15th meeting of the PSN IUCLID sub-group
15 April 2026



UPDATE ON FORMAT CHANGES

FDP/IDATA

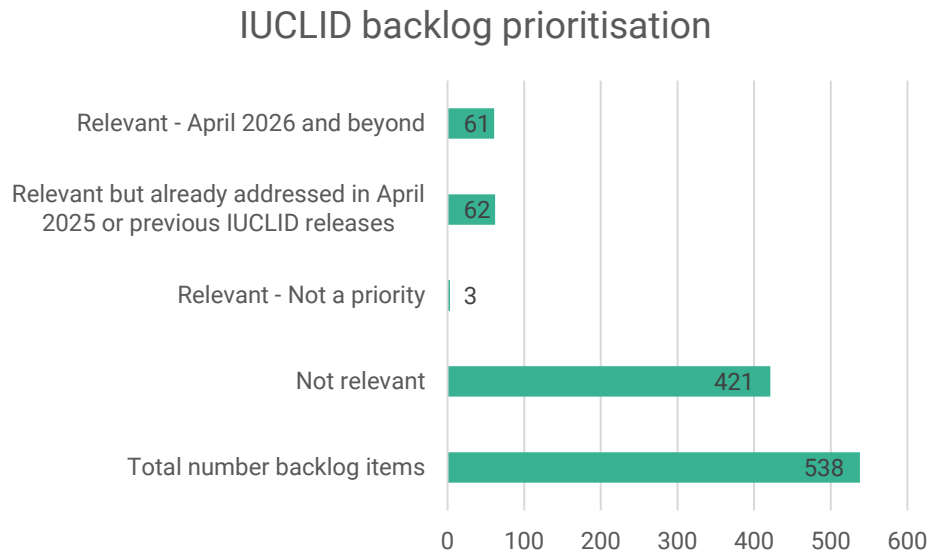
EUROPEAN FOOD SAFETY AUTHORITY

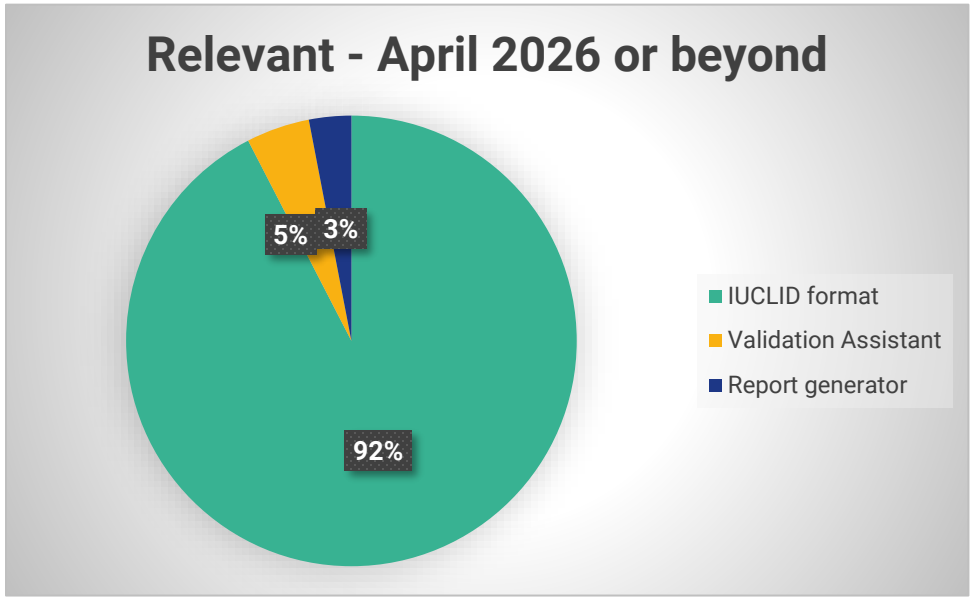
FORMAT CHANGES AND IUCLID BACKLOG FILE

- Requests for IUCLID format changes must be submitted via the dedicated **IUCLID backlog file**.
- Since last year, the backlog file has been **reviewed annually** to increase transparency in its management.
- To ensure that items relevant for EFSA are appropriately considered, **EFSA and ECHA are carrying out an annual joint assessment** of backlog items.
- In 2026, the joint assessment is expected to be **finalised by the beginning of May**.

FORMAT CHANGES AND IUCLID BACKLOG FILE

During last year's joint assessment exercise, **126 backlog items relevant for EFSA** were classified as 'To be closed', 'To be prioritised' or 'Not a priority'. The prioritisation and corresponding justifications are reflected in the IUCLID backlog file





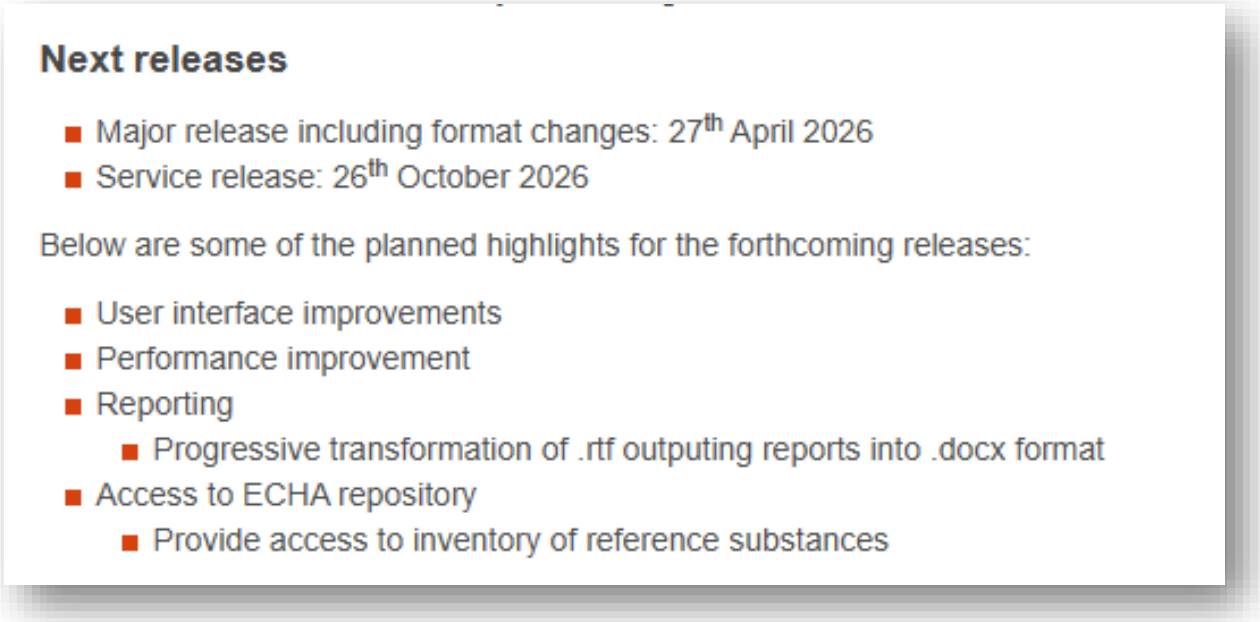
*The analysis was conducted using backlog items added up to July 2025.

IUCLID 6.10 RELEASE

- The next IUCLID major release, **IUCLID 6 Version 10**, scheduled for release on 27 April 2026, will include:

  ➢**EFSA-specific format changes**

  ➢**OECD-CORE-DOMAIN format changes**



Do you need to prepare for the new IUCLID format and features introduced in version 10?
Watch ECHA's webinar on 12 May at 11:00 - 15:00 CEST



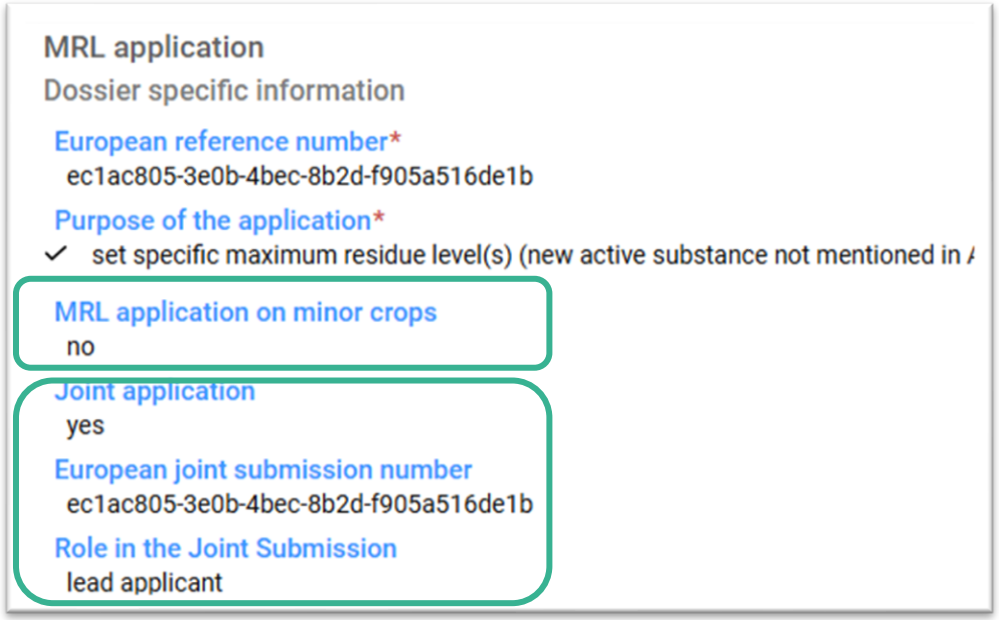
EFSA-SPECIFIC FORMAT CHANGES: EU_PPP

#EFSA_EU

DOSSIER HEADER: MRL

DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS

- **Addition of '*Joint submission*' fields**
- New field '***MRL application on minor crops***' to indicate whether the application concerns minor crops



METABOLITES

❑ FLEXIBLE_SUMMARY.Metabolites

- ➢ **New** fields added to describe metabolite origin, presence in the product, and relevant non-dietary exposure groups.

Link to metabolite dataset	Compound found in	The metabolite is present in the product	Relevant exposed group
Test GB | EC 123332-66-8 | 72652-978-1	soil	yes - present in the product	✓ Operators

❑ FLEXIBLE_SUMMARY.InformationEcotoxicityMetabolites and InformationToxicityMetabolites

- ➢ New field '*Link(s) to relevant study record(s)*' added to support the identification/characterization of the eco/toxicological properties of the metabolite

Backlog #3169 #3266 # 3267

ECOTOXICOLOGICAL STUDIES

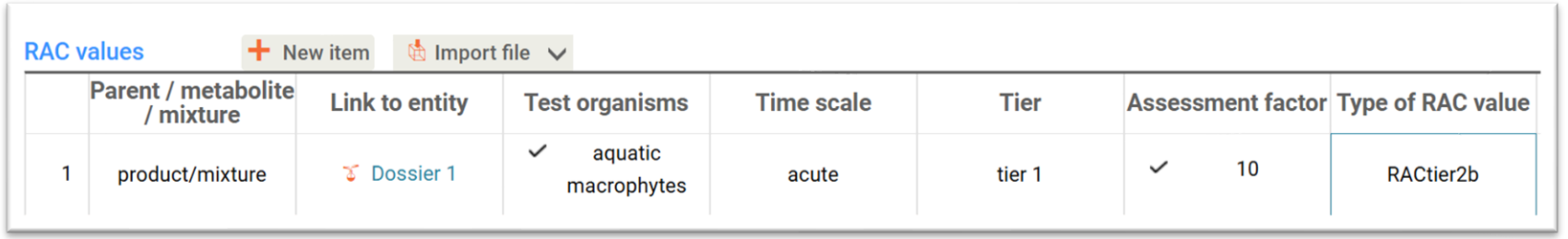
Backlog #3264 #3263 #3315

❑ FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides

- New fields added to provide additional summary information for ecotoxicological risk assessment. Tier 1, Tier 2, Tier 3 and higher-tier assessments can be reported to summarise the overall risk characterisation, including metabolites

❑ FLEXIBLE_SUMMARY.AquaticToxicityRacReporting

- RAC values can be referred to the product/formulation.
- The field '**Type of RAC value**' has been aligned with the values outlined in the EFSA (2013) guidance on **Pesticides and aquatic organisms**
- The document has been removed from the Active substance dataset and Other substance datasets (e.g. metabolite, impurities) and is kept in the Product dataset. A legacy section has been added to allow migration of data reported in previous submissions.


RAC values

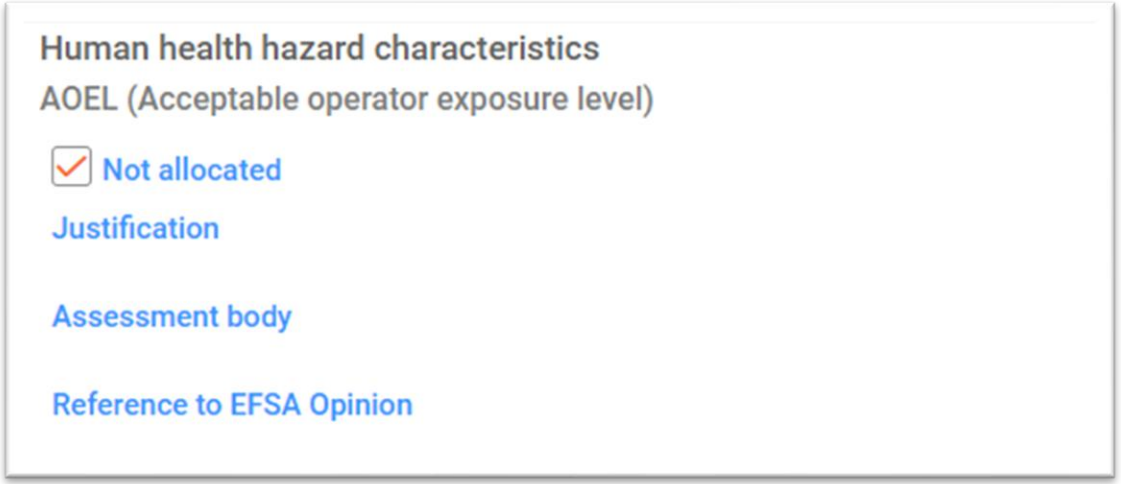
+ New item | Import file

	Parent / metabolite / mixture	Link to entity	Test organisms	Time scale	Tier	Assessment factor	Type of RAC value
1	product/mixture	Dossier 1	✓ aquatic macrophytes	acute	tier 1	✓ 10	RACtier2b

TOX AND EXPOSURE

- **FLEXIBLE_SUMMARY.ExpectedExposure**
  - Minor changes to picklists and field types (from numeric values to range values). The changes are made to align with FLEXIBLE_SUMMARY.ToxRefValues.

- **FLEXIBLE_SUMMARY.ToxRefValues**
  - New dynamic rule to hide fields when derivation of the reference dose (AOEL) is '*Not allocated*'
  - New field "***Reference to EFSA Opinion***" added to all blocks within the document, to be used when the critical endpoint is not available.

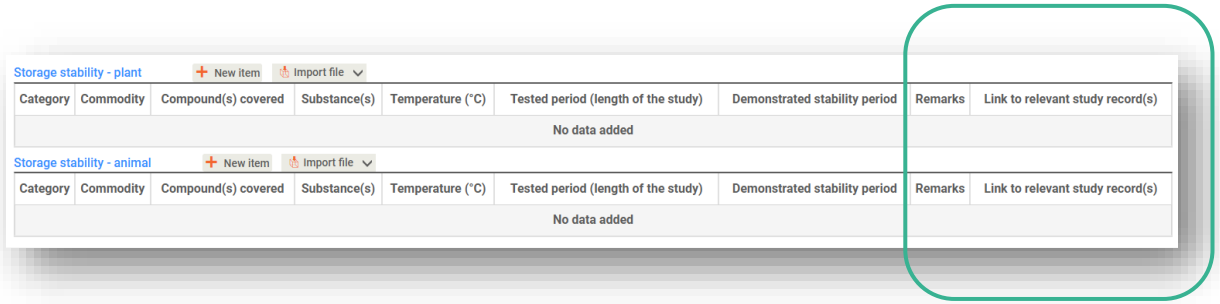


Backlog #3265 #3270

RESIDUES

ENDPOINT_SUMMARY.StabilityResiduesCommodities

- The field "*Link to relevant study record*" has been moved to "**Storage stability – plant**" and "**Storage stability – animal**" to clearly distinguish between plant and animal studies.



Storage stability - plant + New item Import file

Category	Commodity	Compound(s) covered	Substance(s)	Temperature (°C)	Tested period (length of the study)	Demonstrated stability period	Remarks	Link to relevant study record(s)
No data added								

Storage stability - animal + New item Import file

Category	Commodity	Compound(s) covered	Substance(s)	Temperature (°C)	Tested period (length of the study)	Demonstrated stability period	Remarks	Link to relevant study record(s)
No data added								

FLEXIBLE_SUMMARY.ResiduesInLivestock

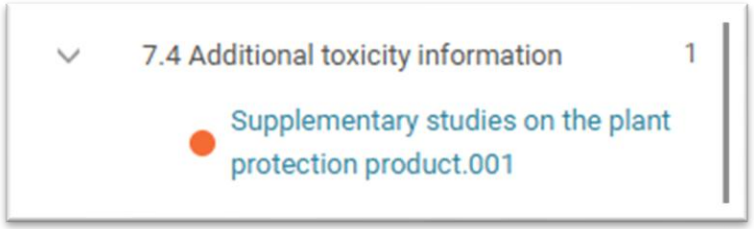
- New fields added to align with the official format for List of Endpoints.

Closest feeding level	Residue definition monitoring	Residue definition Risk Assessment	Mean residue at closest feeding level	Highest residue at closest feeding level
mg/kg bw per day			mg/kg	mg/kg

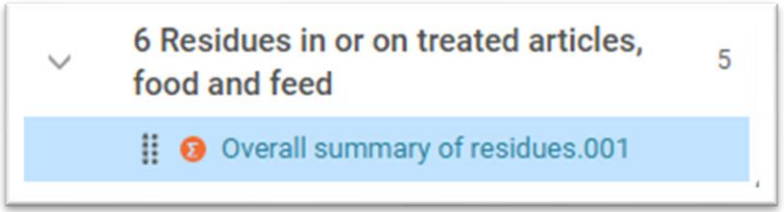
Backlog #3261 #3269

MICROORGANISM – TOC UPDATE

- **ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes** added to section 7.4 of the Product dataset to allow reporting of additional acute toxicity data via other exposure routes.



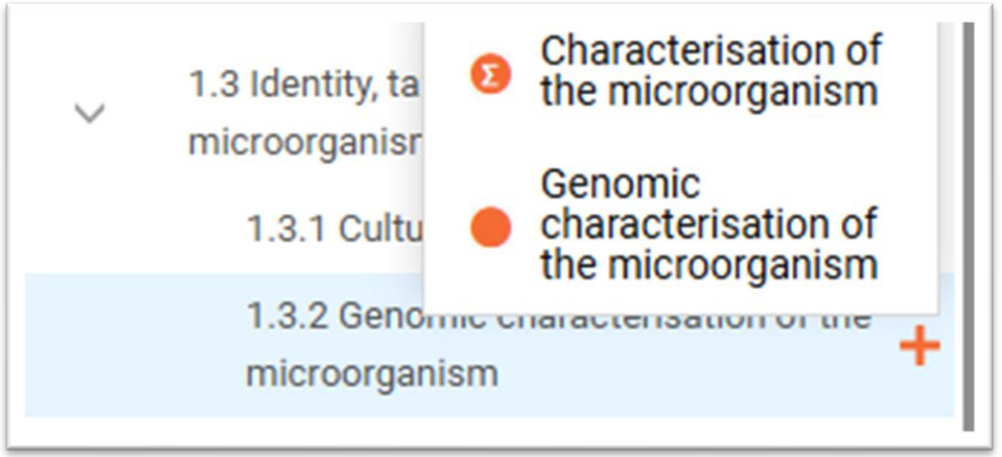
- **ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs** moved from section 11 ‘Documents applicable to the former data requirements’ to section 6 of the active substance dataset to provide an overall summary of residues



Backlog #3317 #3316

MICROORGANISM

- **ENDPOINT_SUMMARY.CharacterisationMicroorganism**
  - New Endpoint Summary introduced to conclude on the key characteristics of the microorganism.



IUCLID 2027 – Open point

- Should a new Endpoint Study Record (ESR) be introduced to report characterisation/identification studies not based on WGS/sequencing?
- Or should the existing document “Genomic characterisation of the microorganism” be extended to cover these study types?

Backlog #3260

CHANGES FROM THE WP CONFIDENTIAL INFORMATION

Backlog #3262 #3305 #3306

❑FLEXIBLE_RECORD.ManufacturerEFSA

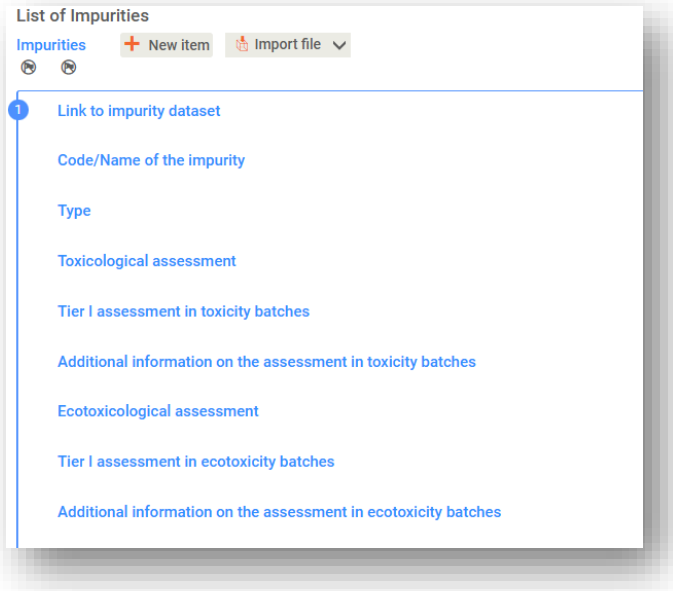
- ➢New “Data source” block added to allow reporting of literature references for studies related to the manufacturing process.

❑ ENDPOINT_STUDY_RECORD.AnalyticalProfileOfBatches

- ➢New endpoints have been added to report data on the batches used in mammalian toxicity and ecotoxicity studies.

❑FLEXIBLE_SUMMARY.Impurities

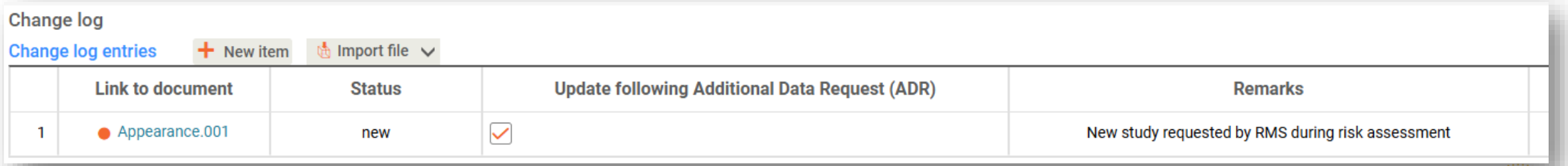
- ➢ New fields introduced to summarise the risk assessment of impurities present in batches used for toxicity and ecotoxicity studies.



OTHER CHANGES

- **FLEXIBLE_RECORD.AssessmentOtherAuthorities** added to mixture datasets other than the main mixture dataset to allow reporting of available assessment information carried out by other authorities, for example on co-formulants

- **FLEXIBLE_RECORD.ChangeLog**
  - **New** helptext added to clarify which **studies** submitted in the application should be considered **new, updated, obsolete,** or **previously used**.
  - A **checkbox** has been added to indicate whether a **study** was **submitted** in response to an **additional data request by the Competent Authority**.


Change log

Change log entries + New item Import file

	Link to document	Status	Update following Additional Data Request (ADR)	Remarks
1	Appearance.001	new	☑	New study requested by RMS during risk assessment

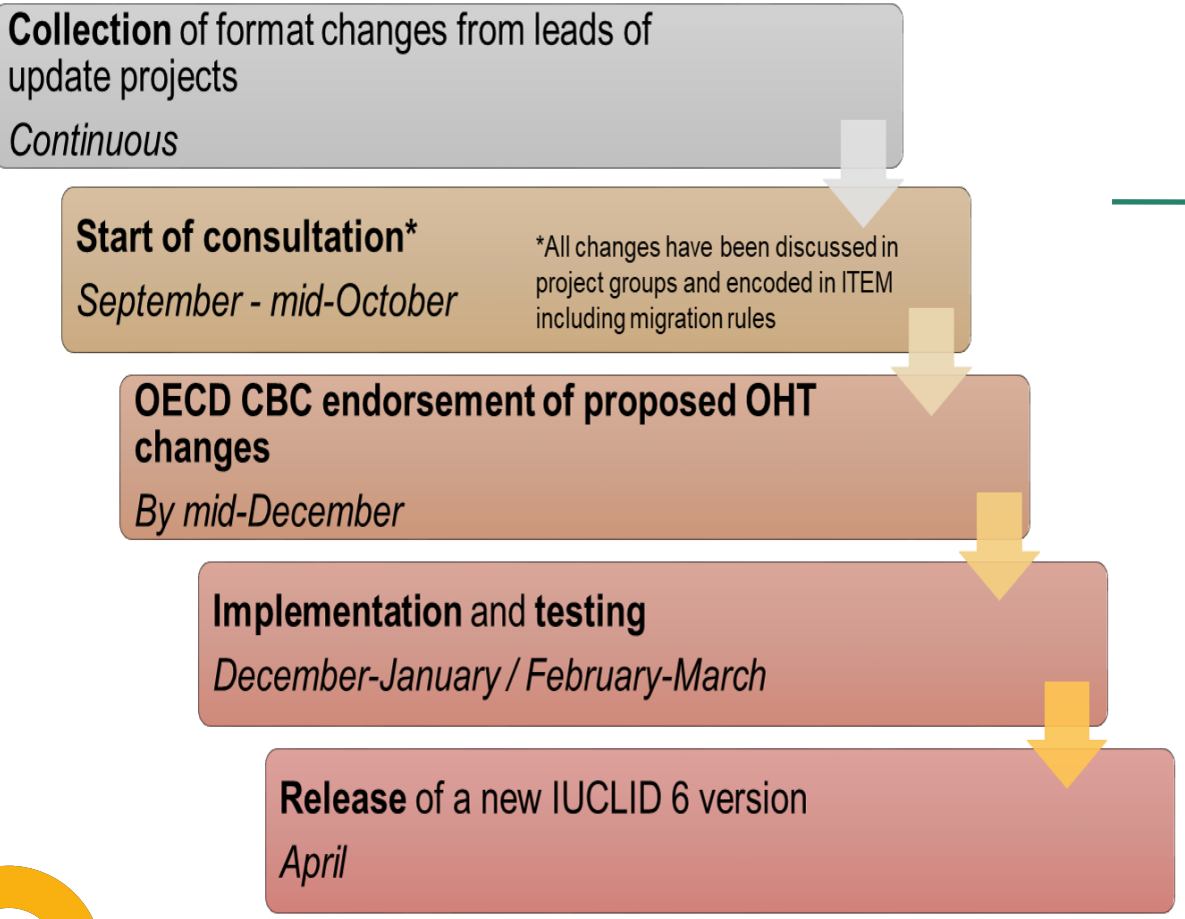
Backlog #3318 #3319



IUCLID FORMAT CHANGES: OECD – CORE - DOMAIN

#EFSA_EU

OECD CONSULTATION 2025 – OUTCOME



EFSA's proposal for changes:

- **59** harmonised documents
- **14 revised** OECD predefined tables
- **12 new** OECD predefined tables

Several OECD format changes were **postponed to 2026** due to lack of time/resources by OECD member countries to provide OECD secretariat with a sound revision of EFSA's proposal.

1) EFSA'S PROPOSAL FOR CHANGES (OECD) IMPLEMENTED IN IUCLID APRIL 2026 RELEASE



- **Series on physico-chemical properties**

  - OHT 10 and 10S - ENDPOINT_STUDY_RECORD.SurfaceTension_EFSA and ENDPOINT_SUMMARY.SurfaceTension_EFSA (backlog #3167): making the unit "vol %" obsolete in the "Concentration" field, as value "% (v/v)" introduced
    - Changes retained: updates to "Concentration" field to report units such as %w/w, %v/v and %w/v.

Backlog #3167

- **Series on AnalyticalMethods**

  - OHT 87 - ENDPOINT_STUDY_RECORD.AnalyticalMethods_EFSA (backlog #3168): proposed picklist items made generic, not regulatory specific
    - Changes retained: picklist item added to "Endpoint" field.

Backlog #3168

2) EFSA'S PROPOSAL FOR CHANGES (OECD) IMPLEMENTED IN IUCLID APRIL 2026 RELEASE

- **Series on health effects**



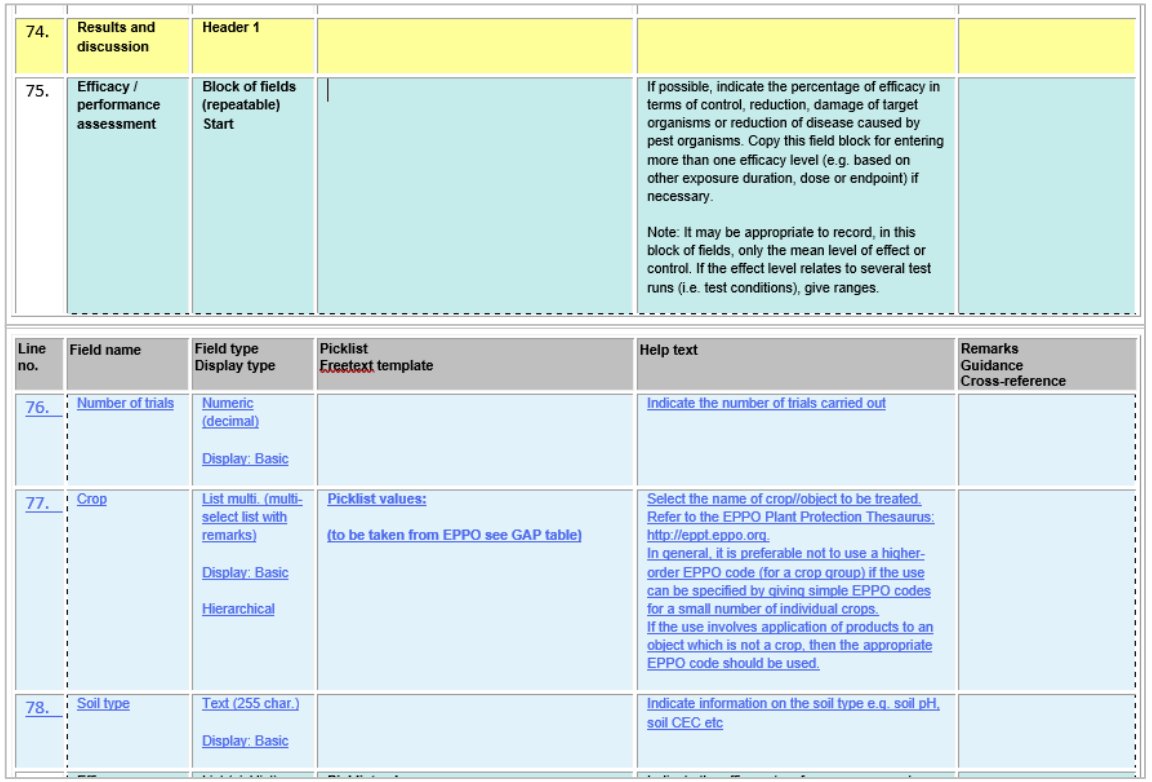
- OHT 59 - ENDPOINT_STUDY_RECORD.DermalAbsorption_EFSA (backlog #3209): proposed units amended
  - Changes retained: changes to "Doses" field (data type), "Remarks on result" (addition in picklist);
- OHT 70 - ENDPOINT_STUDY_RECORD.GeneticToxicityVitro_EFSA (backlog #3206): amendments to proposed helptexts
  - Changes retained: helptext amendments (the one on Version/remarks of guideline applicable to all OHTs, see modified template), text templates revision, picklist field modification "Remarks on result";
- OHT 71 - ENDPOINT_STUDY_RECORD.GeneticToxicityVivo_EFSA (backlog #3208): no amendments made to the original proposal, recirculated to allow more time for reviewing the proposed changes
  - Changes retained: new field "Remarks on result" (format taken as modified in OECD Template #70: Genetic toxicity in vitro), helptext/text template revisions;
- OHT 73 - ENDPOINT_STUDY_RECORD.ToxicityReproduction_EFSA (backlog #3203): amendment to helptext
  - Changes retained: new "historical control data" rich text field added; helptexts revision applicable to Results block;
- OHT 74 - ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity_EFSA, ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity_EFSA_CLE (backlog #3205): positioning of helptext amendments changed, existing "Historical control data" field removed
  - Changes retained: new "historical control data" rich text field added, new fields for Fetuses section;

Backlog
#3203
#3206
#3208
#3209

3) EFSA'S PROPOSAL FOR CHANGES (OECD) IMPLEMENTED IN IUCLID APRIL 2026 RELEASE

Series on health effects

- OHT 89 - ENDPOINT_STUDY_RECORD.EfficacyData_EFSA (backlog #3160): proposal to introduce regulatory specific helptexts revoked
  - Changes retained: new fields ("Number of trials, "Crop", "Soil type", "Treatment", "Efficacy (Mean in %)", "Application details") added to the "Results and discussion" block of field.



74.	Results and discussion	Header 1			
75.	Efficacy / performance assessment	Block of fields (repeatable) Start		If possible, indicate the percentage of efficacy in terms of control, reduction, damage of target organisms or reduction of disease caused by pest organisms. Copy this field block for entering more than one efficacy level (e.g. based on other exposure duration, dose or endpoint) if necessary. Note: It may be appropriate to record, in this block of fields, only the mean level of effect or control. If the effect level relates to several test runs (i.e. test conditions), give ranges.	

Line no.	Field name	Field type Display type	Picklist Freetext template	Help text	Remarks Guidance Cross-reference
76.	Number of trials	Numeric (decimal) Display: Basic		Indicate the number of trials carried out	
77.	Crop	List multi. (multi-select list with remarks) Display: Basic Hierarchical	Picklist values: (to be taken from EPPO see GAP table)	Select the name of crop//object to be treated. Refer to the EPPO Plant Protection Thesaurus: http://eppt.eppo.org. In general, it is preferable not to use a higher-order EPPO code (for a crop group) if the use can be specified by giving simple EPPO codes for a small number of individual crops. If the use involves application of products to an object which is not a crop, then the appropriate EPPO code should be used.	
78.	Soil type	Text (255 char.) Display: Basic		Indicate information on the soil type e.g. soil pH, soil CEC etc	

Backlog #3160

"…To comply with Commission Regulation (EU) 2024/1487 defining the data requirements for safeners and synergists"

4) EFSA'S PROPOSAL FOR CHANGES (CORE, DOMAIN) IMPLEMENTED IN IUCLID APRIL 2026 RELEASE

ENTITY.REFERENCE_SUBSTANCE

Backlog #3218



- To enable full characterisation of microorganisms (e.g., type, genus, species, full taxonomy etc.) vs. info on chemicals;
- To align with the data requirements on MO (Reg. (EU) No 283/2013 and Reg. (EU) No 284/2013).
- Comments received from New Zeeland EPA (Dec. 2025)

Line no.	Field name	Field type Display type	Picklist Freetext template Cross-reference	Help text	
1		Confidentiality Display: Basic		Set confidentiality and regulatory program flags.	
	Reference substance type	List (picklist) Display: Basic	Picklist values: - Chemical - Microorganism	Select the type of reference substance to be described	Migration: by ~~default~~default, "Chemical". "Microorganism" only for REFERENCE_SUBSTANCE linked to SUBSTANCE with function "active substance" (in the MIXTURE_COMPOSITION) in dossiers with context EU PPP Microorganisms – active substance application (product) (NOTE: TBD if for other cases such as
	Strain	Text (255 char.) Display: Basic		Indicate the specific strain designation of the microorganism, as assigned by the discoverer, culture collection, or publication. Include any other designation which may be relevant to the microorganism (e.g. isolate level, if relevant for viruses).	Customisation: To be displayed ONLY if the Reference substance type is set to 'Microorganism'
	Serovar/Pathovar/Other denomination	Text (255 char.) Display: Basic		Provide any additional ~~classification~~denomination relevant to ~~of~~ the microbial strain (e.g. pathovar, serovar, biovar, subspecies~~type~~), if applicable ~~names or denominations of the (e.g., serotype/pathovar).~~	Customisation: To be displayed ONLY if the Reference substance type is set to 'Microorganism'
	Full taxonomy	Text (2000 char.) Display: Basic		Indicate the complete taxonomic classification from domain to species (e.g., Domain > Phylum > Class >	Customisation: To be displayed ONLY if the Reference substance type is set to 'Microorganism'

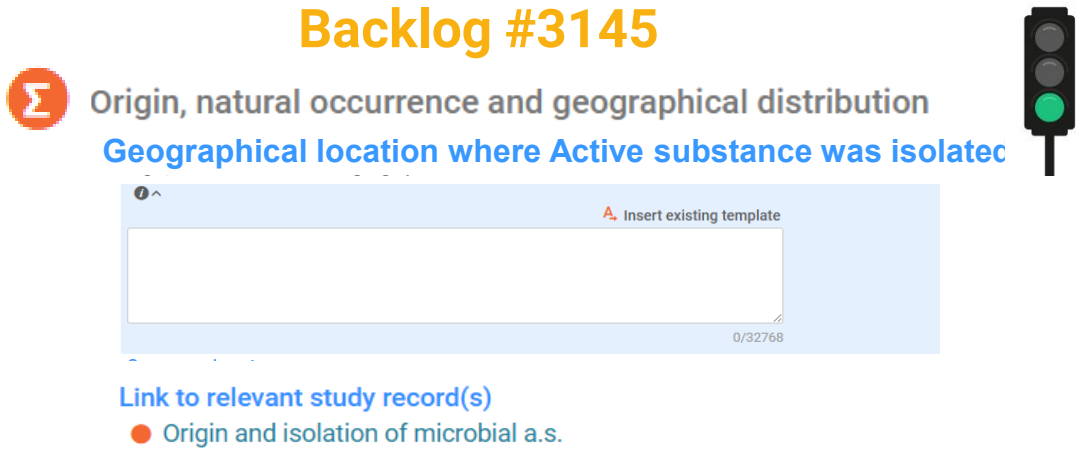
- All newly proposed fields will be conditional on the 'Reference substance type' field and will be displayed only when the value 'Microorganism' is selected.
- The migration of data from existing fields to the new structure has been assessed and is described in the final column of the proposed changes.

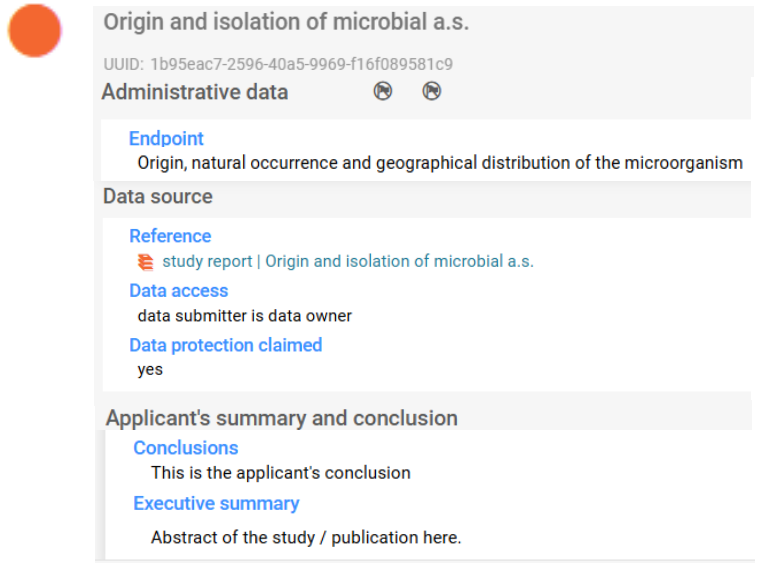
5) EFSA'S PROPOSAL FOR CHANGES (CORE, DOMAIN) IMPLEMENTED IN IUCLID APRIL 2026 RELEASE

- **FLEXIBLE_RECORD.BioPropertiesMicro is proposed to be converted into a FLEXIBLE_SUMMARY.**

Main changes:

- Addition of new fields under "*Growth requirements and Robustness to environmental*" to capture bioproperties.
- Replacement of 'link to references' by 'link to study'
- Removal of the fields "Reference", "Data access", and "Data protection claimed" throughout the document. These fields will instead be migrated to the corresponding fields within a new ENDPOINT_STUDY_RECORD.BiologicalPropertiesMicroorganism.
- The new **ENDPOINT_STUDY_RECORD** will enable reporting of actual studies, while the **FLEXIBLE_SUMMARY** will serve as a structured summary of those results.





1) EFSA'S PROPOSAL FOR CHANGES (OECD) POSTPONED TO 2026 CONSULTATION

Series on health effects



- OHT 60 to 63 S - ENDPOINT_SUMMARY.AcuteToxicity_EFSA (backlog #3217), new field "Pathogenicity and infectiveness" added to report PPP microorganisms active substances details.
- OHT 60 - ENDPOINT_STUDY_RECORD.AcuteToxicityOral_EFSA (backlog #3217), updates to the "Endpoint" (addition of picklist item) and "new field "Pathogenicity and infectiveness" added to report PPP microorganisms active substances details.
- OHT 61 - ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation_EFSA (backlog #3217), new field "Pathogenicity and infectiveness" and new fields to the "Results and discussions" block of fields added to report PPP microorganisms active substances information;
- OHT 67 - ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral_EFSA (backlog #3201) updates to several help texts, addition of new field "Historical control data" to the "Detailed toxicology results block of fields;
- OHT 68 - ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation_EFSA (backlog #3201), updates to several help texts, enhanced format for Detailed toxicological results block of fields, new "historical control data" rich text field;

Backlog #3201, #3202, #3204, #3217

- OHT 67 - ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral_EFSA (backlog #3201) updates to several help texts, addition of new field "Historical control data" to the "Detailed toxicology results block of fields;
- OHT 68 - ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation_EFSA (backlog #3201), updates to several help texts, enhanced format for Detailed toxicological results block of fields, new "historical control data" rich text field;
- 69-1 - ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal_EFSA, 69-2 - ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOtherRoute_EFSA (backlog #3201) updates to several help texts, enhanced format for Detailed toxicological results block of fields, new "historical control data" rich text field;
- 69-2 - ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOtherRoute_EFSA (backlog #3201) updates to several help texts, enhanced format for Detailed toxicological results block of fields, new "historical control data" rich text field;
- OHT 72 - ENDPOINT_STUDY_RECORD.Carcinogenicity_EFSA (backlog #3202) detailed toxicological results table format added, new "historical control data" rich text field added, helptext amendments to "Any other information on materials and methods incl. Tables" and "Any other information on results incl. Tables" (applicable to all OHTs see modified template;
- OHT 76 - ENDPOINT_STUDY_RECORD.Neurotoxicity_EFSA (backlog #3204) new "historical control data" rich text field added;
- OHT 78 - ENDPOINT_STUDY_RECORD.SpecificInvestigations_EFSA (backlog #3217), new fields added to "Results and discussion" block of fields to structure details on test results;

2) EFSA'S PROPOSAL FOR CHANGES (OECD) POSTPONED TO 2026 CONSULTATION



- **Series on Biotic Systems**

- Changes to "Test solutions" and "Study design" block of fields proposed to the following OECD Harmonised Templates (the IUCLID open backlog number #3216 is given for reference) from the Series on Environmental Fate and Behaviour and on Effect on biotic systems:

- OHT 41 - ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish_EFSA
- OHT 42 - ENDPOINT_STUDY_RECORD.LongTermToxToFish_EFSA
- OHT 43 - ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv_EFSA
- OHT 44 - ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv_EFSA
- OHT 45 - ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae_EFSA
- OHT 46 - ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant_EFSA
- OHT 48-1 - ENDPOINT_STUDY_RECORD.ToxicityToOtherAqua_EFSA
- OHT 48-2 - ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua_EFSA
- OHT 49 - ENDPOINT_STUDY_RECORD.SedimentToxicity_EFSA

Backlog #3216

- OHT 49 S - ENDPOINT_SUMMARY.SedimentToxicity_EFSA
- OHT 50-1 - ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods_EFSA
- OHT 50-3 - ENDPOINT_STUDY_RECORD.ToxicityToBees_EFSA
- OHT 50-4 - ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropodsOtherThanBees_EFSA
- OHT 50-5 - ENDPOINT_STUDY_RECORD.ToxicityToSoilArthropods_EFSA
- OHT 51 - ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants_EFSA
- OHT 52 - ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms_EFSA
- OHT 53 - ENDPOINT_STUDY_RECORD.ToxicityToBirds_EFSA
- OHT 54 - ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms_EFSA
- ENDPOINT_SUMMARY.TerrestrialToxicity_EFSA (OHT 50-1 to 54 S)

3) EFSA'S PROPOSAL FOR CHANGES (OECD) POSTPONED TO 2026 CONSULTATION



- **Series on Environmental Fate and Behaviour**

  - Changes to "Test solutions" and "Study design" block of fields proposed to the following OECD Harmonised Templates (the IUCLID open backlog number #3216 is given for reference) from the Series on Environmental Fate and Behaviour and on Effect on biotic systems:
    - Series on Environmental Fate and Behaviour
      - OHT 29 - ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests_EFSA
      - OHT 30 - ENDPOINT_STUDY_RECORD.BiodegradationInSoil_EFSA
      - OHT 32 - ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment_EFSA
      - OHT 33 - ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial_EFSA
      - OHT 39 - ENDPOINT_STUDY_RECORD.FieldStudies_EFSA (backlog #2650)

Backlog #3216

CLE submitted proposal for changes to **OHT 30** and **30 S** – any feedback from IUCLID-PSN members?

FORMAT CHANGES PROPOSAL UNDER DISCUSSION

- IUCLID format alignment with the **Guidance Document on risk assessment for birds and mammals**
- Creation of **new templates** to report data on:
  - **Impact of water treatment processes** (Endpoint Study Record and Endpoint Summary)
  - **Kinetic evaluations** (Endpoint Study Record)
- **ENTITY.LITERATURE**
  - Addition of a field to capture studies on vertebrate animals (backlog #3158); rejected during OECD consultation 2025.
  - EFSA is considering alternative options

IUCLID FORMAT CHANGES 2027 – NEW PROCESS

- All OECD format changes proposals to be agreed with ECHA **by 11 June 2026** (IUCLID webinar)
- **New IUCLID Backlog items form:**
  - Collecting more information about the **type of change**, the **rationale**, potential **impact**, maturity level, engagement level with stakeholders, etc.
  - ECHA in charge of all EU for only EU agreed changes with the OECD
- New OECD Expert Group on **IUCLID and Data Reporting Standards** (merging of **OHTs Expert Group** and **IUCLID Users Group Expert Panel)** to streamline IUCLID format changes process



PSN-IUCLID consultation Information on vertebrate studies

As the proposal to add a field for capturing vertebrate animal studies in the literature reference entity was rejected, EFSA is exploring alternative options to support RMS/EMS in identifying such studies.

CONSULTATION VIA EU SURVEY

Addressing Member States' Feedback

- EFSA has identified three possible options to address the issue raised by several Member States in previous meetings
  - Format change across all OHTs to introduce a Yes/No (or similar picklist) field to indicate whether a study was conducted on vertebrates
  - Automatic retrieval of information *(based on mapping of OHT type, fields, and test guidelines)*
  - Status quo (no change)



Your Input Needed

- PSN–IUCLID members are invited to select their preferred option
- **Deadline: Friday, 24 April**
- **EU Survey**: https://ec.europa.eu/eusurvey/runner/bbfcd342-aa1c-3445-473b-3c94771f3d6b

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