Validation rules for C&L notifications

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1. Introduction

This document provides short descriptions of the validation rules and quality rules which are relevant for Classification and Labelling (C&L) notifications submitted via the system to system (S2S) route to ECHA.

Note that non-compliance of validation rules constitutes a failure and non-acceptance of the submission, whereas quality warnings issued under the Quality checks warn you of common inconsistencies and shortcomings in your data. Quality warnings will not prevent you from successfully submitting your dossier to ECHA and obtaining a notification number.

2. Validation rules

2.1 List of validation rules in IUCLID and REACH-IT

Business rules regarding CLP notification	
BR018	The dossier section 'Identification' must contain a reference substance.
BR019	The dossier section 'Composition' must contain at least one record. The following requirements are also to be fulfilled: All created compositions must contain at least one constituent. All constituents must be linked to a reference substance.
BR020	Each reference substance in a dossier must contain a substance identifier. An acceptable substance identifier is: EC/List number CAS number IUPAC name If you use a reference substance to report unknown constituents/impurities, they must be "identified" by inserting 'Unknown constituent/impurity' in the IUPAC name field. If categories are used, this rule is applied to all the category member substances.
BR024	The 'Submission Type' in the dossier header must be 'CLP Notification'.
BR025	A new dossier cannot be submitted when the previous submission for the same substance is still being processed.
BR026	A dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset.
BR033	If no reference number for a notification is granted yet, it is not allowed to submit an update submission for the notification. Note that if you are resubmitting due to a business rule failure you should make a new initial submission and not tick 'The submission is an update' checkbox.

BR035	In an update dossier, insert the submission number of the most recent successful submission as the 'Last submission number' in the dossier header.
BR036	Parallel submissions are not allowed for the same annotation number in the dossier header field 'Number' under 'Further to a request/decision from a regulatory body'.
BR037 (BR034 in IUCLID)	The annotation number in the dossier header field 'Number' under 'Further to a request/decision from a regulatory body' must be valid.
BR038	Initial submission is not allowed after a notification submission has already been successfully completed and a reference number has been granted. If you need to modify/add data, an update submission is required.
BR039	Legal entity change cannot be performed by submitting and update to the dossier. The 'Legal entity change' module in REACH-IT is to be used to carry out the administrative changes related to ownership of the registration/notification.
BR040 (BR503 in IUCLID)	Update submission must include in the Regulatory programme field 'CLP notification number' the reference number issued for the notification.
BR042	It is not allowed to submit an initial/update CLP notification, if the substance has been registered by the submitting legal entity.
BR043	It is not allowed to submit an initial/update CLP notification, if the submitting legal entity has submitted a registration dossier for the substance, and the submission is in progress.
BR055	At least one set of classification and labelling information must be provided in GHS format.
BR069	If you wish to submit a spontaneous update then the following conditions must be fulfilled: In the dossier header tick the boxes 'The submission is an update' and 'Spontaneous update'. If you wish to update your dossier following a request by the Agency then the below conditions must be fulfilled: In the dossier header tick the boxes 'The submission is an update' and 'Further to a request/decision from a regulatory body'.
BR071	At least one of the following fields must be provided for the reference substance: EC/List number CAS number Molecular formula AND molecular weight AND structural formula SMILES notation Remarks

BR072	If at least one classification is provided in a C&L record then: a 'Signal word' must be provided under the 'Labelling' heading of the same record. If no classification is provided, the tick box 'Not classified' should be selected and no signal words should be provided.
BR073	If at least one classification is provided in a C&L record then: a 'Hazard statement' or a 'CLP supplemental hazard statement' must be provided under the 'Additional labelling requirements' heading of the same record. If no classification is provided, the tick box 'Not classified' should be selected and no hazard statements should be provided.
BR074	For each 'Specific concentration limit' entry that is created in a C&L record, at least one of the two fields under 'Concentration range (%)' must be provided. In addition, at least one selection must be made under 'Hazard categories'. If no classification is given in a C&L record, the tick box 'Not classified' should be marked and no specific concentration limits should be indicated in that record.
BR075	At least one value and a unit must be provided for the 'Degree of purity' for each 'Legal entity composition of the substance'.
BR076	The full 'Concentration range' (lower and upper value together with a unit) must be provided for each constituent, impurity and additive of a legal entity composition. When reporting a constituent, impurity or additive at exactly 0% or 100%, provide this value, together with the unit, in the field 'Typical concentration' and leave the 'Concentration range' fields empty.
BR077	If the substance is classified, a 'Hazard category' and a 'Hazard statement' must be provided, or a 'Reason for no classification' for each hazard class should be indicated. If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.
BR078	If the substance is classified, at least one entry for 'Specific target organ toxicity – single' and 'Specific target organ toxicity – repeated' must be provided. For each entry, a 'Hazard category', a 'Hazard statement', and 'Affected organs' must be provided, or indicate a 'Reason for no classification'. If the substance is not classified, the tick box 'Not classified' should be marked and no classification.
BR089	A new dossier cannot be submitted when the previous submission for the same substance is still being processed (applied during technical issues).
BR090	If the substance is defined as mono-constituent, the reference substances must be same in one dossier.
BR092	A notification that is undergoing a legal entity change cannot be updated.

BR093	No submissions can be made from the account of a legal entity, which at the time of submission undergoes the legal entity change (merge) process.
BR097	Any EC/List number must exist in the REACH-IT EC inventory.
BR098	In an update submission, the substance must be identified by an EC/List number.
BR099	All constituents of a multi-constituent or of a UVCB substance must identify distinct reference substances.
BR100	If the substance is defined as a multi-constituent substance, the reference substance cannot be identical to any of the constituents defined in the first composition of type 'legal entity composition of the substance'.
BR103	The annotation number in the Dossier header field 'Number' under 'Further to a request/decision from a regulatory body' must belong to your company.
BR162	When creating a substance dataset containing multiple compositions of type 'Legal entity composition of the substance', all of them must be linked to a classification and labelling record.
BR171	The submitting legal entity address country must be a EU country (ECHA account information).
BR175	At least one of the compositions must reflect the composition of the substance manufactured/imported by the registrant. This composition must be marked as the 'Legal entity composition of the substance'.
BR176	All compositions must have the composition type indicated.
BR199	Only compositions of type 'Legal entity composition of the substance' are allowed.
BR202	The CAS number in a reference substance must be valid.
BR265	A confidentiality claim on a notifier name must be supported by a selection of a justification category in the dossier header.
BR280	If the field 'Reason for no classification' is populated, the 'Hazard category' and 'Hazard statement' fields must be empty.
BR282	The hazard classes Mutagenicity, Carcinogenicity and Reproductive toxicity must be distinguished between Category 1A, Category 1B or Category 2.
BR283	The 'Contact' UUID is either missing or is not valid.
BR284	The UUID for the 'Group of manufacturers or importers' is not valid.
BR306	Type of substance must be selected. If you select 'other:', the adjacent text field must be filled in.

BR506	When you are reporting several compositions in section 1.2 and several records in classification and labelling (C&L) in section 2.1 then each C&L record must contain under 'Related composition' the link to the compositions to which the C&L refers to.

2.2 List of quality rules in IUCLID

Quality rules regarding CLP notification	
QLT056	You have used the same reference substance to identify more than one component (constituent, impurity, additive) within a composition document in section 1.2. Each reference substance represents a collection of identifiers for a specific chemical component, and may only be used once in each composition
QLT080	This record contained a corrupted attachment (broken reference or missing content) and that has been amended when you ran the attachment corrector tool on your IUCLID database. The attachment corrector tool has created a placeholder attachment with the name "missing-attachment" in each location where a corrupted attachment was found. Please remove the placeholder attachment, and replace it with the appropriate file to ensure that your submission contains all the intended information.
QLT111	The reference substance used to identify the substance is listed in Annex VI (Part 3) of the CLP regulation. As a consequence, the classification provided in IUCLID section 2.1 must follow, as a minimum, the harmonised classification of Table 3.1 of Annex VI. This message is a reminder and does not verify the classification you have provided in section 2.1, nor whether the substance is present at a concentration above its cut-off value (Annex I, 1.1.2.2 of the CLP regulation). If you already followed the above recommendations, you can ignore this message.
QLT112	The reference substance used to identify an impurity/additive in section 1.2 is listed in Annex VI (Part 3) of the CLP regulation, but the checkbox 'this impurity/additive is considered relevant for the classification and labelling of the substance' has not been checked. Any impurity and additive that is classified as hazardous, and which is present in a concentration above the cut-off value (Annex I, 1.1.2.2 of the CLP regulation), should be taken into account when classifying the substance. This message is a reminder and does not check the classification you have provided in section 2.1, nor whether the impurity/additive is present at a concentration above its cut-off value (Annex I, 1.1.2.2 of the CLP regulation). If you already followed the above recommendations, you can ignore this message.
QLT113	An inconsistency has been detected in section 2.1 of your substance dataset / dossier. You have ticked the box 'Not classified' for the indicated GHS record, but you have also entered a labelling in the same record under 'Hazard statements' or 'Additional labelling requirements'. Please correct the information as appropriate.
QLT114	You have provided a 'Hazard statement' in the 'Labelling' part of a GHS record in section 2.1. In this case, you are also expected to provide at least one classification ('Hazard category' and 'Hazard statement') in the 'Classification' part of the same GHS record.

QLT115	You have indicated for one or more of the impurities/additives in section 1.2 that 'this impurity/additive is considered relevant for the classification and labelling of the substance'. However, in section 2.1 you have not provided any classification for the substance. Please correct the information as appropriate.
QLT116	This composition has been linked to multiple GHS records under section 2.1. If the same composition gives rise to different hazard profiles with different classifications, it should be reported as separate compositions. Please correct the information as appropriate.
QLT117	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Explosives' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT118	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Flammable gases and chemically unstable gases' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT119	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Aerosols' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT120	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Gases under pressure' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT121	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Flammable liquids' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT122	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Self-reactive substances and mixtures' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT123	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Self heating substances and mixtures' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT124	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Substances and mixtures which in contact with water emits flammable gases' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT125	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Oxidising liquids' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.

QLT126	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Oxidising solids' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT127	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Organic peroxides' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT128	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Acute toxicity - oral' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT129	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Acute toxicity - dermal' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT130	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Acute toxicity - inhalation' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT131	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Skin corrosion / irritation' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT132	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Serious eye damage/eye irritation' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT133	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Aspiration hazard' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT134	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Reproductive toxicity' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT135	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Germ cell mutagenicity' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT136	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Carcinogenicity' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.

QLT137	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Specific target organ toxicity - single (STOT-SE)' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT138	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Specific target organ toxicity - repeated (STOT-RE)' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT139	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Hazardous to the aquatic environment (acute / short-term)' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT140	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Hazardous to the aquatic environment (long-term)' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT141	An inconsistency has been detected in section 2.1, under 'Classification'. The 'Hazard statement' that you have provided for the hazard class 'Hazardous to the ozone layer' is inconsistent with the selected 'Hazard category'. Please correct the information as appropriate.
QLT187	Section 2.1 is inconsistent. You have selected a hazard category under the hazard class <hazard class e.g. Explosives> that is not included in the CLP Regulation. When submitting a dossier under the REACH and CLP Regulations, you should adhere to the classification criteria defined in the CLP Regulation. Classification criteria from other legislation or directives should not be applied. Please amend the issue as appropriate.
QLT209 (April 2022)	Section 2.1 is inconsistent. Please indicate under the "Type of classification" field, if the registered substance has a harmonised classification and labelling (CLH), as listed in Table 3 to Annex VI of the CLP Regulation (EC) No 1272/2008; or a self-classification, if there is no CLH available. More information on the classification can be found on the ECHA website: https://echa.europa.eu/regulations/clp/classification.

2.3 List of file format and content validations

In order of ECHA systems to be able to process the dossier it must be in the agreed format. File format validations and Content validations check that the format of the file is correct.

FILE FORMAT VALIDATIONS	
EIM_FFC1	Incorrect file format.
EIM_FFC2_NOT_A_DOSSIER	Import request should contain only one dossier archive
EIM_XML_GEN	There was a problem with the XML input. Detailed error was: <detailed exception message>

EIM_UNKNOWN_I5_DOCUMENT_TYPE	Unknown document type in input archive: <filename>
EIM_WRONG_FILE_FORMAT_GENERIC	Wrong file format. An error occurred during XSD validation: <uuid key>
EIM_METADATA_VALIDATION_ERROR	Wrong file format. An error occurred during document metadata validation:<detailed error message>
EIM_WRONG_FILE_FORMAT_MANIFEST	Wrong file format. Review the manifest.xml file and run the import process again.
EIM_MISSING_DOSSIER_HEADER	Corrupted file. Dossier header was missing from the archive. If you are using IUCLID to prepare the dossier, when all the required information is included to the dataset create the dossier (which includes the dossier header) by clicking 'Create dossier'.
EIM_INVALID_REPLACE_OVERWRITE_MODE	REPLACE overwrite mode is not applicable for importing dossier datasets.
EIM_DOSSIER_EXCLUDED_THROUGH_DOCUMENT_SELECTION	Dossier (uuid: <dossier_uuid>) was excluded by document selection process.
EIM_MULTIPLE_FILES_FOUND	More than one files were uploaded for import
EIM_INVALID_USER_POOL	PublicGroup with name <group_name> is not one of <username> public groups.
EIM_UNLINKED_DOCUMENT	<entity_type> with name '<entity_name' (UUID: <entity_uuid>) is contained in the archive but is not linked to any other entity.
EIM_INVALID_OVERWRITE_MODE_FOR_TEMPLATE_INHERITANCE	This dataset cannot be imported in '<overwrite_mode>' overwrite mode, as it will lead to invalid links between the sections of <entity_representation> and the sections of <template_representation>. Please select a different overwrite mode.
EIM005	Import cannot proceed due to security constraints.
EIM006	Wrong file format. Review the file and run the import process again (uuid: <uuid key>).
EIM008	Invalid import file <filename>. Manifest.xml is missing.
EIM010	Invalid import file <filename>. The documents referred in the table of contents file do not agree with the contents of the file to be imported. Document(s): %s.
EIM012	Document contains a missing reference (<referenced_document_key>, uuid:<refering_document_key>).
EIM013	Dossier already exists in the database (uuid: <dossier_uuid>).
EIM014	The file you are importing is not supported by your Iuclid instance. You do not have the necessary legislation installed <legislation_name>
EIM014b	The file you are importing is not supported by your Iuclid instance. No legislation installed containing document definition <document_definition>

EIM016	Unsupported IUCLID5 version. Please use only files from the latest IUCLID5 version.
EIM019	No importable items could be found.
EIM020	You are trying to import an entity in a pool different from those that is currently shared. Entity: %s, %s, UUID: %s, Rejected Pool: %s (%s)
EIM021	Invalid import file <filename>. All documents in the file should be linked in a direct or indirect way. Unlinked document(s): <list_of_unlinked_document_keys>.
EIM022	Invalid import file<filename>: <detailed_error_message>
EIM025	Archive contains unreferenced attachments (that are not linked to any document). (attachment-uuid: <attachment_key>).
EIM026	Inconsistency detected between the actual <actual_md5> and the declared <declared_md5> md5 of the attachment (attachment-uuid: <attachment_key>)
EIM027	Inconsistency detected between the actual (%s) and the declared (%s) mime-type of the attachment (attachment-uuid: <attachment_key>)
EIM029	Invalid attachment path (<attachment_path>)
EIM030	You are importing a light dossier and the attachments that were omitted cannot be found in the target database. Please verify that the base dossier from which you created the light dossier was successfully submitted to this recipient in the past. Otherwise a standard dossier can be exported and submitted.
EIM031	Current user has no instance access to any of the associated attachments.
EIM032	Document has invalid type referenced from field (document: <document_key>, field: <field_path>, found: <actual_value>, expected: <expected_value>)
EIM050	Invalid import file <filename>. The attachments referred in the table of contents file do not agree with the contents of the file to be imported. Attachments(s): <list_of_attachment_keys>.
EIM051	Invalid import file<filename>. The linked document attachments (linked-doc) referred in the table of contents file do not agree with the contents of the file to be imported. Document(s): <list_of_document_keys>.
EIM052	Invalid import file <filename>. Missing base-document-uuid
EIM053	Invalid import file <filename>. DOSSIER document uuid does not match base-document-uuid (<base_document_uuid_from_manifest>)
EIM054	Invalid import file<filename>. No document uuid matches with base-document-uuid (<base_document_uuid_from_manifest>)
EIM055	Invalid import file <filename>. Attachment's container uuid (<uuid>) does not match with any contained documents uuid
EIM056	Invalid import file <filename>. Contained document's uuid (<contained_doc_uuid>) is different than document's id (<document_id>)

EIM057	Invalid import file <filename>. Document link with ref-uuid <ref_uuid>, is missing from contained documents
EIM058	Invalid import file <filename>. Document link with ref-uuid <ref_uuid> points to its container document
EIM059	Invalid import file <filename>. Document with id <document_id> is missing name element)
EIM060	Invalid import file <filename>. Attachment with id <attachment_id> is missing name element
EIM061	Invalid import file <filename>. Dossier UUID (snapshot UUID) is invalid: <uuid>
MR0048_TMI	Test material information field 'Link to a substance identity record' was switched to 'No' during detach, since the source identity could not be found (document affected: %s, unknown referenced document: %s).
CONTENT VALIDATON ERRORS	
duplicate.language.error	The multilingual content contains duplicated languages: [<list_of_languages>]
unknown.language.error	The multilingual content contains unknown languages: [<list_of_languages>]
max.chars.exceeded.error	The maximum characters allowed for this field (<max_number_of_characters>) is exceeded. Characters entered: {<number_of_characters_entered>}
invalid.picklist.value.error	Invalid list value. Please select one of the available options.
invalid.picklist.remarks.error	Supplementary remarks are not allowed without an accompanying phrase.
physical.range.value.error	Invalid data, please, check the highlighted data fields.
physical.range.value.warning	At least one of the values are not set.
physical.quantity.value.warning	At least one of the values is not set.
integer.error	The value of the field should be an integer
selfreference.error	Invalid document reference. Self-reference isn't allowed.
cas.number.error	CAS number is incorrect. Please fill in the appropriate format.
at.least.one.required	<list_of_field_paths> cannot all be empty. Please fill at least one.
pattern.of.nine.digits.error	Incorrect data. Value should be of the format xxx-xxx-xx-a, x=numeric, a=alphanumeric.
mfactor.warning	Incorrect data. Value must be between 1 - 1000000000 and of the format 1, 10, 100, 1000, ..., 1000000000
VR01	Value is a Year (1000-9999). *Used in Year fields validation*

VR02	Value must be higher than <lower_bound> and lower than <upper_bound> (included) *Used in Numeric field validation*
VR03	Value must be higher than <lower_bound> and lower than <upper_bound> (excluded) *Used in Numeric field validation*
VR07	A percentage field should be between 0 and 100 *Used in Range and Numeric field validation*
FV001	<field_path> cannot be empty. *Generic validation message for required values*

3. Changes to this document

Version	Changes
1.0	First version