2nd PSN IUCLID subgroup meeting – 31 Jan 2022

# Filtering

Trusted science for safe food

efsa
European Food Safety Authority

# 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 | None<br>EU: PPP | 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 | CBI<br>EU: PPP | 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

efsa
European Food Safety Authority

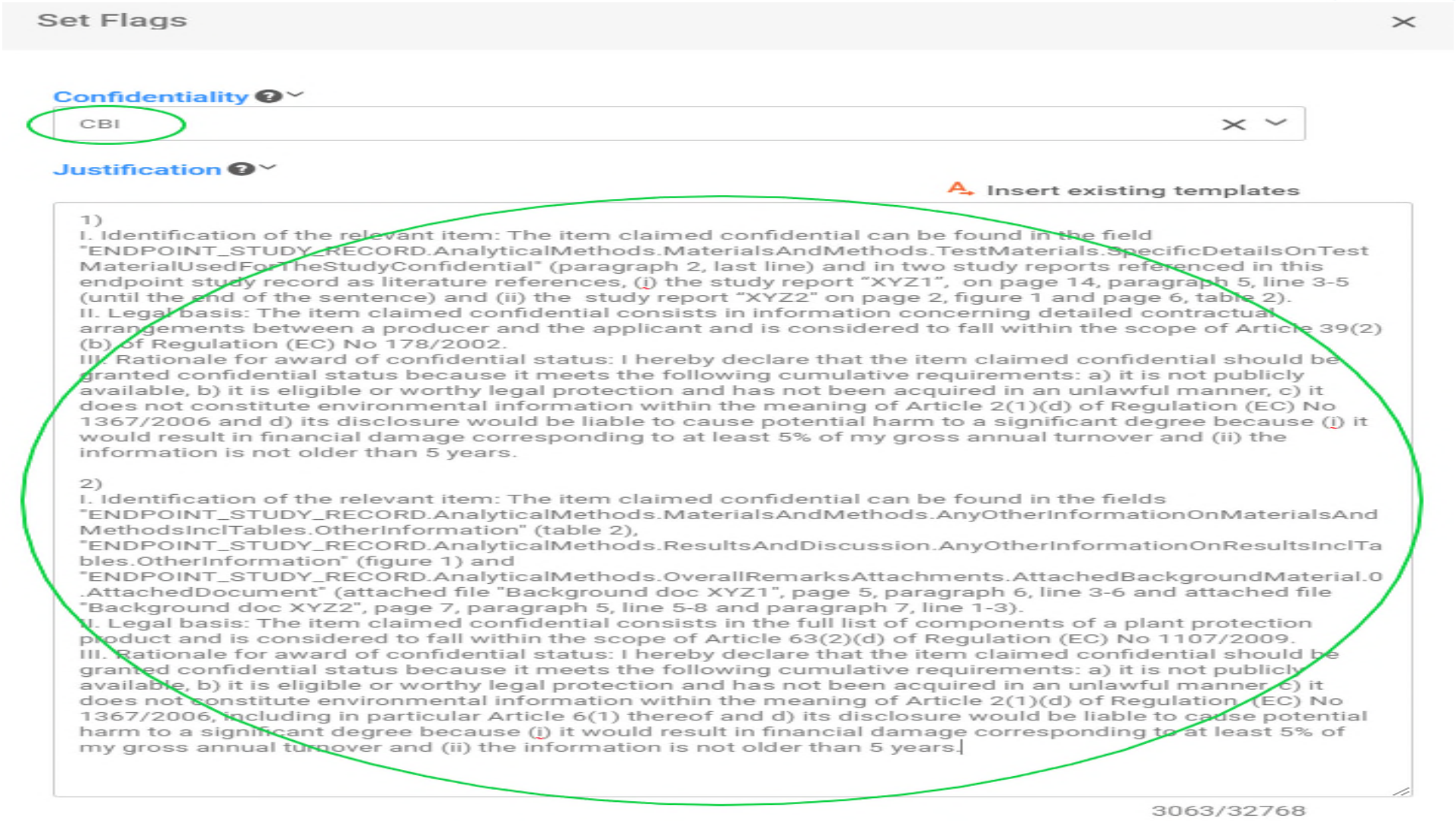
# Outline

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

# Revised confidentiality section in the IUCLID manuals

- **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



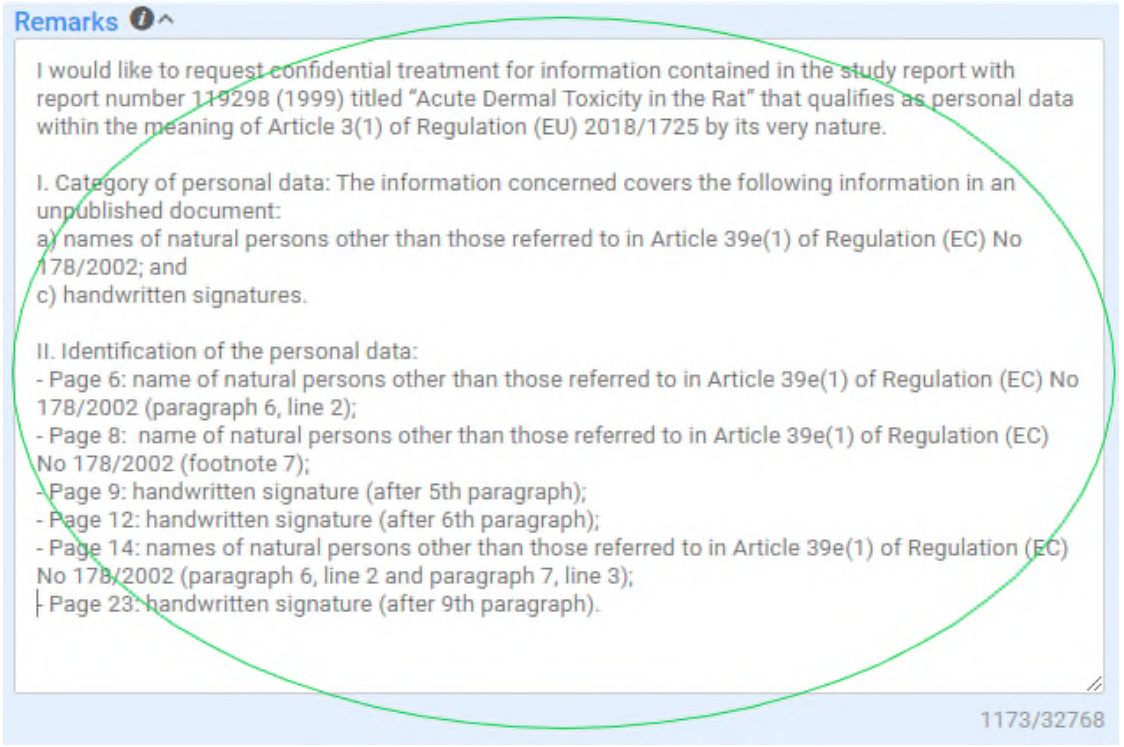
# Proposal for further improvement separation of CBI and PD requests

- **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)



# 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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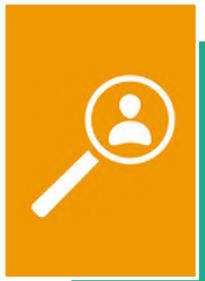

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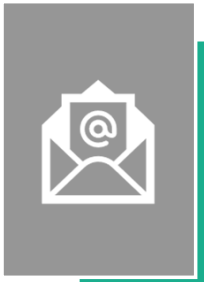

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