

## **How to apply for a consent for the contained use of Genetically Modified Organism (GMOs, i.e. GM animal or GM plant) in accordance with the requirements of the GMO (Contained Use) Regulations S.I. No 73 of 2001**

The Contained Use of Genetically Modified Organisms is dealt with under Part III (page 27)<sup>1</sup> of the GMO (Contained Use) Regulations, S.I. No 73 of 2001 - [link](#).

**Note:** The Classification system that exists for GMMs does not apply to GMOs. Therefore GMOs are not classified as Class 1, 2, 3 or 4.

### **Applying for consent for the Contained Use of a GMO**

In order to obtain a consent for the contained use of a GMO, the GMO user must apply to the EPA submitting a notification comprising

- A Risk Assessment (in accordance with Part II of the 7<sup>th</sup> Schedule, Page 58) containing details of disposal of the GM plant/animal
- Information set out under Part I of the 7<sup>th</sup> Schedule (Page 57)

#### **Agency review period**

A notification for the contained use of a GMO must be reviewed by the EPA within 45 days.

This review period does 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.

### **Issue of consents by the EPA**

Under the Legislation the EPA is not required to issue the user with consent conditions. Consequently the Agency will issue the user with:

- a Letter of Agreement permitting the user to proceed with the contained use activity; and,
- Guidelines on containment measures for Genetically Modified Animals or Guidelines on containment and control measures for the use of GMO plants in Plant Growth Facilities - Greenhouses/Growth rooms and Growth cabinets whichever is appropriate.

### **Fees**

There is no requirement for the payment of fees in respect of an application for the Contained Use of GMOs.

### **Annual Reporting**

All users of GMOs are required to submit an Annual Report to the Agency. See section of Webpage entitled Annual Reporting.

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<sup>1</sup> Reference to page numbers relates to the GMO (Contained Use) Regulations, S.I. No 73 of 2001 which may be referenced on the GMO contained use webpage [www.epa.ie/Licensing/GMOLicensing/ContaineduseofGMOs](http://www.epa.ie/Licensing/GMOLicensing/ContaineduseofGMOs)

