

**Please, note that the notification/application must be filled in Finnish or Swedish. This English version is for informational purposes only - for submitting your notification/application to the Board for Gene Technology use either the Finnish or Swedish version of the form!**

## **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 14 a 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 14 b 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 14 c 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 ([gtk.stm@stm.fi](mailto:gtk.stm@stm.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 (if any):
- 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 Invoicing address:
- 13 Information on the working groups the operator has possibly set up to deal with biological safety:

## II THE ORGANISMS USED

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

<input type="checkbox"/> Bacteria	<input type="checkbox"/> RNA viruses	<input type="checkbox"/> DNA viruses
<input type="checkbox"/> Fungi	<input type="checkbox"/> Human cell cultures	<input type="checkbox"/> Animal cell cultures
<input type="checkbox"/> Plant cell cultures	<input type="checkbox"/> 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:
- 3 The risk classification of the recipient 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/parental 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:
- a) Pathogenicity, toxicity or allergenicity  
 unchanged  increased  reduced  not known  
 Detailed account:
- b) Survival, reproduction or dispersal ability  
 unchanged  increased  reduced  not known  
 Detailed account:
- c) Ability to transfer hereditary material  
 unchanged  increased  reduced  not known  
 Detailed account:
- d) 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:
- |  |  |  |
|--|--|--|
| <input type="checkbox"/> bioanalytics  | <input type="checkbox"/> bio process development | <input type="checkbox"/> diagnostics       |
| <input type="checkbox"/> food research | <input type="checkbox"/> animal breeding         | <input type="checkbox"/> enzyme production |
| <input type="checkbox"/> gene therapy  | <input type="checkbox"/> plant breeding          | <input type="checkbox"/> plant protection  |

- laboratory animal services     pharmaceutical development     forest research  
 teaching     basic research–biology     basic research–medicine  
 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:

#### 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 <sup>1)</sup> and easy to clean	<input type="checkbox"/>	<input type="checkbox"/>	
Effective control of vectors	<input type="checkbox"/>	<input type="checkbox"/>	
Surveillance window into the room	<input type="checkbox"/>	<input type="checkbox"/>	
Protective clothing	<input type="checkbox"/>	<input type="checkbox"/>	
Other containment and protective measures:			

<sup>1)</sup> 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 that are resistant to liquid substances <sup>1)</sup> and easy to clean	<input type="checkbox"/>	<input type="checkbox"/>	
Microbiological safety cabinet/facility	<input type="checkbox"/>	<input type="checkbox"/>	
Particular measures to control aerosols	<input type="checkbox"/>	<input type="checkbox"/>	
Biohazard sign on the door	<input type="checkbox"/>	<input type="checkbox"/>	
Limited access by outsiders	<input type="checkbox"/>	<input type="checkbox"/>	
Efficient control of vectors	<input type="checkbox"/>	<input type="checkbox"/>	
Surveillance window into the room	<input type="checkbox"/>	<input type="checkbox"/>	
Protective clothing	<input type="checkbox"/>	<input type="checkbox"/>	
Other containment and protective			

measures

<sup>1)</sup> 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 substances <sup>1)</sup> and easy to clean	<input type="checkbox"/>	<input type="checkbox"/>	
Microbiological safety cabinet/facility	<input type="checkbox"/>	<input type="checkbox"/>	
Particular measures to control aerosols	<input type="checkbox"/>	<input type="checkbox"/>	
Biohazard sign on the door	<input type="checkbox"/>	<input type="checkbox"/>	
Limited access by outsiders	<input type="checkbox"/>	<input type="checkbox"/>	
Efficient control of vectors	<input type="checkbox"/>	<input type="checkbox"/>	
Surveillance window into the room	<input type="checkbox"/>	<input type="checkbox"/>	
Protective clothing	<input type="checkbox"/>	<input type="checkbox"/>	
The laboratory can be sealed for fumigation	<input type="checkbox"/>	<input type="checkbox"/>	
Entry to lab via airlock	<input type="checkbox"/>	<input type="checkbox"/>	
Air pressure lower than in immediate environment	<input type="checkbox"/>	<input type="checkbox"/>	
HEPA filtration of supply and exhaust air	<input type="checkbox"/>	<input type="checkbox"/>	
Shower	<input type="checkbox"/>	<input type="checkbox"/>	
Laboratory to contain its own equipment	<input type="checkbox"/>	<input type="checkbox"/>	
Description of the establishment or its parts:			
Other containment and protective measures:			

<sup>1)</sup> 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 National Supervisory Authority for Welfare and Health or to the Board for Gene Technology.
- 2 Possible 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 /matters of use under class 1:  
 GMMs /matters of use under class 2:  
 GMMs /matters of use under class 3:  
 GMMs /matters of use under class 4:

## 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:

# INSTRUCTIONS FOR FILLING IN THE GMM FORM

Version 9.7.09

## Important

The operator shall always make a written risk assessment of the use of GMMs prior to commencing their use. Provisions on the principles to be observed in the risk assessment are laid down in the Decree of the Ministry of Social Affairs and Health No. 1053/2005. The risk assessment can be made by using the risk assessment form prepared for the purpose. The risk assessment documents shall be included in the information recorded by the operator.

The notification regarding classes 1–2 to be submitted to the Board for Gene Technology includes a summary of the risk assessment, while the entire risk assessment document must be appended to the application for use under classes 3 and 4.

If you intend to wholly replace an old notification by a new notification, don't refer on the form to the previous notification but fill in the new notification as if the previous notification would not exist. Remember however to tell about the replacement in the covering letter for the notification.

## Front page of the form

The type of notification/application must always be defined depending on the class of use and if the operator has a previous valid notification of the premises in question. You may have to tick more than one of the boxes.

1: Note that after the operator has submitted a notification of taking into use of premises the operator will not have a new duty to give notice regarding later use on the premises concerned under class 1. If the use comes under classes 2–4, box 1 is ticked only if the operator does not already have a valid notification in accordance with section 14 of the Gene Technology Act (377/1995) of the premises in question.  
The notification of taking into use must always be appended with the layout of the premises in question.

2: If a notification of the premises is not submitted simultaneously (see item 1), also the record number of the previous notification under section 14 of the Act regarding the premises must be given. The notification must be a valid one. In case you want to refer to a notification made in the name of another operator, please note that it is possible only in cases referred to in section 7 of the Decree of the Ministry of Social Affairs and Health 272/2006!

3: Note that in regard to classes 3–4 of use it is always question of an application, not only of a notification, and that commencing the use is only permitted after the operator has obtained a decision on consent regarding the application from the Board for Gene Technology. The risk assessment document must always be appended to the application in its entirety.

4: Notifications/applications are always public documents. If the documents contain confidential information, please tick this box. In that case the notification must be drawn up so that all confidential information is collected in a separate appendix/appendices. In other respects the notification is handled as a public document that can be submitted as such to a third party.

Before marking that some piece of information is confidential, please read the restrictions laid down in section 32 of the Gene Technology Act!

5: A decision by the Board for Gene Technology is not normally required for use under class 2 but the use may be commenced within 45 days of submitting the notification, or immediately after submitting the notification if it is question of later use. The operator may however wish to obtain a written decision of the Board for Gene Technology (subject to a charge) on the notification of commencing use under class 2.

## **I Operator**

1: Write here the name of the body that you want to be recorded in the gene technology register as the operator (cf. section 3 (8) of the Act). As the operator must be named a body that is able to fulfil the obligations laid down for the operator in the Gene Technology Act. It is not usually appropriate to choose a natural person as the operator but for instance a research group, department, unit, institute or comparable body. If the same operator has previous notifications, give the name always in the same form.

4: This is filled in only if the notification (also) concerns taking into use of premises, i.e. box 1 has been ticked on the front page. Addresses must be given for all those buildings in which there are indoor premises that are included in the notification.

5: As the person with main responsibility is named a person who, as the representative of the operator, in practice is in charge of supervising the use described in the notification and its safety and who has the expertise and experience necessary for attending to the task. When dealing with the operator, the authorities are always chiefly in contact with the person with main responsibility.

8: A deputy should be named for the person with main responsibility that will attend to the tasks when the person with main responsibility is prevented from doing so.

11: Another contact person is appointed only when that person is to take care of contacts (correspondence) with the Board for Gene Technology instead of the person with main responsibility.

12: If the invoice for the notification/application has to be addressed to a body other than the operator named in item 1, or to an address other than that informed in item 3, give the necessary information.

## **II The organisms used**

1: Note that also virus vectors are GMMs.

2: By recipient organism is meant the organism whose hereditary material is modified or has been modified by gene technology. If a notification includes various species, list them all. Note that also virus vectors are receptor organisms!

3: A summary of the properties dealt with under 1.1.2– 1.1.11 on the risk assessment form.

4: cf. 1.2.1. on the risk assessment form.

5: cf. 1.2.2–1.2.5. on the risk assessment form.

6: Concerns cases in which the hereditary material to be transferred is synthetic or originates from an unidentified source.

7: cf. part 1.3. on the risk assessment form.

8: cf. part 1.4. on the risk assessment form.

9: If the notice includes several organisms in regard to which the answers in a–b differ from each other, a separate line of alternatives to be ticked can be copied on the form for each organism in the items mentioned above. If, on the other hand, the answers to be ticked for the different organisms are the same, it is enough to fill in one line. Give reasons for each answer in ‘Detailed account’.

10: Inform, for instance, by which methods the GMMs can be separated from the original recipient organism.

### **III Description of use**

1: The terms chosen are used for the classification of notifications in the gene technology register.

2: Tell what is done by the GMMs that are used and what is the aim of the use. You need not yet include information at this point of the notification about the containment measures to be used or explain why the use does not involve any danger.

### **IV.1. Description of premises and containment measures**

N.B.! If the notification/application does not concern taking into use of premises (see 1 on the front page) but it is referred in regard to them to some earlier notification, it is enough that the containment level observed is ticked in this part and it is specified in which (indoor) premises the use takes place.

Tick the containment levels of the premises that the notification applies to. List at the beginning of each part that you have ticked all the rooms at the containment level concerned and give an overall description of them. Remember to include all the premises on which GMMs are handled or kept, including the waste management premises. Use codes if the numbers of the rooms are confidential information. Also attach to the notification the layouts of all the above-mentioned premises.

Tick on the line for each individual requirement the ‘yes’ or ‘no’ column depending on if the premises meet the requirement in question or not. If the premises coming under the same containment level differ in regard to a requirement, specify that in the column Detailed account. Also give the necessary additional information on each containment measure (e.g. if protective clothing is used, tell what kind of). The requirements included in the containment levels are described in tables 1–4 in the Appendix to the Decree of the Ministry of Social Affairs and Health 1053/2005. Note that if it is question of use in a greenhouse, an animal unit or for instance industrial production premises, you have to make sure that the requirements laid down in the table regarding the situation are met and that this also appears from the information given in the notice.

**IV.2. Waste management** Tick the methods used and complement with other necessary information, as appropriate. The notification must include information on waste management in regard to all the material that possibly contains GMMs (growing media, equipment, waste water etc.)

## V Conclusions of the risk assessment

Confirm with a tick that you have made the risk assessment required in section 8 of the Gene Technology Act. It is advisable to make the risk assessment by using the form prepared for the purpose.

Present in this part a short summary of what kind of effects the GMM could have as a result of the use described in the notification if the containment and protective measures fail. Specify shortly how the containment and protective measures used hinder the emergence of those harmful effects. You need not repeat the detailed information given above, however.

3: Tick the appropriate classes of use. If the notification includes use under more than one class, you should specify clearly in regard to each class of use which GMMs or what kind of use comes under the class concerned. In this context, manner of use can refer for instance to a situation where the handling of a certain vector before affirming replication incompetence comes under class 2 but where after testing the handling of the same GMM comes under class 1.

## VI. Preparedness for exceptional situations

All operators must draw up for their use of GMMs either an action plan for unexpected situations or an actual rescue plan. Note that the obligation to draw up a rescue plan applies to operations coming under classes 2–4 in case failure of the containment measures could cause an immediate or a later serious danger for people outside the premises or for the environment. In such cases the rescue plan must also be attached to the notification/application.

An action plan is prepared always when the use is such that no rescue plan is needed.

