**Guidelines for the inactivation and disposal of waste contaminated with Genetically Modified Organisms (GMMs and GMOs).**

**Genetically Modified Micro-organisms (GMMs)**
Irrespective of the class of activity, all material and waste contaminated with GMMs must be inactivated by validated means before disposal.

**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’. However ‘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.

With the prior agreement of the EPA (generally at the time of notification), waste material containing viable Class 1 GMMs 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 at least Class 1 GMM waste.

**Class 2 / 3 / 4 GMMs**
The containment measures for the contained use of Class 2 / 3 / 4 GMMs (Table IA under Part B of the Fourth Schedule, GMO (Contained Use) Regulations, 2001 to 2010) states that their ‘inactivation in contaminated material and waste’ is ‘required’.

Waste material containing:
- viable Class 2 GMMs must be inactivated on the same site as the contained use activity is taking place;
- viable Class 3 GMMs must be inactivated in an autoclave that is situated within the laboratory suite i.e. it must not be removed from the laboratory for purpose of inactivation;
- viable Class 4 GMMs must be inactivated in a double ended autoclave.

Part B (Class 2 GMMs) and Part C (Class 3 / 4 GMMs) of the 5th Schedule of the GMO (Contained Use) Regulations, 2001 to 2010, require the notifier to provide information about waste management in the notification, including the wastes to be generated, their treatment, final form and destination. Where autoclaving is the method of inactivation being used, information relating to the time, temperature and pressure of the autoclave cycle should be included in the Part B information.

**Genetically Modified Organisms (GMOs)**
Genetically Modified Organisms include GM plants and GM animals.

**GM plants**
All GM plants, GM/non-GM plants inoculated with GMMs, pots, trays, compost, soil or other growth media must be decontaminated by validated means, on the same site as the contained use activity is taking place, prior to cleaning and / or disposal.
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 interest of public perception GM animal carcasses should be decontaminated prior to disposal.

Where the on-site decontamination 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 decontamination;
   a. in the Republic of Ireland, where decontamination facilities:
      • have the appropriate licences/permits required by the Waste Management Act; and,
      • are registered/regulated in accordance with the GMO Regulations,
   b. abroad, where decontamination facilities comply with the provisions of the appropriate National & European legislation and protocols.

Where GMMs are not being shed, waste material such as bedding, faeces and urine are not considered to be GM waste. In the event that GMMs are being shed, prior consultation with the EPA to discuss the disposal of bedding, urine etc is advised.

Treatment of GM waste
Inactivation methods
The chosen method of inactivation (e.g. autoclaving or chemical inactivation) must be validated annually under normal working conditions. A copy of the validation protocol and the results of the validation exercise must be retained by the user.

Validation of inactivation
Where waste is being autoclaved, biological indicators (or similar) must be used at least monthly in order to validate inactivation. Decontaminated waste should not be removed off-site until such time as there is a positive inactivation result. A record of the validation must be maintained by the user.

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

Waste disposal
Companies that provide waste handling and disposal services must be authorised under the GMO (Contained Use) Regulations 2001 to 2010 and the Waste Management Act, 1996 to 2011, as amended.

Records
Records of GMM inactivation events for the previous 12 month period must be retained by the user, for inspection by the EPA on request.

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,
o its classification.
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 e.g. procedure for the storage, removal of GM waste from the laboratory to the autoclave room, autoclave cycle parameters (temperature, time and pressure), validation procedures and disposal of decontaminated 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 duration of contact and how the waste is finally disposed of;
  - Where waste is inactivated in-house, the notification should provide details of the validation procedure for the inactivation of waste;
  - 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, including their waste licence/permit number. The information should also include details of how the waste is treated and disposed of by the contractor.