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

Regulation | Date: 02/09/2005 | Ministry of Climate and Environment
(http://www.regjeringen.no/en/dep/kld/id668/)

Originally published by: Ministry of the Environment

Laid down by Crown Prince Regent's Decree of 2 September 2005 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.

The translation is not official; it is provided for information purposes only. In the event of any inconsistency, the Norwegian version shall prevail.

Chapter 1. General rules

Section 1. Object

The object of these Regulations is to simplify the transport and import of genetically modified organisms, fulfil Norway's obligations under the Cartagena Protocol relating to genetically modified organisms, ensure consumer choice and prevent adverse effects of genetically modified organisms.

Section 2. Scope

The provisions in Chapter 2 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 a-e of the Act, or which are approved or have been reported pursuant to section 7 of the Act for contained use as defined in section 5 of the Act.

The provisions in Chapter 4 governing labelling apply to genetically modified organisms as stated in the first paragraph, in addition to genetically modified organisms which are approved pursuant to 10 of the Act for deliberate release as defined in section 9 f of the Act, 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 in section 19, first and second paragraphs.

Genetically modified organisms which are subject to rules applying to the transport of dangerous goods are exempt from the provisions in sections 7 - 8, 10 - 14, 18 and Chapter 4 of these Regulations.

In other respects, these Regulations apply to all genetically modified organisms.

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 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

With the exception of genetically modified organisms listed in section 7, the transport and import of genetically modified organisms may take place without special approval when the requirements in these Regulations regarding labelling and packaging are fulfilled. Transport of genetically modified organisms which is covered by and fulfils the requirements in or is approved pursuant to rules applying to the transport of dangerous goods may take place without special approval as laid down in these Regulations.

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, cell and tissue cultures of animal cells

e. Transport where it is not possible to satisfy the requirements in these Regulations regarding packaging and labelling.

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: taxonomic status, scientific name, common name, characteristics of the genetically modified organism and donor, recipient organism or (if applicable) parental organisms

d. Quantity: number of organisms or litres of culture and number of consignments 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.

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

Section 9. Records

All transport and import of genetically modified organisms 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 check that everything has been received. 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 10. Accompanying documents during transport (transport documents)

Transport documents shall be enclosed with all consignments of genetically modified organisms from sender to recipient. The documents shall contain the following information in addition to the requirements in section 19:

a. For genetically modified organisms intended for contained use:

1. information that the organism is intended for contained use,
2. a description of the organism, including common, scientific and (if available) commercial names of the organism,
3. a description of genetic modification, applied technique and the subsequent changes in the properties of the organism
4. precautions in connection with handling, storage, transport and use,
5. risk class
6. specification for use
7. unique identification if such exists, and
8. specification of a contact point for further information, including the recipient of the organism, and exporter or importer.

b. For genetically modified organisms for deliberate release:

1. a declaration that the transport complies with the requirements of the Cartagena Protocol,
2. a description of the organism, including common, scientific and (if available) commercial names of the organism,
3. a description of genetic modification, applied technique and the subsequent changes in the properties of the organism or a unique identification code if such exists,
4. precautions in connection with handling, storage, transport and use,
5. risk class
6. import permit if this is required under section 7, and