

2nd PSN IUCLID subgroup meeting – 31 Jan 2022

Filtering

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Proposed ruleset change


Section 1.9: Specification of purity of the active substance

IUCLID 6.6 path and rule	Rule type
FLEXIBLE_RECORD.SubstanceComposition= PUBLISHED	PUBLISHED
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.Name= PUBLISHED	PUBLISHED
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.TypeOfComposition= PUBLISHED	PUBLISHED
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.StateForm= PUBLISHED	PUBLISHED
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.DescriptionOfComposition= UNLESS_CONF	UNLESS_CONF
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.JustificationForDeviations= UNLESS_CONF	UNLESS_CONF
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription= PUBLISHED	PUBLISHED
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.AttachedDocument= NOT_PUBLISHED	NOT_PUBLISHED
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.Remarks= UNLESS_CONF	UNLESS_CONF
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions.RelatedComposition= PUBLISHED	PUBLISHED
FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions.ReferenceToRelatedCompositions= UNLESS_CONF	UNLESS_CONF

- 4 fields currently set to UNLESS_CONF
- There is no confidentiality flag covering the General information in this IUCLID document
- Short term: EFSA proposes to set these fields to NOT_PUBLISHED
- Long term: new/amended filter rule (potentially linked elsewhere in the dossier?) or new confidentiality flag

New filter rules? Points for analysis

1  Clodinafop-propargyl | clodinafop-propargyl | (R)-2-[4-(5-chloro-3-fluoro-pyridin-2-yloxy)-phenoxy]-propionic acid prop-2-ynyl ester | 105512-06-9 active substance

2  Cloquintocet-methyl | Cloquintocet-mexyl | Cloquintocet-mexyl | 99607-70-2 other: safener

Certain documents in IUCLID are more sensitive e.g. Analytical Methods, Active Substance Composition (batch analysis)

Are there cases where filtering and publication of the information is not just dependant on the study but also on the confidentiality status of the substance (as captured in the Flexible_Record.MixtureComposition)?

Do we need more intelligent filtering rules which are dependent on fields other than the confidentiality flag in the IUCLID document or the dossier header new active vs renewal?

Can we improve the filtering algorithm to support secure redaction of the information traditionally entered in Document J?

Example Analytical methods

.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.InstrumentDetector= UNLESS_CONF

.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.DetailsOnAnalyticalMethod= UNLESS_CONF

.MaterialsAndMethods.EnforcementMethodIfApplicable.InstrumentDetectorForEnforcementMethod= UNLESS_CONF

.MaterialsAndMethods.EnforcementMethodIfApplicable.DetailsOnEnforcementMethod= UNLESS_CONF

.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.InstrumentDetectorForConfirmatoryMethod= UNLESS_CONF

.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.DetailsOnConfirmatoryMethod= UNLESS_CONF

.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation= UNLESS_CONF

.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.RecoveryResults= UNLESS_CONF

.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.CharacteristicsOfAnalyticalMethod= UNLESS_CONF

.ResultsAndDiscussion.ResultsUsingEnforcementMethod.RecoveryResults= UNLESS_CONF

.ResultsAndDiscussion.ResultsUsingEnforcementMethod.CharacteristicsOfEnforcementMethod= UNLESS_CONF

.ResultsAndDiscussion.IndependentLaboratoryValidation.IndependentLaboratoryValidation= UNLESS_CONF

.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation= UNLESS_CONF

Currently 50 out of 123 fields are set as UNLESS_CONF

This study type is frequently included in Document J

Is there a need to refine the assignment of the existing rules?

Is there a need to redact additional fields if the analytical method describes a confidential impurity?

Is there a need to redact additional fields if the endpoint is 'method for the analysis of the active substance / formulated product / microorganism as manufactured'?

Working party on sensitive IUCLID documents?

Tasks

- Identify sensitive IUCLID documents
- Review existing rules for refinement
- Identify more complex cases
- Propose specification for intelligent rules (if needed)
- Report back at next PSN for filtering config update in October



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Update on confidentiality features

Legal Affairs Services

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- 1) For information: update of confidentiality section in Manual
- 2) For discussion and endorsement: decoupling confidentiality requests from personal data requests

- **Example(s)** of compliant justifications for confidentiality requests;
- **Template justification** for confidentiality requests concerning Confidential Business Information ('CBI')
- **“One item – one justification” approach**: possibility to submit single justification in justification box for all fields/attachments concerning the same subject

Example of procedurally compliant justifications in Manual

Set Flags

Confidentiality ? ▾

CBI

Justification ? ▾

 Insert existing templates

1)
I. Identification of the relevant item: The item claimed confidential can be found in the field "ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential" (paragraph 2, last line) and in two study reports referenced in this endpoint study record as literature references, (i) the study report "XYZ1", on page 14, paragraph 5, line 3-5 (until the end of the sentence) and (ii) the study report "XYZ2" on page 2, figure 1 and page 6, table 2).
II. Legal basis: The item claimed confidential consists in information concerning detailed contractual arrangements between a producer and the applicant and is considered to fall within the scope of Article 39(2) (b) of Regulation (EC) No 178/2002.
III. Rationale for award of confidential status: I hereby declare that the item claimed confidential should be granted confidential status because it meets the following cumulative requirements: a) it is not publicly available, b) it is eligible or worthy legal protection and has not been acquired in an unlawful manner, c) it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006 and d) its disclosure would be liable to cause potential harm to a significant degree because (i) it would result in financial damage corresponding to at least 5% of my gross annual turnover and (ii) the information is not older than 5 years.

2)
I. Identification of the relevant item: The item claimed confidential can be found in the fields "ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsIncITables.OtherInformation" (table 2), "ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.AnyOtherInformationOnResultsIncITables.OtherInformation" (figure 1) and "ENDPOINT_STUDY_RECORD.AnalyticalMethods.OverallRemarksAttachments.AttachedBackgroundMaterial.0.AttachedDocument" (attached file "Background doc XYZ1", page 5, paragraph 6, line 3-6 and attached file "Background doc XYZ2", page 7, paragraph 5, line 5-8 and paragraph 7, line 1-3).
II. Legal basis: The item claimed confidential consists in the full list of components of a plant protection product and is considered to fall within the scope of Article 63(2)(d) of Regulation (EC) No 1107/2009.
III. Rationale for award of confidential status: I hereby declare that the item claimed confidential should be granted confidential status because it meets the following cumulative requirements: a) it is not publicly available, b) it is eligible or worthy legal protection and has not been acquired in an unlawful manner, c) it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006, including in particular Article 6(1) thereof and d) its disclosure would be liable to cause potential harm to a significant degree because (i) it would result in financial damage corresponding to at least 5% of my gross annual turnover and (ii) the information is not older than 5 years.

3063/32768

Proposal for further improvement separation of CBI and PD requests

- **AS-IS:** PD and CBI requests have to be submitted using the same confidentiality flag and related justification box
- **Problems resulting from current solution:**
 - Notable impact on transparency
 - Sub-optimal use of justification box of the confidentiality flag

Proposal – separation of CBI and PD requests

- **Proposal for enhancement:** use remarks field linked to attachments for PD requests (“*AttachedBackgroundMaterial.Remarks*” for attachments NOT linked to a literature reference entry and “*LITERATURE.GeneralInfo.Remarks*” for attachments linked to a literature reference entry)

Remarks ⓘ ^

I would like to request confidential treatment for information contained in the study report with report number 119298 (1999) titled “Acute Dermal Toxicity in the Rat” that qualifies as personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 by its very nature.

I. Category of personal data: The information concerned covers the following information in an unpublished document:

- a) names of natural persons other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002; and
- c) handwritten signatures.

II. Identification of the personal data:

- Page 6: name of natural persons other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002 (paragraph 6, line 2);
- Page 8: name of natural persons other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002 (footnote 7);
- Page 9: handwritten signature (after 5th paragraph);
- Page 12: handwritten signature (after 6th paragraph);
- Page 14: names of natural persons other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002 (paragraph 6, line 2 and paragraph 7, line 3);
- Page 23: handwritten signature (after 9th paragraph).

1173/32768

Proposal under discussion – separation of CBI and PD claims

Opportunities	Challenges
Improved transparency	Multiple uses of remarks field
More space for CBI justification	Required change of filter rule
More intuitive (?)	Need to ensure no personal data is inserted in the remarks field
	Usability of the remarks field in the project of integration with EFSA's confidentiality workflow

Subject to availability of report and testing and endorsement from PSN

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