

Validation rules for poison centres notifications

Version 9.1
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Table of Contents

1. INTRODUCTION	3
2. VALIDATION RULES	3
2.1 List of PCN Validation rules in IUCLID	3
2.2 List of PCN Validation rules in ECHA Submission Portal.....	16
3. KNOWN ISSUES	20
3.1 Validation report links	20
4. CHANGES TO THIS DOCUMENT	20

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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 number	Short description of the rule	Type
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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: <ul style="list-style-type: none"> • 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 (version 4). 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
BR870	If the update reason 'cease product from market' is indicated in the dossier header, then at least one country should exist under the ceased market list in at least one 'Product' record	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: <ul style="list-style-type: none"> • last name • organisation • phone • email • country. <p>Please note that if "Last name" is not available or not relevant, a more generic name can be used instead (e.g. Helpdesk, Support)</p>	only L
QLT893	If in the 'Contact person' record ' Contact type ' is indicated to be ' other: ' then it must be explained in all the relevant languages .	S + G

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: $-3 \leq \text{pH} \leq 15$	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 $\text{pH} \leq 3$ or $\text{pH} \geq 10$).	S + G
QLT510	Maximum pH value range width is 3 units (when $3 < \text{pH} < 10$).	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
BR846	Mixture composition should not refer to itself as a compositions component: The notification (Mixture dataset) cannot have itself included as Mixture-in-mixture component in composition (compares Mixture composition record UUID's)	S + G
BR634 for S	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
BR852 for G		
BR639 for S	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
QLT692	Component must be indicated in the same way regarding Standard formula (SF), Interchangeable Component Group (ICG) and General Component Identifier (GCI) tick boxes in all the provided 'Mixture composition' records. (Same tick box selection for the same constituent (none/SF/ICG/GCI) in all 'Mixture composition' records).	G

<p>BR580 for S</p> <p>BR861 for G</p>	<p>If 'Component' is indicated to be 'SF (Standard formula)' then name of the standard formula or fuel must be provided:</p> <ul style="list-style-type: none"> • 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'. 	<p>S + G</p>
<p>BR855 for S</p> <p>BR830 for G</p>	<p>If component is indicated to be 'fuels' then it must have the specific fuel name. More precisely if the 'Standard formula' checkbox is ticked and in 'Other identifiers' table 'Name type' is selected to be 'fuels' then the adjacent 'Name' field must have selected the fuel name from the dropdown list.</p>	<p>S + G</p>
<p>BR640 for S</p> <p>BR863 for G</p>	<p>ICG: Interchangeable Component Group (ICG) should be reported as Mixture dataset (MiM), not as 'Substance'.</p>	<p>S + G</p>
<p>BR827 for S</p> <p>BR828 for G</p>	<p>ICG: 'Interchangeable component group' cannot be indicated both in MainMixture and in Mixture in mixture (MiM) level</p>	<p>S + G</p>
<p>BR682 for S</p> <p>BR890 for G</p>	<p>Standard formula 'Fuels' can be reported only in MainMixture, not as MiMs.</p>	<p>S + G</p>
<p>BR860</p>	<p>The compositions can have difference only in components which 'Function' is indicated to be 'perfumes'.</p>	<p>G</p>
<p>BR859</p>	<p>For Group submissions the difference between the compositions cannot be more than 5%.</p> <p>(Rule is currently implemented in a way that it fails if less than 90% of the composition is same)</p>	<p>G</p>
<p>BR851</p>	<p>Each 'Mixture composition' record should be referenced in exactly one 'Toxicological information' record.</p> <p>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:'.</p>	<p>G</p>

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
BR888	Each 'Mixture composition' record should be referenced from exactly one Classification and labelling record. Therefore make sure that each 'Mixture composition' is linked from one 'Classification and labelling' records field 'For group submission, specify to which mixture it applies:'.	G
QLT894 for S QLT821 for G	If in the Mixture composition the Component's function is indicated to be ' other: ' then it must be explained in all the relevant languages	S + G

MIXTURE COMPONENTS (MiM)		
BR527 for S BR690 * For G	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 + G
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
QLT881 for S QLT822 for G	MiM's UFI can be the same as mixture's UFI only if the composition is reported to be 100% MiM (MainMixture has one 'Mixture' constituent which exact concentration is indicated to be 100%)	S + G

BR606	<p>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:</p> <ul style="list-style-type: none"> • legal entity name • phone • email. <p>Standard formula (SF) and Interchangeable component group (ICG) components are excluded from this rule.</p>	S + G
BR681 for S	SF: Mixture in mixture components that are indicated to be 'Standard formula (SF) components' must have compositional information included (at least one 'Component' reported).	S + G
BR823 for G		
BR683 for S	ICG: Mixture in mixture components that are indicated to be 'Interchangeable component groups (ICG)' must have compositional information included (at least two 'Component' reported).	S + G
BR880 for G		
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 for S	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 + G
QLT847 for G		
BR577	<p>'Reference substance' datasets and 'Mixture' datasets cannot be linked from 'Mixture' (MiM). Only 'Substance' datasets can be linked from 'Mixture' (MiM).</p> <p>Exception is that Standard formula (SF) components and ICG components can add 'Mixture' datasets. (i.e. can have 'MiM in a MiM')</p>	S + G

SUBSTANCE COMPONENTS (SiM)		
BR539	<p>Substance components must have linked 'reference substance' datasets.</p> <p>Components identified using the Generic component identifier (GCI) are an exception.</p>	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 ' <i>not available</i> ' or ' <i>proprietary substance</i> ' 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 ' <i>not available</i> ' or ' <i>proprietary substance</i> ' are not correct Substance names.	S + G
QLT825 for S QLT826 for G	'If in Substance > Other substance identifiers > Identifier > is selected to be 'other:' then it must be explained what is meant by 'other' in all the relevant languages in the adjacent field(s)	S + G
QLT592 for S QLT899 for G	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 for S BR897 for G	The combined concentration of the GCI type components 'Colourant' must not exceed 25 %.	S + G
BR603 for S BR898 for G	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
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<p>BR841 for S</p> <p>BR544 for G</p>	<p>ICG: Concentration is to be provided only for the 'Interchangeable component group (ICG)' – not for the individual interchangeable components (IC's).</p>	<p>S + G</p>
<p>BR590</p>	<p>Components must have concentrations (value and unit).</p> <p>Components which 'function' is 'perfume' and classification is only regarding the below mentioned hazard(s) are excluded from this rule:</p> <ul style="list-style-type: none"> • Skin sensitisation 1, 1A, 1B • Aspiration hazard Asp. Tox. 1 <p>Interchangeable component groups (ICG) components (IC's) are excluded from this rule.</p>	<p>G</p>
<p>BR581 for S</p> <p>BR862 for G</p>	<p>Either 'Typical concentration' (exact concentration) or 'Concentration range' must be provided, not both.</p>	<p>S + G</p>
<p>BR607 for S</p> <p>BR864 for G</p>	<p>Report only components which are present in the mixture;</p> <ul style="list-style-type: none"> • 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 >. <p>Negative values are not allowed as concentration values.</p> <p>Exception is that Standard formula (SF) components can have lower concentration value reported as 0%.</p>	<p>S + G</p>
<p>QLT502</p>	<p>If the concentration is above 1 %, the recommended number of decimals is one.</p>	<p>S + G</p>
<p>QLT505</p>	<p>If the concentration value is 0.1-1 %, the recommended number of decimals is two.</p>	<p>S + G</p>
<p>BR950 for S</p> <p>BR951 for G</p>	<p>Reported concentration value cannot be above 100% (rule checks each constituent's concentration value separately)</p>	<p>S + G</p>
<p>BR518</p>	<p>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.</p> <p>Exception is that Standard formula (SF) components and Interchangeable component group (ICG) components do not need to comply with this rule.</p>	<p>S + G (not L)</p>
<p>BR588</p>	<p>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.</p> <p>Exception is that Standard formula (SF) components and Interchangeable component group (ICG) components do not need to comply with this rule.</p>	<p>S + G (not L)</p>

BR556 for S	Total concentration of the mixture is too low (below 70 %). If the reported concentration is lower than 70 %, the dossier cannot be accepted.	S + G (not L)
BR853 for G	Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.	
QLT506 for S	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 + G (not L)
QLT854 for G	Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.	
BR593 for S	Total concentration of the mixture exceeds 100%. If the reported concentration is higher than 105 %, the dossier cannot be accepted.	S + G
BR882 for G	Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.	
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 concentration 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
BR842	All provided 'Classification and labelling' records must be linked to 'Mixture composition' record(s).	G

PRODUCT INFORMATION		
BR517	At least one 'Product information' 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 information' record must have at least one linked UFI number.	S + G (not N)
QLT1000 *	There should be only one trade name per 'Trade name' field. If the product has multiple trade names they should be provided separately each in their own row in 'Trade names' table. <i>This rule is triggered if the provided trade name contains ; or : character since in cases where multiple trade names were provided in the same field they were often separated by these characters. (S + G)</i>	S + G
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 information' 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 information' record(s) 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': <ul style="list-style-type: none"> - '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

[BR849]	Disabling can be only performed on the latest valid submission per PCN number. If there exists a newer submission (submission date of the disabling is earlier than the latest valid submission having the same PSSI), it should fail.	S + G
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DOSSIER HEADER		
[BR570]	Submitter legal entity UUID in 'ECHA Submission portal' must be same as the legal entity UUID included in the 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.	S + G
[BR952]	Submitter legal entity's country in 'ECHA Submission portal' must be same as the legal entity' country included in the 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.	S + G
[QLT953]	Submitter legal entity's name in 'ECHA Submission portal' must be same as the legal entity name 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]	<p>Any changes to the notification should be reported as an 'update' and not as a new 'initial' submission.</p> <p>Therefore new 'initial' submissions:</p> <ul style="list-style-type: none"> (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 <p>are not allowed.</p>	S + G
[QLT514]	<p>Any changes to the notification should be reported as 'update' and not as a new 'initial' submission.</p> <p>Therefore new 'initial' submissions:</p> <ul style="list-style-type: none"> (i) for products having the same UFI (ii) made by the same company (iii) where concentration: <ul style="list-style-type: none"> • 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) <p>are not allowed.</p>	S + G

[QLT954]	<p>Notifiers should not use same UFI for different compositions.</p> <p>Therefore new 'initial' submissions:</p> <p>(i) for products having the same UFI (ii) made by the same company (iii) for different PCN number are not allowed unless the composition is the same.</p>	S
[QLT620]	<p>'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'.</p> <p>'Standard formula (SF)' components are excluded from this rule</p>	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.	S + G
[QLT891]	Adding, replacing or removing ICG components in updates is not allowed.	S + G
[BR597]	<p>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.</p> <p>Exception is that 'Standard formula (SF)' and 'Interchangeable component group (ICG)' components do not need to comply with this rule.</p>	S
[BR868]	<p>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.</p> <p>Exception is that 'Standard formula (SF)' and 'Interchangeable component group (ICG)' components do not need to comply with this rule.</p> <p>Exception is that the components which 'Function' is indicated to be 'perfume' do not need to comply with this rule.</p>	G
[BR599]	<p>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.</p> <p>Exception is that 'Standard formula (SF)' and 'Interchangeable component group (ICG)' components do not need to comply with this rule.</p>	S

<p>[BR866]</p>	<p>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.</p> <p>Exception is that the components which 'Function' is indicated to be 'perfume' do not need to comply with this rule.</p> <p>Exception is that 'Standard formula (SF)' and 'Interchangeable component group (ICG)' components do not need to comply with this rule.</p>	<p>G</p>
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UNIQUE FORMULA IDENTIFIER (UFI) AND OTHER IDENTIFIERS		
<p>[BR569]</p>	<p>'CLP related PCN number' should refer to existing PCN number from the same legal entity notified by a succeeded submission.</p>	<p>S + G</p>
<p>[BR611]</p>	<p>'CLP related PCN number' indicated in the case of a significant change of composition must be retained across updates.</p>	<p>S + G</p>
<p>[QLT618]</p>	<p>One UFI cannot correspond to more than one PCN number submitted in the same market placement country.</p>	<p>S + G</p>
<p>[BR572]</p>	<p>UFI(s) can be added but never removed in updates.</p>	<p>S + G</p>
<p>[QLT571]</p>	<p>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.).</p>	<p>S + G</p>
<p>[QLT516]</p>	<p>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.).</p>	<p>S + G</p>
<p>[BR596]</p>	<p>A MiM component identified by UFI, which has been notified for only Industrial use, cannot be used in other cases (Professional/Consumer use).</p> <p><i>(This rule is not triggered in cases where the MiM has in addition to the UFI the Supplier information and if it was hazardous the component(s) were provided)</i></p> <p>Exception is that Standard formula (SF) components, Interchangeable component group (ICG) components and General Component Identifier (GCI) component do not need to comply with this rule.</p> <p>Since the mixture has professional or consumer end use the MiM(s) should be notified accordingly by the supplier. We would advise to discuss with the relevant supplier the need to update their submission.</p>	<p>S + G</p>

[QLT955] *	<p>A MiM component identified by UFI, which has been notified for only Industrial use, cannot be used in other cases (Professional/Consumer use).</p> <p><i>(This rule is triggered in cases where the MiM has in addition to the UFI the Supplier information and if it was hazardous the component(s) were provided)</i></p> <p>Exception is that Standard formula (SF) components, Interchangeable component group (ICG) components and General Component Identifier (GCI) component do not need to comply with this rule.</p> <p>Since the mixture has professional or consumer end use the MiM(s) should be notified accordingly by the supplier. We would advise to discuss with the relevant supplier the need to update their submission.</p>	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 <ul style="list-style-type: none"> • 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	<p>January 2020</p> <ul style="list-style-type: none"> • 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	<p>May 2020</p> <p>Legal entity:</p> <ul style="list-style-type: none"> • 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 <p>MiM:</p> <ul style="list-style-type: none"> • 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' <p>Substance:</p> <ul style="list-style-type: none"> • Rule type changed from 'failure' to 'warning': BR592 changed to QLT592 <p>Fragrance related changes:</p> <ul style="list-style-type: none"> • 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 <p>Concentration:</p> <ul style="list-style-type: none"> • 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 <p>C&L</p> <ul style="list-style-type: none"> • 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 <p>[Dossier header]:</p> <ul style="list-style-type: none"> • [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

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 than 132 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 April 2021)*
- [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.*

6.1	<p>7th of February 2022</p> <p>ADDED: BR846 Mixture composition should not refer to itself as a compositions component: The notification (Mixture dataset) cannot have itself included as Mixture-in-mixture component in the composition (compares Mixture composition record UUID's)</p> <p>Correction in this document: In last IUCLID update (in October 2021) also rule BR685 was added, but it was missing from this document. BR685 checks that if Interchangeable component groups (ICG) components did include classification records, then the hazard classifications and hazard statements must be identical (excluding the environmental hazards).</p>
7.0	<p>April 2022</p> <p>ADDED: BR842 All provided 'Classification and labelling' records must be linked to 'Mixture composition' record(s). (G)</p> <p>BR870 If the new update reason 'cease product from market' is indicated in the dossier header, at least one country should exist under the ceased market list in at least one Product record (S + G)</p> <p>BR882 Reported total concentration exceeds 105% (G)</p> <p>QLT692 Same tick box selection for the same constituent (none/SF/ICG/GCI) in all 'Mixture composition' records (G)</p> <p>QLT881 MiM's UFI can be the same as mixture's UFI only if the composition is reported to be 100% MiM (MainMixture has one 'Mixture' constituent which exact concentration is indicated to be 100%) (S)</p> <p>QLT893 If in the 'Contact person' record 'Contact type' is indicated to be 'other:' then it must be explained what is meant by the 'other' in all the relevant languages in the language specific field(s). (S + G)</p> <p>QLT894 If in the Mixture composition the Component's function is indicated to be 'other:' then it must be explained what is meant by the 'other' in all the relevant languages in the language specific field(s). (S)</p> <p>QLT899 Same constituent (reference substance) cannot be in reported in 'Mixture composition' multiple times unless the classification and labelling is different (Group)</p> <p>MODIFIED: [QLT620] 'New submission after significant change of composition' is not allowed if there is no change in the composition from the previous notification. <i>to exclude components that are indicated to be 'Standard formula component SF'.</i></p>
8.0	<p>October 2022 (IUCLID v.6.27.0 release planned for 31st October)</p> <p>ADDED: BR823 SF: Mixture in mixture (MiM) components that are indicated to be 'Standard formula (SF) components' must have compositional information included (at least one 'Component' reported) (G)</p> <p>BR827 ICG: 'Interchangeable component group' cannot be indicated both in MainMixture and in Mixture in mixture (MiM) level (S)</p> <p>BR841 ICG: Concentration is to be provided only for the 'Interchangeable component</p>

group (ICG)' – not for the individual interchangeable components. (S)

BR855 'If component is indicated to be 'fuels' then it must have the specific fuel name. More precisely if the 'Standard formula' checkbox is ticked and in 'Other identifiers' table 'Name type' is selected to be 'fuels' then the adjacent 'Name' field must have selected the fuel name from the dropdown list.) (S)

BR861 SF: If 'Component' is indicated to be 'SF (Standard formula)' then name of the standard formula or fuel must be provided. (G)

BR863 ICG: 'Substance' datasets cannot be used for components that are indicated to be 'Interchangeable component group (ICG)'. Only 'Mixture' datasets are allowed if component is indicated to be ICG. (G)

BR880 ICG: Mixture in mixture components that are indicated to be 'Interchangeable component groups (ICG)' must have compositional information included (at least **two** 'Components' reported). (G)

BR888 Each 'Mixture composition' record should be referenced from exactly one Classification and labelling record. (G)

BR897 The combined concentration of the GCI type components 'Colourant' must not exceed 25 %. (G)

BR898 The combined concentration of the GCI type component 'Perfume' must not exceed 5 %. (G)

MODIFIED:

[BR596] 'A MiM component identified by UFI, which has been notified for only Industrial use, cannot be used in other cases (Professional/Consumer use)'. *modified to pass in cases where the MiM is identified with 'available components' or is GCI/SF/ICG in addition to the UFI (change already done in September 2022)*

BR683 was changed from 'At least **one** component must be reported for ICG MIM' to 'At least **two** components must be reported for ICG MIM' (S)

QLT634 and **QLT635**: key words added: 'Substance' and 'C.B.I'

INACTIVATED:

BR685 'ICG: The 'Interchangeable component group (ICG)' components classification for health and physical effects must be identical: If 'Classification and labelling' records were provided for the 'Interchangeable component group (ICG)' components then their 'Hazard category' and 'Hazard statement' must be same regarding the physical hazards and health hazards' *was inactivated in February 2022 due to request to make rule less strict. Rule will be modified to allow differences in hazard statement sub-categories)*

BUGS FIXED:

QLT881 'The UFI in MiM is same as the UFI in MainMixture (S)' *was incorrectly failing if more than two MiM's were provided. (fixed in July 2022)*

BR537 'Packaging size must be provided' *was incorrectly passing if only value or unit (not both) was provided (fixed in v.6.27.0 October 2022)*

BR590 'Concentration must be provided' *was incorrectly failing for ICG components (IC's) (G) (fixed in July 2022)*

Correction to this document:

- **[BR849]** 'Disabling can be only performed on the latest valid submission per PCN number. If there exists a newer submission (submission date of the disabling is earlier than the latest valid submission having the same PSSI), it should fail.' *Rule was added in Portal already in 2021 December*

9.0

May 2023 (IUCLID 7.0.0 planned for May 22th)

ADDED:

BR544 ICG: Concentration is to be provided only for the 'Interchangeable component group (ICG)' – not for the individual interchangeable components. (G)

BR828 ICG: 'Interchangeable component group' cannot be indicated both in MainMixture and in Mixture in mixture (MiM) level (G)

BR830 SF Fuels: 'If component is indicated to be 'fuels' then it must have the specific fuel name. More precisely if the 'Standard formula tickbox is ticked and in 'Other identifiers' table 'Name type' is selected to be 'fuels' then the adjacent 'Name' field must have selected the fuel name from the dropdown list.) (G)

BR890 SF Fuels: 'Fuels' can be reported only in MainMixture, not as MiMs (G)

BR950 Reported concentration value cannot be above 100% (rule checks each constituent's concentration value separately) (S)

BR951 Reported concentration value cannot be above 100% (rule checks each constituent's concentration value separately) (G)

QLT821 If in the Mixture composition the Component's function is indicated to be 'other:' then it must be explained in all the relevant languages (G)

QLT822 MiM's UFI can be the same as mixture's UFI only if the composition is reported to be 100% MiM (MainMixture has one 'Mixture' constituent which exact concentration is indicated to be 100%) (G)

QLT825 If in the Substances 'Other substance identifiers' table 'Identifier' is indicated to be 'other:' then it must be explained in all the relevant languages (S)

QLT826 If in the Substances 'Other substance identifiers' table 'Identifier' is indicated to be 'other:' then it must be explained in all the relevant languages (G)

QLT847 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. (G)

June/July 2023 (ECHA Submission Portal specific rules are planned to be updated June-July 2023)

ADDED:

[BR952] Submitter legal entity's **country** in 'ECHA Submission portal' must be same as the legal entity' country included in the 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.

[QLT953] Submitter legal entity's **name** 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'.

[QLT954] Notifiers should not use same UFI for different compositions.

Therefore new 'initial' submissions:
 (i) for products having the same UFI
 (ii) made by the same company
 (iii) for different PCN number
 are not allowed unless the composition is the same (or in notifiers specific case it is expected).

9.1

October 2023 (IUCLID 7.10.1 planned for October 30th)

ADDED:

BR690 MiM: For identifying the MiM, it is mandatory to provide either:

- c) UFI
- d) 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. (G)

QLT1000 There should be only one trade name per 'Trade name' field. If the product has multiple trade names they should be provided separately each in their own row in 'Trade names' table.

This rule is triggered if the provided trade name contains ; or : character since in cases where multiple trade names were provided in the same field they were often separated by these characters. (S + G)

[QLT955] 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) fail.' Rule is similar to [BR596] the difference being that this rule is triggered in cases where the MiM has in addition to the UFI the Supplier information and if it was hazardous then the component(s) were provided. This rule was added in Portal already in **2023 June**

BUG FIXED:

QLT501 'Maximum pH value range width is 1 unit (when pH =<3 or >=10)' Rule was previously incorrectly considering only the lower value of the range. Now it is modified to consider cases where pH ranges lower value is from -3 to 3 or pH ranges higher value is from 10 to 15

Clarification added to rule description:

- **BR553** 'The PCN number must be indicated and it must be in UUID format' it was clarified that it must be specifically **version 4** of the UUID format.