Unofficial translation

Ministry of Social Affairs and Health, Finland

No. 198/2007

Decree of the Ministry of Social Affairs and Health on Inspection Procedures under the Gene Technology Act

Issued in Helsinki on 16 February 2007

Section 1

Scope of application

This Decree provides for the inspection procedures relating to the contained use of and the deliberate release into the environment of genetically modified organisms and for the minutes of the inspection to be drawn up on the basis of them.

Section 2

Defining the scope of inspections

(1) The scale and details of the inspection can vary on a case-by-case basis according to the nature of the contained use of genetically modified organisms or the deliberate release of genetically modified organisms that the inspection concerns.

(2) The inspection can be based on either an inspection visit or a written inspection procedure. The written procedure can be applied if the supervisory authority considers that it is sufficient for the supervision when taking into account the observations and conclusions based on a prior inspection to the object of inspection.

Section 3

Inspections based on an inspection visit

(1) An inspection is considered to have started on the day when the inspector makes the inspection visit to the object of inspection. The inspector can make more than one inspection visit during an inspection if the completion of the inspection so requires. The inspector shall see to it that the start of the inspection is without delay recorded in the gene technology register.

(2) The inspector shall draw up the minutes of the inspection without delay and at the latest within 30 days from the last inspection visit included in the inspection. When calculating the time limit, account is not taken of the following:
1) the time during which the inspector is awaiting the additional information referred to in section 5h (3) (2) of the Gene Technology Act; and

2) the time during which the inspector is awaiting the results of the measurements or the tests made or the analysis of the samples taken in the context of the inspection as referred to in section 28 of the Gene Technology Act.

(3) An inspection is considered completed when the inspector has signed the minutes of the inspection. If several inspectors have taken part in the carrying out of the inspection, all of them shall sign the minutes of the inspection.

(4) The inspector shall see to it that the minutes of the inspection are entered into the gene technology register as soon as possible after the completion of the inspection.

(5) Provisions on the notification of the minutes of inspections are laid down in section 39 of the Administrative Procedure Act (434/2003).

Section 4

Inspections based on a written procedure

(1) An inspection based on a written procedure is considered to have started on the day when the inspector notifies the operator of the inspection and asks the operator to submit the information necessary for the inspection. The inspector shall see to it that the start of the inspection is without delay recorded in the gene technology register.

(2) The minutes of the inspection shall be drawn up as laid down in section 39 (2) of the Administrative Procedure Act (434/2003). The essential observations made on the basis of the documents submitted by the operator shall appear from the minutes. The inspector shall see to it that the minutes of the inspection are entered into the gene technology register as soon as possible after the completion of the inspection.

(3) Should there appear circumstances at the start of the inspection or in the course of it on the basis of which the inspector considers an inspection visit necessary, the inspection shall be carried out as laid down in section 3.

Section 5

The content of an inspection regarding contained use

(1) When carrying out an inspection of the contained use of genetically modified organisms, the inspectors shall pay particular attention to the following:
1) that the information on the use, premises, containment measures and waste management that the operator has submitted in his or her notification or application regarding the contained use is valid;
2) the genetically modified organisms to be used comply with the description presented in the notification or application;
3) the operator follows the conditions, if any, for the written consent granted by the Board for Gene Technology;
4) the operator has carried out the risk assessment referred to in section 8 of the Gene Technology Act;
5) the operator is in the manner provided for in section 9 of the Gene Technology Act aware of the properties of the genetically modified organisms used and of their possible effects on health and the environment;

6) the operator has submitted to the Board for Gene Technology the information referred to in section 9a of the Gene Technology Act, as well as other necessary information regarding possible alterations in the use of the genetically modified organisms;
7) the operator has observed the duty to keep a record under section 10 of the Gene Technology Act;
8) the classification of the use of the genetically modified organisms that the operator has taken into use by recording their use according to section 16 (1) is correct;
9) the operator has in accordance with section 16c of the Gene Technology Act notified the Board for Gene Technology of any accidents and hazardous situations; and
10) the staff working on the premises intended for contained use has been given adequate guidance so as to ensure the safe use.

(2) The written inspection procedure is subject to the provisions of paragraph 1, as applicable.

Section 6

Inspections of deliberate release for any other purpose than for placing on the market

(1) When carrying out an inspection of the deliberate release of genetically modified organisms for any other purpose than for placing on the market, the inspectors shall pay particular attention to the following:
1) the information provided by the operator in the application for deliberate release on the properties of the genetically modified organisms and on the conditions of release and the receptor environment is valid;
2) the operator follows the conditions, if any, for the consent granted by the Board for Gene Technology;
3) the operator is in the manner provided for in section 9 of the Gene Technology Act aware of the properties of the genetically modified organisms used and of their possible effects on health and the environment;
4) the operator has submitted the information referred to in section 9a of the Gene Technology Act to the Board for Gene Technology;
5) the operator observes the duty to monitor under section 11 of the Gene Technology Act;
6) the operator has in accordance with section 19a of the Gene Technology Act notified the Board for Gene Technology of any new information obtained during the deliberate release; and
7) the staff involved in the deliberate release has been given sufficient guidance so as to ensure safe release.

(2) The written inspection procedure is subject to the provisions of paragraph 1, as applicable.

Section 7

Inspections regarding the placing on the market of products

When carrying out an inspection of the placing on the market of products, the inspectors shall pay particular attention to the following:
1) that the labelling of the product is in compliance with section 21c of the Gene Technology Act; and
2) the operator observes the duty to monitor under section 11 of the Gene Technology Act.

Section 8

Cooperation of the inspectors

If several supervisory authorities supervise the same deliberate release into the environment of genetically modified organisms, the inspectors of the supervisory authority shall cooperate so that the inspection is carried out appropriately and taking into account the operator's interests.

Section 9

Checking and updating the information in the register

In the context of the inspections referred to in sections 5 – 6 the inspector shall see to it that the operator provides all the information necessary for updating the information on the object of inspection and the operator in the gene technology register and for correcting any errors referred to in section 26a of the Gene Technology Act.

Section 10

Notification of observations made in the context of an inspection

(1) The inspector shall inform the Board for Gene Technology and the relevant supervisory authorities of such observations made in the context of the inspection that constitute grounds for the regulations for or restricting and prohibiting the use as referred to in section 22 of the Gene Technology Act.

(2) The inspector shall without delay submit to the Secretariat of the Board for Gene Technology information on the observations made in the context of the inspection as far as it concerns the operator's responsibility for making a new notification or application or the operator's responsibility for submitting to the Board for Gene Technology information that supplements the documents submitted previously.

Section 11

Content of the minutes of an inspection

(1) The minutes of the inspection drawn up on the basis of an inspection visit shall include at least the following information:
1) the record number of the inspection in the gene technology register;
2) the date of start of the inspection and the dates of any other inspection visits included in the same inspection and the duration of each inspection visit;
3) the name and postal address of the operator who is responsible for the contained use or the deliberate release into the environment of the genetically modified organisms that is subject to the inspection;
4) the record numbers of the notifications or applications regarding the contained use and deliberate release into the environment of genetically modified organisms or other identification of the object of inspection;
5) a possible limitation of the inspection;
6) the visiting address of the premises for the contained use or the inspected object of deliberate release;
7) the measurements and tests possibly made and the samples possibly taken under section 28 of the Gene Technology Act and the results of their analyses;

8) the name(s) of the inspector or inspectors who carried out the inspection and of any other persons present at the inspection;
9) the observations made during the inspection regarding circumstances referred to in sections 5 – 7;
10) the conclusions made by the inspector of the circumstances noted during the inspection and possible further measures to be undertaken based on them; and
11) the signature of the inspector or inspectors who carried out the inspection and the date of signature.

(2) The inspector shall see to it that it clearly appears from the minutes of the inspection which pieces of information contained in them are subject to confidentiality based on the view of the operator or the information obtained by the inspector and on what grounds they are subject to confidentiality.

(3) What is laid down in paragraphs 1 and 2 regarding the minutes of an inspection shall apply, as applicable, to the minutes of an inspection drawn up on the basis of a written inspection procedure.

Section 12

Entry into force

(1) This Decree enters into force on 27 February 2007.

(2) This Decree repeals the Decree of the Ministry of Social Affairs and Health on Inspection Procedures under the Gene Technology Act (184/2005) of 18 March 2005.