National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

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OVERVIEW OF NATIONAL REQUIREMENTS

Summary:
The GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs are regulated under the deliberate release framework (Directive 2001/18- Part B).

Directive 2001/18/EC on the deliberate release into the environment of GMOs has been transposed into Irish law under the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003.

The applications to seek authorisation under clinical trials and under GMO frameworks can be submitted in parallel (*i.e.* the sponsor should apply for GMO authorisation but does not need to wait for the GMO authorisation before submitting the clinical trial application).

Additional information can be found at:
https://www.epa.ie/pubs/advice/gmo/guidancenotetogeneticallymodifiedorganismsdeliberatereleaseregulations.html

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

There is no specific application form for the purposes of notifying the GMO aspect of clinical trials to the EPA. A list of notification requirements can be found at:
http://www.epa.ie/pubs/forms/lic/gmo/notificationrequirementsforpartbapplication.html

Language requirements:
Applications can be submitted in English.

PUBLIC CONSULTATION

Applicants intending to carry out a deliberate release of GMOs for purposes other than placing on the market, are required to place a public notice in a newspaper circulating in the area in which the proposed deliberate release is scheduled to take place.

The public notice will inform members of the public about the proposed deliberate release. It will also invite members of the public to make submissions in writing to the EPA, in relation to the proposed deliberate release, within 28 days of publication of said notice.

Persons who have made submissions in relation to the proposed deliberate release will be informed of

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the Agency's decision within 14 days of informing the notifier. The decision will also be made available on the EPA's website.

NATIONAL AUTHORITIES INVOLVED

Authorisation of clinical trials:

- **Health Products Regulatory Authority**

  Contact details: Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2.
  Email: clinicaltrials@hpra.ie

Authorisation of GMO aspects:

- **Environmental Protection Agency**

  Contact details: Environmental Licensing Programme, Office of Environmental Sustainability, PO Box 3000, Johnstown Castle Estate, Wexford. Y35 W821.
  Email: licensing@epa.ie