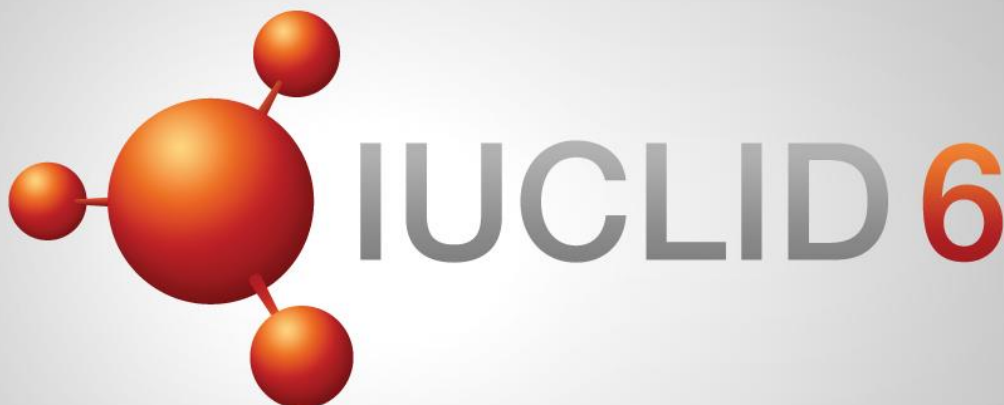


IUCLID 6

IUCLID Template Manager (ITEM)

User manual

30/06/2020



IUCLID 6 is developed by the European
Chemicals Agency in association with the OECD



Table of Contents

| | |
|---|-----------|
| 1. INTRODUCTION | 5 |
| 1.1 How to access ITEM? | 5 |
| 1.2 Purpose of this manual..... | 5 |
| 1.3 What is ITEM?..... | 5 |
| 1.4 Elements of the IUCLID format..... | 7 |
| 1.5 ITEM user interface | 8 |
| 1.5.1 Search | 8 |
| 1.5.2 Labels and languages..... | 9 |
| 1.5.3 Comments | 10 |
| 1.6 User management..... | 11 |
| 1.6.1 Role based user management | 12 |
| 1.6.2 Definition Provider-based user management | 12 |
| 2 USING ITEM FOR REGULATORY-SPECIFIC JURISDICTIONS..... | 14 |
| 2.1 What is customizable | 14 |
| 2.2 Re-use of existing Documents..... | 15 |
| 3 DATA MANAGEMENT IN ITEM..... | 16 |
| 3.1 ITEM elements hierarchy | 16 |
| 3.2 Version control system and approval mechanisms..... | 17 |
| 3.2.1 Version control: revisions, versions, editions in ITEM..... | 17 |
| 3.2.2 Versioning..... | 17 |
| 3.2.3 Naming conventions | 18 |
| 3.2.4 Approval | 20 |
| 3.2.5 Revisions | 22 |
| 3.3 Show usages functionality | 24 |
| 3.4 Replace all occurrences functionality | 24 |
| 3.5 Validation | 25 |
| 4 ITEM ELEMENTS AND THEIR COMMON FUNCTIONALITY | 26 |
| 4.1 Definition Providers | 26 |
| 4.2 Entities | 27 |

| | | |
|----------|--|------------|
| 4.3 | Documents | 28 |
| 4.4 | Blocks | 30 |
| 4.5 | Phrases and PhraseGroups | 33 |
| 4.5.1 | Features of Phrases..... | 33 |
| 4.6 | Text Templates | 34 |
| 4.7 | Available functionality for ITEM elements | 35 |
| 4.7.1 | Create..... | 35 |
| 4.7.2 | Update | 39 |
| 4.7.3 | Delete | 46 |
| 4.7.4 | Bulk upload of Phrases to a PhraseGroup (and bulk Phrases creation) | 51 |
| 4.7.5 | Export | 53 |
| 4.8 | Components of IUCLID Documents and Blocks | 55 |
| 4.8.1 | Available components' operations..... | 59 |
| 4.8.2 | Available operations during edit of Fields, Repeatable set/lists and Headers | 61 |
| 4.8.3 | Basic/detail attribute..... | 67 |
| 4.8.4 | Confidential attribute | 68 |
| 5 | MIGRATION RULES | 70 |
| 5.1.1 | Forward and backward migration rules | 70 |
| 5.1.2 | Migration Rule types | 71 |
| 5.1.3 | Encoding different types of migration rules | 73 |
| 5.1.4 | Working with Migration Rules..... | 76 |
| 5.1.5 | Create a Migration Rule Instance..... | 82 |
| 5.1.6 | Migration Rule including a Document deletion | 88 |
| 5.1.7 | Migration Rule including a Field deletion..... | 89 |
| 5.1.8 | Create a symmetrical Migration Rule Instance | 91 |
| 5.1.9 | Update a Migration Rule Instance | 93 |
| 5.1.10 | Delete a Migration Rule Instance | 94 |
| 5.1.11 | Migration of fields using PhraseGroups..... | 95 |
| 5.1.12 | Automatically create Migration rules between GHS documents | 101 |
| 6 | DYNAMIC CONTENT RULES..... | 104 |
| 6.1 | Creation of Dynamic Content Rule | 104 |
| 6.2 | Representation in IUCLID..... | 108 |
| 6.3 | Update/deletion of Dynamic Content Rule..... | 109 |

| | | |
|-----------|--|------------|
| 6.4 | Export of Dynamic Content Rules..... | 110 |
| 6.5 | Display of Dynamic Content Rules in ITEM Definitions..... | 111 |
| 7 | REVISION / ELEMENT COMPARISON | 112 |
| 8 | SUBMISSION TYPES | 114 |
| 8.1 | Default Submission Types..... | 116 |
| 8.2 | Create a Submission Type | 117 |
| 8.3 | Update a Submission Type properties..... | 119 |
| 8.4 | Advanced options..... | 120 |
| 8.4.1 | Clone a Submission Type | 120 |
| 8.4.2 | Changing section number for A Document..... | 121 |
| 9 | APPLICATION TAGS..... | 122 |
| 9.1 | Introduction | 122 |
| 9.2 | Advanced functions | 122 |
| 9.3 | Create an Application Tag | 124 |
| 10 | FIELD TAGS | 127 |
| 10.1 | Introduction | 127 |
| 10.2 | Create a Field Tag | 129 |
| 10.3 | Update a Field Tag..... | 129 |
| 10.4 | Delete a Field Tag | 130 |
| 10.5 | Available operations of Field Tags..... | 131 |
| 11 | TEST DATA..... | 135 |
| 11.1 | Create a Test Dataset | 135 |
| | APPENDIX 1. THE ITEM COMPARISON REPORT. GUIDANCE..... | 137 |
| 1 | THE ITEM COMPARISON REPORT | 137 |
| 2 | GUIDANCE..... | 138 |
| 2.1 | Added / Deleted Definition Providers..... | 138 |
| 2.2 | Added / Deleted Submission Tree Nodes..... | 138 |
| 2.3 | Added / Deleted Submission Types..... | 139 |
| 2.4 | Added / Deleted Documents..... | 139 |
| 2.5 | Added / Deleted Common Blocks..... | 140 |
| 2.6 | Added / Deleted PhraseGroups..... | 140 |
| 2.7 | Changes to Submission Tree Nodes and Names | 141 |

2.8 Changes to Document Definitions 141

2.8.1 Fields 142

2.8.2 PhraseGroups..... 143

2.8.3 Common blocks 143

2.9 Brief Glossary..... 144

1. INTRODUCTION

1.1 How to access ITEM?

Contact the IUCLID team's mailbox iuclid6@echa.europa.eu to request access to the production environment of ITEM and/or the test environment of ITEM.

Before starting to use ITEM to define your IUCLID format it is recommended that you:

- Read this manual;
- Try using ITEM's test environment;
- Create Specifications which map your regulatory requirements to the various elements in ITEM to build the IUCLID format.

These steps will help you to analyse and plan what you want to include in the IUCLID format as well as help the person(s) implementing your IUCLID format using the ITEM software.

1.2 Purpose of this manual

The purpose of this manual is to provide a description of the key features and capabilities of the ITEM environment and to provide guidelines on how to use ITEM in the context of its use by multiple regulations.

1.3 What is ITEM?

ITEM is a user-friendly web application used to define and update the IUCLID format and to manage the migration of IUCLID data between different versions of the format. The development of the IUCLID format involves multiple different stakeholders and partners and has the goal of maximising the harmonisation of information collected on chemicals.

ITEM provides a collaborative space to design, edit and view templates (Documents in IUCLID and ITEM terminology) designed to store different information on chemicals. The IUCLID format is primarily based around Documents (Definitions), such as Endpoint Study Records and Endpoint Summaries. All Document definitions are grouped by three levels of so-called 'Definition Providers' or what is referred to in OECD documentation as 'Provider Definitions'.

First Definition Provider level – OECD Harmonised Templates

The first Definition Provider level in the diagram below contains all the OECD Harmonised Templates (OHTs). These Documents can be re-used by any regulatory-specific Definition Provider (third Definition Provider level), **but are only updated** in ITEM when changes to these Documents are agreed at the level of the OECD.

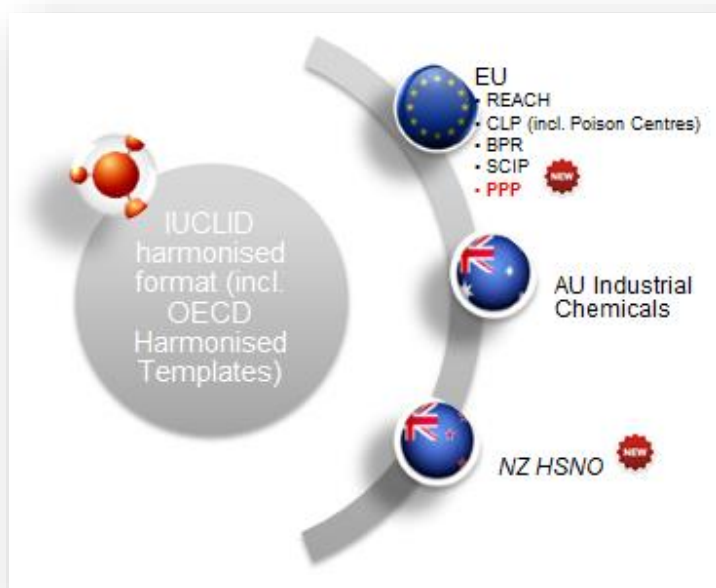
Second Definition Provider level – IUCLID CORE

The second Definition Provider level contains Documents which are common to two or more third Definition Provider level Documents. These Documents **are only updated** when there is an agreement between the joint-users/owners of these Documents via the OECD IUCLID Users groups.

Third Definition Provider level – Regulatory specific (REACH, PPP, BPR, etc.)

The third level in the diagram below contains Documents which are regulatory-specific, e.g. for the European Union, Canada, Australia, New Zealand. This level can be expanded to include other regulatory jurisdictions. When creating a regulatory-specific Definition Provider, it is important to get familiar with the general principles of Document customisation in ITEM described in this manual.

IUCLID Definition Providers



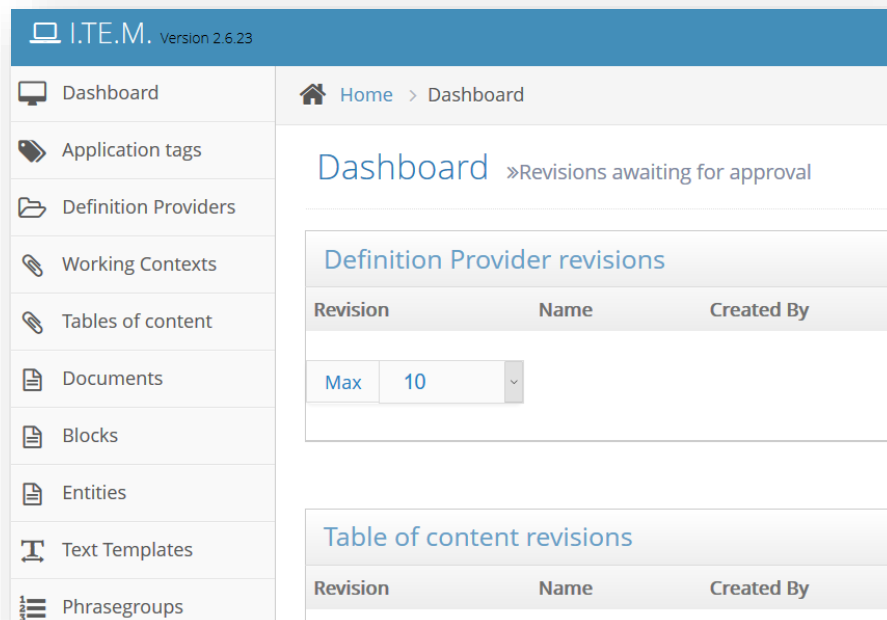
1.4 Elements of the IUCLID format

ITEM provides the following elements or building blocks to structure and define chemical and administrative Documents which are used for entering data in IUCLID:

- **Phrases** are the options that can be selected in IUCLID picklists (PhraseGroups in ITEM terminology), e.g. 'experimental study', 'ERC1', 'LD50';
- **PhraseGroups** contain Phrases and are displayed as picklists in IUCLID. ITEM users can re-use either existing Phrases or create new Phrases when creating or updating a PhraseGroup;
- **Text Templates** are IUCLID text fields which contain a customised and pre-defined Text Template to guide users on what information is expected in the field. More than one Text Template can be added to a Text Template field;
- **Entities** are re-usable sets of fields, such as reference substances, legal entities, test materials, etc., which are stored in an inventory of entities in IUCLID. Entities are structured like IUCLID Documents, can contain all the elements of Documents, and can themselves include links to other entities;
- **Blocks** are re-usable sets of fields which can be reused in multiple Documents. For example, the Administrative data record Block in ITEM contains a set of standardised fields re-used in many OHTs;
- **Documents** represent a collection of IUCLID fields where data can be entered and stored inside the IUCLID database. Each field has several components. The primary component is the datatype, which governs what type of IUCLID fields it is. Based on the datatype, Documents can re-use Entities, Text Templates and PhraseGroups (with the Phrases). Documents can also re-use Blocks;
- **Tables of content (ToC)** are Definition Provider-specific and contain IUCLID section trees which organise the information requirements for that Definition Provider. ToCs also provide entry points to the Documents IUCLID users can use to fulfil the information requirements of a particular Definition Provider;
- **Definition Providers** are the highest part of the IUCLID hierarchy and act as a "provider" to all the above building blocks. Every building block, whether it is a Phrase, Block, Entity, etc., will have a Definition Provider.

1.5 ITEM user interface

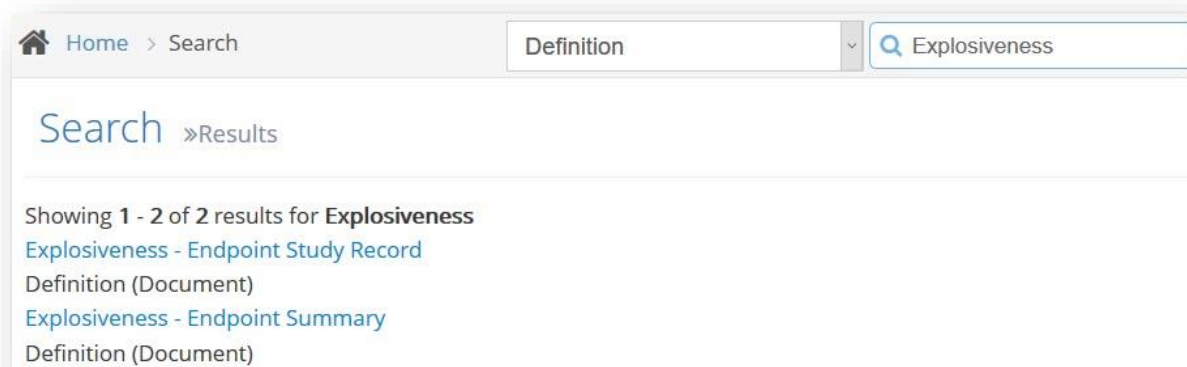
Under the left-hand side menu, all the elements of ITEM can be accessed for reviewing or editing purposes.



1.5.1 Search

On the upper right corner of the ITEM user interface, there is the search box which allows to quickly lookup different elements in ITEM by **Element label** or **Element path**. Users can search using specific search criteria, e.g. Definition, Phrase, PhraseGroup, Element or Definition, Text Template, Element label, Element path, by utilising the dropdown menu next to the search box.

For instance, to quickly find a specific Document in ITEM, e.g. Explosiveness Endpoint Study Record or Endpoint Summary, select “Definition” in the dropdown menu and enter



“Explosiveness” in the Search field (see the image below). Search by keywords is also possible. For example, if a user wants to quickly view the Toxicity to birds Endpoint Study Record, it is enough to select “Definition” and type “birds” in the search box.

The same Explosiveness Endpoint Study Record can be found by its path. It is enough to paste the following path *ENDPOINT_STUDY_RECORD.Explosiveness* in the search box. If a user wants to locate a specific field within the Explosiveness Definition, e.g. Qualifier, the following should be pasted in the search box:

ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods.Guideline.Qualifier

In the case above, the search results will list all the revisions of Explosiveness Definition. If a user simply searches for “Qualifier”, ITEM may list all the Documents/Entities/PhraseGroups that have this string in the label or path. Hence, users should use different search techniques based on the search purpose.

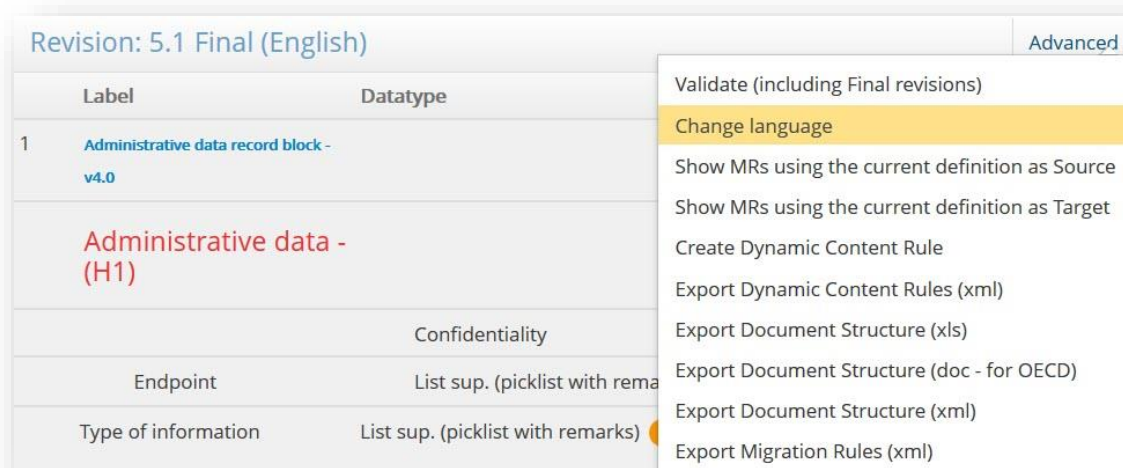
Note that, when viewing a Definition, a field can be quickly located by its label with the “Ctrl +F” functionality of a browser.

1.5.2 Labels and languages

Almost every component in a Definition (Document, Block, and Entity) has a label that appears on the left side of that component. ITEM provides the capability to define the labels for all components in various languages without affecting the Definition’s structure.

In the Definition’s design screen, the user can define a different label for each language installed on the system. This label is bound to a specific component in a specific Definition’s version. This means that each Definition’s version may have a different label in various versions.

A Definition revision is displayed in the language defined by the user. The language of a viewed Definition appears at the top, next to the Definition's version. English is the default language of ITEM. The user can change the language by selecting the "Change language" option at the top of the revision under the "Advanced" menu:

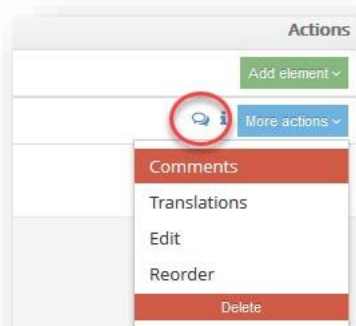


The language selection feature does not affect Definition's revision in any way. It only allows the user to check how the specific Definition revision will appear in IUCLID for a specific language. In case a label is missing for a particular language, the default (English) should be used. If a label is missing for the default language as well, then the label should appear blank.

The user can, for each component used in a Definition, to have a translation table where he can manage all translations for the specific component.

1.5.3 Comments

Every component (Field, Header, Repeatable list/set, etc.) of a Definition (Document, Entity, Block) can accept comments. This feature allows users to collaborate while working on the same definition. A Comment is bound to a specific component and is transferred between Definition versions:



A comment, when entered, cannot be edited or exported. A comment can only be deleted by the creator of that comment. The author of the comment, as well as date and time, are also visible with the comment itself.

Comments can be managed from the “More actions” menu next to the component of a Document. A quick link (comment icon) also exists next to the “More actions” menu.

1.6 User management

ITEM's user management system is based on the role of the user and the Definition Provider(s) for which the user has access to. Users with “Super Administrator” rights can give out access rights to all the other user roles. Each user profile consists of the following information:

| Property | Description |
|--|--|
| Last name | The last name of the user. It is a free-text field with a size of 255 characters and it is mandatory. |
| First name | The first name of the user. It is a free-text field with a size of 255 characters and it is mandatory. |
| Username | The username of the user that will be used for login. It is a free-text field with a size of 255 characters and it is mandatory. |
| Password | The password of the user that will be used to login. It is a free-text field with a size of 255 characters and it is mandatory. |
| E-mail | The e-mail of the user. It is a free-text field with a size of 255 characters and it is not mandatory. At this e-mail address, the user can receive various notifications from the application. |
| User role | The user role that the specific user has. It is a dropdown field which facilitates the assignment of one or more of the predefined roles. At least one role must be selected to be able to save or update the given user's profile. All new users will be assigned the role “Read-only”, by default. |
| Accessible Definition Providers | This field indicates which Definition Provider the user can access. This effectively defines the subset of the data which the user can edit provided the given user role. |
| Enabled | This field indicates if the respective user has an enabled or disabled account. If the account is disabled then the user will not be able to login into the application. |
| Account expired | This field indicates if the respective user's account is expired. If the account is expired, then the user will not be able to login into the application. |

| | |
|-------------------------|--|
| Account locked | This field indicates if the respective user's account is locked. If the account is locked, then the user will not be able to login into the application. |
| Password expired | This field indicates if the respective user's password is expired. If the password is expired, then the user will not be able to login into the application. |

1.6.1 Role based user management

Currently, one out of four predefined roles can be assigned to a user. These roles are:

- **“Read-only”**: a default role assigned to each newly created user. Users with this role can read/view all data of ITEM but are not allowed to modify any of the ITEM elements;
- **“Simple”**: users with this role can create new data but also can modify the content of Documents which are in the draft mode, within the Definition Provider(s) the user is assigned to. Users assigned to this role cannot delete data in ITEM;
- **“Advanced”**: this role enables users to delete data from the application. Moreover, it allows to perform some specific operations such as delete final versions, finalise definition providers, reassign elements for approval (other than their own), remove Phrases from PhraseGroups' (instead of making them obsolete);
- **“Super administrator”**: users with this role can manage other users' access rights and assign roles to them in addition to performing tasks of an “Advanced user”. They have access to all resources, with no regard to the resource's Definition Provider. They can create new Definition Providers, manage Application Tags, Migration Rules and 'orphan' elements (those without a Definition Provider). Furthermore, they can modify the Test Data generation configuration.

1.6.2 Definition Provider-based user management

Definition Providers are further elaborated below in Chapter 4.1 Definition Provider. Definition Providers-based user management is crucial for the security of ITEM. Every user with a different role than “Read-only” has to be assigned at least one Definition Provider by a “Super administrator” when a new user is created. In practice, this means that a user with any kind of role that permits editing is only able to exercise those rights under a provider Definition Provider assigned to that user. To every other Definition Provider, the user only has “Read-only” rights.

For users with the role “Read-only”, it is unnecessary to apply the rule because they have only “Read-only” rights which prevent them from editing data.

A user can be assigned to more than one Definition Provider. For every Definition Provider a user has an access to, the extent to which they can work on that Definition Provider is governed by the role the user has been assigned to. When a user with a role capable of editing has access to a Definition Provider, such as REACH, but not to another Definition Provider, such as OECD, and a Document is shared by both Definition Providers, then the user cannot edit the Document.

Illustration of User management (assigning Definition Providers to User) in ITEM.

| | | |
|-----------------|-------------------------|-------------------------------|
| Migration Rules | User role | Advanced |
| | Accessible Legislations | AU Industrial Chemicals |
| | | BPR |
| | | z_old_EU BPR submission types |
| | Enabled | <input type="checkbox"/> |
| MR Instances | Account Expired | <input type="checkbox"/> |
| PG Mappings | | |
| Test Data | | |
| Users | | |

2 USING ITEM FOR REGULATORY-SPECIFIC JURISDICTIONS

2.1 What is customizable

1. Definition Providers

A Definition Provider is created in ITEM as the starting point for a regulatory jurisdiction that would like to use the IUCLID format to manage data on chemicals. A Definition Provider is specific to the regulatory jurisdiction which creates it.

2. Tables of content

- The users can create their own section/sub-section names in the ToC;
- The users can insert existing Documents in these sections/subsections and change the name of the Document which is displayed in the ToC view;
- The users can set each Document's status to "required"/"optional (not selected by default)"/"optional (selected by default)";
- The user can modify the ordering of the sections/sub-sections and their associated Documents in the ToC.

3. Dossier headers

Dossier headers are stored as Documents in ITEM. Dossier headers appear in IUCLID when a dossier (a read-only snapshot of the dataset) is created from an editable dataset. Dossier headers usually store and indicate:

- What regulatory obligation is the dossier satisfying, e.g. a company can create and send to ECHA a 1-10 tonnes registration dossier to meet the requirements of Annex VII of the REACH regulation;
- Information about the particular submission which is being sent to a regulatory authority, for example, and, if known: the submission number, the registration number, the creation date of the dossier, why the dossier has been created, etc.

Because each Dossier header contains fields specific to a particular regulation and Definition Provider type, the user can create own regulatory-specific Dossier headers in ITEM which, when a registrant creates a dossier, provides the regulatory authority with the submission information

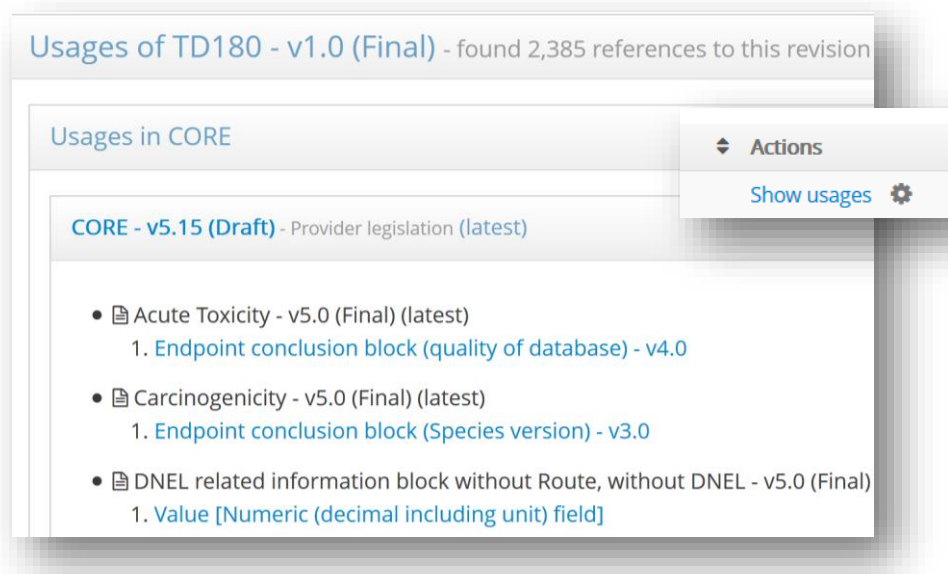
they require from the registrant. The information contained in a dossier header is stored with the dataset information and can be viewed by the regulatory authority receiving the dossier.

2.2 Re-use of existing Documents

Important! Re-use existing Documents in a regulatory-specific Definition Provider/Table of content to ensure and maximise the harmonisation of data on chemicals. By re-using existing Documents, such as the OECD Harmonised Templates for reporting study summaries, the data on chemicals can be shared, compared and analysed between different regulatory jurisdictions.

It is important to analyse the update and, if possible, apply it across all the relevant instances. For example, if a PhraseGroup is used across a few Documents of different Definition Providers and is planned to be updated, it is essential to check if all the Documents can have the same update so the creation of a new PhraseGroup can be avoided. This way data harmonisation will be achieved. The same logic goes for all the other ITEM elements.

For instance, the PhraseGroup TD180 shown below is used in multiple CORE Documents and the planned changes may or may not be relevant for all of these Documents:



For more information on how the management of the IUCLID format works, please consult the OECD IUCLID customisation Document (OECD (2019), Customisation Opportunities of IUCLID for the Management of Chemical Data, OECD Series on Testing and Assessment, No. 297, OECD Publishing, Paris). If you would like to know more about the management of the format, please contact the IUCLID team who can advise and support in this matter.

Contact details: iuclid6@echa.europa.eu

3 DATA MANAGEMENT IN ITEM

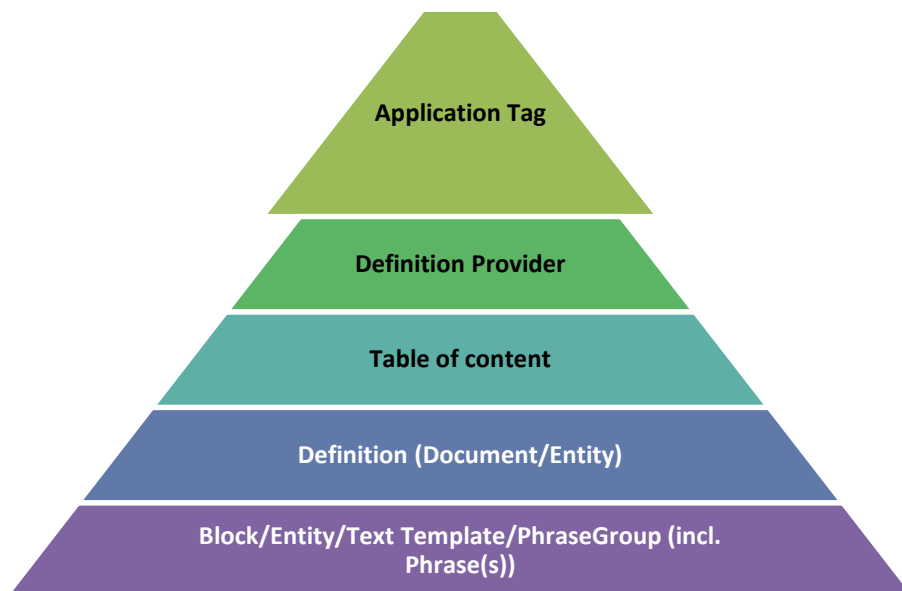
3.1 ITEM elements hierarchy

All elements in ITEM are structured in hierarchical order. The highest element is the Application Tag which contains Definition Providers. It represents a container of all the elements (Document definitions, PhraseGroups, Phrases etc.) updated and finalized before IUCLID release.

Please note that even though the Application Tag is the highest element of ITEM hierarchy, the Definition Provider is the highest element in the IUCLID hierarchy and all updates should start with a new revision of a Definition Provider. When all updates are performed and finalised, a new Application Tag is created to include all the updates planned for IUCLID release. The final Application Tag for a major IUCLID release is standardised and is easily found, and will read for example “IUCLID6_5”, “IUCLID6_4” etc., depending on the IUCLID version number.

Note: all elements of a Definition Provider can be updated only if the Definition Provider is in a draft revision and when Definition Provider is finalised and all the elements are finalised too.

ITEM hierarchy



3.2 Version control system and approval mechanisms

3.2.1 Version control: revisions, versions, editions in ITEM

Every element in ITEM must have a Definition Provider. The update process in ITEM starts with the creation of a new version (major changes) or edition (minor changes) of a Definition Provider. An update of a Definition Provider will impact its Definitions.


3.2.2 Versioning

A key capability of the ITEM tool is the version control system. This feature provides the ability to have multiple revisions of the various elements of ITEM (Definition Provider, Table of content, Document, Text Template, PhraseGroup, Phrase, Entity, and Block) and keep track of the changes applied in different versions.

ITEM decides the type of the new Document revision. The decision is based on the following logic: if the versions of the Definition Provider of the latest revision of the Document span two major versions, then a Version is created; otherwise an Edition is created. This logic applies to other versionable elements in ITEM, e.g. Tables of content, PhraseGroups, Phrases, and Text Templates.

There are two types of revisions:

- Major versions (Versions);
- Minor versions (Editions).



| | |
|-----------|-------------------------|
| 2.1 Final | Edition of version v2.0 |
| 2.0 Final | Version v2.0 |
| 1.0 Final | Version v1.0 |

The main concept of Versions is that it corresponds to a major update in the IUCLID format. For example, a change to the data type of a field in a Document, a new Document has been created for a Definition Provider or a change to the nodes of the Table of content. Editions are used to indicate smaller changes in a Document such as a change to the help text of a field, a change to the field label, or a change to the text for a Text Template.

At the level of the Definition Provider, you can explicitly choose whether you want a new Version or a new Edition of the Definition Provider. This is important, because based on the choice here, any element of the Definition Provider (Documents, Text Templates, PhraseGroups, Phrases, Entity, Blocks) which is thereafter updated, will be either a new Version or a new Edition according to the choice made in the Definition Provider. When making major changes to an

element of a Definition Provider, you should check whether the latest version of the Definition Provider is a new Edition or Version so that you know what type of revision will be applied to the element.

Process in ITEM:

1. A new version/edition of a Definition Provider is created as a draft;
2. New revisions of elements (for example, Tables of content, Documents or blocks) which require an update are created and the planned updates to relevant elements are done. Note that all the elements remain in the draft mode;
3. Definition Provider is finalised with a new version/edition, all relevant elements are automatically finalised with new versions/editions;
4. Note that Documents which were not updated will remain of the same version as before.
5. A new Application Tag is created containing finalised Definition Providers;
6. Updates are included into new IUCLID version.

3.2.3 Naming conventions

When creating a new data element in ITEM (Definition Provider, Table of content, Block, Entity, Document Text Template, PhraseGroup), you always need to provide a technical identifier, a readable name or description, and a Definition Provider.

An identifier can have:

- Letters;
- Numbers;
- Underscores “_”;
- Dashes “-”.

An identifier cannot:

- Have spaces;
- Start with a number.

Here are a few examples of a correct and an incorrect identifier:

| Correct | Incorrect |
|------------------|-----------|
| Class_R-P | Class R P |
| Test5Min | 5MinTest |

There are two important parts of the identifier naming convention for **PhraseGroups** and **Documents**, outlined below.

When providing an identifier for a **PhraseGroup specifically**, this must end with a dash '-', for example. "PG6-", "GHS-", or "PCN-" etc.

Below is an example of a new PhraseGroup. Notice the identifier prefix ends in "-", and has no spaces. The description is an understandable name. ITEM automatically adds a sequential numbering system to this identifier after the "-", so there is no need in adding numbers to PhraseGroup identifier unless it is a part of a common name (e.g. IUCLID 6 all relevant PGs have PG6- identifier).

Naming of a PhraseGroup

The screenshot displays the 'Phrasegroup' creation form in IUCLID 6. The form includes the following fields:

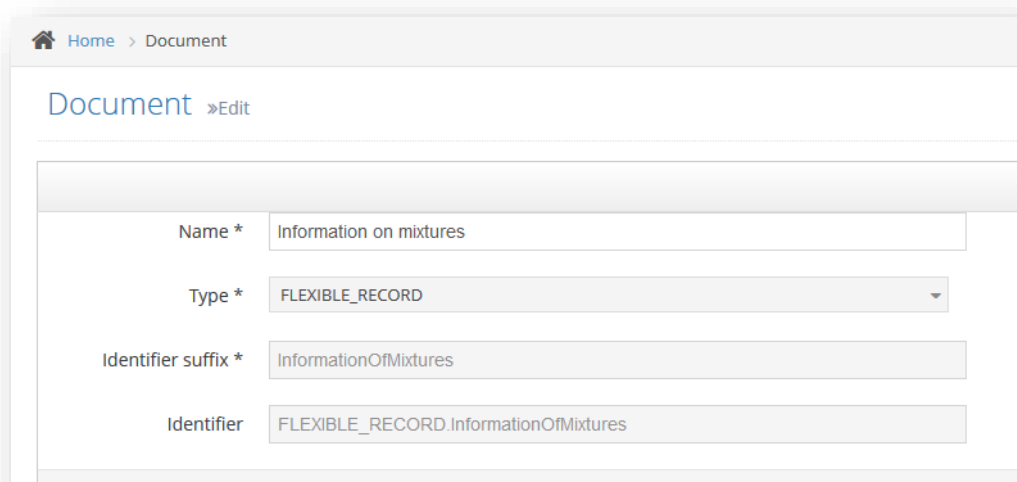
- Identifier prefix ***: HSNONZ-
- Description**: Classification for New Zealand
- Provider Legislation ***: NZ_HSNO - v1.0

A modal window on the right side of the form shows the following information:

- Breadcrumb: Home > Phrasegroup > HSNONZ-60616
- Identifier: HSNONZ-60616 » List
- Message: ✓ Phrasegroup HSNONZ-60616 created

When providing an identifier for a **Document specifically**, the naming convention is the same as for all other data elements, but note that the identifier is automatically prefixed by ITEM with the 'type' of Document selected. The component identifier also has 80 characters limit. See the example below:

Naming of a Document



The screenshot shows a web interface for naming a document. At the top, there is a breadcrumb navigation: Home > Document. Below this, the title 'Document' is followed by an '»Edit' link. The main form contains four fields:

| | |
|---------------------|---------------------------------------|
| Name * | Information on mixtures |
| Type * | FLEXIBLE_RECORD |
| Identifier suffix * | InformationOfMixtures |
| Identifier | FLEXIBLE_RECORD.InformationOfMixtures |

3.2.4 Approval

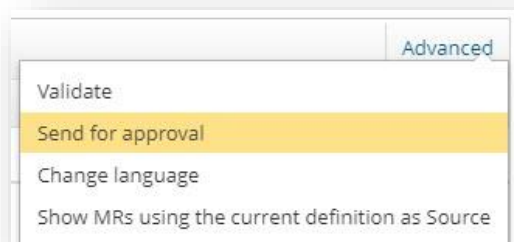
Every element of ITEM that supports versioning (except for Phrases) also uses the ITEM approval system. The approval system allows you to send any of the ITEM elements used in creating the IUCLID format, e.g. Documents, Entities, etc., to another ITEM user for approval of the work you have done. For example, if I am building a new Document to be included in a Canadian Definition Provider, I can send the Document to a colleague to check that what I have added is indeed correct and according to specifications.

You can only send for approval those elements which are in “Draft” status, meaning that they are in edit-mode. When sending an element for approval, element’s version status changes to “Pending”. The approver can see the element awaiting approval in the dashboard of ITEM and can either choose to approve or reject. When a version is “Approved” its status changes to “Approved” and the element cannot be edited further unless it is re-opened. When a version is “Rejected” its status changes back to “Draft” and can be edited by all users that have access to it.

Note: To be able to “Finalise” a version the user has to have either “Advanced” or “Super Administrator” role as the element is finalised when the overarching Definition Provider is finalised, which is an action only the “Advanced” or “Super Administrator” can perform.

Approval steps are the following:

1. A user sends a “Draft” version to an approving user;



2. “Draft” status changes to “Pending” status;
3. Approving user sees a task in a relevant section within the Dashboard;
4. Approving user rejects or approves the revision: both options are available at the bottom of a definition;



5. If approved, the revision needs to be finalised by the sending user for the status to change to “Final”. If rejected, the status is reverted to “Draft” and the process has to be repeated after necessary adjustments;
6. Updates included into new IUCLID version.

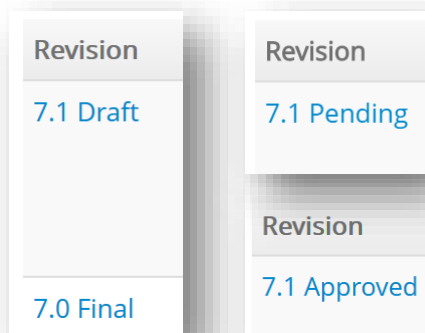
Documents, Blocks, PhraseGroups, Text Templates, and Tables of content get finalised once the relevant Definition Provider is finalised.

Another simple yet critical rule, bound to the approval mechanism, is that during the approval of an Entity’s version, the system validates that all its children (i.e. all Entities contained within the Entity that is being approved) do not contain more than one revisions of the same Entity.

3.2.5 Revisions

There are four types of statuses mentioned above:

- Draft;
- Pending;
- Approved;
- Final.



3.2.5.1 Draft

By default when a new Definition revision is created it receives Draft status. Draft status means that every user that has access to a specific Definition, can edit it. When Definition editing is completed, the user should be enabled to select another user to approve it. At this stage, the status of the Definition changes to Pending.

When a new Definition revision is created, all the Definition's components are cloned from the previous Final revision, if any. A Definition can only have only one Draft revision at any time.

3.2.5.2 Pending

When at Pending state, only the Approver can re-assign, update, reject or approve the Definition. All other users that had update/delete access on this Definition cannot edit the Definition, as now they have read-only access.

In case the Approver is not available when needed, the users that belong to the Administrator role are also able to re-assign the pending Document to another user.

The re-assign option is visible only when the Document is in pending state and the viewer of the Document is the current approver or a user that belongs to the Super Administrator role.

As mentioned above, the approver user is able to update the Definition. If the approver user decides to reject the specific Definition revision, the status of the Definition changes back to Draft. If the user decides to approve the specific Definition revision, the status of the Definition revision changes to Approved. A Definition can have only one Pending revision at a time.

3.2.5.3 *Approved*

When at Approved stage the Definition can be referenced by other Definitions in Draft or Pending stages.

The Definition in the Approved stage can be finalised by finalising Definition Provider, which can be done by a user with the role “Advanced” or “Super Administrator”.

Note: Finalisation rights are only given to “Advanced” and “Super Administrator” roles.

A Definition can have only one Approved revision at a time.

In case the Definition has not been finalised, a new version cannot be created but the approved version can be re-opened for editing.

3.2.5.4 *Final*

This status is the final status of a Definition revision. A Definition marked as Final cannot be updated or deleted by anyone (it can be deleted when not referenced).

A Definition can have multiple Final revisions.

A Definition can only become final when finalised by a user with role “Advanced” or “Super Administrator”.

A Definition automatically becomes Final when its provider Definition Provider is finalised.

3.2.5.5 *Constraints*

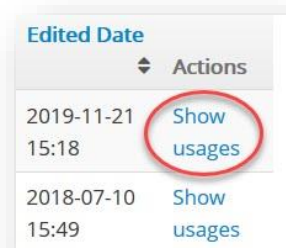
During the pending and approving process, the following constraints are checked:

- Component types should not be empty in case of Field elements;
- Picklists should not be empty except for picklists inside blocks which can be optional;
- Text Templates should not be empty.

All versionable entities included inside the selected revision should be of the same revision.

3.3 Show usages functionality

As mentioned in section 2.2, it is crucial to maintain data harmonisation in ITEM and re-use the existing data whenever possible. The “Show usages” feature always displays where the latest revision of an Element (e.g. Definition Provider, Document, PhraseGroup) is used. It is accessible by selecting the “Show usages” element:



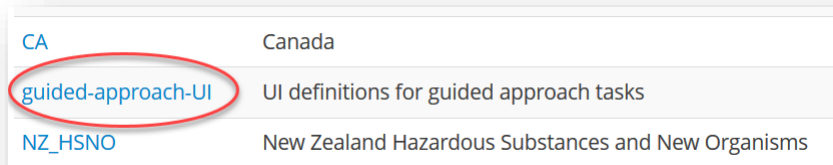
3.4 Replace all occurrences functionality

Every ITEM element (except Phrases) can be replaced at once in all its locations through ‘Replace all occurrences’ feature. When replacing all occurrences, the elements (e.g. Documents) in the final state will get a new revision assigned and a draft status.

For example, a new revision of a picklist was created and it is used in few Definitions. To maintain data harmonization in ITEM, the picklist may need to be replaced in all locations where it is used. To do so click on “Show usages” of the latest final revision of the picklist which will display all locations of the picklist for each Definition Provider. Then click on ‘Replace all occurrences’ and select a newly created draft of the picklist. After replacing, all Definitions (e.g. Documents, Blocks) which have the picklist will be updated.

Note that in case an element is used in other Definition Providers, before replacing it, should be finalised first (by finalising Definition Provider of that element).

Important note! No changes should be done in the UI definitions. They are not part of the IUCLID format and their update cycle is different. This means the element even it is used in **guided-approach-UI** Definition Provider should not be replaced there (see below).



| | |
|--------------------|--|
| CA | Canada |
| guided-approach-UI | UI definitions for guided approach tasks |
| NZ_HSNO | New Zealand Hazardous Substances and New Organisms |

3.5 Validation

ITEM has various validations defined in order to assist in creating valid structures and ensure data consistency. The performance of Validation at a certain level means that all Validation Rules that belong to elements are executed. Thus, for instance, successful Validation at Definition Provider level means that:

- All Documents included at the Definition Provider are checked for validation and include valid Fields and Picklists, and;
- All rules at Definition Provider level are also checked (e.g. there are no two versions of the same Block used by different Documents provided by the same Definition Provider).

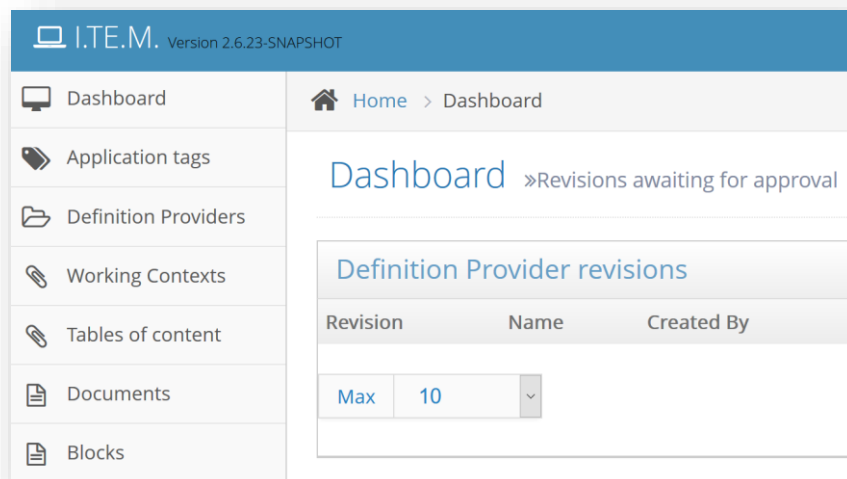
There are some automatic validation rules triggered in ITEM during e.g. finalization of a draft Definition Provider or a Document, creation/update of a Migration Rule, addition of an element in a Definition Provider, export of a draft Definition Provider etc. Validation is happening also for Phrases, e.g. identical Phrases are not allowed unless 'open' status is different.

Validation functionality on demand is available at an ITEM element level through "Advanced" options.

4 ITEM ELEMENTS AND THEIR COMMON FUNCTIONALITY

4.1 Definition Providers

Definition Providers defined in ITEM are at the top of the data pyramid in IUCLID.



In ITEM a regulation is identified only by a name (e.g. REACH, Biocides, etc.). By default, ITEM does not contain any predefined Definition Providers and a user can define and customise their Definition Providers. Every Definition Provider in ITEM is under the version control system meaning that new versions and editions can be created on top of previous versions.

A Definition Provider contains all the following elements: Tables of content, Documents (which contain IUCLID fields), Blocks, PhraseGroups (which contain Phrases) and Text Templates. If the user has an editing role for the Definition Provider, they can add and remove these elements from the Definition Provider.

During the creation of a Definition Provider, ITEM does not require users to define any of the elements. These relationships may be defined and modified once the Definition Provider is created. Besides, when creating a new revision of a Definition Provider, users have an option to create an empty revision. If the option is selected, no Documents, Blocks, PhraseGroups, Tables of content, Text Templates from a previous revision are copied into the new revision. Definition Providers are identified by a unique identifier and a name.

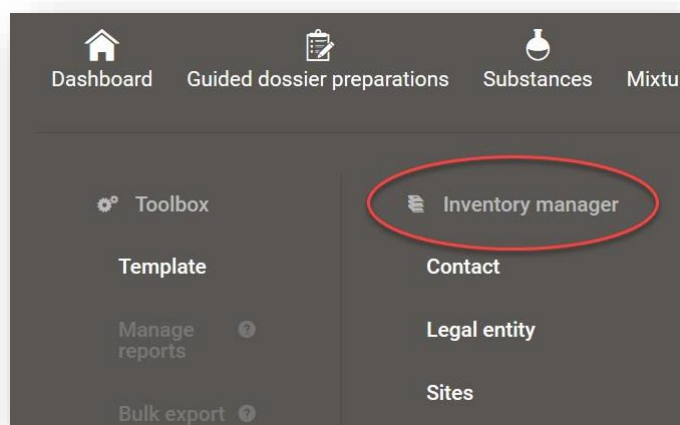
Note: Because the Definition Providers are the top level of data organisation in ITEM and IUCLID, they have a role downwards in the hierarchy. No other definition can be created without a Definition Provider. This means that all the elements, whenever a new definition is created, have to be assigned to a Definition Provider.

4.2 Entities

In IUCLID, an Entity is usually an inventory of information which can be linked to and re-used by any Document. For example, all Endpoint study records link to a Test material Entity, which is a standardised set of fields for entering data on the test material and is re-used amongst the relevant endpoints. Here is the full list of IUCLID Entities:

- Legal Entities;
- Legal Entity sites;
- Reference substances;
- Literature references;
- Contacts;
- [Chemical] Inventory;
- Test materials.

Inventory of entities in IUCLID



In ITEM, users can design and create Entities in the same way as Documents. An Entity can only be assigned to the CORE Definition Provider.

In ITEM, other Entities exist as well:

- Annotation;
- Category;

- Data protection;
- Mixture;
- Substance.

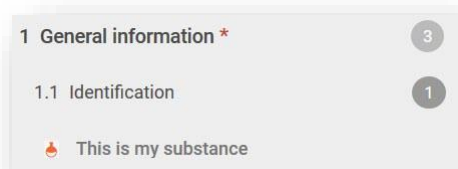
A Table of content should always have an Entity, for example, a Substance or Mixture. If there is no Entity in the Table of content, a dummy Entity should be created. The reason for that is that the basic information of the Entity is a part of the Dataset (IUCLID Section 1.1 Identification).

4.3 Documents

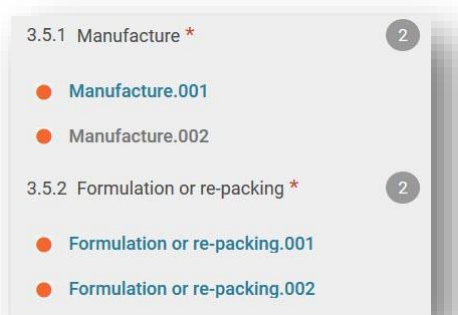
A dataset is considered to be a group of Documents that belong to an Entity. For example, all sections that are linked to a Substance Entity are called Substance Dataset. These Documents have no difference in the design functionality from Entities. Dataset Documents are also linked to different Tables of content and Definition Providers.

There are also specific types of Documents that ITEM supports and are the following:

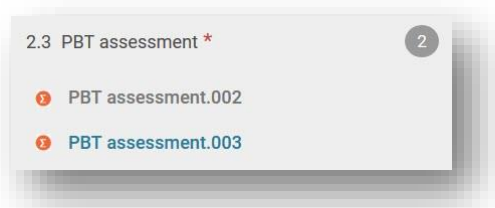
- Fixed records: only one record can be created. An example of a fixed record is under section 1.1 (of a Substance dataset) in IUCLID:



- Flexible records: more than one record can be created. An example of a flexible record is the Documents within Sections 3.5.1 and 3.5.2:



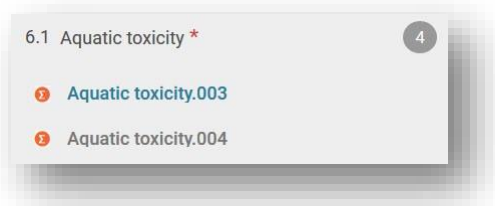
- Flexible summaries: more than one summary can be created under each endpoint. Example of a flexible summary in IUCLID is PBT assessment summary:



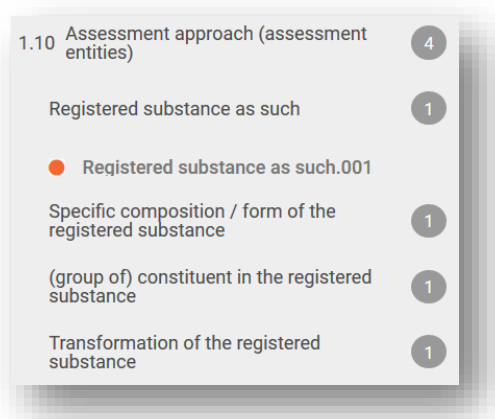
- Endpoint records: flexible records that can be created under every endpoint e.g. 6.1.1:



- Endpoint summaries: flexible summaries that can be created under every endpoint e.g. 6.1:

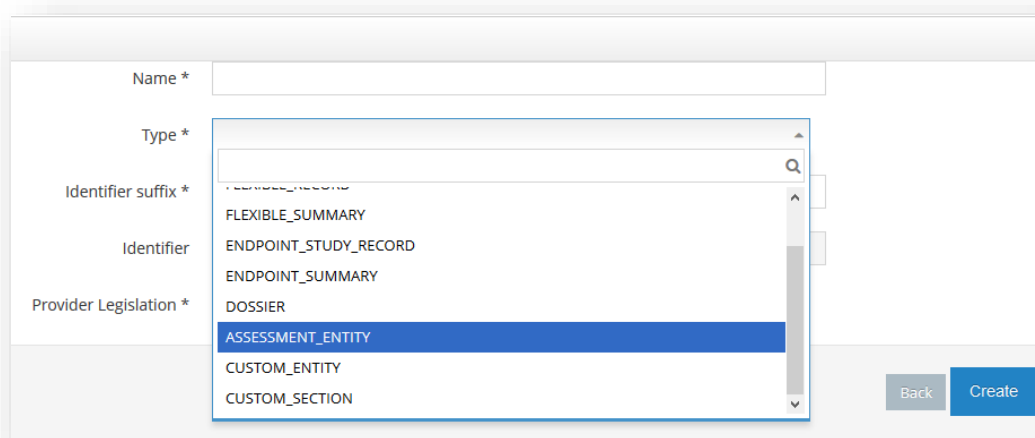


- Assessment Entity: it is a wrapper for a set of substance property data (across endpoints) that is used for assessment purposes. It enables the definition of consistent sets of properties that are relevant to the assessment of specific compositions/forms of the substance (placed on the market or generated upon use). Assessment Entities are under section 1.10 of the REACH Tables of content. There is a fixed record for the whole section and four subsections under which multiple records can be created:



- Custom Entity: a special Document Definition that has an alternative UI form from another Document Definition. It can be created independently from other Documents.
- Custom Section: a special Document Definition that has an alternative UI form from another Document Definition. Custom Section belongs always belongs to an Entity.
- Dossier: this Document type is used for creating dossier headers, which IUCLID users fill in when creating a dossier (a read-only snapshot of IUCLID data) from a raw dataset.

The Document type selection is mandatory when creating a Document in ITEM. The name of the Document is what you see in IUCLID interface.



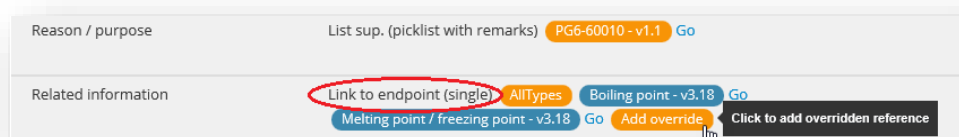
The screenshot shows a web form for creating a document in IUCLID. The form has several fields: 'Name *', 'Type *', 'Identifier suffix *', 'Identifier', and 'Provider Legislation *'. The 'Type *' dropdown menu is open, showing a list of document types: 'FLEXIBLE_SUMMARY', 'ENDPOINT_STUDY_RECORD', 'ENDPOINT_SUMMARY', 'DOSSIER', 'ASSESSMENT_ENTITY' (highlighted in blue), 'CUSTOM_ENTITY', and 'CUSTOM_SECTION'. There is a search icon in the top right of the dropdown. At the bottom right of the form are 'Back' and 'Create' buttons.

4.4 Blocks

Blocks have common design features just like Entities and Documents. Moreover, Blocks can also be included in other Documents and practically give the option of reusing a pre-defined set of components.

When a Block is used within a Document, all the components of the inherited Block are a part of the Document. However, users might want to link a specific field to another PhraseGroup or Text Template by overriding the default component of the Block. The concept of overriding Block components applies for picklists (PhraseGroups), Text Templates and referenced Documents/Entities.

An example of the overriding options for different fields is presented in the picture below. The orange PhraseGroups are the default ones and set on the Block level, whereas the blue ones are the overridden values.



An example of a block, such as Administrative data, in the IUCLID environment, is presented below. This block is used in every Endpoint Study Record within IUCLID, e.g. Density, Boiling point.

Administrative data
None
None

Endpoint
dissociation constant

Type of information
None

Adequacy of study
None

☐ Robust study summary

☐ Used for classification

☐ Used for SDS

Study period
None

Reliability
None

Rationale for reliability incl. deficiencies
None

Data waiving
None

Justification for data waiving
None

Justification for type of information
None

Attached justification
+ New item

| # | Attached justification | Reason / purpose | Action |
|---|------------------------|------------------|--------|
|---|------------------------|------------------|--------|

Cross-reference
+ New item

| # | Reason / purpose | Related information | Remarks | Action |
|---|------------------|---------------------|---------|--------|
|---|------------------|---------------------|---------|--------|

Blocks may contain several elements. When a Block is included in another Document, then all these elements are visible but not editable inside the container Document. All the elements within a block are “optional” by default. It means that the user can hide a specific element of a Block within a Definition. For example, the user could hide the “Reliability” field of the “Administrative data record Block” (see above) in the Density Endpoint Study/ Record but leave it visible in the Boiling point Endpoint Study Record.

If a user wants to “hide” all the fields of a repeatable list, e.g. “Attached justification”, then the “hide” feature can be applied directly to the repeatable and all the fields, “Attached justification”, “Reason / purpose”, “Action”, will be hidden. The same applies to Headers and fields below them. If a Header of a Block is hidden/unhidden within a Definition, then all the fields below that Header are hidden/unhidden as well.

4.5 Phrases and PhraseGroups

Phrases in IUCLID are words or short sentences which are shown as selectable options in IUCLID picklists. For example, the field “Type of information” is a picklist containing many Phrases, such as “experimental study” or “experimental study planned”. These Phrases may be shared amongst different picklists. In ITEM terminology, picklists are called PhraseGroups.

New revisions of both PhraseGroups and Phrases can be created and this allows checking how a PhraseGroup or a Phrase has been changed over different revisions and releases of IUCLID. Every user can create a newer revision of a Phrase and approve it.

Phrases and PhraseGroups can be deleted unless they have at least one reference inside a Definition (Document or Block or Entity). Please note that only users with Advanced and Super Administrator rights can delete data from ITEM.

4.5.1 Features of Phrases

A Phrase is not a versionable element of ITEM, which means that a Phrase should be approved by a user to be finalised. This is different from a process for other versionable elements when finalisation of a Definition Provider leads to the finalisation of all its elements.

Open status of the Phrase. If you want an additional textbox (255 character length) to appear next to the new Phrase in the IUCLID user interface, a checkbox identifying the open status of the Phrase should be selected during the Phrase creation.

As can be seen from the picture below, some specific Phrases (e.g. “other:”) include an additional and optional textbox in the IUCLID6 user interface:

A specific Phrase, if needed, can be set as a default picklist value. Users may want to select a default picklist value for PhraseGroups that contain only one Phrase.

4.6 Text Templates

Text Templates are textual indications of what IUCLID user should enter inside a text field (32,768 characters). Text Templates are usually long sentences or even whole paragraphs. You can add more than one Text Template component per field in ITEM.

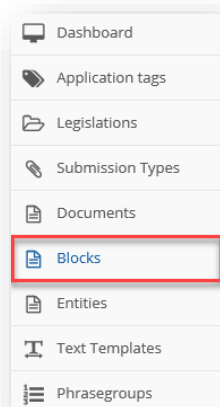
Text Templates are linked to specific component called also Text Template. Text Templates are included in the version control system because they are directly bound to components.

4.7 Available functionality for ITEM elements

4.7.1 Create

All ITEM elements can be created by following these steps:

A) Go to Element tab (e.g. Block);



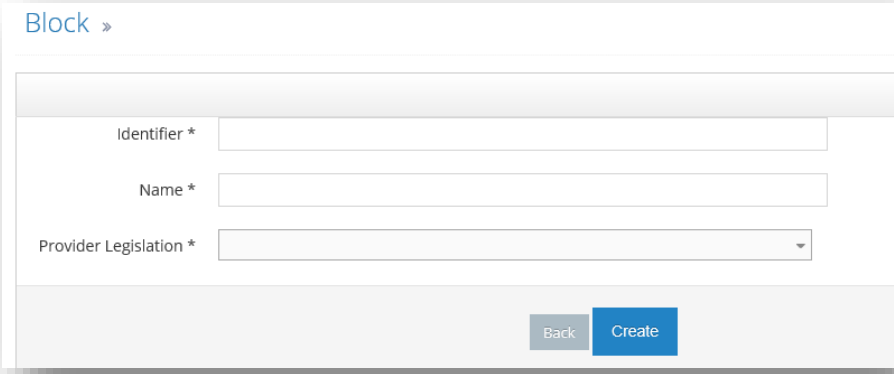
B) Click “New [Element]”;



C) Fill in the required fields (*) depending on the element type e.g. “Identifier”, “Name”, “Type”, “Identifier prefix” or “Identifier suffix”;

Note: for all elements except Definition Provider a provider Definition Provider must be specified.

The Identifier fields, as specified before, may only contain English alphanumeric characters, underscores (_) and dashes (-) but no gaps between words. The Name can contain gaps and/or other symbols. Please refer to the ‘Naming conventions’ chapter for further instructions.



Block »

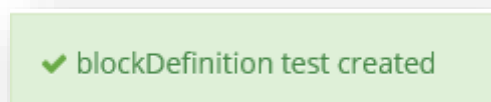
Identifier *

Name *

Provider Legislation *

Back Create

- D) Link to the Provider Definition Provider;
- E) Press “Create”;
- F) A message will notify that the Entity has been created.



A newly created element will be in a draft version (except Definition Provider) and will be finalized when Definition Provider is finalized.

Note Definition Provider element will not be created as a Draft because this is the highest element in ITEM and doesn't have a provider element. A new version should be created for a new Definition Provider.

4.7.1.1 *Phrase creation*

As mentioned earlier, Phrases are not versionable elements of IUCLID which means that a user can approve Phrases after creation.

To create a Phrase:

- A) Go to Phrases tab, click “New Phrase”, select ‘open’ status if needed and specify Definition Provider, click “Create”;

- B)** Write the desired text of the Phrase under “Text”. Under “Additional text”, you can elaborate on the Phrase if necessary. Note that the “Additional text” is also displayed in IUCLID;

Revision: 1.0 Draft

| | |
|-----------------|--|
| Text* | |
| Additional text | |

- C)** Press “Update” to update the Phrase. This will keep the Phrase as a “Draft”;

| | | |
|--------|--------|---------|
| ← Back | Update | Approve |
|--------|--------|---------|

| Revision | Text |
|-----------|--------|
| 1.0 Draft | manual |

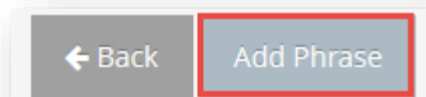
- D)** Press “Approve” to approve the Phrase. This will set the Phrase as “Approved” and locks the Phrase for further editing unless it is “re-opened”.

| | | |
|--------|--------|---------|
| ← Back | Update | Approve |
|--------|--------|---------|

| Revision | Text |
|--------------|--------|
| 1.0 Approved | manual |

4.7.1.2 Adding Phrases into a PhraseGroup

A) To add Phrases to the PhraseGroup, press “Add Phrase”;



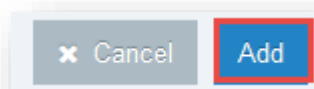
B) Start typing the text of the Phrase to be added;

A screenshot of a dialog box titled 'Please select a Phrase'. It contains a text input field labeled 'Text*' with a red border. Below the field is a placeholder text 'Please enter 1 or more character'. At the bottom right are 'Cancel' and 'Add' buttons.

C) Select the Phrase from the dropdown list;

A screenshot of the 'Please select a Phrase' dialog box with a dropdown menu open. The menu lists several options: 'colour', 'colour index', 'Colour Index', 'colourant', and a detailed description of 'Colouring agents'. The 'colour index' option is highlighted. The 'Add' button is visible at the bottom right.

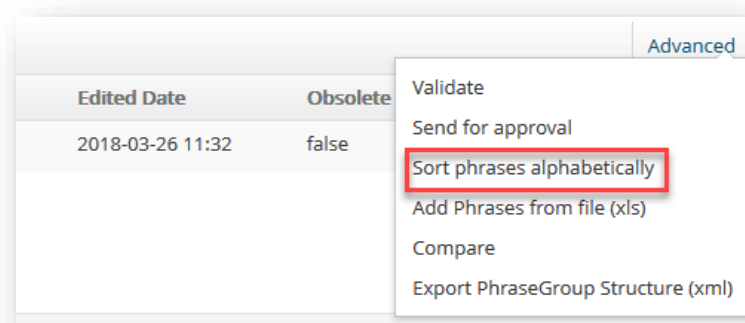
D) Click “Add”;



E) The Phrase has been added to the PhraseGroup.

Please note, in case PhraseGroup is used in a migration rule in a PG mapping, you will be notified while creating a new PG revision.

Phrases in a PhraseGroup can be ordered alphabetically. In case the Phrase 'other:' is present in the list, it will stay at the end of the PhraseGroup.



Note: Phrases provided by one Definition Provider can only be used by other Definition Providers if they are finalised.

4.7.2 Update

There are two types of updates available in ITEM:

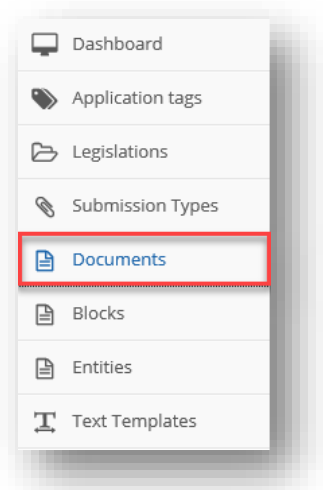
1. Update of **Element content**, such as the addition of a new field or update of a field datatype. Such update is available for all elements when both Definition Provider and the Definition itself are in a draft status.
2. Update of **Element properties**, such as changing Name or Identifier.

Note: all updates in ITEM are propagated upwards and not downwards. For example, if a change in a Block is done on a Document level, such as an update of a PhraseGroup of the field, the block won't be updated for other Documents it is used in. The change will apply only to the Document. In case all Documents should be updated, the change should be performed on a block level and then "Replace in all occurrences" functionality should be used (see section "Show usages functionality" for further information).

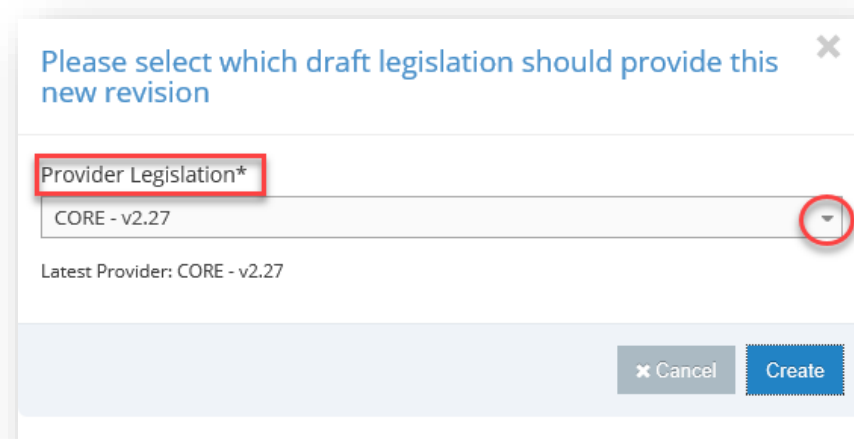
4.7.2.1 Update of Element content

To update the content of an Element:

- A)** Select an Element, e.g. Document;



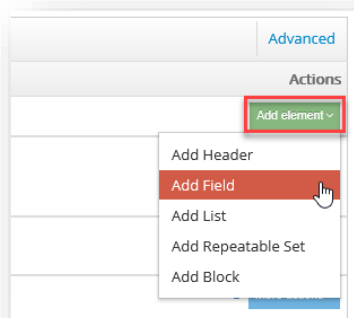
- B) Find an Element to be updated;
- C) Create a draft revision of the element by clicking “New Revision”;
- D) Definition Provider is displayed by default in a popup window. Press “Create”;



Note: if needed, Definition Provider can be changed at this step, otherwise Definition Provider which was initially selected for the Element will be displayed by default.

- E) The recently created Element is an exact copy of the previous revision of the Element, in terms of UI, which can be further updated by applying specific changes such as:
 - Updating a PhaseGroup
 - Updating a label
 - Adding comments to a field

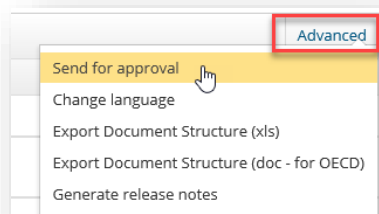
- Adding a new field, header, repeatable set/list and/or block;



Consumer uses block (used in 3.5) »Show

| Revision: 3.0 Final (English) | | | Advanced |
|---|---|--|--|
| Label | Datatype | | Actions |
| 1 ▼ Consumer uses - (TB) | | | More actions ▼ |
| 2 ▼ | Confidentiality | | More actions ▼ |
| 3 ▼ Registration/ Notification status for the use | List (picklist) PG6-60374 - v1.0 Go | | More actions ▼ DCR-2870347 |
| 4 ▼ Use number | Numeric (integer) | | More actions ▼ |
| 5 ▼ Use name | Text (2,000 char.) | | More actions ▼ |
| 6 ▼ Further description of use | Text (rich-text area) | | More actions ▼ |
| 7 ▼ Regulatory status | List multi. (multi-select list) PG6-60372 - v1.1 Go | | More actions ▼ DCR-2870337 |
| 8 ▼ Explanation for the regulatory status | Text (32,768 char.) | | More actions ▼ |
| 9 ▼ Any precursor use(s) | Check box | | More actions ▼ DCR-2870344 |
| 10 ▼ Link to the precursor use(s) | Link to endpoint (multiple) FLEXIBLE_RECORD.ProfessionalWorkers Go FLEXIBLE_RECORD.Formulation Go FLEXIBLE_RECORD.Manufacturer Go FLEXIBLE_RECORD.UseAtIndustrialSites Go | | More actions ▼ |

- F) The updated element is in a “Draft” mode and if it is needed can be sent for approval as shown below:



Please select the user who should approve

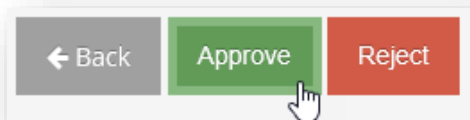
User*

Test_1 Alexis (alex_test)

Cancel

- G)** The updated element, until it is finalized, will remain in a “Draft” status and only after being finalized the status will change to “Final”.

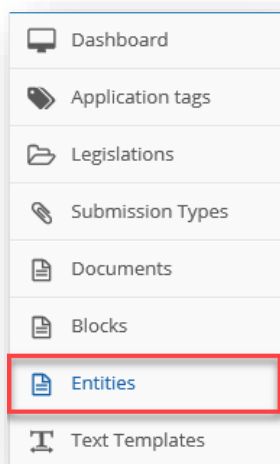
The User that is assigned to approve the specific element needs to open the element by clicking on the “Revision” Pending-edition and approve it by pressing “Approve” at the bottom of the element page.



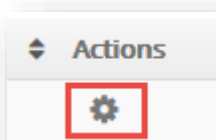
4.7.2.2 Update of Element properties

To update information about the Element (which is the “Update” function in ITEM)

- A)** Go to Element tab e.g. Entities.

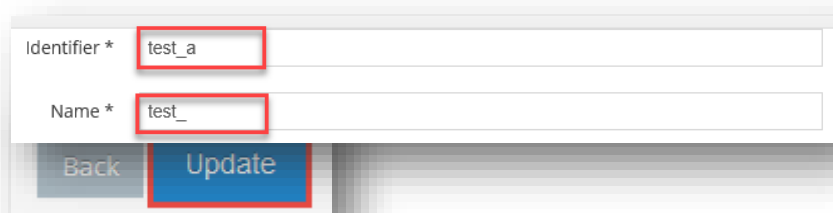


- B)** Find the Element to be updated.
- C)** Click on the “Configure” icon under “Actions”.



- D) Update target fields e.g. “Identifier” and/or “Name” field.
E) Click “Update”.

Note: in case element is in ‘Draft’ status all fields can be updated, in case element is finalized (‘Final’) only some fields such as description can be updated.



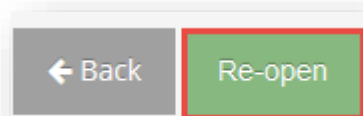
4.7.2.3 Phrase update

Note: It is only possible to update a Phrase when the Phrase is not part of a “Final” PhraseGroup. So it is possible to perform this option only when:

- The Phrase is still not part of any PhraseGroup;
- The Phrase is part of a PhraseGroup but the PhraseGroup is still in draft status or pending;
- The Phrase is part of a PhraseGroup with the status “Approved”.

If the Phrase has been “Approved”, then to update the Phrase:

- A) Find the Phrase to be updated.
B) Press “the blue part (the identifier)”.
C) Press “the blue part (the revision)” of the revision to be updated.
D) Press “Re-open”.

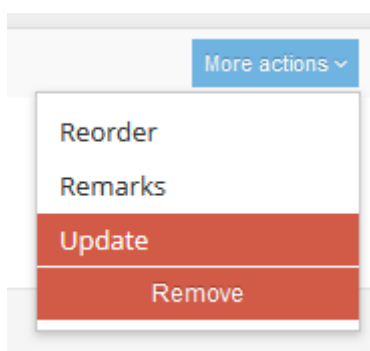


Update the text and either “Update” to keep the Phrase in draft mode, or “Approve” to signal that the Phrase is ready to be finalised.

Note: Definitions with *Final* status cannot be updated, the only way to modify *Final* versions/editions is to create a new revision. To do that:

- A) Go to “Phrase” and find the Phrase to be updated.
- B) Press “the blue part (the identifier)”.
- C) Press “New version”.

Note, in some cases when Phrase revision was updated and it is included into a PhraseGroup, you should go to a PhraseGroup and update the Phrase manually. In order to do so go to PhraseGroup, find target Phrase, select ‘More actions’ and ‘Update’.



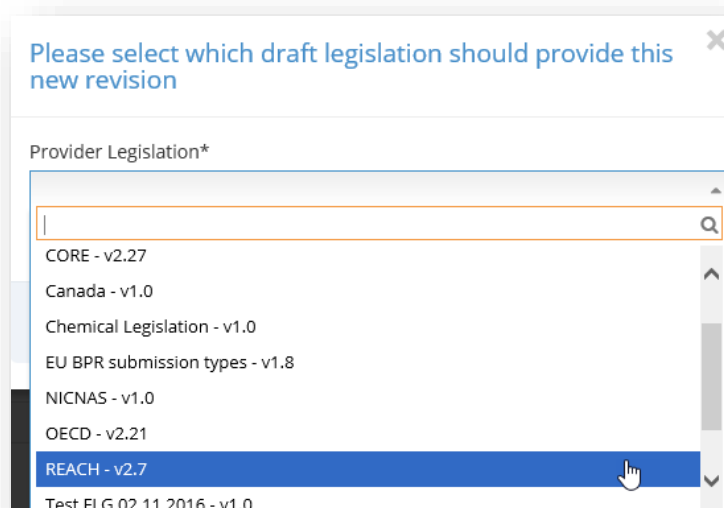
4.7.2.4 Update a Phrase to 'open'

A new Phrase should be created with the same label and marked as open. Then, the migration rule instance will have to be created.

Note: two Phrase revisions can have the same combination of ‘Text’ / ‘Additional Text’ only if their ‘open’ status is different.

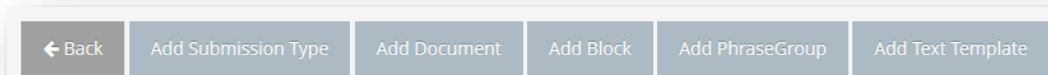
4.7.2.5 Adding elements to a Definition Provider revision

There are five different elements that can be added to a Definition Provider revision (Table of content, Document, Block, PhraseGroup, Phrase and Text Template). For a new version of every one of those five elements, the user should select to which Definition Provider it belongs as shown in the picture below:



In this chapter the user is able to follow how to add already created versions of the elements mentioned above, to a Definition Provider revision.

- A) Go to Definition Providers.
- B) Look up and select the Definition Provider to be edited and click on the blue part, the Identifier.
- C) Click on the revision to be edited.
- D) Go to the bottom of the page to found the following buttons.



- E) Update Definition Provider by adding elements

Once a specific Element has been added to the Definition Provider it cannot be added once again. In order to be able to include e.g. Text Template more than once in a Definition Provider the user has to add it to higher level in the hierarchy (i.e. to a Block or a Document).

When creating a new element under a specific Definition Provider it will be automatically included in the Definition Provider meaning there is no need to add manually following the above described steps. However if the definition already exists then the user has to follow the described method and add them manually.

Note: it is possible to change provider Definition Provider for an existing element such as Phrase, PhraseGroup or a Document while creating a new revision. ITEM will ask user to specify provider Definition Provider during revision creation process.

4.7.3 Delete

An ITEM entry can be completely removed as soon as it is not used by another element.

Term 'used', per Revision type, means:

Documents: 1. being part of a Definition Provider; 2. being referenced in another Document (by default or override);

Entities: 1. being referenced in another Document (by default or override);

Blocks: 1. being part of a Definition Provider; 2. being included in another Document;

Text Templates: 1. being part of a Definition Provider; 2. being referenced in another Document (by default or override)



Phrasegroups: 1. being part of a Definition Provider; 2. being referenced in another Document (by default or override)

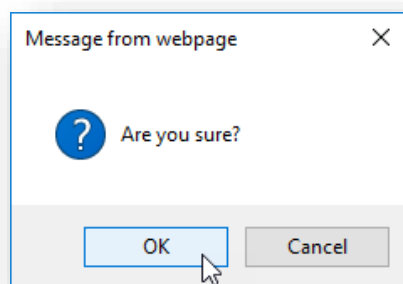
Phrases: 1. being part of a PhraseGroup.

Legislations: 1. being part of an Application Tag

In order to do delete a revision of an element, click the red trash bin icon on the right side of the screen, under “Actions”. The Draft Revision will be deleted after clicking “OK” at the notification message that will appear on the screen.

Custom_section_test - Custom Section »Revisions

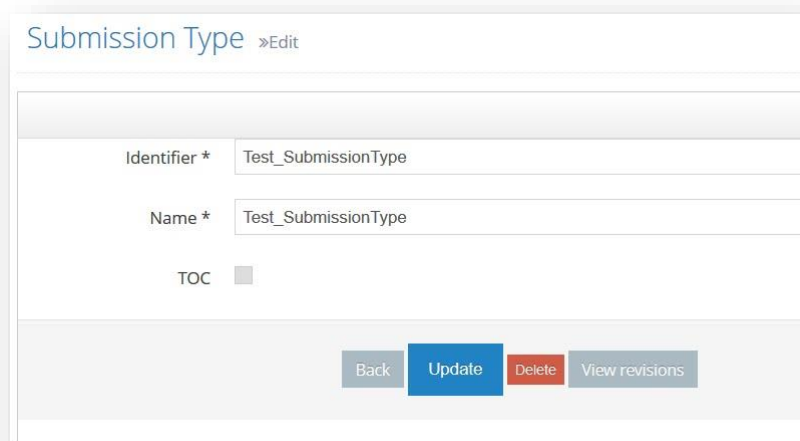
| Revision | Last approver | Created By | Created Date | Edited By | Edited Date | Actions |
|--------------|---------------|------------|---------------------|-----------|---------------------|---|
| 1.0 Draft | | | 2020-02-20 16:02 | | 2020-02-20 16:04 | Show usages   |



When all the revisions are deleted the user can delete the Element completely (if it is not referenced in other element as mentioned above). Remember, that element is not completely deleted when all revisions are removed, the actual element should be deleted as well.

For example, in order to delete Submission element:

1. Delete all revisions.
2. Then the Submission Type itself should be deleted (this is a step which might be overlooked).
3. When you see the empty list of Submission Type revisions you have to click on 'Submission Type' in the breadcrumb at the top of the page to reach the deletion option as displayed below:



Note: When Revision of a Definition is deleted, the Definition Provider Revision which provided the Revision of the Definition starts providing previous Revision of the same underlying Definition.

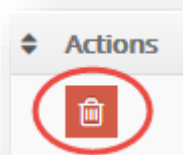
For instance, PhraseGroup PG_1 has 2 revisions: v1.0 which is provided by OECD - v1.0 and v1.1 which is provided by OECD - v1.1. When the user deletes PG_1 - v1.1, the system makes OECD - v1.1 provide the previous revision of the PhraseGroup, i.e. PG_1 - v1.0.

4.7.3.1 Delete Definition Provider

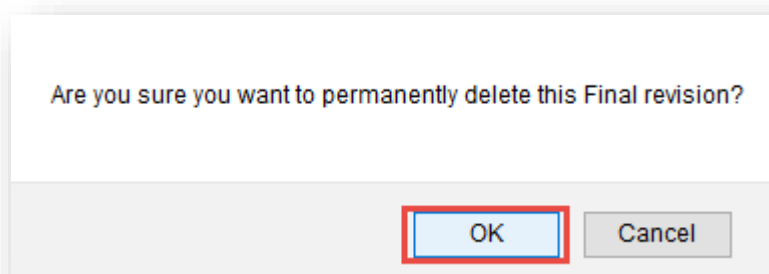
As explained before Definition Providers in ITEM are the top of the hierarchy and they provide every other definition. The Definition Provider and Role based user model provides a basic security level by having user roles with no delete rights. This is to avoid deletion of the valuable data stored under a Definition Provider.

To be able to delete a whole Definition Provider, the user, as it is mentioned above, has to delete every version/edition under it beforehand. To do that:

- A) Go to “Definition Providers”.
- B) Find the Definition Provider to be deleted.
- C) Click on the blue part, the “Identifier”.
- D) Delete the version(s)/edition(s) one by one by clicking the red trash bin icon on the right side of the UI, under “Actions”.



- E) A question will pop-up, click “OK” to delete the version/edition permanently.



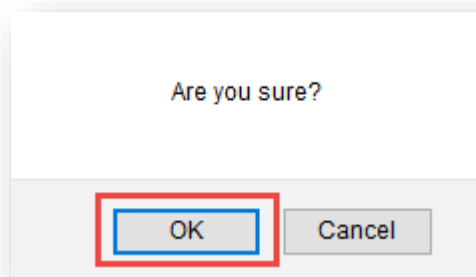
- F) A message will appear to notify the successful deletion of the revision.

After the deletion of all revisions included in a Definition Provider, to completely and permanently delete a Definition Provider follow the steps below:

- A) Go to “Definition Providers”.
- B) Find the Definition Provider to be deleted.
- C) Click on the red trash bin icon on the right side of the screen, under “Actions”.



- D) A question will pop-up, click “OK” to permanently delete the Definition Provider.



- E) A message will appear to notify the successful deletion of the Definition Provider.

Note 1: After permanently deleting a Definition Provider there is no way to retrieve any information or data structure it contained.

Note 2: In case a Definition Provider revision is included in an “Application Tag” that revision is not possible to delete, therefore in such cases it is not possible to permanently delete a whole Definition Provider.

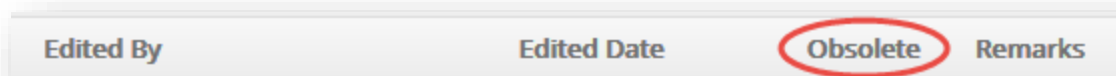
4.7.3.2 *Make Phrases obsolete*

When a Phrase is discontinued for business reasons and should not appear in the next IUCLID release, the Phrase can be marked as obsolete from within the PhraseGroup -> ‘More actions’, and Deactivate.

By marking a Phrase as obsolete, the Phrase is handled in a specific way. Take the following example:

- Phrase “study” exists in IUCLID v6.1.
- Phrase “study” is deactivated in ITEM.
- Phrase no longer appears in IUCLID v6.2.
- However, if the IUCLID user has selected the Phrase in v6.1, then when the IUCLID data is migrated from v6.1 to v6.2, the Phrase will still appear as a selected option in IUCLID v6.2.

A Phrase can be marked as *Obsolete* in a PhraseGroup revision only when this specific Phrase already exists in a previous revision of the specific PhraseGroup. As soon as a Phrase already exists in a previous revision of a specific PhraseGroup, it can no longer be deleted from any future revisions of the specific PhraseGroup, it can only be marked/unmarked as *Obsolete*.



| Edited By | Edited Date | Obsolete | Remarks |
|-----------|-------------|----------|---------|
|-----------|-------------|----------|---------|

4.7.3.3 Phrase deletion, removing Phrases from PhraseGroups

Note: If a Phrase is part of any PhraseGroup revision which has “Final” status then there is no possibility to remove the Phrase. Therefore the following method does not apply to any cases where a Phrase has been included in a “Final” PhraseGroup revision.

Deleting Phrases that have been included in PhraseGroups still can be done, however they mostly need to be manipulated first in the actual PhraseGroups. The starting point is to do not try to delete a Phrase that is present in more than one PhraseGroup. In case the Phrase satisfies the before mentioned conditions and is to be deleted:

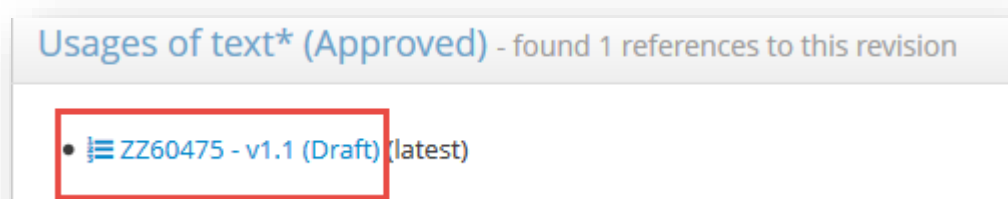
- A) Go to Phrases.
- B) Find the Phrase to be deleted.
- C) Click on the blue part, the “Identifier”.

D) Find the latest revision.



E) Click “Show usages” on the right side of the page under “Actions”.

F) Find the PhraseGroup it is under and click the blue part.



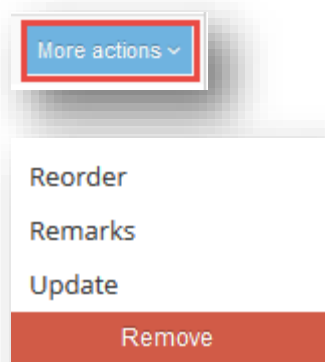
G) A new page will open showing the specific PhraseGroup revision. Find the Phrase to be deleted.

H) Click on the “More actions” button on the right side of the screen under “Actions”.

I) Select the red line “Remove”.

J) A question will pop-up, to remove the Phrase from the PhraseGroup click “OK”.

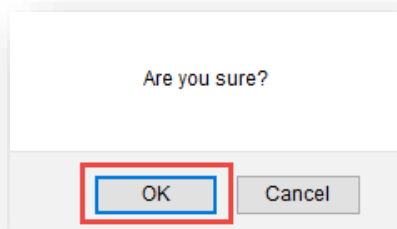
When a Phrase is not used by any PhraseGroup, it can be deleted.



4.7.4 Bulk upload of Phrases to a PhraseGroup (and bulk Phrases creation)

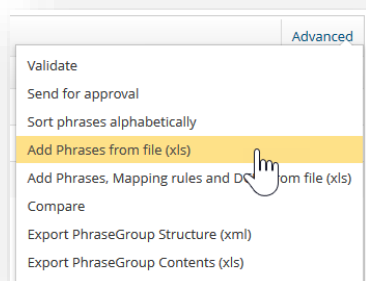
When working with PhraseGroups containing a lot of Phrases, a bulk option is available.

A) Go to Phrases.



B) Open a PhraseGroup in draft mode and click 'Advanced':

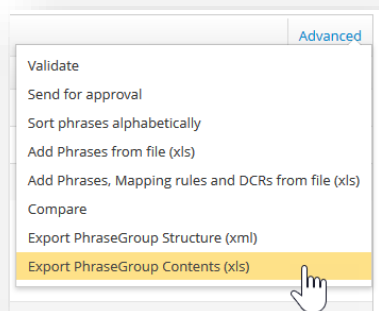
C) Select 'Add Phrases from file (xls)'.



D) Browse for an Excel file containing all Phrases to be added to the PhraseGroup. The Excel file should have the following structure:

| | A | B | C | D | E |
|---|------------|----------------------|--------------|----------|---------------------|
| 1 | PhraseText | AdditionalPhraseText | ObsoleteFlag | OpenFlag | SourcePhraseGroupID |
| 2 | °C | | FALSE | FALSE | |
| 3 | K | | FALSE | FALSE | |
| 4 | °F | | FALSE | FALSE | |

Note that you can utilise the “Export PhraseGroup Contents (xls)” functionality and download a file that has the format of the ‘Phrase-import’ file. You only need tweak it according to specific requirements.



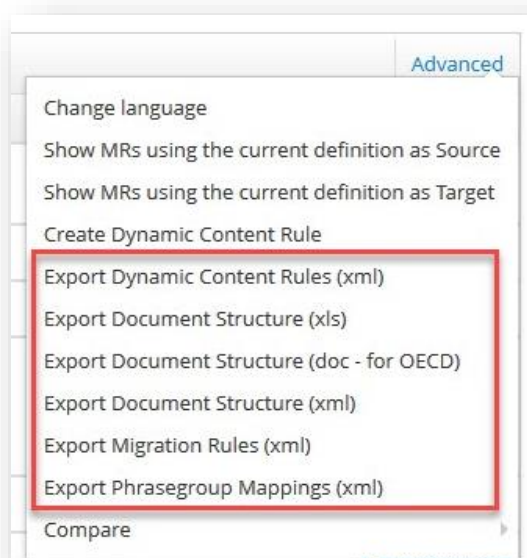
- E) Click the 'Import file' button and after reviewing Import Phrases validation report Phrases can be imported.

Any existing Phrase recognised by the application will be used and added to the PhraseGroup. Phrases that are not already created will be created and then added to the PhraseGroup.

In case the PhraseGroup already contains Phrases, the new Phrases will be added at the end of the list.

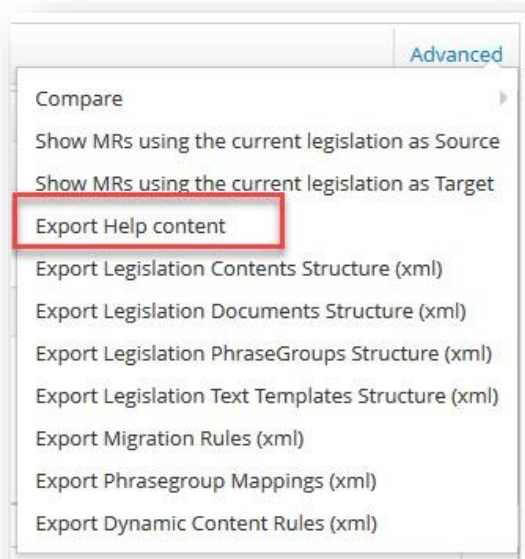
4.7.5 Export

There are different options available for the elements' export in ITEM. Most of export option are available under 'Advanced' feature for each component. E.g. in order to export a Document go to Document revision and choose 'Advanced' option.



Available export outcome formats are: Word, Excel, XML. There are cases when ITEM generates zip file which includes Excel or HML files (e.g. Help content of Application Tags).

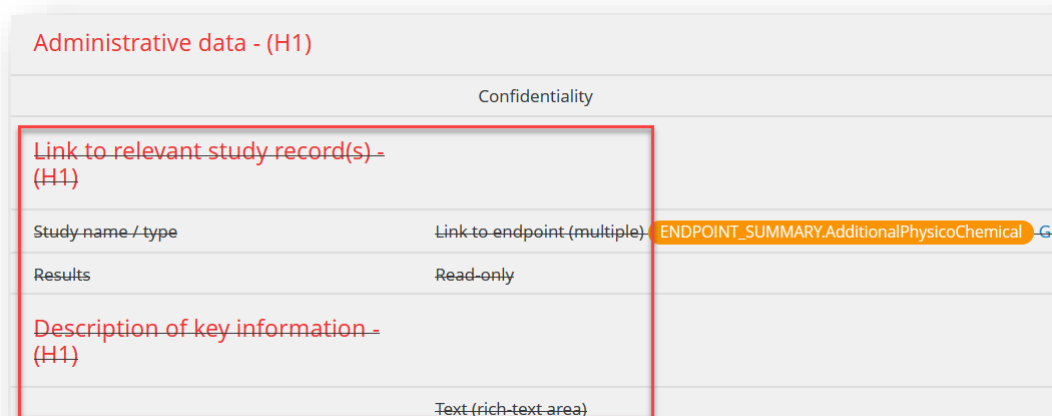
Export help content functionality is available when viewing an Application Tag or a Definition Provider revision.



When a Document structure is exported, some of the elements are differentiated from others with a unique attribute. For instance, repeatable blocks have a type with values = 'list'/'repeatable' and are displayed in the XML file like this:

- `<repeatableBlock name="BlockLabel" type="list">`
- `<repeatableBlock name="BlockLabel" type="repeatable">`

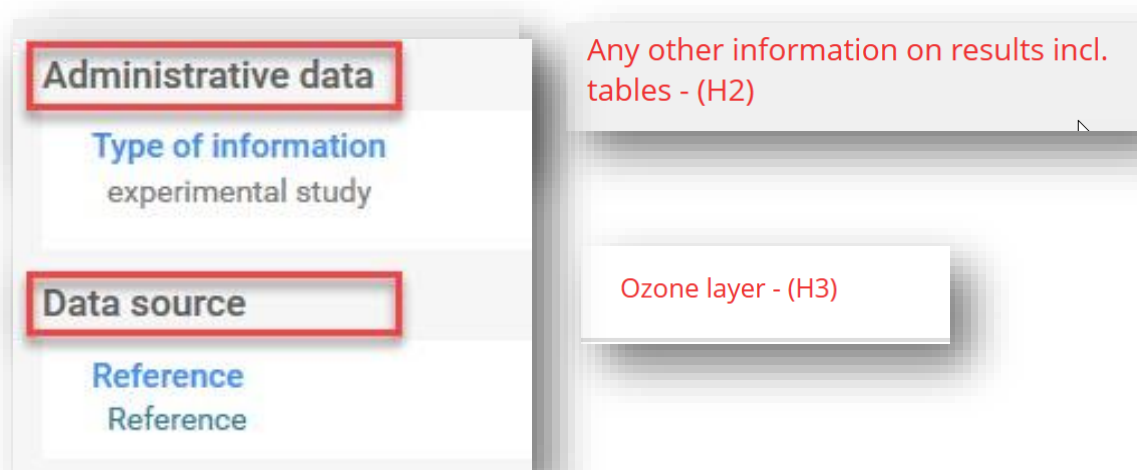
Note: hidden elements will not be exported. For example, neither the hidden headers, nor the fields will be exported for the following document:



4.8 Components of IUCLID Documents and Blocks

Components are the core elements used to construct various Definitions of ITEM: Documents, Entities, Blocks. Components are predefined in ITEM/IUCLID in terms of their structure and UI appearance, and therefore cannot be customised. However, customisation and flexibility is provided by the option to use different types of components to construct customised Definitions. Components do not support versioning, and they are classified into five categories as follows.

Headers are labels to distinguish between different parts of an ITEM Definition. Each header is given a level, e.g. H1, H2, H3, H4 etc. which determines the font properties of that header in IUCLID user interface. For example, all Endpoint Study Records start with the header H1 “Administrative data”.



Fields are data entry points in IUCLID. Each field in IUCLID has a data type associated with it. The data type determines how that field is represented in IUCLID user interface. For example, the datatype “List (picklist)” is a closed picklist (meaning only the picklist options are available to select, with no free text options available).

| Administrative data - (H1) | |
|----------------------------|---|
| | Confidentiality |
| Endpoint | List sup. (picklist with remarks) PG6-60326 - v1. |
| Type of information | List sup. (picklist with remarks) Z05 - v2.4 Go |
| Adequacy of study | List (picklist) Y14-3 - v2.1 Go |
| Robust study summary | Check box |

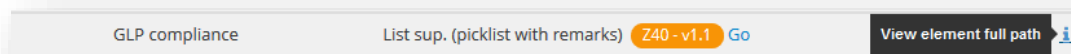
Adequacy of study ? v

Please select

- key study
- supporting study
- weight of evidence

Each field has a **unique identifier**. The identifier is used, for example, to extract IUCLID information when running the IUCLID Report Generator or exchanging data between IUCLID and other IT systems. You can view the field identifiers in ITEM. See the [Naming conventions](#) section for how to specify identifiers.

To see a field's identifier in ITEM, simply select the “i” on the right side of a field:



The field's “GLP compliance” identifier can be broken down as follows:

| ENDPOINT_STUDY_RECORD | Document type identifier |
|------------------------|-----------------------------------|
| General information | Document identifier |
| MaterialsAndMethods | Header identifier in the Document |
| GLPComplianceStatement | Unique field identifier |

Repeatable Lists are a set of fields that can be added multiple times and appear as tables in the IUCLID user interface. Lists can only support fields as child elements.

| Cross-reference L.S. | | | | |
|----------------------|--------------------------------------|---|---------|--------|
| Reason / purpose | | List sup. (picklist with remarks) PG6-60010 - v1.1 Go | | |
| Related information | | Link to endpoint (single) AllTypes | | |
| Remarks | | Text (32,768 char.) | | |
| Cross-reference L.E. | | | | |
| # | Reason / purpose | Related information | Remarks | Action |
| 1 | data waiving: supporting information | Toxicity to reproduction.001 | None | |
| 2 | assessment report | Toxicity to reproduction.001 | None | |

Repeatable Sets are a set of fields that indicate repeatability and appear in the form of blocks in the IUCLID user interface. Repeatable sets support all 5 basic component categories as child elements and therefore can include any type of field between the start and end of the repeatable set. Repeatable Sets can also include other Repeatable Sets as well as Repeatable Lists.

Note that Repeatable Lists cannot include other Repeatable Lists and/or Repeatable Sets.

Results and discussion - (H1)

| | |
|--|---|
| Physical state at 20°C and 1013 hPa | List sup. (picklist with remarks) A19 - v1.0 Go |
| Form / colour / odour R.S. | |
| Key result checkbox BLOCK (OHT) - v1.0 | |
| Key result | Check box |
| Form | List sup. (picklist with remarks) A101 - v2.1 Go |
| Colour | Text (2,000 char.) |
| Odour | List (picklist) A100 - v1.0 Go |
| Form / colour / odour R.E. | |

Results and discussion

Physical state at 20°C and 1013 hPa
None

Form / colour / odour [+](#) New item

2 ☒ **Key result**

Form
aerosol dispenser: not specified

Colour
Blue

Odour
biting

Note that a set of fields (Repeatable Set and Repeatable List), has a IUCLID path as well:

i More actions ▾

i More actions ▾

(S) MR-251

(T) MR-250

i More actions ▾

Blocks as mentioned before, are a special case. They are a component of a Document or Entity, but are defined as Definition in ITEM (under 'Blocks') and can contain all the components as

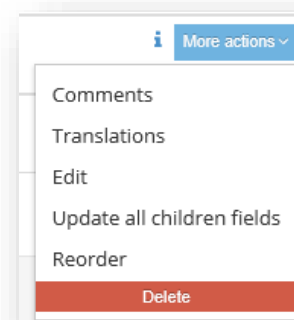
described above, so they can be reused in other Documents or Entities. For example, the block “Data source block (Literature Reference)” is user in every OHT.

| | |
|---|--|
| Data source block (Literature Reference) - v3.0 | |
| Data source - (H1) | |
| Reference | Link to lit. reference (multiple) |
| Data access | List sup. (picklist with remarks) Z03 - v2.0 Go |
| Data protection claimed | List sup. (picklist with remarks) Z30 - v1.0 Go |

4.8.1 Available components' operations

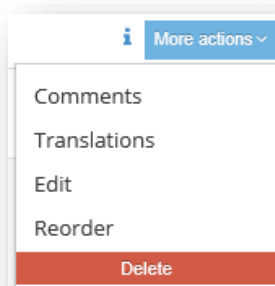
Header/Repeatable List/Repeatable Set/Block:

- Comments: add comments to a specific element;
- Translations: add a translation of the label name (e.g. Header) in other languages;
- Edit: enter additional information for a specific element (e.g. edit help text);
- Update all children fields: set confidentiality and field level options for all the children fields;
- Reorder: change the position of the element;
- Delete: delete the element.



Field:

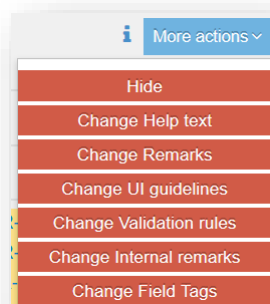
- Comments;
- Translations;
- Edit;
- Reorder;
- Delete.



Header inside a block:

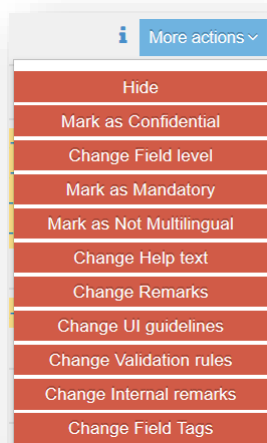
- Hide;

- Change Help text;
- Change Remarks;
- Change UI guidelines;
- Change Validation rules;
- Change Internal remarks;
- Change Field Tags.



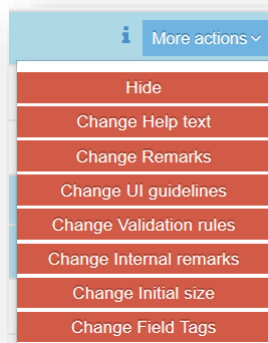
Field inside a block:

- Hide;
- Mark as Confidential;
- Change Field level;
- Mark as Mandatory;
- Mark as Not Multilingual;
- Change Help text;
- Change Remarks;
- Change UI guidelines;
- Change Validation rules;
- Change Internal remarks;
- Change Field Tags.



Repeatable List/Set inside a block:

- Hide;
- Change Help text;
- Change Remarks;

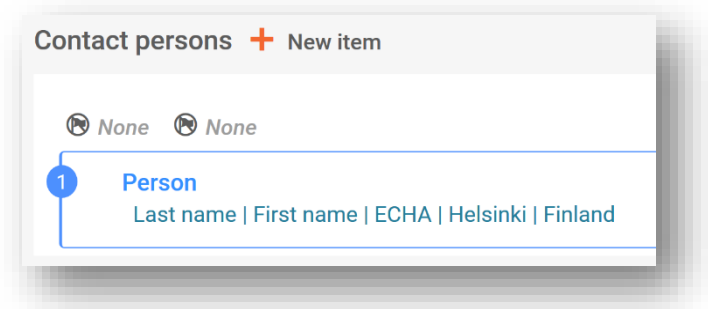


- Change UI guidelines;
- Change Validation rules;
- Change Internal remarks;
- Change Initial size;
- Change Field Tags.

4.8.2 Available operations during edit of Fields, Repeatable set/lists and Headers

- Label: label is the “name” of a Field, Set/List, Header as shown in IUCLID user interface;
- Datatype (fields): data type defines what kind of data can be stored in a field (e.g. free text, attachment, etc.);
- Component Identifier: the last piece of string of the component identifier;
- Remarks;
- Mandatory: making a field mandatory will require users to perform an action related to such field in the user interface;
- Level: Detail level and Basic level. Detailed fields can be either included or excluded from dossiers or generated PDF documents. If excluded, the content of a “detailed” field will not be visible either in the dossier or the PDF document.
- Confidential: if this option is set in a field’s settings, then that field is labelled as confidential by having the text (confidential) appended to its name. Confidential field’s content can be included or excluded from dossiers or generated PDF documents.
- Multilingual: the feature allows the user to provide content of every textual field in multiple languages. For instance, EU_CLP notifications may be relevant to multiple countries. Hence, free-text fields are expected to be provided in multiple languages that are specific to the target country. Multilingual field flag is set by default when applicable.

- Part of Document summary: the functionality allows setting the “Part of Document summary” flag for different fields. Information in the “Part of Document summary” Fields is displayed whenever a Definition is referenced in a cross-reference Field. In the example below, the Entity Contact has five Fields set as “Part of Document summary”. Information in these Fields is displayed when the Entity is referenced.



- Shift: This option will be used by IUCLID to indicate that this field will appear next to the previous component
- Validation rules
- UI guidelines
- Help text
- Internal remarks
- Field Tags

Label: This field shows the default label of the header. Localized texts can be managed from the Translations' menu.

- Datatype: This dropdown shows the available datatype of Field. The following datatypes are available, illustrated with screenshots from IUCLID 6:
 - Attachment (single / multiple) – users can attach a single attachment/multiple attachments

Type of report
None

Document / report ?

Assessment.docx

0.00 bytes / Uploaded: 22/11/2019

press Esc to close

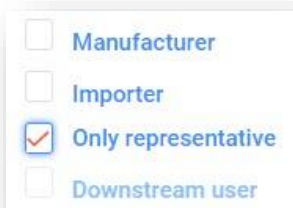
Further information on the attachment / remarks
None

Attached justification

+ New item

| #.. | Attached justification | Reason / purpose | Action |
|-----|------------------------|--------------------------------------|--------|
| 1 | Justification.docx | data waiving: supporting information | |
| 2 | Justification2.docx | exposure-related information | |

- Check box – users can select/unselect a check box



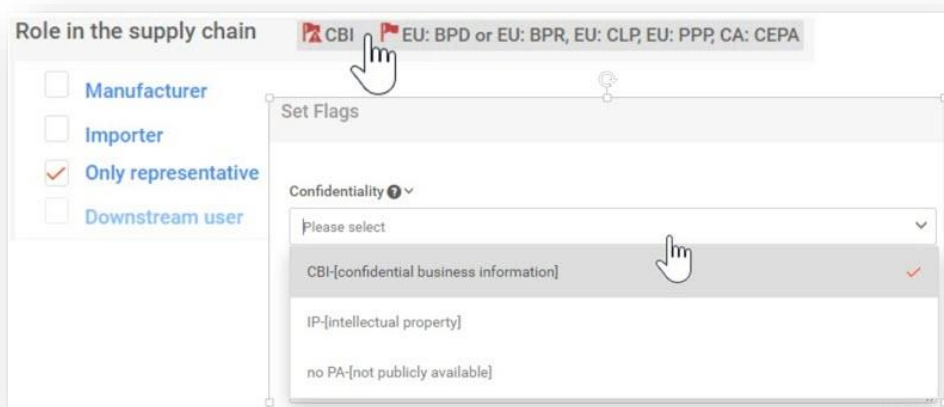
Manufacturer

Importer

☒ Only representative

Downstream user

- Confidentiality – users can set confidentiality flags and choose relevant regulatory programmes



Role in the supply chain

☒ CBI ☒ EU: BPD or EU: BPR, EU: CLP, EU: PPP, CA: CEPA

Manufacturer

Importer

☒ Only representative

Downstream user

Set Flags

Confidentiality ?

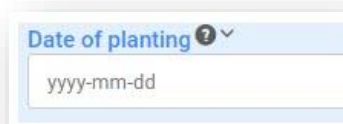
Please select

CBI-[confidential business information]

IP-[intellectual property]

no PA-[not publicly available]

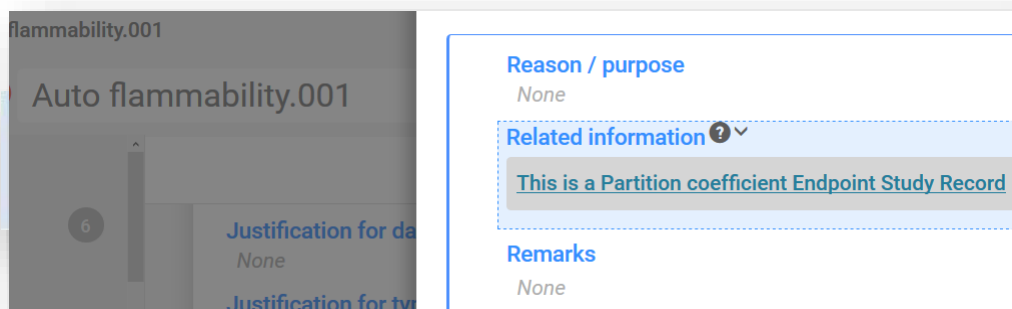
- Date – users can enter date in *yyyy-mm-dd* format



Date of planting ?

yyyy-mm-dd

- Endpoint reference representation



flammability.001

Auto flammability.001

6

Justification for data

None

Justification for type

Reason / purpose

None

Related information ?

This is a Partition coefficient Endpoint Study Record

Remarks

None

- Image upload – users can attach an image

- Link to endpoint (single / multiple) – users can select an endpoint/multiple endpoints as a reference

| Cross-reference + New item | | | | |
|---|--------------------------------------|---------------------------------|---------|--------|
| #.. | Reason / purpose | Related information | Remarks | Action |
| 1 | data waiving: supporting information | Toxicity to reproduction.001 | N/A | ✕ |
| 2 | assessment report | Skin irritation / corrosion.002 | Remarks | ✕ |

- Link to Entity (single / multiple) – users can select a single Entity/multiple Entities as a reference

Legal entity* None None
European Chemicals Agency

Category members

- Article
- my substance 1
- My substance
- + Select

- Link to literature reference (multiple) – users can select multiple Literature reference Entities as a reference

| Reference | | | | |
|-----------------------|------------|--------|------|---------|
| study report | Reference | Author | 2019 | No. 111 |
| publication | Reference2 | Author | 2018 | 111 |
| + Select | | | | |

- List (multi-select / multi-select with remarks (255 characters) / multi-select with remarks (2,000 char.) / multi-select with remarks (32,000 char.) / picklist / picklist with remarks (255 char.) / picklist with remarks (2,000 char.) / picklist with remarks (32,000 char.)) – users can select either a single picklist value or multiple values and add an optional remark to support the selection (if the type is “with remarks”)

The first screenshot shows the 'Type of information' dialog box with the dropdown menu set to '(Q)SAR'. A red box highlights the 'Add remark' button. The second screenshot shows the same dialog box with the 'Remark' text area expanded for input.

○

- Numeric (decimal including unit / decimal / integer) – users can add a numerical value (decimal or integer) and select a relevant unit (if the type is “including unit”)
- Numeric range (decimal precise / decimal / decimal with picklist / half bounded) – users can add a numerical value range (decimal) and select a relevant unit/other picklist value (if the type is “with picklist”); decimal precise field type rounds up the decimal value; half bounded field type allows indicating only left/right interval bound

The 'Effect concentration' dialog box displays a range from 10.1 to 20.2 with the unit 'ng/L'. It includes dropdown arrows for the comparison operators and the unit.

The 'Duration' dialog box shows a value of 12.5 with the unit 'min' selected from a dropdown menu.

The 'Typical aspect ratio (:1)' dialog box displays a value of 10.2 with the ratio ':1' selected from a dropdown menu.

- Text (255 char. / 2,000 char. / 32,768 char.) – users can add free text

The 'Remarks' dialog box features a large text area for free text. A message at the top indicates: 'You can enter 32,768 characters in this field.'

- Text (rich-text area) – users can add free text and format it (add bold, italic fonts, tables, bullet points, etc.)

Executive summary

Justification for type of information

JUSTIFICATION FOR DATA WAIVING
[Specific explanation in addition to field 'Justification for data waiving']

Attached justification + New item

| #.. | Attached justification |
|-----|------------------------|
| | |

Insert existing templates

- Type 'Waiving of standard information'
- Type 'Experimental study planned / Testing proposal on vertebrate animals'
- Type 'QSAR prediction'
- Type 'Read-across (analogue)'
- Type 'Read-across (category)'

- Text Template – users can add free text by following a predefined structure of a template
- Link to repeatable entry – users can reference a repeatable entry (select it in a picklist)

Contributing scenario for the environment (related to workers activities)

Contributing scenario for the environment (related to workers activities) + New item

None None

1 Linked contributing activity

Search

Name 1

Name 2

Contributing activity / technique for the environment + New item

1 Name of activity / technique

Name 1

Environmental release category (ERC)

✓ ERC6a: Use of intermediate

2 Name of activity / technique

Name 2

Environmental release category (ERC)

✓ ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article)

4.8.3 Basic/detail attribute

From all the components defined in IUCLID 6 and ITEM only the following support the attribute of basic/detail (regardless if they are part of a block or not):

- Fields
- Lists
- Repeatable sets

This attribute in ITEM is used as an indication in IUCLID at a later stage where it will be used as a filtering option in various IUCLID processes (i.e. Dossier creation, Export, etc.).

4.8.4 Confidential attribute

The Confidential attribute will mark the field, by default, as confidential and used as a filtering option in various IUCLID processes (i.e. Dossier creation, Export, etc.).

The components where the confidential attribute is applicable in ITEM and in IUCLID are:

- Fields
- Lists
- Repeatable sets

In the picture below, the Field “Dynamic viscosity of test material” has “Detail” attribute set in ITEM while the Field “Specific details on test material used for the study (confidential)” has the attribute “Confidential”. Depending on the selection in Dossier Settings creation window, users will either see or will not see the content of these Fields in a Dossier.

Density.001

tonnes

6

1

1

Specific details on test material used for the study (confidential)

This is my details on test material used for the study (confidential).

Dynamic viscosity of test material ?

This is my data on dynamic viscosity of test material.

Dossier Settings

Include legal entity

☐ Include legal entity

Detail level of document fields

☐ Detailed fields (e.g. needed for robust endpoint summaries)

☐ Fields marked "confidential"

Specific details on test material used for the study (confidential)

None

Dynamic viscosity of test material

None

Dossier Settings

Include legal entity

☐ Include legal entity

Detail level of document fields

☒ Detailed fields (e.g. needed for robust endpoint summaries)

☒ Fields marked "confidential"

Specific details on test material used for the study (confidential)

This is my details on test material used for the study (confidential).

Dynamic viscosity of test material

This is my data on dynamic viscosity of test material.

5 MIGRATION RULES

The purpose of the version control system in ITEM is to manage and track the changes made in the Document definitions. Document definitions may change due to regulatory reasons such as Definition Provider amendments, or ongoing improvements to the information available or displayed in a Document definition resulting in for example, the update of picklists, a change to field labels or datatypes, or the addition or removal of fields. In such cases, the data has to be transferred from one revision of the Document definition to another.

When the change to a Document definition is **minor** the transfer from one revision to another is supported by the version control system and requires no additional work in ITEM to manage. Such minor changes can include field label changes, a change to the help text for a field, or a change to the position of a field when it does not alter the field path. However, when a **major** change occurs in a Document definition, this change requires a well-defined description of how data stored in the affected field(s) will behave when transferred to another version of a Document. In ITEM, this is called a **migration** and is managed in ITEM through **migration rules**. Examples of major changes include changing a field's path, deleting a field, or adding a field.

5.1.1 Forward and backward migration rules

When a major version of IUCLID is released with format changes, this creates a need to allow the latest version to be compatible with the previous version of IUCLID. To allow for this compatibility between IUCLID versions, ITEM's migration rules refer to the direction the data is being transferred, either **forward** from a previous version of IUCLID to a new version of IUCLID, or **backward** from the latest version of IUCLID to the previous version. ITEM's Document definitions and version control system reflect the above so that a:

- **forward migration rule** describes a situation when the data is being transferred from an older version of the Document to a newer one e.g. migration from *Flexible record - Toxicity 3.5* to *Flexible record - Toxicity 4.0*
- **backward migration rule** describes a situation when the data is being transferred from a newer version of the Document to an older one e.g. migration from *Flexible record - Toxicity 4.0* to *Flexible record - Toxicity 3.5*

Note: After forward migration rule is encoded it should be always checked if backward migration should be also specified. General approach is as such, ***it should be possible to migrate data both ways from a previous version to a new and from a new version to old one.***

5.1.2 Migration Rule types

ITEM has pre-defined migration rules to cover the majority of migration use cases. These are called 'Migration Rule types' and can be re-used by an ITEM user to safely and consistently migrate data between major versions of a Definition Provider.

The Migration Rule types can be divided into:

- **Structured migrations types** – these migrations is where data is transferred directly from one field to another without any change in the structure of the data. This behavior is repeatable and easily reproducible. For structured migrations types the migrations logic is already pre-encoded in ITEM.
- **Unstructured migrations types** – in these cases the data may have to be aggregated (when transferred from two or more fields into one) or, in the opposite situation, split between two or more new fields. If a corresponding field is not available, then the data is stored in a text file attached to the Document. The same logic applies to a situation when an element of a Document or a whole Document itself is deleted.

As a general rule, data which cannot be mapped to a Document/field/PG are stored in a text field attached to a Document.

Several of the most common structural cases when migration rules are applicable are already predefined in ITEM and include the following migration types:

- **Field path mapping** – path of the field has changed e.g. due to a change of the name of one of the components
- **PhraseGroup mapping** – new Phrases have been added to/removed from a PG.

Document mapping – MR when user specifies the source Document version that should be mapped to the target one. In case the target Document (with the same Document definition ID) exists in the previous major Definition Provider version, ITEM will automatically select the last final version of the Document as source. In case of different Document type, different Document sub-type or in case of the same Document definition ID, coming from a different Definition Provider, the user should define explicitly which the exact source Document last version is.

Note: After applying this MR type, the system will ensure that all the fields (which have the same relative path amongst the source and the target Document) will be automatically mapped. For any fields of the target Document that no match can be found from the source Document, the user will have to define an explicit MR at field level.

- **Document deletion** – a whole Document is being deleted. The data is stored as an attachment.
- **Field deletion** – a Document definitions' field is not present in the version to which the data is being migrated. The data is either being migrated to a new field or stored as an attachment.
- **Incompatible text field mapping** - this MR Type covers the case that the data type of the target text field is incompatible with the source field (i.e. it is smaller and the content cannot be transferred). In that case, based on the selected source and target fields, ITEM applies by default the following migration logic: creation of Attachment entry with default format.
- **Repeatable into single field mapping / Single into repeatable field mapping** - if there is a single repeatable block entry in the source, the source field is migrated to the single target field. If there are multiple repeatable block entries in the source, then the first existing source field is migrated to the target field. The fields from the remaining repeatable block entries are put inside an attachment. If there is any data loss on the specific field migration, an attachment entry is created.
- **Document / Field merging** – the data is migrated from two or more fields to one or from a single source Document to a single target Document. This process may include data concatenation.
- **Data type change** - MR Type covers the case that the data type of the target text field is incompatible with the source field. Depending on the case of data type change data will be stored as an attachment or in the source/target field (in case data type is suitable).
- **Target default value** - MR Type covers the case that a default value should be set for the target field. This rule is applicable for the fields with a datatype which have default value option available.

When a migration rule is not within the scope of the list above, a so-called Custom migration rule needs to be created to define how the data which is affected by the migration, will be migrated.

Custom migration rules for specific cases:

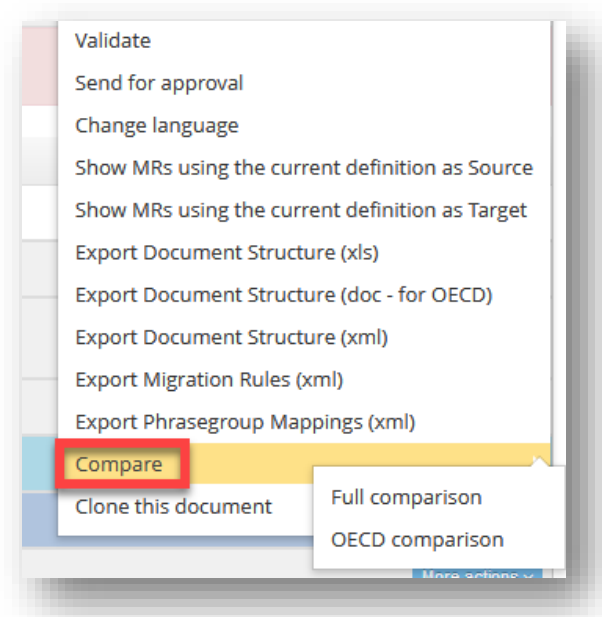
- **New Document per repeatable entry** – ITEM can create one target Document per each repeatable block found in the source Document. The rest of the mappings or other types of migrations, for the fields of the repeatable block, should be customized.

- Default Migration Rule for multilingual information data loss in case of backwards export
- Custom migration rules

5.1.3 Encoding different types of migration rules

The most convenient way to identify a need for a migration rule encoding is comparing of updated Document with previous revision.

This functionality is available for Documents under 'Advanced' function.



Please note that 'OECD comparison' should be used. A comparison Excel Document will be created. Check column 'Change Type' and 'Changed Property' in a Definitions tab. Depending on change type and property manual migration rule is required or not.

| Change Type | Migration rule encoding is required |
|-------------|--|
| ADD | Yes (backward migration, field deletion) |
| CHANGE | Yes/No (see 'Change Property' column) |
| DELETE | Yes (forward migration, field deletion) |

| Change property | Migration rule encoding is required |
|-----------------------|-------------------------------------|
| Path | Yes |
| PhraseGroup revision* | Yes |

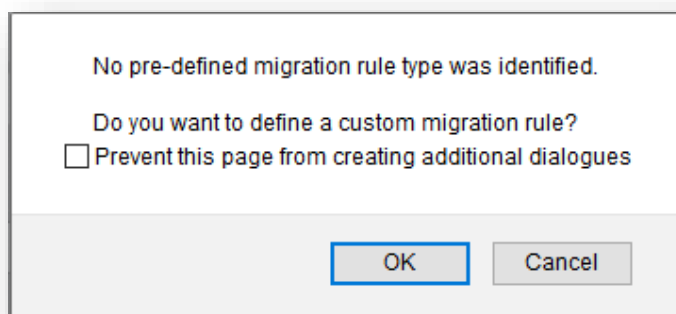
| | |
|------------------------|-----|
| PhraseGroup definition | Yes |
| Field data type | Yes |
| Remarks/UI guidelines | No |
| Help text | No |
| Text Template | No |

* Note, in case only existing Phrases were updated and no new added to a PhraseGroup, a new migration rule is not needed, because such migration is already encoded in ITEM based on Phrase IDs.

When it is identified that a manual encoding of a migration rule is required, start with Migration instance creation.



Fill in required source and target fields depending on the level of the update (i.e. field, Document). Note that MRI Type (backward, forward, mapping) will be automatically populated by the system; explicit user input will be requested when the MRI Type cannot be automatically resolved (e.g. when migrating between different Definition Providers). In addition, ITEM will automatically assign MR Type after Migration instance is created (i.e. PG Mapping, Custom, Path mapping etc.).



In case no Migration Rule type is identified this means either no migration rule is needed and the logic is handled by the system automatically or a custom rule should be specified.

Note, migration is not needed when a new element is added and no data should be stored in that element, for example, a new Document or a field. However, as it was specified above it is still required that data from new version can be migrated to old version, for these scenarios only backward migration should be specified. For further instructions please refer to chapters 'Migration rule including a Document deletion', 'Migration rule including a Field deletion'. Some examples provided below.

If a new Document was created and forward migration rule is encoded or there is no need in forward migration, because the new Document won't store any data from previous version. In this case, backward migration rule should be encoded in ITEM. Migration rule type will be Document deletion.

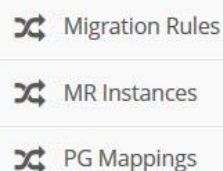
Similar process applies on a field level, for example, a new field is created for a new version of a Document. Backward migration rule for field deletion should be specified, so during migration data from new field will be stored as an attachment.

Note, minor versions of Documents will have migration rules automatically copied from previous revisions. When a new major revision of a Document created migration rules will be removed. Please refer to section 'Version control system and approval mechanisms' for further details.

5.1.4 Working with Migration Rules

You can access the Migration Rules tools form the ITEM's left-side toolbar. Here you will find the following buttons:

- Migration Rules
- MR Instances
- PG Mappings



Migration rule refers to pre-defined functionality in ITEM which applies suitable configuration for of data migration in a particular case e.g. field or Document deletion, field path mapping etc.

Migration rule instance is unique and specific to a Definition, it might use one or multiple migration rules e.g. MRI for a new Document X is using Document deletion migration rule.


5.1.4.1 Migration Rules tab

Migration Rules tab allows the user to view the list of all created migration rules in ITEM.

| Migration Rule » List | | |
|-----------------------|--|------------------|
| Identifier | Migration Rule Type(s) | Actions |
| MR-1 | Field path mapping | Show instances ⚙ |
| MR-10 | Phrasegroup mapping | Show instances ⚙ |
| MR-100 | Phrasegroup mapping | Show instances ⚙ |
| MR-101 | Phrasegroup mapping | Show instances ⚙ |
| MR-102 | Field path mapping Phrasegroup mapping | Show instances ⚙ |
| MR-103 | Custom | Show instances ⚙ |
| MR-104 | Phrasegroup mapping | Show instances ⚙ |
| MR-105 | Field path mapping Phrasegroup mapping | Show instances ⚙ |
| MR-106 | Field path mapping Phrasegroup mapping | Show instances ⚙ |
| MR-107 | Field path mapping Phrasegroup mapping | Show instances ⚙ |

1 2 3 4 5 6 7 8 9 10 .. 14 Next
Max 10 ▼

The columns of the list are:

- *Identifier* – this is the unique identifier of a migration rule. The numbering is chronological. You can sort the list by clicking the  button.
- *Migration Rule Type(s)* – this field shows what type of migration rule belongs to the MR. Note that certain Migration rules can have two or more migration rule types.
- *Actions* – the interactive link *Show instances* redirects the user to a list of all the instances of the specific migration rule, namely, it shows every case of data migration where that migration rule is applicable.

Migration Rule: MR-11 »MR Instances

Applicable MR Type(s) : **Phrasegroup mapping**

| MRI Identifier | Source | Target | Created Date |
|----------------|---|---|------------------|
| MRI 2407602 | OECD - v4.5 Toxicity to terrestrial arthropods - v5.2 Guideline [List (picklist) field] | OECD - v3.11 Toxicity to terrestrial arthropods - v4.19 Guideline [List (picklist) field] | 2018-07-03 14:00 |
| MRI 2299285 | OECD - v4.4 Toxicity to terrestrial arthropods - v5.1 Guideline [List (picklist) field] | OECD - v3.11 Toxicity to terrestrial arthropods - v4.19 Guideline [List (picklist) field] | 2018-05-22 16:39 |

The *Configure*  button redirects a user to a configuration parameters page.

Migration Rule: MR-1 »Configuration

| MR Type | Config Param | Config Value |
|--------------------|--------------------|--------------|
| Field path mapping | Field Path Mapping | Yes |

[Back](#)
[Migration Rule Instances](#)

Migration Rule: MR-106 »Configuration

| MR Type | Config Param | Config Value |
|---------------------|--------------------|---------------|
| Field path mapping | Field Path Mapping | Yes |
| Phrasegroup mapping | phraseGroupMapping | BIO01_forward |

[Back](#) [Migration Rule Instances](#)

Migration Rule: MR-103 »Configuration

| MR Type | Config Param | Config Value |
|---------|--------------|---|
| Custom | logic | free-text to rich text data type change |
| Custom | description | free-text to rich text data type change |

[Back](#) [Migration Rule Instances](#)

5.1.4.2 MR Instances tab


MR Instances tab shows the list of all created migration rule instances. Unlike in the *Migration Rules* tab, the migration rule instances are not grouped by a migration rule (e.g. MR-1). Each migration rule instance also has the applicable MR type specified in the second column. It is possible to have a MRI belonging to one or more migration types.

Migration Rule Instances » List

Q Search by

| MRI Identifier | MR | Applicable MR Type(s) | Source | Target |
|----------------|-------|-----------------------|---|---|
| MRI 2474081 | MR-1 | Field path mapping | CORE - v3.16 Biodegradation in water and sediment: simulation tests - v4.2 Half-life in water [Numeric (decimal including unit) field] | CORE - v4.10 Biodegradation in water and sediment: simulation tests - v5.1 Half-life in marine water [Numeric (decimal including unit) field] |
| MRI 2474070 | MR-7 | Field deletion | CORE - v4.10 Biodegradation in water and sediment: simulation tests - v5.1 Half-life in freshwater [Numeric (decimal including unit) field] | CORE - v3.16 Biodegradation in water and sediment: simulation tests - v4.2 |
| MRI 2474064 | MR-7 | Field deletion | CORE - v3.16 Biodegradation in water and sediment: simulation tests - v4.2 Half-life in water [Numeric (decimal including unit) field] | CORE - v4.10 Biodegradation in water and sediment: simulation tests - v5.1 |
| MRI 2473485 | MR-7 | Field deletion | CORE - v3.16 Acute Toxicity - v3.10 Study name / type [Link to endpoint (multiple) field] | CORE - v4.10 Acute Toxicity - v4.0 |
| MRI 2473481 | MR-65 | Document deletion | OECD - v4.5 Gases under pressure - v3.2 | CORE - v4.10 |





The list contains the following columns:

- MRI Identifier** – this is a unique number given to a MRI to differentiate it from the others. You can sort the list by clicking the  button. Each MRI Identifier is linked to a MRI, by clicking the link you can navigate to a read only view of MRI and by clicking 'Edit' you can update MRI if needed.
- MR** – this is a migration rule of which the MRI is a part of. Different MRIs can be a part of the same MR.
- Applicable MR Type(s)** – this field shows to which type of MRs belongs specified instance as well as, if applicable, which PhraseGroup Mapping is being used. Certain instances can have two or more migration rule types.
- Source** – this column contains the information from where the migrated data are taken. This field can contain such information as:
 - the Definition Provider and the revision used
 - the name of the Document definition and the revision used
 - specific field and field type (e.g. List (picklist) field or Header 1)

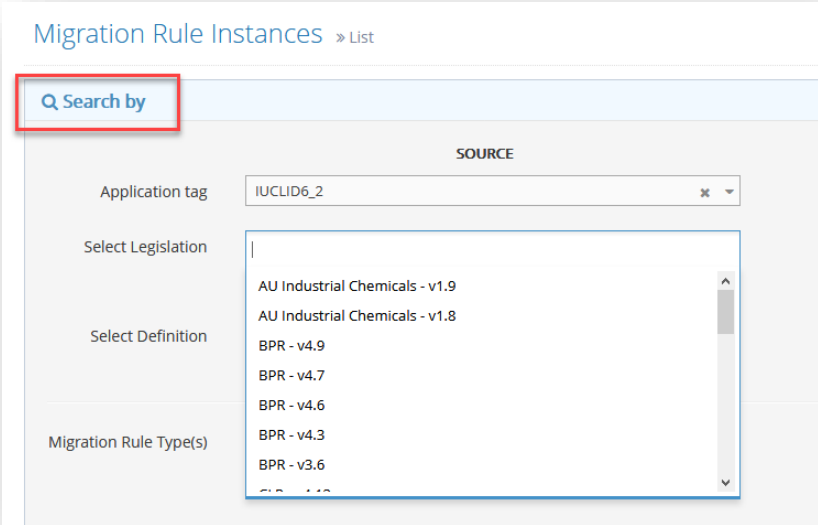
The least specific source provided can be the name of the Document definition and the Definition Provider to which it belongs.

- *Target* - this column contains the information to where the data will be migrated. This field can contain such information as:
 - the Definition Provider and the revision used
 - the name of the Document definition and the revision used
 - specific field and field type (e.g. *List (picklist) field* or *Header 1*)

The least specific target information provided can be the Definition Provider. This applies only to a Document deletion migration rule case.

- *Edited By* – an information on which user made the latest edit to the MRI. You can sort the list by clicking the  button.
- *Edited Date* – an information on when was made the latest edit to the MRI. You can sort the list by clicking the  button.
- *Actions* – the *Configure*  button allows the user to update the MRI as well as delete it using the *Delete*  button. The detailed processes of MRI update and deletion is are described in a separate chapters of this manual.

Search by functionality can be used for filtering different Migration Rule Instances relevant to different versions of Source/Target Application Tags, Definitions, Definition Providers, Migration Rule type, PhraseGroup Mapping.



Migration Rule Instances » List

Q Search by

SOURCE

Application tag: IUCLID6_2

Select Legislation: AU Industrial Chemicals - v1.9, AU Industrial Chemicals - v1.8

Select Definition: BPR - v4.9, BPR - v4.7, BPR - v4.6, BPR - v4.3, BPR - v3.6

Migration Rule Type(s):






5.1.4.3 PG Mappings tab

PG Mappings tab shows the list of all created PhraseGroup Mappings.

PG Mappings » List

| Identifier | Description | Created By | Created Date |
|----------------------|----------------------|------------|------------------|
| GHS33_2_1_to_3_1 | GHS33_2_1_to_3_1 | ... | 2019-08-29 14:53 |
| GHS03_2_to_3_1 | GHS03_2_to_3_1 | ... | 2019-08-29 13:22 |
| PG6-60387_2_1_to_1 | PG6-60387_2_1_to_1 | ... | 2019-09-11 14:35 |
| PG6-60385_2_1_to_1 | PG6-60385_2_1_to_1 | ... | 2019-09-10 16:42 |
| PG6-60385_1_to_2_1 | PG6-60385_1_to_2_1 | ... | 2019-09-10 16:39 |
| GHS33_3_1_to_2_1 | GHS33_3_1_to_2_1 | ... | 2019-08-29 14:54 |
| GHS03_3_1_to_2 | GHS03_3_1_to_2 | ... | 2019-08-29 14:51 |
| NM14_2_1_to_1_1 | NM14_2_1_to_1_1 | ... | 2019-08-29 08:37 |
| PG6-60335_2_3_to_1_0 | PG6-60335_2_3_to_1_0 | ... | 2019-08-29 08:36 |
| NM14_1_1_to_2_1 | NM14_1_1_to_2_1 | ... | 2019-08-29 08:30 |

The list contains the following columns:

- *Identifier* – this is an identifier given by the user to a specific PG Mapping. You can sort the list by clicking the  button.
- *Description* – here an additional information regarding the PG Mapping are stored.
- *Created by* – an information on which user has created the PG Mapping.
- *Created Date* – creation date of the PG mapping. You can sort the list by clicking the  button.
- *Edited by* – an information on which user made the latest edit to the PG Mapping. You can sort the list by clicking the  button.
- *Edited Date* – an information on when was made the latest edit to the PG Mapping. You can sort the list by clicking the  button.
- *Actions* – the *More actions*  button allows the user to:
 - *Show usages* – this option will redirect the user to the *MR Instances* showing only those MR instances which include the selected PG Mapping.

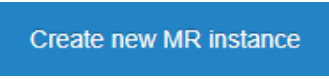
- *Edit* – allows the user to edit parameters of the PG Mapping.
- *Export PhraseGroup Mapping (xml)* – generates an xlm file containing mappings of the Phrases.

5.1.5 Create a Migration Rule Instance

5.1.5.1 MRI on the Document level

The steps for creating a Migration rule are:

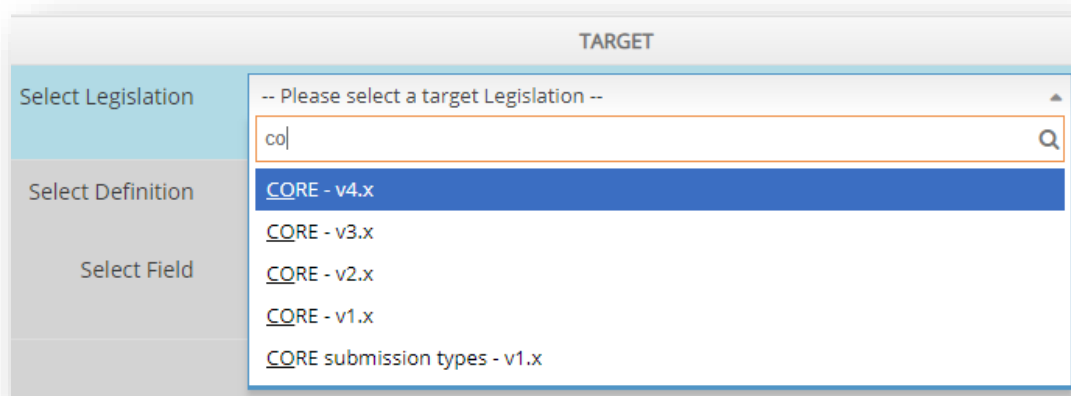
A) Go to either *Migration Rules* or *MR Instances* tab.

B) Click *Create new MR instance*  on the bottom of the page.

C) You will be redirected to a New MR instance page.

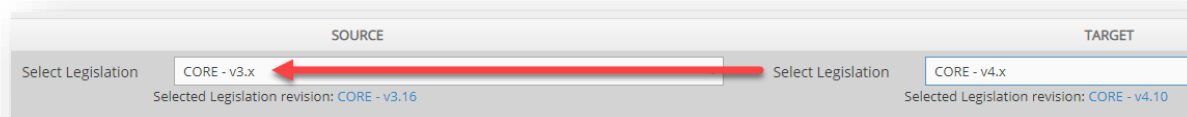
Fill the required information for both **source** (left side of the form) and **target** (right side of the form) of the MR instance. The target Definition Provider field is marked blue. This is the starting point of the MR instance creation process.

- *Select Definition Provider* - From this picklist you can select a Definition Provider to which your Document belongs to. If you type first letters of the Definition Provider name, ITEM will hint the matching available Definition Providers and their revisions.

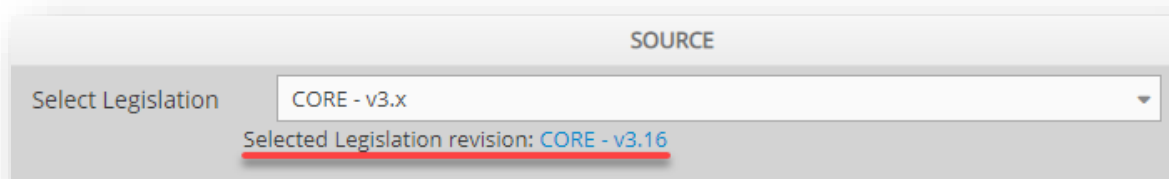


| TARGET | |
|--------------------|--|
| Select Legislation | -- Please select a target Legislation -- |
| Select Definition | co |
| Select Field | <div> <div>CORE - v4.x</div> <div>CORE - v3.x</div> <div>CORE - v2.x</div> <div>CORE - v1.x</div> <div>CORE submission types - v1.x</div> </div> |

When you select a target Definition Provider, ITEM will automatically populate the source Definition Provider field with the latest previous finalised major version of the Definition Provider.



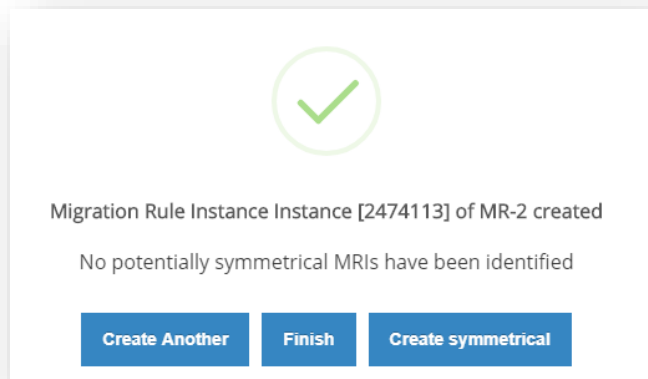
You can verify whether the selected Definition Provider is the desired one by clicking on the link below the corresponding field.



The following structure with an older version of the Definition Provider selected as a source and a newer one as the Target is a structure for a forward migration rule. You can change the source Definition Provider manually. If the version of the source Definition Provider is higher than that of the target, the migration rule is being considered as a backward migration.

- *Select Definition* - Both target and source fields will be inactive if the source and target Definition Providers are not being selected.
- D)** Start from the target Definition. From the picklist select a Document Definition either to be migrated or to which a specific field belongs to. If you type first letters of the Document Definition name, ITEM will hint the matching Document. When you select a target Document Definition, ITEM will automatically populate the source Document Definition field with the latest previous finalized major version of the Document. Specify MRI Type (Forward, Backward, Mapping)

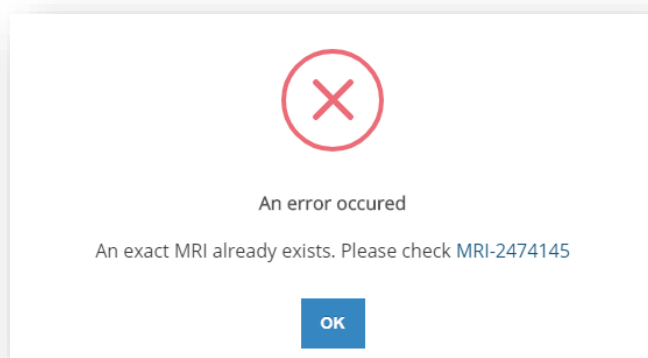
- E) If you create a MRI on a Document level, this is the last step of the process. Click [Continue](#) button at the bottom of the page to approve creation of a new MRI. You will receive a notification that the new MRI has been created:



Select:

- *Create another* - to create a new MRI.
- *Finish* – to finish the process of MRI creation.
- *Create symmetrical* – to create a symmetrical MRI. Symmetrical migration rules are described in detail further in this manual.

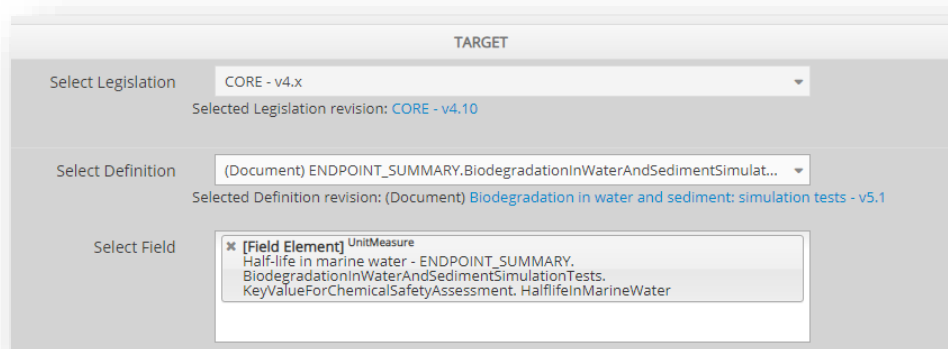
If the exact same source and target settings have been predefined in another MRI you will get a notification that an exact MRI already exists with a link to the MRI.




5.1.5.2 MRI on a field level

If you want to create a MRI on a field level, proceed in the same way as with Document level MRI (points **A** to **C** from the previous chapter). Then:

- D) Select Field** – click on the field to view the list of all available Document elements. You can also search for the element you need by typing the first letters of its name or by inserting path identifier. Select Document elements for both Source and Target fields. Please note, in case field is mandatory it will be in red text.



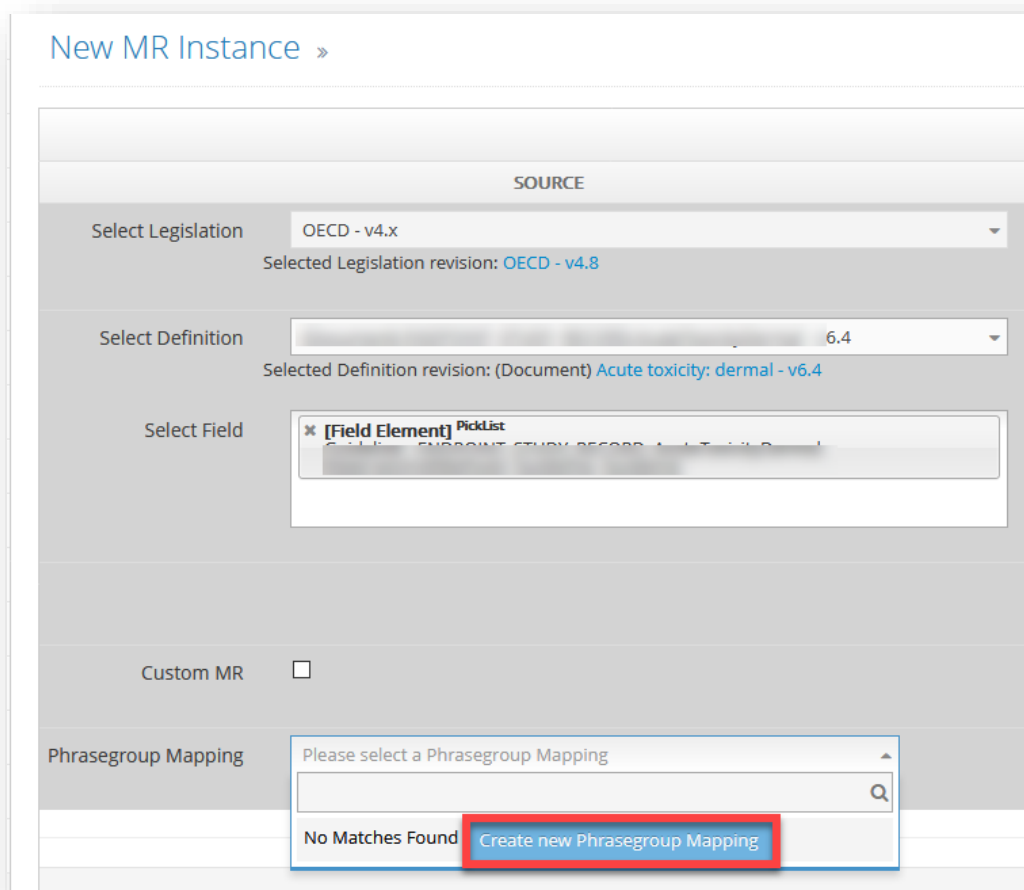
- E) Specify MRI Type**

- F) Click Continue**  button at the bottom of the page to approve creation of a new MRI. Again you will receive a notification that the new MRI has been created. Click finish or proceed working on other MRIs creation.

If the exact same source and target settings have been predefined in another MRI you will get a notification that an exact MRI already exists with a link to the MRI.

5.1.5.3 MRI for a picklist field


When you start creating MRI for a field that uses a picklist you will be asked to provide a PhraseGroup mapping.



By clicking 'Create new PhraseGroup Mapping' button you will be navigated to the page with pre-defined source and target PhraseGroups which need to be mapped. It is possible that some Phrases have migration mapped already (when migrations logic is already pre-encoded in ITEM). The Phrases which don't have selection should be manually mapped. Define selections and create PG Mapping. Note, there is a naming convention for PG mappings. Identifier should only include underscore sign and should identify from which PG to which mapping is done, including revisions of PhraseGroups for example PG6_00001_1_1_to_PG6_00001_2_0. The name should be unique, if the same name already exists you will be notified.

You will find more information on creation of PG mappings in the chapter covering this subject (Migration of fields using PhraseGroups). Then proceed in the same way as with field level MRI.

When you select the Source and Target fields ITEM will automatically assign a proper PG Mapping to be used in the MRI (given that the mapping was already predefined) with a preview of the Phrases pairing.

- G)** Click Continue  button at the bottom of the page to approve creation of a new MRI. Again you will receive a notification that the new MRI has been created. Click finish or proceed working on other MRIs creation.

If the exact same source and target settings have been predefined in another MRI you will get a notification that an exact MRI already exists with a link to the MRI.

5.1.5.4 Custom MRI


If you want to create a Custom MRI on the field level, proceed in the same way as with Document level MRI (points **A** to **C** from the earlier chapter). Then tick the box:

New fields will appear:

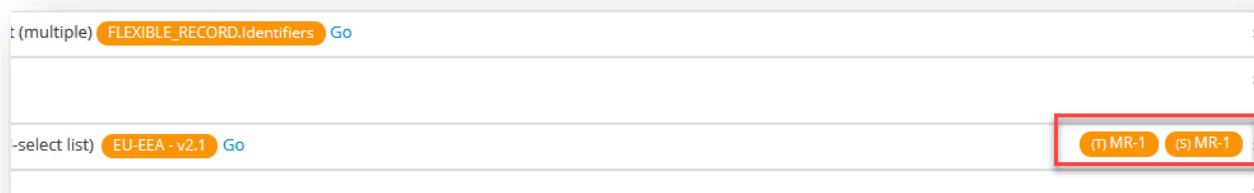
- *Description* – provide an informative name for your custom MR
- *Migration guidelines* – provide the guidelines for the MR in XML.

Note that in nearly all situations, the predefined migration rules should cover the different types of migration usually needed between major versions of IUCLID. Ensure that a Custom MRI is

really necessarily, and if so, contact the IUCLID team to ensure the Custom rule is clear enough for implementation.

- H) Click Continue  button at the bottom of the page to approve creation of a new MRI. Again you will receive a notification that the new MRI has been created.

Note, all encoded migration rules will be displayed in the Documents depending on MR location, it will be also identified if a field is used as a source (S) or a target (T).



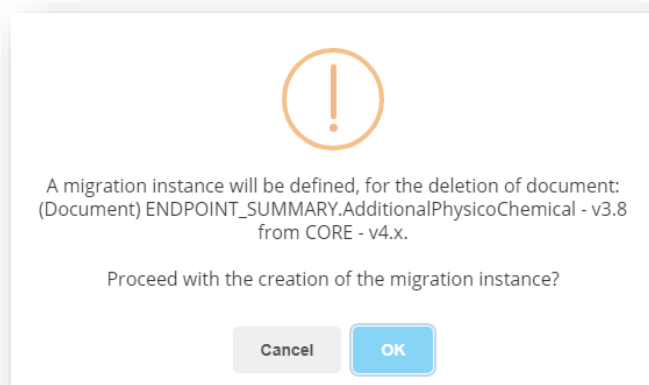
5.1.6 Migration Rule including a Document deletion

In a situation when a Document Definition is no longer present in an earlier or a later revision of a Definition Provider and there is no corresponding new Definition for the data to be transferred to, we deal with a Document Deletion Migration type.

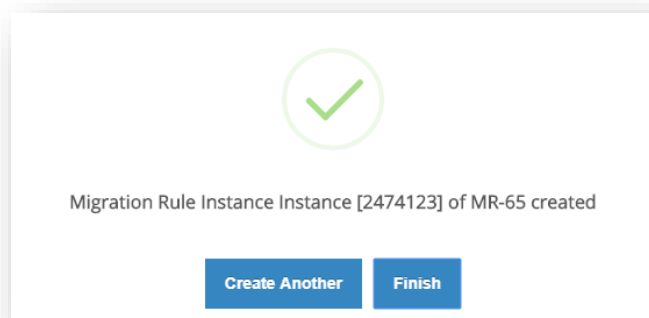
To create a MRI for a Document Deletion Migration type proceed as follows:

- A) Go to Create a New Migration Instance page.
- B) Select Target and Source Definition Providers. Depending whether the Document no longer exist in a newer or older version of the Definition Provider, select revisions of the Definition Provider to create either a forward or a backward MRI.
- C) Select the Document to be deleted in the source *Select Definition* field. Leave the target *Select Definition* field empty.

D) Click *Continue*. A following notification including the name of your Document will appear:



E) Click OK. You will receive a notification that the new MRI has been created:



In case of a Document deletion type of migration it is not possible to create a symmetrical migrarion instance.

Click finish or proceed working on other MRIs creation.

The data from the deleted Document are stored in a text file attachment. You can find it in the information panel of IUCLID.

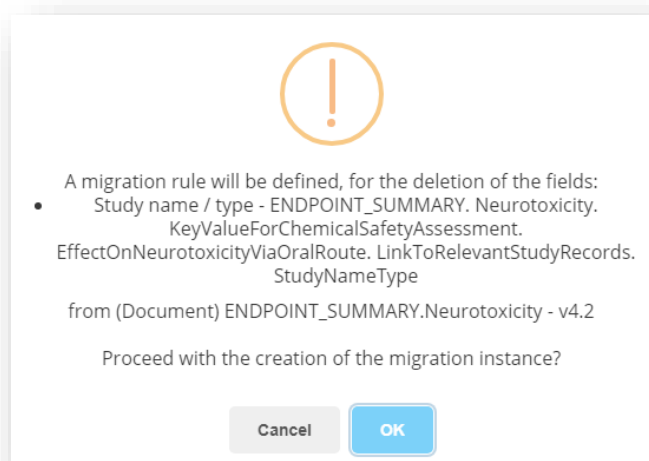
5.1.7 Migration Rule including a Field deletion

In a situation when a Document Definition's field is no longer present in an earlier or a later revision of the Document the data from the field can be:

- Migrated to another field. In this case proceed as with any other field mapping and select other corresponding field.
- Deleted and stored in an attachment to the Document so there is no data loss.

To create a MRI for a Field Deletion Migration type (second option) proceed as follows:

- A) Go to Create a New Migration Instance page.
- B) Select target and source Definition Providers and a target and source Document Definition. Depending whether the field no longer exist in a newer or older version of the Document, select revisions of the Document to create either a forward or a backward MRI.
- C) Select the field to be deleted in the source *Select Field* field. Leave the target *Select Field* field empty.
- D) Click *Continue*. A following notification including the name of your Document and the field name will appear:



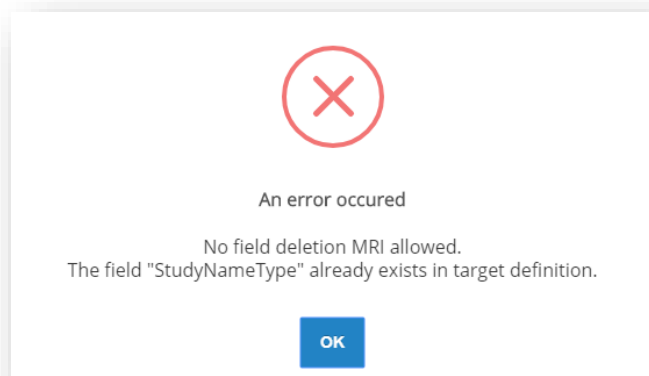
- E) Click OK. You will receive a notification that the new MRI has been created.

In case of a field deletion type of migration it is not possible to create a symmetrical migration instance.

Click finish or proceed working on other MRIs creation.

The data from the deleted Document are stored in a text file attachment. You can find it in the information panel of IUCLID.

Important: it is not possible to create a field deletion type migration instance for fields that exist in both revisions of the selected Document Definitions. The following notification will appear:



5.1.8 Create a symmetrical Migration Rule Instance

ITEM facilitates the creation of symmetrical MRIs. Creating a symmetrical MRI means creating a new MRI based on the existing one, where Target and Source fields are swapped. The population of the form will be automatic.

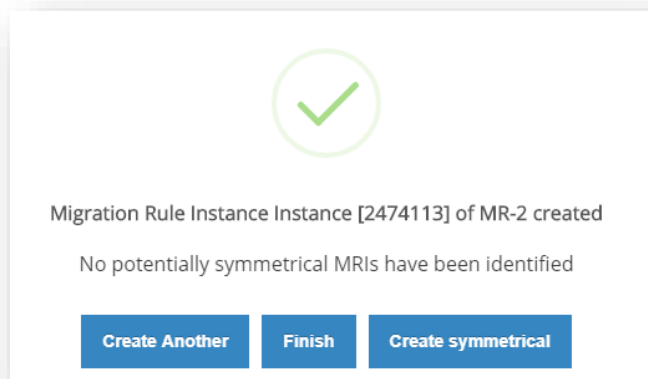
5.1.8.1 Symmetrical MRI for a new MRI

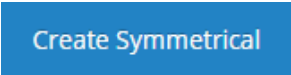
The steps to create a new symmetrical MRI are:

A) Create any MRI as described in the previous chapters. Click

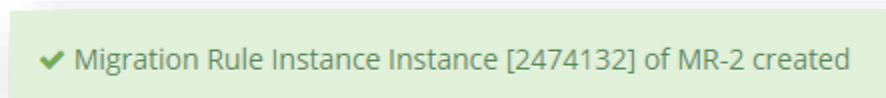
Continue

B) You will receive a notification that the new MRI has been created:



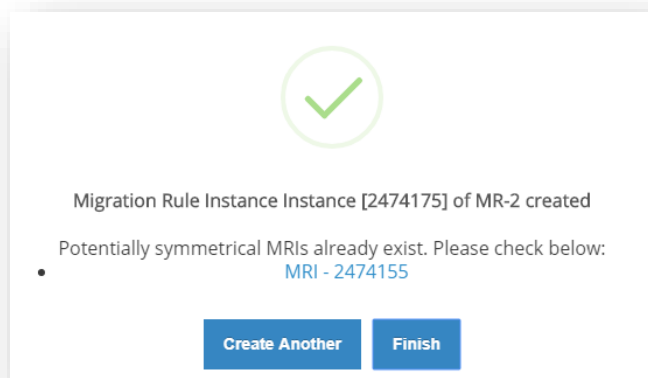
The notification states that no potentially symmetrical MRIs have been identified. It means that the user is free to create a new symmetrical MRI. Select  button.

C) Above the New MR Instance form you will receive a notification that the new MRI has been created. A new form for a symmetrical MRI will open with the fields populated automatically.



Important: to create a symmetrical MRI for a field migration using a PG mapping, the PG mapping has to be predefined in both directions.


If a symmetrical rule already exist for this specific MRI you will be notified with a message stating that a potentially symmetrical MRIs already exist with a link to this MRI:




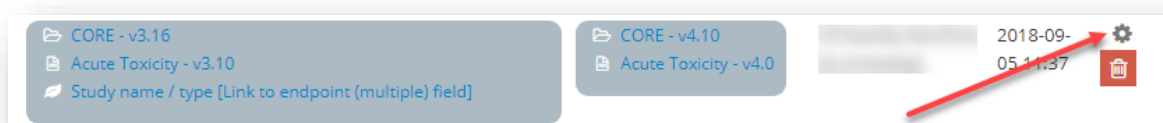
5.1.8.2 Symmetrical MRI for a pre-existing MRI

The steps to create a symmetrical MRI for a pre-existing MRI are:

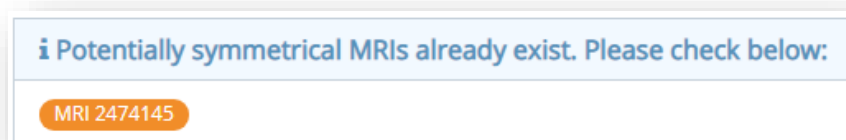
A) Go to *MR Instances* tab.

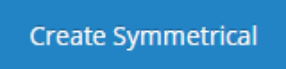
B) Use the  Search by < feature above the migration instances list to look for your migration instance.

C) Use the *Configure*  button to access the edition page of the Instance.




D) If a symmetrical rule already exist for this specific MRI you will be notified by a message at the top of the MRI panel stating that a potentially symmetrical MRIs already exist with a link to this MRI.



E) If no predefined symmetrical MRI exists continue with creation of a new one. At the bottom of the page you will find  button. Click it.

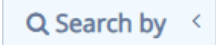
F) A new form for a symmetrical MRI will open with the fields populated automatically.


G) Click  to approve the creation of the new MRI.

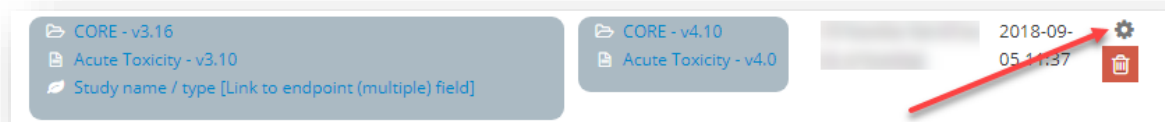
5.1.9 Update a Migration Rule Instance

The steps for updating a Migration Rule Instance are:

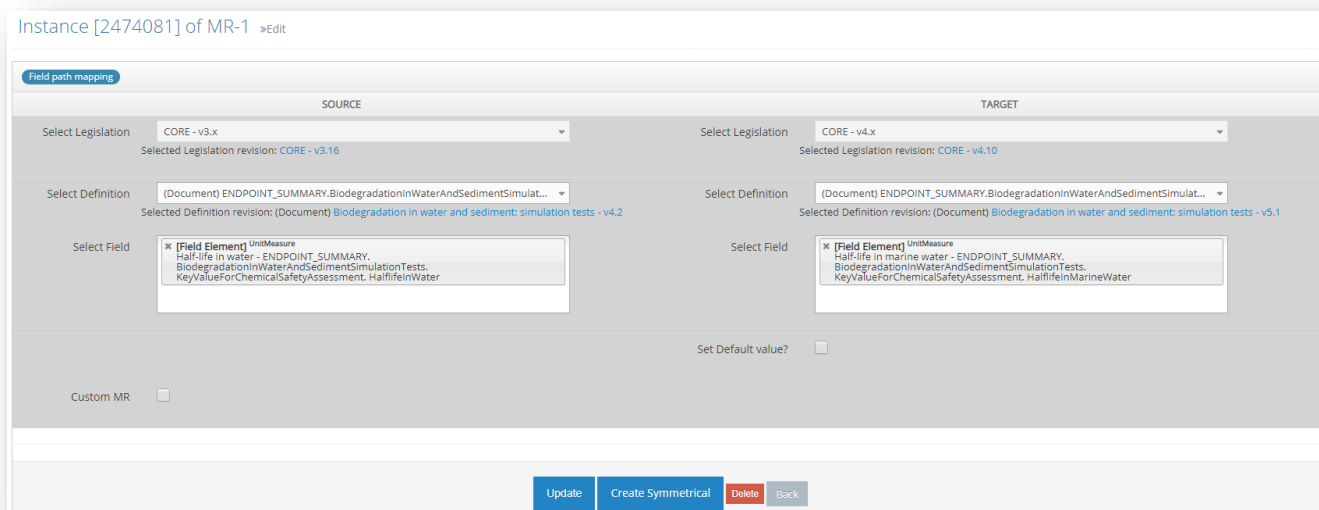
H) Go to *MR Instances* tab.


I) Use the  feature above the migration instances list to look for your migration instance.

J) Use the *Configure*  button to access the edition page of the Instance.

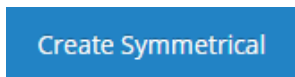


K) Introduce required changes using the exact same form as in case of the creation process of the MR instance.



L) When you finish, click .

M) If you want to create a symmetrical MR to the one already existing, click



5.1.10 Delete a Migration Rule Instance

The steps for deleting a Migration Rule Instance are:

A) Go to *MR Instances* tab.

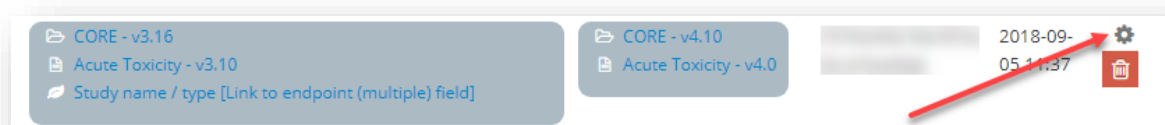
B) Use the  feature above the migration list to look for your migration instance.

C) Use the *Delete*  button to delete the instance.

D) Confirm that you want to delete the instance. Your instance has been deleted.

Or:

C) Use the *Configure*  button to access the edition page of the Instance.



D) Access the edit MR Instance page.

E) Use the *Delete*  button at the bottom of the page to delete the instance.

F) Confirm that you want to delete the instance. Your instance has been deleted.

5.1.11 Migration of fields using PhraseGroups

The most common migration rules require migration of the data from one field to another. These fields can be of different types storing e.g. only text or numerical values. A specific situation is when data has to be migrated from a **picklist** field. These field types use a predefined, selectable set of Phrases and does not contain any information itself. This set of Phrases is called a PhraseGroup in ITEM.

During migration, PhraseGroups have to be treated separately and as an additional element of the field mapping process. A new migration, called *PhraseGroup Mapping* (also *PG mapping*) has to be defined first, before or during proceeding with a creation of the migration rule for a field.

PG mapping allows to map (or 'pair'), selected Phrases between different versions of the PhraseGroup. Phrases contained in a PhraseGroup have their unique ID numbers. Due to that, Phrases whose IDs have remained unchanged between the versions are going to be mapped automatically. Phrases whose IDs have changed together with the Phrases themselves, can be mapped manually to a Phrase of the user's choice. Usually for this purpose a generic Phrase like *Other:* is being used. The user can also decide not to map those Phrases – this will be treated as a Phrase deletion and the information will be stored as a Document attachment.

5.1.11.1 Create a PG Mapping

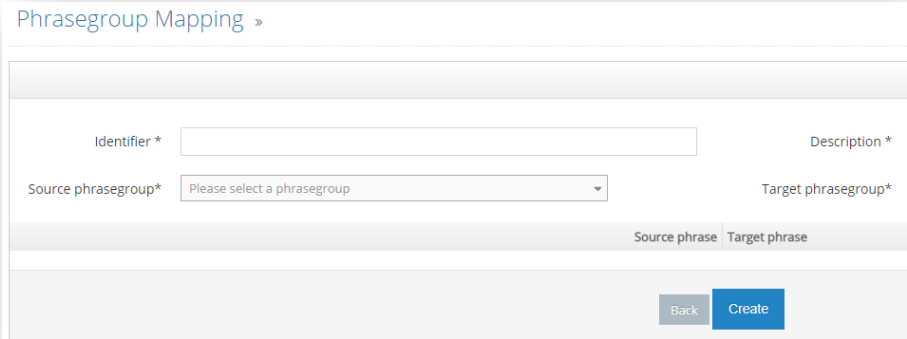
There are two ways to create PG Mapping in ITEM.

5.1.11.1.1 Creating PG Mapping from PG Mappings tab

The steps for creating a PG Mapping are:


A) Go to “PG Mappings”. Click the  button.

B) A new page will open with a form that needs to be filled in order to create a new PG Mapping.

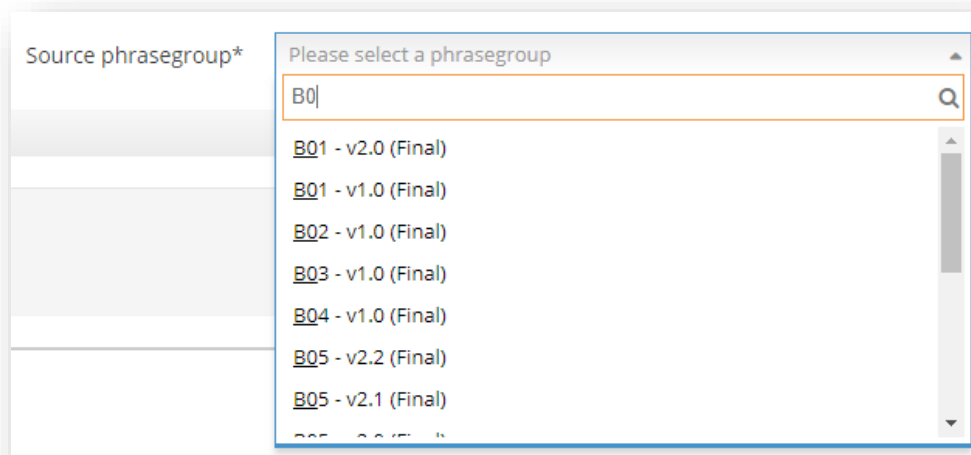


Fill in the following fields:

- *Identifier* – this is a name of your PG mapping. Give it an unambiguous name describing the direction of the mapping. For example mapping from an older to a newer version of a PhraseGroup *B05* can be named *B05_v1_0_to_v2_0*.



- *Description* – this field allows you to add any additional information about your PG mapping.
- *Source PhraseGroup* – it is a PhraseGroup from which the information are going to be migrated to the target PhraseGroup. Provide an actual name of a pre-existing PhraseGroup. Upon typing first letters of the PhraseGroup's name, ITEM will provide you with suggestions.



Those include: a PhraseGroup matching the name provided as well as all of its available revisions.

Important: only finalized PhraseGroups can be selected from this field. Phrasegroups in a Draft status are not going to be visible on the list.

Select the PhraseGroup you want to use in the PG mapping.

- *Target PhraseGroup* – this field is not populated automatically as in case of Definition Provider or Document Definitions in MRI creation process. Manually select either a revision of your PhraseGroup or a different PhraseGroup you want to use as the target of your PG mapping.

If the same PhraseGroup in different revisions is selected, depending on which revision of the PhraseGroup you will use as a source or target, the PG mapping will have a forward or backward direction. Bear in mind that the direction of the PG mapping has to be consistent with the direction of the MR Instances where you want to use it.

- C)** Then review the PG mappings: If you use different revisions of the same PhraseGroup and the IDs of Phrases belonging to the PhraseGroups have not changed, ITEM will automatically pair matching Phrases.

Phrasegroup Mapping »Edit

| Identifier | NM14_2_1_to_1_1 | Description | NM14_2_1_to_1_1 |
|--|---|--------------------|---------------------|
| Source phrasegroup | NM14 - v2.1 (Final) | Target phrasegroup | NM14 - v1.1 (Final) |
| Source phrase | Target phrase | | |
| analytical centrifugation - [AC] - (58209) | analytical centrifugation - (58209) | | |
| atomic force microscopy - [AFM] - (58280) | AFM - (58213) | | |
| dynamic light scattering - [DLS] - (65575) | DLS - (58208) | | |
| Mie scattering - (58212) | Mie scattering - (58212) | | |
| particle tracking analysis - [PTA] - (58210) | particle tracking - (58210) | | |
| scanning electron microscopy - [SEM] - (58279) | SEM - (58206) | | |
| sedimentation (centrifugal) - (58214) | sedimentation (centrifugal) - (58214) | | |
| sedimentation (gravitational) - (58215) | sedimentation (gravitational) - (58215) | | |
| transmission electron microscopy - [TEM] - (58278) | TEM - (58207) | | |
| UV/Visible spectroscopy - (61570) | UV-VIS - (58211) | | |
| Open other: - (1342) | Open other: - (1342) | | |

[Back](#) [Edit](#)

In a situation when Phrase's ID has changed or the Phrase has been deleted, ITEM will not be able to create a pairing. Those Phrases are going to be marked as *No Mapping / Phrase deletion*.

| Source phrase | Target phrase | |
|--|--------------------------------|-----------------|
| mL - (58371) | mL - (58371) | |
| mg - (64929) | -- No Mapping -- | Phrase deletion |
| L - (58372) | L - (58372) | |
| g - (58373) | g - (58373) | |
| kg - (58374) | kg - (58374) | |
| tonnes - (64930) | -- No Mapping -- | Phrase deletion |
| cm³ - (58375) | cm³ - (58375) | |
| m³ - (58376) | m³ - (58376) | |
| not applicable, ready to use product - (58377) | not applicable, ready to use p | |
| Open other: - (1342) | -- No Mapping -- | Phrase deletion |

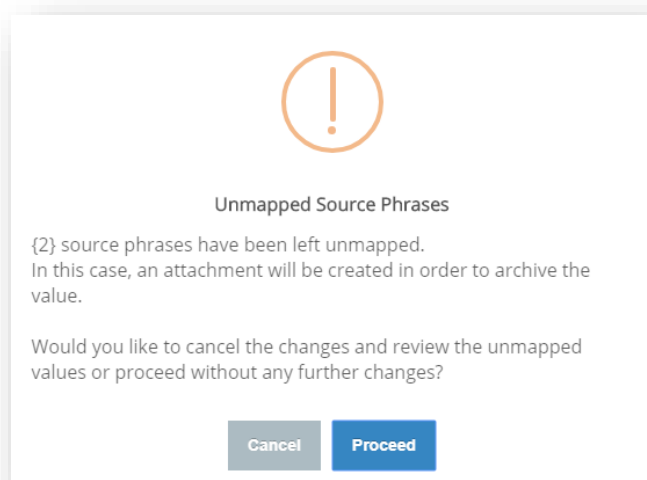
In this case the Phrase can either be deleted and stored as an attachment or matched to a different Phrase. This user can choose manually by selecting whichever Phrase from the picklist. Good approach is to match the unpaired Phrase to the open Phrase *Other*:. The

unpaired Phrase will then be migrated as *Other:* position in the picklist with the original Phrase stored in the additional *Remarks* field that follows the field.

| Source phrase | Target phrase |
|--|---|
| mL - (58371) | mL - (58371) ▼ |
| mg - (64929) | -- No Mapping -- ▼ Phrase deletion |
| L - (58372) | -- No Mapping -- |
| g - (58373) | mL - (58371) |
| kg - (58374) | L - (58372) |
| | g - (58373) |
| | kg - (58374) |
| | cm³ - (58375) |
| | m³ - (58376) |
| tonnes - (64930) | not applicable, ready to use product - (58377) |
| | other: - (1342) on |
| cm³ - (58375) | cm³ - (58375) ▼ |
| m³ - (58376) | m³ - (58376) ▼ |
| not applicable, ready to use product - (58377) | not applicable, ready to use p ▼ |
| Open other: - (1342) | -- No Mapping -- ▼ Phrase deletion |

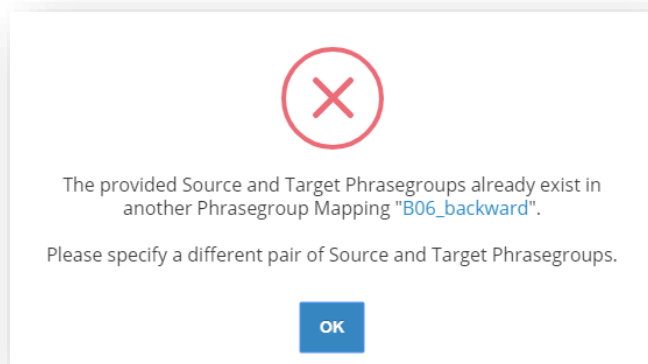
This mechanism also applies when a mapping is created between two completely different PhraseGroups.

- D) You can also make changes to already predefined pairings. Afterwards click Create to create a new PG mappings. If the mappings does not include Phrases to be deleted you will receive an information that your PG mapping has been created. Otherwise you will receive a following notification:



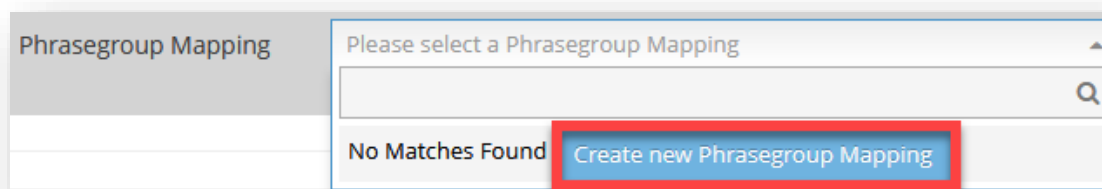
- N) Click **Proceed** to approve the creation of the new PG mapping. Your new PG mapping has been created.

Important: it is not possible to create another PG mapping for a PhraseGroup pair already used in another PG Mapping. The following notification will appear:



5.1.11.1.2 PG Mapping through MR instance creation

In case PG mapping is required for MR instance ITEM will automatically suggest creation of a new PG Mapping.



By clicking the button you will be navigated to the page with predefined PG mapping. ITEM will automatically pair Phrases with the same ID and mark those which are not possible to pair.

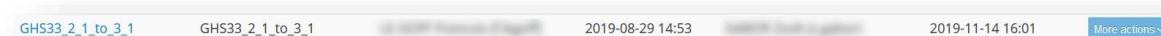


You should fill in Identifier and Description and encode mapping for the unmapped Phrases. If no mapping is specified Phrase will be deleted.

5.1.11.2 Update a PG Mapping

The steps for updating a PG Mappings are:

- A) Go to *PG Mappings* tab.
- B) Find the desired PG mapping on the list.
- C) Go to *More actions* -> *Edit* to access the edition page of the PG Mapping.



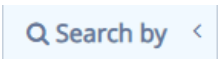

| | | | | |
|-------------------|-------------------|------------------|------------------|----------------|
| GHS333_2_1_to_3_1 | GHS333_2_1_to_3_1 | 2019-08-29 14:53 | 2019-11-14 16:01 | More actions ▾ |
|-------------------|-------------------|------------------|------------------|----------------|

- D) Introduce required changes using the exact same form as in case of the creation process of the PG Mapping.

- E) When you finish click .

5.1.11.3 Delete a PG Mapping

The steps for deleting a PG Mapping are:

- A) Go to *MR Instances* tab.
- B) Use the  feature above the migration list to look for your migration instance.
- C) Use the *Delete*  button to delete the instance.
- D) When asked, confirm that you want to delete the instance. Your instance has been deleted.

5.1.12 Automatically create Migration rules between GHS documents

It is possible to automatically create Migration rules (as well as Dynamic content rules, cf. 6. Dynamic content rules) with the “Add Phrases, Mapping rules and DCRs from file (xls)” functionality. It is accessible via the “Advanced” menu of a PhraseGroup.

This functionality should be utilised when users want to create an error-free mapping between the GHS Flexible Record and a Custom GHS Document. It maps the single (multiple-selection) picklist field of the Custom GHS with the relevant picklist fields (Hazard Category/Statement fields) of the Custom GHS.

The Excel file to be imported should follow a predefined and more complex structure than the one required to simply import Phrases into a PhraseGroup from an xls file. An example of the structure:

| | A | B | C | D |
|----|---|-----------------------------|---------------------|-----------------|
| 1 | PhraseText | AdditionalPhraseText | ObsoleteFlag | OpenFlag |
| 2 | Unst. Expl.-H200: Unstable explosives. | | FALSE | FALSE |
| 3 | Expl. Div. 1.1-H201: Explosive; mass explosion hazard. | | FALSE | FALSE |
| 4 | Expl. Div. 1.2-H202: Explosive; severe projection hazard. | | FALSE | FALSE |
| 5 | Expl. Div. 1.3-H203: Explosive; fire, blast or projection hazard. | | FALSE | FALSE |
| 6 | Expl. Div. 1.4-H204: Fire or projection hazard. | | FALSE | FALSE |
| 7 | Expl. Div. 1.5-H205: May mass explode in fire. | | FALSE | FALSE |
| 8 | Expl. Div. 1.6-No hazard statement | | FALSE | FALSE |
| 9 | Des. Expl. 1-H206: Fire, blast or projection hazard; increased risk of explosion if deser | | FALSE | FALSE |
| 10 | Des. Expl. 2-H207: Fire or projection hazard; increased risk of explosion if desensitisin | | FALSE | FALSE |

| | E |
|----|--|
| 1 | standard-category-path |
| 2 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardCategory |
| 3 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardCategory |
| 4 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardCategory |
| 5 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardCategory |
| 6 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardCategory |
| 7 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardCategory |
| 8 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardCategory |
| 9 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.HazardCategory |
| 10 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.HazardCategory |

| | F |
|----|---|
| 1 | standard-statement-path |
| 2 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardStatement |
| 3 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardStatement |
| 4 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardStatement |
| 5 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardStatement |
| 6 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardStatement |
| 7 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardStatement |
| 8 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardStatement |
| 9 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.HazardStatement |
| 10 | FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.HazardStatement |

| | G | H |
|----|-------------------------------------|--|
| 1 | group | custom-element-path |
| 2 | (Physical)-Explosives/ | CUSTOM_SECTION.PCN_GHS.Classification.HazardCategoriesStatements |
| 3 | (Physical)-Explosives/ | |
| 4 | (Physical)-Explosives/ | |
| 5 | (Physical)-Explosives/ | |
| 6 | (Physical)-Explosives/ | |
| 7 | (Physical)-Explosives/ | |
| 8 | (Physical)-Explosives/ | |
| 9 | (Physical)-Desensitized explosives/ | |
| 10 | (Physical)-Desensitized explosives/ | |

Instructions for importing phrases from xls file and automatic DCR/Mapping-rules creation:

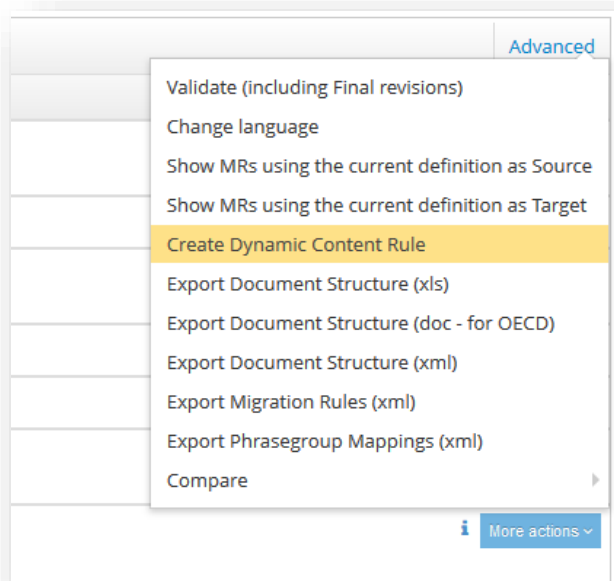
- A)** Create a new PhraseGroup.
- B)** Associate this new (empty) PhraseGroup with the target picklist field.
- C)** Navigate to the PhraseGroup revision page and click the option “Add Phrases, Mapping rules and DCRs from file (xls)” from the ‘Advanced’ menu.
- D)** In the pop-up window, provide the import file that has the structure visualized above.
- E)** Click the “Import Phrases” button at the bottom of the “Import phrases validation report” page.

6 DYNAMIC CONTENT RULES

Document dynamic content functionality allows to encode rules in ITEM-defined entities and Documents so certain fields, blocks or pick-list values can be deactivated or hidden conditionally on the presence or absence of other values in the same Entity or Document.

Dynamic Content Rule functionality can be accessed through 'Advanced' features of an ITEM element (Document, block or Entity).

Note that Dynamic Content Rules can be encoded both for a draft and finalized definition.



By selecting 'Create Dynamic Content Rule' user is navigated to a new page to define the DCR instance as shown below.

6.1 Creation of Dynamic Content Rule

Dynamic Content Rules describe IUCLID UI behavior in a form of user-defined Condition(s) and Action(s).

Dynamic Content Rule Condition consists of a Document element, e.g. field 'Endpoint', and one of the following operators:

- `_is_`:
 - In a single picklist: the Document element solely matches a specific Phrase value from the available Phrases included in the PhraseGroup

- In a multi picklist: set of the values of the Document element is equal to the set of selected Phrase values
- _is not_:
 - In a single picklist: the Document element will not have a specific Phrase value
 - In a multi picklist: the Document element will not have the selected Phrase values from the set of the Phrases
- _is any of_: the Document element will have any of the selected values
- _is none of_: the Document element will not have the selected values
- _is selected_: the Document element will be selected
- _is not selected_: the Document element won't be selected
- _is empty_: the Document element will not be populated
- _is not empty_: the Document element will be populated
- _contains_: the selected Document element should contain the selected values

Dynamic Content Rule Action consists of a Document element, e.g. field 'Data waiving', and one of the following actions:

- _Disable picklist's values_: certain value(s) cannot be selected
- _Hide field_: field or block of fields is hidden entirely
- _Mark as required_: field is marked as mandatory, error message can be modified.
- _Disable_: field or block of fields becomes non-editable

Specific operators and actions are dependent on the field type. For instance, pick-lists in Condition will have only _is selected_ and _is not selected_ operators as well as Disable, Hide, and Mark as required actions.

Example:

Requirements: Given an OHT Document 'Flash point - Endpoint Study Record', it is required that a user **cannot** insert any data into the fields 'Data waiving' and 'Justification for data

waiving' if 'experimental study planned' or 'experimental study planned (based on read-across)' is selected in the field 'Type of information'.

Implementation through DCR functionality:

- A. Check if the fields defined in the Document are only Document specific or belong to a block of fields. In case the fields belong to a block, unless specified, DCR should be encoded on a block level.
- B. For this example the fields belong to an 'Administrative data record block'. This means the block should be updated with DCRs and the updates will be introduced in all Definitions there the block is used.

| Label | Datatype |
|---|---|
| 1 Administrative data record block - v4.0 | |
| Administrative data - (H1) | |
| Confidentiality | |
| Endpoint | List sup. (picklist with remarks) PG6-60051 - v1.2 Go |
| Type of information | List sup. (picklist with remarks) Z05 - v2.4 Go |

- C. Go to the block
- D. Check if the block is of the latest revision (DCR can be encoded only for the latest version of a Definition)
- E. Open DCR creation page through 'Advanced' features → 'Create Dynamic Content Rule'
- F. Fill in relevant fields for Conditions and Actions:

Condition

- Document Element: Type of information
- Operator: is any of

- Value: 'experimental study planned', 'experimental study planned (based on read-across)'

| Condition 1 | | |
|---|-----------------|--|
| Select Document Element | Select operator | Value Select all <input type="checkbox"/> |
| Type of Information - AdministrativeData. StudyResultType | is any of | <input checked="" type="checkbox"/> 1896 - experimental study planned <input checked="" type="checkbox"/> 60002 - experimental study planned (based on read-across) |
| Add another Condition | | |

Actions

Action 1:

Document Element: Data waiving

| Action 1 | |
|--|---------------|
| Select Document Element | Select action |
| Data waiving - AdministrativeData. DataWaiving | Disable |

Action: Disable

Action 2:

Document Element: Justification for data waiving

Action: Disable

| Action 2 | |
|---|---------------|
| Select Document Element | Select action |
| Justification for data waiving - AdministrativeData. DataWaivingJustification | Disable |
| Add another Action | |

Outcome: the rule which handles the logic of disabling specific field(s) based on specific selections in another field is created. Note that the rule instance will be displayed for the Condition field and not for the Action field. DCR instance has a prefix 'DCR-' and a unique numerical identifier:

DCR-2945702

Note that the logical operator for both the Conditions and Actions of a Dynamic Content Rule is a logical AND.

This means that only if all the Conditions specified in a DCR are true, then all the Actions of that DCR will be performed.

In order to create DCRs whose Conditions are a logical OR, multiple DCRs must be created: one for each different Condition, having the same Actions.

Note that in case the Document element selected in Action is a header element, all the sub-fields of the relevant header element will be disabled.

6.2 Representation in IUCLID

Given the DCR above, a user will see the following behaviour in every Document that has the Administrative data record block with the following fields: 'Type of information', 'Data waiving', and 'Justification for data waiving':

Administrative data None None

Endpoint
boiling point

Type of information
experimental study planned

Adequacy of study
None

☐ Robust study summary

☐ Used for classification

☐ Used for SDS

Study period
None

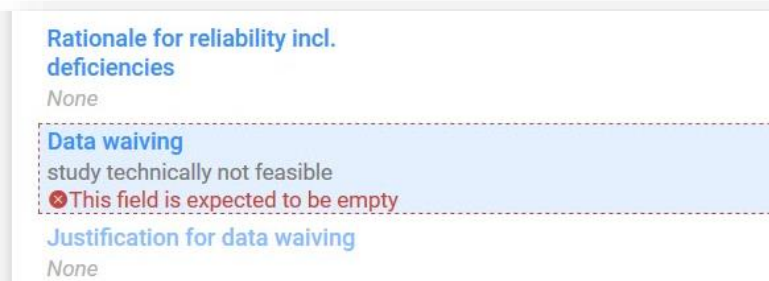
Reliability
None

Rationale for reliability incl. deficiencies
None

Data waiving
None

Justification for data waiving
None

In case user populates either Data waiving and/or Justification for data waiving fields when they are not disabled and then selects 'experimental study planned' in the field 'Endpoint', the following message(s) is displayed and user is not able to save the Document as show below:



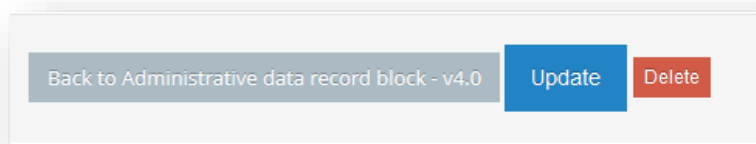
Rationale for reliability incl. deficiencies
None

Data waiving
study technically not feasible
✖ This field is expected to be empty

Justification for data waiving
None

6.3 Update/deletion of Dynamic Content Rule

In order to delete a DCR instance, find the DCR instance in the Condition field of a Definition, and click on the DCRinstance identifier. Introduce required updates and click 'Update' - the rule will be updated and saved for the Definition. Or delete the rule.



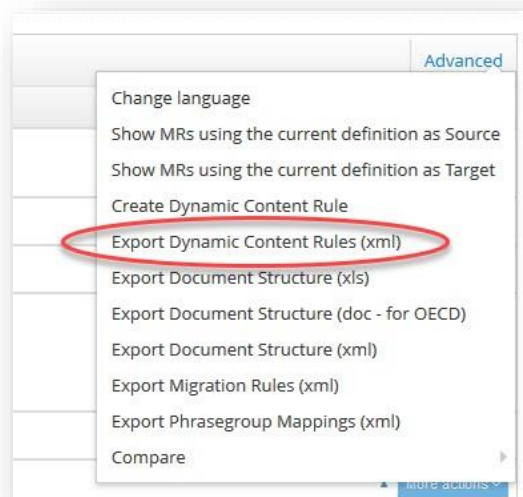
Back to Administrative data record block - v4.0 Update Delete

Important note: it is critical to check the hierarchical level of definition which requires dynamic content functionality. In case a Definition has common block which is used in few Definitions the block should be updated so the change is implemented across all relevant Documents.

Note that DCR identifier changes from the original with every new Document/Entity revision.

6.4 Export of Dynamic Content Rules

All Dynamic Content Rules within a Document can be exported with the help of 'Export Dynamic Content rules (xml)' feature. The export functionality can be accessed through 'Advanced' features of an ITEM element (Document, block or Entity).



The exported Document displays all the Dynamic Content Rules within the Document, their actions, conditions and related elements. Some data types have a special marking in the exported document. For instance, element having a 'multiple' data type is explicitly marked with the square brackets marker, i.e. []:

```
<Path>CharacterisationOfNanoforms.Crystallinity.Structures[].BravaisLattice[]</Path>
```

Dynamic Content Rules can also be exported from an Application Tag or a Definition provider. The generated file includes all the Dynamic Content Rules within all the Document/block revisions associated with that particular Application Tag or Definition provider.

When a Dynamic Content Rule is specified on a Common Block, then in the exported XML the <ApplicableDocuments> tag lists all the Documents where this Common Block is integrated.

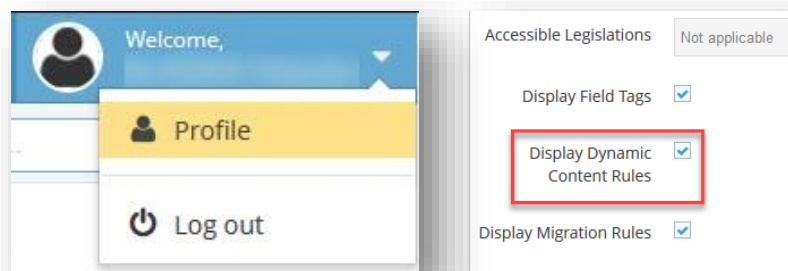
```
<Rule id="2868742">
  <Definition>Administrative_data_record_block</Definition>
  <ApplicableDocuments>
    <ApplicableDocument>ENDPOINT_STUDY_RECORD.AcuteToxicityDermal</ApplicableDocument>
    <ApplicableDocument>ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation</ApplicableDocument>
    <ApplicableDocument>ENDPOINT_STUDY_RECORD.AcuteToxicityOral</ApplicableDocument>
    <ApplicableDocument>ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes</ApplicableDocument>
    <ApplicableDocument>ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation</ApplicableDocument>
    <ApplicableDocument>ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood</ApplicableDocument>
    <ApplicableDocument>ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour</ApplicableDocument>
  ...

```

In case of nested Common Blocks when a block is integrated in another block, the <ApplicableDocuments> tag should display the actual Documents where the nested common block is used, and not another common block from the nested hierarchy.

6.5 Display of Dynamic Content Rules in ITEM Definitions

Display of DCR can be enabled/disabled in user profile settings:



Click 'Update' button.

7 REVISION / ELEMENT COMPARISON

The ITEM Comparison Engine facilitates the comparison of two Revisions of some ITEM Versionable element. Such elements are:

- Application Tags
- Definition Providers
- Submission Types
- Definitions (Documents/Entities/Common Blocks)
- PhraseGroups
- Text Templates

Currently the Comparison Engine can operate on the following two modes:

Full Comparison: The structure of Definition Revisions is represented with information about integrated Common Blocks. The values of all properties of each element are compared. This option is mostly used by technical users and provides specific details of element updates.

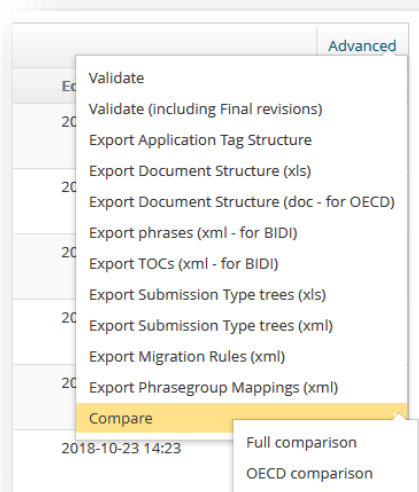
OECD Comparison: this option gives detailed overview of the updates on different levels e.g. update of field path or PhraseGroup revision.

The output of Comparison process is stored in a Comparison report as an Excel file. Please refer to “Appendix 1: The ITEM Comparison Report. Guidance” for further instructions on how generate comparison report.

The Report is a spreadsheet, each row of which reports the differences detected for a particular property of an ITEM's Element (Document field, Phrase, Text Template, etc.). If there is no difference there is no entry in the Report. In addition, the report might have several sheets for the respective element type (e.g. Definition Provider Revisions, Definition Revisions, PhraseGroup Revisions, etc.)

Depending on the element type the report has different level of comparison and values populated in the report. Each spreadsheet of the comparison report represents one level. For example, if two revisions of a Document are compared, report will have Document, PhraseGroup and Text Template level spreadsheets with the updates.

The report can be generated from the element view though 'Advanced' settings, 'Compare' option (Full or OECD comparison).



Note Application Tags are the only non-versionable elements that the Comparison Engine compares. Since an Application Tag is a container for Definition Provider Revisions, the comparison is performed for each one of the included Definition Provider Revisions. The outcome report is generated as a zip file which contains various Excel report files.

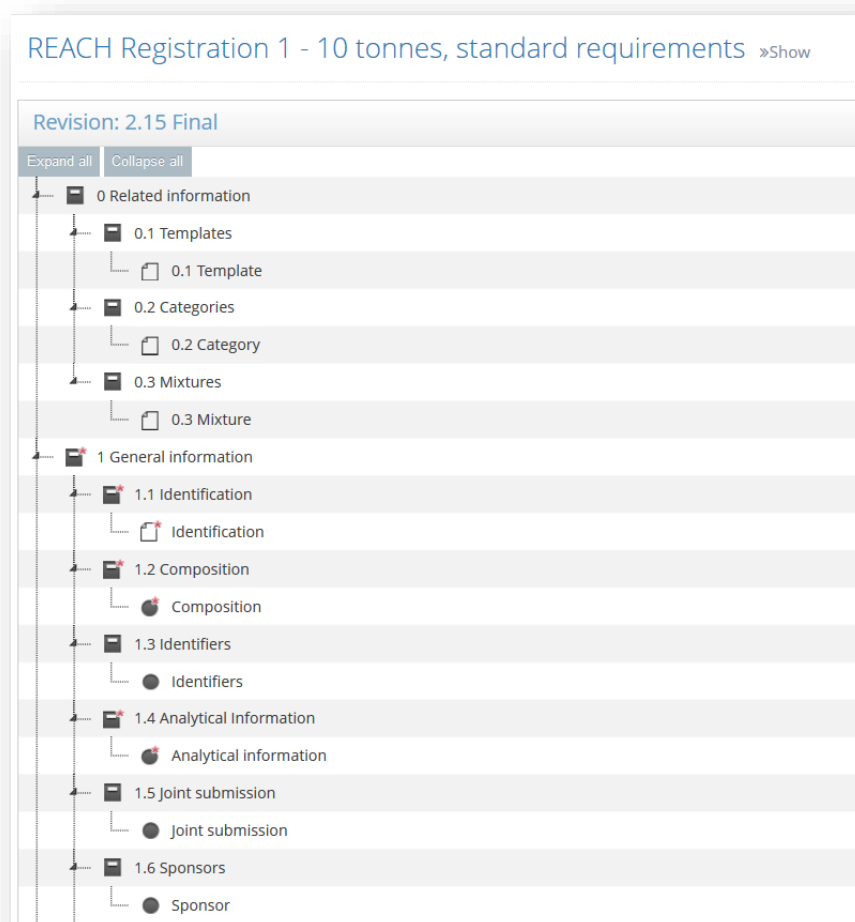
The files will include one Excel file describing the Application Tag-level comparison (e.g. which Definition Provider Revisions were added/removed and any changes in the versions of 'common' Definition Providers - i.e. present in both Application Tags) and one Excel file for each 'common' Definition Provider, describing the differences between the different Revisions of each such 'common' Definition Provider. In case a 'common' Definition Provider has the same version in both Application Tags, or its two different Definition Provider Revisions do not have any differences, then no Excel Comparison Report file will be created for this Definition Provider as there is nothing to report.

For other elements such as Definition Provider, Submission Type, Documents etc. a comparison report will be generated as one excel file with different spreadsheets.

8 SUBMISSION TYPES

A Submission Type is used by different Definition Providers to specify what information requirements are expected from a IUCLID user, and is fully customisable to fit the needs of a Definition Provider. For example, under the REACH Definition Provider, there are a number of Submission Types, such as REACH 1-10 tonnes standard information requirements. When a user in IUCLID selects this Submission Type, the user is presented with a section tree indicating what information is expected and collected for this Submission Type. ITEM is used to define the components of this section tree, and what Documents are available to IUCLID users to enter data into.












In ITEM, each Submission Type has a parent Definition Provider, an identifier and a name. The Submission Type replicates the IUCLID section tree view so you have a good idea how it will look like in IUCLID proper. The name you give to the Submission Type (e.g. OECD Harmonised templates, REACH application for authorisation, etc.), appears for the IUCLID user and is selectable as an option to display the Submission Type's section tree.



Submission Type revisions appear in ITEM as section tree components. You can edit the section tree components using the following ITEM functionalities:

- Creating/renaming/deleting sections and child sections in a Submission Type revision
- Adding/removing existing Document revisions to a Submission Type revision
- Overriding the Document's revision name for a specific Submission Type revision
- Reordering sections or Documents by using drag and drop functionality (note that elements can be reordered only in the same level)

The tree component also provides different icons for almost every of its elements and more specifically:

| Element | Icon | | |
|---|---|---|---|
| | Required | Optional | Not required |
| Section / child section |  |  |  |
| Endpoint study record / flexible record |  |  |  |
| Endpoint summary / flexible summary | N/A |  |  |
| Fixed record |  |  |  |

The available operations of the tree elements are the following:

| Action | Available in Element | Description |
|------------------------|-------------------------|---|
| Add Document | Section / child section | Assigns a Document revision to a specific section |
| Create (child) section | Section / child section | Creates a (child) section under a parent section if available |
| Rename | All elements | Renames the specific element |

| | | |
|------------------------|--|--|
| Delete | All elements | <ul style="list-style-type: none"> In case of sections it deletes the specific element In case of Documents it removes the references the specific Document revision |
| Mark as > Required | Endpoint study record / flexible record Fixed record | Marks the specific Document type as Required |
| Mark as > Optional | All Documents | Marks the specific Document type as Optional |
| Mark as > Not Required | All Documents | Marks the specific Document type as Not Required |

8.1 Default Submission Types

As soon as a Definition Provider is created and a Document is added to that Definition Provider, ITEM automatically creates by default what is called a “Default Submission Type” for the Definition Provider, named “<Definition Provider name>_TOC”. Every Document you add is then included in the Submission Type.

Every time a Document is added to the Definition Provider, the Document is added to the “Default Submission Type” under the last section tree node created in the Submission Type. You can re-organise the section tree (its nodes and associated Documents) accordingly by going into the Submission Type. All operations are available in the “Default Submission Type” except for the removal of Documents.

The version of the “Default Submission Type” follows the lifecycle of the Definition Provider it belongs to. For example, if in Definition Provider A, a new version is created in “Draft” status then the same version number in “Draft” status will be created for its “Default Submission Type” as well. If the user deletes a specific revision of a Definition Provider then its “Default Submission Type” is also removed.

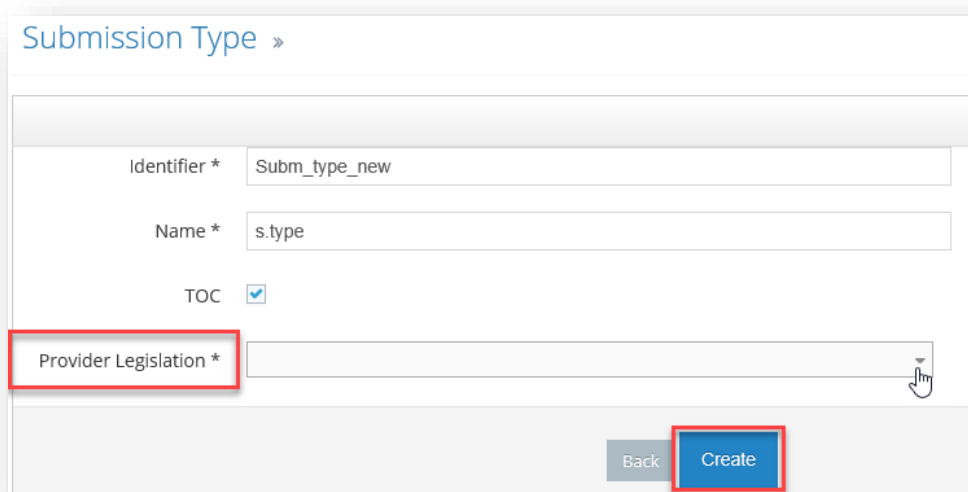
8.2 Create a Submission Type

The steps for creating a Submission Type are:

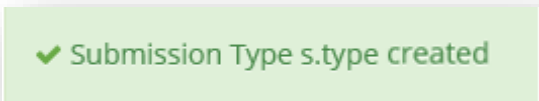
- A) Go to “Submission Type”
- B) Click “New Submission Type”



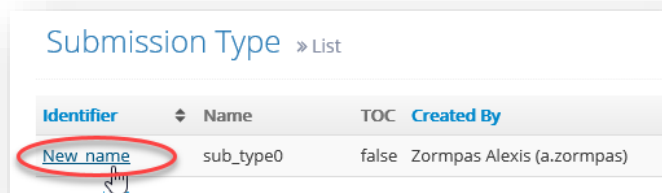
- C) Fill in the required fields of “Identifier” and “Name”. The Identifier may only contain English alphanumeric characters, underscores (_) and dashes (-) but no gaps between words. The Name can contain gaps and/or other symbols.
- D) Click, if relevant, the checkbox for TOC.
- E) Link to the Provider Definition Provider



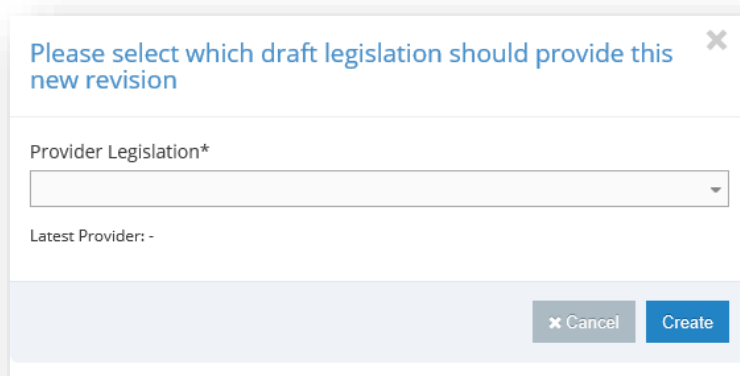
- F) Press “Create”
- G) A message will notify that a Submission Type has been created.



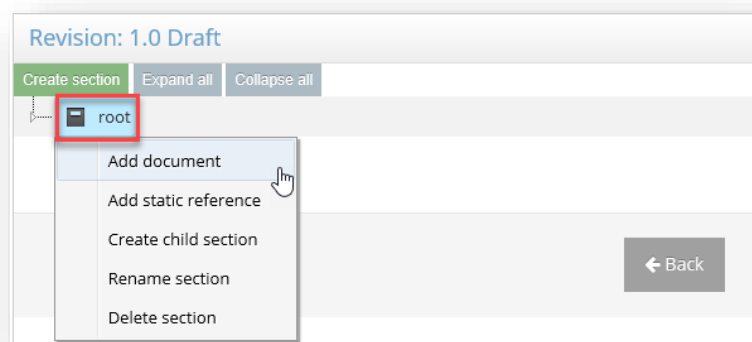
- E) To create sections within the recently created Submission Type, click on the “Identifier” name of the specific Submission Type.



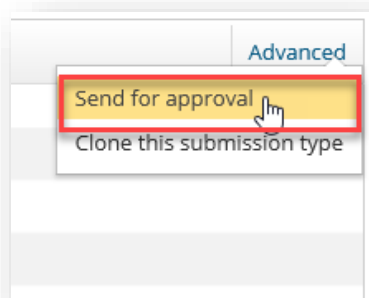
- F) Create a New revision of the Submission Type and make sure that you link the Submission Type to the correct draft Definition Provider.



- G) Create new sections by clicking the “Create section” button. The new Section (named automatically root) can be further edited, by right-click on the name (e.g. root).

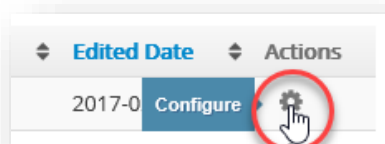


- H) After the Section tree has been created the Submission Type can be sent for approval to another user as shown below:



8.3 Update a Submission Type properties

- A) Go to “Submission Type”
- B) Find the Submission Type to be updated.
- C) Click on the “Configure” button under “Actions” of the specific Submission Type.




Edit the field of Identifier and/or Name.

Identifier *

Name *

TOC ☒

For the Submission Type in which there is a Section Tree created the Update option will have the options below. These options further define three elements of the Submission Type and each are associated with an Entity, such as a Substance. 

- Export/Import – allow a IUCLID user to export and print from the Submission Type
- Dossier creation – allow a IUCLID user to create a dossier from the Submission Type

- Section tree – allow IUCLID users to view this Submission Type as a section tree for the associated Entity, such as ‘Substance’. For example, allow a Submission Type REACH Inquiry to be viewed only in the Substance Entity.

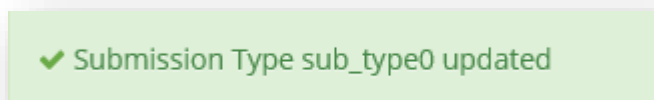
Revision: 1.0 Draft

Applicable for:

| | |
|-----------|--|
| Substance | <input checked="" type="checkbox"/> Export/Print |
| | <input type="checkbox"/> Dossier creation |
| | <input checked="" type="checkbox"/> Section Tree |
| Mixture | <input checked="" type="checkbox"/> Export/Print |
| | <input type="checkbox"/> Dossier creation |
| | <input checked="" type="checkbox"/> Section Tree |
| Template | <input checked="" type="checkbox"/> Export/Print |
| | <input type="checkbox"/> Dossier creation |
| | <input checked="" type="checkbox"/> Section Tree |
| Category | <input checked="" type="checkbox"/> Export/Print |
| | <input type="checkbox"/> Dossier creation |

Back Update

- D) Press “Update”.
- E) A message will notify that the Submission Type has been updated.



8.4 Advanced options

8.4.1 Clone a Submission Type

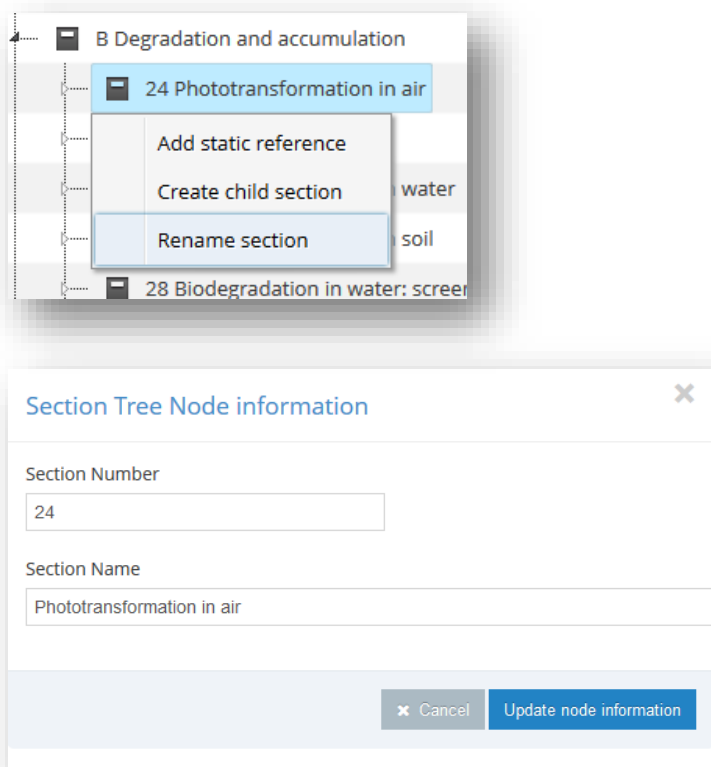
The ITEM user is able to select a Submission Type and clone it.

In order to do so go to Submission Type revision and select ‘Advanced’ option, click ‘Clone this Submission Type’. Specify Identifier, name and Definition Provider. Cloning will copy the Submission Type tree as it is in the newly defined one.

Cloning functionality is also available for the Documents.

8.4.2 Changing section number for A Document

In order to change the section number, go to the relevant Submission Type, right-click on a Document which is associated with a section tree node, and 'rename'; you will then have the option to change the Section number and Section name:



9 APPLICATION TAGS

9.1 Introduction

An Application Tag corresponds to a single IUCLID6 version. For every older IUCLID6 Version there is a unique Application Tag in ITEM defining which Definition Providers are part of this specific IUCLID version.

For the preparation of a new IUCLID6 version new Definition Providers may need to be included (or excluded), thus a new Application Tag needs to be created with the new/updated list of applicable Definition Providers.

9.2 Advanced functions

The advanced functions of Application Tags can be found within a version of IUCLID6. As shown below, the User has to open a specific IUCLID version by clicking on the name.



| Name | Description | Created By | Created Date |
|---------------------------|-------------|------------------------------|------------------|
| IUCLID6_0 | IUCLID6_0 | Super Administrator (sadmin) | 2015-05-12 13:56 |

Within the chosen Application Tag, the User can see the list of Definition Providers that are linked to the specific version of IUCLID. On the upper corner of the page there is the “Advanced” option including:

- **Validate:** this option verifies that there is no conflict between the Documents that are assigned in the specific Application Tag. If there will be any dependencies between the Definition Providers the validate function will inform the user if any issue will be flagged.

An example of a validation report is shown below:

IUCLID6_1 »Show

Multiple versions of the following elements are provided by the included Legislations:

Definitions:

- **Test conditions block:** 'CORE - v2.25' provides v2.1 and 'OECD - v2.20' provides v2.3
- **Effect levels BLOCK (OHT 67-69, 72-74):** 'CORE - v2.25' provides v1.2 and 'OECD - v2.20' provides v1.6
- **REACH Registration 1 - 10 tonnes, physicochemical requirements:** 'CORE - v2.25' provides v1.5 and 'REACH - v2.5' provides v1.6
- **Dossier Header Type of and Specific Information:** 'CORE - v2.25' provides v1.5 and 'REACH - v2.5' provides v1.6
- **Dossier Header Type of and Specific Information JS:** 'CORE - v2.25' provides v1.5 and 'REACH - v2.5' provides v1.6

PhraseGroups:

- **E123:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **T44:** 'CORE - v2.25' provides v2.0 and 'OECD - v2.20' provides v2.1
- **F23:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **P13:** 'CORE - v2.25' provides v2.0 and 'OECD - v2.20' provides v2.1
- **F06-2:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **E113:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **E08:** 'CORE - v2.25' provides v2.0 and 'OECD - v2.20' provides v2.1
- **T165:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.2
- **E03-2:** 'CORE - v2.25' provides v2.0 and 'OECD - v2.20' provides v2.3
- **F26-1a:** 'CORE - v2.25' provides v2.0 and 'OECD - v2.20' provides v2.3
- **T115:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **F02-1:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **E102:** 'CORE - v2.25' provides v2.0 and 'OECD - v2.20' provides v2.2
- **T141:** 'CORE - v2.25' provides v2.0 and 'OECD - v2.20' provides v2.1
- **NM14:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **E25:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **P36:** 'CORE - v2.25' provides v1.1 and 'OECD - v2.20' provides v1.2
- **T125:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v2.0
- **C106:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v2.0
- **E136:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **T59:** 'CORE - v2.25' provides v1.1 and 'OECD - v2.20' provides v1.3
- **E09-2:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.2
- **F128:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **E09-1:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.2
- **E111:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **F126:** 'CORE - v2.25' provides v1.0 and 'OECD - v2.20' provides v1.1
- **P07:** 'CORE - v2.25' provides v1.1 and 'OECD - v2.20' provides v1.2

- **Validate (including Final revisions)**
- **Export Application Tag Structure**
- **Export Document structure (xls/xml):** the User is able to export the list of paths, names/editions of Definition Providers, Document name, label, IUCLID6 Datatype etc. in xls or doc format.

| | A | B | C | D | E | F | G |
|---|-------------|-------------|---------------------|---------------------------|-----------|--------------|---------------|
| 1 | Legislation | Legislation | Legislation Edition | Automated testing path | Type | Document ID | Section Title |
| 2 | CORE | 2 | 25 | Complete table of content | Fixed Rec | 0_1_Template | 0.1 Template |
| 3 | CORE | 2 | 25 | Complete table of content | Fixed Rec | 0_1_Template | 0.1 Template |
| 4 | CORE | 2 | 25 | Complete table of content | Fixed Rec | 0_1_Template | 0.1 Template |
| 5 | CORE | 2 | 25 | Complete table of content | Fixed Rec | 0_1_Template | 0.1 Template |
| 6 | CORE | 2 | 25 | Complete table of content | Fixed Rec | 0_2_Category | 0.2 Category |
| 7 | CORE | 2 | 25 | Complete table of content | Fixed Rec | 0_2_Category | 0.2 Category |
| 8 | CORE | 2 | 25 | Complete table of content | Fixed Rec | 0_3_Mixture | 0.3 Mixture |
| 9 | CORE | 2 | 25 | Complete table of content | Fixed Rec | 0_3_Mixture | 0.3 Mixture |

- **Export Submission Type trees (xls/doc):** Each Definition Provider has Submission Type(s). With this option the User is able to extract, in xls or doc format, all the Submission

| | A | B | C | D | E |
|----|----------------------|-----------------------------|----------------------------------|---------------------|--------------------------------|
| 1 | Submission Type Name | Automated testing path | Parent node | Document Identifier | Section Title |
| 2 | OECD TOC | OECD TOC;A Physico-chemical | 1 Appearance / physical | ENDPOINT_STUDY_RECC | Appearance / physical |
| 3 | OECD TOC | OECD TOC;A Physico-chemical | 2 Melting point / freezing | ENDPOINT_STUDY_RECC | Melting point / freezing |
| 4 | OECD TOC | OECD TOC;A Physico-chemical | 3 Boiling point | ENDPOINT_STUDY_RECC | Boiling point |
| 5 | OECD TOC | OECD TOC;A Physico-chemical | 4 Density | ENDPOINT_STUDY_RECC | Density |
| 6 | OECD TOC | OECD TOC;A Physico-chemical | 5 Particle size distribution | ENDPOINT_STUDY_RECC | Particle size distribution |
| 7 | OECD TOC | OECD TOC;A Physico-chemical | 6 Vapour pressure | ENDPOINT_STUDY_RECC | Vapour pressure |
| 8 | OECD TOC | OECD TOC;A Physico-chemical | 7 Partition coefficient | ENDPOINT_STUDY_RECC | Partition coefficient |
| 9 | OECD TOC | OECD TOC;A Physico-chemical | 8 Water solubility | ENDPOINT_STUDY_RECC | Water solubility |
| 10 | OECD TOC | OECD TOC;A Physico-chemical | 9 Solubility in organic solvents | ENDPOINT_STUDY_RECC | Solubility in organic solvents |
| 11 | OECD TOC | OECD TOC;A Physico-chemical | 10 Surface tension | ENDPOINT_STUDY_RECC | Surface tension |
| 12 | OECD TOC | OECD TOC;A Physico-chemical | 11 Flash point | ENDPOINT_STUDY_RECC | Flash point |
| 13 | OECD TOC | OECD TOC;A Physico-chemical | 12 Auto flammability | ENDPOINT_STUDY_RECC | Auto flammability |
| 14 | OECD TOC | OECD TOC;A Physico-chemical | 13 Flammability | ENDPOINT_STUDY_RECC | Flammability |
| 15 | OECD TOC | OECD TOC;A Physico-chemical | 14 Explosiveness | ENDPOINT_STUDY_RECC | Explosiveness |
| 16 | OECD TOC | OECD TOC;A Physico-chemical | 15 Oxidising properties | ENDPOINT_STUDY_RECC | Oxidising properties |

Types including their name, path, parent node, Document Identifier, Section title etc.

- **Export Migration Rules (xml)**
- **Export PhraseGroup Mapping (xml)**
- **Compare (Full comparison, OECD comparison)**

9.3 Create an Application Tag

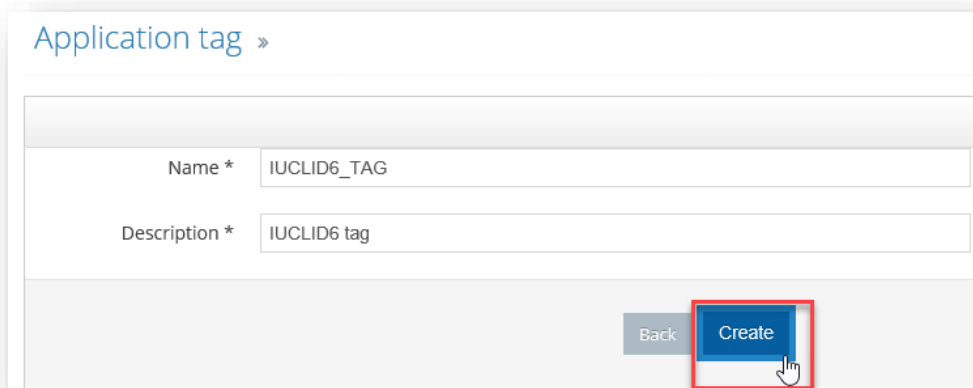
A) Go to “Application Tags”

B) Click “New Application Tag”

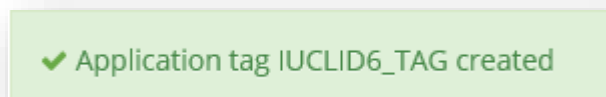
New Application tag

C) Give a “Name” and a “Description”; both required fields. The Name may only contain English alphanumeric characters, underscores (_) and dashes (-) (no spaces included).

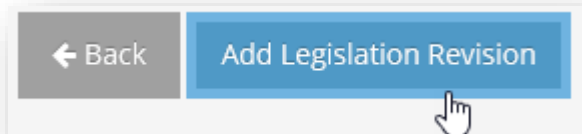
D) Press “Create”




E) A message will notify that the Application Tag has been created.



F) The new Application Tag is empty and a Definition Provider revision can be added.



G) Select the corresponding Definition Provider revision and press "Save".



H) The Definition Provider is linked to the Application Tag. The user, as described in steps F-G, can add additional Definition Provider Revisions or remove existing ones.

IUCLID6_TAG »Show

Application tag: IUCLID6_TAG

Advanced

| Legislation | Revision | Created By | Created Date | Edited By | Edited Date | Actions |
|-------------|-------------|------------|------------------|-----------|------------------|------------------------|
| CORE | 2. 27 Draft | | 2016-11-07 15:39 | | 2017-02-21 14:55 | Remove |

Max

10

▼

← Back

Add Legislation Revision

Note: an Application Tag contains various Definition Provider revisions each of which provides various elements (e.g. Definitions, PhraseGroups, Text Templates, etc.). Whereas inside the scope of a Definition Provider revision only one revision of each element is allowed, this constraint does not apply to Application Tags, where different revisions of the same element may be provided by the different Definition Providers contained in the Tag.

A validation check regarding the providers of each element in an Application Tag is available that enables the user to have an overview of elements being provided by multiple providers inside an Application Tag.

10 FIELD TAGS

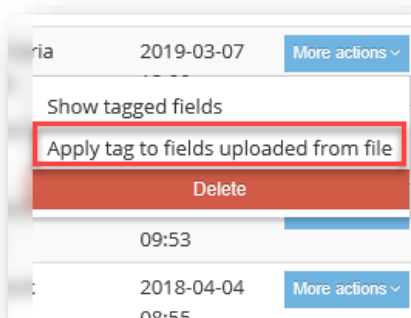
10.1 Introduction

Fields can be “tagged” in ITEM in order to record the fact that they are being used by other systems, such as eChemPortal, REACH-IT, the report generator. This information is important in order to anticipate the impact of planned format changes in the future. Some format changes on a field being used by a specific IUCLID feature or another system than IUCLID can have an impact and require adaptations to be implemented by other stakeholders.

Note, visibility of the Field Tags can be customized for the user through user profile functionality. In order to disable/enable display of the tags, go to your user profile and untick/tick ‘Display Field Tags’.

When you go into the list of Field Tags from the ITEM menu, you will see the ‘more actions’ drop-down, and includes two options:

- “Apply tag to fields uploaded from file” allows you to directly import into ITEM, in bulk, a list of fields and associated tags so you do not need to go to each field and tag it.
- System adds the relevant Field Tag to the relevant fields from the Document revisions that appear in the selected "Application Tag" without creating new revisions for those Document definitions. If a field-path refers to a Document definition that does not appear in the selected Application Tag, then it is ignored.
- Remember that for this;
 - The content of the imported files replaces all previously available information



- Regarding the format of the file to be imported, each row of the file must include the path value of a single IUCLID Document field, i.e. there should only be a single path value per row
- Any empty rows will be skipped
- “Show tagged fields” allows you to view all the fields which have been tagged with this particular Field Tag, e.g. all the fields tagged by ‘eChemPortal’. Before viewing all the tagged fields, you will need to select which ‘Application Tag’ you wish to look inside (the latest Application Tag will contain the latest Document changes and their respective fields and Field Tags). You can also export the Field Tags you are viewing as a text file.

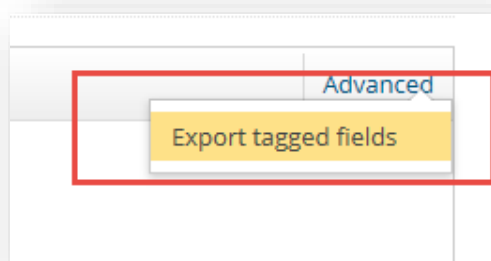
test version creation »Show usages

Field Tag: test version creation

Show fields from document revisions in Application Tag:

Found 1 elements tagged as 'test version creation' in documents of Application Tag 'IUCLID6_2_0_0_batch11'

| Document identifier | Document version | Field type | Field label | Field path |
|---|------------------|------------|------------------------|--|
| ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms | 5.0 | Field | Background information | ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrga |



Note: the Field Tags are kept for the Documents also when a new revision of Application Tag is created. When a new version of application is released the Field Tags that reflect fields used by previous version should be kept for the Documents which were not updated for a new application release.

In case Document using Field Tags was updated for a new Application Tag then Field Tags should be updated as well.

For example, Document X, which has fields used by IUCLID 6.3 and eChemPortal v1, was not updated for a new Application Tag for IUCLID 6.4 and eChemPortal was updated to v2. In this case Document X will have Field Tags for eChemPortal v1 (obsolete) and eChemPortal v2.

In case Document X was updated for a new Application Tag IUCLID 6.4 then only Field Tags relevant for IUCLID 6.4 and eChemPortal v2 will be encoded.

10.2 Create a Field Tag

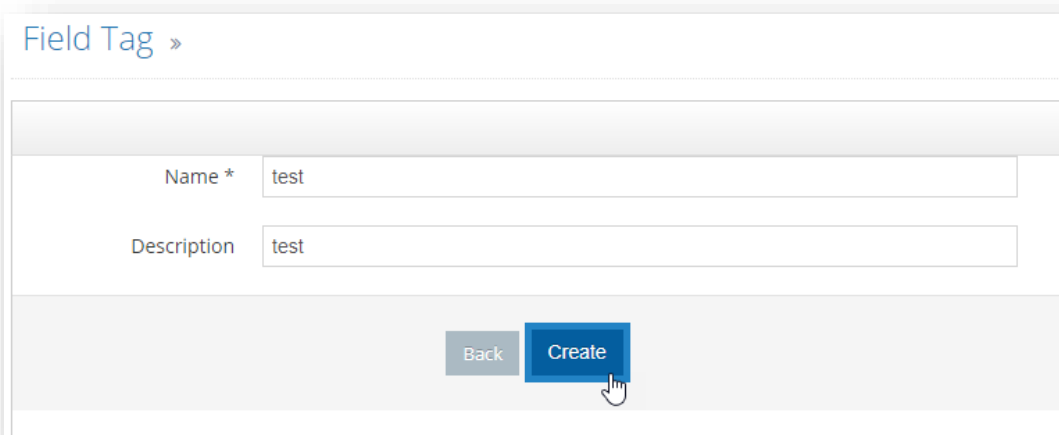
The steps for creating a Field Tag are:

- A) Go to “Field Tags”
- B) Click “New Field Tag”



New Field Tag

- C) Fill in the required field “Name”. “Description” is an optional field. Both fields can contain English alphanumeric characters, gaps and other symbols.
- D) Press “Create”



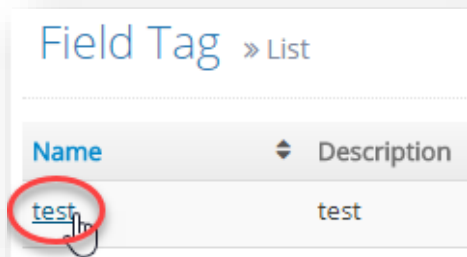
Field Tag »

| | |
|-------------|------|
| Name * | test |
| Description | test |

Back Create

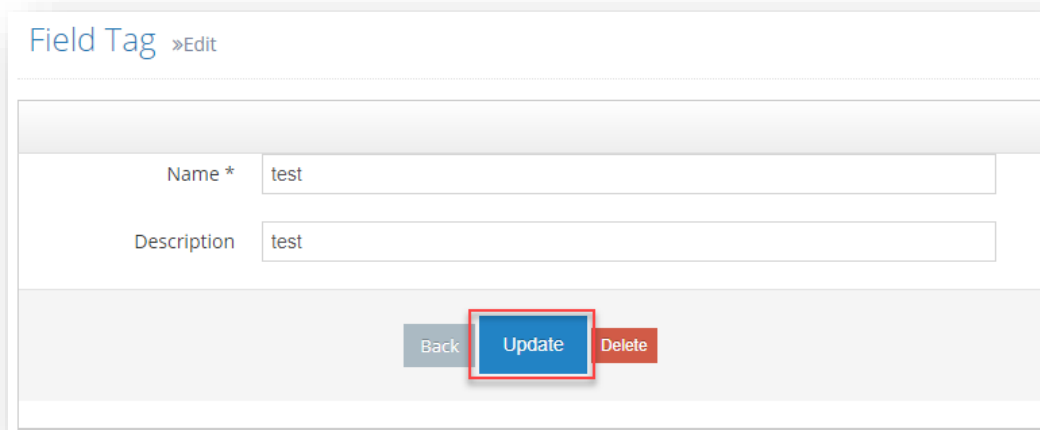
10.3 Update a Field Tag

- A) Go to “Field Tags”
- B) Find the Field Tag to be updated. Click on its name.

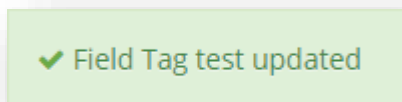


C) Edit the field of “Name” and/or “Description”.

D) Click “Update”



E) A message will notify that the Field Tag has been updated.



10.4 Delete a Field Tag

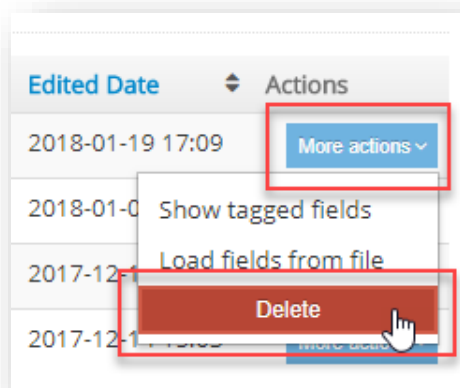
Field Tag can be deleted in two ways:

By clicking on the tag name and clicking delete button.

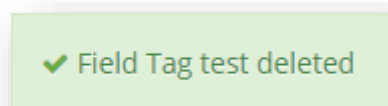
By deleting it through more actions menu by selecting delete.

A) Go to “Field Tags”

- B)** Find the Field Tag to be deleted. Click the blue “More actions” icon on the right side of the screen. Select “Delete” from the available options.



- C)** A notification message appears: “Are you sure”. Press OK.
- D)** A message will notify that the Field Tag has been deleted.



10.5 Available operations of Field Tags

Field Tags can be added to or removed from Document fields, headers, and repeatable lists/sets. They can be added either whilst creating a new Document, or whilst editing the Document in a draft status.

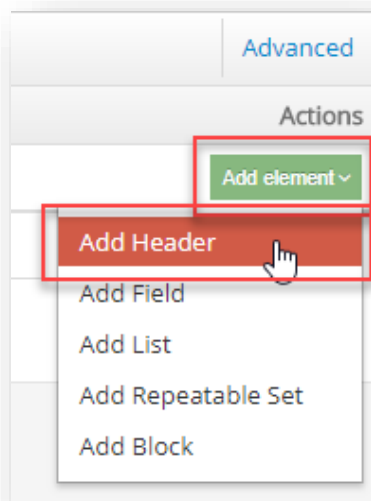
In case tagged field belongs to a Common Block, then the Fields of all Blocks that are used by several Documents will appear automatically as Tagged.

It is possible to override the Field Tag assigned to a Block's Field with a new Field Tag. This override is only applied to the particular Field Tag appearing to the Document Field at which the override action was performed (i.e. it has no effect to the respective Fields of any other Document).

When the Field Tag of a Block Field is removed, then all Tags from the field's appearance at points where the block is used are also removed, except those being already overridden.

To add a Field Tag:

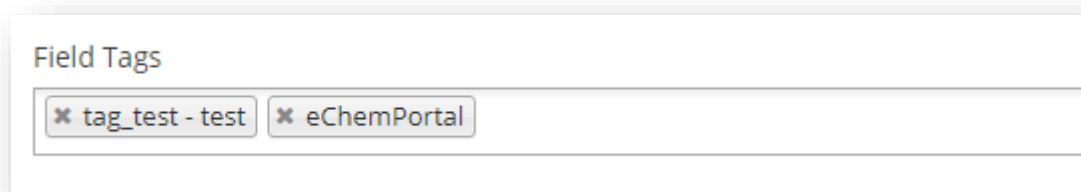
- A)** Open the Document (e.g. Endpoint Study Record, Endpoint Summary). Go to the “Add element” tab and add a new field, for example.



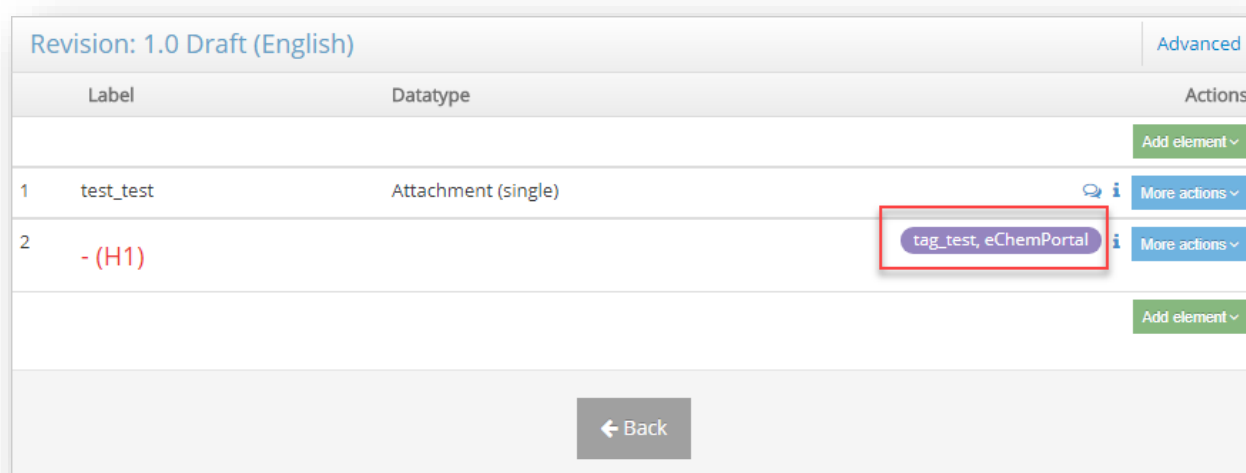
- B)** Fill all the necessary information such as “Label”, “Field type” etc. Scroll down to the “Field Tags” field. Clicking on the field will show the list of all available Field Tags. You can also search for a specific Field Tag by typing its name.

A screenshot of a form titled 'Please enter data for the Header' with a close button (X) in the top right corner. The form contains several input fields: 'Help text', 'Migration rules' (with a placeholder 'Please select one or more Migration rule'), 'Migration guidelines', and 'Internal remarks'. At the bottom, there is a 'Field Tags' section, which is highlighted with a red rectangle. This section contains a search bar and a list of three tags: 'eChemPortal', 'tag_test - test' (which is highlighted in blue), and 'test version creation'.

- C) Click on the Field Tag to add it to the field. There is no limit to the number of Field Tags added.

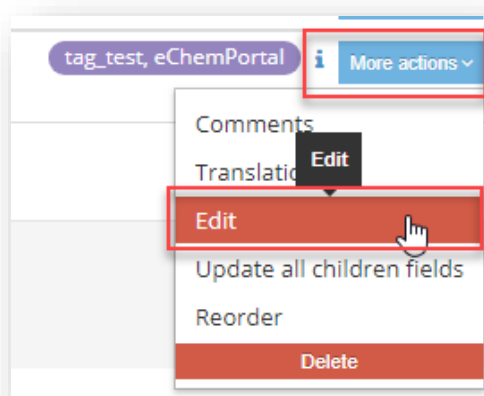


- D) Added Field Tags are now visible on the right side of the row of a field, header, and repeatable list/set.



To add a Field Tag to existing fields, headers, repeatable lists/sets:

- A) Open the Document (e.g. Endpoint Study Record, Endpoint Summary). Find the element that will be tagged and select "More actions" button on its right side. Go to "Edit".

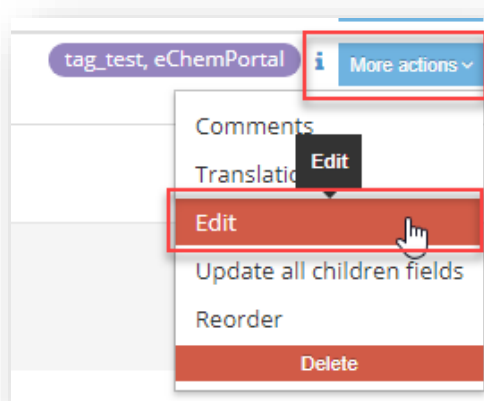


E) In the “Edit” window scroll down to the “Field Tags” field. Clicking on the field will show the list of all available Field Tags. You can also search for a specific Field Tag by typing its name. Click on the Field Tag to add it to the field. There is no limit to the number of Field Tags added.

F) Added Field Tags are now visible on the right side of the Document’s element.

To remove or change a Field Tag attached to an existing component:

G) Open the Document (Endpoint Study Record, Endpoint Summary). Find the element that you want to modify and select “More actions” button on its right side. Go to “Edit”.



H) In the “Edit” window scroll down to the “Field Tags” field. You can remove your Field Tags by clicking the x symbol next to its name.

11 TEST DATA

11.1 Create a Test Dataset

B) Go to “Test Data”

C) Click “New Test Dataset”



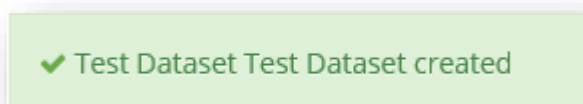
D) Give a “Name” and link the Test Dataset to the corresponding Definition Provider Revision.

A screenshot of a web form titled "Test Dataset" with a right-pointing arrow. The form has two input fields: "Name" with the value "Test Dataset" and "Legislation Revision" with a dropdown menu showing "CORE - v2.26". At the bottom right, there are two buttons: "Back" (light blue) and "Create" (blue). A mouse cursor is pointing at the "Create" button.

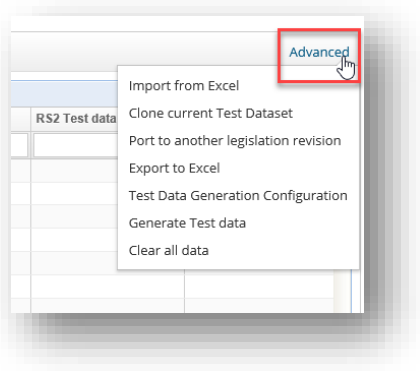
| | |
|----------------------|--------------|
| Name | Test Dataset |
| Legislation Revision | CORE - v2.26 |

E) Press “Create”

F) A message will notify that the Text Template has been created.



G) A Test Dataset content list appears with “Advanced” options on the upper side of the Dataset list as shown below.



Appendix 1. The ITEM Comparison Report. Guidance.

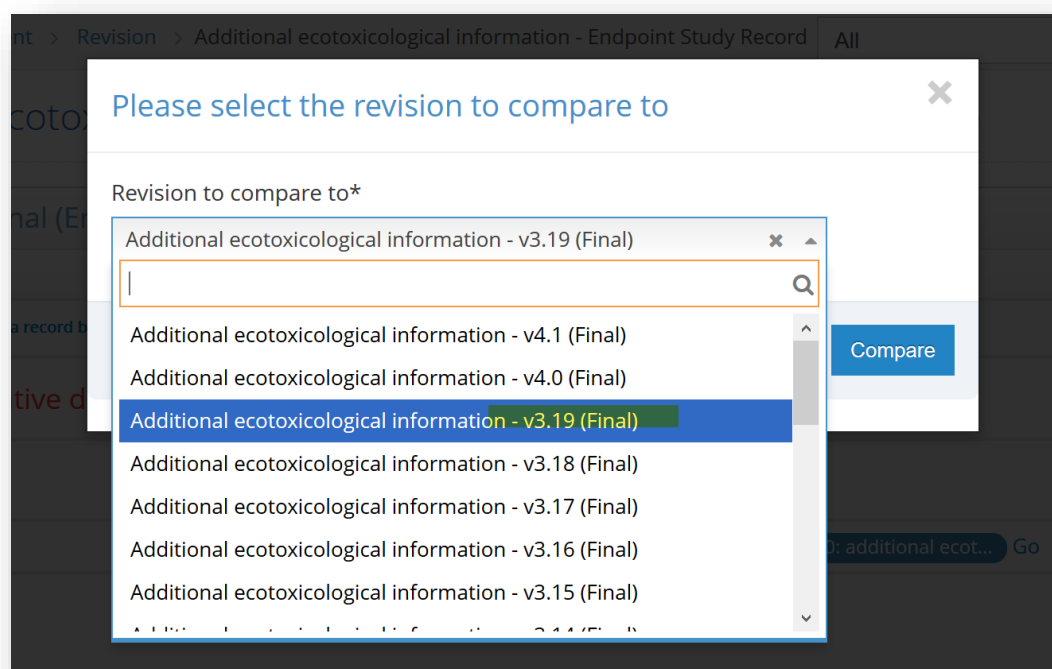
1 THE ITEM COMPARISON REPORT

You can generate an ITEM Comparison report between different versions of **Application Tags**, **Definition Providers**, and **Document Definitions**.

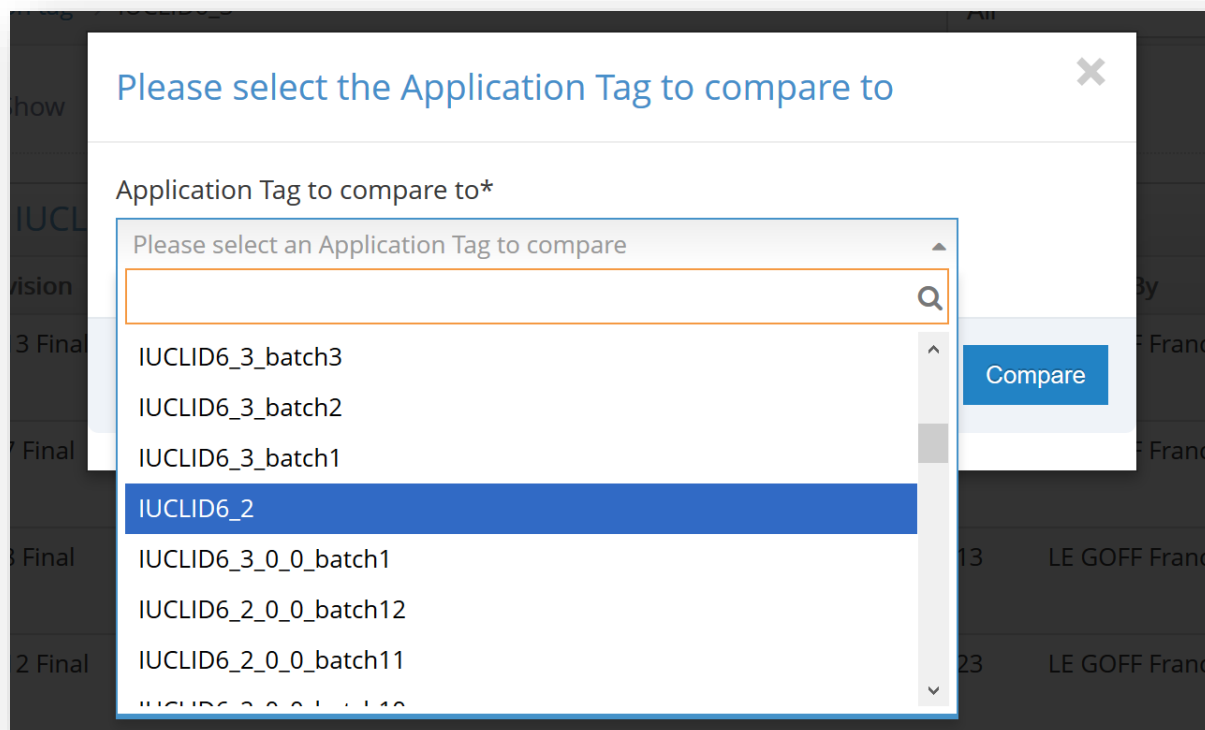
The comparison report provides information on what has been **ADDED**, **DELETED** or **CHANGED** between major versions of the IUCLID format.

Typically, a user wants to know the differences between major versions, as this includes format changes which affect other IT systems pushing or extracting data to and from IUCLID, and shows in general the changes to the IUCLID data structure.

To generate a report, go to the latest version of the **Definition Provider** or **Document definition**, click on 'Advanced', hover over 'Compare' and select to generate a 'Full Comparison', from which you can select which version you want to compare against. Select the last major version (indicated by the first digit of the version number). E.g. if the latest version you have selected is 4.2, the last major version will begin with 3 (choose the highest number after the first decimal place).



To generate a report from an **Application Tag**, go to the latest IUCLID 6 Tag which does not have a 'batch' suffix (E.g. IUCLID6_3) and compare against the previous IUCLID version (E.g. IUCLID6_2). Which again, does not have a batch suffix.



2 GUIDANCE

2.1 Added / Deleted Definition Providers

To identify new or deleted Definition Provider modules in IUCLID (such as the new NICNAS Definition Provider), generate an **Application Tag** comparison report. In the zip file, go to:

- **Full_Comparison_Application_Tag_<previous version>-<latest version>.xlsx**

Any new Definition Provider is identified in the 'Change Type' column by filtering for 'Add'. A deleted Definition Provider is identified in the 'Change Type' column by filtering for 'Delete'.

2.2 Added / Deleted Submission Tree Nodes

To identify new or deleted submission tree nodes in IUCLID, generate an **Application Tag** comparison report. In the zip file, open all Definition Provider modules. For example, in IUCLID 6.3:

- **Comparison_CORE_<versions to and from>.xlsx**

- **Comparison_EU_BPR<versions to and from>.xlsx**
- **Comparison_EU_CLP<versions to and from>.xlsx**
- **Comparison_EU_REACH_<versions to and from>.xlsx**
- **Comparison_OECD_<versions to and from>.xlsx**

In tab 'Submission Types', go to 'Change Type'. A new submission tree node is identified in the 'Change Type' column by filtering for 'Add'. A deleted submission tree node is identified in the 'Change Type' column by filtering for 'Delete'.

2.3 Added / Deleted Submission Types

To identify new or deleted Submission Types in IUCLID (such as the new BPR Microorganisms Submission Type), generate an **Application Tag** comparison report. In the zip file, open all Definition Provider modules. For example, in IUCLID 6.3:

- **Comparison_CORE_<versions to and from>.xlsx**
- **Comparison_EU_BPR<versions to and from>.xlsx**
- **Comparison_EU_CLP<versions to and from>.xlsx**
- **Comparison_EU_REACH_<versions to and from>.xlsx**
- **Comparison_OECD_<versions to and from>.xlsx**

In tab 'Definition Providers', go to 'Element Type' and filter for 'SUBMISSION TYPE'. A new Submission Type is identified in the 'Change Type' column by filtering for 'Add'. A deleted Submission Type is identified in the 'Change Type' column by filtering for 'Delete'.

2.4 Added / Deleted Documents

To identify new or deleted Documents in IUCLID (such as the new BPR Document for the properties of microorganisms), generate an **Application Tag** comparison report. In the zip file, open all Definition Provider modules. For example, in IUCLID 6.3:

- **Comparison_CORE_<versions to and from>.xlsx**
- **Comparison_EU_BPR<versions to and from>.xlsx**

- **Comparison_EU_CLP<versions to and from>.xlsx**
- **Comparison_EU_REACH_<versions to and from>.xlsx**
- **Comparison_OECD_<versions to and from>.xlsx**

In tab 'Definition Providers', go to 'Element Type' and filter for 'DOCUMENT'. A new Document is identified in the 'Change Type' column by filtering for 'Add'. A deleted Document is identified in the 'Change Type' column by filtering for 'Delete'.

2.5 Added / Deleted Common Blocks

To identify new or deleted common blocks in IUCLID, generate an **Application Tag** comparison report. In the zip file, open all Definition Provider modules. For example, in IUCLID 6.3:

- **Comparison_CORE_<versions to and from>.xlsx**
- **Comparison_EU_BPR<versions to and from>.xlsx**
- **Comparison_EU_CLP<versions to and from>.xlsx**
- **Comparison_EU_REACH_<versions to and from>.xlsx**
- **Comparison_OECD_<versions to and from>.xlsx**

In tab 'Common blocks', go to 'Change Type'. A new common block is identified in the 'Change Type' column by filtering for 'Add'. A deleted common block is identified in the 'Change Type' column by filtering for 'Delete'.

2.6 Added / Deleted PhraseGroups

To identify new Documents in IUCLID, generate an **Application Tag** comparison report. In the zip file, open all Definition Provider modules. For example, in IUCLID 6.3:

- **Comparison_CORE_<versions to and from>.xlsx**
- **Comparison_EU_BPR<versions to and from>.xlsx**
- **Comparison_EU_CLP<versions to and from>.xlsx**
- **Comparison_EU_REACH_<versions to and from>.xlsx**
- **Comparison_OECD_<versions to and from>.xlsx**

In tab 'Definition Provider', go to 'Element Type' and filter for 'PHRASEGROUP'. A new PhraseGroup is identified in the 'Change Type' column by filtering for 'Add'. A deleted PhraseGroup is identified in the 'Change Type' column by filtering for 'Delete'.

2.7 Changes to Submission Tree Nodes and Names

To identify changes to submission tree nodes and names in IUCLID, generate an **Application Tag** comparison report. In the zip file, open all Definition Provider modules. For example, in IUCLID 6.3:

- **Comparison_CORE_<versions to and from>.xlsx**
- **Comparison_EU_BPR<versions to and from>.xlsx**
- **Comparison_EU_CLP<versions to and from>.xlsx**
- **Comparison_EU_REACH_<versions to and from>.xlsx**
- **Comparison_OECD_<versions to and from>.xlsx**

In tab 'Submission Types', go to 'Change Type' and filter for '**CHANGE**'. Then, in 'Changed Property' select the change you want to see (Node number / Node name / Node position). Read in 'Node Tree Path' to see what the name of the affected node, and the full node hierarchy above.

2.8 Changes to Document Definitions

To identify changes to Document definitions in IUCLID, generate an **Application Tag** comparison report. In the zip file, open all Definition Provider modules. For example, in IUCLID 6.3:

- **Comparison_CORE_<versions to and from>.xlsx**
- **Comparison_EU_BPR<versions to and from>.xlsx**
- **Comparison_EU_CLP<versions to and from>.xlsx**
- **Comparison_EU_REACH_<versions to and from>.xlsx**
- **Comparison_OECD_<versions to and from>.xlsx**

Two search options:

1. In tab 'Definitions', go to 'Document Identifier' and filter for the **<Document type_Document sub type>**. It is easier to filter by **Document sub type**, e.g. for the Document short-term toxicity to fish search for '**ShortTermToxicityToFish**'. Or,
2. In tab 'Definitions', go to 'Document Name' and filter for the Document name as given in ITEM/IUCLID or a key part of the name. E.g. 'short-term toxicity' will filter the results enough to easily find a specific Document.

You can either keep your Document definition filter on as part of your search for changes to Fields / PhraseGroups / Common blocks, or remove the filter if you want to search all Document definitions.

2.8.1 Fields

2.8.1.1 *Field path changes*

In tab 'Definitions', go to 'Path Identifier' and remove the blanks (this is to remove common block names/paths). Then go to 'Changed Property' and filter for '**Path**'. This will list all field path changes for all Document definitions for the Definition Provider that is open. Check the 'From Value' to 'To Value' to see specific path changes.

2.8.1.2 *Field position changes*

A field position change does not necessarily entail a path change. The way to find out if it does or not, is to go to the tab 'Definitions', and filter for 'CHANGE' in 'Change Type'. Then, in 'Changed Property' filter for both 'Path' and 'Position'. If there is a change in the path because of a position change, the same 'Path Identifier' will have a row for 'Path' and a separate row for 'Position'. If the change does not affect the path, then the 'Path Identifier' will only have one row for a 'Position'.

2.8.1.3 *Field label changes*

In tab 'Definitions', go to 'Path Identifier' and remove the blanks (this is to remove common block names/paths). Then go to 'Changed Property' and filter for '**Label**'. This will list all field label changes for all Document definitions for the Definition Provider that is open. Check the 'From Value' to 'To Value' to see specific field label change.

2.8.1.4 *Field datatype changes*

In tab 'Definitions', go to 'Path Identifier' and remove the blanks (this is to remove common block names/paths). Then go to 'Changed Property' and filter for '**Field data type**'. This will list all field datatype changes for all Document definitions for the Definition Provider that is open. Check the 'From Value' to 'To Value' to see specific datatype change.

2.8.1.5 *Field additions*

In tab 'Definitions', go to 'Path Identifier' and remove the blanks (this is to remove common block names/paths). Then go to 'Change Type' and filter for '**Add**'. This will list all new fields for all Document definitions for the Definition Provider that is open. Check the 'Path Identifier' for the new field identifier and 'Field Label / Block Name' for the field label.

2.8.1.6 *Field deletions*

In tab 'Definitions', go to 'Path Identifier' and remove the blanks (this is to remove common block names/paths). Then go to 'Change Type' and filter for '**DELETE**'. This will list all deleted fields for all Document definitions for the Definition Provider that is open.

2.8.2 **PhraseGroups**

2.8.2.1 *Phrase additions*

In tab 'PhraseGroups', go to 'Phrase Type of Change' and filter for '**ADD**'. This will list all new PhraseGroups for all Document definitions for the Definition Provider that is open.

2.8.2.2 *Phrase deletions*

In tab 'PhraseGroups', go to 'Phrase Type of Change' and filter for '**DELETE**'. This will list all deleted PhraseGroups for all Document definitions for the Definition Provider that is open.

2.8.2.3 *Phrase changes*

In tab 'PhraseGroups', go to 'Changed Property' and filter for '**Phrase text**'. This will list all Phrases which have been changed for all Document definitions for the Definition Provider that is open.

2.8.3 **Common blocks**

In tab 'Common blocks', go to 'Change Type' and filter for '**CHANGE**'. This will list all changes to common blocks used by the 'Definition Provider' in column A.

To find which Documents use a changed common block, in the 'Common blocks' tab go to 'Block Name', copy a block name you are interested in, go to the 'Definitions' tab (with all filters removed) and filter for the common block name in 'Field Label / Block Name' and read the 'Document Identifier'.

2.9 Brief Glossary

| | |
|---------------------|--|
| ITEM | IUCLID Template Manager |
| Comparison report | A report outlining what has been ADDED/DELETED or CHANGED between different versions of Application Tags / Definition Providers / Document Definitions |
| Document type | e.g. 'FLEXIBLE_RECORD' / 'ENDPOINT_STUDY_RECORD' |
| Document sub type | e.g. 'SubstanceComposition' / 'ShortTermToxicityToFish' |
| Application Tag | A Group of Definition Providers (with versioning) |
| Definition Provider | A Definition Provider such as OECD, CORE, REACH, which contains a group of Document Definitions. |
| Document Definition | A set of structured fields which are added to submission tree nodes |