OVERVIEW OF NATIONAL REQUIREMENTS

Summary:
The GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs can be regulated under either the contained use or the deliberate release frameworks. A decision is taken case-by-case taking into account the biological characteristics and environmental risk assessment of the GMO.

Where there is uncertainty regarding which regulatory framework is appropriate, applicants should seek guidance from the regulatory authorities (including the SACGM compendium of guidance on using GMOs in a clinical setting).

The applications to seek authorization under clinical trials and under GMO frameworks are not linked (i.e. the applicant can decide the timing of the submission of the GMO application). Both applications can be submitted in parallel but it is not mandatory.

Additional information can be found at:

http://www.hse.gov.uk/biosafety/gmo/notifications/process.htm

https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Contained use: https://www.hse.gov.uk/forms/genetic/

Deliberate release (Directive 2001/18- Part B): The application form is attached. Potential applicants are encouraged to make enquiries via the e-mail address provided.

[deliberate release - non-plant application]
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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### PUBLIC CONSULTATION

When the clinical trial is regulated as a deliberate release, the application is published on the Defra website and the GMO public register. The public are invited to make any representations within a given deadline and can do so by e-mailing Defra, or writing to them at their London office.

### NATIONAL AUTHORITIES INVOLVED

**Authorisation of clinical trials:**

- **Medicines and Healthcare products Regulatory Agency (MHRA)**
  
  **Contact details:** 151 Buckingham Palace Road, Victoria, London SW1W 9SZ  
  Email: clintrialhelpline@mhra.gov.uk

**Authorisation of GMO aspects:**

**Deliberate Release** (Directive 2001/18- Part B):

- **Department for Environment Food & Rural Affair (Defra)**
  
  **Contact details:** Nobel House, 17 Smith Square, London, SW1P 3JR  
  Email: gm-regulation@DEFRA.GSI.GOV.UK

**Contained use:**

The UK competent authority (CA) for the Genetically Modified Organisms (Contained Use) Regulations comprises representatives of the four responsible authorities for GMO(CU) in the UK. The GMO(CU) 2014 regulations apply to England, Scotland and Wales. The GMO(CU) (Northern Ireland) 2015 Regulations apply to Northern Ireland.

In England and Wales, HSE and the Secretary of State for Defra acting jointly form the competent authority. The functions are delegated to HSE and Defra officials. Officials from Welsh Government are included in any matters relating to Wales.

In Scotland, the competent authority comprises Scottish Ministers and HSE acting jointly and
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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Similarly these functions are delegated to HSE and Scottish Government officials.

In Northern Ireland, the competent authority is the Health and Safety Executive for Northern Ireland (HSENI) and the Department of Agriculture, Environment and Rural Affairs, acting jointly.

HSE and HSENI take the lead on behalf of the other parts of the CA for administering the respective Regulations and act as the point of contact for notifications and enquiries in Great Britain and Northern Ireland respectively.

- **Health and Safety Executive (HSE).**  
  Contact details: Redgrave Court, Merton Road, Bootle, L20 7HS  
  Email: [Bioagents@hse.gov.uk](mailto:Bioagents@hse.gov.uk)

- **Health and Safety Executive for Northern Ireland (HSENI)**  
  Contact details: 83 Ladas Drive, Belfast, BT6 9FR

- **Department of Agriculture, Environment and Rural Affairs**  
  Contact details: Dundonald House, Upper Newtownards Road, Ballymiscaw, Belfast BT4 3SB

- **Scottish Government GM Policy Team**  
  Contact details: Saughton House, Broomhouse Drive, Edinburgh, EH11 3XD

- **Nature Environment and Agriculture Team, Welsh Government**  
  Contact details: Rhodfa Padarn, Llanbadarn Fawr, Aberystwyth, SY23 3UR