Trusted science for safe food

2nd PSN IUCLID subgroup meeting – 31 Jan 2022

IUCLID latest news and updates

efsa
European Food Safety Authority

Communication channels & activities

Our current communication channels are the following:

- Applicants toolkit (https://www.efsa.europa.eu/en/applications/toolkit#iuclid-software) – always up-to-date
- Linked In group (not PPP specific): https://www.linkedin.com/groups/9083910/
- Targeted emails sent to all applicants

Additional resources

User manuals:

- Active substance manual
- MRL manual
- Microorganisms manual
- Basic substance Manual

Filter rules:

- IUCLID for PPP filter rules

Crosswalks:

- Crosswalks IUCLID 6.6 EU PPP Microorganisms - active substance application (product) to KMA&KMP
- Crosswalks IUCLID 6.6 EU PPP Active substance application (product) to KCA&KCP

Report generator:

- Documents M EU PPP for IUCLID report generator
- Documents D (GAP) EU PPP for IUCLID report generator
- Confidentiality report EU PPP for IUCLID report generator
- Notification of Studies (NoS) Extraction Request EU PPP for IUCLID report generator

Training material:

- IUCLID for applicants training
- IUCLID tutorials
- Video: Table of Contents (TOC) for application submission
- Webinar on Metapath: How to complete MSS composers for pesticides metabolism studies – plants (primary and rotational crops) and livestock
- IUCLID for applicants: Recording and supporting material
- Webinar: MetaPath - How to complete DER composers for pesticide mammalian toxicology metabolism studies
- Webinar: IUCLID for regulators

Communication channels & activities

- Revised Active Substance manual published (https://doi.org/10.5281/zenodo.5091463)
  - The new introduction is very relevant
- Other manuals to be published shortly
- Training on "**Most common mistakes in IUCLID submissions and how to solve them**" is being prepared → delivered in spring 2022
- "**IUCLID for the general public**" in early summer
- Do you have any specific elements which you would like to receive more training on?

Key messages: Resubmission of IUCLID dossiers

1. **Following request from RELEVANT REGULATORY BODY** (RMS/EMS/EC/EFSA)
   i. Request for update during admissibility check
   ii. Request for update of confidentiality claims after declaration of admissibility
   iii. Request for update during application evaluation
   iv. Request for update of confidentiality claims after conclusion of the evaluation.
2. **Spontaneus re-submissions**
   i. re-submission following changes in administrative information for renewal applications
   ii. re-submission following identification of potentially harmful or unacceptable effects

(p.39 AS manual)

Key messages: Letters after IUCLID submission

- EFSA, EC, the RMS, co-RMS and other MSs are informed via an automated email once a valid pesticide IUCLID application is submitted. Confirmation of IUCLID submissions via **email or letter is not needed**
- In relation to the validation assistant (p. 31 AS manual) please provide the excel file with the justification for not resolving the warning(s) directly to the RMS. Other files/documents relevant to the submission should be added to the respective IUCLID sections
- Under the TR, **IUCLID is the standard data format** for all pesticides applications. IUCLID submissions are the only relevant ones and they are available to all actors

Key messages: personal data management

- Despite extensive communication on the topic, there are still severe issues in relation to unsanitised personal data in IUCLID dossiers
- **Every** IUCLID dossier published until now has been taken offline within a couple of hours due to the inclusion of personal data
  - As per Article 39b(1)(a) of Reg. 178/2002, upon admissibility of validity of an application, EFSA *"shall make public the non-confidential version of the application as submitted by the applicant"*
  - Even though EFSA identifies the personal data there is no legal basis for contacting the applicant, requesting a re-submission or publishing a version of the dossier other than the one which was declared admissible by the RMS/EMS

Key messages: personal data management

- EFSA has taken measures to improve personal data management within IUCLID itself (e.g. contact person details are now **not published** by default) however, the "sanitised" study reports typically still include names of physical persons, signatures, etc
- Under the current situation if EFSA publishes IUCLID dossiers we are typically in breach of the GDPR/EUDPR and if we do not publish, we are in breach of our obligations under the TR
- **EFSA has currently suspended IUCLID dossier publication** if personal data is detected and will currently publish only after the confidentiality assessment process has been finalised
- A better process is needed and clear responsibilities must be defined (involving the applicant, the MS and EFSA)

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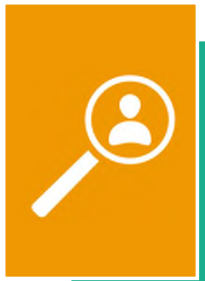

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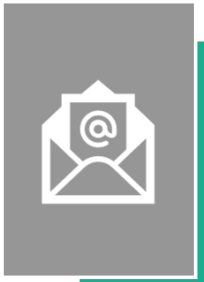

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