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OVERVIEW OF NATIONAL REQUIREMENTS

Summary:

Depending on the characteristics and mode of administration of the medicinal product, it is possible that the GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs do not require an authorisation under the deliberate release frameworks (Directive 2001/18/EC – Part B). When there is no possible release of the GMO in the environment that may confer a risk to human health or the environment (*e.g.* in case of GM medication taken at home, no risk of shedding, spreading,...), or if proper management procedures and/or working practices are taken to prevent any possible release conferring a risk, then a ‘contained use’ procedure will generally be sufficient. However, if there is a probability of possible release that may confer a risk to human health or the environment which cannot be avoided by proper management procedures or working practices, a notification under ‘deliberate release’ is also required.

If the framework to be followed is not clear to the applicant, it is strongly advised to request a national scientific-technical advice (STA) from the Federal Agency for Medicines and Health Products (FAMHP) prior to the submission of the clinical trial application.

Contained use (Directive 2009/41/EC)

In order to obtain authorisations under the contained use framework, a biosafety dossier should be submitted according to the Regional Decrees transposing Directive 2009/41/EC. Depending on the risk level of the contained use, a simple notification or a prior written authorization from the regional competent authority will be needed. The scientific evaluation is conducted by the SBB for all three Regions.

In case of a CTA following only the GMO contained use procedure, the SBB is the contact point for the submission of the application and to address questions related to the dossier submitted in the framework of 2009/41/EC.

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

The deliberate release of a GMO into the environment is regulated at the federal level. In order to obtain an authorisation under the ‘deliberate release procedure’, an application is submitted to the FAMHP. The application will be evaluated by the Belgian Biosafety advisory Council which transmits its advice to the FAMHP.

An application for an authorisation under the ‘deliberate release procedure’ does not exempt to apply a dossier according to the Regional Decrees transposing Directive 2009/41/EC on the contained use (CU) of GMO's and/or pathogen organisms. It will need to cover all the related contained use activities (*e.g.* storage and handling of medication, biological samples, hospital

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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rooms, waste disposal).

Timeline of the submission of the applications for authorisation

The applications to seek authorization under clinical trials and under GMO frameworks can be submitted in parallel (*i.e.* the sponsor should apply for GMO authorization but does not need to wait for the GMO authorization before submitting the clinical trial application).

Additional information can be found at:

https://www.famhp.be/en/human_use/medicines/medicines/scientific_technical_advice

https://www.famhp.be/en/human_use/medicines/medicines/scientific_technical_advice

https://www.biosafety.be/sites/default/files/guideline_version_published.pdf

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Contained use:

In Flemish region: <https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-flemish-region>

In Walloon Region : <https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-wallonia>

<http://www.wallonie.be/fr/demarches/20520-demander-un-permis-d-environnement-ou-un-permis-unique-pour-un-etablissement-de-classes-1-et-2>

In Brussels Region : <https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-brussels-capital-region>

Deliberate release:

<https://www.biosafety.be/content/notification-procedures-clinical-trials-gmos-human-or-veterinary-use>

Request for a national and scientific-technical advice :

https://www.fagg-afmps.be/en/human_use/medicines/medicines/scientific_technical_advice

https://www.fagg-afmps.be/en/human_use/medicines/medicines/scientific_technical_advice/applicvation_procedures

Language requirements:

The submission of the biosafety dossier of a clinical trial submitted under deliberate release may be done in English, except for the documents for the public consultation that are to be provided in the language of the region where the clinical trial will be conducted (French or

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Dutch).

The biosafety dossier of a clinical trial submitted under contained use comprises a technical part and a public part. Only the public part needs to be submitted in the language of the region where the clinical trial will be conducted.

PUBLIC CONSULTATION

A public consultation (*i.e.* a process where information for the public is made available on a publicly consultable and dedicated website) is conducted within the context of the ‘deliberate release’ framework (Directive 2001/18/EC) and lasts 30 days. The public consultation starts within 5 days following the acknowledgement of receipt of the application by the FAMPH and is included in the legal timeline of 90 days that also includes a formal consultation of the Biosafety Advisory Council and the subsequent formal decision.

Under the framework of the regional decrees implementing Directive 2009/41/EC, the biosafety dossier comprises a public part, which is not made available on a public website.

NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

- **Federal Agency for Medicines and Health Products (FAMHP):** FAMHP (R&D) is the competent authority for approval of all clinical trials.

FAMHP is also responsible for issuing a decision on the biosafety aspects of an application under the deliberate release framework; FAMHP takes this decision on the basis of a scientific advice of the Biosafety Advisory Council.

Contact details: Research and development department,
Eurostation II, 8th floor, Place Victor Horta 40 bte 40, 1060,
Brussels
Email: ct.rd@fagg-afmps.be

Authorisation of GMO aspects:

- **STA (Scientific-Technical Advice unit)** of the national Innovation Office at the FAMHP: advisory body.

Contact details: Eurostation II, 8th floor, Place Victor Horta 40 bte 40, 1060
Brussels

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Email: sta-wta@fagg-afmps.be

Contained use:

The contained use of genetically modified organisms is regulated in Belgium at the regional level. Regional authorities from the Flemish, Walloon and Brussels-Capital Region are each responsible for the follow-up of administrative procedures, for authorisations and for inspections. However, the scientific evaluation is centralized and conducted by the SBB.

- **SBB:** It is involved in the scientific evaluation of clinical trials regulated under the 'contained use' framework. It is the point of contact for the submission of the application and/or queries regarding the dossier submitted under the contained use framework.

Contact details: Sciensano
Biosafety and Biotechnology Unit (**SBB**)
Rue Juliette Wytsmanstraat, 14, 1050 Brussels
Email: contained.use@sciensano.be

- **Flemish region :**

Departement Omgeving
Afdeling Gebiedsontwikkeling, omgevingsplanning en -projecten (GOP)
Graaf de Ferrarisgebouw
Koning Albert II-laan 20 bus 8
B-1000 Brussel
Email: GOP.omgeving@vlaanderen.be
<https://www.lne.be/>

- **Walloon region:**

Service Public de Wallonie
Direction Générale Opérationnelle "Agriculture, Ressources naturelles et de l'Environnement (D GARNE)
Département des Permis et Autorisations
Avenue Prince de Liège 15
B-5100 Namur
Email: <http://environnement.wallonie.be>

- **Brussels-Capital Region**

Bruxelles Environnement-Leefmilieu Brussel
Site de Tour & Taxis
Avenue du Port 86C / 3000
1000 Bruxelles
<http://www.environnement.brussels/qui-sommes-nous/nous-contacter>
Email: cjansinski@environnement.brussels; or ugeebelen@environment.brussels

Deliberate release:

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- In case of a CTA GMO under the deliberate release framework, **FAMHP** is the contact point for the deliberate release procedure: ct.rd@fagg-afmps.be
- **Belgian Biosafety Advisory Council**: it is an advisory body involved in the scientific evaluation of GMO clinical trials regulated under the 'deliberate release' framework. (www.bio-council.be)