IUCLID submissions: latest news and updates

Chiara Macchi

Alessandro Delfino

FDP Unit

Trusted science for safe food

efsa
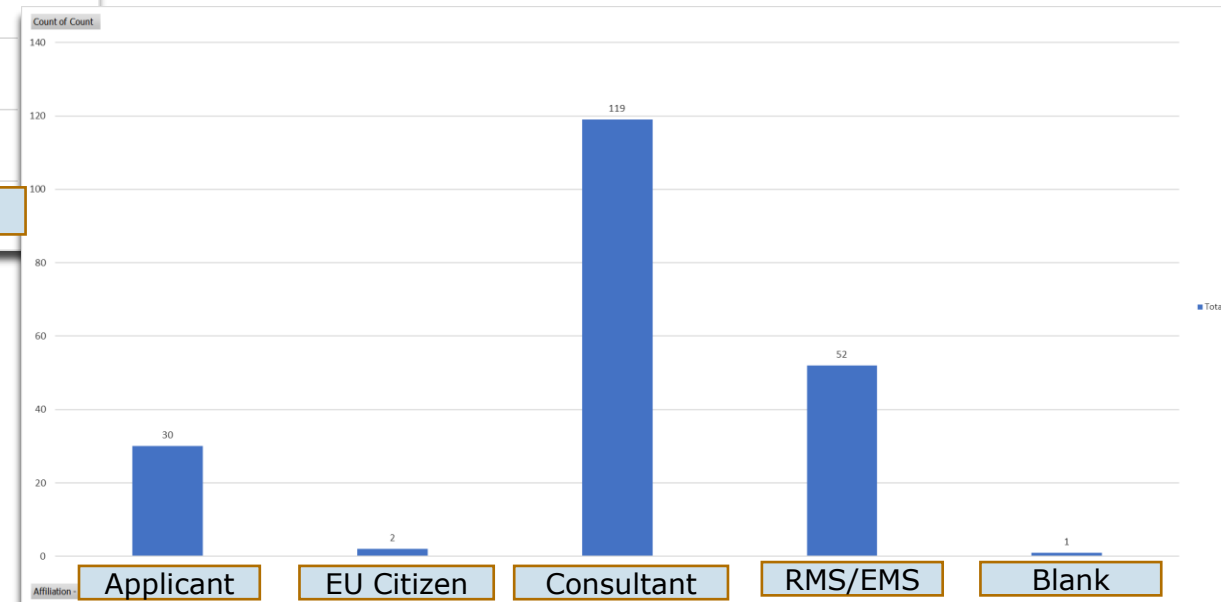European Food Safety Authority

IUCLID questions - update

- We have received 211 IUCLID requests via the **Ask a question** service (https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request)
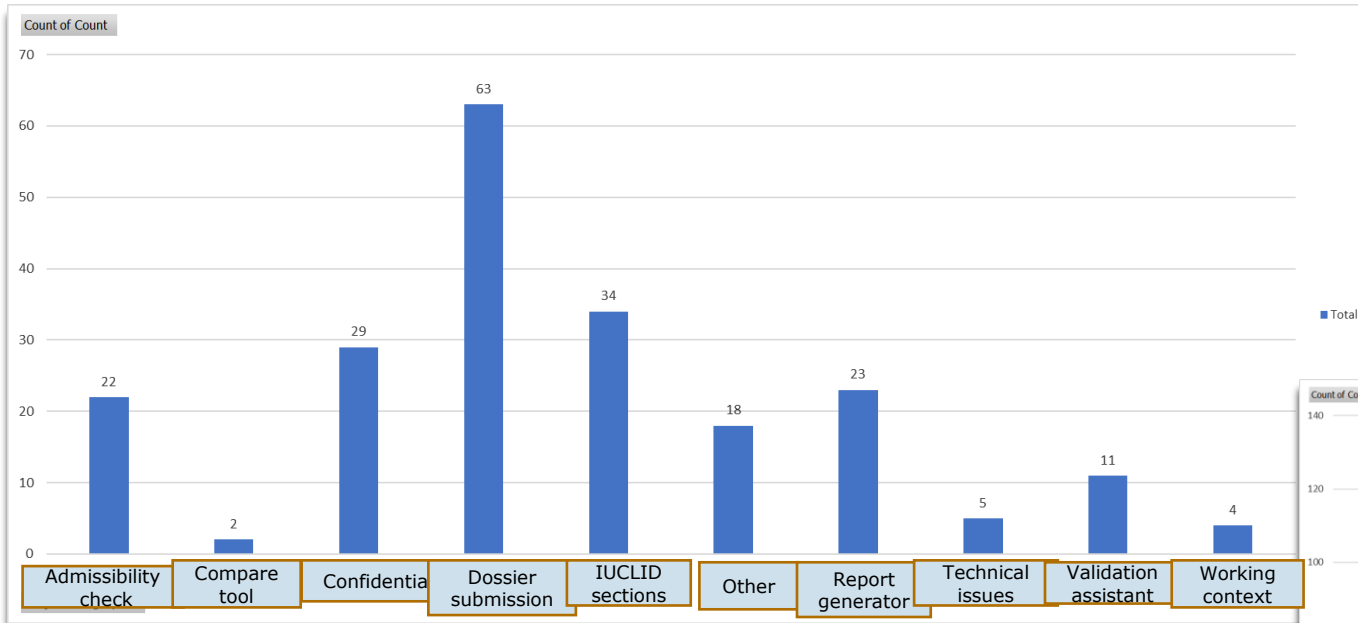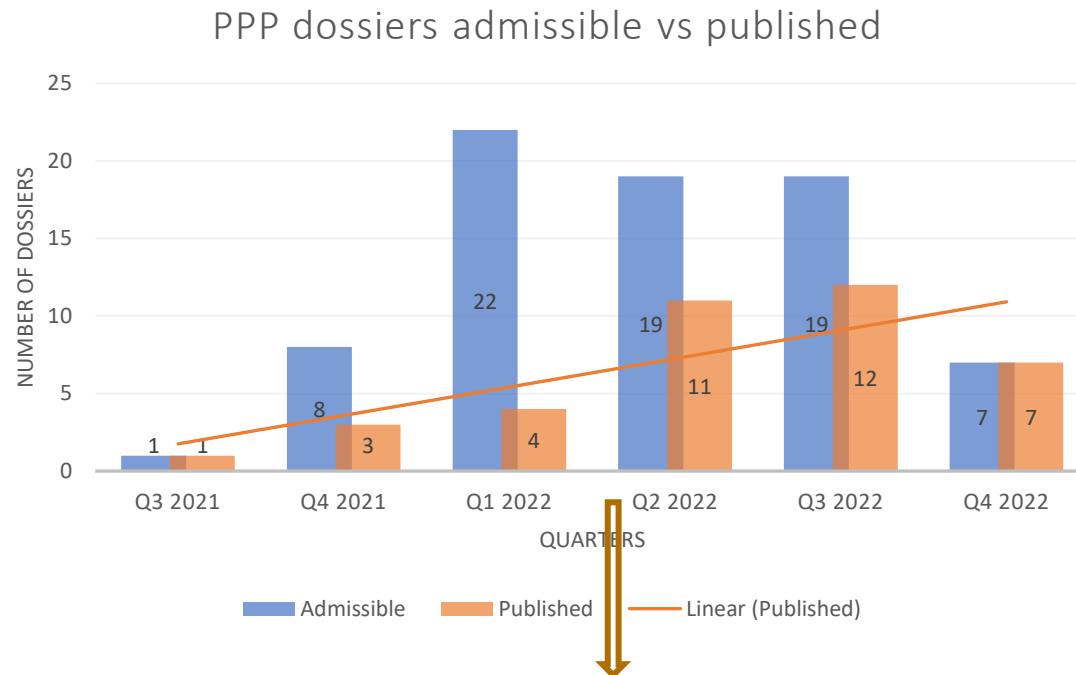

No. of requests per category

No. of requests per requestor type

We have always had problems in publishing PPP dossiers due to the presence of personal data

PPP dossiers admissible vs published

As of Q2 2022 the number of PPP dossiers which remains online is much higher than in the past

To overcome this issue, as of Q2 2022 FDP has taken several actions:

☐ Internal instructions for the publication steps, introducing a light check on personal data

☐ Admissibility checklist for the RMS/EMS which introduces a comparable light check of personal data

☐ Awareness raising with applicants and MSs during IUCLID PSN sub-group meetings.

☐ DEMO on the light check of personal data

IUCLID: dossier publication and support to MS

Teleconferences with RMS/EMS/Applicants in 2022
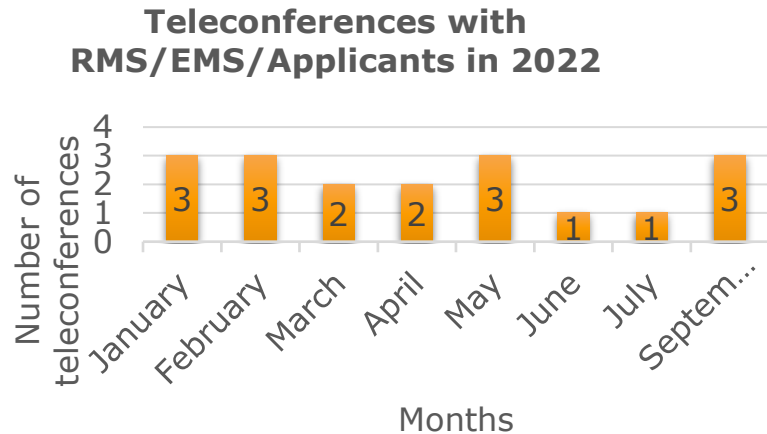
In 2022, 18 ad-hoc teleconferences organised by FDP. Main topics discussed:
- admissibility check
- scientific evaluation
- support RMS/EMS/Applicants on the use of IUCLID

On-going activities:

- Collaboration with CTGB (NL) to optimise admissibility/NoS check

What comes next

- Round of bilateral meetings with Rapporteur Member States to discuss most relevant issues and challenges (including problems with IUCLID, admissibility check, technical IT issues, etc). 10 RMS to begin with

First meeting scheduled on 30 November

General updates

- EFSA has initiated the revision of the "Administrative guidance for the processing of applications for regulated products", stakeholders will be consulted and we aim to publish in Q1 2023

- "IUCLID for the general public training" is almost finalised and should be made available in January 2023
  - Requires advertising
  - Will support public consultations on pesticide dossiers

- Regularly check the **Applicants Toolkit** (https://www.efsa.europa.eu/en/applications/toolkit) for any news

- Consult the "Wiki" tab of the IUCLID PSN channel with most useful links

Admissibility checklist

☐ Action point from previous PSN-IUCLID meeting: MSs to review and comment the admissibility checklist ➡ Deadline 31 October 2022

Updated version available here

Main points reviewed are:

➢ Step 2 NoS check
- Notifier **Legal entity** (LE) vs Submitter/Owner LE
- NoS **justifications**
- **Pre-Application ID mandatory** when notifying studies

STEP 1a – Completeness check of the application				
1.	VALIDATION assistant report has been generated from Agency IUCLID by the RMS according to the latest available validation rules	Yes	No	NA
2.	Error/warnings messages in the Validation report are present	Yes	No	NA
	If YES			
3.	Error/warnings evaluated and commented for resolution/resubmission of dossier by the applicant	Yes	No	NA
	If NOT, proceed with point 4			
4.	Sanitised version of attachments as described in the introduction chapter of the IUCLID manuals is provided by the applicant	Yes	No	NA
5.	Additional mandatory attachments according to National provisions (e.g. application fee proof of payment) are provided by the applicant via email directly to the RMS/EMS	Yes	No	NA
STEP 1a – completeness check passed/not passed				
	Completeness check passed	**Yes**	**No**	
Useful documents				
	• IUCLID active substance application manual: 10.5281/zenodo.509			
	• IUCLID MRL application manual: 10.5281/zenodo.4630193.			

The admissibility checklist will be included in the updated version of the **Administrative guidance** on PPP dossiers which will be released in **Q1 2023**.

Validation Assistant rules

❑ Consultation on proposed changes of Quality warnings (QLT) to Business rules (BR) ended on 25 November 2022

No objections received therefore the **QLT** rules available <u>here</u> **will be converted to BRs** as from April 2023

Priorities for Validation Assistant (VA) rules April 2023 release:

➢ Change of existing rules impacted by the April 2023 format release
➢ REACH type rules (Parent rule=REACH in the <u>RulesMasterFile</u>)
➢ BR_PPP_090:Remove any duplicate datasets from the Other Representative Product section

All the others proposal for April 2023 are deprioritised and will be released in October 2023

An MRL application should be submitted separately <u>ONLY</u> 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
https://zenodo.org/record/6088599#.Y35ANnbMLD4

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

Other submission related information

☐ MRL application dossier is submitted simultaneously
Submission number of the MRL application dossier

Submission number will be replaced by the **European Reference Number** (ERN) as from April 2023

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