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MINISTRY OF SOCIAL AFFAIRS AND HEALTH, FINLAND

No. 771/2014

Decree of the Ministry of Social Affairs and Health on principles of risk assessment of the contained use of genetically modified animals, on classification of the contained use, and on containment and other protective measures

Issued in Helsinki on 17 September 2014

In accordance with the decision taken by the Ministry of Social Affairs and Health the following is enacted by virtue of sections 8(4) and 13(5) of the Gene Technology Act (377/1995), as laid down in the Act 847/2004:

Section 1

Scope of application

This Decree shall apply to the use of those genetically modified animals referred to in the Gene Technology Act (377/1995) which have not been authorised for placing on the market as products in accordance with the provisions of 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 or Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.

Section 2

Minimum requirements for risk assessment

The operator shall observe in the risk assessment of the contained use of genetically modified animals at least what is laid down in sections 3–12. However, a simplified risk assessment procedure may be used if the species and genetic modification are commonly used and their properties are well known. In such cases, those paragraphs of sections 5 and 10(3) that are not relevant to the results of the risk assessment may be excluded from detailed examination in the risk assessment.

Section 3

General principles of risk assessment

(1) The risk assessment shall identify the potentially increased or reduced harmful properties of a genetically modified animal that are due to a genetic alteration or alterations in the previous properties of the recipient animal. The following are considered as potentially harmful properties of a genetically modified animal:

1) adverse health effects, diseases or other harmful effects on humans, animals or plants, including allergenic or toxic effects, infections and parasitic infestations;

2) deleterious effects due to the impossibility of treating a disease potentially transmitted by the animal or providing an effective prophylaxis, including the indirect effects caused by changes in the host range of a pathogen, the animal becoming a new source of a pathogen or a disease vector, or decreased drug susceptibility of a parasite;

3) deleterious effects due to the establishment or dispersal of the genetically modified animals in the environment;

4) deleterious effects due to the natural transfer of inserted genetic material to other organisms; and

5) changes in the diet, behaviour, reproductive capacity and modes of reproduction of the genetically modified animal that may broaden its prey spectrum, increase its level of aggression or uncontrolled reproduction, or cause other significant and harmful effects on health and the environment.

(2) The risk assessment shall be based on:

1) the identification of all potentially harmful effects, in particular those associated with:

a) the recipient animal;

b) the inserted genetic material originating from the donor organism;

c) the vector;

d) the resulting genetically modified animal;

2) the nature of the activity;

3) the severity of the potentially harmful effects; and

4) the likelihood of the occurrence of the potentially harmful effects.

Section 4

The stages of risk assessment

(1) The risk assessment consists of two stages of which:

1) at stage 1, the potentially harmful properties of the genetically modified animal referred to in section 3 are first identified and the initial classification of the contained use of the genetically modified animal is determined taking into account the severity of the potentially harmful effects; thereafter, the likelihood of the harmful effects resulting from the exposure of humans and the environment is assessed taking into account the nature and scale of the activity, and containment measures are chosen according to the initial classification; and

2) at stage 2, at first the final classification of the contained use and the containment measures required by it are determined, and thereafter the final classification and the appropriateness of the final containment measures are reviewed by repeating stage 1.

(2) Provisions on stage 1 are laid down in sections 5–10 and provisions on stage 2 in sections 11 and 12.

Section 5

Identification of harmful properties

(1) When identifying the potentially harmful properties of the genetically modified animal, the following shall be taken into account in regard to the unmodified recipient animal, as necessary:

1) pathogenicity, allergenicity, toxicity and other possible harmful effects on human, animal or plant health as well as the capacity to act as a parasite, a source of pathogens or a disease vector;

2) natural habitat and geographical distribution;

3) types of reproduction, life cycle and ability to form survival structures;
4) capability to survive, become established, reproduce and compete in Finnish nature;
5) disabling mutations or prior genetic modifications;
6) the host range in the case of parasites, symbionts or commensals;
7) significant physiological, phenotypic or behavioural properties that may change as a result of genetic modification;
8) significant involvement in environmental processes; and
9) interactions with and effects on other organisms in the environment, including symbiotic properties.

(2) When identifying the potentially harmful properties of the genetically modified animal, the following considerations shall be taken into account in regard to the donor organism, the insert, the vector used or any other method of modification, as necessary:
1) the identity of the insert and its function;
2) the level of expression of the inserted genetic material;
3) the source of the genetic material and the identity and characteristics of the donor organisms;
4) the location of the inserted genetic material taking into account that the insertion may activate or inactivate genes of the recipient animal;
5) the predicted tissue and developmental stage specificity of the inserted genetic material; and
6) the function of any deleted genetic material and the impact of the deletion on the expression of other genetic material.

(3) When identifying the potentially harmful properties of the genetically modified animal, the following shall be taken into account, as necessary:
1) the foreseeable toxic and allergenic effects of the tissues and metabolites or excreta of the genetically modified animal;
2) the tissues and developmental stages in which the genetic modification is expressed;
3) the significant physiological, phenotypic, behavioural, reproductive or spreading properties that have changed in the genetically modified animal;
4) the altered pathogenicity of the genetically modified animal;
5) altered capacity to act as a pathogen source or a disease vector;
6) the ecosystems to which the genetically modified animal could unintentionally be released, and its foreseeable survivability, reproduction and spreading in them; and
7) the anticipated result of altered interaction with organisms that may be exposed to the genetically modified animal that has been unintentionally released into the environment.

Section 6

Initial classification of the genetically modified animal

(1) When any risks possibly associated with the recipient and donor organisms, the vector, the insert or some other genetic alteration have been identified, the genetically modified animal is initially classified. The requirements for the properties of genetically modified animals included in class 1 and class 2, as laid down in sections 14–16, shall be used in the classification. The containment and other protective measures laid down in sections 17–20 shall be used as a point of comparison when assessing whether the control of the identified harmful effects requires more stringent containment and other protective measures.

(2) The risk of harmful effects related to the properties of the genetically modified animal is evaluated by taking into account the severity of each effect and all biological properties which may reduce or increase the likelihood of the effect. The severity and

likelihood of harmful effects shall be evaluated independently so that the estimate of the severity of consequences will not be based on how likely a harmful effect is to occur in a certain case. The estimated severity of effects shall be taken into account in the initial classification of the use, and it shall also be ensured that the severity of the harmful effects on human health and on the environment has been taken into account in all respects.

Section 7

Principles of evaluating the likelihood of harmful effects

When evaluating the likelihood of harmful effects, it is essential to consider to what extent and how people and the environment will be exposed to the genetically modified animal. The likelihood of exposure depends on the nature of the activity involving exposure and on the containment measures undertaken in connection with the work involving exposure. The special characteristics of the activity shall be taken into account in the final classification and the choice of containment measures. The nature and scale of the activity need to be considered in order to estimate the likelihood of exposure of humans and the environment. Furthermore, the nature and scale of the activity affect the choice of risk management methods. The management of waste, including dead animals, and effluents shall be taken into account in the assessment when necessary.

Section 8

The nature of the planned use in the evaluation of the likelihood of harmful effects

(1) When evaluating the likelihood of harmful effects, it shall be taken into account that the nature of the planned activities affects the degree of risk and application of protective measures lowering the putative risks of the genetically modified animal to a sufficient level.

(2) In laboratory activities in which the effects of standardised laboratory methods and established practices on exposure are well known, it is not necessary to evaluate in detail the risks associated with each method, unless the genetically modified animal itself or another organism used in connection with it is dangerous to human or animal health or the environment. A detailed consideration may however be necessary for methods other than routine methods or for practices that may considerably affect the risk level.

Section 9

The scale of activity in the evaluation of the likelihood of harmful effects

When evaluating the likelihood of harmful effects, it shall be taken into account that a large number of animals and the frequent repetition of a handling process may increase the likelihood of the exposure of humans and the environment as well as harmful effects if containment measures fail. The scale of the activity shall be taken into account when determining the most appropriate containment and protective measures.

Section 10

The conditions of rearing and use in the evaluation of the likelihood of harmful effects

(1) When assessing the likelihood of harmful effects, attention shall be paid to the reliability and possible failures of the rearing facilities, their equipment and control systems as well as the equipment used in the procedures to which animals are subjected where failure can lead to exposure of humans and the environment to genetically modified animals. Where unintentional exposure is foreseeable, additional containment measures are required.

(2) In addition to physical containment measures, biological and chemical measures may constitute a considerable part of the required containment measures and reduce the likelihood of harmful effects. Biological containment measures may include measures that influence the reproductive capacity or the behaviour of the animal, or other similar measures. Chemical containment measures may include the use of disinfecting, inactivating, attracting or repelling chemical compounds appropriate for the particular animal species or other similar measures.

(3) The following factors shall be taken into account, where applicable, when evaluating how the properties of the receiving environment affect the likelihood of harmful effects and thus also the level of risk and the choice of containment measures:

1) the environment potentially exposed; the scale of environmental exposure may be influenced by the nature and scale of the activity and the ways of dispersal of the genetically modified animals into the environment;

2) susceptible species in the environment potentially exposed, taking into account protected species in particular;

3) the possibility for the genetically modified animal to survive and persist in the environment;

4) the effects on the physico-chemical properties of the environment potentially exposed; and

5) the permanence and reversibility of the harmful effects on the environment potentially exposed.

Section 11

Determination of the final classification of the genetically modified animal and of the final containment measures

(1) The final classification of the genetically modified animal and the final containment measures can be determined when the severity and likelihood of all potentially harmful effects and the adequacy of the containment and other protective measures according to the initial classification have been evaluated. In that context, it shall be reviewed whether the initial classification is appropriate taking into account the nature of the proposed activity and measures.

(2) A comparison of the initial classification referred to in section 6 and the related containment measures with the final classification and the related containment measures can give rise to three results:

1) the initial classification has not adequately taken into account all harmful effects, and therefore the containment measures initially chosen at stage 1 are not sufficient and have to be supplemented by other containment measures, and the classification of the activity may have to be revised;

2) the initial classification is correct and the related containment measures are sufficient to prevent or minimise the harmful effects on human health and the environment; or

3) in the initial classification, the risk associated with the activity was estimated too high, and therefore a lower risk level and corresponding containment measures must be chosen.

Section 12

Confirmation of the final containment measures

(1) Once the final classification and the final containment measures have been determined, the level of human and environment exposure to harmful effects has to be reassessed. This is to confirm that the possibility of any harmful effects occurring, taking into account the nature and scale of the activity and the proposed containment measures, is acceptably low. When this has been done, the risk assessment has been completed.

(2) The risk assessment shall be reviewed later on if the nature or scale of the activity changes significantly, or if there is reason to suspect in the light of new scientific and technical knowledge that the assessment is no more appropriate. Any alterations in containment measures due to this review shall be applied without delay to maintain an adequate level of protection for human health and the environment.

Section 13

General principles of operation

(1) For the handling of genetically modified animals the following principles of risk management and good occupational safety and hygiene shall apply:

1) to keep the workplace and environmental exposure to any genetically modified animal to the lowest practicable level;
2) to exercise engineering control measures at the place of work and to supplement them with appropriate protective clothing and equipment, when necessary;
3) to test adequately and maintain control measures and equipment;
4) to test, when necessary, the presence of living genetically modified animals or their viable life stages outside the primary physical containment;
5) to keep adequate records of operations;
6) to provide appropriate training for personnel;
7) to establish biological safety committees, if required;
8) to formulate and implement local codes of practice for the safety of personnel, when required;
9) in class 2 activities, to display biohazard signs where appropriate;
10) when working with genetically modified parasites, to provide washing and decontamination facilities for personnel and to prohibit eating, drinking, the storing of food or feed and mouth pipetting in the work area; and
11) to provide written standard operating procedures where appropriate to ensure safety.

(2) As regards the keeping of animals, the provisions of the Animal Welfare Act (247/1996) and the Act on the Protection of Animals Used for Scientific or Educational Purposes (497/2013) shall also apply.

Section 14

Principles of classification of use

(1) The contained use of genetically modified animals is classified, on the basis of the results of the risk assessment, into two classes of use.

(2) Class 1 includes activities with genetically modified animals of no or at most a low risk. Level 1 containment, corresponding to class 1 activity, can be achieved by using conventional rearing facilities appropriate for each animal species and measures that efficiently limit the access of genetically modified animals outside the area of contained use.

(3) Class 2 includes activities with genetically modified animals of moderate or higher risk. To achieve level 2 containment, which corresponds to class 2 activity,

conventional rearing facilities and measures shall be complemented with containment measures that the Board for Gene Technology has approved on a case-by-case basis and that prevent the possible harmful effects of genetically modified animals and their access outside the area of contained use.

Section 15

Genetically modified animals included in class 1

(1) Class 1 includes the following genetically modified animals:
1) species conventionally used as laboratory animals;
2) conventional domestic animals; and
3) animals that are unable to survive, reproduce or interbreed with other species in natural conditions in Finland.
(2) Other conditions for inclusion in class 1 are that the genetically modified animal:
1) is unlikely to cause harmful effects on the health of humans or of animals or plants in the environment likely to be exposed;
2) is not a possible source or vector of pathogens;
3) is unlikely to have direct or indirect adverse effects on the environment; and
4) is unlikely to have a greater ability to reproduce or spread in Finnish nature than the recipient species.
(3) Derogation from the conditions referred to in subsections 1 and 2 is possible if the Board for Gene Technology considers it justified with regard to a specific genetically modified animal or group of animals.

Section 16

Genetically modified animals included in class 2

(1) A genetically modified animal included in class 2 shall meet at least one of the following conditions:
1) the recipient species is native in Finland or it is expected to be able to survive, reproduce or interbreed with other species in Finland; moreover, the animal is not an animal referred to in section 15(1), and the genetically modified individuals have not been rendered infertile in a reliable manner;
2) the genetic modification is such that the genetically modified animal may cause disease to humans or to other organisms in the environment likely to be exposed;
3) as a result of the genetic modification, the genetically modified animal can act as a source of pathogens or as a vector for a human, animal or plant pathogen;
4) the nature of the genetic modification is such that the genetically modified animal can reproduce, interbreed or spread in Finnish nature significantly more efficiently than the recipient animal species or that the genetically modified animal may otherwise have a permanent and irreversible adverse effect on the environment.
(2) Derogation from the classification principles referred to in subsection 1 is possible if the Board for Gene Technology considers it justified with regard to a specific genetically modified animal or group of animals.

Section 17

Containment levels

(1) When using genetically modified animals, their containment level shall comply with the corresponding class of use. The containment level is determined on the basis of the level of the physical containment of the facilities, biological containment and the containment and protective measures to be applied. The physical properties of the

premises for contained use shall efficiently limit or prevent the spread of genetically modified animals into the environment, and the properties of the premises shall be appropriate for the animal species used. Rearing facilities can be located either indoors or, in certain cases, also outdoors if they are fenced or otherwise isolated. The containment and protective measures applied are chosen on a case-by-case basis so that they prevent any potential harm to health and the environment associated with the particular genetically modified animals.

(2) To achieve an adequate level of containment, at least the following shall be ensured:

1) the exit of living genetically modified animals outside the premises for contained use is sufficiently prevented;

2) interbreeding or mixing with any unmodified animals possibly handled on the same premises is prevented, or all of the animals are handled as genetically modified ones;

3) the personnel working on the premises have received appropriate training and are aware of the operating procedures for genetically modified animals;

4) sufficient measures have been taken to prevent unauthorised persons from accessing the premises for contained use;

5) the contact details of the person responsible for the use of genetically modified animals are clearly visible on the premises;

6) the genetically modified animals are appropriately identified individually or, when individual identification is technically unfeasible, by the smallest possible units;

7) the uncontrolled reproduction of animals is prevented; and

8) genetically modified animals and any material originating from them are prevented from entering the feed or food chain or animal breeding processes.

(3) For justified reasons, the Board for Gene Technology may grant an operator permission not to apply a particular requirement associated with a containment level.

Section 18

Containment and protective measures applied to vertebrate laboratory and domestic animals

When using genetically modified vertebrate laboratory and domestic animals, the following shall be ensured in addition to the measures referred to in section 17:

1) the physical containment of the animal facilities corresponds to the class of use and efficiently limits the possibilities of the animals, their offspring and their viable life stages being released into the environment; and

2) a method appropriate for each species is used to prevent the uncontrolled reproduction of the animals.

Section 19

Containment and protective measures applied to fish and other aquatic animals

When using genetically modified fish and other aquatic animals, the following shall be ensured in addition to the measures referred to in section 17:

1) the release of living animals and gametes of externally spawning species outside the premises for contained use through effluents, the sewerage system or other routes is efficiently limited or prevented in compliance with the requirements of the class of use;

2) the animals reared or their gametes cannot spread outside the rearing facilities if genetically modified animals are reared in covered outdoor tanks;

3) material originating from genetically modified animals is prevented from entering the feed and food chain; and

4) a method appropriate for each species is used to prevent the uncontrolled

reproduction of the animals.

Section 20

Containment and protective measures applied to insects and other invertebrates

In the contained use of genetically modified insects and other invertebrates, the following shall be ensured in addition to the measures referred to in section 17:

1) the release of living animals and their different life stages outside the premises for contained use through the sewerage system, ventilation systems, host organisms or other routes is efficiently limited or prevented in compliance with the requirements of the class of use; and

2) in rooms where genetically modified individuals may be unintentionally released in connection with their rearing or other handling, traps or other capturing methods appropriate for the particular species shall be used continuously.

Section 21

Waste management

(1) The treatment of waste originating from genetically modified animals and their rearing facilities shall comply with the provisions laid down in the Waste Act (646/2011) and Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).

(2) Special attention shall be paid to ensuring that waste treatment does not lead to release of living genetically modified animals or their different life stages into the environment or to the food or feed chain. All materials removed from the premises of contained use shall be appropriately cleaned or inactivated before their final disposal, ensuring that they do not include any viable eggs, pupae or other life stages of genetically modified animals.

Section 22

Entry into force

This Decree enters into force on 1 October 2014.

Helsinki, 17 October 2014

Susanna Huovinen Minister of Health and Social Services

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