

Ministry of Social Affairs and Health, Finland

NB: Unofficial translation, legally binding only in Finnish and Swedish

## **Government Decree on Chargeable Performances under the Gene Technology Act (1158/2009)**

Issued in Helsinki on 17 December 2009

### **Section 1**

#### **Scope of application**

This Decree provides for the amount of charges collected for the processing of notifications and applications under the Gene Technology Act (377/1995) as well of charges for the inspections and testing covered by supervision under the said Act.

### **Section 2**

#### **Charges for performances related to the contained use**

The charges collected from an operator for performances related to the contained use of genetically modified organisms are as follows:

- 1) the charge for processing a notification referred to in section 14 of the Gene Technology Act, EUR 375;
- 2) the charge for processing a notification referred to in section 14a of the Gene Technology Act in case the operator has not asked for a written decision in accordance with section 14c, EUR 375;
- 3) the charge for processing a notification referred to in section 14a of the Gene Technology Act in case the operator has asked for a written decision in accordance with section 14c, EUR 495;
- 4) the charge for processing an application referred to in section 14b of the Gene Technology Act, EUR 935; and
- 5) an inspection based on a written procedure carried out by the National Supervisory Authority for Welfare and Health under the Gene Technology Act, EUR 140.

An operator is charged for the inspections based on an inspection visit carried out by the National Supervisory Authority for Welfare and Health a charge that is based on the number of hours spent on the inspections so that EUR 75 is collected per hour. The number of hours includes the time spent on the preparation of an inspection, on the inspection visits and on subsequent measures related to the inspection. No charge is however collected for the time spent on preparation and subsequent measures as far as each of them separately exceeds three hours. No charge is collected for the time spent by the inspector on journeys or for their costs.

An operator is charged in regard to the measuring and testing related to an inspection referred to in paragraph 2 and the sampling included in them for the direct costs incurred by the operator.

### **Section 3**

#### **Charges for performances related to deliberate release into the environment**

The charges collected from an operator for performances related to the deliberate release into the environment of genetically modified organisms are as follows:

- 1) the charge for processing an application regarding the deliberate release of genetically modified organisms referred to in section 17 of the Gene Technology Act for purposes other than placing on the market, EUR 3,300;
- 2) the charge for processing an application for the placing on the market of products referred to in section 20 of the Gene Technology Act, EUR 6,600; and
- 3) the charge for an inspection based on a written procedure carried out by the National Supervisory Authority for Welfare and Health, the Finnish Environment Institute or the Food Safety Authority under the Gene Technology Act, EUR 140.

An operator is charged for the inspections based on an inspection visit carried out by the National Supervisory Authority for Welfare and Health, the Finnish Environment Institute or the Food Safety Authority a charge that is based on the number of hours spent on the inspections so that EUR 75 is collected per hour. The number of hours includes the time spent on the preparation of an inspection, on the inspection visits and on subsequent measures related to the inspection. No charge is however collected for the time spent on preparation and subsequent measures as far as each of them separately exceeds three hours. No charge is collected for the time spent by the inspector on journeys or for their costs.

An operator is charged in regard to the measuring and testing related to an inspection referred to in paragraph 2 and the sampling included in them for the direct costs incurred by the operator.

### **Section 4**

Invoicing of the charges for the processing of notifications and applications

The Board for Gene Technology invoices the charges referred to in section 2, paragraph 1 (1) – (4), and in section 3, paragraph 1 (1) and (2).

### **Section 5**

#### **Invoicing of the charges related to inspections**

Each supervisory authority invoice themselves the charges referred to in section 2, paragraph 1 (5) and paragraphs 2 and 3, and in section 3, paragraph 1 (3) and paragraphs 2 and 3, related to their supervision.

### **Section 6**

#### **Waiving of charges**

Provisions on waiving a charge provided for in this Decree partly or wholly are laid down in section 35, paragraph 2, of the Gene Technology Act.

## **Section 7**

### **Charges for submitting a document and retrieval of information**

The Board for Gene Technology and each supervisory authority decide on the charges to be collected for the retrieval of information referred to in section 34, paragraph 2, of the Act on the Openness of Government Activities (621/1999) and for the access to information referred to in paragraph 3 of the section in the form of a copy or printout in compliance with what is provided in the said section.

## **Section 8**

### **Entry into force**

This Decree enters into force on 1 January 2010 and will remain in force until 31 December 2012.