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Developments The General Food Law and implications for biocontrol

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Trusted science for safe food

efsa
European Food Safety Authority

General European Food Law

- Regulation (EC) No 178/2002
  (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20080325:EN:PDF)
- Laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food law

- What we are familiar with, currently governs EFSA activities including for plant protection products which also follow the Plant Protection Product

  Regulation (EC) No 1107/2009
(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1107-20181110&from=EN)

General European Food Law amendment

- Regulation (EU) No 2019/1381
  (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1381&from=EN)

- on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002,……,(EC) No 1107/2009,…..

- Shall apply from 27 March 2021

General European Food Law amendment

Four Pillars

- Sustainability & governance of EFSA
- Quality & reliability of studies
- Improved risk communication
- Transparency of EU risk assessment

Transparency

- Improve and clarify **the rules on transparency** (in particular as regards scientific studies supporting risk assessment).

- Increased **reliability, objectivity and independence of studies used by EFSA** in its risk assessment (mainly **authorisation dossiers)**.

In particular the need to:

  - involve more public authorities in the process of deciding which studies need to be conducted;
  - enhance auditing of compliance with GLP principles (Commission responsible for fact finding missions to Member States);
  - publication of full study reports to increase transparency while respecting confidential business information;
  - exceptionally commission ad-hoc studies in specific cases.

Transparency (and confidentiality)

- Scientific data, information supporting authorisations and other requests for scientific output to be made publicly available proactively **once an application has been considered valid**;
- Industry data to be published on EFSA's website and easily accessible, in an **electronic format**, which is searchable, downloadable and printable;
- Disclosure of scientific data, information on which scientific outputs are based and summary of pre-submission advice to be **without prejudice to rules concerning IP rights**

Dossier preparation and Submission

Now

- Format of dossiers not prescribed (though guidance is available)
- Confidentiality claims assessed solely by RMS, confidential information physically separated in the dossier
- EFSA makes the summary dossier publicly available
- Article 63 of 1107: There is a list of information normally deemed confidential

After 27 March 2021

- Standard data formats, where they exist, that need to be made available by EFSA have to be used
- Confidentiality claims assessed by RMS after consulting with EFSA, confidential information physically separated in the dossier
- EFSA makes the whole dossier publicly available including supplementary information submitted by the applicant
- Article 63 of 1107: There is a defined list of information for which confidentiality can be claimed. Claims on other topics not foreseen

Dossier preparation, what hasn't changed

- Macro organisms used in plant protection (e.g. nematodes, parasitic wasps) are not regulated via harmonised European regulations. Regulation is defined by national frameworks. EFSA has no involvement
- Systematic review of published peer review journal literature according to EFSA (2011) guidance

  (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2092)

  is always required in addition to any narrative use of published peer review journal literature
- Plant derived materials, semiochemicals and inanimate microorganisms etc.: not published safety studies require Good Laboratory Practice certification, efficacy studies require officially recognised testing status
- Microorganisms including viruses: not published safety studies for human health require Good Laboratory Practice certification, all other not published studies require officially recognised testing status

Dossier preparation and Submission

Now

- Notification of commissioned studies that will not be published (as peer review journal literature) by applicants not required
- Notification of studies that will not be published (as peer review journal literature) by contract laboratories not required
- No legal basis for EFSA to commission verification studies to clarify applicant's results (other than an external mandate request)

After 27 March 2021

- Notification of commissioned studies that will not be published (as peer review journal literature) to an EFSA data base (title, scope, who, planned finish date) by applicants is required
- Notification of studies that will not be published (as peer review journal literature) to an EFSA data base (title, scope, planned finish date) by (European) contract laboratories is required
- EFSA may commission verification studies (commission ad-hoc studies in specific cases) to clarify applicant's results or reduce regulatory uncertainty raised by dossier and literature information

Consequences of not notifying studies

- If a dossier contains an unpublished study not notified in the EFSA data base the dossier will be considered inadmissible. The dossier processing will be delayed for 6 months after the study is notified to the database
- If a relevant study notified in the EFSA data base is missing from a dossier the dossier will be considered inadmissible. The dossier processing will be delayed for at least 6 months from the date the study is added to the dossier
- If a notified study is terminated before completion, reasons for the termination and any results will need to be reported and included in the dossier

Note entries in the EFSA notification data base will be made public once the associated application has been received

Implications for biocontrol

- The detailed planning required for timing dossier preparation, now needs more consideration

When contracting research, researchers will need:

- to have clear priority and planning for publishing in peer reviewed journals
- or ensure that their organisations have obtained GLP certification or are officially recognised testing facilities for efficacy testing or non-human health testing with microorganisms

Dossiers will be considered inadmissible and their processing will be delayed if unpublished studies are not appropriately notified in the EFSA database

Take home message

- When you commission a study or initiate a study yourself after 27 March 2021 it should be notified to an EFSA database

Notification needs to include at least: study title, scope, organisation doing the work and planned finish date.

- Note entries in the database will be made public but only after the first associated application is received at EFSA

- Note EFSA also makes the applications for approval public

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