

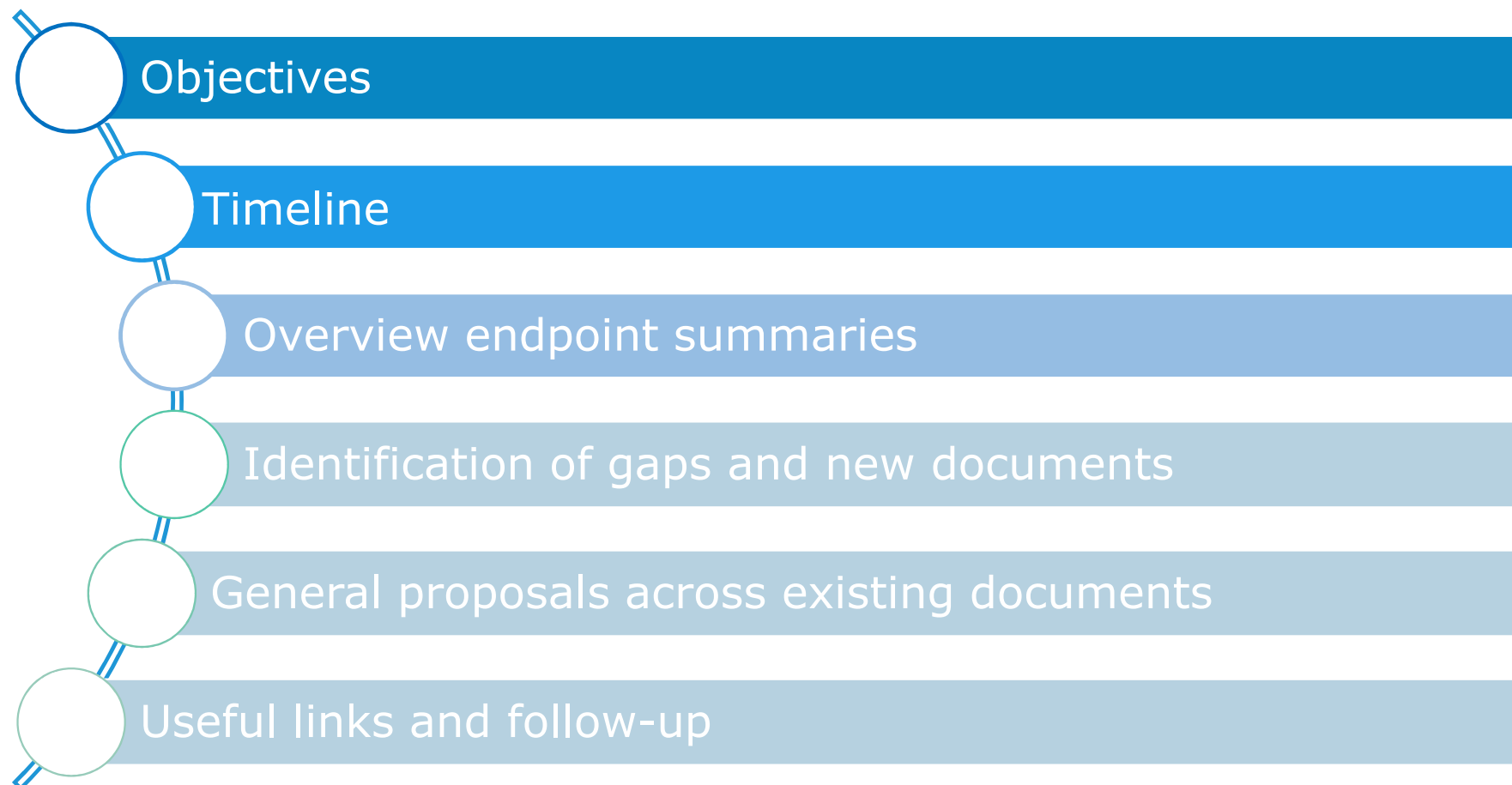


TG IUCLID PESTICIDE meeting
17-18 June 2020

Section 8 Ecotoxicology

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Trusted science for safe food



to **agree adaptations to endpoint summaries which can be proposed for inclusion in the October release of IUCLID** (i.e. straight forward and non-controversial amendments), focusing on the endpoints for which comments were received during the pilot phase of IUCLID and in line with the EU pesticides LoEP.

Where the sub-group agrees a more thorough review of a document is required, it is sufficient to identify these **documents which a can be analyzed at a later phase in the project** and worked on in small group over the year and may be **included in the October 2021 release**

Timeline for ecotox experts

08/05

- Finalization of OHTs

12/05-
29/05

- Review of summary endpoints ***

20/05

- 1st Interim meeting – progress of the work, outstanding issues
- Experts are invited to suggest points for discussion

29/05

- Pilot case meeting
- DL for providing comments

01/06-
08/06

- Addressing of the comments received
- 2nd interim meeting (if necessary, based on the comments received; planned for **10th June 2020**)

17/06-
18/06

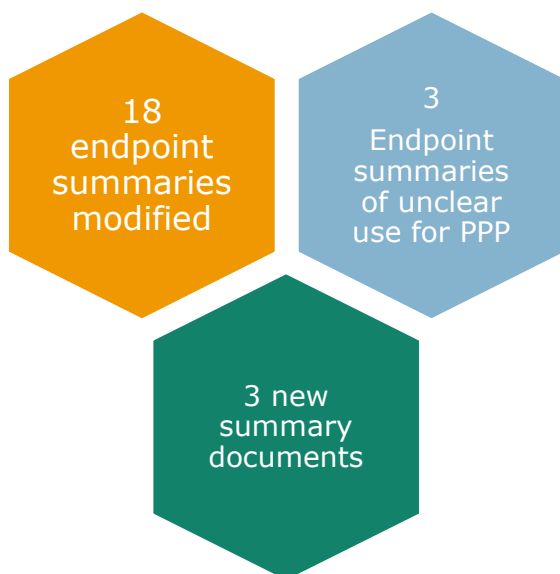
- CORE technical group meeting (formal invitation and documents published)
- Dates confirmed (**17/06 (PM)- 18/06(AM)**)
- Presentation of final agreements

Comments considered during the review of the existing endpoint summaries:

- Comments included in the IUCLID backlog
- Comments were provided from NZ EPA, Bayer, UBA and JKI during the commenting phase May 2020

THANK YOU!

Overview of the ENDPOINT SUMMARIES



- AquaticToxicity
- BiologicalEffectsMonitoring
- SpecificInvestigationsOtherStudies
- BioaccumulationAquaticSediment
- EcotoxicologicalInformation
- ToxicityTo Aquatic Invertebrates (2)
- ToxicityToFish (2)
- SedimentToxicity
- ToxicityPlants
- ToxicityToAquaticAlgae
- ToxicityToBirds
- ToxicityToOtherAboveGroundOrganisms
- ToxicityToSoilMacroorganismsExceptArthropods
- ToxicityToSoilMicroorganisms
- ToxicityToTerrestrialArthropods
- ToxicityToTerrestrialPlants
- Effects on biological methods of STP
- Risk assessment summary document
- RAC reporting document

Identification of “gaps”

- Several “gaps” were identified
 - Gaps related to the reporting of taxa as well as to the risk assessment
 - **All risk assessment** documents are missing
 - However, those documents are not fully fit for purpose for structured data and do not reflect the guidance documents in used.
 - If this needs to be done, the proposal is to update/create documents for October 2021 release if necessary
 - NEW IUCLID documents were created for that purpose:
-
- ✓ Effects on biological methods of STP
 - ✓ Risk assessment summary document (New document)
 - ✓ Aquatic toxicity_RAC reporting (Aquatic toxicity document?)

Risk assessment reporting

Line no.	Field name	Field type Display type	Picklist Freetext template	Help text	Remarks Guidance Cross-reference
1.	Administrative data	Header 1		Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.	
2.		Confidentiality Display: Basic			
3.	Ecotoxicological risk assessment	Header 1			
4.	Risk assessment to birds	Header 2			
5.		Text (rich-text area) Display: Basic		Please provide a summary of the risk assessment to birds	

24.	Additional information for the ecotoxicological risk assessment of pesticides	Header 1		A document as attachment pdf/doc can be provided where the risk assessment for the different taxa is conducted according to the agreed guidelines and for addressing the EU pesticides data requirements	
25.		Text (rich-text area) Display: Basic			

- ✓ Risk assessment fields for free text
- ✓ Possibility of including attachments (e.g. CP volume)

Link to the newly created documents after 2nd interim meeting

<https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objaction=overview&objid=23430592>

Line no.	Field name	Field type Display type	Picklist Freetext template	Help text	Remarks Guidance Cross-reference
26.	Summary and evaluation	Header 2		Each row in the table can contain one attachment. To add a row, click on the button Add.	
27.		Block of fields (repeatable) Start			
28.	Type of report	Text (255 char.) Display: Basic		This field is used to define the type of document that is attached.	
29.	Attached document	Attachment (single) Display: Basic		To add an attachment, click on the blue paper-clip icon, and then the green plus icon. This opens a dialogue box for file upload.	
30.	Sanitised Attached document	Attachment (single) Display: Basic		Option to include as sanitised version of the document above for publication	
31.	Remarks	Text (255 char.) Display: Basic		If needed, give any further explanations concerning attachment(s).	
32.		Block of fields (repeatable) End			

RAC reporting for aquatic toxicity

- ✓ Test organisms
 - ✓ Time-scale
 - ✓ Tier
 - ✓ Assessment factor
 - ✓ Type of RAC value
-
- ✓ Possibility of including attachments (e.g. SSD calculation, mesocosm studies, etc)
 - ✓ Generic but pragmatic approach

Link to the newly created documents after 2nd interim meeting

<https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objaction=overview&objid=23430592>

9.	Test organisms	List multi. (multi-select list with remarks) Display: Basic	Picklist values: - Freshwater fish - Marine fish - Freshwater aquatic invertebrates - Marine aquatic invertebrates - Freshwater sediment dwelling organisms - Marine sediment dwelling organisms - Algae - Aquatic macrophytes - other:		
10.	Time scale	List (picklist) Display: Basic	Picklist values: - Acute - Chronic	Select the time scale for the risk assessment	
11.	Tier	List (picklist) Display: Basic	Picklist values: - Tier 1 - Tier 2a - Tier 2b - Tier 2c - Tier 3	Select the tier for the risk assessment	
12.	Assessment factor	List multi. (multi-select list with remarks) Display: Basic	Picklist values: - 10 - 100 - other:	Select the assessment factor for the risk assessment	
13.	Type of RAC value	List (picklist) Display: Basic	Picklist values: - RAC _{tier1} - RAC _{mesocosm} - RAC _{SSD} - RAC _{tier2a} - ETO-RAC - ERO-RAC	Select the type of RAC derived	
14.	RAC value	Numeric (decimal including unit) Display: Basic	Unit [xx]: - ng/L - µg/L	Please include the RAC value and the pertinent units	
16.	Additional information for supporting the RAC values derivation	Header 1		Geomean calculations, SSD calculations, and mesocosm studies can be summarized and attached under this section.	
17.		Text (rich-text area) Display: Basic			
18.		Block of fields (repeatable) Start			
19.	Type of report	Text (255 char.) Display: Basic		This field is used to define the type of document that is attached.	
20.	Attached document	Attachment (single) Display: Basic		To add an attachment, click on the blue paper-clip icon, and then the green plus icon. This opens a dialogue box for file upload.	

Proposals across endpoint summaries

- No merging of documents – so, short-term and long-term documents were kept as previously organized
- **Cross-references** were added in all the documents (list of “links to relevant study records”).
- Possibility of **reporting higher tier testing** is now given for all relevant taxa
- Endpoints (dose descriptors) were included when necessary. E.g. NOEC, LC₁₀ or EC₁₀, etc.
- Description of key information was completed (more aligned with LoEP)
- Inclusion of pick lists for basis for effects and test organisms in all documents based on the information in the study records
- Additional units were reported (a.s., metabolite)
- Also the possibility of reporting greater than values (EC₅₀>2000 mg/kg bw).
- IUCLID wording and structure were kept as much as possible!
- Possibility of having **attachments** was included in the risk assessment summary document

Proposals across endpoint summaries

Line no.	Field name	Field type Display type	Picklist Freetext template	Help text	Remarks Guidance Cross-reference
1.	Administrative data	Header 1		Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.	
2.		Confidentiality Display: Basic			
3.	Link to relevant study record(s)	Header 1		Provide here the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.	
4.	Study name / type	Link to endpoint (multiple) Display: Basic			Cross-reference: <u>ENDPOINT_STUDY_RECORD.ToxicityToBirds</u>
5.	Results	Read-only Display: Basic			

- ✓ Administrative data – flag for confidentiality
- ✓ List of relevant studies
- ✓ Field for additional information
- ✓ Reporting of higher tier studies

27.	Higher tier testing for safety assessment	Header 1		Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	
28.		Text (rich-text area) Display: Basic			

Proposals across endpoint summaries

Key information section

11.	System identifier	List (picklist) Display: Basic	Picklist values: - Freshwater invertebrates - Marine water invertebrates	Select the system identifier (indicate fresh, estuarine or marine)	
12.	Test organisms (species)	List (picklist) Display: Basic	Picklist values: - Daphnia magna - Daphnia cucullata - Daphnia pulex - Daphnia pulex - Daphnia pulex - Daphnia sp. - Americacysis babia (previous name: Mysidopsis babia) - Artemia salina - Artemia sp. - Asellus intermedius - Asellus sp.	Select the organism(s) for which the endpoint was derived.	
13.	Parent/Metabolite	List (picklist) Display: Basic	Picklist values: - Parent - Metabolite - Formulated product		
14.	Substance	Link to entity (single) Display: Basic			Cross-reference: SUBSTANCE

Line no.	Field name	Field type Display type	Picklist Free-text template	Help text	Remarks Guidance Cross-reference
15.	Basis for effect	List multi. (multi-select list with remarks) Display: Basic	Picklist values: - reproduction - reproduction: embryo numbers in the brood pouch (for Potamopygus, TG 242) - reproduction: production of clutches per surviving parent organism (for L. stagnalis, TG 243) - mortality - mortality: Number of living offspring produced per surviving parental animal (for Daphnia magna, TG 211) - mortality: Total number living offspring produced at the end of the test per parent daphnia at the start of the test excluding from the analysis parental accidental and/or inadvertent mortality (TG 211) - immobilisation - growth - growth: proportion of abnormal eggs (for L. stagnalis) - behaviour - morphology - sex ratio (for D. magna) - other: - not specified	Select the basis for effect from which the endpoint was derived. If not available, select 'other' and enter name of the basis for effect.	
16.	Dose descriptor	List multi. (multi-select list) Display: Basic	Picklist values: - LC ₅₀ for aquatic invertebrates - EC ₅₀ for aquatic invertebrates	Select the dose descriptor(s) associated to the endpoint assessed.	
17.	Effect conc.	Numeric range (decimal with picklist) Display: Basic	Upper numeric field [xx]: - < - <= - ca. Unit [xx]: - µg a.s./L (nom) - mg a.s./L (nom) - g a.s./L (nom) - µg a.s./L (mm) - mg a.s./L (mm) - g a.s./L (mm) - µg-product/L (nom) - mg-product/L (nom)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable	

- ✓ List of spp and basis for effects in picklist (in line with endp study records)
- ✓ Inclusion of greater than values
- ✓ New units
- ✓ New endpoints (dose descriptors) when necessary

Follow-up and useful links

IUCLID shared folder:

<https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objId=21942353&objAction=browse&sort=name>

Background material:

<https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objId=23303284&objAction=browse&viewType=1>

Document updated plan:

<https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objaction=overview&objid=23175806>

Endpoint summaries ECOTOX (section 8) – See folder (Endpoint summaries REVIEWED):

<https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objId=23315545&objAction=browse&viewType=1>

DL for further comments (via e-mail): **18/06 CoB**

For further questions, please let us know: laura.villamarbouza@efsa.europa.eu;
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attention and
collaboration!!!**