

7th meeting of the PSN IUCLID sub-group
19-20 June 2023

FILTERING RULES - FEEDBACK FROM THE WP

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IUCLID PSN FILTERING WP

- The filtering WP ran between 15 September 2022 and 15 June 2023
 - It will currently be suspended in order to prioritise the microorganisms WP and may resume at a later stage (either with regular or ad-hoc sessions)
- 16 participants
- Updated filter rule excel for the current IUCLID release available here: [10.5281/zenodo.8052372](https://doi.org/10.5281/zenodo.8052372)



DECISIONS TAKEN

- Established **filter rules for all the new/updated IUCLID documents** included in the IUCLID 6 v.7 release using the newly agreed principles of reducing the number of UNLESS_CONF fields to the extent possible
- A **new filter rule “COMPONENTS_PPP”** developed for more sophisticated filtering of the Mixture composition table
 - If the function of a 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)



DOC J REMOVAL

- Aim to **no longer support Doc J** as from April 2024
 - In order to **reduce over-filtering of dossiers** prior to publication
 - In order to gather the data in a structured manner (as for all other data) which can only be achieved by filling in the appropriate IUCLID fields
 - Subject to having a report on confidential data generated through Report Generator
 - Subject to a limited number of format changes to be made to IUCLID
 - With an agreed plan on dealing with already submitted/published dossiers
- **N.B. It is important for applicants to be aware as from now that they should provide the data in the appropriate fields in IUCLID**
 - EFSA to continue implementing quality warnings on this data in the future



DECISIONS TAKEN

- The “Closed list for confidentiality” was established by mapping all items for which a confidentiality request can be made against IUCLID to identify which parts of the dossier may host these items → aim to lean the confidentiality request process (fewer claims to be made, assessed, etc)
- A draft set of filter rules extending the UNLESS_CONF reduction also to existing documents/fields has been agreed with a strong drive to publish more data
 - **The file will be made available for public consultation end June – mid August with an EU Survey to provide feedback**
 - The intention is to apply these revised filter rules as from April 2024
- CBI flags added to new Closed List IUCLID documents with results linked to a reference substance (Analytical methods & Analytical Profile of batches)



DECISIONS TAKEN

- **All UNLESS_CONF rules analysed**
 - For UNLESS_CONF fields in closed list UNLESS_CONF maintained or converted to NOT_PUBLISHED in exceptional cases
 - Information reported in Summaries, Administrative data (including Data Waiving), Methods descriptions, Results descriptions, Background material remarks, Discussion which were UNLESS_CONF are switched to PUBLISHED – This information should be made available for the Public Consultation
 - DetailsOnMethods set to PUBLISHED → it is recommended to put confidential information in a cross-referenced Analytical Methods document
 - The HTML text boxes
AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation &
AnyOtherInformationOnResultsInclTables.OtherInformation remain UNLESS_CONF
 - Specific attention was applied to FLEXIBLE_PACKAGING & FLEXIBLE_RECORD.AssessmentOtherAuthorities – Attachments should NOT be set to PUBLISHED (IUCLID backlog item to be created for adding a non-confidential attachment)



IUCLID FILTERING AUXILIARY RULES

- All fields in IUCLID have a dedicated filter rule (listed in the filter rule configuration file) except picklists associated with free text fields:
 - a) When you select "Other" from a picklist (Rule DS0008)
 - b) When you select "Other" from a picklist, followed by "Remarks" (Rule DS0009)
- These are also displayed separately when running the Dissemination preview for a dossier:

Text Filters

Search

- (Select All)
- Flagged confidential – Not published
- Not published
- Published
- Removed (not published)
- Removed open picklist 'Other' field
- Removed picklist remark



BEHAVIOUR OF AUXILIARY RULES

- The two rules are independent from each other (one governing “Picklist: Other” and the other governing “Picklist: Other + Remarks”)
- They are currently both switched ON → the information is REMOVED from the dossier
- PROPOSAL: the rules should be switched OFF → the information is PUBLISHED by default
- N.B. these are “all or nothing” rules so they are set once upfront and are then applicable to all documents within each dossier



DECISIONS TAKEN

- The Auxiliary rules on the picklists will be switched OFF → the information will be PUBLISHED by default
- The above will be included in the public consultation to be launched in the summer on the April 2024 ruleset so that EFSA can collect feedback on the proposal before implementing
- If there are major changes compared to the proposed rules, the filtering WP will reconvene after the summer to discuss



TIMING FOR CHANGES

Consultation

Mid June – Mid August

All rules aligned with the minimal UNLESS_CONF approach

New filtering rules defined for fields in the Closed List docs to streamline decision making

List of changed fields

Auxiliary rules turned OFF

Post-Consultation (autumn 2023)

Modification of rules based on feedback

Publication of rules, check list for applicants

Presentation on change to filtering rules

New filtering rules available for Beta testing

Definition of IUCLID document changes to support removal of Doc J

Identification of need for additional closed list rules for Doc J content

Report generator for Doc J

IUCLID April 2024 Release

Minimal UNLESS_CONF & efficient Closed List rules in production

Doc J no longer accepted in IUCLID dossiers



ANALYTICAL METHODS TEMPLATE OHT 87

IUCLID feedback

Analytical methods

[Technical Material and Preparations - Analytical methods for Annex II \(part A, Section 4\) and Annex III \(part A, Section 5\) SANCO/3030/99 rev.5](#) - 22 March 2019

[Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes - SANTE/2020/12830](#). Rev 2 – 14 February 2023

[Guidance document on analytical quality control and method validation procedures for pesticide residues analysis in food and feed - SANTE/11312/2021](#) – 1 January 2022

[Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods - SANTE/2017/10632](#). Rev.5 – 11 May 2023

[Working document on the summing up of LOQs in case of complex residue definitions - SANCO/12574/2014 rev.5.1](#), 30 November-1 December 2015

[European Commission Guidelines – Maximum Residue Levels](#)

OHT 87 - mix of confidential and non-confidential information

Problem: Depending on structure one method may contain analytical information for confidential and non-confidential substances (e.G. relevant and non-relevant impurities) – applies also to other data e.G. QSAR

- Filtering simple and straight forward for tabular fields:

The screenshot shows a software interface with two main sections: LOQ/LOD and Calibration. The LOQ/LOD section has a table with columns: #, Analyte, Matrix, Limit of quantification, Limit of detection, Remarks, and Actions. The Calibration section has a table with columns: #, Analyte, Standards, Matrix, MRM/ m/z, Calibration..., Calibration..., Correlation..., Correlation..., Number re..., Remarks, and Actions. Below the calibration table is a link for 'Matrix effects (%)'. The LOQ/LOD table contains one entry for a specific analyte with its matrix and limits.

#	Analyte	Matrix	Limit of quantification	Limit of detection	Remarks	Actions
1	5-methoxymethyl-2-(4-methyl-4-propyl-5-oxo-2-imidazolin-2-yl)nicotinic acid	Matrix 1	0.001 mg/kg	0.000001 mg/kg		

#	Analyte	Standards	Matrix	MRM/ m/z	Calibration...	Calibration...	Correlation...	Correlation...	Number re...	Remarks	Actions
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- Detailed filtering impossible for free-text fields:

The screenshot shows a document with several tabs: Administrative data, Data source, Background, Materials and methods, Results and discussion, Overall remarks, attachments, and Applicant's summary and conclusion. The 'Results and discussion' tab is active. The text in this tab is partially obscured by a large red 'X' with a green border, indicating that confidential information has been redacted. The text visible includes 'The correlation factors of > 0.99 show acceptable linear correlation for the tested concentration range', 'Accuracy was demonstrated by a [redacted] at concentrations of approx. 5 mg/kg, 10 mg/kg and 100 mg/kg. For each fortified level six samples were prepared independently. Accuracy of the method was determined by [redacted] of the cyanide added with the measured concentrations determined applying the method. Appropriate mean recoveries were obtained.', and 'Limit of quantification can be established at the lowest [redacted] showing appropriate mean recoveries and precision.' Below the text is a table with columns: Level, [redacted], Added Content [mg CN/l], Measured Content [mg CN/l], and Recovery [%].

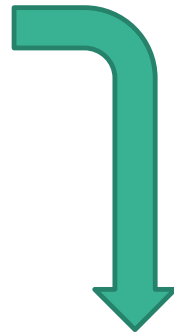
Level	[redacted]	Added Content [mg CN/l]	Measured Content [mg CN/l]	Recovery [%]
		0.048	0.048	96.0
		0.1314	0.047	94.0
		0.1243	0.047	94.0
low	Approx.5	0.1003	0.05	98.0
		0.1175	0.05	94.0
		0.1133	0.05	94.0

Proposed solution: Split out of information in several OHTs to separate confidential and public information

Option I: Keep all OHTs under the AI dataset and make OHT as a whole confidential

- For Analytical methods implementation of further substructure reflecting Data requirements
- Anyhow recommended for better overview and structure

- > 3 Further information on the active substance
- 4 Analytical methods
- > 5 Toxicological and metabolism studies on the active substance



- ▶ KCA 3: Further Information on the active substance
- ▼ KCA 4: Analytical Methods
 - ▼ KCA 4.1: Method used for the generation of pre-approval data
 - ▶ KCA 4.1.1: Methods for the analysis of the active substance as manufactured
 - ▶ KCA 4.1.2: Methods for risk assessment
 - ▶ KCA 4.2: Methods for post-approval control and monitoring purposes

[-] Analytical methods

KCA 4.1.1_01 (2022)_S22-00001

Example, active substance in TGAI, SANCO 3030/99
"methods for the analysis of the active substance as manufactured (QC)"

Analytical methods (CA 4.1.1)

Analytical methods for risk assessment (CA 4.1.2)

KCA 4.1.1_02 (2022)_S22-00002

Example, significant impurity in TGAI, SANCO 3030/99
"methods for significant impurities"

KCA 4.1.1_03 (2022)_S22-00003

Example, relevant impurity in TGAI, SANCO 3030/99
"methods for relevant impurities and metabolites of concern"

Analytical methods for Monitoring/Enforcement methods (CA 4.2)

KCA 4.1.2_(a)_01(Year)_Report Number

KCA 4.1.2_(b)_01(Year)_Report Number

KCA 4.1.2_(c)_01(Year)_Report Number

KCA 4.1.2_(d)_01(Year)_Report Number

KCA 4.1.2_(e)_01(Year)_Report Number

KCA 4.1.2_(f)_01(Year)_Report Number

KCA 4.1.2_(g)_01(Year)_Report Number

Example, analyte in ecotox matrix for Algae study, SANTE/12830/2020
old SANCO/3029 "methods for risk assessment"

KCA 4.2_(a)_plant_01(2023)_S23-00103

KCA 4.2_(a)_plant_02(2023)_BPL-RF-00011 ILV

KCA 4.2_(a)_animal_01(2023)_S23-00104

KCA 4.2_(a)_animal_02(2023)_BPL-RF-00012 ILV

KCA 4.2_(b)_soil_01(2023)_S23-00106

KCA 4.2_(b)_water_01(2023)_S23-00105

KCA 4.2_(b)_water_02(2023)_BPL-RF-00013 ILV

KCA 4.2_(c)_air_01(2023)_S23-00107

KCA 4.2_(d)_body fluids and tissues_01(2023)_S23-00108

Example, analyte in environmental matrices for water, SANTE/12830/2020,
old SANCO/825 "methods for post-approval control and monitoring purposes"

Option I: Keep all OHTs/EPs under the AI dataset and make OHT as a whole confidential

- Expansion of Endpoint picklists
- Depending on Selection OHT/EPs would be filtered completely or not
- CBI justifications to be provided as before

The screenshot displays a software interface for managing regulatory data. On the left, a sidebar shows a tree view under 'Working context' (EU PPP Active substance information) and 'Testeron'. The selected item is 'CA 4.1.1 Methods for the analysis of the active substance as manufactured: non-relevant impurities'. The main panel shows the details for this item, including a UUID and a set of tabs: 'Administrative data', 'Data source', 'Background', 'Materials and met...', 'Results and discu...', 'Overall remarks, att...', and 'Applicant's summary an...'. The 'Administrative data' tab is active, showing an 'Endpoint' dropdown menu with 'Other:' selected and 'Methods for non-relevant impurities' as the chosen option. Below this, there are sections for 'Type of information' and 'Adequacy of study', with checkboxes for 'Robust study summary' and 'Used for classification'.

Working context

EU PPP Active substance information

Type at least 3 characters

Testeron

1 Identity of the active substance and applicant 1

2 Physical and chemical properties of the active substance

3 Further information on the active substance

4 Analytical methods 2

CA 4.1.1 Methods for the analysis of the active substance as manufactured: relevant impurities

CA 4.1.1 Methods for the analysis of the active substance as manufactured: non-relevant impurities

CA 4.1.1 Methods for the analysis of the active substance as manufactured: non-relevant impurities

UUID: 7af24713-ba8a-4f7e-a113-f65c0aaa1db2

Administrative data | Data source | Background | Materials and met... | Results and discu... | Overall remarks, att... | Applicant's summary an...

Administrative data

Endpoint ? ^ ? ^

Other: x v

Methods for non-relevant impurities

Type of information

Adequacy of study

Robust study summary

Used for classification

Option II: Split OHT by substance dataset

Gabirobilin
535797a1-1466-4a83-bf93-d2043fa9f156

1 Identity of the plant protection product and applicant 2

1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant 1

1.2 Producer of the plant protection product

1.3 Producer's development code number if appropriate

1.4 Detailed quantitative and qualitative information on the composition of the plant protection product 1

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

1.4.5 Other representative products

1.5 (Cf. 1.4) Type and code of the plant protection product

Detailed quantitative and qualitative information on the composition of the plant protection product.001

UUID: f9b78fb5-9e29-4538-9ad8-cefc436f06bf

None None

Administrative data General information Components

Mixture/product name

Trade names + New item Import file

Brief description

Formulation type

Components

+ New item Import file

#	Componen...	Name	Function	Typical co...	Concentrat...	Remarks	Substa
1	CBI None	Water	other: significant impurity				<input type="checkbox"/>
2	None None	Weeexs	active substance	500 mg/L			<input type="checkbox"/>
		DMSO					<input type="checkbox"/>

- Impurities linked as individual substance datasets as needed
- Non-relevant impurity data sets filtered out by flagging currently in the mixture composition document
- CBI justifications only to be provided once within composition document

Option II: Split OHT by substance dataset

The screenshot displays two side-by-side views of the 'Gabirobilin' substance dataset. Both views show a sidebar with a tree structure of categories, a main content area with tabs for 'Administrative data', 'Data source', and 'Background', and a search bar. The 'Administrative data' tab is active in both views, showing options like 'Robust study summary', 'Used for classification', and 'Used for SDS'. The 'Robust study summary' option is checked in the relevant impurity view and unchecked in the non-relevant impurity view.

- Non-relevant impurity data set contains only information related to confidential substances
- Relevant Impurity or AI dataset contain all relevant public information regarding the analytical methods
- Corresponding literature reference linked to all relevant instances of the OHT

Linking of impurities

Current situation: If Impurity substance datasets exist they can only be linked to the mixture composition (AI composition allows only for reference substance linking):

- Creates confusion on mixture composition level
- Prevents the re-use of data sets across submissions as relevant data are only available on impurity level linked to any mixture datasets
- Proposed improvement: Enable linking of substance data sets to the TGAI composition document (Specification of purity of the active substance)

#	Compo...	Name	Function	Typical...	Concen..
1		Test IIP	emulsifier		
2		Testeron (2R)-3-(4-[ethyl(pyridazin-4-yl)carbamoyl]-5-methyl-1H-pyrazol-1-yl)-2-methylbutanoic acid	other: relevant impurity		

Impurities					
+ New item Import file					
#	Reference subst...	Typical concentr...	Concentration ra...	R	
1	Testeron	< 0.4 g/kg		F	



YOUR FEEDBACK IS NEEDED

Slido



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