

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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**ROMANIA** (December 2017)

**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- part B of Directive 2001/18. The application is assessed by the National Environmental Protection Agency ("NEPA") which consults the Biosafety Commission.

Authorization of GMO aspects is required prior to the submission of the clinical trial application.

NEPA decides if the notification dossier is accepted within 15 days. After the notification is accepted, NEPA transmits, within 10 days, a copy of the notification dossier to the involved authorities and to BC. The Biosafety Commission gives the written consent within 60 days and sends it to the competent authority and to the involved authorities, which transmit their written consent in 15 days, after the BC to NEPA.

Within 90 days of receipt of the notification NEPA gives a favourable or unfavourable notice to the applicant for the deliberate release into the environment of GMOs.

**Additional information can be found at:** [www.anpm.ro](http://www.anpm.ro).

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

Applicants should present a notification dossier to NEPA containing: the request for authorisation, the technical dossier, the notification summary, the risk assessment on human health and environment, a declaration to assume the responsibility for any harm which the deliberate release could cause, the information for the public, and evidence of payment of the fee.

**Language requirements:**

Application should be submitted in the national language.

**PUBLIC CONSULTATION**

All the notifications are published on JRC and NEPA's websites.

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NEPA starts the public consultation for a period of 30 days. The summary of the notification is published on the NEPA website and at Local Environmental Protection Agencies (LEPAs) or at the local municipality where the deliberate release is intended. If necessary, public debates are organized during the authorization procedure for deliberate release of GMOs.

The risk assessments submitted by the applicants and the summary of the decisions taken by the competent authority are published on the NEPA's website [www.anpm.ro](http://www.anpm.ro).

### NATIONAL AUTHORITIES INVOLVED

#### Authorisation of clinical trials:

- **National Agency for Medicines and Medical Devices**  
contact: dr. Mirela Vita  
e-mail: [mirela.vita@anm.ro](mailto:mirela.vita@anm.ro)
- **Ministry of Health**

#### Authorisation of the deliberate release of GMO:

- **National Environmental Protection Agency**  
Contact: Steluța Ghinea  
e-mail: [steluta.ghinea@anpm.ro](mailto:steluta.ghinea@anpm.ro)

#### Authorities with an advisory role in the decision making process by NEPA

- **The Biosafety Commission (BC)**
- **Ministry of Health**