Validation rules for poison centres notifications

October 2019

Table of Contents

1. Introduction

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

2. Validation rules

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.

'Group notifications' are not included in October 2019 release of IUCLID and ECHA Submission portal.

2.1 List of PCN 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.

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	**Legal entity** provided in dossier header must be the same as the one provided in in 'Mixture identity and legal submitter' record.	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. (International chemical name should be reported in the IUPAC name field.)	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 not exceed 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
BR557	'PCN number' reported in dossier header cannot be same as 'CLP related PCN number'.	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. Exception if use type is only 'Industrial'.	S
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

2.2 List of PCN validation rules in ECHA Submission portal

Rules marked in blue (**BR**) lead to the failure of the submission. Rules marked in orange (**BR**) warn or remind the notifier of common shortcomings and inconsistencies. These warnings will not lead to the failure of the submission, but can result in further clarification requests from Member state(s) at a later stage.

GENERAL RULES		
BR564	The exactly same dossier cannot be submitted again.	All
BR565	ECHA Submission portal currently only accepts dossiers of which the submission type is 'CLP Poison centres notification'.	All
BR619	'Group submissions' are not allowed.	G
BR573	Mixture name should remain same in update dossier.	All

DOSSIER HEADER		
BR570	Submitter legal entity in 'ECHA Submission portal' must be same as the legal entity included in the dossier header.	All
BR567	A new 'PCN number' should be provided for initial notifications and significant change of composition notifications.	All
BR568	An existing 'PCN number' should be used in updates notified by the same legal entity.	All
BR576	In case of updates, the dossier creation date should be greater than the previously submitted notifications creation date.	All
BR600	Adding or removing market placement countries is not allowed.	All
BR574	Any changes to the notification should be reported as an 'update' and not as a new 'initial' submission. Therefore 'initial' submissions (i) for products having the same trade name (ii) made by the same company (iii) targeted at the same market area/country and (iv) and belong to the same product category are not allowed.	All
BR620	'New submission after significant change of composition' is not allowed if there is no change in the composition from the previous notification. Therefore, submissions where there is no change in composition should be reported as an 'update' not as a 'New submission after significant change in composition'.	All

Components concentrations		
BR601	Same concentration units must be used across updates.	All
BR598	Adding, replacing or removing components in updates is not allowed.	All
BR597	Change of concentration ranges beyond limits in updates (as indicated in Annex VIII to the CLP Regulation, Table 1 and 2 of Part B) is not allowed.	All
BR599	Change of typical concentrations beyond limits in updates (as indicated in Annex VIII to the CLP Regulation, Table 3 of Part B) is not allowed.	All

UNIQUE FORMULA IDENTIFIER (UFI) AND OTHER IDENTIFIERS		
BR569	'CLP related PCN number' should refer to existing PCN number from the same legal entity notified by a succeeded submission.	All
BR611	'CLP related PCN number' indicated in the case of a significant change of composition must be retained across updates.	All
BR618	One UFI cannot correspond to more than one PCN number.	All
BR572	UFI(s) can be added but never removed in updates.	All
BR571	UFI(s) which have been notified by another legal entity are not allowed unless there is a valid reason (e.g. you are successor of that legal entity, you are a toll formulator's customer and you act with an agreement on the re-use of the UFI, same UFI is used by different subsidiaries companies etc.).	All
BR566	The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component).	All

BR596	A MiM component identified by UFI, which has been notified for Industrial use, cannot be used in other cases (Professional/Consumer use).	All

PRODUCT INFORMATION		
BR575	'Trade names' can be added, but not removed in updates.	All

3. Known issues

3.1 Validation report links

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

4. Changes to this document

Version	Changes
1.0	April 2019 First version
2.0	October 2019 • Rules embedded in 'ECHA Submission portal' added to this document. • **BR540** It was clarified that 'International chemical name' should be reported in IUPAC name field. • **BR542** It was clarified that if use type is only 'Industrial use' then they excluded from the requirement to provide Packaging record. • **BR557** *'PCN number' cannot be same as 'CLP related PCN number'* rule was added • Known issues: ''Regarding BR608: Legal entity information must be included from 'Advanced settings'' was removed