Notification requirements for the deliberate release of GMOs into the environment for purposes other than placing on the market i.e. for the performance of clinical / veterinary trials involving human /veterinary medicinal products containing or consisting of GMOs, or for the performance of field trials involving GM plants.

A person intending to carry out a deliberate release of a GMO for purposes other than placing on the market is required to submit a notification to the Environmental Protection Agency (EPA) (hereafter referred to as 'the Agency') under Article 14 of the GMO (Deliberate Release) Regulations, S.I. No. 500 of 2003.

In accordance with Article 14 the notification must contain the following:

1. Information set out in the Third Schedule of S.I. No 500 of 2003 in so far as it is appropriate to the proposed deliberate release.
   - Part I of the Third Schedule relates to the release of GMOs other than higher plants, i.e. the performance of clinical trials
   - Part II of the Third Schedule relates to the release of Genetically Modified Higher Plants i.e. field trials.

2. A summary of the notification (i.e. **S**ummary **N**otification **I**nformation **F**ormat or SNIF) in accordance with Council Decision 2002/813/EC
   - Part 1 of Council Decision 2002/813/EC relates to a SNIF for the release of GMOs other than higher plants
   - Part 2 of Council Decision 2002/813/EC relates to a SNIF for the release of Genetically Modified Higher Plants

3. An Environmental Risk Assessment carried out in accordance with the principles and methodology outlined in **Part B** (General Principles) and **Part C** (Methodology) of the Second Schedule of S.I. No 500 of 2003.

4. The conclusions arrived at by the notifier, on the potential environmental impact from the release of the GMO, in accordance with Part D of the Second Schedule of S.I. No 500 of 2003, together with any bibliographic references and details of methods used
   - Part D.1. of the Second Schedule refers to GMOs other than higher plants
   - Part D.2. of the Second Schedule refers to Genetically Modified Higher Plants.

5. In addition to the information outlined under 1 – 4 above, the notifier may:
   - include or refer to data or results, from a notification previously submitted to the same or another Competent Authority, by another notifier, provided the other notifier has agreed in writing and a copy of that written agreement is enclosed with the notification. The data or results must not comprise confidential information.
   - provide additional relevant information.

6. The deliberate release of a combination of GMOs on the same site, or a GMO or a combination of GMOs on different sites, may be notified to the Agency in the same notification, provided that:
   - the purpose of the proposed deliberate release is the same; and,
   - the release will be carried out within a defined period of time.

7. The fee for notification of a proposed deliberate release is €3,000, as set out in Article 46 of S.I. No 500 of 2003.

Notices (Article 15)

Under Article 15, the notifier is required to inform the public of its proposed deliberate release by placing a public notice in a newspaper, circulating in the area in which the proposed deliberate release is scheduled to take place. This must be completed within 14 days of receipt of the notification by the Agency,

The format of the public notice is set out under **Article 15(1**).
In accordance with **Article 15(2)** the location of the proposed deliberate release given in the public notice must correspond with that placed on the public register in accordance with Article 9.
The Agency recommends that a draft of the public notice be forwarded to the Agency for agreement prior to submitting it to the newspaper for publication.

Within 14 days of the date of receipt of the notification by the Agency, a copy of the public notice must be sent to:

- the owner of the site of the proposed deliberate release;
- the Local Authority in whose functional area the deliberate release is proposed to take place.

Confidential Information
Confidential information is dealt with under Article 10 of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003. It is strongly advised that the notifier inform the Agency of the proposed inclusion of confidential information in the application. A procedure dealing with the receipt, handling and control of confidential information sets out the format in which confidential information must be submitted to the Agency in order to ensure its safekeeping.

For further assistance please contact the EPA at Licensing@epa.ie