set requirements regarding clear labelling of all packages and consignments which consist of or contain genetically modified organisms in order to ensure that users, distributors, consumers and authorities are made aware of this.

Section 2. *Scope*
These Regulations apply to the labelling, transport, import and export of genetically modified organisms.

The provisions governing transport and import apply to genetically modified organisms which are approved, pursuant to section 10 of the Gene Technology Act, for deliberate release as defined in section 9, second paragraph, a-e, of the Act, or which, pursuant to section 7 of the Act, have been approved or notified for contained use as defined in section 5 of the Act. The provisions relating to labelling also apply to products which, pursuant to Section 10 of the Act, are approved for deliberate release as defined in Section 9 f, or which may be transported pursuant to Section 10 of the Act and the provisions in Chapter 2 of these Regulations. Food, feed and seed are exempt from the provisions relating to labelling.

Section 3. *Definitions*
For the purposes of these Regulations the following definitions apply:
Genetically modified organisms: microorganisms, plants and animals whose genetic composition has been modified by the use of gene or cell technology.
Risk classes: microorganisms are classified according to Section 6 of the Regulations No. 1600 of 21 December 2001 on the contained use of genetically modified organisms. The activity is classified according to risk classes 1, 2, 3 and 4.

Section 4. *General precautions*
Persons responsible for labelling, transport, import and export of genetically modified organisms shall ensure that the conditions stated in these Regulations are complied with, and otherwise show due care and take reasonable measures to ensure that all handling of genetically modified organisms is undertaken without any adverse effects on health and on the environment.

Section 5. *Other regulations*
These Regulations in no way limit any requirements following from other regulations on the labelling, transport, import or export of plants, animals or micoorganisms.

Chapter 2. Transport and import

Section 6. *General rule for transport and import*
Unless otherwise stated in section 7, the transport and import of genetically modified organisms governed by these Regulations may take place without special approval when the requirements regarding labelling and packaging laid down in these Regulations are fulfilled.

Section 7. *Transport and import for which approval is required*
Approval is required for the transport and import of the following genetically modified organisms:

a. Genetically modified microorganisms where the activity is classified in risk classes 3 and 4.
b. Volume of culture exceeding 10 litres of genetically modified microorganisms where the activity is classified in risk class 2.
c. Live animals and plants used as host organisms for genetically modified microorganisms.
d. All genetically modified animals, with the exception of
    1. traditional livestock that have no wild relatives in Norwegian fauna with which they can cross,
    2. laboratory animals, e.g. mice, rats, hamsters intended for use in laboratories approved for contained use of genetically modified organisms,
    3. embryos, eggs, semen, and cell and tissue cultures
e. Transport where it is not possible to satisfy the requirements regarding packaging and labelling in these Regulations.

Section 8. *Contents of the application*
Applications for transport and import shall include the following information:

a. Name, address, telephone and fax numbers of the following: applicant, person responsible pursuant to section 4, sender, recipient and carrier
b. Information concerning packaging, means of transport, transport route and dates of dispatch and delivery
c. Information concerning the organism: Ordinary and scientific name, description of the genetically modified organism and donor, recipient or (if applicable) parent organisms
d. Quantity: Number of organisms or litre of culture and number of packages to be transported and/or imported
e. An assessment of the risks to health and the environment associated with the transport and/or import
f. Information concerning when and by which authority the genetically modified organism was approved or reported for contained use or deliberate release pursuant to sections 7 and 10 of the Gene Technology Act
g. Precautions to be taken when handling the organism(s)
h. Safety routines in connection with accidents
i. Signature.

Section 9. *Request for further information*
If necessary, the authority responsible for granting approval may request further information from the applicant.

Section 10. *Records*
All transport and import of genetically modified organism(s) shall be recorded by the recipient in Norway, and also by the sender when both are located in Norway. The record shall describe the genetically modified organisms in question, state the dates of dispatch and delivery and the result of the inspection of the material on arrival. The record shall be available at all times for inspection by the supervisory authority. Copies of the transport documents shall be enclosed with the record.

Section 11. *Transport documents*
Transport documents shall be enclosed with all consignments of genetically modified organisms from sender to recipient. The documents shall contain the information listed in section 8. A copy of the

approval shall be enclosed with all consignments of genetically modified organisms for which approval is required pursuant to section 7.

Chapter 3. Export

Section 12. *Requirement of prior consent*
Prior to the initial export of genetically modified organisms intended for deliberate release into the environment in countries outside the European Economic Area, the exporter shall obtain prior consent, or see to it that this is obtained. The exporter shall send notification with information as mentioned in Sections 13 and 14, or see to it that this is sent, to the relevant national authorities in the country of import. Export is not approved and cannot be undertaken until the authority in the country of import has given its written consent to the undertaking. The exporter shall make sure that the information provided is correct.

The exporter is under obligation to keep a copy of the notification, the import country's confirmation of receipt and written import permits for at least five years and send a copy of these documents to the Directorate for Nature Management.

The following are exempt from the requirements in the first and second paragraphs:

a. Genetically modified organisms in transit or exports of genetically modified organisms intended for contained use when the transfer takes place in compliance with the requirements in the import country.
b. Exports of genetically modified organisms to countries which have stated to the Mechanism for Information Exchange that import can take place without informed prior consent, provided that sufficient measures are initiated to ensure safe transboundary movement of genetically modified organisms in accordance with the objective of the Cartagena Protocol on Biosafety.
c. Exports of genetically modified organisms intended for direct use as food or feed or for processing to
   - countries which have made decisions on imports in accordance with domestic regulatory frameworks which are in keeping with the objective of the Cartagena Protocol and
   - developing countries or countries with an economy in transition which have declared through the Mechanism for Information Exchange that decisions prior to the initial import will be made in line with Article 11 (6) of the Cartagena Protocol. In these cases export shall not take place until the procedure in Article 11 has been completed. The failure of a country to communicate its decision may not be interpreted either as consent to or refusal of such import.

Section 13. *Notification of export of genetically modified organisms*
Notification prior to the export of genetically modified organisms shall contain the following information:

a. The exporter's name, address and contact details
b. The importer's name, address and contact details
c. Name and identity of the living modified organism, if applicable with the national classification of biosafety level for the living modified organism in Norway
d. Intended date or dates for transboundary movement, if known
e. Taxonomic status, common name, source (place of collection or procurement) and characteristics of the recipient organism or parental organisms relevant to biosafety
f. Centres of origin and centres of genetic diversity, if known, for the recipient organism and/or parent organisms and a description of habitats where the organisms may persist and proliferate
g. Taxonomic status, common name, source (place of collection or procurement) and characteristics of donor organism(s) relevant to biosafety
h. Description of the inserted nucleic acid or the modification carried out, technique used and the subsequent changes in the characteristics of the living modified organism

i. Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology
j. Quantity or volume of living modified organism to be transferred
k. Risk assessment report
l. Proposed methods for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingence procedures, where applicable
m. Regulatory status of the living modified organism in Norway (for example, whether it is prohibited in the export state, whether other restrictions apply or whether it is approved for general release) and, if the living modified organism is prohibited, the reason or reasons for its prohibition
n. The result and purpose of every notification from the exporter to other states about the living modified organism to be transferred
o. Declaration that the above information is in agreement with the facts.

Section 14. *Notification of export of genetically modified organisms intended for direct use as food or feed or for processing*
Notification prior to export of genetically modified organisms intended for direct use as food or feed or for processing shall contain the following information:

a. Name and contact details of the authority responsible for the decision
b. Name and identity of the living modified organism
c. Description of the genetic modification, applied technology and the subsequent changes in characteristics of the living modified organism
d. Any unique identification of the living modified organism
e. Taxonomic status, common name, source (place of collection or procurement) and characteristics of the recipient organism or parental organisms relevant to biosafety
f. Centres of origin and centres of genetic diversity, if known, for the recipient organism and/or parental organisms and a description of habitats where the organisms may persist or proliferate
g. Taxonomic status, common name, source (place of collection or procurement) and characteristics of donor organism(s) relevant to biosafety
h. Approved uses of the living modified organism
i. Risk assessment report
j. Proposed methods for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where applicable

Section 15. *Dispatch of information relating to the export of genetically modified organisms*
The exporter shall make sure that the following information, in addition to the information listed in Section 16, can be seen from the accompanying documents and is sent to the importer who receives the genetically modified organism:

In the case of genetically modified organisms intended for direct use as food or feed or for processing:
a declaration from the exporter that the genetically modified organisms are intended for such use and not for deliberate release into the environment, and also a contact point for further information.

In the case of genetically modified organisms intended for contained use:
a declaration from the exporter about precautions in connection with handling, storage, transport and use, and information about a contact point for further information, including the name and address of the recipient of the organisms.

In the case of genetically modified organisms intended for deliberate release into the environment in the import country and any other genetically modified organisms that are subject to these Regulations:
a declaration from the exporter that the transport complies with the requirements in the Cartagena Protocol regarding the exporter and the following additional information:

a. information about the organism: Common and scientific names, characteristics of the genetically modified organism and donor, recipient and any parental organisms, and
b. precautions relating to handling, storage, transport and use.

Chapter 4. Labelling

Section 16. *Labelling*
When transported and sold, genetically modified organisms and products containing genetically modified organisms shall be labelled in Norwegian and/or English with the words "*Dette produktet inneholder genmodifiserte organismer*" alternatively "*Dette produktet inneholder* (name of organism(s))" and/or "This product contains genetically modified organisms" alternatively "This product contains genetically modified (name of organism(s))". On packaged products, the information shall be given on a label on each packaged unit. For other products, the information shall be given on an accompanying document or notice.

In the case of genetically modified organisms which are approved for sale, a unique identification code shall also be stated in accompanying document, if such code exists. For combinations of genetically modified organisms which can only be used directly as food or feed or for processing, the unique identification code may be substituted with a declaration that the combination is intended for such use, and a list enclosed of the unique identification codes for all the genetically modified organisms that have been used to make the combination.

Chapter 5. Packaging

Section 17. *Packaging*
Genetically modified organisms or products containing genetically modified organisms shall be packaged for transport as stipulated in Sections 18-20. The authority responsible for granting approval may make other packaging requirements a condition of approval.

Section 18. *Packaging of microorganisms*
The packaging shall be watertight, sealed and fracture proof, etc. in order to prevent any unintentional leakage of the contents.

For microorganisms where the activity is classified in risk classes 2, 3 and 4, there shall always be an inner and an outer container, both of which shall be waterproof. Between the inner and the outer containers, there shall be fluid-absorbent material capable of absorbing a quantity of fluid equivalent to that in the container. If two or more inner containers are carried in the same outer container, each inner container shall be separately packaged in shock-absorbent and fluid-absorbent material. The outer container shall be watertight, sealed and fracture proof, etc. in order to prevent any unintentional leakage of the contents.

Section 19. *Packaging of plants and parts of plants*
There shall always be an inner and an outer container, both of which shall be impervious to spores and pollen. The outer container shall be sealed and fracture proof, etc. in order to prevent any unintentional leakage of the contents.

Section 20. *Packaging of animals*
The packaging shall consist of either a cage or a container that ensures that the animals are not able to escape or cross with other animals outside the cage or container. Packaging of embryos, eggs and semen, cell and tissue cultures, and insects and other invertebrates shall be carried out in accordance with the rules in section 18, first paragraph.

Chapter 6. Accidents

Section 21. *Obligation to report*
Accidents during transport that have resulted in or can result in the release of genetically modified organisms shall be reported without undue delay to the Directorate for Nature Management. Accidents involving genetically modified organisms that are classified as dangerous goods shall also be reported to the local fire and rescue services.

Section 22. *Duty in connection with accidents*
The person responsible pursuant to section 4 of these Regulations has a duty to prevent and limit damage, pursuant to section 21 of the Gene Technology Act.

Chapter 7. Implementation and enforcement

Section 23. *Approval and supervision*
The Directorate for Nature Management is responsible for approving applications for the transport or import of genetically modified plants and animals and supervises the implementation of the provisions in these Regulations. The authorities shall deal with applications as quickly as possible. If the matter has not been decided within one month of the authorities' receipt of the application, the applicant shall be informed in writing of this and of when a decision can be expected.

Section 24. *Exceptions*
The authorities may, if special grounds so indicate, either by means of individual decisions or by issuing regulations, make exceptions from the provisions laid down in these Regulations.

Section 24. *Penalties*
Anyone contravening these Regulations shall be subject to penalties in accordance with section 25 of the Gene Technology Act.

Section 26. *Coercive fines*
In order to ensure the implementation of the provisions set out in these Regulations or of decisions made pursuant to these Regulations, the supervisory authority may impose coercive fines, cf. section 24 of the Gene Technology Act.

Section 27. *Appeals*
Any appeals against individual decisions made pursuant to these Regulations shall be addressed to the Ministry of the Environment.

Section 28. *Entry into force*
These Regulations enter into force on xx.xx.xxxx.