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

NORWAY (March 2021)

OVERVIEW OF NATIONAL REQUIREMENTS

Summary:
Clinical trials with medicinal products for human use containing or consisting of GMOs, where the clinical trial subject leaves the contained use facility after treatment, are regarded as deliberate release - Part B of Directive 2001/18.

The manufacture, storage, handling, and administration of the GMOs at the clinical trial test site is approved as contained use according to Directive 2009/41/EC.

Both Directive 2001/18/EC and Directive 2009/41/EC is implemented in the EEA agreement and transposed into the Norwegian Gene Technology Act.

Authorisations under the clinical trials framework and under the GMO framework must be obtained before the clinical trial can start. It is therefore advisable that applicants submit their applications under both regulatory frameworks at the same time. To this end the relevant authorities, The Norwegian Medicines Agency (NoMA), the Norwegian Directorate for Health (NDH) and the Norwegian Environment Agency (NEA) have established a common mailbox for the submission of applications via eudralink for approval of medicinal products containing GMO for clinical trials: GMO@legemiddelverket.no.

More information in national webpages
Regulations:
https://www.regjeringen.no/en/dokumenter/gene-technology-act/id173031/

Guidance for applications
NoMA: Søknad om klinisk utprøving - Legemiddelverket
Application - Legemiddelverket
NDH: Genmodifiserte mikroorganismer - Helsedirektoratet
NEA: https://www.environmentagency.no/clinical-trials-human-gmo

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Contained use:
Application form for approval of the contained site area:
https://helsedirektoratet.no/Documents/Genteknologi/GMM_godkjenning_laboratorier.doc
Notification form:
https://helsedirektoratet.no/Documents/Genteknologi/GMM_melding_eller_soknad.docx

Deliberate release (Directive 2001/18 – Part B):

NORWAY (March 2021)

Online guidance and application forms can be found here:
https://www.environmentagency.no/clinical-trials-human-gmo

Language requirements:
Applications can be submitted in Norwegian or English.

PUBLIC CONSULTATION

Pursuant to the Gene Technology Act all applications for **deliberate release** (Part B notifications Directive 2001/18) are subject to public consultation.

The consultation takes place via the official public consultation's website of the Norwegian Environment Agency (https://www.miljodirektoratet.no/hoeringer/). The SNIF (summary notification information format) is made available as part of the consultation. The period of consultation is restricted to 30 days.

NATIONAL AUTHORITIES INVOLVED

Authorisation of the clinical trial:	
• **The Norwegian Medicines Agency** P.O.Box 240 Skøyen N-0213 Oslo	**Submission:** GMO@legemiddelverket.no **Questions:** gmo@noma.no
Authorisation of GMO aspects:	
• **The Norwegian Directorate for Health** (for contained use) Dept. of Health Legislation and Biotechnology, P.O. Box 220 Skøyen, N-0213 Oslo, Norway	**Submission:** GMO@legemiddelverket.no **Questions:** GMO-boksen@helsedir.no
• **The Norwegian Environment Agency** (for deliberate release) P.O.Box 5672 Torgarden, NO-7485 Trondheim NORWAY	**Submission:** GMO@legemiddelverket.no **Questions:** GMO@miljodir.no