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

FINLAND (December 2017)

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 (Directive 2001/18- Part B). A decision is taken case-by-case depending on factors such as the replicative capacity of the GMOs and whether specific containment measures are used to limit their contact with the general population and the environment and to provide a high level of safety for the general population and the environment.

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).

Additional information can be found at:
http://www.fimea.fi/web/en/supervision/clinical_drug_trials
http://tukija.fi/en/frontpage
http://geenitekniikanlautakunta.fi/en/contained-use/microorganisms
http://geenitekniikanlautakunta.fi/artikkeli/-/asset_publisher/gm-laakkeita-koskevista-menettelyista-julkaistu-ohje

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Contained use:
http://geenitekniikanlautakunta.fi/suljettukaytto/mikro-organismit

Deliberate release:
http://geenitekniikanlautakunta.fi/avoin-kaytto/hakemuksen-laatiminen

Language requirements:
Applications in English may be acceptable in a some cases (see http://geenitekniikanlautakunta.fi/en/article/-/asset_publisher/ilmoitusten-kielivaatimuksista)

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PUBLIC CONSULTATION

There is no public consultation in the framework of contained use. There is however a public consultation when the deliberate release framework applies (60 days).

NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

- **Finnish Medicines Agency FIMEA** (CA for clinical trial applications of medicinal products).
  Contact details: Finnish Medicines Agency, Clinical Trials, P.O. Box 55, FI-00034 FIMEA
  Email: clinicaltrials@fimea.fi

- **National Committee on Medical Research Ethics (TUKIJA)**: an expert on research ethics advising regional ethics committees in matters of ethical principle related to medical research and providing training.
  Contact details: National Supervisory Authority for Welfare and Health (Valvira), P.O. Box 210, FI-00281 Helsinki
  Email: tukija@valvira.fi

Authorisation of GMO aspects:

- **Board for Gene Technology**
  Contact details: P.O. Box 33, FI-00023, Helsinki
  Email: gtlk.stm@stm.fi