

How to apply for a consent for the contained use of Genetically Modified Micro-organisms (GMMs) in accordance with the requirements of the GMO (Contained Use) Regulations S.I. No 73 of 2001

The Contained Use of Genetically Modified Micro-organisms is dealt with under Part II (page 14) of the GMO (Contained Use) Regulations, S.I. No 73 of 2001 - **link**.

Where a premises is being used for the first time for the contained use of a GMM, the GMM user must apply to the EPA for a consent, by submitting a notification for the **first time use of the premises** to the EPA. (see **Section 1 - link**).

Where the user has already obtained a consent for the first time use of the premises and now wishes to utilise a new Class 1 - 4 GMM which has not previously been notified to the EPA or which is not contained on their GMO Register Entry, then the user must submit a new notification for the **subsequent contained use** of the GMM to the EPA, (see **Section 2 - link**).

Other relevant aspects of the legislation dealt with in this Guidance note include:

Annual Reporting, (see **Section 3 - link**);

Issue of consents by the EPA, (see **Section 4 - link**);

Fees, (see **Section 5 - link**);

Refund of Fees, (see **Section 6 - link**).

Note

- Reference to page numbers relates to the GMO (Contained Use) Regulations S.I. No 73 of 2001 which in turn may be referenced on the GMO contained use webpage www.epa.ie/Licensing/GMOLicensing/ContaineduseofGMOs
- Examples of Class 1 GMM and Class 2 GMM Risk Assessments may also be referenced on the contained use webpage

1. Where a premises is being used for the first time for a GMM contained use activity Class 1 – 4 (Article 16)

Where a premises is being used for the first time for a GMM contained use activity (Class 1, 2, 3 or 4), the user is required to forward a notification to the EPA. Such a notification comprises three aspects outlined under 1.1, 1.2 and 1.3 below.

- 1.1 describes the notification requirements under Article 16
- 1.2 describes additional notification requirements detailed under ensuing articles 17 (Class 1 GMM activities), 18 (Class 2 GMM activities), and 19 (Class 3 and 4 GMM activities).

1.1 Notification requirements under article 16

In accordance with Article 16 of S.I. No 73 of 2001, a notification for the first time use of a premises shall contain the following:

- A Risk Assessment (refer to Article 13 of the aforementioned Regulations);
- Information set out under Part A of the 5th Schedule (Page 51);

- The appropriate fee based on Class of the activity as set out in the Table 1 below. (Also refer to Table B, 8th Schedule, Page 61).

Table 1: Fees payable to the Agency for a notification for the first time use of the premises

	Class 1	Class 2	Class 3	Class 4
Fee	€250	€1,250	€3,000	€15,000

1.2 Additional Notification requirements for the first time use of the premises

1.2.1 Further information required for Class 1 GMM activities

No further information is required for a Class 1 GMM activity at this stage.

1.2.2 Further information required for Class 2 GMM activities (Article 18)

In addition to the aforementioned information required for a notification for the first time use of the premises, a user of a Class 2 GMM activity must also submit the following to the EPA in accordance with Article 18:

- Information set out under Part B of the 5th Schedule (Page 51);
- Fee of €625 (Table B, 8th Schedule, Page 61).

1.2.3 Further information required for Class 3 GMM activities (Article 19)

In addition to the aforementioned information required for a notification for the first time use of the premises, a user of a Class 3 GMM activity must also submit the following to the EPA in accordance with Article 19:

- Information set out under Part C of the 5th Schedule (Page 51);
- Fee of €1,500 (Table B, 8th Schedule, Page 61)

It is also required that notice of the notification shall be published in a newspaper in accordance with Article 22 of the GMO (Contained use) Regulations S.I. No 73 of 2001.

1.2.4 Further information required for Class 4 GMM activities (Article 19)

In addition to the aforementioned information required for a notification for the first time use of the premises, a user of a Class 3 GMM activity must also submit the following to the EPA in accordance with Article 19 (Page 18):

- Information set out under Part C of the 5th Schedule (Page 51);
- Fee of €7,500 (Table B, 8th Schedule, Page 61).

It is also required that notice of the notification shall be published in a newspaper in accordance with Article 22 of the GMO (Contained use) Regulations, S.I. No 73 of 2001

1.3 Additional Information required for assessment of a Class 1 / 2 contained use notification.

The Class 1 / 2 GMM contained use notification cover sheet should be completed and submitted with every Class 1 or Class 2 notification.

Note:

For a first time use of a premises for a Class 2 GMM contained use activity, the Article 16 and Article 18 notifications can be submitted together. Similarly, for a first time use of a premises for a Class 3 or 4 contained use activity, the Article 16 and Article 19 notifications can be submitted together.

Agency review period

A notification for the first time use of a premises for Class 1 and Class 2 GMM Contained Use activities must be reviewed by the EPA within 45 days.

A notification for the first time use of a premises for Class 3 and Class 4 GMM Contained use activities must be reviewed by the EPA within 90 days.

These review periods do not take account of clock stoppage time i.e. in accordance with Article 7 of the GMO (Contained Use) Regulations S.I. No 73 of 2001, the clock shall be stopped during any period of time the EPA is awaiting receipt of further information from the notifier. The clock will not restart until such time as the required information is received by the EPA.

A premises may not be used for the first time for the contained use of a GMM without the prior consent of the EPA.

Note: Article 16(4) (page 16) states that '*....a consent granted for the first time use of a premises for a particular class of contained use shall be treated as a consent for the first time use of a premises for that class and for any lower class of contained use and accordingly a further consent shall be required in respect of the first time use of the premises for any higher class of contained use*'. For example, if a user has obtained consent for the first time use of a premises for a class 2 contained use activity, this also covers Class 1 GMM activities.

2. Where a consent has been obtained from the EPA for the first time use of the premises and the user wishes to utilise a new Class 1 – 4 GMM not previously notified to the EPA or not previously recorded on his/her GMO Register Entry.

2.1 Subsequent Contained Use – Class 1 (Article 17(2))

Where a user has already obtained a consent from the EPA for the contained use of a Class 1 GMM and wishes to utilise a new Class 1 GMM not previously notified to the EPA or not previously recorded on his/her GMO Register Entry, the user must carry out a Risk Assessment. This Risk Assessment must be submitted to the EPA and the EPA notified of pending changes to the corresponding GMO Register Entry. There is no requirement for the payment of further fees.

2.2 Subsequent Contained Use – Class 2 (Article 18)

Where a user has already obtained a consent from the EPA for the first time use of a premises for a Class 2 GMM and wishes to utilise a new Class 2 GMM not previously notified to the EPA or not previously recorded on

his/her GMO Register Entry, the user must submit a new notification in accordance with article 18 comprising the following:

- Information set out under Part B of the 5th Schedule (Page 51);
- Fee of €625 (Table B, 8th Schedule, Page 61).

Agency review period

Where the premises has been the subject of a previous notification to carry out a Class 2 or higher Class of contained use and where the user has complied with any associated requirements the contained use activity may proceed within 10 days of receipt of the notification by the Agency.

2.3 Subsequent Contained Use – Class 3, (Article 19)

Where a user has already obtained a consent from the EPA for the first time use of a premises for a Class 3 GMM and wishes to utilise a new Class 3 GMM not previously notified to the EPA or not previously recorded on his/her GMO Register Entry, the user must submit a new notification in accordance with Article 19 comprising the following:

- Information set out under Part C of the 5th Schedule;
- Fee of €1,500. (Table B, 8th Schedule, Page 61).

Under Article 22 (page 19) the notifier must give public notice of its proposed contained use of Class 3 activities in a newspaper circulating in the district in which the proposed activity is scheduled to take place. Members of the public may then make representations in writing to the Agency regarding the notification.

Agency review Period

A Class 3 GMM contained use activity shall not proceed unless consent has been granted by the Agency. The Agency must review a notification submitted in accordance with Article 19 within a period of 45 days.

2.4 Subsequent Contained Use – Class 4, (Article 19)

Where a user has already obtained a consent from the Agency for the first time use of a premises and subsequent contained use of a Class 4 GMM and wishes to utilise a new Class 4 GMM, the user must submit a new notification in accordance with article 19 comprising

- Information set out under Part C of the 5th Schedule;
- Fee of €7,500 (Table B, 8th Schedule, Page 61).

Under Article 22 (page 19) the notifier give public notice of its proposed contained use of Class 4 activities in a newspaper, circulating in the district in which the proposed activity is scheduled to take place. Members of the public may then make representations in writing to the Agency regarding the notification.

Agency review period

A Class 4 GMM contained use activity shall not proceed unless consent has been granted by the Agency. The Agency must review a notification submitted in accordance with Article 19 within a period of 45 days.

3. Annual Reporting

All users of GMMs are required to submit an Annual Report to the Agency.

See section of Webpage entitled Annual Reporting.

4. Issue of consents by the EPA

The Agency will issue its consent with or without conditions or refuse its consent. (Article 26, page 21)

5. Fees

A notification is not deemed valid until such time as fees are received by the EPA. The Agency does not issue invoices. Where an invoice is required, the EPA can provide the user with a letter on EPA headed paper stating the appropriate fee to be paid in respect of the GMM activity being applied for.

6. Refund of fees

Article 48 (Page 31/32) permits users to seek a waiver or refund of up to 50% of fees payable in certain limited circumstances. Users applying for such a refund should do so in writing stating their reasons. The granting of a waiver or refund is at the absolute discretion of the Board of the Agency.