Ministry of Social Affairs and Health, Finland

N.B. Unofficial translation. Legally valid only in Finnish and Swedish

No. 272/2006

Decree of the Ministry of Social Affairs and Health on notifications and applications relating to the contained use of genetically modified organisms, on keeping a record of the contained use and on an emergency plan

Issued in Helsinki on 27 March 2006

Chapter 1

Notifications and applications

Section 1

Content of the notification regarding premises intended for the contained use of genetically modified organisms

The notification referred to in section 14 of the Gene Technology Act (377/1995) shall include the following information:
1) the name and postal address of the operator;
2) the visiting address, a general description of and the layout of the premises;
3) a description of the work to be carried out;
4) the class of the contained use;
5) the names of the persons in charge of supervision and safety, their education, qualifications and contact information, as well as which of the persons carries the main responsibility, and his or her deputy and possible other contact person;
6) information on waste management;
7) detailed information on working groups dealing with biological safety possibly set up by the operator; and
8) in regard to the use under class 1 of genetically modified organisms, a summary of the risk assessment according to the Decree of the Ministry of Social Affairs and Health on principles of risk assessment of the contained use of genetically modified micro-organisms, on classification of the contained use and on containment and other protective measures (1053/2005).

Section 2

Content of the notification regarding commencing the use under class 2 of genetically modified micro-organisms and genetically modified plants

The notification referred to in section 14a of the Gene Technology Act shall include the following information:
1) the name and postal address of the operator;
2) the date of submitting the notification referred to in section 14 of the Gene Technology Act and the record number of the notification, except when the notifications regarding the taking into use of premises and commencing of use are submitted simultaneously;
3) the recipient, donor or parental organisms and vectors;
4) the sources and uses of the genetic material used in modification;
5) the identification data and characteristics of the genetically modified organisms;
6) the purpose of the use and foreseeable results;
7) an estimate of the volumes of culture or amounts of genetically modified organisms;
8) the names of the persons in charge of supervision and safety, their education, qualifications and contact information, as well as which of the persons carries the main responsibility, and his or her deputy and possible other contact person;
9) a description of the containment and other protective measures;
10) information on waste management, such as the quality and form of the waste produced, its treatment, final form and destination;
11) a summary of the risk assessment according to the Decree of the Ministry of Social Affairs and Health on principles of risk assessment of the contained use of genetically modified micro-organisms, classification of the contained use and on containment and other protective measures (1053/2005); and
12) in addition to the emergency plan referred to in section 10, information on when and to which authorities the emergency plan has been submitted.

Section 3

Content of the application regarding commencing the use under class 3 or 4 of genetically modified micro-organisms and genetically modified plants and regarding commencing the use under class 2 of genetically modified animals

The application referred to in section 14b of the Gene Technology Act shall include the following information:
1) the name and postal address of the operator;
2) the date of submitting the notification referred to in section 14 of the Gene Technology Act and the record number of the notification except when the notification regarding the taking into use of premises and the application for commencing use are submitted simultaneously;
3) the purpose of the use and foreseeable results;
4) the recipient, donor or parental organisms;
5) the host vectors;
6) the sources and uses of the genetic material used in modification;
7) the identification data and characteristics of the genetically modified organisms;
8) the volumes of culture or amounts of the genetically modified organisms;
9) the names of the persons in charge of supervision and safety, their education, qualifications and contact information, as well as which of the persons carries the main responsibility, and his or her deputy and possible other contact person;
10) a description of the containment and other protective measures;
11) information on waste management, such as the quality and form of the waste produced, its treatment, final form and destination;
12) a description of the establishment or its parts;
13) the following information about measures to prevent accidents and emergency plans:

a) particular hazards that are due to the location of the establishment;
b) preventive measures, for instance safety and alarm devices and manners of containment;
c) procedures and plans to check the continuous effectiveness of the containment measures;
d) a description of the information that has been given to the staff;
e) in addition to the emergency plan referred to in section 10, information on when and to which authorities the emergency plan has been submitted; and

14) a copy of the risk assessment according to the Decree of the Ministry of Social Affairs and Health on principles of risk assessment of the contained use of genetically modified micro-organisms, on classification of the contained use and on containment and other protective measures (1053/2005).

Chapter 2

The procedure in certain special situations

Section 4

Operators working on the same premises

(1) If there are several research groups or comparable separate operators operating on the same premises intended for contained use, each of them shall make the notification referred in section 14 of the Gene Technology Act separately.

(2) A joint notification can however be accepted, if it is made in the name of the upper level of the organisation or comparable corporation and if the person named in the notification as the operator is in charge of keeping a record of the use and supplying of documents to the Board for Gene Technology and the supervisory authorities in a centralised way.

Section 5

Laboratory animal establishments

(1) In laboratory animal establishments and other comparable operational units using genetically modified animals, the notification referred to in section 14 of the Gene Technology Act can be made in a centralised way in the name of the laboratory animal establishment or operational unit, in which case the establishment or operational unit is considered as the operator. In that case the operator gives in the notification only a general description of the work carried out on the premises. The laboratory animal establishment or operational unit shall according to section 9 of this Decree incorporate in the information recorded by it on the contained use information on each genetically modified animal population, including a risk assessment.

(2) The micro-organisms used in laboratory animal establishments are subject to the provisions on the notification procedure for genetically modified organisms in the Gene Technology Act and elsewhere in this Decree.

Section 6

Taking into use of new indoor premises

(1) If an operator has a valid notification referred to in section 14 of the Gene Technology Act and intends to take into use later other indoor premises intended for contained use, the operator shall submit a notification or notice regarding those premises to the Board for Gene Technology as follows:
1) in regard to premises in the same building as the premises notified before and in the use on which it is necessary to observe containment level 1, a notice;
2) in regard to premises in the same building as the premises notified before and in the use on which it is necessary to observe containment level 2, a notice;
3) in regard to premises in the contained use on which it is necessary to observe containment level 3 or 4, a new notification referred to in section 14 of the Gene Technology Act, and
4) in regard to premises in a different building than where the premises notified before are located, a new notification referred to in section 14 of the Gene Technology Act.

(2) The notice referred to in paragraph 1 (1) and (2) shall include the following information:
1) the name of the operator;
2) the record number of the operator's previous notification referred to in section 14 of the Gene Technology Act; and
3) the visiting address of the premises to be taken into use, numbers of the rooms and information on the containment level as well as the layout of the premises.

Section 7

Commencing the use on premises notified by another operator

If the notification referred to in section 14 of the Gene Technology Act has been made in the name of a corporation referred to in section 4 (2) of this Decree, it is enough that the other operator commencing the use under classes 2 – 4 on the premises concerned only makes the notification referred to in section 14a or the application referred to in section 14b of the Gene Technology Act. A further condition is that the procedure and the later coordination necessitated by it have been agreed on with the operator that made the notification referred to in section 14 of the Gene Technology Act.

Section 8

Commencing a later use under class 2 of genetically modified micro-organisms and genetically modified plants

(1) If the operator has a valid notification referred to in section 14a (2) of the Gene Technology Act and he or she intends to take into use later under class 2 on the same premises new genetically modified micro-organisms, the use can be commenced without a new notification referred to in section 14a (2) if the recipient organism and the source of the genetic material to be transferred are the same as for the genetically modified micro-organism notified before. A further condition is that there is no reason to assume based on the risk assessment that the new genetically modified micro-organisms have harmful effects other than those notified before. Before commencing the use the operator shall however submit to the Board for Gene Technology a notice of the taking into use of such new genetically modified micro-organisms.

(2) If the operator has a valid notification referred to in section 14a (3) of the Gene Technology Act and he or she intends to take into use later under class 2 on the same premises new genetically modified plants, the use can be commenced without a new notification referred to in section 14a (3)

if the recipient plant is the same as for the genetically modified plant notified before. A further condition is that there is no reason to assume based on the risk assessment that the new genetically modified plant has greater capacity to survive, reproduce or spread than the genetically modified plant notified before or that its possible harmful effects on the health of humans or animals are greater. Before commencing the use the operator shall however submit to the Board for Gene Technology a notice of the taking into use of such new genetically modified plants.

(3) The notice referred to in paragraphs 1 and 2 above shall include the following information:
1) the name of the operator;
2) the record number of the operator's earlier notification referred to in section 14a of the Gene Technology Act; and
3) a short description of the genetically modified organisms to be taken into use indicating that the conditions laid down in paragraphs 1 and 2 are met.

Chapter 3

Keeping of a record

Section 9

Content of the duty to keep a record

(1) In virtue of the duty to keep a record laid down in section 10 of the Gene Technology Act the operator shall include in the information recorded on the contained use of genetically modified organisms:
1) copies of the notifications and applications submitted to the Board for Gene Technology, as well as other documents related to them, the notices submitted by the operator included;
2) a copy of the emergency plan referred to in section 10 or of the plan of operation drawn up for unforeseeable situations referred to in section 12;
3) information on the instructions and training provided to employees working with genetically modified organisms, and copies of written instructions, if any;
4) a risk assessment of every genetically modified organism that is being used;
5) in regard to those genetically modified organisms that have been taken into use based on the keeping of a record:
    a) the date of taking into use;
    b) the code of the population or other identification data;
    c) data on the species of the recipient organism;
    d) the trait brought about by genetic modification or, if that is not known, the purpose of the research study and data on the origin of the transferred genetic material;
    e) the class of the use; and
    f) the date when the possible notice of taking into use was submitted to the Board for Gene Technology;
6) information on waste management and on the containment and protective measures as far as the measures undertaken differ from the information given in the notification or application;
7) such observations made after the taking into use of the genetically modified organism that are of significance for risk assessment and risk management;
8) a description of deviations or hazardous situations that have led or could have led to an unintended release of genetically modified organisms within the establishment or their access to premises outside the premises for contained use, and an account of the measures that the operator has undertaken to prevent comparable situations from being repeated; and

9) inspections carried out by authorities other than those referred to in section 5g of the Gene Technology Act as far as they apply to the work with genetically modified organisms, as well as a description of the measures that the operator has undertaken to remedy the defects identified in the context of inspections.

(2) The information referred to in paragraph 1 (4) and (5) can be recorded by group of organism if the genetically modified organisms closely resemble each other and if a similar risk is associated with them.

(3) The recorded information shall be arranged so that it is easily accessible on request by inspectors of the supervisory authority or the Board for Gene Technology. The person with main responsibility shall see to it that the recorded information remains at the disposal of the operator despite changes in staff.

Chapter 4

Emergency plan

Section 10

Drawing up of the emergency plan

(1) When it is question of contained use under classes 2 – 4, the operator shall draw up an emergency plan for hazardous situations and in order to prevent accidents where failure of the containment measures could lead to a serious hazard, whether immediate or delayed, to people outside the premises or to the environment. It is not necessary to draw up an emergency plan, however, if a comparable emergency plan has been drawn up in virtue of other legislation.

(2) The Board for Gene Technology shall indicate before the contained use referred to in paragraph 1 is commenced that the operator has drawn up an emergency plan and supplied information on it and the appropriate safety measures to be applied to all those authorities and other bodies liable to be affected by the accident. The information shall be supplied in an appropriate manner, and without their having to request it, to the competent authorities or other bodies. The information shall be updated at appropriate intervals. The information shall also be made publicly available.

Section 11

Content of the emergency plan

The emergency plan applied in the contained use of genetically modified organisms shall include:
1) the names and duties of the persons who are authorised to start emergency operations and who are responsible for the emergency operations within the establishment, and the name and duties of the person who is responsible for contacts with the authorities responsible for the exterior emergency plan;
2) in regard to each predictable hazardous situation, a description of the measures that shall be undertaken to control the situation and to limit its consequences;
3) the operating instructions issued to the staff; and
4) the information needed by the fire and rescue authorities about the properties of the genetically modified organisms and instructions for how to handle them in an accident.

Section 12

The emergency plan drawn up for unforeseeable situations

Although the operator is not obliged under section 10 to draw up an emergency plan, the operator must have drawn up a plan of operation for unforeseeable situations affecting the use of genetically modified organisms. The plan must include a description of the measures that the operator will undertake if it will be suddenly necessary to withdraw from use the premises intended for the use of genetically modified organisms or if there happens something on the premises that will essentially affect the effectiveness of the containment and safety measures.

Chapter 5

Entry into force

Section 13

Entry into force

This Decree enters into force on 13 April 2006.