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

**OVERVIEW OF NATIONAL REQUIREMENTS**

**Summary:**
Clinical trials with medicinal products for human use containing or consisting of GMOs are regulated under the deliberate release framework - Part B of Directive 2001/18.

A single submission procedure applies to seek authorization under the clinical trials framework and under the GMO framework (submission to PEI).

**Additional information can be found at:**
http://www.pei.de/EN/information/license-applicants/clinical-trial-authorisation/gmo/clinical-trial-gmo-node.html

**APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS**

Application forms can be found at:
PART B SNIF application form
form requesting additional information on activities with GMO

**Language requirements:**
Applications can be submitted in English.

**PUBLIC CONSULTATION**

Publication on the JRC website after the clinical trial has been authorised.
**National authorities involved**

### Authorization of clinical trials:
- **Paul-Ehrlich-Institut** ("PEI"). PEI is responsible for the assessment and approval of the Clinical Trial Applications; a release permission is included in the authorisation of the clinical trial.

**Contact details:**
- Clinical trial section, Paul-Ehrlich-Str. 51-59, D-63225 Langen.
- Email: ct@pei.de
- [www.pei.de](http://www.pei.de)

### Authorisation of GMO aspects:
- **Federal Office of Consumer Protection and Food Safety** (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) (BVL). BVL is involved in an internal process without involvement of the applicant.

**Contact details:**
- Mauerstraße 39-42, 10117 Berlin
- [www.bvl.bund.de](http://www.bvl.bund.de)

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1 In some cases the BfArM might be the responsible Competent Authority – the procedures and relevant requirements remain unchanged. Contact information: ct@bfarm.de