Class 1 – GMM Risk Assessment

Class 1 GMM activities are classified on the basis that SOPs Containment Level 1 conditions and procedures are appropriate to mitigate the hazards associated with the GMM work in terms of protecting human health and the environment. Completing the GM Risk Assessment (next section) is required to make this determination and the following link details the requirements for SOPs Containment level 1.

How to apply for consent for the contained use of GMM in accordance

Class 1 Risk Assessment & Cover sheet
Edit the sample Class 1 GMM risk assessment below in-line with your requirements.

TCD Class 1 GMM risk assessment - based on - EPA example
Complete the cover sheet

TCD Class 1 GMM Cover Sheet

Internal Procedure
Forward the GM application and cover sheet to the University Biosafety Officer, for circulation to relevant members of the Biosafety Committee.

Fee
The relevant fee must accompany the GMM applications, or where the fee has been paid by an electronic funds transfer to the Agency's account, the provision of confirmation of payment with the notification will be acceptable.

Where a fee is not received with the application, the EPA will be obliged to consider the notification invalid and return it to the applicant.

The relevant fee for the first time contained use of a Class 1 GMM under Article 16 as indicated in the Eight Schedule of S.I. No. 73 of 2001 is 250 euro.

The Agency don't issue invoices, therefore, during the initial stages of preparing the Risk Assessment, the PI must request an invoice letter for a class 1 GMM activity from the EPA. Email: Ms. Cox (N.Cox@epa.ie) & Ms. Murray (B.Murray@epa.ie).

Payment can be made via cheque, credit card or bank transfer. Select the following for EPA's bank details:

Agency's bank details
If you wish to pay by credit card please contact in the Agency's Dublin office (01-2680100).

The Financial Services Division generally won't process electronic transfers without the invoice letter. Additionally, communicate to your FSD contact, that you are paying a licence fee and
complete/forward the Irish Non-Staff Payment Requisition Form which can be located on the FSD website.

If you decide to generate a cheque, then send it to the address below in the next section, along with an unsigned hardcopy of the risk assessment and cover sheet. The Agency’s Accounts Department has requested that, all remittances relating to GMO payments MUST be emailed to accountsreceivable@epa.ie once the payment has been made. This will help to remove much of the problems associated with tracking electronic payments.

**EPA submission**

Once all of the above requirements are met and fees paid, then proceed with submission to the EPA. It is acceptable to post or e-mail the application.

Licensing Unit, Environmental Protection Agency,
Office of Climate, Licensing & Resource Use, PO Box 3000,
Johnstown Castle Estate,
County Wexford.
Telephone Local 1890 33 55 99 or 053 91 60600
Email info@epa.ie for the attention of the Licensing Unit.

**EPA Timelines**

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

**EPA Approval & Consent Conditions**

After ~45 days, the EPA will issue consent with or without conditions or refuse permission.

A template copy of the consent conditions is supplied here for information purposes.

**SOPs**

You will note from the Preceding Sample Consent Conditions that various Standard Operating Procedures (SOPs) must be instituted upon receiving consent and before commencing work. It is prudent to commence preparation of these SOPs during the 45 day review period. Select the following link to review samples:

**Researcher Training**

All those conducting GM work must read and sign that they have understood the GM risk assessment and associated consent conditions. Such individuals must also complete a Project Risk assessment to identify all the hazards and risks related to the work and the suitable control measures required to mitigate the risks.

Such training is the responsibility of the PI and requires review, training and sign-off of the following:

1. GM risk assessment
2. Consent conditions

3. Project risk assessment

4. Local safety Statement

5. SOP

6. Experimental protocols/procedures

**Copies of such documents must be kept in the Lab.**

**Annual Reporting**
Effective from 1 January 2013, users of Class 1 GMMs are no longer required to submit Annual Reports in respect of Class 1 GMM contained use activities.