Validation rules for poison centres notifications

April 2019

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1. Introduction

This document provides short descriptions of the validation rules in IUCLID which are relevant for poison centres notifications (PCNs).

2. Validation rules in IUCLID

A business rule (**BR**) failure leads to the failure of the submission. A quality rule (**QLT**) warns or reminds the notifier of common shortcomings and inconsistencies. Quality rules will not lead to the failure of the submission, but can result in further clarification requests from Member state(s) at a later stage.

2.1 List of PCN validation rules in IUCLID

Current PCN submission types include standard submissions (**S**), limited submissions (industrial use only) (**L**) and non-hazardous submissions (voluntary submissions) (**N**). A rule can be relevant for the specific submission type or for the **all** the above mentioned submission types. This is indicated in the third column of the tables.

'Group notifications' are not included in April 2019 release of IUCLID.

Rules marked with asterisk (*) in the tables below are not provided in the April 2019 release of IUCLID. We aim to provide these rules in the coming IUCLID releases this year.

Rule number	Short description of the rule	Type
LEGAL ENTITY – IDENTIFICATION OF THE SUBMITTER		
BR608	**Legal entity** must be provided in dossier header and in 'Mixture identity and legal submitter' record.	All
BR520	The legal entity provided in dossier header must be the same as the one provided in in 'Mixture identity and legal submitter' record (the rule compares legal entity UUIDs).	All
BR519	The contact details of the legal entity must include: • address 1 • town • country • phone • email • postal code.	All
BR522	Email address must be in email format.	All

DOSSIER HEADER		
BR553	The **PCN number** must be indicated and it must be in UUID format. The UUID format is described in https://en.wikipedia.org/wiki/Universally_unique_identifier and https://tools.ietf.org/html/rfc4122	All
BR554	At least one **'Country (market placement)'** must be selected.	All
BR558	Each country mentioned as **'Country (market placement)'** must have at least one corresponding 'Product information' record.	All
BR559	At least one **'Language'** must be selected.	All
BR561	Either 'The submission is an initial notification', 'The submission is a new notification after a significant change in composition' or 'The submission is an update' must be selected.	All
BR562	If 'The submission is a new notification after a significant change of composition' is selected, 'CLP related PCN number' must be provided in the 'Unique formula identifiers (UFI) and other identifiers' section.	All
BR543*	If 'The submissions is an update' is selected, 'Reason for updating' must be reported.	All

CONTACT PERSON		
BR552	An emergency contact must be provided in the 'Contact person' section for each country indicated in the dossier header.	L
BR523	The contact details of the emergency contact must include: • last name • organisation • phone • email • country.	L

pH		
BR512	Exactly one 'pH' record must be provided.	S, L
BR545	Either 'pH not relevant' must be selected or a pH value must be reported (one value or range).	S, L
BR524	Allowed pH values: -3=< pH =<15	All
BR615*	Allowed pH qualifiers: one value cannot have qualifiers, range cannot have 'c.a.'.	All
QLT504*	pH value must be indicated as an integer or specified to one decimal.	All
QLT501	Maximum pH value range width is 1 unit (when pH =<3 or >=10).	All
QLT510	Minimum pH value range width is 3 units (when pH 3 < pH <10).	All

BR585	If pH is relevant, 'Solution concentration' must be provided.	All

TOXICOLOGICAL INFORMATION		
BR515	Exactly one 'Toxicological information' record must be provided.	S, L
BR538	Toxicological information must be provided (at least 200 characters) in 'Toxicological information (section 11 of SDS)' field(s) in all relevant languages.	S, L

MIXTURE COMPOSITION		
BR509	Exactly one 'Mixture composition' record must be provided.	All
BR521	At least one 'Mixture' (MiM) or 'Substance' component must be provided in 'Mixture composition' (Main mixture).	All
BR551	'Reference substance' datasets cannot be linked from 'Mixture composition' (MainMixture). Only 'Mixture' (MiM) and 'Substance' datasets can be linked from 'Mixture composition' (MainMixture).	All

MIXTURE COMPONENTS (MiM)		
BR527	For identifying the MiM, it is mandatory to provide either a Safety data sheet (SDS) attachment or a UFI. Components identified using the Generic Product Identifier (GPI) are an exception.	All
BR578*	There cannot be more than one UFI per MiM.	All
BR579	If the MiM is identified using a Safety data sheet (SDS), the 'Suppliers' record is mandatory.	All
BR606	If the MiM is identified using an SDS, the legal entity in the 'Suppliers' record must include the contact details: • legal entity name • phone • email.	All
QLT512	Reminder that a MiM should be identified using an SDS only as a last resort. This approach should used only if there is no possibility to obtain full compositional information or the UFI from the MiM supplier.	All
BR577*	'Reference substance' datasets and 'Mixture' datasets cannot be linked from 'Mixture' (MiM). Only 'Substance' datasets can be linked from 'Mixture' (MiM).	All

SUBSTANCE COMPONENTS (SiM)		
BR539	Substance components must have linked 'reference substance' datasets. Components identified using the Generic Product Identifier (GPI) are an exception.	All

BR540	'Reference substance' must have at least one of the following identifiers: EC number, CAS number, IUPAC name, INCI or colour index name.	All
QLT509*	If no EC number, CAS number or IUPAC name is provided for the 'reference substance', then notifier is reminded that more identifiers could be provided	All
BR525	EC number format must be correct.	All
BR526	CAS number format must be correct. The CAS number format is described in: https://www.cas.org/support/documentation/chemical-substances/checkdig.	All
BR592*	Repeating the same 'reference substance' not allowed unless the related classification is different.	All

Substance or mixture components identified using the Generic Product Identifier (GPI)		
BR583	If the component is indicated using the GPI, 'Function' must be 'Colourant, 'Fragrance' or 'Perfume'.	All
BR605	GPI cannot be classified for human hazard.	All
BR604	GPI type 'Perfume' can only be used once.	All
BR616	GPI type 'Fragrance' can only be used once.	All
BR617	GPI type 'Colourant' can only be used once.	All
BR602	The concentration of the GPI type component 'Colourant' must be less than 25 %.	All
BR603	The total concentration of the 'Fragrance' and 'Perfume' GPI type components must be less than 5 %.	All

Components concentrations		
BR590	Components must have concentrations (value and unit). Components described in provision B.3.4.2 of Annex VIII are an exception.	All
BR581	Either 'Typical concentration' or 'Concentration range' must be provided, not both.	All
BR607*	Only positive values are allowed for concentrations.	All
QLT502*	If the concentration is above 1 %, the allowed number of decimals is one.	All
QLT505*	If the concentration value is 0.1-1 %, the allowed number of decimals is two.	All
BR518	Allowed concentration ranges for hazardous components of major concern must be in accordance with Annex VIII to the CLP Regulation, Table 1 of Part B.	S, N
BR588	Allowed concentration ranges for other hazardous components and components not classified as hazardous must be in accordance with Annex VIII to the CLP Regulation, Table 2 of Part B.	S, N

BR556	Total concentration of the mixture is too low (below 70 %). If the reported concentration is lower than 70 %, the dossier cannot be accepted.	S, N
QLT506	Total concentration of the mixture is too low (70-90 %). If the reported concentration is lower than 90 %, the notifier is warned that the full composition is currently not included.	S, N
BR593	Total concentration of the mixture exceeds 100%. If the reported concentration is higher than 105 %, the dossier cannot be accepted.	all
BR591	Units provided for concentrations must be consistent.	All
BR541*	Allowed units for concentrations: v/v % and w/w %.	All
BR548*	Allowed qualifiers for concentrations: 'Typical' cannot have qualifiers; 'c.a.' not allowed for range.	All

UNIQUE FORMULA IDENTIFIER (UFI) AND OTHER IDENTIFIERS		
BR516	'Unique formula identifiers (UFI) and other identifiers' record must be provided.	S, L
BR528	UFI is mandatory. At least one entry with the regulatory programme type 'CLP unique formula identifier (UFI)' and the appropriate UFI value in the field 'Id' must be included.	S, L
QLT508*	UFI is mandatory. At least one entry with the regulatory programme type 'CLP unique formula identifier (UFI)' and the appropriate UFI value in the field 'Id' must be included.	N
BR549	UFI number format must be correct. The UFI format is specified in the UFI Developers Manual: https://poisoncentres.echa.europa.eu/ufi-generator.	All
BR563*	'CLP related PCN number' not allowed for initial submissions.	All
BR562	'CLP related PCN number' is mandatory for 'after significant composition change' notifications.	All
BR609*	Submission cannot have more than one 'CLP related PCN number' reported.	All
BR584	'Unique formula identifiers (UFI) and other identifiers' record must be included in 'Product information' record.	S, L

CLASSIFICATION AND LABELLING		
BR513	Exactly one 'Classification and labelling information' record must be provided in 'Mixture information' (MainMixture).	All
BR510	Exactly one 'Classification and labelling information' record must be provided for each 'Mixture' component (MiM).	All
BR612	Exactly one 'Classification and labelling information' record must be provided for each 'Substance' component.	All

QLT507	Voluntary submissions cannot be classified for health or physical hazards. An exception can be made if classification is only regarding explosive or gases under pressure hazards.	N

PRODUCT INFORMATION		
BR517	At least one 'Product details' record must be provided.	All
BR508	'Trade name' must be provided.	All
BR531	Each 'Product details' record must have at least one linked UFI number.	S, L
BR532	Market placement 'Country' is mandatory.	All
BR610	Each country indicated in the 'Product information' record must be also indicated as a market placement country in the dossier header.	All
BR514	'Colour and physical state' record is mandatory.	S, L
BR529	'Physical state' must be indicated.	S, L
BR547	'Physical state' must be same in all 'Colour and physical state' records.	S, L
BR530	'Colour' must be indicated.	S, L
BR542	Either 'Packaging document' must be linked or 'Product not packaged' must be selected.	S, L
BR536	'Type of packaging in contact with the product (container type)' must be indicated.	S, L
BR537	'Size of packaging in contact with the product (container size)' must be indicated.	S, L
BR535	At least one 'Use type' must be indicated.	S, L
BR587	For limited submissions, 'Use type' can only be 'Industrial'. ''Professional' and 'Consumer' are not allowed.	L
BR534	'Main intended use' must be indicated.	S, L
QLT503	Up to three 'Secondary uses' allowed.	S, L
BR589	Biocides or plant production products cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.	All

3. Known issues in April 2019 release of IUCLID

3.1 Validation report links

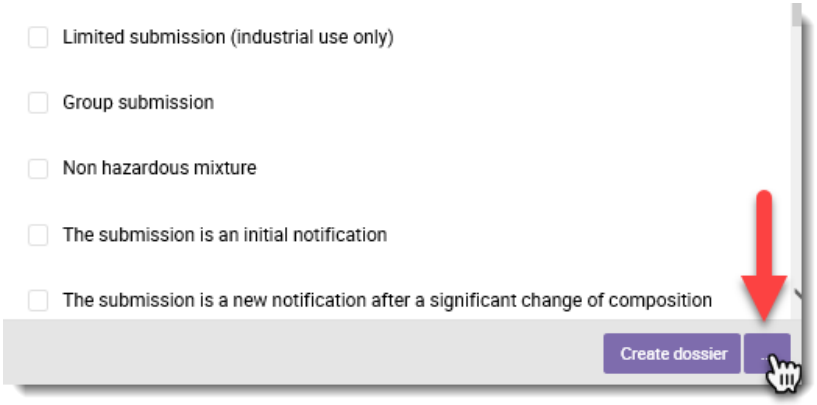
When validating Poison Centres notifications in the *Guided approach for dossier preparation*, the links from validation failures to the corresponding dossier/dataset sections do not work correctly on all occasions. The behavior will be improved in a subsequent IUCLID release this

year.

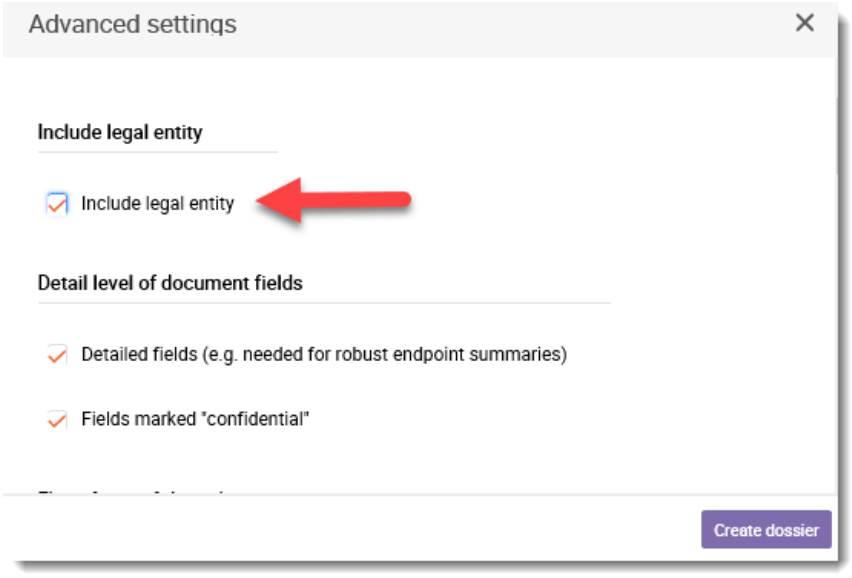
3.2 BR608 Information on the legal entity must be provided in the dossier

At present, the legal entity can only be included in the dossier using the *Advanced settings* feature. The feature is not available when validating the PCN mixture dataset and therefore the rule cannot be made to pass during dataset validation. **The rule should not be disregarded when validating the final dossier**, as this would result in the notification failing the submission checks when uploaded to the ECHA submission portal for poison centres notifications. The feature will be improved in a later IUCLID release this year. To include the legal entity information when creating the dossier:

1) Go to *Advanced settings* by clicking the button '...' in the bottom right-hand corner.



2) Tick 'Include legal entity'. Click 'Create dossier'.



4. Changes to this document

Version	Changes
1.0	April 2019 First version