CropLife Europe inputs to the 5th Meeting of EFSA technical group on Notification of Studies

Key messages

- **CLE sees the system developing positively with continuous improvements being made.**
  - EFSA staff responsiveness is much appreciated.
- **However, we still see issues hindering the process, creating unnecessary delays but also adding burden to companies.**
- **CLE believes there is a need for continuous dialogue with EFSA on this new database to ensure a smoother NoS process**

Process related topics:
NoS ID Check (justifications)

- **Reg. (EU) 2019/1381 requires a NoS if a study to support an application is performed.**
- **Reg. (EU) 2019/1381 does foresee situations in which late notifications may occur:**
  - *Article 32b study notifications submitted in the database in connection to **studies already ongoing or completed**. For example, this could happen because certain studies may have originally been commissioned or carried out by business operators without the intention of using them to support an application for the European Union market. Such already ongoing or completed studies may subsequently need to be notified in the database due to a change of commercial strategy resulting in the European Union becoming a potential market.*

- **The statement lists only one example. Given the associated risk of non-admissibility of a dossier and subsequent penalty in case the justification for late notification, clarification would be of importance.**
  - Possible reasons in our view are:
    - Import tolerances are not possible to be adopted from CODEX and EU IT petition needs to be filed
    - Product specific studies for products not foreseen to be representative
    - Studies initially conducted for the purposes of research investigation, and then subsequently required to support a regulatory submission
    - Studies to support REACH submissions where it was unknown at the time that the test item would be subject to EFSA output (i.e. environmental metabolite)
    - Technical issues with notification / database access
    - Accidental cases/human error resulting in the notification being slightly delayed

Process related topics: NoS ID Check

- **EFSA generates a NoS ID report each time the IUCLID dossier is re-submitted.**
  - ❑ New studies are always performed for new MRL submissions, IT petitions and also as requests for additional data for the submitted dossier. The new notified studies are not in the re-submitted IUCLID dossier.
  - ❑ Studies linked to other PAIs, conducted for the purpose described in that PAI and do not need to be considered on dossier re-submission.
  - ❑ MS responsible for checking the compliance, based on the NoS ID report transmitted by EFSA to MS

- **Certain studies are obviously irrelevant for the respective submission**
  - ❑ Study types not being a data requirement for the type of submission (e.g. ecotox studies in a MRL submission)
  - ❑ Studies for which the test system is not relevant for the respective submission (e.g. residue study in wheat for a MRL submission in apple)
  - ❑ Studies for which the test item is not relevant for the current submission (e.g. storage stability of a formulation not being representative.)

- **The NoS ID check report generated by EFSA should consider the time of the submission of the IUCLID dossier first version**
- **Justification requests for non-submissions of studies being obviously irrelevant for a submission should be avoided.**