6th meeting of the PSN IUCLID sub-group

28 March 2022

UPDATE ON CONFIDENTIALITY

Chiara Macchi (FDP), Federica Bruno (LA)

EUROPEAN FOOD SAFETY AUTHORITY

FEEDBACK FROM THE WP ON FILTER RULES

- **8 meetings** held so far – 16 members: 2 MS, 5 applicants, 1 ECHA, 8 EFSA (FDP, PREV, PLANTS & LA)
- We have established **filter rules for all the new/updated IUCLID documents** included in the April release
  - Whilst respecting the balance between the obligation to publish and applicants' rights to protect CBI, we have adopted the **newly agreed principles of reducing the number of UNLESS_CONF fields**
  - The updated **Filter rules excel file will shortly be made available here**: 10.5281/zenodo.6794600

NEW FILTER RULE FOR THE MIXTURE COMPOSITION

- A **new filter rule "COMPONENTS_PPP"** has been developed for more sophisticated filtering of the Mixture composition table
  - If the function of the mixture component is set to active substance, active substance (other, not to be assessed), safener or synergist → the related information in the table is always published
  - Other components can be flagged confidential within the table → this will remove both the related information in the table and the whole row will be deleted (i.e. it will no longer be possible to derive the total no. of components within the mixture)
- The aim is for applicants to progressively stop providing the full mixture composition in Doc J and to revert to filling out the mixture composition table in the section 1.4 of the dossier
- The behaviour of the rule will be described in the Guideline tab of the filter rule excel

CLOSED LIST FOR CONFIDENTIALITY

- In order to assist in ultimately making the confidentiality process leaner (both for applicants and EFSA/RMS), all items for which a confidentiality request can be made were listed and mapped against IUCLID to identify which parts of the dossier may host these items → Closed list for confidentiality
  - *This exercise refers to CBI and not personal data*
  - Validated within EFSA and discussed/further elaborated within the Filtering WP
  - The aim is to reduce to a minimum the UNLESS_CONF fields in the parts of the dossier which are excluded from the closed list
    - We are aware of the HTML rich text fields in the endpoint study records which are still problematic

CLOSED LIST FOR CONFIDENTIALITY

Item(s) which can be claimed confidential	IUCLID documents in which it/they can be found
the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety	FLEXIBLE_RECORD.Manufacturer_EU_PPP FLEXIBLE_RECORD.Sites
commercial links between a producer or importer and the applicant or the authorisation holder, where applicable	FLEXIBLE_RECORD.Suppliers FLEXIBLE_RECORD.Sites FLEXIBLE_RECORD.Identifiers SUBSTANCE.RoleInSupplyChain MIXTURE.RoleInSupplyChain
commercial information revealing sourcing, market shares or business strategy of the applicant and quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety	FLEXIBLE_RECORD.Manufacturer_EU_PPP FLEXIBLE_RECORD.MixtureComposition FLEXIBLE_RECORD.Suppliers
the specification of impurity of the active substance except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant	FLEXIBLE_RECORD.SubstanceComposition SUBSTANCE REFERENCE_SUBSTANCE TEST_MATERIAL
results of production batches of the active substance including impurities	FLEXIBLE_SUMMARY.AnalyticalProfileBatches FLEXIBLE_RECORD.SubstanceComposition
methods of analysis for impurities in the active substance as manufactured except for methods for impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant	FLEXIBLE_RECORD.AnalyticalInformation ENDPOINT_STUDY_RECORD.AnalyticalMethods ENDPOINT_SUMMARY.AnalyticalMethods
	LITERATURE REFERENCE ENTITY
NEW IUCLID DOCUMENTS APRIL 2023	FIXED_RECORD.AddTranspRegInfo FLEXIBLE_SUMMARY.IsomericCompositionRiskAssessment ENDPOINT_STUDY_RECORD.GenomicCharacterisationMicroorganism

FILTERING WP - NEXT STEPS

- **Finalise the new filter rule excel** in which UNLESS_CONF is only used in Closed list documents
  - Aim for October 2023 release
- **Relocate all data currently included in Doc J** into appropriate documents/fields within the dossier and ensure that the data are filtered and published in an adequate manner
  - Aim to remove Doc J, which is a legacy document
  - April 2024 release?
- **Preliminary planning** for the above has been shared and will be discussed and further refined at the next WP meeting (13 April 2023)
- Identify the need for and **develop more sophisticated filter rules** which will enable further reduction of the number of flags and associated confidentiality requests by linking data within the dossier (e.g. redaction of information from the analytical methods document based on the decision taken in the substance composition document)

KEY MESSAGES – PRIOR INFORMATION & INTERACTION WITH EFSA

- **Consulting the User Guide on confidentiality** (justification templates and examples);
- **Pre-submission interaction with EFSA highly encouraged** → in case of doubts on the confidentiality assessment process: to contact EFSA via 'ASK a question';
- **Effective use of commenting opportunity on EFSA's draft decision** (2-weeks period available);

KEY MESSAGES – PROPER RECOURSE TO CONFIDENTIALITY REQUESTS & ATTACHMENTS

- **Reasonable recourse to CBI requests** → impact on timeline for confidentiality and risk assessment;
- **Importance of compliant CBI requests**:
  - claims to be substantiated;
  - legal basis to be specified;
  - all attachments to be mentioned in the justification;
  - elements claimed confidential in attachments to be clearly identified;
  - too broad and unjustified earmarking to be avoided (e.g. relevant impurities, name of active substance).
- **Sound masking of personal data** in the non-confidential version of attachments (refined concept of personal data in the forthcoming update to the User Guide);
- **Duplication of attachments in the endpoint study record and literature reference to be avoided**

KEY MESSAGES - OPTIMISATION & LEANING OF CONFIDENTIALITY PROCESSES

- EFSA actions under way to speed up the processing of CRs in the short term
- Comes on top of measures already in place since Q4 last year to optimise confidentiality assessment & implementation, including internal and organisational rearrangements

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