UPDATE ON FORMAT CHANGES

IDATA, FDP, PREV

efsa
EUROPEAN FOOD SAFETY AUTHORITY

FOLLOW-UP FROM PREVIOUS PSN IUCLID MEETING

- **IUCLID PSN Working Party (WP) on metabolism studies** (OHT 58, 85-2, 85-3)
  - Kicked off 22/05/2025 (Industry, Member States, LMC, ECHA)
  - Extended till **2026**
  - Next meeting on **6 Nov**.
- **IUCLID backlog items prioritisation**
  - **Sept 2025**: EFSA and ECHA met to prioritise IUCLID backlog items
- **Migration issues on Analytical Methods**
  - Resolved in **IUCLID v9.10.2** build on 30th October 2025

IUCLID FORMAT OVERVIEW

Collection of format changes from leads of update projects
Continuous

Start of consultation*
September - mid-October

*All changes have been discussed in project groups and encoded in ITEM including migration rules

OECD CBC endorsement of proposed OHT changes
By mid-December

Implementation and **testing**
December-January / February-March

Release of a new IUCLID 6 version
April

- Official consultation for **OECD harmonised formats**:
  - **OECD** provider by 30 October
  - **CORE** and **DOMAIN** providers by 24 October

EFSA proposal for changes:

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

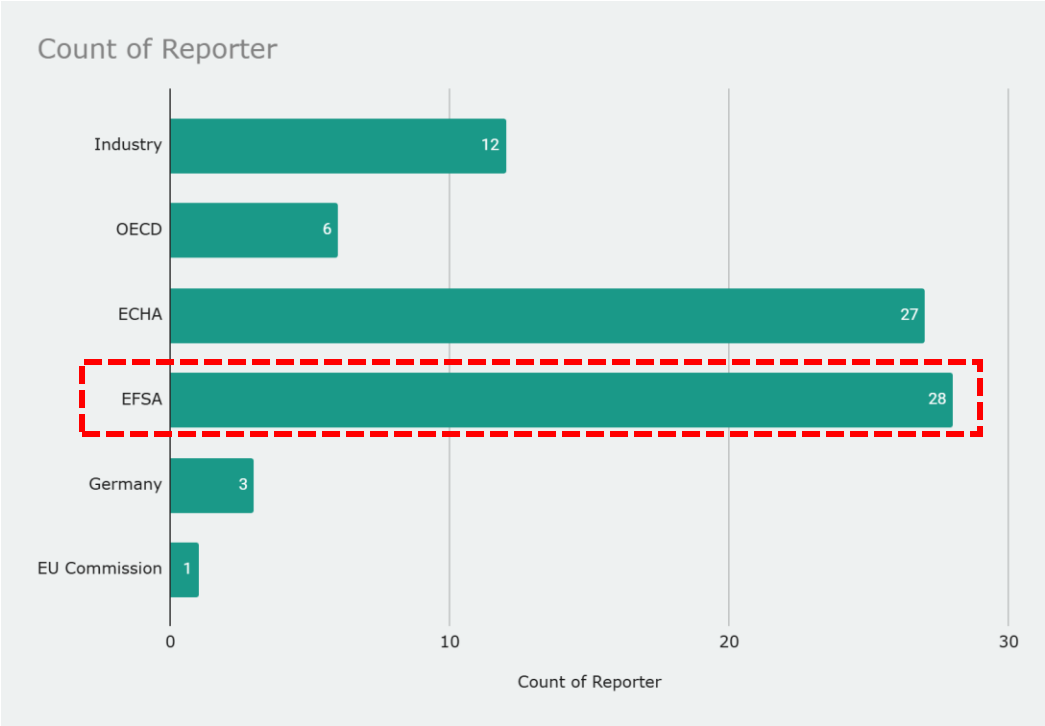
Information package for the format changes planned for April 2026

- The first proposals for changes to the harmonised parts of the IUCLID format have been shared with the relevant consultation groups on 15th of September. You can access the information package containing Word specifications using track-change mode: (.zip | 7.39 MB | 07.10.2025)

ECHA website - IUCLID format

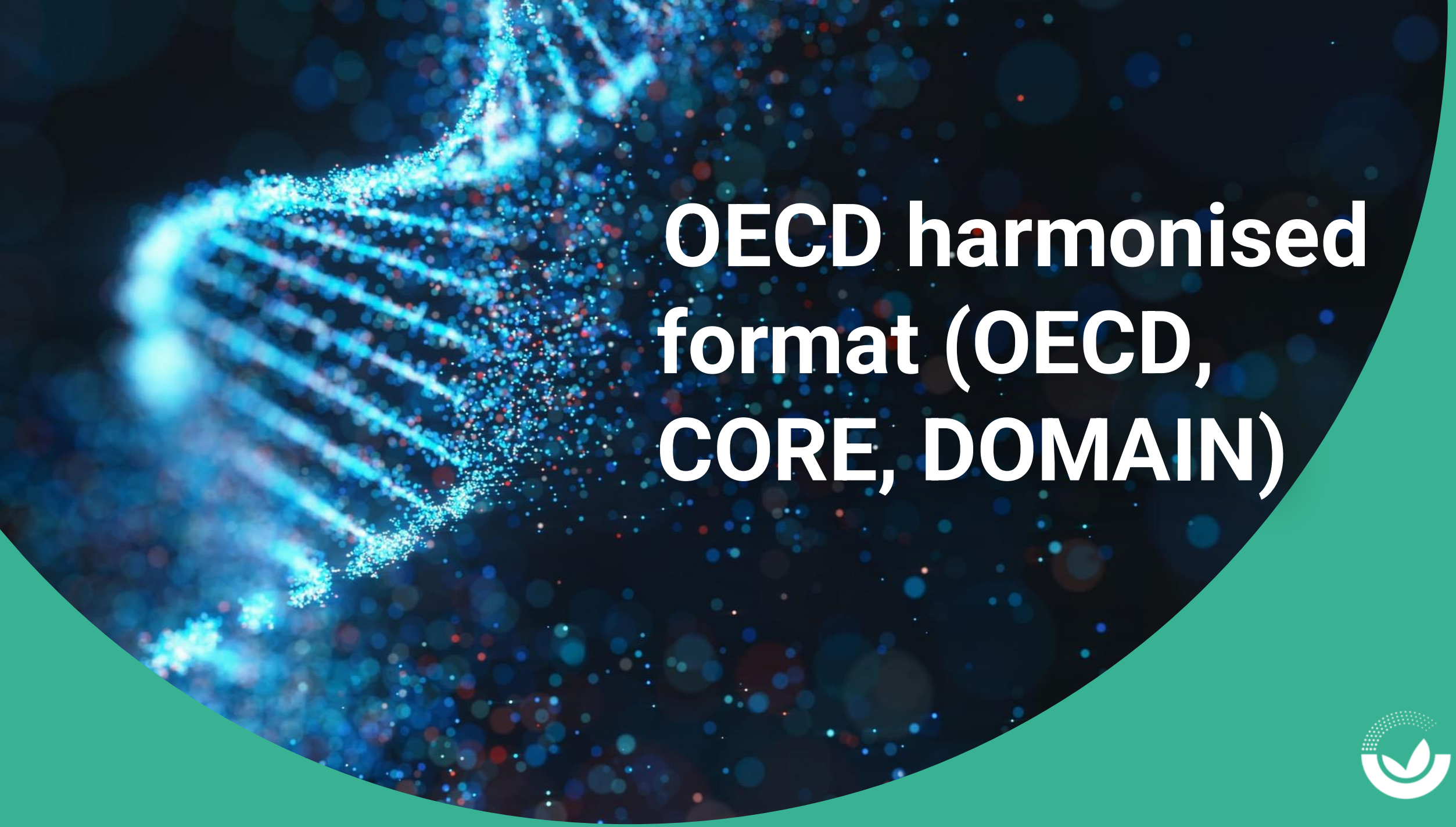
IUCLID FORMAT – MAIN DRIVERS OF THE 2026 UPDATE

- Apart from the standard maintenance of the format based on IUCLID users feedback, the main **drivers** for this format updates are:
  - Latest OECD consultations
  - Endocrine disruption assessment reporting
  - **EFSA review of existing OHTs**
  - EU test guidelines update



Origin of prioritised requirements

Slide kindly provided by ECHA (OECD IUCLID Meeting, Sept. 2025)



OECD harmonised format (OECD, CORE, DOMAIN)

EFSA PROPOSAL FOR CHANGES TO OECD DOCUMENTS (OHTs)

- **Series on health effects**
  - ✓ New field "*Pathogenicity and infectiveness*"
  - ✓ OECD predefined tables

- 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 60 S - ENDPOINT_SUMMARY.AcuteToxicity_EFSA (backlog #3217), 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 66-1 - ENDPOINT_STUDY_RECORD.SkinSensitisation_EFSA (backlog #3210) updates to help text and submission of new predefined tables templates for rich text fields;
- OHT 66-3 - ENDPOINT_STUDY_RECORD.PhototoxicityVitro_EFSA (backlog #3208) updates to help text and submission of new predefined tables templates for rich text fields;

Backlog:
#3208
#3210
#3217

EFSA PROPOSAL FOR CHANGES TO OECD DOCUMENTS (OHTs)

- **Series on health effects**
  - ✓ New field “historical control data”
  - ✓ Enhanced “Detailed toxicological results” block of fields

Backlog: #3201

- 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;

Backlog: #3202, #3208

- OHT 70 - ENDPOINT_STUDY_RECORD.GeneticToxicityVitro_EFSA (backlog #3206), 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", submission of new predefined tables templates for rich text fields;
- OHT 71 - ENDPOINT_STUDY_RECORD.GeneticToxicityVivo_EFSA (backlog #3208), new field “Remarks on result” (format taken as modified in OECD Template #70: Genetic toxicity in vitro), helptext/text template revisions;
- 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;

EFSA PROPOSAL FOR CHANGES TO OECD DOCUMENTS (OHTs)

- **Series on health effects (OHT 89 Efficacy Data)**
  - ✓Addition of a block to report study results on phytotoxic effects of safeners

Backlog: #3160

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

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	

80.	Time to produce effect	Numeric range (decimal with picklist) Display: Basic	**Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. **Picklist values:** - s - min - h	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.	

Line no.	Field name	Field type Display type	Picklist Freetext template	Help text	Remarks Guidance Cross-reference
			- d - wk - mo - yr		
81.	Treatment	Text (255 char.) Display: Basic		If efficacy results are recorded for different treatment conditions (by repeating this block of fields), briefly indicate the type of treatment/application the results refer to. Specify dose, application rate, duration, etc. EU SAFENERS AND SYNERGISTS: Please specify the treatment conditions and application dose the results refer to: - effects of a treatment on a representative use with a plant protection product containing the relevant safener/synergist - effects of a treatment on a representative use with the same plant protection product **without** the relevant safener/synergist - effects of a treatment on a representative use with the same plant protection product containing the relevant safener/synergists **but no active substance** - Results of untreated control may also be included if necessary.	

EFSA PROPOSAL FOR CHANGES TO OECD DOCUMENTS (OHTs)

✓ Changes to “Test solutions” and “Study design” block of fields

Backlog: #3216

- **Series on Environmental Fate and Behaviour**

  - 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
  - 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)

- **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)

EFSA PROPOSAL FOR CHANGES TO CORE, DOMAIN DOCUMENTS

- **ENTITY.REFERENCE_SUBSTANCE** Changes proposed to enable full characterisation of **microorganisms** (e.g., type, genus, species, full taxonomy etc.) and align with the data requirements related to micro-organisms laid down under Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013.

Backlog #2302

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 biocides)
	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/Ppathovar/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.

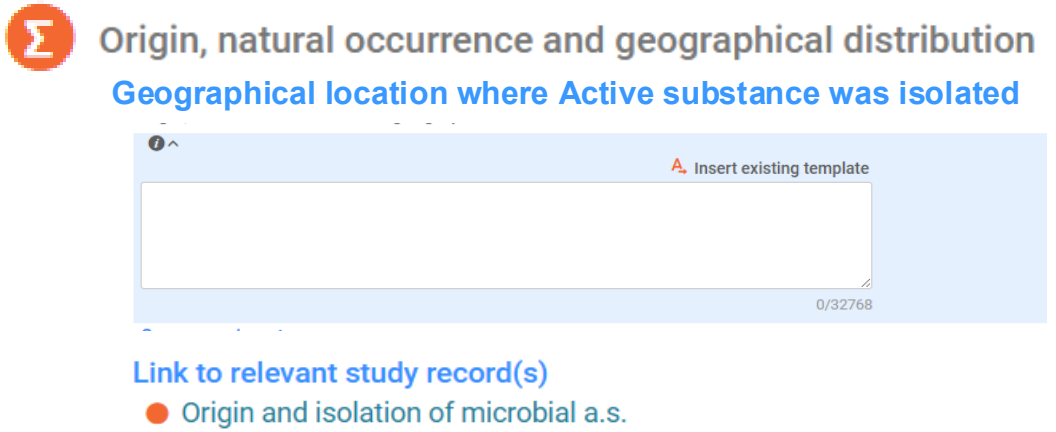
EFSA PROPOSAL FOR CHANGES TO CORE, DOMAIN DOCUMENTS

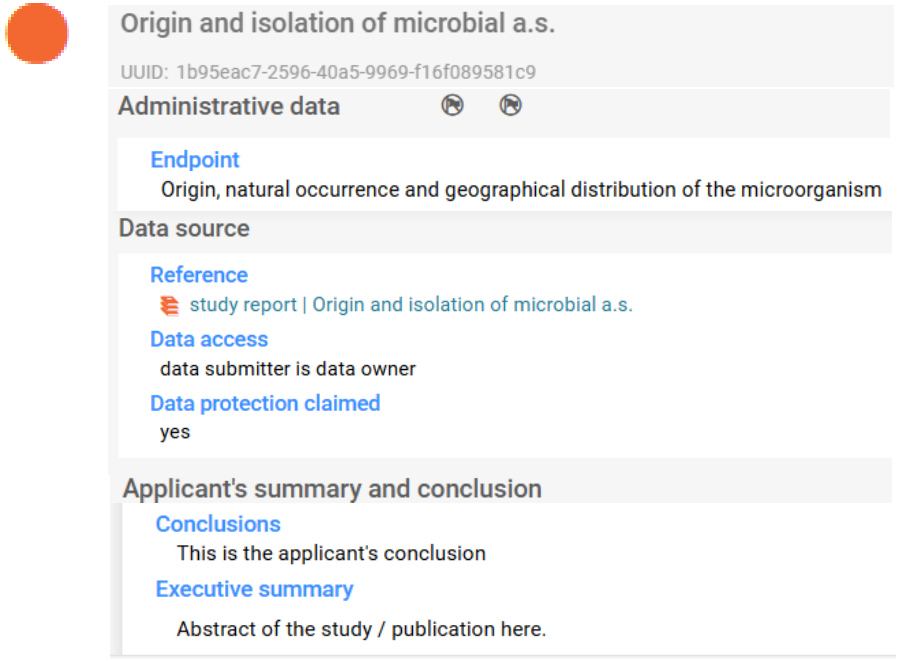
- **FLEXIBLE_RECORD.BioPropertiesMicro is proposed to be converted into a FLEXIBLE_SUMMARY.**

Main changes:

- Addition of new fields under "*Growth requirements and Robustness to environmenta*l" 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.

Backlog #3145





EFSA PROPOSAL FOR CHANGES TO CORE, DOMAIN DOCUMENTS

- **FLEXIBLE_RECORD.MixtureComposition** Addition of two picklist values for the **function**, as "*active substance variant*" and "*active substance acid equivalent*". A new field "*Concentration as % w/w*" in the composition table.

10	**Components**	**Header 1**		
11		**Block of fields (repeatable list) Start**		
12	Component flag	Confidentiality Display: Basic		Set the confidentiality flag and regulatory purpose.
13	Name	Link to document (single) Display: Basic	**Cross-reference:** - ENTITY.MIXTURE - ENTITY.REFERENCE_SUBSTANCE - ENTITY.SUBSTANCE	Specify a substance, mixture or reference substance (dataset) for fully identifying the component under consideration. This is done by creating a link with the desired dataset created previously in your database. Click the Link button. If the dataset is not present in your database, you need to create it before you will be able to link it.
14	Function	List (picklist) Display: Basic	**Picklist values:** - absorbent - active substance - active substance (other, not to be assessed) - active substance variant - active substance acid equivalent - adhesive - adsorbent - anticaking agent	Select the function of the component. ~~For an impurity we suggest to select 'not applicable'.~~ For EU PPP: The value 'active substance' should be used for the active substance under assessment, and linked to a SUBSTANCE dataset. If variants or acid equivalents of the active substance need to be reported, list them using values 'active substance variant' or 'active substance acid equivalent' as corresponds and link them to a REFERENCE_SUBSTANCE.

Backlog #3172

CORE Template #1.2: Composition (mixture) *(Version [10.13.0] [October 2024])*

Line no.	Field name	Field type Display type	Picklist Freetext template Cross-reference	Help text
	Concentration as % w/w	Numeric		Provide the concentration value reported in the field Typical concentration as % w/w.

EFSA PROPOSAL FOR CHANGES TO CORE, DOMAIN DOCUMENTS

- **FLEXIBLE_RECORD.CultureCollection** A new document is proposed under DOMAIN for the deposition of microorganisms in a culture collection

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.	Microorganism	Link to entity (single) Display: Basic		Link to the microorganism depo culture collection.	
4.	**Deposition in culture collection**	**Block of fields (repeatable) Start**			
5.	Deposition in culture collection identifier	Text (255 char.) Display: Basic		Enter the unique identifier or co the culture collection to the dep microorganism	
6.	Contact details of the culture collection	Link to document (single)	Contact details of the culture collection	Link to document (single)	
7.	Official documents relevant for the deposition	Attachment (single) Display: Basic (Confidential)		Attach the certificates of deposi	

Backlog #3214

Line no.	Field name	Field type Display type	Picklist Freetext template	Help text	Remarks Guidance Cross-reference
8.	Official documents relevant for the deposition	Header 2		Upload any official documentation supporting or confirming the deposition	
9.	**Attachments**	**Block of fields (repeatable list) Start**			
10.	Attachment type	List (picklist) Display: Basic	**Picklist values:** - full study report - illustration (picture/graph) - other:		
11.	Attached confidential document	Attachment (single) Display: Basic (Confidential)		An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types.	
12.	Attached (sanitised) document for publication	Attachment (single) Display: Basic		An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed.	
13.	**Attachments**	**Block of fields (repeatable list) End**			
14.	**Deposition in culture collection**	**Block of fields (repeatable) End**			

EFSA PROPOSAL FOR CHANGES TO CORE, DOMAIN DOCUMENTS

Backlog #3158

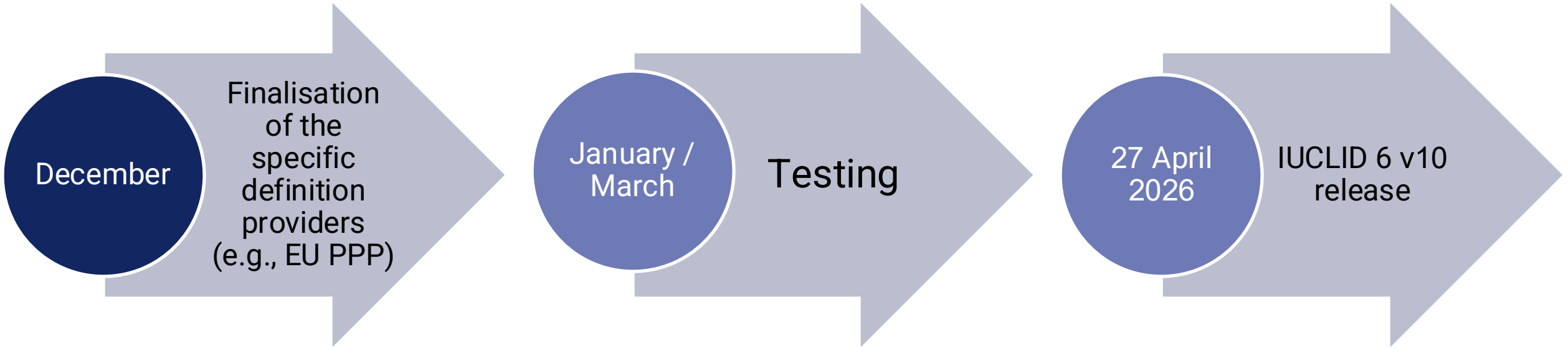
- **ENTITY.LITERATURE** Addition of a field to indicate whether a study involves vertebrate animals, in order to align with the 'List of Literature References' report required for EU pesticide risk assessment.

IUCLID section (endpoint)	Author(s)	Year	Title Report No. Document No. Source, where different from company GLP Published or not	Vert. study Y/N			

Line no.	Field name	Field type Display type	Picklist Freetext template Cross-reference	Help text
7	Testing facility	Text (255 char.) Display: Basic		Enter the name and address (including country) of the testing laboratory.
8	Report date	Date Display: Basic		Specify the complete date of the study report, e.g. '2005-05-12' for 12 May 2005. Note that subfield 'Year' should be completed in any case for sorting and searching purposes. By default, the date of the final report is expected here. In case of a draft report, this field should be left empty, and the expected date of the final report as well as a justification on why a draft report was provided should be given in the field "Remarks" below.
9	Report number	Text (255 char.) Display: Basic		Specify the report number allocated by the testing laboratory. Note that any company-specific study number should be included in the respective field.
10	Study sponsor	Text (255 char.) Display: Basic		Enter the identity of the company who owns the data.
11	Study number	Text (255 char.) Display: Basic		Specify any company study no. if there is such a number and if it is different from the report no. of the testing laboratory. Otherwise leave field empty.
	Vertebrate Study	List (picklist) Display: Basic	Picklist values: - Yes - No	Select 'Yes' if the study involves vertebrate animals such as mammals, birds, reptiles, amphibians, or fish. Select 'No' if it involves only invertebrates or non-animal models.

NEXT STEPS

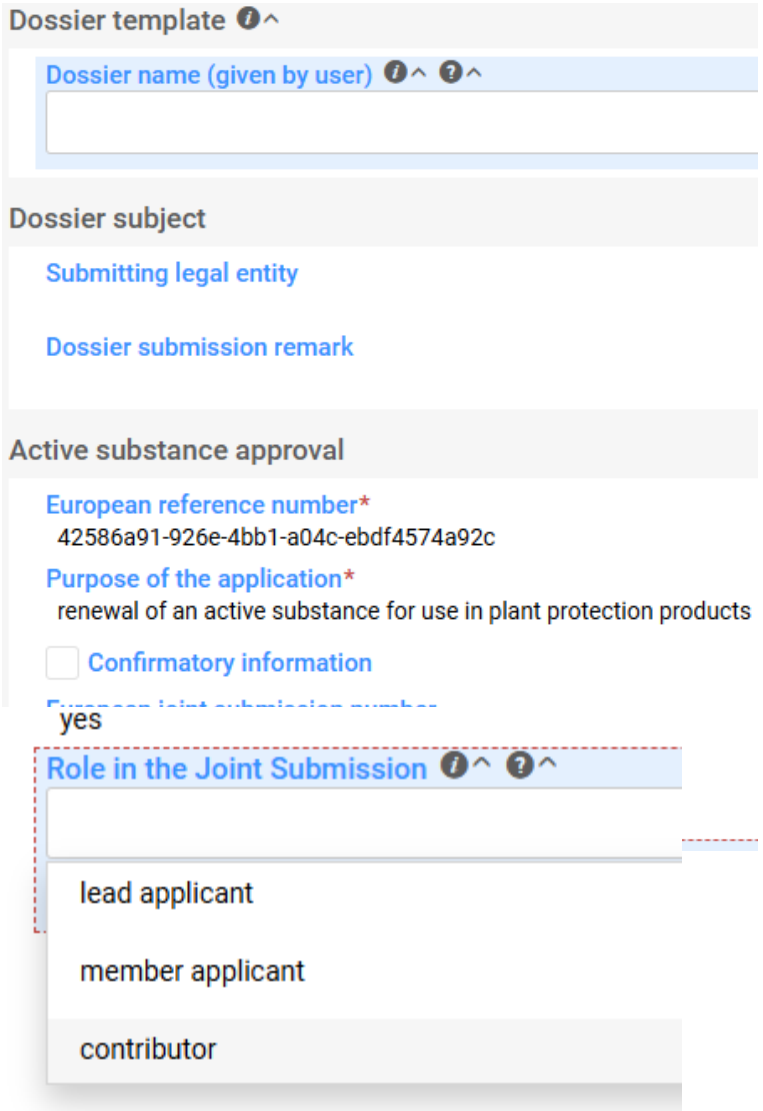
All the changes made in ITEM will be published on the IUCLID website: https://iuclid6.echa.europa.eu/format



EU_PPP format changes

DOSSIER HEADER OF MRL APPLICATIONS

- **Extension of the 'Joint submission' fields** to the MRL working context
- New checkbox in the MRL application '**MRL application on minor crops**'



LITERATURE SEARCH

- A new field, 'Section Covered,' has been added to indicate the specific sections within the dossier that the literature search pertains to

		Confidentiality Display: Basic		
	Section covered	Header 1		
		List multi. (multi-select list) Display: Basic Common block	Picklist values: -Identity -Physical, chemical and/or technical properties -Biological properties of the microorganism -Analytical methods -Efficacy -Toxicology / Effects on human health -Residues -Ecotoxicology / Effects on non-target organisms -Fate and behaviour in the environment -Further information -Application	Indicate the section or sections of the dossier that are covered by the literature search strategy. Separate documents should be created for different sections if the search strategy (search strings, criteria, filters, etc) was different or if the searches were carried out in different dates. If the same search covers several sections, select all that apply.
	Link to relevant studies	**Header 1**		Provide the link to relevant studies included in the dossier or assessment report after detailed assessment of full-text documents for relevance. Relevant endpoint study records should be completed with the information from the relevant studies.
	Literature reference(s)	Link to document (multiple) Display: Basic	**Cross-reference:** - ENTITY.LITERATURE	

METABOLITE

- **Current state**
  Information on **'Compound found in'** (as listed in the *List of Metabolites*, Vol. 1 of the DAR/RAR) is currently captured in the **'Remarks'** field of **FLEXIBLE_SUMMARY.Metabolites**.

- **Proposed change**
  Introduce a dedicated field named **'Compound found in'** within **FLEXIBLE_SUMMARY.Metabolites**.

- **Benefits**

➢ Ensures structured and validated data entry

➢ Enables one-to-one mapping for automated *List of Metabolites* report generation

- Data from the 'Remarks' field could be migrated to the **'Compound found in'** accordingly

ECOTOXICOLOGICAL RISK ASSESSMENT OF PESTICIDES

- The document FLEXIBLE_SUMMARY.EcotoxRiskAssessment Pesticides is proposed to be updated to include additional summary details covering:
  - Risk assessment for birds
  - Risk assessment for wild mammals
  - Risk assessment for other terrestrial vertebrate wildlife (reptiles and amphibians)
  - Risk assessment for aquatic organisms
  - Risk assessment for bees and non-arthropod pollinators other than bees

	Risk assessment to birds	Header 2	
		~~Text (rich-text area)~~ ~~Display: Basic~~	
	Acute risk assessment	**Header 3**	
	Screening assessment	**Header 4**	
		Text (rich-text area) Display: Basic	
	Tier 1 assessment	**Header 4**	
		Text (rich-text area) Display: Basic	
	Metabolites assessment	**Header 4**	
		Text (rich-text area)	

RESIDUES – EXPECTED EXPOSURE

- *FLEXIBLE_SUMMARY.ExpectedExposure* - Introduction of repeatable blocks under the headers **'Chronic Exposure'** and **'Acute Exposure'** to allow reporting of multiple exposure assumptions.
- Many fields are planned to be converted from numeric values to range values

~~10~~	~~Chronic exposure~~	~~Header 3~~		
	Chronic exposure	Block of fields (repeatable set) Start		
11	Exposure assumption	List sup. (picklist with remarks) Display: Basic	**Picklist values:** - estimated daily intake (EDI) - international estimated daily intake (IEDI) - lower bound - maximum recommended dose - minimum recommended dose - national estimated daily intake (NEDI) - national theoretical maximum daily intake (NTMDI) - proposed intake level - theoretical maximum daily intake (TMDI) - upper bound - other:	For pesticides, specify if TMDI or I
12	Assumptions	Text (2,000 char.) Display: Basic		Specify the scenario under assess chronic exposure calculations: e.g were considered such as non-EU drug), other active substances res

U_PPP Template #N/A: Expected exposure *(Version [10.13.0]-[December 2023])*

Line no.	Field name	Field type Display type	Picklist Freetext template Cross-reference	Help text
				from rotational crops were conside risk mitigation measures are appli the calculation are applied.
13	Toxicological reference value (ADI) (converted)	Numeric range (decimal with picklist) Display: Basic Common block ~~Numeric (decimal including unit)~~ ~~Display: Basic~~	Lower numeric qualifiers: - >; - >= - ca. Upper numeric qualifiers: - < - <= - ca. **Picklist values:** - ng/kg bw/day	[Only if needed]: If the TRV taken from the TRV doc conversion, this field is not relevar If there is a need to convert the TF RA (e.g. if the tRV is expressed fo acid), please report the converted rational for the conversion (incl. th

OTHER RESIDUES CHANGES

- *ENDPOINT_SUMMARY.StabilityResiduesCommodities* - To allow separation between plants versus animal studies, it is proposed to move the 'Link to relevant study record' into the blocks **Storage stability – plant** AND **Storage stability – animal** .

- *FLEXIBLE_SUMMARY.ResiduesInLivestock* – Addition of fields to match the LoEP and improved report generator mapping

	Link to relevant study record	Link to document (multiple) Display: Basic	Cross-reference: - ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod
	Storage stability - plant	Block of fields (repeatable list) End	
	Storage stability -	Block of fields	

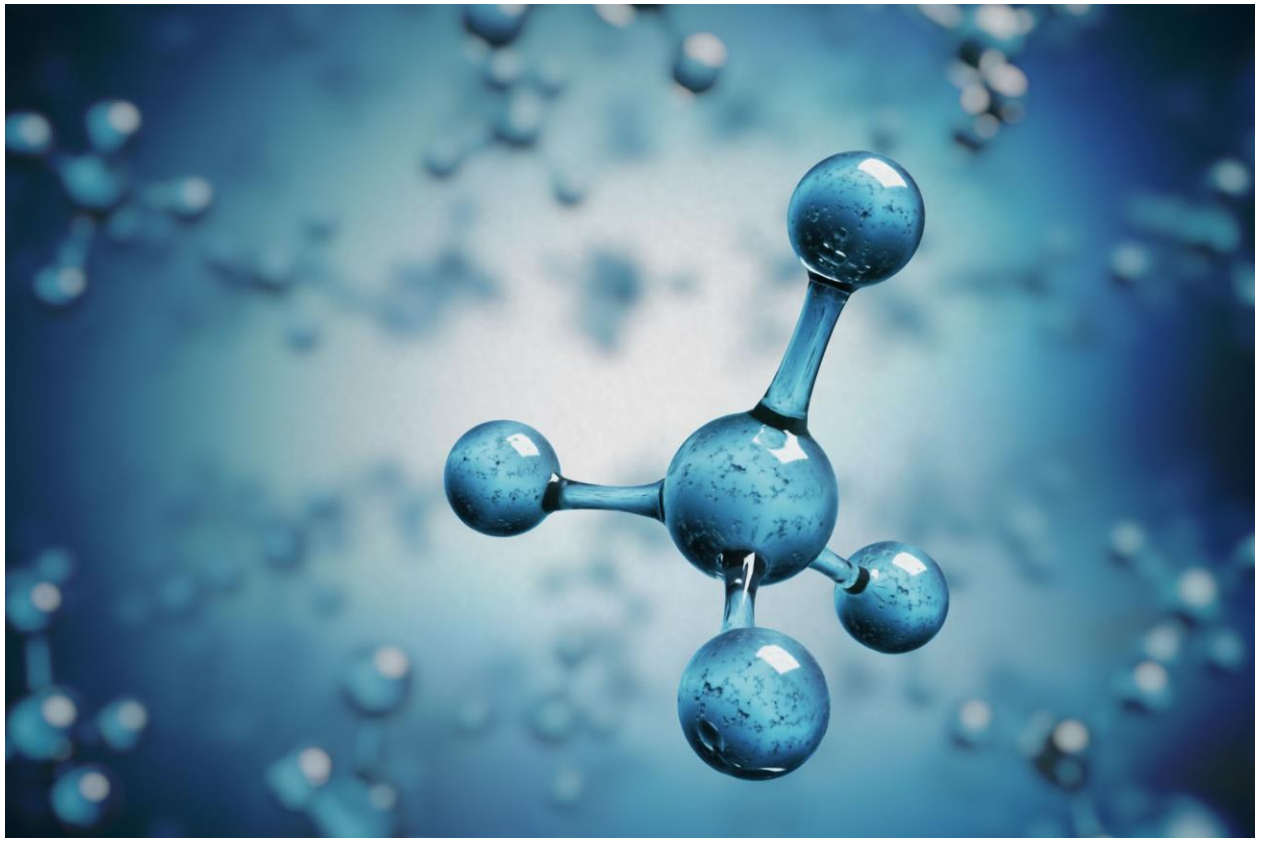
Closest feeding level	Numeric (decimal including unit) Display: Basic	Picklist values: - mg/kg bw per day
Residue definition monitoring	Text (2,000 char.) . Display: Basic	
Residue definition Risk Assessment	Text (2,000 char.) . Display: Basic	
Residues at closest feeding level	Numeric (decimal including unit) Display: Basic	Picklist values: - mg/kg

ADDITIONAL FORMAT CHANGES

- **FLEXIBLE_SUMMARY.InformationToxicityMetabolites** and **FLEXIBLE_SUMMARY.NonDietaryExpo**– Help text updated.

- **FLEXIBLE_SUMMARY.InformationEcotoxicityMetabolites** → 'Link(s) to relevant study record(s) 'added to support the identification/characterization of the ecotoxicological properties of the metabolite (if any).

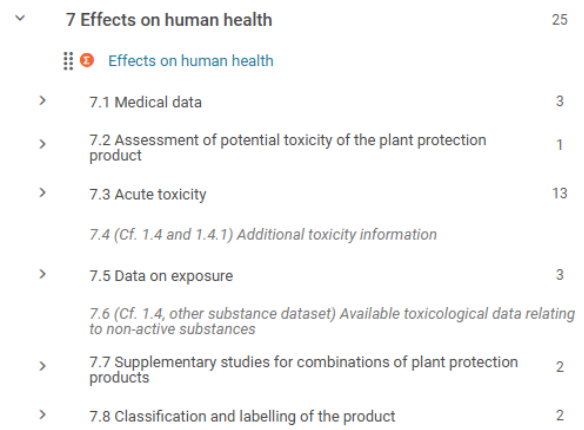
- **FLEXIBLE_SUMMARY.ToxRefValues**– Implemented a dynamic rule to hide fields in cases where derivation of the reference dose is not required.
  - Addition of the field 'Reference to EFSA Opinion' to all block within the document.
  - Changed the 'Justification and comment' field from a rich text field to a plain text field.



UPDATE OF TABLE OF CONTENTS

- **EU PPP Microorganisms -** In the Active substance dataset, both documents currently located in section 5.3.1.3 (*ENDPOINT_SUMMARY.SpecificInvestigationsOtherStudies* and *ENDPOINT_STUDY_RECORD.SpecificInvestigations*) will be moved to section 5.4. A new cross-reference will be added in section 5.3.1.3 as follows:"5.3.1.3 (Cf. 5.4) Intravenous / intraperitoneal or subcutaneous single exposure."

- The document ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes will be added to section 7.4 of the Micro Product dataset.



UPDATE OF TABLE OF CONTENTS

- **EU PPP Chemicals -** For FLEXIBLE_SUMMARY.AquaticToxicityRac Reporting, it is proposed to retain the document only in the Product dataset and remove it from the AS dataset. All related documents under the active substance dataset will be migrated to the Product dataset, and a cross-reference (Cfr) to the Priduct dataset will be added in the AS dataset.

NEXT STEP - CONSULTATION

- We plan to launch a consultation with the PSN-IUCLID members on the proposed EU_PPP format changes.
- The consultation will be conducted in writing, with ad hoc communication via email and the TEAMS channel as needed.
- The consultation is scheduled to take place in November.

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