Validation rules for poison centres notifications

Version 6.0
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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**) and group submissions (**G**). Both can be regarding limited submissions (industrial use only) (**L**) and non-hazardous submissions (voluntary submissions) (**N**). In the third column of the below tables reporting Validation rules it is indicated if Validation rule is regarding Standard or Group submissions or both of them. If the rule is excluded or only relevant to limited submissions or non-hazardous submissions, then that it is also indicated in the third column.

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 added since previous IUCLID release

**rule modified since previous IUCLID release

Rule number	Short description of the rule	Type
LEGAL ENTITY – IDENTIFICATION OF THE SUBMITTER		
BR608	**Legal entity** (Duty holder) must be provided in 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.	S + G
BR519	The contact details of the legal entity must include: • address 1 • town • country • phone • email • postal code.	S + G
BR522	Email address must be in email format.	S + G
DOSSIER HEADER		

BR553	The **PCN number** must be indicated and it must be in UUID format. The UUID format is described in https://tools.ietf.org/html/rfc4122	S + G
BR554	At least one **'Country (market placement)'** must be selected.	S + G
BR558**	'Each country mentioned as **'Country (market placement)**' must be mentioned as 'Active market (country)' or 'Ceased market (country)' in at least one 'Product information' record.	S + G
BR632	'Market placement country' cannot be 'United Kingdom of Great Britain and Northern Ireland [GB]' or 'United Kingdom: Northern Ireland [XN] The ECHA Submission portal cannot be used to notify to the United Kingdom, as their authorities are not connected to ECHA systems. If you need to notify to United Kingdom please contact the United Kingdom authorities for further instructions.	S + G
BR559	At least one **'Language'** must be selected.	S + G
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.	S + G
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.	S + G
BR543	If 'The submissions is an update' is selected, then 'Reason for updating' must be reported either by selection justification from the dropdown list in field 'Justification' or providing description in all the relevant languages in the 'Other update reason' field(s).	S + G

Languages		
BR650	If 'Market placement country' is indicated to be **Austria,** then **Germany** must be selected as 'Language'.	S + G
BR651	If 'Market placement country' is indicated to be **Belgium,** then at least one of the following languages must be selected as 'Language': **French** or **Dutch** or **German** or **English**	S + G
BR652	If 'Market placement country' is indicated to be **Bulgaria,** then **Bulgarian** must be selected as 'Language'.	S + G
BR653	If 'Market placement country' is indicated to be **Croatia,** then at least one of the following languages must be selected as 'Language': **Croatian** or **English**	S + G
BR654	If 'Market placement country' is indicated to be **Cyprus,** then **Greek** must be selected as 'Language'.	S + G
BR655	If 'Market placement country' is indicated to be **Czech Republic,** then **Czech** must be selected as 'Language'.	S + G
BR656	If 'Market placement country' is indicated to be **Denmark,** then at least one of the following languages must be selected as 'Language': **Danish** or **English**	S + G
BR657	If 'Market placement country' is indicated to be **Estonia,** then at least one of the following languages must be selected as 'Language': **Estonian** or **English**	S + G

BR658	If 'Market placement country' is indicated to be **Finland,** then the **Finnish** and **Swedish** must be selected as Languages.	S + G
BR659	If 'Market placement country' is indicated to be **France,** then **French** must be selected as 'Language'.	S + G
BR660	If 'Market placement country' is indicated to be **Germany,** then at least one of the following languages must be selected as 'Language': **German** or **English**	S + G
BR661	If 'Market placement country' is indicated to be **Greece,** then **Greek** must be selected as 'Language'.	S + G
BR662	If 'Market placement country' is indicated to be **Hungary,** then **Hungarian** must be selected as 'Language'.	S + G
BR663	If 'Market placement country' is indicated to be **Icelandic,** then at least one of the following languages must be selected as 'Language': **Icelandic** or **English**	S + G
BR664	If 'Market placement country' is indicated to be **Ireland,** then **English** must be selected as 'Language'.	S + G
BR665	If 'Market placement country' is indicated to be **Italy,** then at least one of the following languages must be selected as 'Language': **Italian** or **English**	S + G
BR666	If 'Market placement country' is indicated to be **Latvia,** then at least one of the following languages must be selected as 'Language': **Latvian** or **English**	S + G
BR667	If 'Market placement country' is indicated to be **Liechtenstein,** then **German** must be selected as 'Language'.	S + G
BR668	If 'Market placement country' is indicated to be **Lithuania,** then at least one of the following languages must be selected as 'Language': **Lithuanian** or **English**	S + G
BR669	If 'Market placement country' is indicated to be **Luxembourg,** then at least one of the following languages must be selected as 'Language': **French** or **German.**	S + G
BR670	If 'Market placement country' is indicated to be **Malta,** then at least one of the following languages must be selected as 'Language': **Maltese** or **English**	S + G
BR671	If 'Market placement country' is indicated to be **Netherlands,** then at least one of the following languages must be selected as 'Language': **Dutch** or **English**	S + G
BR672	If 'Market placement country' is indicated to be **Norway,** then at least one of the following languages must be selected as 'Language': **Norwegian** or **Danish** or **Swedish** or **English**	S + G
BR673	If 'Market placement country' is indicated to be **Poland,** then **Polish** must be selected as 'Language'.	S + G
BR674	If 'Market placement country' is indicated to be **Portugal,** then **Portuguese** or **English** must be selected as 'Language'.	S + G
BR675	If 'Market placement country' is indicated to be **Romania,** then **Romanian** must be selected as 'Language'.	S + G
BR676	If 'Market placement country' is indicated to be **Slovakia,** then **Slovak** must be selected as 'Language'.	S + G
BR677	If 'Market placement country' is indicated to be **Slovenia,** then **Slovenian** must be selected as 'Language'.	S + G

BR678	If 'Market placement country' is indicated to be **Spain,** then at least one of the following languages must be selected as 'Language': **Spanish** or **English**	S + G
BR679	If 'Market placement country' is indicated to be **Sweden,** then at least one of the following languages must be selected as 'Language': **Swedish** or **English**	S + G

CONTACT PERSON		
BR552	An emergency contact must be provided in the 'Contact person' section for each country indicated in the dossier header.	only L
BR523	The contact details of the emergency contact must include: • last name • organisation • phone • email • country. Please note that if "Last name" is not available or not relevant, a more generic name can be used instead (e.g. Helpdesk, Support)	only L

pH		
BR512	Exactly one 'pH' record must be provided.	S (not N)
BR874*	At least one 'pH' record must be provided.	G (not N)
BR875*	All provided 'pH' records must be linked to 'Mixture composition' record. Therefore make sure that in each 'pH' records field 'For a group submissions, specify to which mixture it applies:' includes linked 'Mixture composition'.	G
BR545	Either 'pH is not available' must be selected or a pH value must be reported (one value or range).	S + G (not N)
BR524	Allowed pH values: -3=< pH =<15	S + G
BR615	Allowed pH qualifiers: one value cannot have qualifiers, range cannot have 'c.a.'.	S + G
QLT504	pH value must be indicated as an integer or specified to one decimal.	S + G
QLT501	Maximum pH value range width is 1 unit (when pH =<3 or >=10).	S + G
QLT510	Maximum pH value range width is 3 units (when pH 3 < pH <10).	S + G
BR585	If pH is available, 'Solution concentration' must be provided.	S + G
BR621	If 'pH is not available' was indicated, then explanation why pH was not available should be provided by selecting justification from the adjacent dropdown list.	S + G

TOXICOLOGICAL INFORMATION		
BR515	Exactly one 'Toxicological information' record must be provided.	S (not N)
BR872*	At least one 'Toxicological information' record must be provided.	G (not N)
BR538	Toxicological information must be provided (at least 200 characters) in 'Toxicological information (section 11 of SDS)' field(s) in all relevant languages.	S + G (not N)
BR873*	All provided 'Toxicological information' records must be linked to 'Mixture' record. Therefore make sure that the field 'For a group submission, specify to which mixture it applies:' includes at least one linked 'Mixture composition'.	G

MIXTURE COMPOSITION		
BR509	Exactly one 'Mixture composition' record must be provided.	S
BR698*	At least two 'Mixture composition' records should be provided.	G
BR521	At least one 'Mixture' (MiM) or 'Substance' component must be provided in 'Mixture composition' (MainMixture).	S + G
BR551	'Reference substance' datasets cannot be linked from 'Mixture composition' (MainMixture). Only 'Mixture' (MiM) and 'Substance' datasets can be linked from 'Mixture composition' (MainMixture).	S + G
BR634 for S **BR852*** for G	All provided 'Components' blocks must be complete: If concentration was provided for the component then either 'Substance' or 'Mixture (MiM)' dataset must be included.	S + G
BR639	Component can be indicated to be only one of the following Standard formula (SF), Interchangeable Component Group (ICG) or General Component Identifier (GCI). (Only one tick box can be ticked per one 'Component' for SF/ICG/GCI.)	S
BR580*	If 'Component' is indicated to be 'SF (Standard formula)' then name of the standard formula or fuel must be provided: • If composition is **fully** conforming to the standard formula please indicate the standard formula name in MainMixture level in 'Other identifiers' by selecting 'Name type' to be 'standard formula (SF)' and include in the 'Name' field the allowed SF name from dropdown list. • If the composition is only **partially** conforming to the standard formula please indicate the standard formula name in the component by selecting in 'Other substance identifiers' the 'Identifier' to be 'standard formula (SF)' and 'Identity' field to include the SF name from dropdown list. • If composition is regarding **fuels** then in Main mixture 'Other identifiers' select 'Name type' to be 'fuels'.	S
BR640	Interchangeable Component Group (ICG) should be reported as MiM, not as Substance.	S

BR682	Standard formula 'Fuels' can be reported only in MainMixture, not as MiMs.	S
BR860*	The compositions can have difference only in components which 'Function' is indicated to be 'perfumes'.	G
BR859*	For Group submissions the difference between the compositions cannot be more than 5%. (Rule is currently implemented in a way that it fails if less than 90% of the composition is same)	G
BR851*	Each 'Mixture composition' record should be referenced in exactly one 'Toxicological information' record. Therefore make sure that each 'Mixture composition' is linked from one 'Mixture safety data sheets and toxicological information' records field 'For group submission, specify to which mixture it applies:'.	G
BR850*	Each 'Mixture composition' record should be referenced in exactly one 'pH' record. Therefore make sure that each 'Mixture composition' is linked from one 'pH' records field 'For group submission, specify to which mixture it applies:'.	G
BR699*	Each 'Mixture composition' record should be referenced at least once in some Product record(s). Therefore make sure that each 'Mixture composition' is linked from at least one 'Product information' records field 'For group submission, specify to which mixture it applies:'.	G

MIXTURE COMPONENTS (MiM)		
BR527	For identifying the MiM, it is mandatory to provide either: a) UFI b) Available component(s): - If MiM is hazardous 'Supplier' record and available components (at least one Substance). - If MiM is non-hazardous, then providing the 'Supplier' record is enough. Components identified using the Generic component identifier (GCI), Standard formula (SF) and Interchangeable component group (ICG) are an exception.	S
BR684 for S **BR857*** for G	MiM cannot have more than one 'Composition' record.	S + G
BR578	There cannot be more than one UFI per MiM.	S + G

BR606	If the MiM is identified with providing the available component(s) of the composition, then the legal entity in the 'Suppliers' record must include the contact details: • legal entity name • phone • email. Standard formula (SF) and Interchangeable component group (ICG) components are excluded from this rule.	S + G
BR681	Mixture in mixture components that are indicated to be 'Standard formula (SF) components' must have compositional information included (at least one 'Component' reported).	S
BR683	Mixture in mixture components that are indicated to be 'Interchangeable component groups (ICG)' must have compositional information included (at least one 'Component' reported).	S
QLT624	If the MiM does not have UFI and is instead identified with providing the available component(s) of the composition, then the legal entity in the 'Suppliers' record should be different than the Submitting Legal entity (Submitting legal entity is reported in 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.)	S + G
QLT869*	If the MiM does not have UFI and is instead identified with providing the available component(s) of the composition, then the legal entity in the 'Suppliers' record should be from EU country. Please note that the responsibility for mixtures imported into the EU remains on the importer.	S
BR577	'Reference substance' datasets and 'Mixture' datasets cannot be linked from 'Mixture' (MiM). Only 'Substance' datasets can be linked from 'Mixture' (MiM). Exception is that Standard formula (SF) components and ICG components can add 'Mixture' datasets. (i.e. can have 'MiM in a MiM')	S + G

SUBSTANCE COMPONENTS (SiM)		
BR539	Substance components must have linked 'reference substance' datasets. Components identified using the Generic component identifier (GCI) are an exception.	S + G
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.)	S + G
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.	S + G
BR525	EC number format must be correct.	S + G
BR526	CAS number format must be correct. The CAS number format is described in: https://www.cas.org/support/documentation/chemical-substances/checkdig.	S + G

QLT634	If 'IUPAC name/International chemical name' was provided, then it should be meaningful. For instance '*not available'* or '*proprietary substance'* are not IUPAC names. If you do not have 'IUPAC name/International chemical name' for the substance, then leave the field empty.	S + G
QLT635	The provided 'Substance name' should be meaningful. For instance '*not available'* or '*proprietary substance'* are not correct Substance names.	S + G
QLT592	Repeating the same 'reference substance' not allowed unless the related classification is different.	S + G

Substance or mixture components identified using the Generic component identifier (GCI)		
BR583	If the component is indicated using the GCI, 'Function' must be 'Colourant, or 'Perfume'.	S + G
BR605	GCI cannot be classified for human hazard.	S + G
BR602	The combined concentration of the GCI type components 'Colourant' must not exceed 25 %.	S + G
BR603	The combined concentration of the GCI type component 'Perfume' must not exceed 5 %.	S + G

Components concentrations		
BR629	Components must have concentrations (value and unit). Interchangeable component groups (ICG) components (IC's) are excluded from this rule.	S
BR590*	Components must have concentrations (value and unit). Components which 'function' is 'perfume' and classification is only regarding the below mentioned hazard(s) are excluded from this rule: • Skin sensitisation 1, 1A, 1B • Aspiration hazard Asp. Tox. 1 Interchangeable component groups (ICG) components (IC's) are excluded from this rule.	G
BR581 for S **BR862*** for G	Either 'Typical concentration' (exact concentration) or 'Concentration range' must be provided, not both.	S + G

BR607 for S **BR864*** for G	Report only components which are present in the mixture; • Components which 'Typical concentration' (exact concentration) is 0% are not allowed. • Components which lower concentration range value is **exactly** 0% are not allowed. Therefore, lower concentration range values which are reported with qualifier => to be 0% are not allowed. Please note that concentration ranges where lower value is indicated to be **above** 0% are allowed. To this end indicate the concentration value with qualifier >. Negative values are not allowed as concentration values. Exception is that Standard formula (SF) components can have lower concentration value reported as 0%.	S + G
QLT502	If the concentration is above 1 %, the recommended number of decimals is one.	S + G
QLT505	If the concentration value is 0.1-1 %, the recommended number of decimals is two.	S + G
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. Exception is that Standard formula (SF) components and Interchangeable component group (ICG) components do not need to comply with this rule.	S + G (not L)
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. Exception is that Standard formula (SF) components and Interchangeable component group (ICG) components do not need to comply with this rule.	S + G (not L)
BR556 for S **BR853*** for G	Total concentration of the mixture is too low (below 70 %). If the reported concentration is lower than 70 %, the dossier cannot be accepted. Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.	S + G (not L)
QLT506 for S **QLT854*** for G	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. Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.	S + G (not L)
BR593	Total concentration of the mixture exceeds 100%. If the reported concentration is higher than 105 %, the dossier cannot be accepted. Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.	S
BR591 for S **BR858*** for G	Units provided for concentrations must be consistent.	S + G
BR541	Allowed units for concentrations: v/v % and w/w %.	S + G

BR548	Allowed qualifiers for concentrations: - 'Typical concentration' cannot have qualifiers - 'Concentration range' 'c.a.' not allowed.	S + G
BR625	If 'Concentration range' is provided then qualifiers must be included. To that end include either '>' or '=>' qualifier to the lower concentration range value and either '<' or '<=' to the upper concertation range value. Standard formula components (SF) are excluded from this rule.	S + G

UNIQUE FORMULA IDENTIFIER (UFI) AND OTHER IDENTIFIERS		
BR516	'Unique formula identifiers (UFI) and other identifiers' record must be provided.	S + G (not N)
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 + G (not N)
QLT508	UFI should be provided. 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.	only 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.	S + G
BR635	All 'Regulatory Programme Identifiers' entries must be complete: If 'Regulatory Programme' is indicated then the 'ID' must be included as well, if 'ID' is provided then 'Regulatory Programme' must be included.	S + G
BR563	'CLP related PCN number' not allowed for initial submissions.	S + G
BR562	'CLP related PCN number' is mandatory for 'After significant composition change' notifications.	S + G
BR609	Submission cannot have more than one 'CLP related PCN number' reported.	S + G
BR557	'PCN number' reported in dossier header cannot be same as 'CLP related PCN number'.	S + G
BR584	'Unique formula identifiers (UFI) and other identifiers' record must be included in 'Product information' record.	S + G (not N)
BR693*	If 'PCN multi-component product identifiers' is indicated then the identifier must be associated with 'Product information'. Therefore make sure that the record that contains the 'PCN multi-component product identifiers' is linked from at least on 'Product' record.	S + G

CLASSIFICATION AND LABELLING		
BR513	Exactly one 'Classification and labelling information (GHS)' record must be provided in 'Mixture information' (MainMixture).	S

BR696*	At least one 'Classification and labelling information (GHS)' record must be provided 'Mixture information' (MainMixture).	G
BR510	Exactly one 'Classification and labelling information' record must be provided for each 'Mixture' component (MiM). 'Interchangeable component group (ICG)' Components are excluded from this requirement.	S + G
BR633	Exactly one 'Classification and labelling information' record must be provided for each 'Substance' component included in 'Mixture' component (MiM). 'Interchangeable component group (ICG)' components are excluded from this requirement.	S + G
BR612	Exactly one 'Classification and labelling information' record must be provided for each 'Mixture information' (MainMixture) 'Substance' component.	S + G
BR636	'Classification and labelling' record must be provided either in (MiM) or for all MiM's components if the MiM is indicated to be 'Interchangeable component group (ICG)'	S + G
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.	only N
BR546 for S **BR697*** for G	In 'Mixture information' (MainMixture): Either **'Not classified'** must be selected or at least one selection in **'Hazard categories and statements'** must be made.	S + G
BR613	In 'Mixture information' (MainMixture): 'Classifications' must be complete: If 'Hazard category' is selected then also the adjacent 'Hazard statement' must be selected.	S + G
BR614	In 'Mixture information' (MainMixture): Labelling '**Signal word'** must be selected (any selection is valid) if mixture is classified ('Not classified' is not ticked). If 'Not classified' is ticked, then 'Signal word' can be empty or 'No signal word' can be selected.	S + G
BR626	In 'Mixture information' (MainMixture): If Mixture is classified then under 'Labelling' at least one 'Hazard statement' is selected (selection of 'No hazard statement' is also valid.) If Mixture is 'Not classified' then under 'Labelling' either no selection in 'Hazard statement' field is made or 'No hazard statement' is selected.	S + G
BR628	In all 'Substance' and 'Mixture' component (MiM) classification records: Either **'Not classified'** must be selected or at least one selection **in 'Hazard categories and statements'** must be made.	S + G

PRODUCT INFORMATION		
BR517	At least one 'Product details' record must be provided.	S + G
BR508	'Trade name' must be provided.	S + G
QLT691*	'Trade name' seems to be quite short or long ('Trade name' is expected to be at least 3 and less than 132 characters)	S + G

BR531	Each 'Product details' record must have at least one linked UFI number.	S + G (not N)
BR532	Market placement 'Country' is mandatory.	S + G
BR695*	Same country cannot be both 'Market placement country' and 'Ceased market' in same 'Product' record.	S + G
BR610**	Each country indicated in the 'Product information' record as 'Active market (country)' or 'Ceased market (country)' must be also indicated as a market placement country in the dossier header.	S + G
BR514	'Colour and physical state' record is mandatory.	S + G (not N)
BR877*	All 'Colour and physical state records' must be linked to a 'Product' record.	S + G
BR529	'Physical state' must be indicated.	S + G (not N)
BR530	'Colour' must be indicated.	S + G (not N)
BR542	Either 'Packaging document' must be linked or 'Product not packaged' must be selected. Exception if use type is only 'Industrial'.	S + G
BR536	'Type of packaging in contact with the product (container type)' must be indicated.	S + G (not N)
BR537	'Size of packaging in contact with the product (container size)' must be indicated.	S + G (not N)
BR876*	All 'Packaging' record(s) must be linked to a 'Product' record.	S + G
BR535	At least one 'Use type' must be indicated.	S + G (not N)
BR587	For limited submissions, 'Use type' can only be 'Industrial'. ''Professional' and 'Consumer' are not allowed.	only L
BR534	'Main intended use' must be indicated.	S + G (not N)
QLT694*	'Main intended use' is recommended to provide in 'Product' records also for Voluntary submissions.	only N
QLT503	Up to three 'Secondary uses' allowed.	S + G (not N)
BR589	Biocides or plant production products cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.	S + G

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/QLT**) 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		
[QLT732]	ECHA Submission Portal can show maximum 500 failures/warnings per one notification.	S + G
[BR564]	The exactly same dossier cannot be submitted again.	S + G
[BR565]	Currently only the following submission types are accepted in 'ECHA Submission Portal': - 'Poison centre notifications' - 'SCIP notifications' - 'EU PPP Active substance application (product)' - 'EU PPP Basic substance application' - 'EU PPP Microorganisms - active substance application (product)' - 'EU PPP MRL application'	S + G
[QLT573]	'Mixture name' should remain same in update dossier.	S + G
[BR627]	Submitting company must be located in EU.	S + G

DOSSIER HEADER		
[BR570]	Submitter legal entity in 'ECHA Submission portal' must be same as the legal entity included in the 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.	S + G
[BR567]	A new 'PCN number' should be provided for initial notifications and significant change of composition notifications.	S + G
[BR568]	An existing 'PCN number' should be used in updates notified by the same legal entity.	S + G
[BR576]	In case of updates, the dossier creation date should be greater than the previously submitted notifications creation date.	S + G
[BR623]	Removing market placement countries is not allowed.	S + G
[QLT513]	Notice that 'Update' or 'New notification after significant change in composition' has more market placement countries than the previous successful notification.	S + G
[QLT574]	Any changes to the notification should be reported as an 'update' and not as a new 'initial' submission. Therefore new '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.	S + G

[QLT514]	Any changes to the notification should be reported as 'update' and not as a new 'initial' submission. Therefore new 'initial' submissions: (i) for products having the same UFI (ii) made by the same company (iii) where concentration: • Ranges have not changed beyond the initial submissions' concentration ranges • Typical (exact) concentrations have not changed beyond the allowed limits (accordance with Annex VIII to the CLP Regulation, Table 3 of Part B.) • Components have not been altered (added or deleted) are not allowed.	S + G
[QLT620]	'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'.	S + G

Components concentrations		
[BR601]	Same concentration units must be used across updates.	S + G
[QLT598] for S **[QLT867]*** for G	Adding, replacing or removing components in updates is not allowed. 'Interchangeable component group (ICG)' components are excluded from this rule	S + G
[QLT891]*	Adding, replacing or removing ICG components in updates is not allowed.	S + G
[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. Exception is that 'Standard formula (SF)' and 'Interchangeable component group (ICG)' components do not need to comply with this rule.	S
[BR868]*	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. Exception is that 'Standard formula (SF)' and 'Interchangeable component group (ICG)' components do not need to comply with this rule. Exception is that the components which 'Function' is indicated to be 'perfume' do not need to comply with this rule.	G
[BR599]	Change of exact concentrations (indicated in field 'Typical concentration') beyond limits in updates (as indicated in Annex VIII to the CLP Regulation, Table 3 of Part B) is not allowed. Exception is that 'Standard formula (SF)' and 'Interchangeable component group (ICG)' components do not need to comply with this rule.	S

[BR866]*	Change of exact concentrations (indicated in field 'Typical concentration') beyond limits in updates (as indicated in Annex VIII to the CLP Regulation, Table 3 of Part B) is not allowed. Exception is that the components which 'Function' is indicated to be 'perfume' do not need to comply with this rule. Exception is that 'Standard formula (SF)' and 'Interchangeable component group (ICG)' components do not need to comply with this rule.	G

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.	S + G
[BR611]	'CLP related PCN number' indicated in the case of a significant change of composition must be retained across updates.	S + G
[QLT618]	One UFI cannot correspond to more than one PCN number submitted in the same market placement country.	S + G
[BR572]	UFI(s) can be added but never removed in updates.	S + G
[QLT571]	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.).	S + G
[QLT516]	The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component) in the relevant market placement countries if the MiM was not 'identified with substances.' ('Identified with substances' means that MiM did include Supplier information and if it was hazardous component(s) were provided.).	S + G
[BR596]	A MiM component identified by UFI, which has been notified for only Industrial use, cannot be used in other cases (Professional/Consumer use).	S + G
[QLT865]*	If 'CLP multi-component product identifier' was included, then there should be another notifications submitted with this same 'CLP multi-component product identifier' identifier.	S + G

PRODUCT INFORMATION		
[BR575]	'Trade names' can be modified or removed only if in dossier header the 'Reason for updating' the justification was selected to be '**correction/deletion of trade name**'.	S + G

3. Known issues

3.1 Validation report links

When validating Poison Centers notifications, the links from validation failures to the corresponding dossier/dataset sections do not work correctly in some occasions. The behavior will be improved in a subsequent IUCLID release.

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
2.1	January 2020 • **QLT510** wording: '**Minimum** pH value range width is 3 units (when pH 3 < pH <10)' changed to '**Maximum** pH value range width is 3 units (when pH 3 < pH <10).' • **BR589** wording: 'Biocides or plant production **products** cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.' Changed to 'Biocides or plant **protection** products cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.' • **BR573** changed to be warning **BR573**
3.0	May 2020 **Legal entity:** • **BR608** MODIFIED: requirement to provide Legal entity in both 'dossier header' and in 'Mixture identity and legal submitter' record changed to requirement to provide the legal entity just in 'Mixture identity and legal submitter' record • **BR520** DEACTIVATED requirement to provide same legal entity in 'Dossier header' and in 'Mixture' deleted • **[BR570]** MODIFIED Legal entity in the 'Mixture identity and legal submitter' must be the same as the Submitting Legal entity in ECHA Submission portal was changed to Legal entity in the 'Mixture identity and legal submitter' must be the same as the Submitting Legal entity in ECHA Submission portal **MiM:** • **BR527** MODIFIED 'MiM identified with SDS' changed to 'MiM identified with available Substance(s)' and Supplier record • **BR579** DEACTIVATED 'If the MiM is identified using a Safety data sheet (SDS), the 'Suppliers' record is mandatory.' (rule was merged to BR527) • **BR606** MODIFIED 'MiM identified with SDS' changed to 'MiM identified with available Substance(s)' • **BR624** NEW If MiM is identified with available substances then the Supplier

	(Legal entity reported in 'MiM Supplier record field 'Name') must be different from the duty holder (legal entity reported 'Mixture identity and legal submitter') • **QLT512** DEACTIVATED 'MiM identified with SDS should be used as last resort' **Substance:** • Rule type changed from 'failure' to 'warning': **BR592** changed to **QLT592** **Fragrance related changes:** • **BR583** MODIFIED reference to Fragrance removed • **BR616** DEACTIVATED Rule regarding 'GPI type Fragrance can be reported once' • **BR603** MODIFIED reference to Fragrance removed • **BR590** MODIFIED in exception regarding Fragrances removed **Concentration:** • **BR607** MODIFIED 'Only positive values are allowed rule is modified' to also check that lower concentration range cannot be reported to be exactly zero. • **BR625** NEW Qualifiers are mandatory if concentration range is reported **C&L** • **BR546** NEW Either 'Not classified' must be ticked or at least one selection in 'Hazard categories and statements' must be made. • **BR613** NEW If 'Hazard category' is selected then also the adjacent 'Hazard statement' must be selected **[Dossier header]:** • **[BR600]** DEACTIVATED Changing 'Market placement countries' is not allowed. • **[BR623]** NEW Removing 'Market placement countries' not allowed. • **[QLT513]** NEW Notice that update has more 'Market placement countries' • **[QLT514]** NEW Dossier must be 'update' and not new 'initial' if there is already 'initial' notification for the same Legal entity, UFI and composition **[UFI]** • **[BR618]** MODIFIED 'One UFI cannot correspond to more than one UFI' is modified to 'One UFI cannot correspond to more than one UFI in the same market placement country'. • **[BR566]** DEACTIVATED 'The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component).' • **[QLT515]** NEW 'The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component)' in the relevant market placement countries.'
3.1	June 2020 • **[BR627]** NEW: Submitting company must be located in EU. • **[BR575]** MODIFIED: "'Trade names' can be added, but not removed in updates." changed to "'Trade names can be removed only if Reason for update was selected to be 'correction of error' and in the adjacent Remarks field it was stated either 'Correction of Trade name' or 'Removal of incorrect Trade name'." July 2020 **C&L** • **BR614** NEW In 'Mixture information' (MainMixture): Labelling '**Signal word'** must be selected (any selection is valid) if mixture is classified. If 'Not classified' is ticked, then 'Signal word' can be empty or 'No signal word' can be selected. • **BR626** NEW In 'Mixture information' (MainMixture): If Mixture is classified then under 'Labelling' at least one 'Hazard statement' is selected. If Mixture is 'Not classified' then under 'Labelling' either no selection in 'Hazard statement' field is made or 'No hazard statement' is selected.

	• **BR628** NEW In all 'Substance' and 'Mixture' component (MiM) classification records: Either **'Not classified'** must be selected or at least one selection **in 'Hazard categories and statements'** must be made.
4.0	October 2020: **ADDED:** • **BR632** 'Market placement country' indicated in dossier header cannot be 'United Kingdom of Great Britain and Northern Ireland [GB]' or 'United Kingdom: Northern Ireland [XN] • **QLT634** 'IUPAC name should be meaningful' and **QLT635** 'Substance name should be meaningful' (rules checks that the provided name is not for instance 'not available' or 'proprietary substance'.) • **BR629** Components must have concentrations (value and unit). (similar rule BR590 which was inactivated) • **BR633** Each MiM's Substance component must include exactly one 'Classification and labelling' record. • **BR636** 'Classification and labelling' record must be provided either in MiM or for all MiM's components if the MiM is marked to be ICG • **BR621** If 'pH not available' was indicated, then justification must be provided • **[QLT516]** The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component) in the relevant market placement countries if the MiM was not 'identified with substances.' ('Identified with substances' means that MiM did include Supplier information and if it was hazardous component(s) were provided.). **INACTIVATED:** • **BR590** Components must have concentrations (value and unit). Components described in provision B.3.4.2 of Annex VIII are an exception. (similar rule BR629 added) • **[QLT515]** deactivated (similar rule [QLT516] created] **MODIFIED:** • **BR543** Since option 'other:' was removed from 'Justification' dropdown list from 'Reasons for update' BR543 rule was modified to: 'If submission is an update' is indicated, then 'Justification' must be selected from dropdown list and/or 'Other update reason' must be provided for each relevant language. • **BR542** rule was changed so that 'Product not packaged' and Link to packaging information can be provided both in the same Packaging record. • **[BR575] "** 'Trade names' can be modified or removed only if in dossier header the 'Reason for updating' the justification was selected to be 'correction of error' and in 'Remarks' field it was stated either 'Correction of Trade name' or 'Removal of incorrect Trade name'". *was changed to* "'Trade names' can be modified or removed only if in dossier header the 'Reason for updating' the justification was selected to be 'correction/deletion of trade name'." • Rule type changed from 'failure' to 'warning': **BR624** changed to **QLT624** • **[BR565]** ECHA Submission Portal accepts now also 'SCIP' notification dossiers • **[BR623]** 'Cannot restrict the market area(s) in updates' to allow removal of [GB] as 'Market placement country' • Wording changed**:** 'Generic Product Identifier (GPI)' was changed to 'Generic component identifier (GCI)' • Rules regarding Mixture identification BR527, BR606, BR577, concentrations BR625, BR607, BR518, BR588, [BR597], [BR599] and Classification and labelling BR510, BR533 were adapted to facilitate the notifications which include Standard formula (SF), Fuels and Interchangeable component groups (ICG) that do not have so extensive information requirements. Coming in late November 2020/December2020: • **BR634** All provided 'Components' blocks must be complete: If concentration

	was provided then either Substance or Mixture (MiM) dataset must be included. • **BR635** All 'Regulatory Programme Identifiers' entries must be complete: If 'Regulatory Programme' is indicated then the 'ID' must be included as well, if 'ID' is provided then 'Regulatory Programme' must be included. • **BR630** MiM cannot have more than one 'MiM composition' record included.
4.1	December 2020: **BR621** *failure* "If 'pH not available' was indicated, then justification must be provided" changed temporarily to **QLT621** *warning*. (Rule is planned to be changed back to **BR621** *failure* in April 2021 when IUCLID is updated.)
5.0 DRAFT	April 2021 **ADDED:** **BR650-BR679** Rules regarding 'Language' requirements based on 'Market placement country' added **BR639** only one tickbox (SF/ICG/GCI) can be ticked per one component **BR640** Interchangeable component group (ICG) should be reported as MiM, not as Substance **BR683** Interchangeable component group (ICG) MiMs should have compositional information reported **BR681** Standard formula (SF) component MiMs should have compositional information reported **BR682** 'Fuels' can be reported only in MainMixture, not as MiMs **INACTIVATED:** **BR604** GCI type 'Perfume' can only be used once. **BR617** GCI type 'Colourant' can only be used once. **BR547** 'Physical state' must be same in all 'Colour and physical state' records. **MODIFIED:** **QLT621** to **BR621** "If 'pH not available' was indicated, then justification must be provided": rule changed from *warning* to *failure* **BR630** to **BR684** 'MiM can have only one 'Composition' record. If more than one rule fails.': only rule number changed Planned for May 2021 **MODIFIED:** **[QLT513]** Notice that 'Update' has more market placement countries than the previous successful notification.: Rule extended to check also 'New notification after a significant change of composition'. Rule code switched from **[BRXXX]** to **[QLTXXX]:** **[BR571]** to **[QLT571]** **[BR573]** to **[QLT573]** **[BR574]** to **[QLT574]** **[BR598]** to **[QLT598]** **[BR620]** to **[QLT620]**
5.1	May 2021 IUCLID Cloud release **FIXED:** **BR674** Rule corrected so that English was added as the other accepted language. New version of the rule is therefore: *If 'Market placement country' is indicated to be Portugal, then Portuguese or English must be selected as 'Language'.*
6.0	October 2021 Standalone + Cloud release (planned for 27th October)

ADDED:

Validation assistant in IUCLID:
BR580 If 'Component' is indicated to be 'SF (Standard formula)/fuel' then name of the standard formula/fuel must be provided (Standard)
BR693 All 'PCN multi-component product identifiers' must be linked from 'Product' records. (Standard and Group)
BR695 Same country cannot be both 'Market placement country' and 'Ceased market' in same 'Product' record (Standard and Group)
BR696 At least one 'Classification and labelling (GHS)' record must be provided (Group)
BR697 In 'Mixture information' (MainMixture): Either 'Not classified' must be selected or at least one selection in 'Hazard categories and statements' must be made. (Group)
BR698 At least two 'Mixture composition' records should be provided (Group)
BR699 Each 'Mixture' record should be referenced at least once in some Product record(s) (Group)
BR850 Each 'Mixture' record should be referenced in exactly one 'pH' record (Group)
BR851 Each 'Mixture' record should be referenced in exactly one 'Toxicological information' record (Group)
BR852 All provided 'Component' blocks must be complete: If concentration was provided for the component then either 'Substance' or 'Mixture (MiM)' dataset must be included (Group)
BR853 Check that the concentration for each mixture is not too low 70% (Group)
BR857 MiM: cannot have more than one 'Composition' record. (Group)
BR858 Units provided for concentrations must be consistent (Group)
BR859 For Group submissions the difference between the compositions cannot be more than 5%. (Group)
BR860 The compositions can have difference only in components that have been indicated to be 'perfumes' (Group)
BR862 Either 'Typical concentration' (exact concentration) or 'Concentration range' must be provided, not both (Group)
BR864 Report only components which are present in the mixture. Concentration value must be above 0% for each Substance component and Mixture component (Group)
BR872 At least one 'Toxicological information' record must be provided (Group)
BR873 All 'Toxicological information' record(s) must be linked to 'Mixture composition' record. (Group)
BR874 At least one pH record must be provided (Group)
BR875 All 'pH' record(s) must be linked to 'Mixture composition' record. (Group)
BR876 All 'Packaging' record(s) must be linked to a 'Product' record. (Standard and Group)
BR877 All 'Colour and physical state' record(s) must be linked to a 'Product' record. (Standard and Group)

QLT691 'Trade name' seems to be quite short or long (expected to be at least 3 and less than132 characters) (Standard and Group)
QLT694 'Main intended use' is recommended to be provided in 'Product' records also for Voluntary submissions. (Standard and Group)
QLT854 Check that the concentration in each mixture is not too low 70-90% (Group)
QLT869 If MiM does not have UFI then the Supplier should be from EU country (Standard)

Portal:
[BR866] Change of exact concentrations beyond limits in updates (as indicated in Annex VIII to the CLP Regulation, Table 3 of Part B) is not allowed unless component is indicated to be 'perfume'. (Group)
[BR868] 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 unless component is indicated to be 'perfume'. (Group)

[QLT865] If 'CLP multi-component product identifier' was included then there should be other notification(s) submitted with this same identifier.

[QLT867] Adding, replacing or removing components in updates is not allowed. (Group)
[QLT891] ICG component should not be added/deleted in update

INACTIVATED:
[BR619] 'Group submissions' are not allowed.

MODIFIED:

BR558 'Each country mentioned in dossier header as **'Country (market placement)**' must have at least one corresponding 'Product information' record.' *Was changed due to addition of the 'Ceased markets' field to be:* 'Each country mentioned as **'Country (market placement)**' must be mentioned as 'Active market (country)' or 'Ceased market (country)' in at least one 'Product information' record.'
BR610 'Each country indicated in the 'Product information' record must be also indicated as a market placement country in the dossier header.' *Was changed due to addition of the 'Ceased markets' field to be:* 'Each country indicated in the 'Product information' record as 'Active market (country)' or 'Ceased market (country)' must be also indicated as a market placement country in the dossier header.'

[BR565] ECHA Submission portal currently only accepts dossiers of which the submission type is 'CLP Poison centres notification' or 'SCIP notification'. *Modified to accept also PPP dossiers (since April2021)*

[QLT598] 'Adding, removing or replacing components in updates is not allowed' *modified not to consider ICG component changes that will fail [QLT891] instead*

BUGS FIXED:
BR538 'Toxicological information' must be over 200 characters. *Rule was incorrectly passing if table was included without the required 200 characters.*