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

SPAIN (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 applications to seek authorization under the clinical trials framework and under the GMO framework are not linked (*i.e.* the applicant can decide the timing of the submission of the GMO application).

Additional information can be found at:
https://sede.mapama.gob.es/portal/site/se/ficha-procedimiento?procedure_id=413&procedure_suborg_responsable=79&by=theme

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:

http://www.mapama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/notificaciones-y-autorizaciones/proc_autorizacion.aspx

Language requirements:
Application should be submitted in the national language but technical documents in English are acceptable.

PUBLIC CONSULTATION

Information about public consultation on GMO aspects can be found at:
http://www.mapama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/participacion-publica/liberacion-voluntaria/default.aspx

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NATIONAL AUTHORITIES INVOLVED
Authorisation of clinical trials: • **Agencia Española de Medicamentos y Productos Sanitarios** (Spanish Agency of Medicines and Medical Devices) Contact details: Calle Campezo 1, Edificio 8, E-28022 Madrid Email: aecaem@aemps.es. Phone: +34 91 822 59 97
Authorisation of GMO aspects: • **Consejo Interministerial de OMG (CIOMG).** • **Comisión Nacional de Bioseguridad (CNB)** Contact details: Paseo Infanta Isabel, 1, 28014. Madrid. CIOMG: ciomg@mapama.es. Phone 34 91 347 65 93 CNB: secretariaomg@mapama.es. Phone 34 91 597 5650