

CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS

The Board for Gene Technology

Translation 25.11.2025

Please note that there are separate guidelines regarding the classification and containment measures for the use of genetically modified viruses, as well as for the manufacturing and research use of medicinal products containing genetically modified organisms.

Contents

CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS.....	1
1. Duties of the Operator	2
2. Key Concepts.....	2
2.1. Genetically Modified Microorganism, Recipient and Donor Organisms	2
2.2. Contained Use	3
2.3. Operator and Responsible Persons	3
2.4. Notifications, Applications and Notices.....	3
2.5. Risk Assessment	4
2.6. Classification of Use and Containment Level	4
2.7. Record-keeping.....	5
3. Contained Use in Class 1	5
4. Contained Use in Class 2	6
5. Contained Use in Class 3 or 4	7
6. Processing of Notifications and Applications at the Board for Gene Technology	7
7. Updating Notifications, Introduction of New Genetically Modified Microorganisms and Premises	8
8. Emergency Plan and Plan for Unforeseen Situations	9
9. Accidents and Dangerous Situations	9
10. Import and Other Transport of Genetically Modified Microorganisms.....	9
11. Fees for Contained Use.....	10
12. Supervision of Contained Use	10
SUMMARY SCHEME FOR THE NOTIFICATION PROCEDURE FOR CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS	11
REGULATIONS ON CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS.	12

1. Duties of the Operator

The contained use of genetically modified microorganisms (GMM) is regulated by the Gene Technology Act (377/1995) and its subordinate regulations. Every operator using these organisms must comply with the general obligations specified in the Act, the most important of which is the duty to conduct a risk assessment. All use must also be carried out with care, and the operator must be aware of the characteristics of the genetically modified organisms used.

In addition to the general obligations, the operator shall submit the relevant notifications or applications to the Board for Gene Technology concerning premises intended for the use of GMMs and their intended use. Once the activities have begun, the operator is obliged to keep a record of its contained use and notify the Board for Gene technology of certain changes in the activities.

2. Key Concepts

2.1. Genetically Modified Microorganism, Recipient and Donor Organisms

According to the Gene Technology Act, a genetically modified microorganism is defined as a microorganism whose genetic material has been modified in a way that does not occur naturally through mating or natural recombination. The Act defines a microorganism as a microbiological cell or other structure capable of replication or transferring genetic material, including viruses, viroids, and animal and plant cell cultures, as well as human cell and tissue cultures. Infectious cDNA and various viral vectors are also considered GMM, while naked DNA, such as replication-incompetent plasmids, is not covered by the Act.

The Government Decree on Gene Technology ([928/2004](#)) further defines the techniques and methods by which organisms are considered genetically modified. The application of gene technology regulations can also be influenced by decisions of the European Union Commission and the Court of Justice of the European Union.

Example: The bacterium *Escherichia coli*, in which a human gene has been cloned, is a genetically modified microorganism. In this case, *E. coli* is the recipient organism, and the human is the donor organism. However, *E. coli*, in which its own gene has been introduced using genetic modification, is not considered a GMM in contained use if the organism is harmless. This case is considered internal cloning under Section 1 of Decree 928/2004.

A virus whose genetic material has been modified with genes from another organism is genetically modified. Such a GM virus is also a vector according to the regulations, if it is used to transfer genetic material to another organism. Note that a recipient cell line infected with a GM virus also becomes genetically modified, if the viral genome, or parts of it, remain permanently in the cell line. Genetically modified bacteriophages are also considered genetically modified microorganisms.

2.2. Contained Use

Contained use refers to all measures where organisms are genetically modified or genetically modified organisms are cultured, stored, transferred, destroyed, removed, or used in other ways, and where special containment measures are used to which specific containment measures are used to limit their contact with the general population or the environment.

Example: Contained use includes the cultivation of GMMs in laboratories or production facilities and the handling of living GMMs, but also the storage of these organisms, for example, frozen. Activities where laboratory animals are infected with GM viral vectors are also considered to be the use of GMMs. Clinical trials on humans where human subjects are given investigational medicinal products (IMP) containing living GMMs may in some cases be considered contained use.

2.3. Operator and Responsible Persons

According to the Act on Gene Technology, the operator is the natural or legal person responsible for the contained use of genetically modified organisms and the documents related to this. At universities and similar institutions, it is usually best to appoint a research group as the operator.

In the notification or application, the operator appoints a person with main responsibility and their deputy. It is also possible to appoint other another contact person if they are to handle the correspondence instead of the person with main responsibility. The responsible persons must be familiar with the notified activities on a practical level so that they are able to communicate with the Board for Gene Technology and the supervisory authority (Fimea).

2.4. Notifications, Applications and Notices

A notification is a document that the operator must submit to the Board for Gene Technology for contained use of classes 1 and 2. The activity can then start without an official decision from the Board. According to the Act on Gene Technology, there are two types of notifications for contained use: a notification according to Section 14 for premises intended for the use of genetically modified organisms (required of all operators regardless of the class of use) and a notification according to Section 14 a for commencing the use of genetically modified organisms (when the use belongs to class 2). Often, both notifications are made simultaneously, so that all information is provided on one form.

A document submitted to the Board is **an application** in cases where the use may only be started after the Board has granted a written consent for the contained use. Such an application according to Section 14 b of the Act is only necessary regarding the use of GMMs under classes 3-4.

After the submission of the original notification or application, the operator must in some cases submit **a notice** to the Board about changes in their activity, such as new working

spaces being put into use. Situations requiring a notice are regulated in the Decree ([272/2006](#)) of the Ministry of Social Affairs and Health.

There is a form for GMM notifications and applications on the website of the Board for Gene Technology ([Contained Use > Microorganisms](#)). Before filling out the form, you should carefully read the instructions. If you are making a notice, do not use the notification form to avoid confusion. The notice must contain the information specified in the Decree.

The notification or application should primarily be written in Finnish or Swedish. Documents written in English may be submitted to the Board only if none of the responsible persons is Finnish- or Swedish-speaking and they lack sufficient proficiency in these official languages to provide the required information in accordance with the regulations. The language requirements do not apply to documents that the operator does not need to submit to the Board but are, for example, part of the operator's own record-keeping.

If deficiencies or ambiguities are discovered during the processing of the notification documents, the Board sends a request for additional information via email to the operator.

The Board charges a fee for the processing of a notification or application (see point 11).

2.5. Risk Assessment

According to the Act on Gene Technology, the operator must conduct a risk assessment of their contained use to prevent health risks and environmental damage. The written risk assessment must also be updated as needed during the activities.

In the risk assessment, the potentially harmful properties of the genetically modified organism and the risk factors associated with its planned use must be identified. The risk assessment of GMMs follows the Ministry of Social Affairs and Health's Decree ([1053/2005](#)). It is important that the risk assessment is transparent: the aspects mentioned in the Decree must be considered even when they are not deemed to pose a danger in the current activity, and the conclusions must be justified.

The risk assessment must be conducted for all GMMs to be used before the actual use begins. However, risk assessments can be carried out by organism groups when the GMMs closely resemble each other (e.g., different genetically modified *E. coli* strains). To document the risk assessment, a ready-made form is available on the Board's and Fimea's websites.

2.6. Classification of Use and Containment Level

The operator must classify the use into classes 1-4 based on the risk assessment. The classification of use considers both the properties of the genetically modified microorganism and the way it is used. Therefore, the classification according to the Gene

Technology Act may differ from the classification of the recipient microorganism in another official system, such as the Ministry of Social Affairs and Health's Decree (921/2010) on the classification of biological agents. For plant and animal pathogens, any other applicable regulations must also be considered, such as those concerning quarantine pests or contagious animal diseases.

In contained use, the chosen containment level must correspond to (or exceed) the class of the use. Containment levels 1-4 include containment and protective measures described in Tables 1-4 in the Decree [\(1053/2005\)](#) of the Ministry of Social Affairs and Health. In standard laboratory work, the requirements of Table 1 must be followed. The concept of containment level according to the Gene Technology Act is not entirely identical to the Biosafety Level (BSL) classification of laboratories.

If there is uncertainty about the correct classification, the operator must always follow a higher protection level. The Gene Technology Act allows exceptions from the containment level requirements in exceptional cases with the permission of the Board for Gene Technology.

2.7. Record-keeping

The operator must keep record of all contained use in accordance with Section 9 of the Decree (272/2006) of Ministry of Social Affairs and Health. The operator is responsible for maintaining the records and ensuring they remain available despite personnel changes. The records are always reviewed during an inspection by the supervisory authority (see point 12). The Board for Gene Technology can also request to see the documented information.

3. Contained Use in Class 1

Class 1 activities pose no risk to human or animal health or the environment or the risk is negligible. In such activities, containment level 1 is sufficient. For the use to be classified as class 1, the properties of the genetically modified microorganism must meet the requirements in the Section 5 of the Decree 1053/2005.

For class 1 use, it is sufficient that the operator has a valid notification for premises intended for the use of genetically modified organisms in accordance with Section 14 of the Act on Gene Technology. The operator does not need to submit any new notification or notice to the Board if they later start using new class 1 GMMs in the same premises. However, a risk assessment must always be conducted (see point 2.5). Additionally, all class 1 use must be documented in the operator's own records in accordance with Section 9 of the Decree 272/2006 (see point 2.7).

The main principle is that separate operators working in the same premises, such as research groups, each submit their own notification regarding the premises. However, the notification regarding the premises may also be submitted by a higher-level unit within the

organization, such as a department or similar grouping. This requires that the designated unit can centrally manage, among other things, the record-keeping and submission of documents to the Board.

Use in class 1 can be commenced immediately after the notification regarding the premises has been submitted to the Board. It is not possible to request a written permission from the Board for a notification submitted under Section 14 of the Gene Technology Act.

4. Contained Use in Class 2

Class 2 activities pose a low risk to human or animal health or the environment. In such activities, containment level 2 is sufficient. Typical Class 2 use includes, for example, activities involving most GM viruses, if the replication incompetence of the viral vectors has not been demonstrated.

Class 2 use requires that the operator has a valid notification under Section 14 of the Gene Technology Act for premises at containment level 2 as well as a notification of the use of genetically modified organisms under Section 14a. To start using a new Class 2 GMM in the same premises, a new notification under Section 14a must be submitted, unless a notice under Section 8 of the Ministry of Social Affairs and Health Decree (272/2006) is sufficient. A notice is sufficient if the recipient and donor organisms are the same as in the previous notification, and the risk assessment has not revealed any new harmful effects.

In a notification of the use of genetically modified organisms, it is possible to refer to a notification of premises by a higher organizational level (e.g., a department) if the procedure described in Section 7 of the Decree 272/2006 of the Ministry of Social Affairs and Health is applied. This requires that the procedure has been agreed upon with the operator in question. In these cases, the new operator does not need to make their own notification in accordance with Section 14 of the Act, but only a notification of the use in accordance with Section 14a.

Class 2 use can begin 45 days after the operator has submitted their first notification to the Board according to Section 14a. If the premises have already been approved as containment level 2 premises (notified by any operator), the use can begin immediately after the operator has submitted their notification to Board (see point 7).

If desired, the operator may request a written decision from the Board for Gene Technology on their Section 14a notification. The board must then make a decision within 45 days from the receipt of the request, if the conditions for granting the permit are met (Section 16a). A higher fee is charged for a written decision than the normal fee for processing the notification (see point 11).

5. Contained Use in Class 3 or 4

According to the Gene Technology Act, class 3 activities pose a moderate risk. This involves a genetically modified microorganism that can cause serious disease in humans, animals, or plants or another serious hazard to the environment. In such activities, containment level 3 is sufficient.

Class 4 activities pose a high risk requiring containment level 4.

The operator must always submit an application in accordance with Section 14b of the Gene Technology Act for the commencement of the use under classes 3-4, in addition to which the premises shall be notified in accordance with Section 14 of the Act. Use in classes 3-4 can only begin after the Board has given its consent. The Board has 90 days to make a decision on the consent if it is the operator's first application. For subsequent applications, the Board must make a decision within 45 days after the application is received.

6. Processing of Notifications and Applications at the Board for Gene Technology

Once the Board has received a new notification or application concerning contained use, the secretariat of the Board will conduct a preliminary review of the documents. If any significant deficiencies or ambiguities are found, an inquiry is sent to the operator by email already at an early stage. Otherwise, a registration notice is sent via email to the person in charge or the designated contact person, confirming the receipt of the documents and indicating the registration number for the notification/application in the gene technology register. If you have not received the registration notice within a couple of weeks after the submission, it is advisable to check with the secretariat whether the documents have been successfully delivered.

If the notification is incomplete or the submitted information is unclear, the presenting official processing the notification prepares a request for additional information, which is sent to the operator via email. Once the presenting official has found the notification and any additional information to comply with the provisions, the processing of the notification is considered to have been completed and a confirmation of this is sent to the operator by email. At the same time, the operator receives for inspection a register extract from the data stored in the gene technology register.

In the case of an application, a statement from at least one expert institution is usually requested for its consideration. A decision on approving an application is always made at a meeting of the Board for Gene Technology. The applicant will be informed by email of the decision made at the meeting and will receive the actual signed decision later.

7. Updating Notifications, Introduction of New Genetically Modified Microorganisms and Premises

According to the Section 9a of the Gene Technology Act, the operator is obliged to inform the Board about certain changes in their contained use. The obligation to provide information applies to changes in the operator's or responsible persons' personal or contact details, as well as to the notification of the termination of contained use.

When new genetically modified microorganisms are to be introduced after the notification has been submitted, the operator must first assess the risks associated with the new use (see point 2.5). Different notification procedures are required depending on the class of use based on the risk assessment. Note that a new organism is also considered to be involved when an insert not included in the previous notification or notice is introduced into the same recipient species.

Regarding new class 1 GMMs, no information needs to be sent to the Board; it is sufficient to document the use (see point 2.7) in the operator's own record-keeping. Introduction of new class 2 GMMs requires either a notice or a completely new notification in accordance with Section 14 a of the Gene Technology Act. Cases where a notice is sufficient are described in Section 8 of the Decree (272/2006) of the Ministry of Social Affairs and Health.

Introduction of new organisms in classes 3-4 always requires a new application and a written consent from the Board.

New rooms of the same or lower containment level may later be attached to the notification of premises by means of a notice if they are located in the same building as the previously notified premises. The notice must contain the following information: the operator's name, the registration number of the previous notification regarding the premises, the street address of the premises, room numbers, and information about the containment level, as well as a floor plan.

To avoid confusion, a notice must not be written using the notification form. Note that the Board does not process so-called updated notifications either. If there have been many changes compared to the original notification, the operator may submit a so-called replacement notification even when there is no legal obligation to submit a new notification. In such cases, the old notification is terminated, a completely new registration number is assigned to the new notification, and it is processed like any other notification.

If the operator receives significant new information regarding the risk assessment or they change the contained use in a way that can significantly affect the risk assessment, this must be immediately reported to the Board.

8. Emergency Plan and Plan for Unforeseen Situations

Every operator is obliged to compile either an emergency plan for their activities or a plan for unforeseen situations (Sections 10-12 of the Decree (272/2006) of the Ministry of Social Affairs and Health). An emergency plan is required in cases where failure of the containment measures for class 2-4 use could cause immediate or later serious hazard to people outside the premises or the environment. Therefore, an emergency plan is not automatically mandatory in class 2-4 activities, and at least for class 2, an action plan is usually sufficient.

The action plan must address foreseeable exceptional situations (such as water leaks, fire, broken equipment) and how containment and protective measures required by the genetically modified organisms will be taken care of in such circumstances.

If the operator is required to draw up an emergency plan under the Gene Technology Act, it must be submitted to the relevant authorities and the Board as an appendix to the application.

There are separate instructions for preparing action and emergency plans.

9. Accidents and Dangerous Situations

The operator must immediately notify the Board of accidents and incidents during contained use. The reporting obligation applies to situations that have led to or could have led to the release of GMMs from the contained use premises or that have caused or could have caused hazards to human or animal health or the environment. The operator must also report the corrective actions taken because of the incident.

10. Import and Other Transport of Genetically Modified Microorganisms

When genetically modified organisms are transferred from one country to another, the importer and exporter must comply with the requirements of the Cartagena Protocol on Biosafety. However, transfers between EU countries follow the EU's own regulations. When exporting genetically modified organisms from Finland to countries outside the EU, the [Regulation \(EC\) No 1946/2003](#) of the European Parliament and of the Council on transboundary movements of genetically modified organisms is followed.

In practice, the import of GMMs intended for contained use to Finland requires that their recipient complies with the notification and application procedures laid down in the Gene Technology Act. The recipient must therefore have submitted relevant notifications/applications regarding the premises where the genetically modified microorganisms will be used. There is no obligation to submit a separate notification of import and transport to the Board.

The document requirements for international transport of GMMs intended for contained use are described in a guideline on the Board's website.

For all transport of GMMs within Finland, the general obligations in accordance with chapter 3 of Gene Technology Act must be followed. The risks associated with transport must be assessed and the organisms packed in such a way as to prevent the exposure of outsiders and the unintentional release of GMMs into the environment. Regulations of the Finnish Transport and Communications Agency (Traficom) on the transport of dangerous goods apply to the transport of dangerous GMMs.

11. Fees for Contained Use

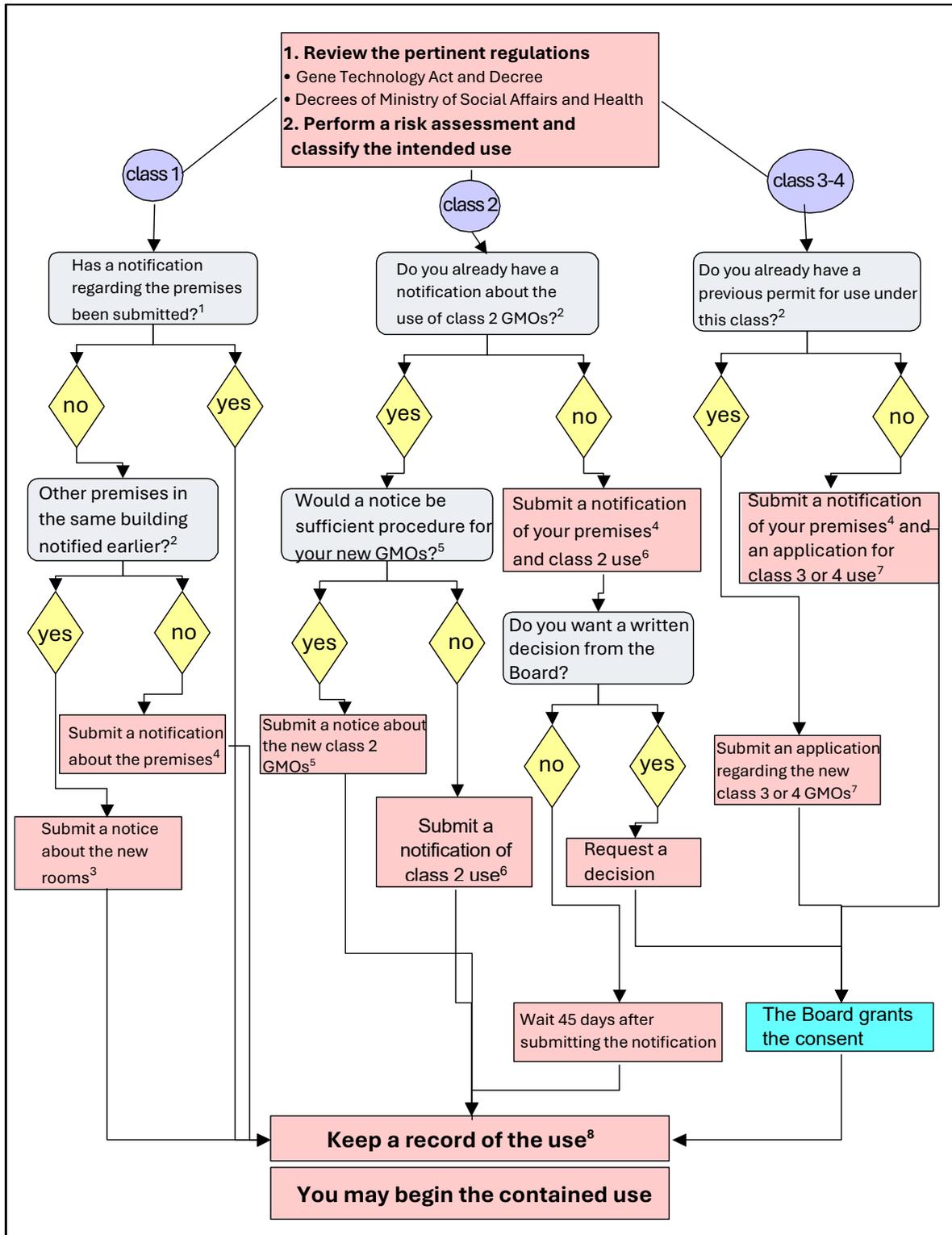
Fees are charged for the processing of notifications and applications submitted to the Board in accordance with the Government Decree on Chargeable Performances under the Gene Technology Act valid at any given time. The amount of the fee varies depending on the class of use and type of notification.

The Board for Gene Technology may, upon application, grant exemptions from the collection of fees if the fee would be unreasonable due to the restricted scope of the research activity or use or for some other reason. Exemption from the charge is applied for by means of a free-form letter, which can be submitted at the same time as the notification.

12. Supervision of Contained Use

Contained use is supervised through regular inspections. The authority responsible for supervising contained use is the Finnish Medicines Agency (Fimea). The inspection activities are subject to the Decree of the Ministry of Social Affairs and Health on the inspection procedure under the Gene Technology Act ([198/2007](#)). More information about inspections can be found on Fimea's website.

SUMMARY SCHEME FOR THE NOTIFICATION PROCEDURE FOR CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS



- 1) Refers to rooms where the intended contained use (including storage) takes place, and a notification according to Section 14 of the Gene Technology Act made by the same operator or the upper level of the organization referred to in Section 4 of the Decree of Ministry of Social Affairs and Health (272/2006).
- 2) Performed by the same operator.
- 3) The notice must contain information according to Section 6 of the Decree of the Ministry of Social Affairs and Health (272/2006).
- 4) Notification in accordance with Section 14 of the Gene Technology Act regarding premises intended for GMO use.
- 5) The criteria are specified in Section 8 of the Decree of Ministry of Social Affairs and Health (272/2006).
- 6) Notification in accordance with Section 14a of the Gene Technology Act regarding commencing the use.
- 7) Application in accordance with Section 14b of the Gene Technology Act regarding commencing the use.
- 8) Provisions on the information to be recorded are laid down in Section 9 of Decree of the Ministry of Social Affairs and Health (272/2006).

REGULATIONS ON CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS

- Gene Technology Act (377/1995)
- Government Decree on Gene Technology (928/2004)
- Decree of the Ministry of Social Affairs and Health on the principles of risk assessment for the contained use of genetically modified micro-organisms, classification of contained use and containment and other protective measures (1053/2005)
- Ministry of Social Affairs and Health Decree on notifications and applications related to the contained use of genetically modified organisms and on the recording of contained use and Rescue Plan (272/2006)
- Government Decree on Chargeable Performances under the Gene Technology Act (*renewed at regular intervals; link to the current Decree is found on the Board website*)
- The supervision of the use of genetically modified organisms is regulated by the Decree of the Ministry of Social Affairs and Health on the inspection procedure under the Gene technology Act (198/2007).