

# Validation rules for poison centres notifications

Version 5.1  
May 2021

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### Legal notice


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

-  'Group notifications' are not included in October 2020 release of IUCLID and ECHA Submission portal.

### 2.1 List of PCN validation rules in IUCLID

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

\*rule modified since previous IUCLID release

Rule number	Short description of the rule	Type
<b>LEGAL ENTITY – IDENTIFICATION OF THE SUBMITTER</b>		
<b>BR608</b>	<b>Legal entity</b> (Duty holder) must be provided in 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.	All
<b>BR519</b>	The contact details of the legal entity must include: <ul style="list-style-type: none"> <li>• address 1</li> <li>• town</li> <li>• country</li> <li>• phone</li> <li>• email</li> <li>• postal code.</li> </ul>	All
<b>BR522</b>	Email address must be in email format.	All

### DOSSIER HEADER

<b>BR553</b>	The <b>PCN number</b> must be indicated and it must be in UUID format.  The UUID format is described in <a href="https://tools.ietf.org/html/rfc4122">https://tools.ietf.org/html/rfc4122</a>	All
<b>BR554</b>	At least one ' <b>Country (market placement)</b> ' must be selected.	All
<b>BR558</b>	Each country mentioned as ' <b>Country (market placement)</b> ' must have at least one corresponding 'Product information' record.	All
<b>BR632</b>	'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.	All
<b>BR559</b>	At least one ' <b>Language</b> ' must be selected.	All
<b>BR561</b>	Either 'The submission is an initial notification', 'The submission is a new notification after a significant change in composition' or 'The submission is an update' must be selected.	All
<b>BR543</b>	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).	All

Languages		
<b>BR650</b>	If 'Market placement country' is indicated to be <b>Austria</b> , then <b>German</b> must be selected as 'Language'.	All
<b>BR651</b>	If 'Market placement country' is indicated to be <b>Belgium</b> , then at least one of the following languages must be selected as 'Language': <b>French</b> or <b>Dutch</b> or <b>German</b> or <b>English</b>	All
<b>BR652</b>	If 'Market placement country' is indicated to be <b>Bulgaria</b> , then <b>Bulgarian</b> must be selected as 'Language'.	All
<b>BR653</b>	If 'Market placement country' is indicated to be <b>Croatia</b> , then at least one of the following languages must be selected as 'Language': <b>Croatian</b> or <b>English</b>	All
<b>BR654</b>	If 'Market placement country' is indicated to be <b>Cyprus</b> , then <b>Greek</b> must be selected as 'Language'.	All
<b>BR655</b>	If 'Market placement country' is indicated to be <b>Czech Republic</b> , then <b>Czech</b> must be selected as 'Language'.	All
<b>BR656</b>	If 'Market placement country' is indicated to be <b>Denmark</b> , then at least one of the following languages must be selected as 'Language': <b>Danish</b> or <b>English</b>	All
<b>BR657</b>	If 'Market placement country' is indicated to be <b>Estonia</b> , then at least one of the following languages must be selected as 'Language': <b>Estonian</b> or <b>English</b>	All
<b>BR658</b>	If 'Market placement country' is indicated to be <b>Finland</b> , then the <b>Finnish</b> and <b>Swedish</b> must be selected as Languages.	All
<b>BR659</b>	If 'Market placement country' is indicated to be <b>France</b> , then <b>French</b> must be selected as 'Language'.	All

<b>BR660</b>	If 'Market placement country' is indicated to be <b>Germany</b> , then at least one of the following languages must be selected as 'Language': <b>German</b> or <b>English</b>	All
<b>BR661</b>	If 'Market placement country' is indicated to be <b>Greece</b> , then <b>Greek</b> must be selected as 'Language'.	All
<b>BR662</b>	If 'Market placement country' is indicated to be <b>Hungary</b> , then <b>Hungarian</b> must be selected as 'Language'.	All
<b>BR663</b>	If 'Market placement country' is indicated to be <b>Icelandic</b> , then at least one of the following languages must be selected as 'Language': <b>Icelandic</b> or <b>English</b>	All
<b>BR664</b>	If 'Market placement country' is indicated to be <b>Ireland</b> , then <b>English</b> must be selected as 'Language'.	All
<b>BR665</b>	If 'Market placement country' is indicated to be <b>Italy</b> , then at least one of the following languages must be selected as 'Language': <b>Italian</b> or <b>English</b>	All
<b>BR666</b>	If 'Market placement country' is indicated to be <b>Latvia</b> , then at least one of the following languages must be selected as 'Language': <b>Latvian</b> or <b>English</b>	All
<b>BR667*</b>	If 'Market placement country' is indicated to be <b>Liechtenstein</b> , then <b>German</b> must be selected as 'Language'.	All
<b>BR668</b>	If 'Market placement country' is indicated to be <b>Lithuania</b> , then at least one of the following languages must be selected as 'Language': <b>Lithuanian</b> or <b>English</b>	All
<b>BR669</b>	If 'Market placement country' is indicated to be <b>Luxembourg</b> , then at least one of the following languages must be selected as 'Language': <b>French</b> or <b>German</b> .	All
<b>BR670</b>	If 'Market placement country' is indicated to be <b>Malta</b> , then at least one of the following languages must be selected as 'Language': <b>Maltese</b> or <b>English</b>	All
<b>BR671</b>	If 'Market placement country' is indicated to be <b>Netherlands</b> , then at least one of the following languages must be selected as 'Language': <b>Dutch</b> or <b>English</b>	All
<b>BR672</b>	If 'Market placement country' is indicated to be <b>Norway</b> , then at least one of the following languages must be selected as 'Language': <b>Norwegian</b> or <b>Danish</b> or <b>Swedish</b> or <b>English</b>	All
<b>BR673</b>	If 'Market placement country' is indicated to be <b>Poland</b> , then <b>Polish</b> must be selected as 'Language'.	All
<b>BR674*</b>	If 'Market placement country' is indicated to be <b>Portugal</b> , then <b>Portuguese</b> or <b>English</b> must be selected as 'Language'.	All
<b>BR675</b>	If 'Market placement country' is indicated to be <b>Romania</b> , then <b>Romanian</b> must be selected as 'Language'.	All
<b>BR676</b>	If 'Market placement country' is indicated to be <b>Slovakia</b> , then <b>Slovak</b> must be selected as 'Language'.	All
<b>BR677</b>	If 'Market placement country' is indicated to be <b>Slovenia</b> , then <b>Slovenian</b> must be selected as 'Language'.	All
<b>BR678</b>	If 'Market placement country' is indicated to be <b>Spain</b> , then at least one of the following languages must be selected as 'Language': <b>Spanish</b> or <b>English</b>	All
<b>BR679</b>	If 'Market placement country' is indicated to be <b>Sweden</b> , then at least one of the following languages must be selected as 'Language': <b>Swedish</b> or <b>English</b>	All

CONTACT PERSON		
<b>BR552</b>	An emergency contact must be provided in the 'Contact person' section for each country indicated in the dossier header.	L
<b>BR523</b>	<p>The contact details of the emergency contact must include:</p> <ul style="list-style-type: none"> <li>• last name</li> <li>• organisation</li> <li>• phone</li> <li>• email</li> <li>• country.</li> </ul> <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>	L

pH		
<b>BR512</b>	Exactly one 'pH' record must be provided.	S, L
<b>BR545</b>	Either 'pH is not available' must be selected or a pH value must be reported (one value or range).	S, L
<b>BR524</b>	Allowed pH values: $-3 \leq \text{pH} \leq 15$	All
<b>BR615</b>	Allowed pH qualifiers: one value cannot have qualifiers, range cannot have 'c.a.'.	All
<b>QLT504</b>	pH value must be indicated as an integer or specified to one decimal.	All
<b>QLT501</b>	Maximum pH value range width is 1 unit (when $\text{pH} \leq 3$ or $\text{pH} \geq 10$ ).	All
<b>QLT510</b>	Maximum pH value range width is 3 units (when $3 < \text{pH} < 10$ ).	All
<b>BR585</b>	If pH is available, 'Solution concentration' must be provided.	All
<b>BR621</b>	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.	All

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

MIXTURE COMPOSITION		
<b>BR509</b>	Exactly one 'Mixture composition' record must be provided.	All
<b>BR521</b>	At least one 'Mixture' (MiM) or 'Substance' component must be provided in 'Mixture composition' (MainMixture).	All

<b>BR551</b>	'Reference substance' datasets cannot be linked from 'Mixture composition' (MainMixture). Only 'Mixture' (MiM) and 'Substance' datasets can be linked from 'Mixture composition' (MainMixture).	All
<b>BR634</b>	All provided 'Components' blocks must be complete: If concentration was provided for the component then either 'Substance' or 'Mixture (MiM)' dataset must be included.	All
<b>BR639</b>	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.)	All
<b>BR640</b>	Interchangeable Component Group (ICG) should be reported as MiM, not as Substance.	All
<b>BR682</b>	Standard formula 'Fuels' can be reported only in MainMixture, not as MiMs.	All

MIXTURE COMPONENTS (MiM)		
<b>BR527</b>	<p>For identifying the MiM, it is mandatory to provide either:</p> <ul style="list-style-type: none"> <li>a) UFI</li> <li>b) Available component(s): <ul style="list-style-type: none"> <li>- If MiM is hazardous 'Supplier' record and available components (at least one Substance).</li> <li>- If MiM is non-hazardous, then providing the 'Supplier' record is enough.</li> </ul> </li> </ul> <p>Components identified using the Generic component identifier (GCI), Standard formula (SF) and Interchangeable component group (ICG) are an exception.</p>	All
<b>BR684</b>	MiM cannot have more than one 'Composition' record.	All
<b>BR578</b>	There cannot be more than one UFI per MiM.	All
<b>BR606</b>	<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"> <li>• legal entity name</li> <li>• phone</li> <li>• email.</li> </ul> <p>Standard formula (SF) and Interchangeable component group (ICG) components are excluded from this rule.</p>	All
<b>BR681</b>	Mixture in mixture components that are indicated to be 'Standard formula (SF) components' must have compositional information included (at least one 'Component' reported).	All
<b>BR683</b>	Mixture in mixture components that are indicated to be 'Interchangeable component groups (ICG)' must have compositional information included (at least one 'Component' reported).	All
<b>QLT624</b>	If the MiM is identified with providing the available component(s) of the composition, then the legal entity in the 'Suppliers' record must 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'.)	All

<b>BR577</b>	'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')	All
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SUBSTANCE COMPONENTS (SiM)		
<b>BR539</b>	Substance components must have linked 'reference substance' datasets.  Components identified using the Generic component identifier (GCI) are an exception.	All
<b>BR540</b>	'Reference substance' must have at least one of the following identifiers: EC number, CAS number, IUPAC name, INCI or colour index name. (International chemical name should be reported in the IUPAC name field.)	All
<b>QLT509</b>	If no EC number, CAS number or IUPAC name is provided for the 'reference substance', then notifier is reminded that more identifiers could be provided.	All
<b>BR525</b>	EC number format must be correct.	All
<b>BR526</b>	CAS number format must be correct.  The CAS number format is described in: <a href="https://www.cas.org/support/documentation/chemical-substances/checkdig">https://www.cas.org/support/documentation/chemical-substances/checkdig</a> .	All
<b>QLT634</b>	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.	All
<b>QLT635</b>	The provided 'Substance name' should be meaningful.  For instance ' <i>not available</i> ' or ' <i>proprietary substance</i> ' are not correct Substance names.	All
<b>QLT592</b>	Repeating the same 'reference substance' not allowed unless the related classification is different.	All

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



Components concentrations		
<b>BR629</b>	<p>Components must have concentrations (value and unit).</p> <p>Interchangeable component groups (ICG) components (IC's) are excluded from this rule.</p>	All
<b>BR581</b>	<p>Either 'Typical concentration' (exact concentration) or 'Concentration range' must be provided, not both.</p>	All
<b>BR607</b>	<p>Report only components which are present in the mixture;</p> <ul style="list-style-type: none"> <li>- Components which 'Typical concentration' (exact concentration) is 0% are not allowed.</li> <li>- Components which lower concentration range value is <b>exactly</b> 0% are not allowed. Therefore, lower concentration range values which are reported with qualifier =&gt; to be 0% are not allowed. Please note that concentration ranges where lower value is indicated to be <b>above</b> 0% are allowed. To this end indicate the concentration value with qualifier &gt;.</li> </ul> <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>	All
<b>QLT502</b>	<p>If the concentration is above 1 %, the recommended number of decimals is one.</p>	All
<b>QLT505</b>	<p>If the concentration value is 0.1-1 %, the recommended number of decimals is two.</p>	All
<b>BR518</b>	<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>	S, N
<b>BR588</b>	<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>	S, N
<b>BR556</b>	<p>Total concentration of the mixture is too low (below 70 %).</p> <p>If the reported concentration is lower than 70 %, the dossier cannot be accepted.</p> <p>Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.</p>	S, N
<b>QLT506</b>	<p>Total concentration of the mixture is too low (70-90 %).</p> <p>If the reported concentration is lower than 90 %, the notifier is warned that the full composition is currently not included.</p> <p>Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.</p>	S, N
<b>BR593</b>	<p>Total concentration of the mixture exceeds 100%.</p> <p>If the reported concentration is higher than 105 %, the dossier cannot be accepted.</p> <p>Exception is that Standard formula (SF) 'Fuel' compositions do not need to comply with this rule.</p>	All

<b>BR591</b>	Units provided for concentrations must be consistent.	All
<b>BR541</b>	Allowed units for concentrations: v/v % and w/w %.	All
<b>BR548</b>	Allowed qualifiers for concentrations: <ul style="list-style-type: none"> <li>- 'Typical concentration' cannot have qualifiers</li> <li>- 'Concentration range' 'c.a.' not allowed.</li> </ul>	All
<b>BR625</b>	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.	All

#### UNIQUE FORMULA IDENTIFIER (UFI) AND OTHER IDENTIFIERS

<b>BR516</b>	'Unique formula identifiers (UFI) and other identifiers' record must be provided.	S, L
<b>BR528</b>	UFI is mandatory. At least one entry with the regulatory programme type 'CLP unique formula identifier (UFI)' and the appropriate UFI value in the field 'Id' must be included.	S, L
<b>QLT508</b>	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.	N
<b>BR549</b>	UFI number format must be correct. The UFI format is specified in the UFI Developers Manual: <a href="https://poisoncentres.echa.europa.eu/ufi-generator">https://poisoncentres.echa.europa.eu/ufi-generator</a> .	All
<b>BR635</b>	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.	All
<b>BR563</b>	'CLP related PCN number' not allowed for initial submissions.	All
<b>BR562</b>	'CLP related PCN number' is mandatory for 'After significant composition change' notifications.	All
<b>BR609</b>	Submission cannot have more than one 'CLP related PCN number' reported.	All
<b>BR557</b>	'PCN number' reported in dossier header cannot be same as 'CLP related PCN number'.	All
<b>BR584</b>	'Unique formula identifiers (UFI) and other identifiers' record must be included in 'Product information' record.	S, L

#### CLASSIFICATION AND LABELLING

<b>BR513</b>	Exactly one 'Classification and labelling information' record must be provided in 'Mixture information' (MainMixture).	All
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<b>BR510</b>	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.	All
<b>BR633</b>	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.	All
<b>BR612</b>	Exactly one 'Classification and labelling information' record must be provided for each 'Mixture information' (MainMixture) 'Substance' component.	All
<b>BR636</b>	'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)'	All
<b>QLT507</b>	Voluntary submissions cannot be classified for health or physical hazards. An exception can be made if classification is only regarding explosive or gases under pressure hazards.	N
<b>BR546</b>	In 'Mixture information' (MainMixture): Either ' <b>Not classified</b> ' must be selected or at least one selection in ' <b>Hazard categories and statements</b> ' must be made.	All
<b>BR613</b>	In 'Mixture information' (MainMixture): 'Classifications' must be complete: If 'Hazard category' is selected then also the adjacent 'Hazard statement' must be selected.	All
<b>BR614</b>	In 'Mixture information' (MainMixture): Labelling ' <b>Signal word</b> ' 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.	All
<b>BR626</b>	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.	All
<b>BR628</b>	In all 'Substance' and 'Mixture' component (MiM) classification records: Either ' <b>Not classified</b> ' must be selected or at least one selection in ' <b>Hazard categories and statements</b> ' must be made.	All

## PRODUCT INFORMATION

<b>BR517</b>	At least one 'Product details' record must be provided.	All
<b>BR508</b>	'Trade name' must be provided.	All
<b>BR531</b>	Each 'Product details' record must have at least one linked UFI number.	S, L
<b>BR532</b>	Market placement 'Country' is mandatory.	All
<b>BR610</b>	Each country indicated in the 'Product information' record must be also indicated as a market placement country in the dossier header.	All
<b>BR514</b>	'Colour and physical state' record is mandatory.	S, L

<b>BR529</b>	'Physical state' must be indicated.	S, L
<b>BR530</b>	'Colour' must be indicated.	S, L
<b>BR542</b>	Either 'Packaging document' must be linked or 'Product not packaged' must be selected. Exception if use type is only 'Industrial'.	S
<b>BR536</b>	'Type of packaging in contact with the product (container type)' must be indicated.	S, L
<b>BR537</b>	'Size of packaging in contact with the product (container size)' must be indicated.	S, L
<b>BR535</b>	At least one 'Use type' must be indicated.	S, L
<b>BR587</b>	For limited submissions, 'Use type' can only be 'Industrial'. 'Professional' and 'Consumer' are not allowed.	L
<b>BR534</b>	'Main intended use' must be indicated.	S, L
<b>QLT503</b>	Up to three 'Secondary uses' allowed.	S, L
<b>BR589</b>	Biocides or plant production products cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.	All

## 2.2 List of PCN validation rules in ECHA Submission portal

Rules marked in blue (**BR**) lead to the failure of the submission. Rules marked in orange (**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		
<b>[QLT732]</b>	ECHA Submission Portal can show maximum 500 failures/warnings per one notification.	All
<b>[BR564]</b>	The exactly same dossier cannot be submitted again.	All
<b>[BR565]</b>	ECHA Submission portal currently only accepts dossiers of which the submission type is 'CLP Poison centres notification' or 'SCIP notification'.	All
<b>[BR619]</b>	'Group submissions' are not allowed.	G
<b>[QLT573]</b>	'Mixture name' should remain same in update dossier.	All
<b>[BR627]</b>	Submitting company must be located in EU.	All

### DOSSIER HEADER

<b>[BR570]</b>	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'.	All
<b>[BR567]</b>	A new 'PCN number' should be provided for initial notifications and significant change of composition notifications.	All
<b>[BR568]</b>	An existing 'PCN number' should be used in updates notified by the same legal entity.	All
<b>[BR576]</b>	In case of updates, the dossier creation date should be greater than the previously submitted notifications creation date.	All
<b>[BR623]</b>	Removing market placement countries is not allowed.	All
<b>[QLT513]</b>	Notice that 'Update' or 'New notification after significant change in composition' has more market placement countries than the previous successful notification.	All
<b>[QLT574]</b>	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.	All
<b>[QLT514]</b>	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: <ul style="list-style-type: none"> <li>• Ranges have not changed beyond the initial submissions' concentration ranges</li> <li>• Typical (exact) concentrations have not changed beyond the allowed limits (accordance with Annex VIII to the CLP Regulation, Table 3 of Part B.)</li> <li>• Components have not been altered (added or deleted)</li> </ul> are not allowed.	All
<b>[BR620]</b>	'New submission after significant change of composition' is not allowed if there is no change in the composition from the previous notification. Therefore, submissions where there is no change in composition should be reported as an 'update' not as a 'New submission after significant change in composition'.	All

### Components concentrations

<b>[BR601]</b>	Same concentration units must be used across updates.	All
<b>[QLT598]</b>	Adding, replacing or removing components in updates is not allowed.	All

<b>[BR597]</b>	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.	All
<b>[BR599]</b>	Change of typical concentrations beyond limits in updates (as indicated in Annex VIII to the CLP Regulation, Table 3 of Part B) is not allowed.  Exception is that Standard formula (SF) and Interchangeable component group (ICG) components do not need to comply with this rule.	All

#### UNIQUE FORMULA IDENTIFIER (UFI) AND OTHER IDENTIFIERS

<b>[BR569]</b>	'CLP related PCN number' should refer to existing PCN number from the same legal entity notified by a succeeded submission.	All
<b>[BR611]</b>	'CLP related PCN number' indicated in the case of a significant change of composition must be retained across updates.	All
<b>[QLT618]</b>	One UFI cannot correspond to more than one PCN number submitted in the same market placement country.	All
<b>[BR572]</b>	UFI(s) can be added but never removed in updates.	All
<b>[QLT571]</b>	UFI(s) which have been notified by another legal entity are not allowed unless there is a valid reason (e.g. you are successor of that legal entity, you are a toll formulator's customer and you act with an agreement on the re-use of the UFI, same UFI is used by different subsidiaries companies etc.).	All
<b>[QLT516]</b>	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.).	All
<b>[BR596]</b>	A MiM component identified by UFI, which has been notified for only Industrial use, cannot be used in other cases (Professional/Consumer use).	All

#### PRODUCT INFORMATION

<b>[BR575]</b>	'Trade names' can be modified or removed only if in dossier header the 'Reason for updating' the justification was selected to be ' <b>correction/deletion of trade name</b> '.	All
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## 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"> <li>Rules embedded in 'ECHA Submission portal' added to this document.</li> <li><b>BR540</b> It was clarified that 'International chemical name' should be reported in IUPAC name field.</li> <li><b>BR542</b> It was clarified that if use type is only 'Industrial use' then they excluded from the requirement to provide Packaging record.</li> <li><b>BR557</b> 'PCN number' cannot be same as 'CLP related PCN number' rule was added</li> <li>Known issues: "Regarding BR608: Legal entity information must be included from 'Advanced settings'" was removed</li> </ul>
2.1	January 2020 <ul style="list-style-type: none"> <li><b>QLT510</b> wording: '<b>Minimum</b> pH value range width is 3 units (when pH 3 &lt; pH &lt;10)' changed to '<b>Maximum</b> pH value range width is 3 units (when pH 3 &lt; pH &lt;10).'</li> <li><b>BR589</b> wording: 'Biocides or plant production <b>products</b> cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.' Changed to 'Biocides or plant <b>protection</b> products cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.'</li> <li><b>BR573</b> changed to be warning <b>BR573</b></li> </ul>
3.0	May 2020 <b>Legal entity:</b> <ul style="list-style-type: none"> <li><b>BR608</b> 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</li> <li><b>BR520</b> DEACTIVATED requirement to provide same legal entity in 'Dossier header' and in 'Mixture' deleted</li> <li><b>[BR570]</b> 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</li> </ul> <b>MiM:</b> <ul style="list-style-type: none"> <li><b>BR527</b> MODIFIED 'MiM identified with SDS' changed to 'MiM identified with available Substance(s)' and Supplier record</li> <li><b>BR579</b> DEACTIVATED 'If the MiM is identified using a Safety data sheet (SDS), the 'Suppliers' record is mandatory.' (rule was merged to BR527)</li> <li><b>BR606</b> MODIFIED 'MiM identified with SDS' changed to 'MiM identified with available Substance(s)'</li> <li><b>BR624</b> NEW If MiM is identified with available substances then the Supplier</li> </ul>

(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.



	<ul style="list-style-type: none"> <li>• <b>BR628</b> NEW In all 'Substance' and 'Mixture' component (MiM) classification records: Either '<b>Not classified</b>' must be selected or at least one selection in '<b>Hazard categories and statements</b>' must be made.</li> </ul>
4.0	<p>October 2020:</p> <p><b>ADDED:</b></p> <ul style="list-style-type: none"> <li>• <b>BR632</b> 'Market placement country' indicated in dossier header cannot be 'United Kingdom of Great Britain and Northern Ireland [GB]' or 'United Kingdom: Northern Ireland [XN]</li> <li>• <b>QLT634</b> 'IUPAC name should be meaningful' and <b>QLT635</b> 'Substance name should be meaningful' (rules checks that the provided name is not for instance 'not available' or 'proprietary substance'.)</li> <li>• <b>BR629</b> Components must have concentrations (value and unit). (similar rule BR590 which was inactivated)</li> <li>• <b>BR633</b> Each MiM's Substance component must include exactly one 'Classification and labelling' record.</li> <li>• <b>BR636</b> 'Classification and labelling' record must be provided either in MiM or for all MiM's components if the MiM is marked to be ICG</li> <li>• <b>BR621</b> If 'pH not available' was indicated, then justification must be provided</li> <li>• <b>[QLT516]</b> 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.).</li> </ul> <p><b>INACTIVATED:</b></p> <ul style="list-style-type: none"> <li>• <b>BR590</b> 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)</li> <li>• <b>[QLT515]</b> deactivated (similar rule [QLT516] created)</li> </ul> <p><b>MODIFIED:</b></p> <ul style="list-style-type: none"> <li>• <b>BR543</b> 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.</li> <li>• <b>BR542</b> rule was changed so that 'Product not packaged' and Link to packaging information can be provided both in the same Packaging record.</li> <li>• <b>[BR575]</b> " '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' ". <i>was changed to</i> " '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' ."</li> <li>• Rule type changed from 'failure' to 'warning': <b>BR624</b> changed to <b>QLT624</b></li> <li>• <b>[BR565]</b> ECHA Submission Portal accepts now also 'SCIP' notification dossiers</li> <li>• <b>[BR623]</b> 'Cannot restrict the market area(s) in updates' to allow removal of [GB] as 'Market placement country'</li> <li>• Wording changed: 'Generic Product Identifier (GPI)' was changed to 'Generic component identifier (GCI)'</li> <li>• 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.</li> </ul> <p>Coming in late November 2020/December2020:</p> <ul style="list-style-type: none"> <li>• <b>BR634</b> All provided 'Components' blocks must be complete: If concentration</li> </ul>

	<ul style="list-style-type: none"> <li>was provided then either Substance or Mixture (MiM) dataset must be included.</li> <li><b>BR635</b> 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.</li> <li><b>BR630</b> MiM cannot have more than one 'MiM composition' record included.</li> </ul>
4.1	<p>December 2020:</p> <p><b>BR621 failure</b> "If 'pH not available' was indicated, then justification must be provided" changed temporarily to <b>QLT621 warning</b>. (Rule is planned to be changed back to <b>BR621 failure</b> in April 2021 when IUCLID is updated.)</p>
5.0	<p>April 2021</p> <p><b>ADDED:</b>  <b>BR650-BR679</b> Rules regarding 'Language' requirements based on 'Market placement country' added  <b>BR639</b> only one tickbox (SF/ICG/GCI) can be ticked per one component  <b>BR640</b> Interchangeable component group (ICG) should be reported as MiM, not as Substance  <b>BR683</b> Interchangeable component group (ICG) MiMs should have compositional information reported  <b>BR681</b> Standard formula (SF) component MiMs should have compositional information reported  <b>BR682</b> 'Fuels' can be reported only in MainMixture, not as MiMs</p> <p><b>INACTIVATED:</b>  <b>BR604</b> GCI type 'Perfume' can only be used once.  <b>BR617</b> GCI type 'Colourant' can only be used once.  <b>BR547</b> 'Physical state' must be same in all 'Colour and physical state' records.</p> <p><b>MODIFIED:</b>  <b>QLT621</b> to <b>BR621</b> "If 'pH not available' was indicated, then justification must be provided": rule changed from <i>warning</i> to <i>failure</i>  <b>BR630</b> to <b>BR684</b> 'MiM can have only one 'Composition' record. If more than one rule fails.': only rule number changed</p> <p>Planned for May 2021</p> <p><b>MODIFIED:</b>  <b>[QLT513]</b> 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'.</p> <p>Rule code switched from <b>[BRXXX]</b> to <b>[QLTXXX]:</b>  <b>[BR571]</b> to <b>[QLT571]</b>  <b>[BR573]</b> to <b>[QLT573]</b>  <b>[BR574]</b> to <b>[QLT574]</b>  <b>[BR598]</b> to <b>[QLT598]</b>  <b>[BR620]</b> to <b>[QLT620]</b></p>
5.1	<p>May 2021 IUCLID Cloud release</p> <p><b>FIXED:</b>  <b>BR674</b> Rule corrected so that English was added as the other accepted language. New version of the rule is therefore: <i>If 'Market placement country' is indicated to be <b>Portugal</b>, then <b>Portuguese</b> or <b>English</b> must be selected as 'Language'</i>. (Please note that the error message in Validation report still do not mention correctly that English is also accepted language for Portugal. The failure message will be corrected in July IUCLID release)</p>

