AT A GLANCE

Requested by the PESTcommittee

Study in Focus

European Parliament

Guidelines for submission and evaluation of applications for the approval of active substances in pesticides

The original full study[1] examines in great details the state of play with **available guidance and guidelines for the approval of active substances in pesticides**. The study was prepared upon the request of the European Parliament's Special Committee on the Union's authorisation procedure for pesticides, which was set up for a limited period of time with a focused mandate, in the 8th legislative term.

Check out the original full study by scanning this QR code!

Background

Regulation (EC) No 1107/2009 puts in place the **legal framework for placing plant protection products on the market**. Commission Regulation (EU) No 283/2013 sets out the **data requirements for active substances** to be used in those products. An applicant who wishes to obtain approval for an active substance must **submit a dossier** through a selected national contact point; this dossier contains an extensive set of documentation, providing with the necessary data for carrying out the risk assessment. Different layers of rules need to be respected such as data requirements, technical guidance, procedural guidance and test guidelines (or test methods).

Key findings

(i) The study reveals the **complex structure of documents guiding the approval process**, and gives a thorough overview on the adoption, update, scope of application and legal status of these documents.

- Communication 2013/C 95/01 was issued by the Commission in the framework of implementing the Commission Regulation, to indicate **technical guidance and guidelines**. Since the publication of the Communication in 2013, **new applicable technical guidance has emerged**; some are published by DG SANTE, others by EFSA, and the two have a different legal value. **Procedural guidance** for active substance approval, generally drafted **by** DG SANTE, is also available. Finally, there are also **test guidelines** which are generally drafted by the OECD.
- As a general rule, guidelines are of primary relevance to applicants, technical guidance to risk assessors, while the primary relevance of procedural guidance depends on the document itself. However, **in practice all guidance documents and guidelines are relevant to both applicants and risk assessors, given that both parties need to know how tests should be conducted, and by which method they will be assessed**.
- While guidance and guidelines are not legally binding, those listed in Communication 2013/C 95/01 or noted/approved by the Standing Committee on Plants, Animals, Food and Feed **can be considered *de facto* mandatory**. Though in theory it is possible to deviate from noted guidance on the basis of scientific justifications, it creates additional complexities or risks and therefore is rarely accepted.

(ii) The study draws conclusions on the **status of harmonisation of guidance and test guidelines across the EU**.

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- It finds that there is **generally a high level of harmonisation** concerning guidance and guidelines for the approval of active substances.
- **Two notable cases of incoherence, however, affects harmonisation**. Some guidance documents include requirements for which no validated test guidelines exist; and there are data requirements for which there is are no guidance documents or guidelines. Efforts have been made, and are continuous, to fill these gaps in guidance documents.

(iii) The **Good Laboratory Practices (GLP) system** and **the studies required for the submission of an application for the approval of active substances** are also examined.

- GLP is a **quality management tool on the method of conducting studies that guarantees process** rather than outcome; it covers all non-clinical safety testing of chemicals, i.e. a wide range of products, including PPPs and actives substances. They are **supplemented by mutually recognised consensus documents**, and with **advisory and guidance documents**.
- **Directives 2004/9/EC** and **2004/10/EC** regulates GLP in the EU and EEA. There is a fairly high level of harmonisation in the application of GLP across the EU, with laboratories routinely inspected every two to three years. The **EU GLP working group** contributes to maintain this continued level of harmonisation.

(iv) Complex issues arise around the **studies required for active substance approval**.

- Though Commission Regulation (EU) No 283/2013 lists those studies and the guidance includes further indications, the **studies required can vary from case to case** and **multiple studies may be required to fulfil some data requirements**.
- **Studies may be rejected for a number of reasons**. More common reasons include the absence of guidelines for studies which leads to more discussion on the methods used and result, and the submission of old studies during the re-approval process.
- The **OECD Mutual Acceptance of Data Agreement** ensures that those studies which are conducted in accordance with OECD test guidelines and under GLP, are accepted for assessment purposes across the OECD.

(v) As overall conclusion, the study notes that applicants may have to deal with **some level of uncertainty** inherent to the system.

- While noted/approved EU guidance is generally is adhered to, other guidance may be used in some cases.
- The emergence of new guidance may pose some challenges if it becomes available close to the time of submission of an application. Both the applicants and the Rapporteur Member State, responsible for the approval process, have to **constantly monitor the development of new guidance from multiple sources**; they are currently **not provided with up-to-date instruments to navigate this complex system**. Member States may still have differences in opinions despite the existence of guidance.

[1] https://www.europarl.europa.eu/RegData/etudes/STUD/2018/626072/IPOL_STU(2018)626072_EN.pdf

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