6th meeting of the PSN IUCLID sub-group
28 March 2023

IUCLID LATEST NEWS & UPDATES

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EUROPEAN FOOD SAFETY AUTHORITY

IUCLID – GENERAL UPDATES (1)

- We are currently working on the **update of the IUCLID manuals** in view of the April release – we remind you that any feedback is welcome (Teams message from Jane Richardson on 20 February 2023) e.g.
  - Could we remove the field path?
  - Could we provide instructions for a repeatable block rather than for each field?
- The **administrative guidance** is being updated and we aim to publish it in May 2023
  - Mainly to update the IUCLID references and process descriptions to what is currently in place. Additional references to confidentiality aspects also added.
- **Dossier name**: please remember to include the ISO name of the substance for a NAS/AIR dossier and the substance name + the crop in an MRL dossier

IUCLID – GENERAL UPDATES (2)

- Thanks to all the measures put in place since April 2022 (light check by both MS and EFSA, awareness-raising with applicants, small process changes) the number of dossiers EFSA publishes has increased considerably
- **Ask a Question** is being used more broadly:
  - We encourage more registered users
  - Correct to use it (both applicants + MS) for all IUCLID questions
  - MS: if requesting a pre-admissibility telco, use the FDP FMB (FDP@efsa.europa.eu) because it is easier to follow up

DOSSIER PUBLICATION

At which stages in the process is a IUCLID **dossier published**?

- For AIR/NAS/Amendment of conditions of approval applications:
  1. Upon the declaration of admissibility/validity by the RMS/EMS
  2. After finalisation of the confidentiality request assessment (assuming that there are changes compared to (1)
  3. At the time of the public consultation on the DAR/RAR the updated dossier will be made available
  4. Together with the final output the final consolidated version of the dossier will be published
- For MRL applications step 3 above is not applicable

PUBLIC CONSULTATIONS

Action item from previous IUCLID PSN Meeting *"EFSA to reflect on how to best communicate timelines for public consultation"*

Where can I find information on Public Consultations?

- List of OPEN public consultations is available on Connect.EFSA: https://connect.efsa.europa.eu/RM/s/publicconsultation
- List of UPCOMING public consultation is available on Connect.EFSA: https://connect.efsa.europa.eu/RM/s/publicconsultation?PublicConsultation2__c-filterId=00B1v000009eNnNEAU
- EFSA is starting to contact proactively RMS/EMS via email to communicate starting of public consultation

What are the timelines of Public Consultations?

- Standard timing for Public Consultations on the non-confidential version of a validated application dossier is **3 weeks** for AIR/NAS/MRL applications, **60 days** for Renewal applications
- Further information on Public Consultations on submitted applications is available in the Practical arrangements document : https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

CLE ANNUAL CONFERENCE – MAIN QUESTIONS RECEIVED

- The April release and data migration from IUCLID 6.6 to 6.7
- Delays in admissibility declaration and/or confidentiality request assessment
- Questions on specific dossiers/cases/issues
- Use of annotations
- Several applicants mentioned that MS are still requesting dossier submission in Caddy format
- NoS data in IUCLID dossiers and in relation to the admissibility check
- Questions on the update of the practical arrangements and the administrative guidance

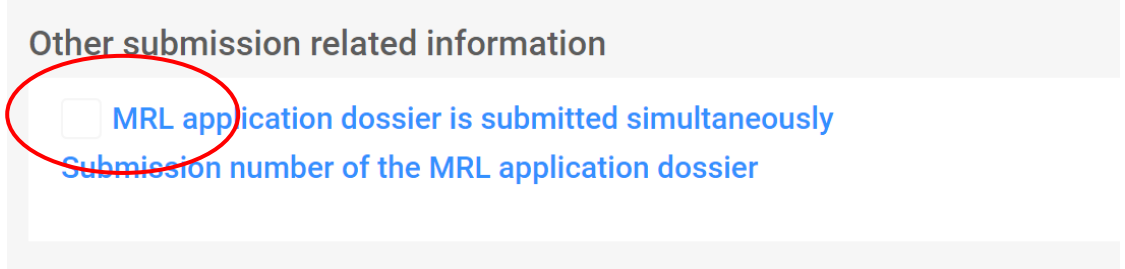
SUBMISSION OF AIR/NAS AND RELATED MRL APPLICATION

An MRL application should be submitted separately ONLY in these cases:

- setting MRLs for additional uses different from representative uses
- assessment of confirmatory data following Art 12 MRL review
- setting import tolerances for uses not authorised in EU

→ More information in the Introduction (page 1-3) to the MRL Applications manual

Remember to tick this box in the dossier header and provide the ERN of the related submission

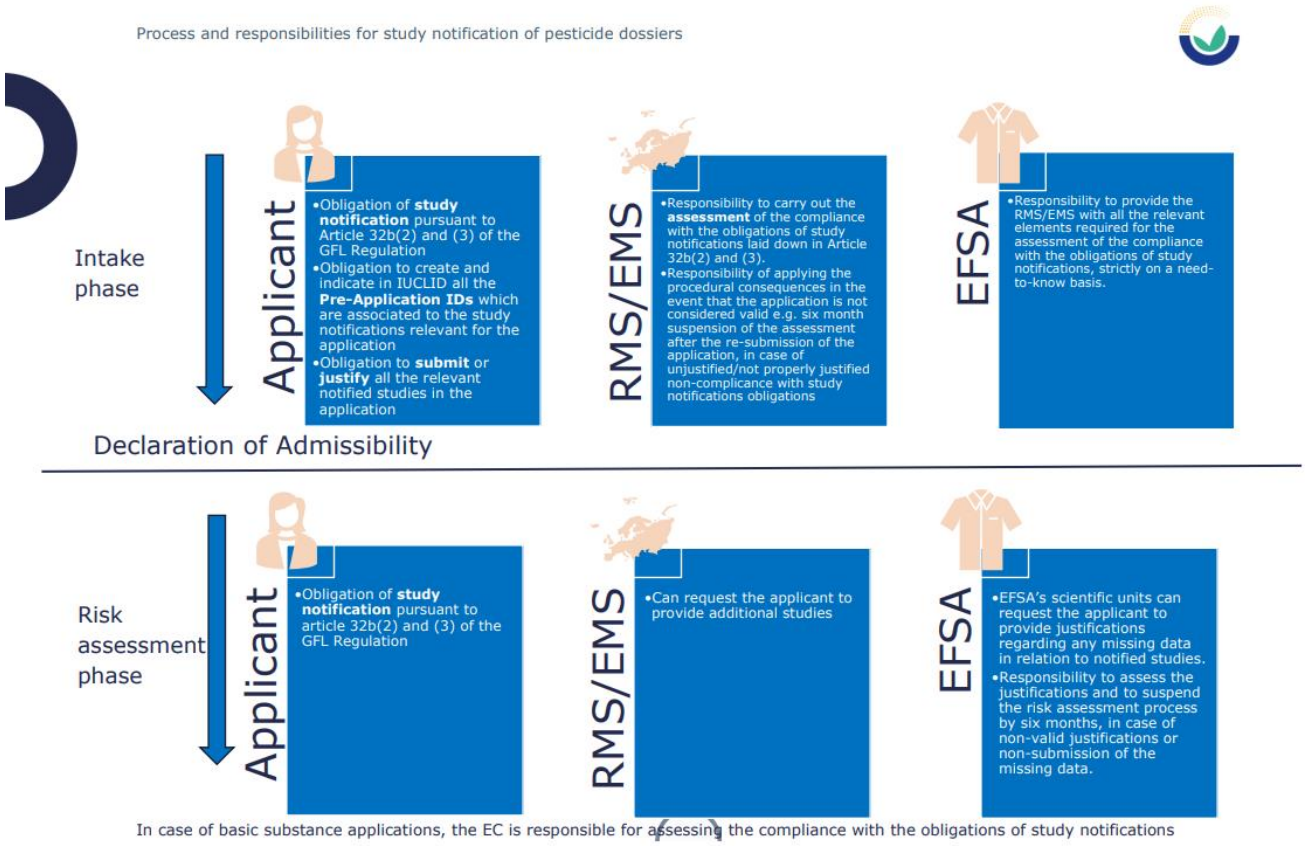


Submission number will be replaced by the **European Reference Number** as from the next IUCLID April release

INTAKE PHASE AND ADMISSIBILITY

- Action point from previous meeting: EFSA to clarify in writing the process and responsibilities for **study notification** of pesticide dossiers

Document available in the Applicant Toolkit webpage https://www.efsa.europa.eu/sites/default/files/2023-01/process-and-responsibilities-for-study-notification-of-pesticide-dossiers.pdf



INTAKE PHASE AND ADMISSIBILITY

- Admissibility checklist will be annexed in the updated version of the Administrative guidance on PPP dossiers

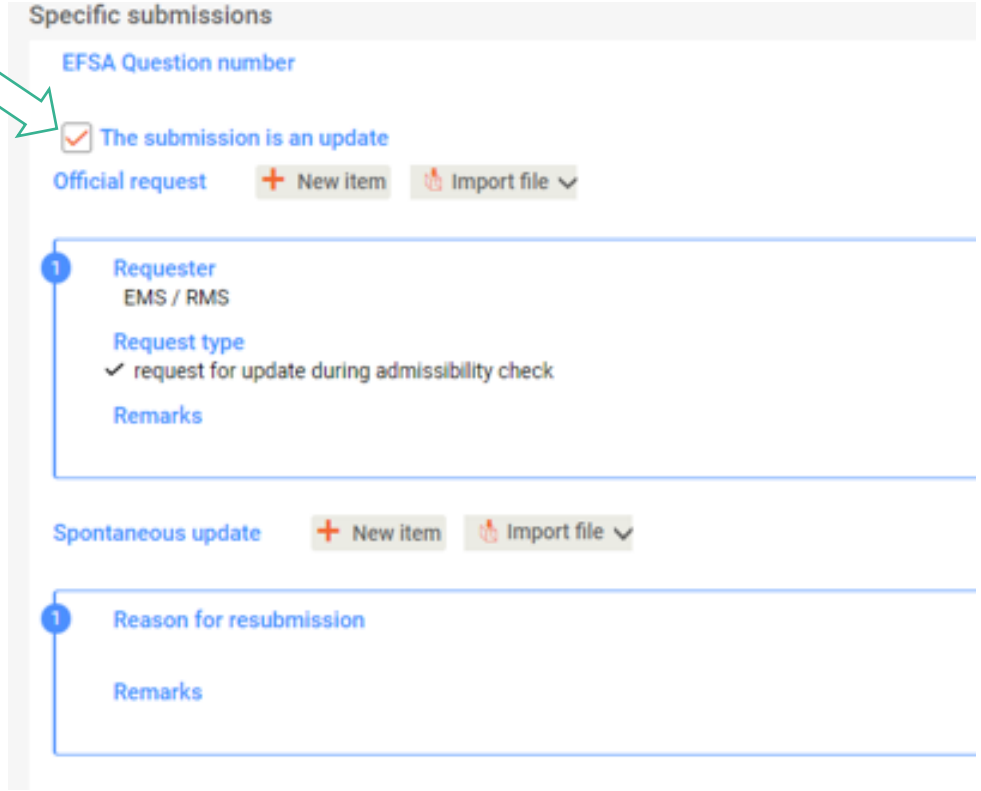
  ⟹ including the check of the ISO name of the 'Active Substance' component (Suggested by DK)

- When preparing your application, make sure to **notify** your **studies** in EFSA's Notification of Studies database and **to submit in the application** all relevant notified studies and information on study notifications (NoS), including, where applicable, any **NoS justification**!!
  - Some tips here https://www.efsa.europa.eu/sites/default/files/2023-01/process-and-responsibilities-for-study-notification-of-pesticide-dossiers.pdf

We would like to hear your feedback on the admissibility process including NoS compliance etc…
Please fill in this excel file

IUCLID APRIL RELEASE

- New feature in the IUCLID dossier header to indicate dossier resubmissions. Please specify '**Official request**' or '**Spontaneous update**'



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