



Guidelines for the Inactivation and Disposal of GM Waste

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Irrespective of the class of activity, all GMM contaminated liquid and solid waste must be inactivated by validated means before disposal.

1. Class 1 GMMs

The containment measures for the contained use of Class 1 GMMs (Table IA, Fourth Schedule of the GMO (Contained Use) Regulations 2001 to 2010) states that the *"inactivation of GMMs in contaminated material and waste"* is *"optional"*. *"Optional"* means that the EPA may decide whether the relevant containment measures shall be applied.

Consent conditions issued by the EPA in respect of Class 1 GMM activities state that inactivation of Class 1 GMM waste is required.

Waste material containing viable Class 1 GMMs may be inactivated on-site. Alternatively, with the prior agreement of the EPA, such waste may be sent to an off-site inactivation facility. This facility must be registered under the GMO (Contained Use) Regulations, 2001 to 2010, to handle Class 1 GMM waste. At present, SRCL Ltd. (G0163-01), Veolia Environmental Services Technical Solutions Ltd. (G0812-01) and Indaver Ireland Ltd. (G0750-01) are the only such registered facilities.

Part A of the Fifth Schedule of the GMO (Contained Use) Regulations, 2001 to 2010¹, requires the notifier to provide information about waste management in the notification.

2. Class 2 GMMs and Class 3 GMMs

The containment measures for the contained use of Class 2 GMMs and Class 3 GMMs (Table IA under Part B of the Fourth Schedule, GMO (Contained Use) Regulations, 2001 to 2010) states that *'inactivation of GMMs in contaminated material and waste'* is *'required'*. This is reflected in consent conditions for Class 2 and Class 3 activities.

Waste material containing viable Class 2 GMMs may be inactivated on-site. Alternatively, with the prior agreement of the EPA, such waste may be sent to an off-site inactivation facility. This facility must be registered under the GMO (Contained Use) Regulations, 2001 to 2010, to handle Class 2 GMM waste. At present, SRCL Ltd. And Veolia Environmental Services Technical Solutions Ltd. are the only such registered facilities.

Waste material containing viable Class 3 GMMs **cannot be sent off-site for inactivation**. Class 3 GMM waste must be inactivated on-site, prior to disposal by a registered waste contractor. Such inactivation must be carried out ensuite. This means that where the autoclave is located outside the laboratory in which the contained use is being carried out but within the laboratory suite, validated procedures shall be in place to ensure the safe transfer of material into the autoclave and to provide a level of protection equivalent to that which would be achieved if the autoclave were in the laboratory.

¹ Information required in the notification of a first time use of a premises or a contained use

Part B (Class 2 GMMs) and Part C (Class 3 GMMs) of the Fifth Schedule of the GMO (Contained Use) Regulations, 2001 to 2010, require the notifier to provide information about waste management in the notification, including the types of waste to be generated, their treatment, final form and destination.

3. GMOs

Genetically Modified Organisms include GM plants and GM animals.

3.1 GM plants

All GM plants, GM/non-GM plants inoculated with GMMs and pots, trays, compost, soil or other growth media, equipment and tools contaminated with GM plant material must be inactivated by validated means, on site, prior to cleaning and/or disposal, in accordance with Agency policy.

3.2 GM animals, non-GM animals inoculated with GMMs

A GM animal presents no greater risk to human health or the environment than a non-GM animal, however, in the interests of public perception GM animal carcasses should be inactivated prior to disposal.

Where the on-site inactivation of GM animals or non-GM animals containing viable Class 1 or Class 2 GMMs is not feasible, the user may, with the prior agreement of the EPA resort to off-site inactivation;

- a. in the Republic of Ireland, where inactivation facilities:
 - have the appropriate licences/permits required by the Waste Management Act; and,
 - are registered/regulated in accordance with the GMO Regulations, (at present, SRCL Ltd. (G0163-01), Veolia Environmental Services Technical Solutions Ltd. (G0812-01) for Class 1 and Class 2 GMMs and Indaver Ireland Ltd. (G0750-01) for Class 1 GMMs are the only such registered facilities).
- b. abroad, where inactivation facilities comply with the provisions of the appropriate National & European legislation and protocols.

Large animals (GM or otherwise) to which GMMs have been administered must be rendered at an appropriately licenced rendering facility prior to disposal.

Waste material such as bedding, faeces and urine are not considered to be GM waste unless the GMM, with which the animal has been inoculated, is being shed.

4. Inactivation methods

Inactivation may be achieved by autoclaving or chemical inactivation. The manufacturer's instructions shall be adhered to for the purposes of chemical inactivation. The inactivation of Class 3 GMM liquid waste using chemicals must be followed by autoclaving prior to disposal.

5. Validation

Validation is defined as a documented process of demonstrating that equipment operates correctly, and consistently complies with specified conditions of use.

5.1 Validation of equipment

Inactivation by autoclaving must be validated under normal working conditions as follows:

- annual thermocouple mapping in order to ensure the autoclave reaches and maintains the prescribed temperature for the prescribed period of time;
- annual calibration of the temperature probe and pressure indicators;
- completion of annual preventative maintenance routines on the electrical and pressure systems by an independent third party;
- maintenance and checking of records of the operating parameters for every load.

A copy of the validation protocol and the results of the validation exercise must be retained by the user.

6. Verification of destruction

Chemical/biological indicators (or similar) must be used at least monthly in order to verify inactivation by autoclaving. Inactivated waste should remain on-site until such time as there is a positive destruction result. A record of the destruction verification must be maintained by the user.

7. Waste disposal

The storage of waste on-site and the transport of waste from the facility for inactivation (Class 1 and Class 2 GMMs and GM/non-GM animals containing viable Class 1 or Class 2 GMMs), disposal etc. must be in secure closed containers.

Companies that provide waste handling and disposal services must be authorised under the GMO (Contained Use) Regulations 2001 to 2010 and the Waste Management (Collection Permit) Regulations, 2007, as amended.

8. Records

Records of GMM inactivation events must be retained by the user for inspection by the EPA on request.

9. Information to be included in the GMO/GMM notification

A GMO/GMM contained use notification to the EPA must contain the following information relating to the generation, storage and treatment of GMO/GMM waste:

- The nature of the waste to be treated:
 - whether the waste is solid or liquid;
 - the amount of waste;
 - the contaminating GMM; and,

- its classification, i.e. Class 1, 2, 3 or 4

Where GM/non-GM, plants and/or animals have been inoculated with GMMs, the classification of the GMM must be specified.

- The method(s) of inactivation:
 - Where solid waste is treated by autoclaving, the notification should provide details of the procedure for the storage and removal of GM waste from the laboratory to the autoclave room, autoclave cycle parameters (temperature, time and pressure), validation procedures and procedures for the disposal of inactivated waste;
 - Where a chemical agent is used to inactivate liquid waste or spillages, the notification should provide details of the inactivating agent used, the concentration of use, the contact time and how the waste is finally disposed of;
 - Procedure for the validation of destruction of waste inactivated in-house;
 - Where GM/non-GM animals inoculated with Class 1 or Class 2 GMMs undergo off-site inactivation, the notification should provide details of the registered waste contractor hired to remove the waste as well as details of how the waste is treated and disposed of.