

Public disclosure of studies

In response to a long-running 2012 objection and appeal procedure involving the Bijenstichting (Bee Foundation) and the authorisation holder, the Ctgb decided to publicly disclose 85 studies on imidacloprid in April 2019. There were conflicting interests between the Bee Foundation and the authorisation holder, and the Ctgb weighed all interests as carefully as possible. The studies have been made public with the exception of personal data, GLP and analysis certificates from laboratories and several other parts. With this Ctgb decision, an initial policy has emerged on how to deal with requests for the public disclosure of studies. In October 2019, the Ctgb held a workshop with data owners involved in the other ongoing objection and appeal cases on the public disclosure of studies. One of the most important questions was whether the Ctgb could provide further details, in particular regarding frameworks for keeping certain information confidential ('blacking out'). Unfortunately, this is not yet possible. With regard to public disclosure, it is also important to note that the amended General Food Regulation will come into force on 21 March 2021; as a result, the frameworks for public disclosure will change.

The Ctgb will apply the following policy from now until 21 March 2021:

- In principle, a disclosure request can be submitted for any document or study that has been submitted to the Ctgb. When processing such a request, the Ctgb assumes that every document can be made public, unless there is a legal basis for keeping parts of a document confidential.
- After receiving a disclosure request, the Ctgb gives the data owner the opportunity to submit a view regarding the documents covered by the disclosure request.
- It is then the data owner's responsibility to submit a view and substantiate its opinion that certain information (the 'blacked out' parts) should be kept confidential.
- After receiving the views, the Ctgb will consider each view, taking all relevant interests into account.
- We understand the need for frameworks for keeping information confidential. However, we cannot provide general indications on which information can be kept confidential. After all, this depends on the submitted view and the explanation. As indicated above, one could say that an initial policy has emerged on how to deal with the public disclosure of studies. However, if a data owner chooses not to submit a substantiated view, for example to keep analysis certificates confidential, Ctgb will in principle make those certificates public.