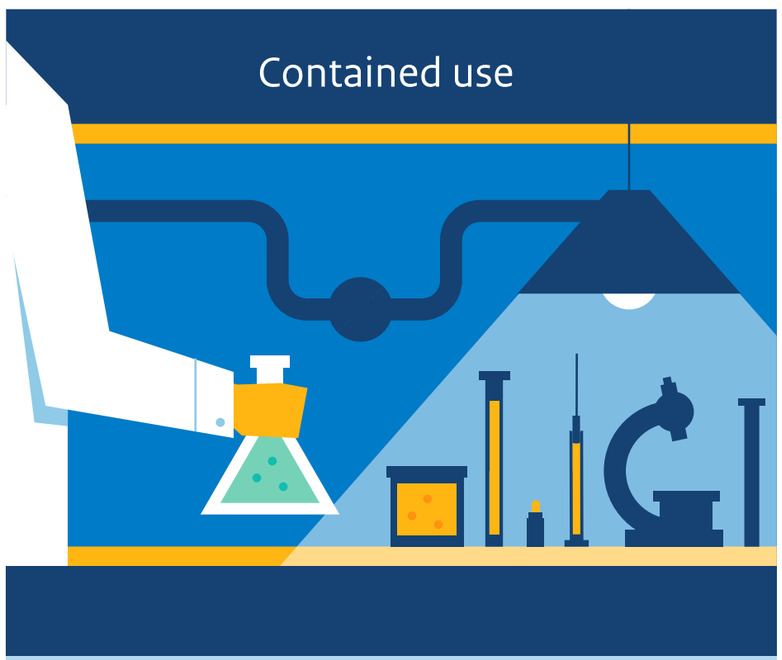
Contained use



Contained use includes the construction, use or storage of GMOs within a facility with specific containment measures, such as a laboratory, a greenhouse or an animal facility. Contained use allows you to conduct experiments with various GMOs. Before you can start working under contained use, you must perform a risk assessment and determine the biosafety level and type of facility required for your activities involving GMOs. You can then file a notification or request a permit for the intended GMO experiments. An authorized Biological Safety Officer (BSO) supervises the safety of all GMO activities performed.

Deliberate release

Deliberate release is the intentional introduction in the environment of a GMO outside of a contained use facility, for example during field trials with GM plants or gene therapy treatments for patients. Under deliberate release you can, for instance, conduct research into a GMO to gather all necessary knowledge on its performance and to test the properties of the GMO in a controlled setting. For activities with GMOs under deliberate release you must complete an environmental risk assessment and apply for a permit. An authorized environmental safety officer (ESO) supervises the safety of all GMO activities performed.

Marketing authorisation applications

If the intended goal is a commercial release of the GMO, then this is considered a marketing authorisation application. When applying for marketing authorisation you request authorisation for the entire European market for one specific GMO (or derived product). All European member states assess the market application, in which all of the data collected under contained use and deliberate release are documented. The European commission decides if the marketing authorisation application is approved or rejected. If you are looking to apply for a marketing authorisation application please reach out to the GMO office in advance.

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