

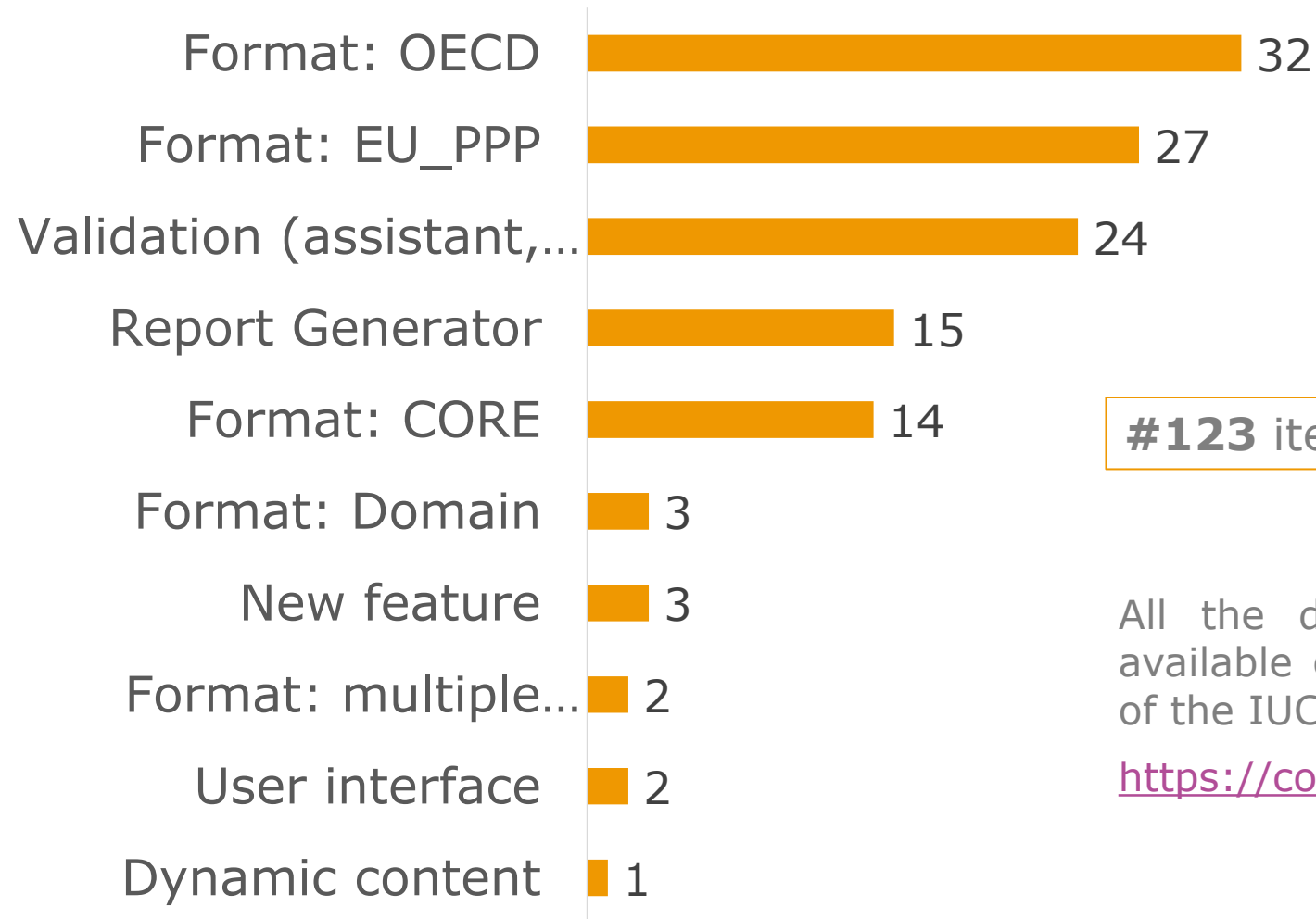


IUCLID 6.6 release: main changes to PPP working context

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Data Officer


Trusted science for safe food



#123 items impacting PPP working context

All the details on the format changes are available on the **OECD ONE community site** of the IUCLID Users Group Expert Panel

<https://community.oecd.org/docs/DOC-195399>

- General updates to all OHTs (as announced in June):
 - New field **“Additional test material”**  (e.g., when different batches are used during a study)
 - Harmonisation of the **attachment fields** under **“Overall remarks, attachments”** (in line with EP summaries)
- Update of **3 OHTs** from the **Pesticide Residues Chemistry** Series (BfR collaboration):
 - OHT **85-4** Residues in livestock
 - OHT **85-8** Nature of Residues in Processed Commodities
 - OHT **85-10** Stability of Residues in Processed Commodities

Overall remarks, attachments

Overall remarks
None

Attachments + New item Import file ▼

#	Type	Attached (confid...	Attached (sanitis...	Remarks
1	None	None	None	None

Type
None

Attached (confidential) document
None

Attached (sanitised) documents for publication
None

Remarks
None

- **Test commodities** picklist
- **Product type** picklist
- **Guideline** picklist
- **Test conditions** (#85-8)
- **Residues Level** (#85-10)

- General updates in **20 OHTs** to report Biopesticides studies (#2138) and specific changes (95% CL; clinical signs) according to backlog:

- **OHT-30**_ENDPOINT_STUDY_RECORD.BiodegradationInSoil
- **OHT-41**_ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish
- **OHT-42**_ENDPOINT_STUDY_RECORD.LongTermToxicityToFish
- **OHT-43**_ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv
- **OHT-44**_ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv
- **OHT-45**_ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae
- **OHT-46**_ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant
- **OHT-50-2**_ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods (**#2137; #2139**)
- **OHT-52**_ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms
- **OHT-53**_ENDPOINT_STUDY_RECORD.ToxicityToBirds
- **OHT-54**_ENDPOINT_STUDY_RECORD.ToxToOtheAboveGroundOrganisms
- **OHT-59**_ENDPOINT_STUDY_RECORD.DermalAbsorption
- **OHT-60**_ENDPOINT_STUDY_RECORD.AcuteToxicityOral (**#2136**)
- **OHT-62**_ENDPOINT_STUDY_RECORD.AcuteToxicityDermal (**#2132**)
- **OHT-67**_ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral (**#2145**)
- **OHT-68**_ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation
- **OHT-78**_ENDPOINT_STUDY_RECORD.SpecificInvestigations (**#2145**)
- **OHT-87**_ENDPOINT_STUDY_RECORD.AnalyticalMethods (**#2135**) (**full revision in 2022**)
- **OHT-88**_ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms (**#2142**)
- **OHT-89**_ENDPOINT_STUDY_RECORD.EfficacyData (**#2142**)

- **OECD** Secretariat sent OHTs to CBC for endorsement by 24 Sept.
- **IBMA** support on MO changes (see slide #10)

- Update of the dossier header for **renewal submission**, addition of:
 - **Confirmatory information**
 - **European Joint submission number**
 - **Joint Application**
 - **Lead applicant**

UUID: e3a0c51c-d17f-434d-8ea2-0b5afdacbefc

Purpose of the application*

renewal of an active substance for use in plant protection products

Remark

0/2000

Confirmatory information

European joint submission number

None

Joint application

None

✖ This field is mandatory.

Lead applicant

no

Submitting only confidential product data

Rapporteur Member State (RMS)*

Austria

Competent authority

AGES

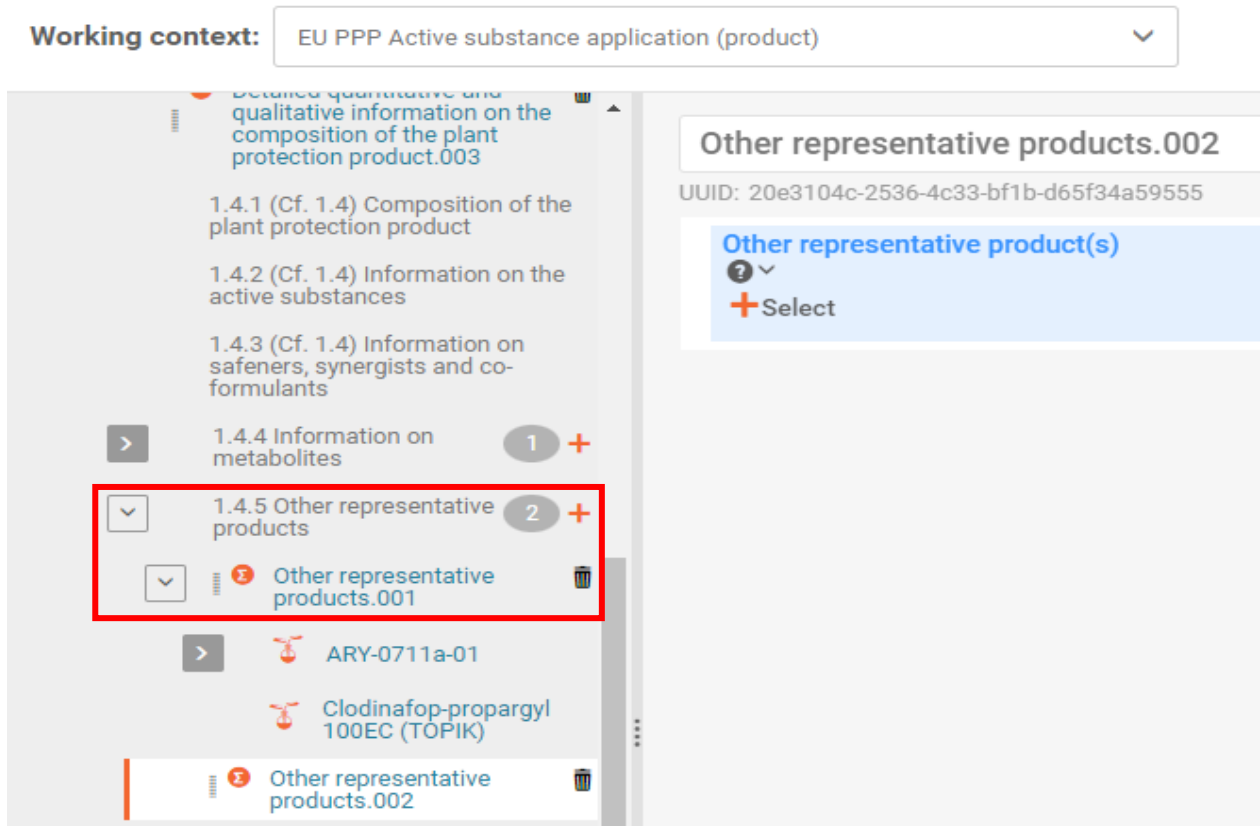
Co-RMS

✓ Belgium

Format changes: PPP

- New document for **Multiple representative products** (1.4.5):
 - Same **TOC** as for the mixtures/product dataset
 - No c.f. to metabolites (1.4.4) possible (only in a.s. dataset)

Working context: EU PPP Active substance application (product)

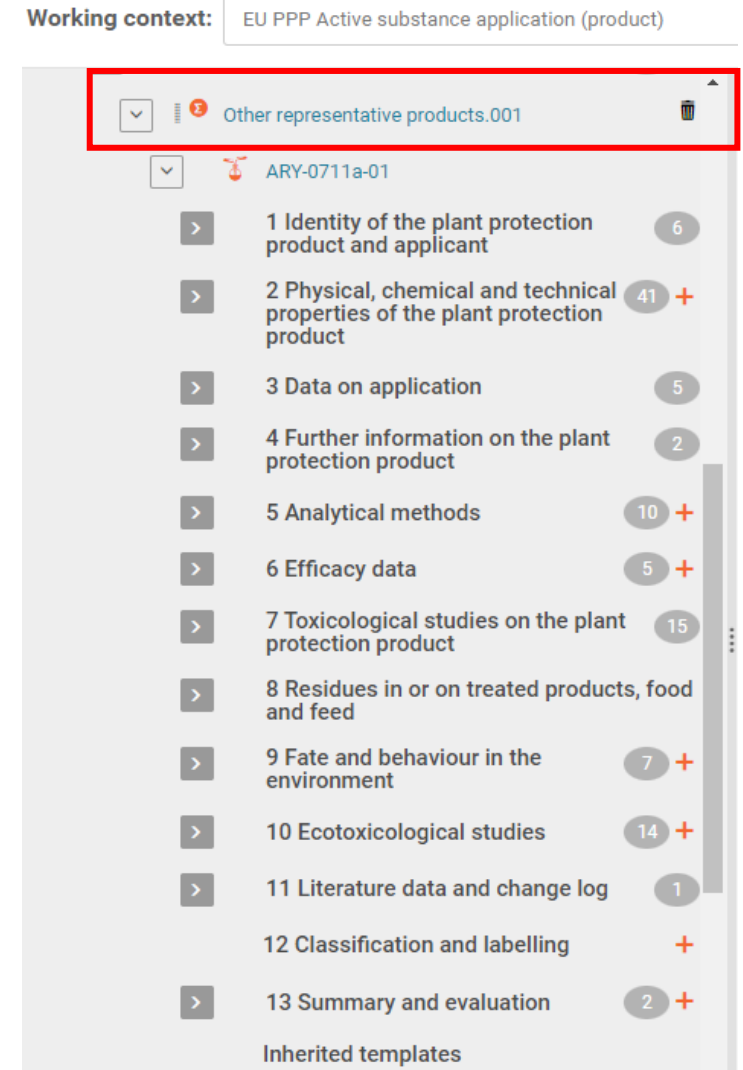


The screenshot shows a sidebar menu on the left with the following items:

- 1.4.1 (Cf. 1.4) Composition of the plant protection product
- 1.4.2 (Cf. 1.4) Information on the active substances
- 1.4.3 (Cf. 1.4) Information on safeners, synergists and co-formulants
- 1.4.4 Information on metabolites (1)
- 1.4.5 Other representative products (2)** (highlighted with a red box)
- Other representative products.001 (highlighted with a red box)
- ARY-0711a-01
- Clodinafop-propargyl 100EC (TOPIK)
- Other representative products.002

The main content area shows a document titled "Other representative products.002" with a UUID of 20e3104c-2536-4c33-bf1b-d65f34a59555. Below the title is a section for "Other representative product(s)" with a dropdown menu and a "+ Select" button.

Working context: EU PPP Active substance application (product)



The screenshot shows a detailed table of contents for the document "Other representative products.001". The table lists 13 sections with their respective page counts and expand/collapse icons:

Section	Page Count
1 Identity of the plant protection product and applicant	6
2 Physical, chemical and technical properties of the plant protection product	41 +
3 Data on application	5
4 Further information on the plant protection product	2
5 Analytical methods	10 +
6 Efficacy data	5 +
7 Toxicological studies on the plant protection product	15
8 Residues in or on treated products, food and feed	
9 Fate and behaviour in the environment	7 +
10 Ecotoxicological studies	14 +
11 Literature data and change log	1
12 Classification and labelling	+
13 Summary and evaluation	2 +

Below the table of contents, the text "Inherited templates" is visible.

Update of **ENDPOINT_SUMMARY**:

- ✓ AcuteToxicity (#2214)
- ✓ AdsorptionDesorption (#2149)
- ✓ BiodegradationInSoil_EU_PPP (#2148)
- ✓ BiodegradationInWaterAndSedimentSimulationTests (#2259)
- ✓ EffectivenessAgainstTargetOrganisms (#1901)
- ✓ GeneticToxicity (#2215)
- ✓ MagnitudeResiduesPlants (#2260)
- ✓ NatureMagnitudeResiduesProcessedCommodities (#2292)
- ✓ Neurotoxicity (#2216)
- ✓ ResiduesLivestock (#2262)
- ✓ StabilityResiduesCommodities (#2263)
- ✓ Toxicokinetics (#2216)



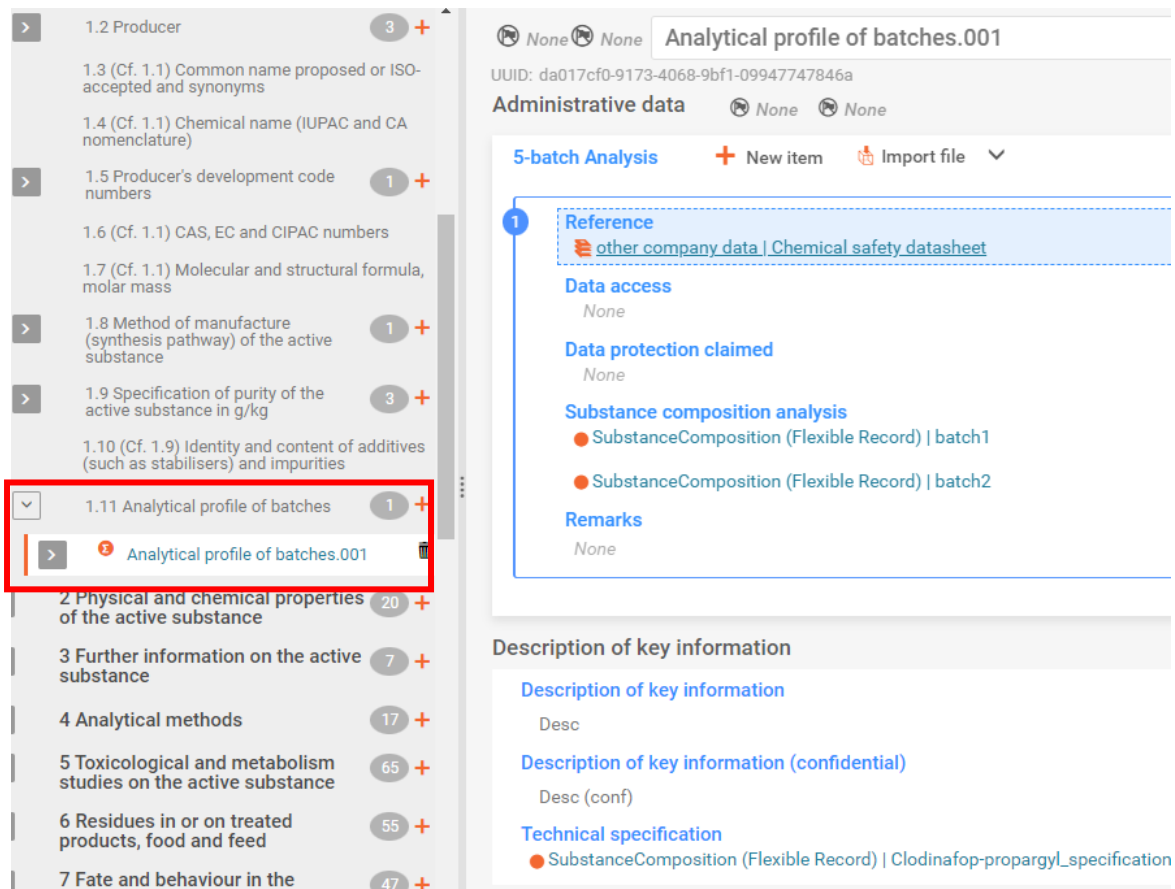
ECHA project on Harmonisation of ENDPOINT_SUMMARY
between CORE (IUCLID) and EU PPP/NZ HSNO definition providers:
→ **Unique assessment outcome, key value** for further safety
assessment, **attachments** fields (in line with OHTs)

Update of **FLEXIBLE_RECORD**:

- ✓ AnalyticalInformation (#2222)
- ✓ BioPropertiesMicro (#2153)
- ✓ GAP (#2063; #2072 #2083; #2092; #2093)
- ✓ Manufacturer_EU_PPP (#2266)
- ✓ AnalyticalProfileBatches (#2204)
- ✓ MRLProposal (#2268)
- ✓ ExpectedExposure (#2269)

Format changes: CORE

1. New FLEXIBLE_SUMMARY document “**Analytical profiles of batches**” (c.f. 1.11 - Active Substance dataset)



1.2 Producer 3 +

1.3 (Cf. 1.1) Common name proposed or ISO-accepted and synonyms

1.4 (Cf. 1.1) Chemical name (IUPAC and CA nomenclature)

1.5 Producer's development code numbers 1 +

1.6 (Cf. 1.1) CAS, EC and CIPAC numbers

1.7 (Cf. 1.1) Molecular and structural formula, molar mass

1.8 Method of manufacture (synthesis pathway) of the active substance 1 +

1.9 Specification of purity of the active substance in g/kg 3 +

1.10 (Cf. 1.9) Identity and content of additives (such as stabilisers) and impurities

1.11 Analytical profile of batches 1 +

Analytical profile of batches.001

2 Physical and chemical properties of the active substance 20 +

3 Further information on the active substance 7 +

4 Analytical methods 17 +

5 Toxicological and metabolism studies on the active substance 65 +

6 Residues in or on treated products, food and feed 55 +

7 Fate and behaviour in the 47 +

None None Analytical profile of batches.001

UUID: da017cf0-9173-4068-9bf1-09947747846a

Administrative data None None

5-batch Analysis + New item Import file

Reference

other company data | Chemical safety datasheet

Data access

None

Data protection claimed

None

Substance composition analysis

SubstanceComposition (Flexible Record) | batch1

SubstanceComposition (Flexible Record) | batch2

Remarks

None

Description of key information

Description of key information

Desc

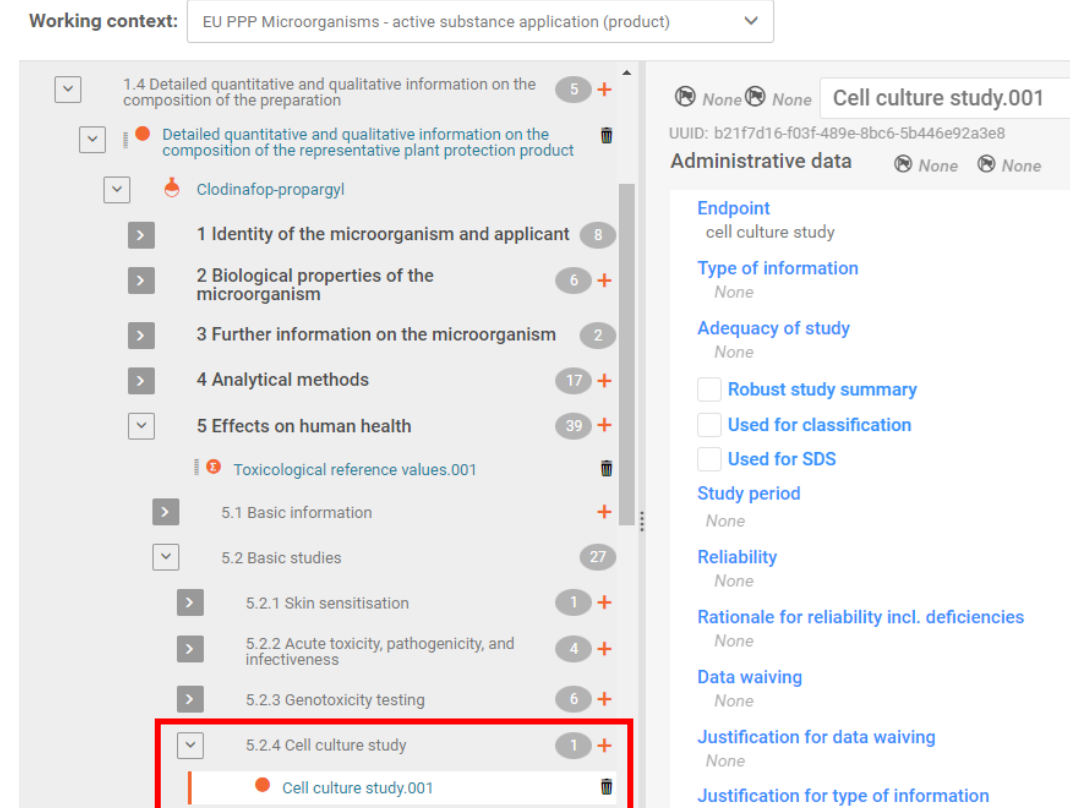
Description of key information (confidential)

Desc (conf)

Technical specification

SubstanceComposition (Flexible Record) | Clodinafop-propargyl_specification

2. New document ENDPOINT_STUDY_RECORD “**Cell culture study**” (c.f. 5.2.4 – EU PPP Microorganism)



Working context: EU PPP Microorganisms - active substance application (product)

1.4 Detailed quantitative and qualitative information on the composition of the preparation 5 +

Detailed quantitative and qualitative information on the composition of the representative plant protection product

Clodinafop-propargyl

1 Identity of the microorganism and applicant 8

2 Biological properties of the microorganism 6 +

3 Further information on the microorganism 2

4 Analytical methods 17 +

5 Effects on human health 39 +

Toxicological reference values.001

5.1 Basic information +

5.2 Basic studies 27

5.2.1 Skin sensitisation 1 +

5.2.2 Acute toxicity, pathogenicity, and infectiveness 4 +

5.2.3 Genotoxicity testing 6 +

5.2.4 Cell culture study 1 +

Cell culture study.001

None None Cell culture study.001

UUID: b21f7d16-f03f-489e-8bc6-5b446e92a3e8

Administrative data None None

Endpoint

cell culture study

Type of information

None

Adequacy of study

None

Robust study summary

Used for classification

Used for SDS

Study period

None

Reliability

None

Rationale for reliability incl. deficiencies

None

Data waiving

None

Justification for data waiving

None

Justification for type of information

Format changes: Domain

- Update of the “**synonym**” field in the **Reference Substance**:

→ from 32k characters to 2k, to facilitate searches in IUCLID

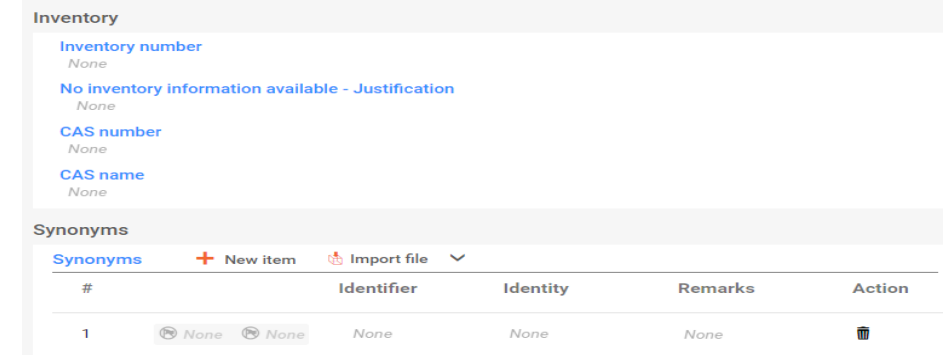
- Update of the **Confidentiality flag**:

→ **CBI** has been changed into “**confidential**” (IPR, no_PA entries in the picklist have been made obsolete)

- Update of **Literature Reference** in line with the proposal in June:

→ Addition of “Study ID type” (Notification of Studies)

→ Change in attachment fields



Inventory

Inventory number
None

No inventory information available - Justification
None

CAS number
None

CAS name
None

Synonyms

Synonyms + New item Import file

#	Identifier	Identity	Remarks	Action
1	None	None	None	

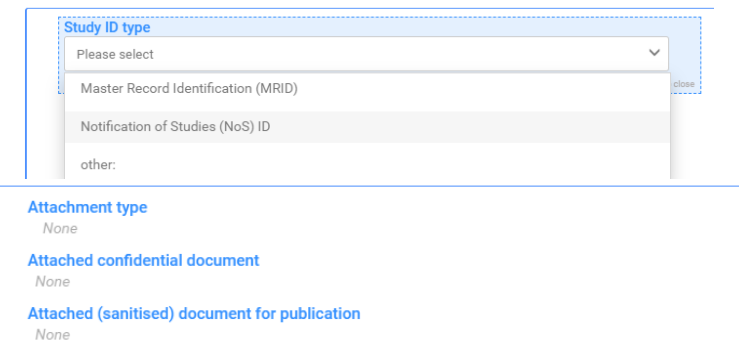
Confidentiality

This flag can be used to mark information for the purpose of a dossier or other report. Verify the default settings: no flag public. Selecting 'confidential' means that the data must be disseminated to the public. Consult any programme-specific NAFTA or EU REACH) on how to use this field.



Please select

CBI-[confidential business information]



Study ID type

Please select

Master Record Identification (MRID)

Notification of Studies (NoS) ID

other:

Attachment type

None

Attached confidential document
None

Attached (sanitised) document for publication
None

- Full revision of **ProcessedCommodities** related docs (backlog #2292) to ensure **complementarity** (e.g., inclusion of study level processing factors and findings from the RUEDIS DB project):
 - **ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities**
 - **ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedCommodities**
 - **ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommodities**
- Update of the **microorganism working context** (backlog #2152) to align with the changes in Legislation (Reg. 283/2013 and Reg. 284/2013)
 - Support needed from IBMA
 - other Organisations interested?

- **OHT 50-2** ToxicityToTerrestrialArthropods **to be split** in (new) ENDPOINT_STUDY_RECORD (backlog #2284) to capture studies on:
 - Pollinators (e.g., solitary bees, honey bee)
 - Non-target arthropods (above ground; e.g., leaf-dwelling)
 - Arthropods (below ground; e.g., soil-dwelling)

- Full revision of **OHT 87** Analytical methods considering 2020 request for changes

- IUCLID backlog is the **driver for IUCLID improvements**

--> please contribute by entering/commenting on backlog items, available at:

<https://docs.google.com/spreadsheets/d/1kFkttA6rXtR2K6LlaauHozq9BSfv6a5EgFDM1GgtmfQ/edit#gid=0>



<https://www.youtube.com/watch?v=PIBEJwcnWCI>



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