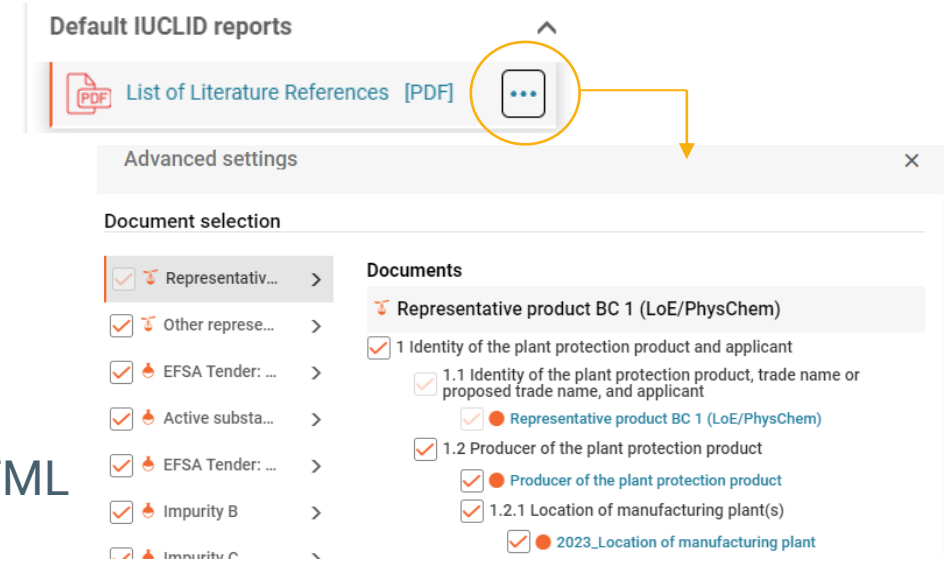
10th meeting of the PSN IUCLID sub-group
11-12 June 2024

IUCLID – REPORT GENERATOR

EUROPEAN FOOD SAFETY AUTHORITY

GENERAL

- New: **advanced settings** from dossiers (from *IUCLID6 8.4.0*)
  - Previously only available for datasets
  - Allows selecting documents to run reports for
    - E.g. get the list of references for only one section of the dossier



- Generation of **DOCX** (Word):
  - since last year it is possible to generate DOCX output from HTML (replacing DocBook) - functionality improved in *IUCLID 8.3.0*
  - some features still under development; incl. generation of PDF
  - first report using HTML/DOCX: PhysChem (see later) - to be expanded in future to other reports

- Remaining **rich-text errors** under investigation by ECHA (see previous communication)

- **Latest templates** (*IUCLID6 v8.0.2*) published in Zenodo

AGGREGATION OF DOSSIERS AND REPORT GENERATOR

- 9th PSN IUCLID meeting: FR asked whether is possible to generate reports for more than one dossier *e.g. AS dossier with several applicants NOT in a task force*

- In principle, there is a possibility to **aggregate dossiers** and run report generator from the aggregated dossier:
  - **Main limitation**: for MIXTURE dossiers (PPP), aggregation works for the product ToC but not for linked substances (e.g. active substance)

- Plan: test current aggregation process on a PPP dossier and analyse whether:
  - Reports can be adapted to cover the requirement, **AND**
  - Aggregation process needs improvements e.g. to work for linked active substances

- PSN to be informed, and potentially asked to test / provide feedback

UPDATE ON ANNOTATIONS (1/3)

- Testing of IUCLID annotation functionality on MRL Application report ("evaluation report")
- Comprehensive feedback received from MSs (HR, EL, DE, FR), on:
  - **Documents to be annotated** i.e., proposal to add annotations
    - on other documents *e.g. LITERATURE* entity → *currently only annotations on summaries and studies are displayed in the report, but this suggestion could be considered if widely agreed and decided how to display*
    - at field level → *not possible now; would introduce high level of complexity to the functionality and the report*
  - **Amendments to the annotations form** (document) i.e., redundant fields, naming conventions, cross reference instead of text field, templates for executive summary and conclusion

    → *to be considered /discussed with ECHA*
  - **Functionality of copying annotations** i.e., copy from a study to a study submitted in another dossier, copy on a case-by-case basis, authorship of copied annotation for resubmitted dossiers

    → *currently only all annotations can be copied in bulk and to a new version of the same dossier but could be proposed as an improvement to ECHA*

UPDATE ON ANNOTATIONS (2/3)

- Comprehensive feedback received from MSs (Croatia, Germany, France), on:
  - **Attachments** i.e., what should be attached (PRIMo, MRL calc., Animal DB calculator. regulatory authorities' evaluation)

    → standard *functionality - its use still to be agreed, but attachments are not required nor printed for the report (if needed, attachment metadata could be printed)*
  - **Display on report** i.e., proposal to separate Executive summary and Conclusions

    → *to be implemented if agreed*
  - Possible **bugs**: name change, created vs modified date

    → *under investigation*
  - **User guide** or instructions for EMS

    → *technical use of annotations described in IUCLID manual, ad hoc documentation for evaluators can be considered*
  - **Access rights** (read, write, delete for users/groups at dossier level i.e., Instance Based Security) & **modification history** - considered essential for full implementation of annotations

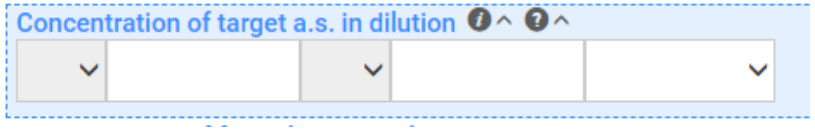
    → *IBS not considered for implementation at the moment (see next slide); modification history improvements to be discussed*

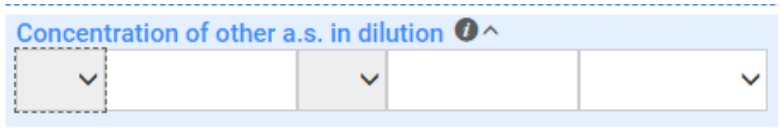
UPDATE ON ANNOTATIONS (3/3)

- **Conclusion and next steps**:
  - EFSA does not consider implementing IBS (Instance Based Security i.e., restricted access at dossier level for different authorities) at this moment
  - EMS can annotate their MRL dossiers in IUCLID and generate the annotated report on a voluntary basis, considering the above-mentioned limitation
  - Proposal:
    - EFSA **amends the display** of annotations in the report as requested
      i.e. separate Conclusions and Executive summary, highlight Conclusions, (if needed) add Attachments metadata
    - Identified **bugs are corrected** i.e., issue with dates
    - If enough interest, EFSA discusses with ECHA the requested **improvements** in the tool
      i.e., annotation form, copying functionality (incl. modification history transfer)
    - The **version of the MRL report with annotations is set as default** in IUCLID
      - NOTE: annotations in the report only appear if set as '*evaluation*' and '*final*'

IMPROVED GAP TABLE REPORT

- GAP table report was improved in IUCLID April release, based on feedback and to align better with official templates:
  - It incorporates the new fields introduced in IUCLID6 8.0.1





  - It presents minor differences between active substance and MRL contexts
  - See mapping file in Excel

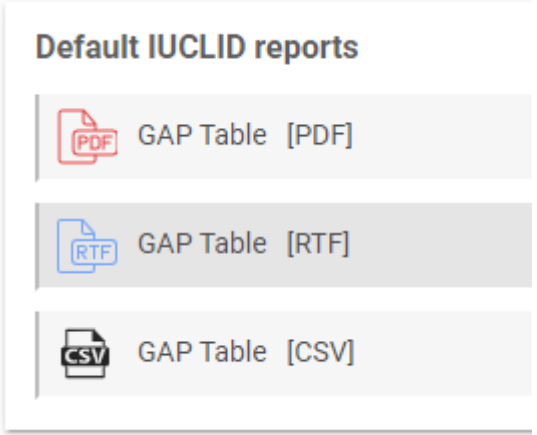
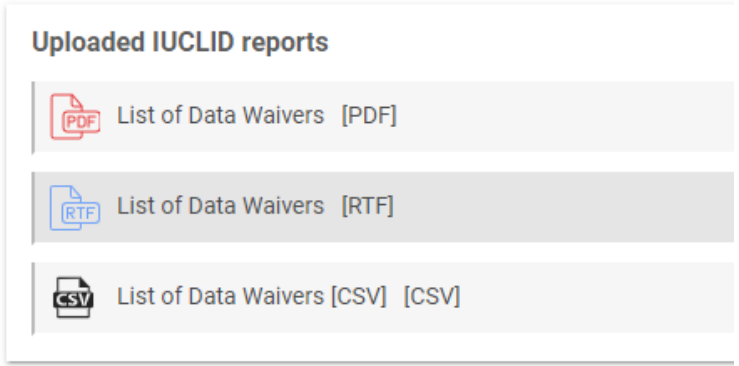


Table 1.1. GAP Table

Crop / situation	MS / country	Product name	F, G or I	Pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					Type	Conc. a.s.	Method / kind	Growth stage and season	No. min-max	Interval (days) min-max	Conc. a.s. in dilution min-max (g/L)	Water min-max (L/ha)	A.s. rate min-max (g/ha)		
Cucumis sativus (Cucumber) - 0232010, (CUMSA) ; Solanum lycopersicum (Tomato) (LYPES)	CEU (BE)	GREENB	G	Onion thrips (Thrips tabaci (THRITB))	WP Wettable powder	>=10 % (w/w)	spraying (3SPRYM) on foliage/ plant by vehicle-mounted - upward spraying ; manual hand-held - upward	BBCH 11 - 89 (- Greenhouse Use: From January to December at infection risk)	6 - 52	7	0.1 - 0.25 **Non-target a.s.:** :	400 - 1000	100 **Non-target a.s.:** :	n.a.	minor use. User: professional. App. rate product: >=1 kg/ha. Max. annual a.s.: <=5200 g/ha.

NEW REPORTS (1/4)

1. Two reports finalised & available under “uploaded reports”:
   - **List of Data Waivers**: provides a list of all data waivers in the dossier, incl. entity (dataset), IUCLID section, document name, data waiving reason and justification



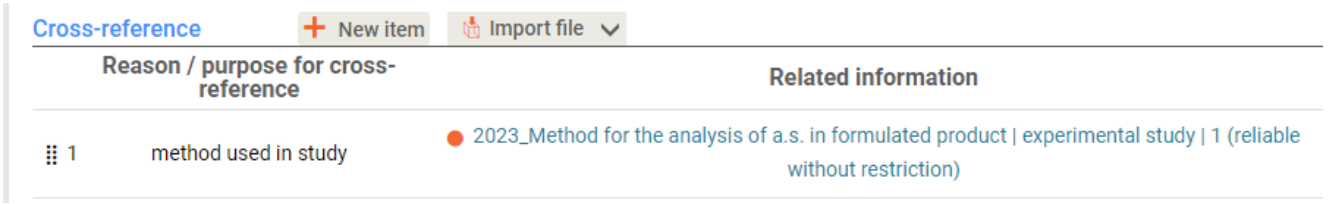
1. List of Data Waivers

Table 1.1. Data waivers

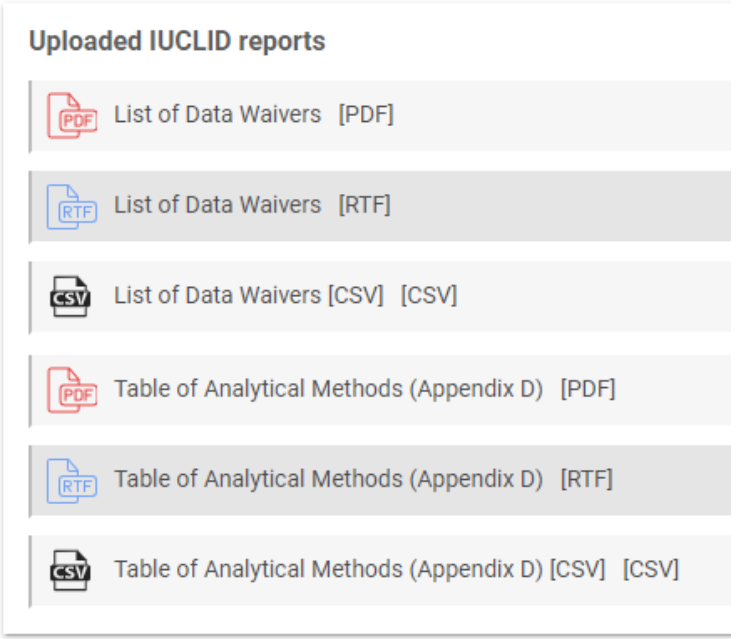
#	Entity	IUCLID section	Document	Data Waiving	Justification for Data Waiving
1	MIXTURE: Representative product BC 1 (LoE/PhysChem)	9.3.2 Transport via air	Transport via air_Justification non-submission	**[study scientifically not necessary / other information available]**	[see below - The type of formulation and inert substances used in the product BC 200 BC are not expected to affect the behaviour of the active substance BC and metabolite 1 in air and data generated with the unformulated material are considered to be applicable to the formulation. Therefore, as it is possible to extrapolate from data provided for the active substance and metabolite 1, no further data is provided on the preparation. For details on the active substance and metabolite 1 data, refer to section CA 7.3 of this dossier.]
2	MIXTURE: Representative product BC 1 (LoE/PhysChem)	2.8 Technical characteristics of the plant protection product	2023_Justification_non-submission_wettability	**[study scientifically not necessary / other information available]**	[Not relevant since the product is an emulsifiable concentrate formulation.]

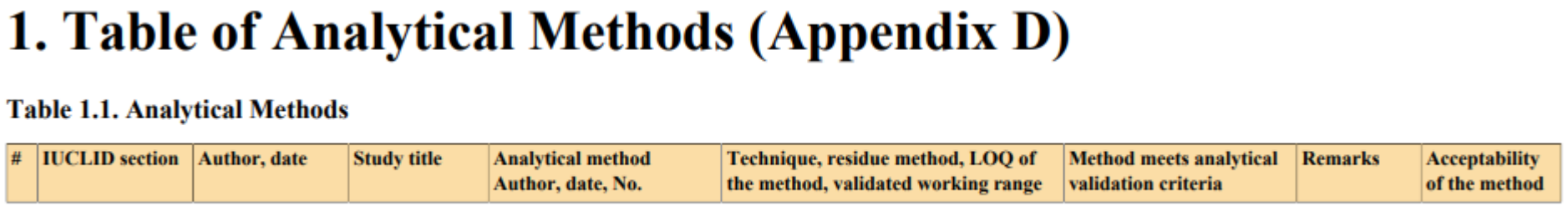
NEW REPORTS (2/4)

1. Two reports finalised & available under “uploaded reports”:
   - **List of Data Waivers**
   - **Table of Analytical Methods (Appendix D):** lists the analytical methods used for each study in the dossier, provided they are linked in the **Cross-reference** section with Reason = ‘*method used in study*’



   - See EFSA’s 2019 admin guidance and Mapping file in excel





1. Table of Analytical Methods (Appendix D)

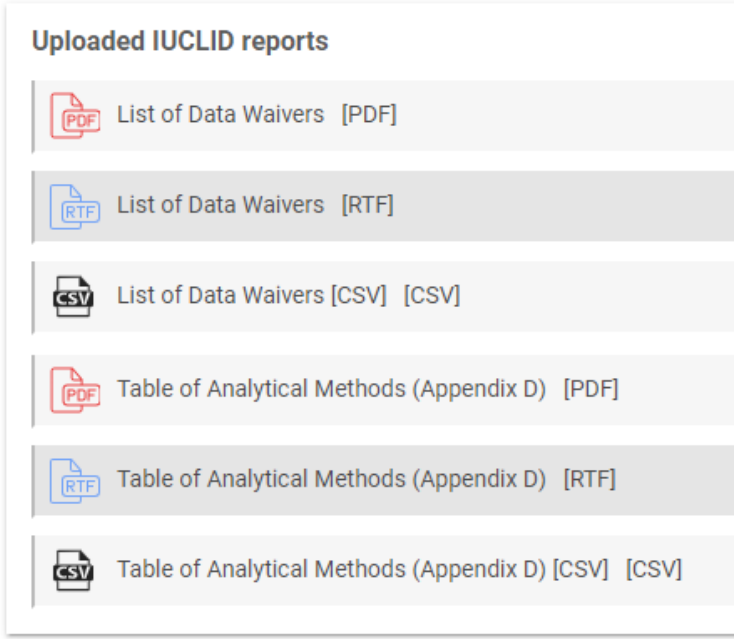
Table 1.1. Analytical Methods

#	IUCLID section	Author, date	Study title	Analytical method Author, date, No.	Technique, residue method, LOQ of the method, validated working range	Method meets analytical validation criteria	Remarks	Acceptability of the method

NEW REPORTS (3/4)

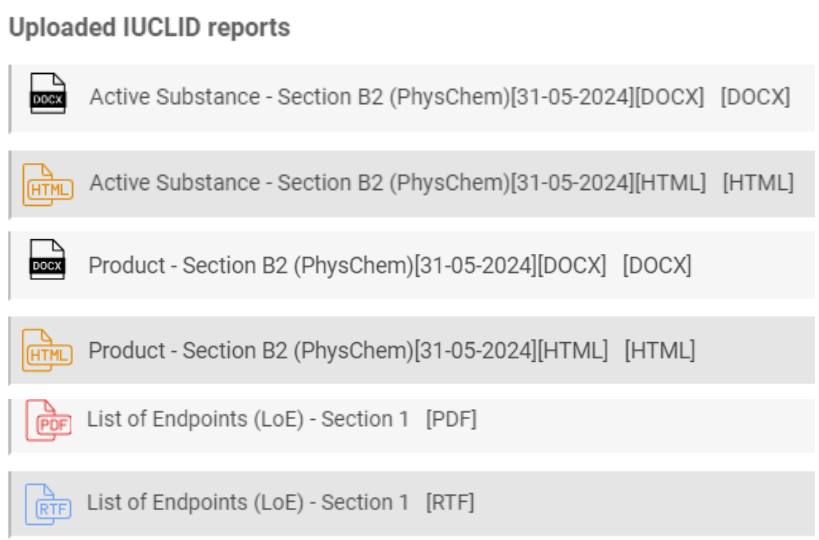
1. Two reports finalised & available under “uploaded reports”:
   - **List of Data Waivers**
   - **Table of Analytical Methods (Appendix D)**

→ To be further tested, collect feedback and push to default by **October IUCLID release**



NEW REPORTS (4/4)

1. Two reports finalised & available under “uploaded reports”
2. Two additional reports to be discussed at ***IUCLID PSN – Working Party on Physical and Chemical Properties and List of Endpoints*** (kick-off on 06/06/2024)
   - 2 reports on **Physical and Chemical properties,** for the active substance and for the product
     → to adapt the existing Document M to the official format (tabular, more concise) and replace it
     → first reports using HTML/DOCX (Word) format



   - the first section of the **List of Endpoints (LoE):** *Identity, Physical and Chemical Properties, Efficacy and Further Information, Methods of Analysis*
     → to be expanded with the remaining sections to have a full LoE following the official template by 2025

→ WP work to be finalised by September-October 2024

OTHER ONGOING AND PLANNED WORK

Report	Description	Status	Estimated deadline
DAR Vol1 (Doc. N1)	• CLH report being developed by a contractor for ECHA • Once finished, result to be adapted by EFSA to create DAR Vol1	Ongoing	• CLH: Dec 2024 • DAR Vol 1: 2025
DAR Vol3 Tox, Ecotox (Doc. M Tox, Ecotox)	• Being reviewed by EFSA experts for feedback	Ongoing	
Appendix I Micoorganisms		Ongoing	Sept 2024
DAR Vol4 (Doc. J)	• Report to be developed to cover Doc J once dismissed	Awaiting requirements	
Microorganism reports	• Reports to substitute old Doc Ms for micro-organisms	Awaiting requirements	

FEEDBACK

- To provide feedback / report issues:
  - Urgent fixes: Ask EFSA
  - Feedback and requests: Report_generator_backlog.xlsx
    - Try to avoid generic statements and provide as much detail as possible
    - Try to distinguish issues regarding the report vs issues with the data entered by the applicant

STAY CONNECTED

SUBSCRIBE TO
efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
Careers.efsa.europa.eu – job alerts

LISTEN TO OUR PODCAST
Science on the Menu –Spotify, Apple Podcast and YouTube

FOLLOW US ON TWITTER
@efsa_eu @methods_efsa
@plants_efsa @animals_efsa

FOLLOW US ON LINKEDIN
Linkedin.com/company/efsa

FOLLOW US ON INSTAGRAM
@one_healthenv_eu

CONTACT US
efsa.europe.eu/en/contact/askefsa

efsa
EUROPEAN FOOD SAFETY AUTHORITY