Version 4/2022

**CONTAINED USE: GENETICALLY MODIFIED MICRO-ORGANISMS**

*Tick the appropriate box and fill in the required information:*

1 [ ]  **Notification** referred to in section 14 of the Gene Technology Act (377/1995) **of premises meant for the use of genetically modified organisms**

2 [ ]  **Notification** referred to in section 14a of the Gene Technology Act (377/1995) **of commencing the use of genetically modified organisms (class 2 of use)**

 The use takes place on premises a notification (record number) of the taking into use of which has been submitted previously:

       *(the record number has to be given if a notification referred to in section 14 is not submitted simultaneously)*

3 [ ]  **Application** referred to in section 14b of the Gene Technology Act (377/1995) **for commencing the use of genetically modified organisms (class 3 or 4 of use)**

The use takes place on premises a notification (record number) of the taking into use of which has been made previously:

      *(the record number has to be given if a notification referred to in section 14 is not submitted simultaneously)*

4 [ ]  This notification/application or the documents attached to it contain confidential information.

The confidential information has been collected in a separate, clearly marked Appendix, number(s):       and no confidential information appears from other parts of the notification/application.

5 [ ]  Based on section 14c of the Gene Technology Act (377/1995), the operator asks for a written decision of the Board for Gene Technology on the notification of commencing use under class 2 (increased processing fee).

 The notice form is accompanied by    Appendices.

 The notification/application is sent to the Board for Gene Technology either via E-mail (gtlk@gov.fi) or in the form of a signed paper version to the following address:

 Board for Gene Technology, Box 33, FI-00023 GOVERNMENT

 PLEASE FOLLOW THE INSTRUCTIONS FOR FILLING IN THE FORM!

# I OPERATOR

1 Name of the operator:

2 Business identity code of the operator:

3 Postal address of the operator:

4 Street address, postal code and post office of the premises for contained use

5 Name and date of birth of the person with main responsibility:

6 Contact information of the person with main responsibility (*postal address, telephone number and E-mail address of the workplace*):

7 Education and experience in the field of the person with main responsibility:

8 Name and date of birth of the deputy for the person with main responsibility:

9 Contact information of the deputy (*postal address, telephone number and E-mail address of the workplace*):

10 Education and experience in the field of the deputy:

11 Other possible contact person (*postal address, telephone number and E-mail address of the workplace*):

12 Electronic billing address and billing reference:

13 Business identity code and postal address of the recipient of the invoice, if other than the operator:

14 Information on the working groups the operator has possibly set up to deal with biological safety:

## II THE ORGANISMS USED

1The notification/application applies to GMMs coming under the following groups:

 [ ]  Bacteria [ ]  RNA viruses [ ]  DNA viruses

 [ ]  Fungi [ ]  Human cell cultures [ ]  Animal cell cultures

 [ ]  Plant cell cultures [ ]  Other, what:

 [ ]  GMMs are used but genetic modification is not carried out

 [ ]  Genetic modification of microorganisms is carried out

2 The species name and other identification data of the recipient organism(or parental organism):

3 The risk classification of the recipient organism (or parental organism) in official systems and its most essential properties from the point of view of risk assessment:

4 The species name and other identification data of the donor organism:

5 The risk classification of the donor organism in official systems and its most essential properties from the point of view of risk assessment:

6 Possible other sources of the genetic material that is (has been) used in the modification, besides those described in point 4:

7 The purpose of the genetic material that is (has been) used in the modification

8 The vectors that are (have been) used in the modification

9 Changes in the properties of the resulting GMM compared with the original recipient organism:

1. Pathogenicity, toxicity or allergenicity

 [ ]  unchanged [ ]  increased [ ]  reduced [ ]  not known

 Detailed account:

1. Survival, reproduction or dispersal ability

 [ ]  unchanged [ ]  increased[ ]  reduced [ ]  not known

 Detailed account:

1. Ability to transfer hereditary material

 [ ]  unchanged [ ]  increased[ ]  reduced [ ]  not known

 Detailed account:

1. Other changed properties, explain:

10 Methods of identification of the resulting GMM

## III DESCRIPTION OF USE

1 Choose the terms that best describe the activity:

 [ ]  bioanalytics [ ]  bio process development [ ]  diagnostics

 [ ]  food research [ ]  animal breeding [ ]  enzyme production

 [ ]  gene therapy [ ]  plant breeding [ ]  plant protection

 [ ]  laboratory animal services [ ]  pharmaceutical development [ ]  forest research

[ ]  teaching [ ]  basic research/biology

[ ]  basic research–medicine [ ]  clinical trial

 [ ]  risk assessment [ ]  disease models [ ]  industrial production

 [ ]  renting of premises & equipment [ ]  environm. research [ ]  other

2 A short description of the contained use, its purpose and expected results:

3 Manner of growing the GMM and estimated culture volumes:

4 If the activity involves clinical drug trials, its EudraCT number:

**IV PREMISES, CONTAINMENT AND PROTECTIVE MEASURES AND WASTE MANAGEMENT**

IV.1. DESCRIPTION OF PREMISES AND CONTAINMENT MEASURES

**N.B.! If the notification only concerns taking into use of premises, layouts of the premises have to be submitted in an Appendix.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| [ ]  **PREMISES AT CONTAINMENT LEVEL 1****Room numbers and an overall description of the rooms** *(if confidential, use codes for the rooms, e.g. A,B,C, and give the actual room numbers only in the Appendix containing confidential information*!):

|  |  |  |  |
| --- | --- | --- | --- |
|  | *yes* | *No* | *Detailed account* |
| *Surfaces that are resistant to liquid substances 1) and easy to clean*  | [ ]  | [ ]  |       |
| Effective control of vectors | [ ]  | [ ]  |       |
| *Surveillance window into the room*  | [ ]  | [ ]  |       |
| *Protective clothing* | [ ]  | [ ]  |       |
| *Other containment and protective measures:* |       |

*1) Water, acids, alkalis, solvents, disinfection and decontamination substances* **Further information** *(in particular if it is question of other than usual laboratory premises):*      |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| [ ]  **PREMISES AT CONTAINMENT LEVEL 2****Room numbers and an overall description of the rooms** *(if confidential, use codes for the rooms, e.g. A,B,C, and give the actual room numbers only in the Appendix containing confidential information*!):

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Yes*  | *No* | *Detailed account* |
| *Surfaces tha are resistant to liquid substances1) and easy to clean*  | [ ]  | [ ]  |       |
| *Microbiological safety cabinet/facility* | [ ]  | [ ]  |       |
| *Particular measures to control aerosols*  | [ ]  | [ ]  |       |
| *Biohazard sign on the door* | [ ]  | [ ]  |       |
| *Limited access by outsiders* | [ ]  | [ ]  |       |
| *Efficient control of vectors*  | [ ]  | [ ]  |       |
| *Surveillance window into the room* | [ ]  | [ ]  |       |
| *Protective clothing*  | [ ]  | [ ]  |       |
| *Other containment and protective measures* |       |

*1) Water, acids, alkalis, solvents, disinfection and decontamination substances* **Further information** *(in particular if it is question of other than usual laboratory premises):*      |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| [ ]  **PREMISES AT CONTAINMENT LEVEL 3–4** **Room numbers and an overall description of the rooms** *(if confidential, use codes for the rooms, e.g. A,B,C, and give the actual room numbers only in the Appendix containing confidential information*!):

|  |  |  |  |
| --- | --- | --- | --- |
|  | *yes* | *no* | *Detailed account* |
| *Surfaces that are resistant to liquid substances1) and easy to clean* | [ ]  | [ ]  |       |
| *Microbiological safety cabinet/facility* | [ ]  | [ ]  |       |
| *Particular measures to control aerosols* | [ ]  | [ ]  |       |
| *Biohazard sign on the door* | [ ]  | [ ]  |       |
| *Limited access by outsiders* | [ ]  | [ ]  |       |
| *Efficient control of vectors* | [ ]  | [ ]  |       |
| *Surveillance window into the room* | [ ]  | [ ]  |       |
| *Protective clothing* | [ ]  | [ ]  |       |
| *The laboratory can be sealed for fumigation* | [ ]  | [ ]  |       |
| *Entry to lab via airlock*  | [ ]  | [ ]  |       |
| *Air pressure lower than in immediate environment*  | [ ]  | [ ]  |       |
| *HEPA filtration of supply and exhaust air*  | [ ]  | [ ]  |       |
| *Shower* | [ ]  | [ ]  |       |
| *Laboratory to contain its own equipment*  | [ ]  | [ ]  |       |
| *Description of the establishment or its parts:*  |       |
| *Other containment and protective measures:* |       |

*1) Water, acids, alkalis, solvents, disinfection and decontamination substances* **Further information** *(in particular if it is question of other than usual laboratory premises):*      |

IV.2. WASTE MANAGEMENT

Methods used in the inactivation of genetically modified micro-organisms, material containing them and waste water

[ ]  Autoclavation

The autoclave is situated: [ ]  on the same premises where people are working with GMMs

 [ ]  in the same building

 [ ]  in the same establishment

 [ ]  elsewhere, where:

 For what waste is it used:

[ ]  Chemical inactivation

 Description of the method:

 For what waste is it used:

[ ]  Other method

 Description of the method:

 For what waste is it used:

[ ]  GMM waste is not inactivated

 Reasons:

 For what waste is it used:

Final disposal of the waste:

## V CONCLUSIONS OF THE RISK ASSESSMENT

1 [ ]  The operator has made a risk assessment of the GMMs described in this notification in accordance with the Decree of the Ministry of Social Affairs and Health No. 1053/2005. The risk assessment document has been included in the information recorded on the contained used, and it can be presented upon request to an inspector of the Finnish Medicines Agency Fimea or to the Board for Gene Technology.

2Possible health impacts linked with the planned use of the GMM:

3 Possible environmental impacts linked with the planned use of the GMM:

4 Classification of the use made on the basis of risk assessment (classes 1–4)

[ ]  GMMs /manners of use under class 1:

[ ] GMMs /manners of use under class 2:

[ ] GMMs /manners of use under class 3:

[ ] GMMs /manners of use under class 4:

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**VI PREPAREDNESS FOR EXCEPTIONAL SITUATIONS**

1 [ ]  The operator has drawn up an action plan for unexpected situations, and a copy of the plan is included in the information recorded on the contained use (*is required always when there has been no obligation to prepare a rescue plan*).

2 [ ] The operator has drawn up a rescue plan that is attached to this notification/application  *(required only* *in cases described in section 10 of Decree No. 272/2006 of the Ministry of Social Affairs and Health).*

 The rescue plan has been submitted to the following authorities:

3 Information on measures to prevent accidents (*applies only to classes 3–4*)

 a) Particular hazard that is due to the location of the establishment:

 b) Preventive measures:

c) Procedures and plans to control the continuous efficiency of the containment measures:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date and signature of the person with main responsibility