

Unofficial translation

Ministry of Social Affairs and Health, Finland

**No. 90/2005**

**Decree of the Ministry of Social Affairs and Health on the differentiated procedure relating to the deliberate release of genetically modified organisms**

Issued in Helsinki on 8 February 2005

**Section 1**

**Scope of application**

This Decree is applied to the deliberate release of genetically modified organisms for any other purpose than for placing on the market if the criteria laid down in section 3 are met.

**Section 2**

**Definition**

Differentiated procedure means a simplified application procedure deviating from the procedure laid down in section 18 of the Gene Technology Act, on the application of which the Commission of the European Communities decides either on its own initiative or on the initiative of the Board for Gene Technology of Finland or competent authorities of other Member States.

**Section 3**

**Criteria**

The differentiated procedure can be applied if sufficient experience has been obtained of the release of a genetically modified organism in certain ecosystems and if the genetically modified organism concerned meets the following criteria:

- 1) the taxonomic status and the biology, such as the mode of reproduction, pollination and ability to cross with related species and pathogenicity, of the non-modified recipient organism are well known;
- 2) there is sufficient knowledge about the safety of the non-modified recipient organism and, as appropriate, of the parental organism for the health of humans and animals and for the environment in the environment of the release;
- 3) information is available on any interaction of particular relevance for the risk assessment between the non-modified recipient organism and, where appropriate, the parental organism and other organisms in the ecosystem where the deliberate release takes place;
- 4) it can be demonstrated that the inserted genetic material is well characterised;
- 5) there is information available on the structure of the possible vector systems or the sequences used with the carrier DNA;

- 6) in cases in which a genetic modification involves the deletion of genetic material, the extent of the deletion is known;
- 7) there is sufficient information on the genetic modification to enable identification of the genetically modified organism and its progeny during a deliberate release;
- 8) under the conditions in which the deliberate release takes place, the genetically modified organism does not present such additional or increased risks to the health of humans and animals or to the environment that are not presented by the release of corresponding non-modified recipient organisms and, where appropriate, parental organisms; and
- 9) possible capacity of the genetically modified organisms to spread in the environment and to invade other ecosystems and capacity to transfer genetic material to other organisms in the environment does not result in harmful effects.

## **Section 4**

### **Procedure based on the initiative of the Board for Gene Technology**

The Board for Gene Technology may submit a reasoned proposal to the Commission of the European Communities for the application of the differentiated procedure to a genetically modified organism meeting the criteria laid down in section 3.

The Commission of the European Communities will make a decision on the application of the differentiated procedure in accordance with Article 7 in Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

## **Section 5**

### **Entry into force**

This Decree enters into force on 16 February 2005.