FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
11-12 JUNE 2024

EUROPEAN FOOD SAFETY AUTHORITY

FEEDBACK FROM FRANCE

QUESTION 1 TO EFSA:

- Could you please clarify which kind of studies need to be notified, simplifying the process for both applicants and RMS?

  Efsa announced previously that discussions were ongoing with Commission in order to refine the scope of the NoS. Is there any feedback?

For instance:

- 5 batch analyses are confidential and will not be made public. Is it mandatory to notify in this case?
- Efficacy trials: study reports are not always submitted in the dossier, but only summaries. Is it relevant to notify in this case?

FEEDBACK FROM FRANCE

QUESTION 2 TO EFSA:

- Is it possible to update the ISO name of the active substance in IUCLID (dossier title and dossier header) when the active substance undergoes a change of name during the assessment process?

For instance:

- Taxonomic change of a microorganism (e.g. Bacillus velezensis, previously referred to as Bacillus amyloliquefaciens).
- Change of ISO name after SID check (often this comes late in the process)

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