Functionalities of IUCLID in the web interface

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Title: Functionalities of IUCLID in the web interface
Issue date: October 2019
Language: en

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# Table of Contents

Table of Contents.................................................................................................................. ii  
Table of Figures ..................................................................................................................... v  
Table of Tables..................................................................................................................... ix  

1. The IUCLID web interface and the IUCLID client .......................................................... 1  
2. Help for users familiar with the IUCLID client ............................................................... 2  
   2.1. Overview of the Home page / Dashboard ................................................................. 2  
   2.2. The listings for Substance and Mixture/Product ................................................... 3  
   2.3. Dossier header ........................................................................................................ 5  
   2.4. Navigation, Information, and Data Panels .............................................................. 6  
      2.4.1. Navigation panel ............................................................................................... 6  
         2.4.1.1. Right-click in the list of entities ................................................................. 6  
         2.4.1.2. Search ......................................................................................................... 7  
         2.4.1.3. TOC ............................................................................................................ 8  
         2.4.1.4. Annotations ............................................................................................... 9  
      2.4.2. Information Panel ............................................................................................. 9  
         2.4.2.1. Information ............................................................................................... 9  
         2.4.2.2. Clipboard manager ................................................................................... 10  
         2.4.2.3. Attachments .............................................................................................. 11  
         2.4.2.4. Modification history .................................................................................. 12  
         2.4.2.5. Annotations ............................................................................................... 12  
         2.4.2.6. References ............................................................................................... 12  
      2.4.3. Data Panel ......................................................................................................... 12  
      2.4.4. Function key F1 for help .................................................................................. 13  
3. Overview of the web interface ....................................................................................... 14  
   3.1. Technical terms specific to IUCLID ......................................................................... 14  
   3.2. The main menu ....................................................................................................... 15  
      3.2.1. Launch the IUCLID client .............................................................................. 16  
      3.2.2. Template ........................................................................................................ 17  
      3.2.3. Reference substance ...................................................................................... 17  
      3.2.4. About ............................................................................................................ 17  
      3.2.5. Help .............................................................................................................. 17  
   3.3. Functionalities available in the data area ................................................................. 17  
      3.3.1. Import ............................................................................................................ 17  
         3.3.1.1. Overwrite settings - Import ..................................................................... 18  
         3.3.1.2. Default Group Access - Import ............................................................... 20  
      3.3.2. Breadcrumbs .................................................................................................... 21  
      3.3.3. Delete an entity from a list .............................................................................. 21  
      3.3.4. Free-text template ......................................................................................... 21  
      3.3.5. Flag .............................................................................................................. 22  
      3.3.6. Rich text input ............................................................................................... 27  
      3.3.7. Tables ........................................................................................................... 28  

https://iuclid6.echa.europa.eu
Functionalities of IUCLID in the web interface

3.3.7.1. Table Width ................................................................. 30
3.3.7.2. Column width ............................................................... 31
3.3.8. Dynamic content rules .................................................... 31
3.3.9. Table of contents ............................................................. 34
3.3.9.1. Complete table of contents ............................................ 38
3.3.9.2. New / Copy from existing ............................................. 39
3.3.9.3. Endpoint study record .................................................. 40
3.3.9.4. Endpoint summary ....................................................... 40
3.3.9.5. Record ................................................................. 41
3.3.9.6. Summary ............................................................. 41
3.3.9.7. Fixed record ............................................................ 41
3.3.10. Hide empty fields ......................................................... 41
3.3.11. Save ................................................................. 42
3.3.12. Modification History ..................................................... 43
3.3.13. Bookmarks, hyperlinks, and the sharing of entities and documents ........................................ 45
3.4. Attachments ................................................................. 48

4. Substance .................................................................................. 51
4.1. The Assessment entity .......................................................... 54
4.1.1. Assessment approach (assessment entities) ......................... 54
4.1.1.1. Approach to fate/hazard assessment ............................. 54
4.1.1.2. Approach to fate/hazard assessment - public information .......................... 54
4.1.2. Types of assessment entity ................................................. 54
4.1.2.1. Assessment entity confidentiality claim ............................ 55
4.1.2.2. Assessment entity name .............................................. 55
4.1.2.3. Relation to the registered substance ............................... 55
4.1.2.4. Assessment entity composition ................................... 55
4.1.2.5. Related Composition ................................................. 55
4.1.2.6. Additional information .............................................. 55
4.1.2.7. Endpoint summary linked ............................... 55
4.1.2.8. Reaction schema ..................................................... 55

5. Mixture/Product .......................................................................... 57

6. Annotation .................................................................................. 60
6.1. Annotation - Basic data ....................................................... 61
6.2. Annotation - Dataset data .................................................... 61

7. Template ...................................................................................... 62
7.1. Attaching a Template to a Substance or a Mixture/Product ......... 63
7.2. Inherit a Template .............................................................. 64
7.3. Copy a Template ............................................................... 65

8. Dossier ......................................................................................... 66
8.1. Dossier header ................................................................. 66
8.2. Creating a Dossier .............................................................. 67
8.2.1. Advanced settings for excluding and including data from the Dossier ........................................... 68
8.2.1.1. Include legal entity .................................................... 69

https://iuclid6.echa.europa.eu
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.2.1.2</td>
<td>Detail level of document fields</td>
<td>69</td>
</tr>
<tr>
<td>8.2.1.3</td>
<td>Flags for confidentiality</td>
<td>70</td>
</tr>
<tr>
<td>8.2.1.4</td>
<td>Flags for regulatory programme</td>
<td>72</td>
</tr>
<tr>
<td>8.2.1.5</td>
<td>Included Annotations</td>
<td>73</td>
</tr>
<tr>
<td>8.2.2.2</td>
<td>Validation during creation of a Dossier</td>
<td>73</td>
</tr>
<tr>
<td>8.2.3.4</td>
<td>Finishing the creation of a Dossier</td>
<td>74</td>
</tr>
<tr>
<td>8.3.4</td>
<td>Viewing the Dossier header of a completed Dossier</td>
<td>74</td>
</tr>
<tr>
<td>8.4.4</td>
<td>Viewing Dossiers and Substances or Mixture/Products</td>
<td>77</td>
</tr>
<tr>
<td>8.5.4</td>
<td>Compare Dossiers</td>
<td>79</td>
</tr>
<tr>
<td>8.5.1.1</td>
<td>References in the comparison report</td>
<td>83</td>
</tr>
<tr>
<td>8.6.4</td>
<td>Calculate Fee</td>
<td>85</td>
</tr>
<tr>
<td>8.6.1.1</td>
<td>Running the Fee calculator</td>
<td>85</td>
</tr>
<tr>
<td>8.6.2.1</td>
<td>Selecting the company size</td>
<td>85</td>
</tr>
<tr>
<td>8.6.3.1</td>
<td>The Indicators needed for the fee calculation</td>
<td>86</td>
</tr>
<tr>
<td>8.6.3.2</td>
<td>Hazardous Substance indicator</td>
<td>86</td>
</tr>
<tr>
<td>8.6.3.3</td>
<td>Safety Data Sheet indicator</td>
<td>87</td>
</tr>
<tr>
<td>8.6.3.4</td>
<td>PBT/vPvB indicator</td>
<td>87</td>
</tr>
<tr>
<td>8.6.3.5</td>
<td>Annex III criteria indicator</td>
<td>88</td>
</tr>
<tr>
<td>8.6.4.1</td>
<td>Dossier is for an update to a previous submission</td>
<td>89</td>
</tr>
<tr>
<td>8.6.5.1</td>
<td>Fee calculator results window</td>
<td>90</td>
</tr>
<tr>
<td>8.6.6.1</td>
<td>Version of the Fee calculator</td>
<td>90</td>
</tr>
<tr>
<td>8.6.7.1</td>
<td>Disclaimer</td>
<td>90</td>
</tr>
<tr>
<td>8.7.4</td>
<td>Dissemination preview</td>
<td>91</td>
</tr>
<tr>
<td>8.7.1.1</td>
<td>Running the Dissemination preview</td>
<td>91</td>
</tr>
<tr>
<td>8.7.2.1</td>
<td>Output of the Dissemination preview</td>
<td>92</td>
</tr>
<tr>
<td>8.7.2.1.1</td>
<td>Fields for which there is a reference within IUCLID</td>
<td>92</td>
</tr>
<tr>
<td>9.4</td>
<td>Guided dossier preparation</td>
<td>97</td>
</tr>
<tr>
<td>9.1.4</td>
<td>Creating a Guided dossier preparation</td>
<td>98</td>
</tr>
<tr>
<td>9.2.4</td>
<td>The record page of a Guided Dossier Preparation</td>
<td>101</td>
</tr>
<tr>
<td>9.3.4</td>
<td>The task hierarchy in a Guided Dossier Preparation</td>
<td>103</td>
</tr>
<tr>
<td>9.4.4</td>
<td>Entering data in to a Guided Dossier Preparation</td>
<td>104</td>
</tr>
<tr>
<td>10.4</td>
<td>Legal entity</td>
<td>111</td>
</tr>
<tr>
<td>10.1.4</td>
<td>General information</td>
<td>111</td>
</tr>
<tr>
<td>10.2.4</td>
<td>Identifiers</td>
<td>111</td>
</tr>
<tr>
<td>10.3.4</td>
<td>Contact information</td>
<td>111</td>
</tr>
<tr>
<td>11.4</td>
<td>Legal entity site</td>
<td>111</td>
</tr>
<tr>
<td>12.4</td>
<td>Reference substance</td>
<td>112</td>
</tr>
<tr>
<td>12.1.4</td>
<td>General information</td>
<td>115</td>
</tr>
<tr>
<td>12.2.4</td>
<td>Inventory</td>
<td>115</td>
</tr>
<tr>
<td>12.3.4</td>
<td>Reference substance information</td>
<td>116</td>
</tr>
<tr>
<td>12.4.4</td>
<td>Molecular and structural information</td>
<td>116</td>
</tr>
<tr>
<td>13.4</td>
<td>Contacts</td>
<td>116</td>
</tr>
</tbody>
</table>

https://iuclid6.echa.europa.eu
14. Test materials ................................................................................................. 119
14.1. Test material for a Mixture/Product ......................................................... 119
15. Literature reference ....................................................................................... 121
16. Validation assistant ....................................................................................... 122
16.1. Structure ...................................................................................................... 122
16.2. Supported validations .................................................................................. 122
16.2.1. Completeness check .................................................................................. 122
16.2.2. Business rules .......................................................................................... 123
16.2.3. Quality checks .......................................................................................... 123
16.3. Run the Validation assistant on a Substance or Mixture/Product ............. 123
16.4. Run the Validation assistant on a Dossier .................................................. 126
16.5. Update a registration - reduced information requirements ...................... 127
16.6. Disclaimer .................................................................................................... 127
17. Export to i6z .................................................................................................... 128
17.1. Export to previous major version ................................................................. 129
17.2. Detail level of document fields ...................................................................... 129
17.3. Flags for confidentiality ................................................................................. 130
17.4. Flags for regulatory programmes ................................................................. 130
17.5. Included annotations ................................................................................... 130
17.6. Included attachments .................................................................................. 130
17.7. Select documents to be included ................................................................ 130
18. Create PDF ...................................................................................................... 132
19. Generate Report ............................................................................................. 133
20. Sharing and Ownership - Instance based security (IBS) .............................. 134
20.1. Common Group ........................................................................................... 134
20.2. Share ............................................................................................................ 134
20.3. Change ownership ....................................................................................... 136
21. Shutting down IUCLID .................................................................................. 138
22. Getting help .................................................................................................... 139
23. Glossary .......................................................................................................... 141

Table of Figures

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>Launch an interface for IUCLID</td>
</tr>
<tr>
<td>Figure 2</td>
<td>Dashboard</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Show a list of datasets</td>
</tr>
<tr>
<td>Figure 4</td>
<td>Substance versus Dossier</td>
</tr>
<tr>
<td>Figure 5</td>
<td>View the Dossiers for a Substance</td>
</tr>
<tr>
<td>Figure 6</td>
<td>View the Substance dataset for a Dossier</td>
</tr>
<tr>
<td>Figure 7</td>
<td>Editing the Dossier header independently of Dossier creation</td>
</tr>
<tr>
<td>Figure 8</td>
<td>Editing the Dossier header at the start of Dossier creation</td>
</tr>
<tr>
<td>Figure 9</td>
<td>Functionalities that can be applied to a specific Dossier</td>
</tr>
</tbody>
</table>

https://iuclid6.echa.europa.eu
Figure 10: Search for an entity...............................................................8
Figure 11: New features in the TOC..................................................8
Figure 12: Where to find Annotations...............................................9
Figure 13: Viewing the UUIDs of a Dossier, and a Substance within it............................10
Figure 14: Copy from existing...........................................................11
Figure 15: Where to find attachments..............................................12
Figure 16: The home page, showing the structure of the web interface of IUCLID.......14
Figure 17: The main menu.................................................................16
Figure 18: Launch the IUCLID client................................................16
Figure 19: Import data in to IUCLID................................................18
Figure 20: Import in to IUCLID 6 where datasets and/or documents already exist in the database..............................................................20
Figure 21: Navigation using breadcrumbs........................................21
Figure 22: Delete an entity from a list..............................................21
Figure 23: Free-text template..........................................................22
Figure 24: Flags applied individually to fields ..................................23
Figure 25: Flags applied individually to items in a section..................24
Figure 26: Flags applied individually to items in a table.....................25
Figure 27: Flags that apply to a whole document..............................25
Figure 28: Setting flags for confidentiality, and/or regulatory programme......26
Figure 29: Setting a confidentiality flag...........................................26
Figure 30: Free-text template for the justification of a confidentiality claim....27
Figure 31: Flag for relevance to a regulatory programme or programmes......27
Figure 32: A rich text field ...............................................................28
Figure 33: Add a row to a table..........................................................29
Figure 34: Editing all the values in a table row...................................30
Figure 35: Set the width of a table....................................................30
Figure 36: Dynamic content rules preventing fields from being edited........32
Figure 37: Effect of breaking a dynamic content rule........................33
Figure 38: Dynamic content rules applied to imported migrated data........34
Figure 39: General structure of the table of contents........................35
Figure 40: Navigating by subsection in the table of contents..............36
Figure 41: Selecting the submission type........................................37
Figure 42: Add a submission type to the menu.................................37
Figure 43: Complete table of contents.............................................38
Figure 44: Example location in table of content: Short-term toxicity to fish under 'REACH' ....39
Figure 45: Example location in table of content: Short-term toxicity to fish under 'Complete table of contents' .................................................................39
Figure 46: Creating documents using New / Copy from existing............40
Figure 47: Hide empty fields.............................................................42
Figure 48: Save .............................................................................42
Figure 49: Option to view a document that has just been saved............43
Figure 50: Access to the modification history....................................43
Figure 51: Modification history of an Endpoint study record................43
Figure 52: Access to the modification history of a Substance................44
Figure 53: Example modification histories for a Substance and an Endpoint study record inside it .................................................................45
Figure 54: Bookmarking a document or entity....................................46

https://iuclid6.echa.europa.eu
Figure 55: The part of a link to an entity or document that depends on the instance of IUCLID...47
Figure 56: Attaching an attachment to a whole document..................................................49
Figure 57: Attaching an attachment within a field ............................................................49
Figure 58: Adding a Mixture/Product as a component in a Mixture/Product ....................57
Figure 59: Viewing and managing the Annotations applied to a document.......................60
Figure 60: Manage Templates – E.g. delete ..................................................................62
Figure 61: Inserting a Template in to a Substance or Mixture/Product ...............................63
Figure 62: Select a Template from the list.........................................................................64
Figure 63: The list of inherited Templates for a dataset.....................................................64
Figure 64: A document within an inherited Template in the table of contents.......................65
Figure 65: Editing the Dossier header independently of Dossier creation.........................66
Figure 66: Start Dossier creation for a Substance dataset ................................................67
Figure 67: Entering values in to the Dossier header during creation of a Dossier..............68
Figure 68: Enter values in to the Dossier header during Dossier creation..........................68
Figure 69: Include/Exclude legal entity from a Dossier...................................................69
Figure 70: Detail level of document fields, to be included in a Dossier ...............................69
Figure 71: Example of a field marked as confidential but with no flag .........................70
Figure 72: Exclude flagged data from a Dossier.................................................................71
Figure 73: Include or exclude data from a Dossier according to confidentiality flags ..........71
Figure 74: Flags for regulatory programme........................................................................72
Figure 75: Include or exclude data from a Dossier according to regulatory programme flags 73
Figure 76: Exclusion of Annotation entities .......................................................................73
Figure 77: Dossier creation – Option to use the Validation assistant................................74
Figure 78: Successful Dossier creation............................................................................74
Figure 79: Opening the header in a Dossier......................................................................75
Figure 80: Viewing the header in a Dossier .....................................................................76
Figure 81: Links to the subject of a Dossier and its source dataset.................................76
Figure 82: Show a list of datasets......................................................................................77
Figure 83: Substance versus Dossier................................................................................77
Figure 84: View the Dossiers for a Substance......................................................................78
Figure 85: View the Substance dataset for a Dossier.......................................................78
Figure 86: Start the comparison of two Dossiers ...............................................................79
Figure 87: Select the second, or target, Dossier in a comparison.........................................80
Figure 88: Comparison report – Top level: Dossiers........................................................81
Figure 89: Comparison report – Second level: Dossier contents......................................81
Figure 90: Comparison report – Third level: Section document comparison....................81
Figure 91: Comparison report – Fourth level: Field-level content differences...................82
Figure 92: Links to duplicate content in the comparison report........................................83
Figure 93: Run the Fee calculator.....................................................................................85
Figure 94: Selecting the company size: example for SME-Small.......................................86
Figure 95: Hazardous substance indicator.........................................................................87
Figure 96: Safety Data Sheet indicator................................................................................87
Figure 97: PBT/vPvB indicator...........................................................................................87
Figure 98: Annex III criteria indicator.................................................................................88
Figure 99: Select the tonnage band of the previous submission, and information on intermediates ...........................................................................................................89
Figure 100: Fee calculator results window – example showing intermediates and confidentiality claims .................................................................................................................90

https://iuclid6.echa.europa.eu
Figure 101: Run the Dissemination preview ................................................................. 92
Figure 102: The link between a referencing field and a referenced field in the Dissemination preview ................................................................. 93
Figure 103: Example Dissemination report for a field in a Substance that links to a Reference substance ............................................................................................... 93
Figure 104: The identifier of a Reference substance in referencedDocumentKey (Column G) ................................................................. 94
Figure 105: Apply a filter to sourceDocumentKey in MS Excel .................................... 95
Figure 106: Output of the Dissemination preview filtered for a single reference to a Reference substance ................................................................. 96
Figure 107: Open the list of Guided dossier preparations ............................................ 97
Figure 108: The list page of Guided dossier preparations ............................................ 98
Figure 109: Page one of the wizard to create a Guided dossier preparation – example of REACH ................................................................. 99
Figure 110: Page two of the wizard to create a Guided dossier preparation - example of REACH ................................................................. 100
Figure 111: An example of the record page of a Guided dossier preparation – upper part ................................................................. 101
Figure 112: An example of the record page of a Guided dossier preparation – lower part ................................................................. 102
Figure 113: Hierarchy in a Guided Dossier Preparation – example for REACH ............................................................................................... 103
Figure 114: The breadcrumbs in a Guided dossier preparation – example for REACH ............................................................................................... 104
Figure 115: A task in Guided dossier preparation – example for REACH ............................................................................................... 105
Figure 116: Options to add a record to an empty section in Guided dossier preparation – example for REACH ............................................................................................... 106
Figure 117: Data entry wizard under Guided dossier preparation – example for REACH ............................................................................................... 107
Figure 118: Add an existing document/record to a Guided dossier preparation – example for REACH ............................................................................................... 108
Figure 119: A subtask (section in a dataset) in a Guided dossier preparation – example for REACH ............................................................................................... 109
Figure 120: The working legal entity ........................................................................ 111
Figure 121: Open the list page for Reference substances ............................................ 113
Figure 122: The list page for Reference substances .................................................... 114
Figure 123: Enter a Reference substance in to the field Impurities for a Substance ............................................................................................... 114
Figure 124: Create a Reference substance, or select one from the IUCLID database ............................................................................................... 115
Figure 125: Save ....................................................................................................... 115
Figure 126: Automatic searching of the EC Inventory in a Reference substance ............................................................................................... 116
Figure 127: Contacts in the identification of a substance dataset .................................. 117
Figure 128: A newly created link to a Contact ............................................................ 117
Figure 129: Place a Contact in an empty link .............................................................. 118
Figure 130: Save ....................................................................................................... 118
Figure 131: Test material in a Mixture/Product – example where the Test material refers to the composition of the Mixture/product ............................................................................................... 120
Figure 132: Literature references in the field Data source ............................................ 121
Figure 133: Navigate to the top level of an entity's record via the breadcrumbs ............................................................................................... 124
Figure 134: Run the Validation assistant on a Substance dataset ............................... 124
Figure 135: The Validation assistant report: Submission checks .................................. 125
Figure 136: The link back to the validation report from a document being edited ............................................................................................... 126
Figure 137: Run the Validation assistant on a Dossier ................................................ 126
Figure 138: Selecting Export to i6z for a Substance dataset ....................................... 128
Figure 139: The settings for Export to i6z .................................................................. 128
Figure 140: Exclude an entity from an Export to i6z file ............................................ 131

https://iuclid6.echa.europa.eu
Functionalities of IUCLID in the web interface

Figure 141: Exclude all the documents in a section from an Export to i6z file .............................. 132
Figure 142: Create PDF ............................................................................................................... 132
Figure 143: Generate report – example of Chemical Safety Report (CSR) .................................. 133
Figure 144: View the permissions of an entity, e.g. a Substance dataset .................................... 135
Figure 145: Example of sharing a Substance dataset .................................................................. 136
Figure 146: Viewing and changing the ownership of an entity, e.g. a Substance dataset............. 137
Figure 147: Data is being imported .......................................................................................... 138
Figure 148: Shut down the IUCLID application ....................................................................... 138
Figure 149: Sources of help in the web interface ..................................................................... 139
Figure 150: External sources of help: The option highlighted is to request help directly from the IUCLID helpdesk at ECHA ................................................................. 140

Table of Tables

Table 1: Technical terms and their meaning within the context of IUCLID ................................. 15
Table 2: The icons for the states of a flag .................................................................................. 22
Table 3: Key for the icons in the Dossier comparison report ..................................................... 82
Table 4: The permissions grantable to a Group using the functionality Share ......................... 134
1. The IUCLID web interface and the IUCLID client

The IUCLID 6.4 application comes with both the client interface that was used for previous releases, and an interface which is displayed in a web browser. The reason for this is that the client interface is being phased out, to be gradually replaced by the web interface. Both interfaces have been made available at the same time to help existing users of the client to transfer over to using the web interface.

Eventually, the IUCLID application will no longer contain the client, so from then on all users must use only the web interface. For the latest news on the schedule, see the IUCLID website.

The web interface of IUCLID 6.4 does not have exactly the same functionalities as the client. In some cases this is because the functionality has not yet been added to the web interface, but it will be in a later release. If you need to do something that you know is possible using the client, but is not available in the web interface, please use the client. The client and the web interfaces can both be launched from the window that is shown on starting IUCLID, as shown below.

Figure 1: Launch an interface for IUCLID

It is possible to use both the client and/or the web interface with a single instance of the IUCLID application. In that case, both interfaces point to the same database. For example, if a particular field is viewable in both interfaces, data saved in the client becomes visible in the web interface as soon as the web page is refreshed.

In the next section, there are some notes to help users who are already familiar with the client, to move over to using the web interface.
2. Help for users familiar with the IUCLID client

If you have not used the older type of IUCLID interface, referred to as the client, or the classic interface, go straight to section 3 Overview of the web interface.

The purpose of this chapter is to help users who are already familiar with the client, to learn how to use the web interface. If you know the client well, reading through all of this chapter will save you time compared to clicking around in the web interface unaided.

Whilst learning how to use the web interface you may find it useful to have both interfaces open at the same time for the same database, and switch back and forth comparing how the data is displayed and manipulated.

2.1. Overview of the Home page / Dashboard

In the client, the home page is the page displayed when the interface is started, or a user logs in. A user can return to the home page from anywhere in the interface by clicking on the house icon. The equivalent to that in the web interface is the Dashboard. A user can return to the Dashboard from anywhere in the interface by clicking on the IUCLID 6 icon at the top left of the interface. An example of the web interface with the Dashboard displayed is shown below.

Figure 2: Dashboard

Only the most commonly used functionalities are presented on the Dashboard. The functionalities retained from the home page of the client are: Substance, Mixture/Product, Search by UUID, Help, and Import. Only the entities Substance, Mixture/Product, Template and Reference substance have a list page from where they can be created or edited. However, all entities can be edited and created from the point in an entity or dataset that refers to them.
A new concept is introduced; *Guided dossier preparation*, as described in section 9 *Guided dossier preparation*. This helps a user to create a Dossier for submission under a particular regulatory programme. It asks the user information about the intended submission, and then creates a tailored set of tasks that must be done, ending in creation of the actual Dossier.

Import allows IUCLID files to be dragged and dropped into an import area.

A search by UUID is available, but only for Dossiers.

## 2.2. The listings for Substance and Mixture/Product

The icons for *Substance* and *Mixture/Product* lead to lists of entities, just as they do from the homepage of the client. However, and importantly, there is no longer an icon for Dossier, because access to Dossiers has been merged with access to Substances or Mixture/Products. The windows for Substances and Mixture/Products can each display either datasets or dossiers. To switch between the two displays, click on the button shown in the example below:

![Figure 3: Show a list of datasets](image)

The type of entity in a record is indicated by an icon at the bottom right, as shown below.

![Figure 4: Substance versus Dossier](image)

There is link from a Dossier to the Substance or a Mixture/Product from which it was created. There is also a list of links from each Substance or a Mixture/Product to the dossier(s) created from them.

Where multiple Dossiers have been created for a Substance, they can all be accessed via either the Substance or the Dossier record.

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To get to a Dossier from a Substance dataset, click on the link View Dossiers at the top right of Substance information. This opens a list of all the Dossiers that refer to the Substance, as shown in the example below. To open a Dossier, click on its entry in the list.

**Figure 5: View the Dossiers for a Substance**

![Dossier versions](image1)

To go in the opposite direction, from a Dossier to a Substance dataset, click on the link Go to source at the top right of Substance information, as viewed from the Dossier. An example is shown below.

**Figure 6: View the Substance dataset for a Dossier**

![Substance information](image2)
If Go to source is not visible, the source Substance or Mixture/Product dataset is not in the IUCLID database.

The other functions have been moved to a menu that is accessed via the three dashes icon (≡) to the left of the window title, which is described later in section 3.2 The main menu.

2.3. Dossier header

In the client, data is entered in to a Dossier header only during the creation of a Dossier. In the web interface, each Substance or Mixture/Product dataset has a Dossier header associated with it which can be edited at any time, and is written in to a Dossier on Dossier creation.

The Dossier header is accessed independently of Dossier creation via the link Submission type details, as shown in the figure below.

**Figure 7:** Editing the Dossier header independently of Dossier creation

When a Dossier is created, the first step is to review and/or edit the Dossier header, as shown in the figure below.
Figure 8: Editing the Dossier header at the start of Dossier creation

2.4. Navigation, Information, and Data Panels

The panels Navigation, Information, and Data that are shown in the client have been replaced by a single central layout, in which data is presented in context. Where to find the new locations of functionalities is described below, per panel.

2.4.1. Navigation panel

A list of all the entities of a particular type is opened in the same way as in the client, that is, by clicking on the icon for that entity, either in the Dashboard or the main menu. The main difference is that the list of entities is shown centrally in the interface, rather than in a separate Navigation panel.

2.4.1.1. Right-click in the list of entities

In the client, there are various functionalities that are accessible per entity by right-clicking on the record of the entity in the list shown in the Navigation panel. Examples include Export and Compare. In the web interface these functionalities are accessed by first opening the record of the entity, and then selecting the functionality from the menu under the three-dot icon in the application bar. An example of the menu for Dossier is shown below.
2.4.1.2. Search

To search for a particular entity, first view the list of that type of entity, enter a search term in to the box at the top left of the list, and then click on the button with the magnifying glass. For Substance, Mixture/Product, and Dossier, the name of the entity and its chemical identifiers are searched. For the identifiers the search term can appear anywhere inside the value. For the name of the entity, the match must be exact, although the wild card * can be used to represent any character. An example is given below in which the wild card * is used.
2.4.1.3. **TOC**

The table of contents (TOC) for a *Substance* or *Mixture/Product* has some new features, which are described in the figure below.

**Figure 10: Search for an entity**

**Figure 11: New features in the TOC**
Legend for Figure 11:
1. The options on the menu from which the Submission type is selected are customisable per dataset;
2. The tree structure of the TOC is shown with all the top level sections for the submission type on the left, and the subsections expandable on the right;
3. The number of documents in a section or subsection is shown in a round icon to the right of the section. Empty sections have no icon.

2.4.1.4. Annotations
There is no global management of Annotations like that presented in the Navigation window of the client. Instead, an Annotation is accessible from only the record of the document with which it is associated. An Annotation connected to a whole Substance dataset is accessible only from the section Identification. An Annotation connected to a whole Mixture/Product dataset is accessible from the first section under the identity of the mixture.

The link to Annotations for a document is at the top right of the record of the document, as indicated by the red ring in the figure below. Clicking on this icon opens a menu from which Annotations can be managed, as described in section 6 Annotation.

Figure 12: Where to find Annotations

2.4.2. Information Panel
The Information and functionality available from the Information panel in the client are accessible as described below.

2.4.2.1. Information
The UUID of an open entity is displayed under its name at the top left of its record. The UUID of a Substance dataset is also displayed under Substance information. An example is shown below for the record on a Dossier, in which the UUIDs of both the Dossier and the Substance to which it refers can be seen at the same time.

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2.4.2.2. Clipboard manager

Documents can be copied from one entity to another using copy Templates, or the new feature Copy from existing, which is accessible from the menu where documents are created. Copy from existing works only across separate entities, rather than within a single entity. An example is shown below in which a document in section 7.1.1 Basic toxicokinetics for REACH is going to be copied from one Substance dataset to another. After selecting Copy from existing, the documents that can be copied are presented in a menu.
2.4.2.3. Attachments

An Attachment is accessible from only the record of the document with which it is associated. An Attachment attached to a whole Substance dataset is accessible from only the section Identification. An Attachment attached to a whole Mixture/Product dataset is accessible from only the first section under the identity of the mixture.

All the Attachments attached to a document are presented in a menu that is opened from the paperclip icon at the top right of the record. This includes attachments attached to the whole document, and those attached in fields. Where an Attachment is attached to a field, there is a direct link to the attached file from the document the record page. An example is shown below for a document in section 13.1 Chemical safety report under REACH. The attachment csr_contact_info.txt is attached to the whole document. The attachment csr.pdf is attached only to the field Chemical safety report CSR.
2.4.2.4. Modification history

The modification history in the web interface is accessed from a button that is displayed at the top right of the data window. The button is visible only whilst the document is open in the data window. It contains the following fields from the classic interface: author, date, and remarks. For more information see section 3.3.12 Modification History.

2.4.2.5. Annotations

See section 2.4.1.4 Annotations.

2.4.2.6. References

To view the Referenced documents, use the IUCLID client.

2.4.3. Data Panel

The data panel is shown to the right of the table of contents. For a description of how data is entered and viewed, see the sections below on the structure of the interface.
2.4.4. **Function key F1 for help**

The field specific help opened using the function key F1 in the client, is accessed from a question mark icon to the right of the field header, as shown in the example below:

For other sources of help, see section 22 *Getting help.*
3. Overview of the web interface

The page shown on starting the web interface, or on logging in, is the home page. The IUCLID icon at the top left of the screen is a link to the home page. The web interface of IUCLID has an area for data entry and navigation, with two horizontal bars above it. The overall structure of the interface is shown below, using the home page as an example.

Figure 16: The home page, showing the structure of the web interface of IUCLID

Key for Figure 16:

1. The top bar. This bar always contains the same options, no matter what is shown in the rest of the interface. The IUCLID icon on the left brings the user back to the Dashboard shown in this figure. The dialogue icon leads to external sources of information. At the top right the name of the IUCLID user is given, which in a multi-user installation of IUCLID is a link to log out.

2. The application bar. The application bar gives access to various functionalities, dependent on what is being viewed in the data area (3). The functionalities are accessed via either their own dedicated button, or a menu under a button labelled with three dots ⋮. There is always a link to the main menu via the button labelled with three bars ⬅️, at the left of the header. When the Dashboard is displayed, the options are the functionality Search for Dossier by UUID, and a link to this manual.

3. The data area. This area is used for data entry and navigation.

3.1. Technical terms specific to IUCLID

The terms in the table below are used throughout the interface and documentation of IUCLID. Knowing that the terms mean will help you understand all of IUCLID, and how it can be used.
### Table 1: Technical terms and their meaning within the context of IUCLID

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entity</td>
<td>Entities in IUCLID are software objects that are used to store data that has a particular purpose, which depends on the type of entity. The types of entity are: Substance, Mixture/Product, Template, Annotation, Legal entity, Legal entity site, Reference substance, Test materials, Contact, Literature reference. Entities can be viewed, printed, and deleted individually. They can also be exported and imported as individual files. With the exception of Dossier, entities are designed to be referred to by other entities. This reduces duplication of data sources, and improves data consistency. On saving a change to an entity, the change is immediately seen in any other entity that refers to it. An exception to that is a Dossier, which is a read-only snapshot of data.</td>
</tr>
<tr>
<td>Dataset</td>
<td>A dataset is a collection of documents that relate to a particular chemical substance, or grouping of chemical substances. It can be of the following types: Substance, Mixture/Product, Template. For clarity and where appropriate, the type of the dataset should be stated, for example Substance dataset.</td>
</tr>
<tr>
<td>Document</td>
<td>A document is a page that contains functionality for creating, viewing or modifying an entity, a record, or a summary. The term document is also used to mean a standardised set of data that exists in a dataset in a particular section. For example, in the OECD harmonised templates under the section named Acute toxicity: oral, there can be one or more documents that all have the same structure, but do not necessarily have the same name, or contain the same values. For more information about types of documents, see section 3.3.9 Table of contents.</td>
</tr>
<tr>
<td>Fixed</td>
<td>The term fixed means that a document is in a section that can contain only one document.</td>
</tr>
<tr>
<td>Field</td>
<td>A field is a location within an entity or document in which a specific piece of data is stored. The type of data is the same throughout an individual field, for example, the field could contain free-text, a text value chosen from a drop-down menu, a number, or a date. There can be many fields in one document. An example of a field is, IUPAC name.</td>
</tr>
</tbody>
</table>

### 3.2. The main menu

The three bar icon (Ξ) at the left of the application bar is a link to the main menu, which contains direct links to various points in the interface. The main menu contains links to lists of entities, and to functionalities that do not necessarily need the context provided by the data window. If a link is greyed out, it is not accessible in this version of IUCLID. The main menu is shown in the figure below, after which there is a description of the functionalities that are accessible from only the main menu.
3.2.1. **Launch the IUCLID client**

This option is shown only when IUCLID is run on a server, and accessed remotely. It opens the classic Java client interface.
3.2.2. Template

This is a link to a page that lists the Templates in the database. For more information, see section 7 Template.

3.2.3. Reference substance

This is a link to a page that lists the Reference substances in the database. For more information, see section 12 Reference substance.

3.2.4. About

About displays the version of IUCLID and its components.

3.2.5. Help

Help contains a link to user documentation.

3.3. Functionalities available in the data area

The following functionalities are used throughout the data area.

3.3.1. Import

Data is imported in to IUCLID from the home page. Only valid IUCLID data from versions 5.6 onwards can be imported. The file extension can be i5z, i6z, or XML. When data is imported that was exported from a previous version of IUCLID 6, the import process applies a set of migration rules to the data to try to import as much data as possible in the most logically consistent manner. The migration rules are documented on the IUCLID website under the section IUCLID format.

More than one file can be imported at once. Either browse to files, or drag and drop them in to the upload area, which is marked by a dashed boundary. Imports are listed per file, as shown in the example below.
**Legend for Figure 19**

1. Overwrite settings. See section 3.3.1.1 Over:

2. The state of the import: A rotating icon means the import is still in progress. Do not shut down IUCLID whilst any import icons are rotating, because it will cancel the import of that particular file. A green tick means that the import was completed successfully. A red cross means that the import failed. If you see a failure, check the file format, and the overwrite settings;

3. To remove items from the list that are no longer required, click on Clear completed;

4. Each successful import has a link labelled Open. In the IUCLID data exchange format, one file contains either a single entity, e.g. a Dossier, or a document. The link Open opens the record page of the entity or document;

5. The upload area.

### 3.3.1.1. Overwrite settings - Import

The overwrite setting for Import, depends on the Universal Unique Identifier (UUID) of the data in the file. The UUID is written in the file. It is not dependent on the filename, which can be any valid name. The import compares the UUID to what is already in the database, and then acts according to one of the following four options listed below.

Overwriting is not allowed for IUCLID 6 Dossiers. An attempt to overwrite a Dossier results in an error message.
1. *If newer than existing:* An entity or document is imported if it has the same UUID as one within the IUCLID database, but only if the modification date is more recent than that in the IUCLID database.

2. *Never:* An entity or document is not imported if one with the same UUID exists within the IUCLID database.

3. *Always:* All entities and documents are imported. If a dataset is imported so that it writes over a dataset in the database, any documents that are already in the database, but not in the import, are still in the dataset after the import.

4. *Replace:* All entities and documents are imported. On overwriting an entity, it and any entities or documents it contains are first completely deleted. For example, if an import overwrites a dataset, after the import, only the imported documents or entities are present in the dataset. This option is useful if you and someone else work on the same dataset in parallel in different instances of IUCLID 6, and a new definitive version becomes available that you want to import without previous documents in your IUCLID 6 getting in the way. Such previous documents may be difficult to delete due to links in the database, but the *Replace* option solves that by removing the links.

The behaviours for the options above are expressed graphically in the figure below.
3.3.1.2. Default Group Access - Import

If Instance Based Security (IBS) is enabled in IUCLID 6, a field is shown called Default group access. For more information about IBS, see section 20 Sharing and Ownership - Instance based security (IBS). Where data is written over during an import, the feature Default group access does not change any access that has previously been defined using IBS.

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3.3.2. **Breadcrumbs**

The term *Breadcrumbs* refers to the statement of the path to a page in the interface that is shown in the application bar. Each level in the page hierarchy is a link delimited by the greater than character `>`. The links provide a convenient way to navigate in the interface. In the example shown below, a link in the breadcrumbs is being clicked to jump from a composition in a *Substance* dataset to the list of *Substance* datasets.

**Figure 21: Navigation using breadcrumbs**

![Dashboard > Substances > table_salt > Composition X](image)

3.3.3. **Delete an entity from a list**

To delete an entity from a list on entities, right-click on the button labelled with three dots `...` at the upper right of its list entry, and then select *Delete*. An example is shown below.

**Figure 22: Delete an entity from a list**

![table_salt](image)

3.3.4. **Free-text template**

A free-text template is a piece of text designed to help the user to enter all the required information into a text field. It provides a model text, which must then be edited to fit in with the particular...
circumstances of the user, in that context. Text that must be changed, is surrounded in square brackets [like this].

To open a free-text template, click on the icon that shows the letter A with an arrow at its lower right, A. To copy the text from the template to the field, click on the button labelled Insert…. Next, edit the text in square brackets, as required. An example is shown below.

**Figure 23: Free-text template**

![Free-text template](image)

### 3.3.5. Flag

Some fields, items, and documents can be labelled with flags to indicate that the data they contain is confidential in some way, and/or that it relates to a particular regulatory programme. Flags allow the data to be excluded when creating a dossier, exporting data, or printing data. There are two types of flag, each with their own icon, as described in the table below:

**Table 2: The icons for the states of a flag**

<table>
<thead>
<tr>
<th>Icon</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>The flag is not set.</td>
</tr>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>A flag is set that involves confidentiality.</td>
</tr>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>A flag is set for a regulatory programme.</td>
</tr>
</tbody>
</table>

Flags are shown as a pair, with the flag for confidentiality on the left, and the flag for regulatory programme on the right.

The flag for a regulatory programme is followed by a code for that programme, which consists of two abbreviations separated by a colon. The first abbreviation denotes the origin of the programme, whilst the second denotes the programme itself: for example, **EU: CLP**. More than one programme can be set per flag.

If a field can have a flag set, flag icons are shown to the right of the field label, as shown in the example below for **Identification**.
Figure 24: Flags applied individually to fields

If an item can have a flag set, the flag icons are shown just above the item. In the example below, for Impurities, item 1 has flags set, but item 2 does not.
Figure 25: Flags applied individually to items in a section

If an item is in a table, the flags are located in a dedicated column, as shown in the example below for Other substance identifiers.
If flags can be set for a whole document, the flag icons are shown in the application bar to the left of the document name, and to the right of the header, Administrative data. An example is shown below for a Chemical Safety Report (CSR).

When a document is created, no flags are set. To edit a flag, click on either of the flag icons in its pair. The flag for confidentiality, and the flag for regulatory programme, are edited from the same page, as shown in the figure below:
Figure 28: Setting flags for confidentiality, and/or regulatory programme

For confidentiality, select the type and then enter a justification. To ensure you select the correct type, read the help under the question mark icon. The type Confidential Business Information (CBI) is being selected in the example shown below.

Figure 29: Setting a confidentiality flag

When setting a flag, if a justification of the confidentiality is required, enter it into the field Justification. The field has a free-text template, which contains suggestions as to what to enter. To open the free-text template, click on the icon that shows the letter A with an arrow at the bottom.
right, A. To copy the text from the template to the field, click on the button labelled Insert…. Next, edit the text in square brackets, as required. An example is shown below.

**Figure 30: Free-text template for the justification of a confidentiality claim**

![Free-text template](image)

To set relevance to a particular programme or programmes, tick the box or boxes as required. In the example shown below REACH is selected.

**Figure 31: Flag for relevance to a regulatory programme or programmes**

![Flag for relevance](image)

### 3.3.6. Rich text input

Some text fields allow text to be entered in rich text format. This allows for various types of formatting, such as tables. A full description of rich text is out of the scope of this document, but see the example below in which a table has been created and is being edited.
### 3.3.7. Tables

Some fields display data in tables that can have rows added and removed. The columns are defined by the IUCLID format, and therefore cannot be changed. An example is shown below, in which a row is being added:
A row is deleted using the black cross icon on the right. Changes to a table are written to the database only after clicking on Save. A new row contains empty fields. Empty fields are indicated by the word *None*, in pale grey italic text, or an empty check box. The value of such a field is not literally “None”.

To edit only a check box, click in the box. To edit any or all the fields in a row, click anywhere inside the row. The fields for that row are shown in a data entry window, as shown below.
To record the new values in the view of the table, either click on the Close button at the bottom right, or click anywhere in the grey area to the left. When you have finished editing the table, remember to click on the orange button at the bottom right labelled Save.

### 3.3.7.1. Table Width

The position of the left margin against the table of content is fixed. The overall width of a table is set by sizing the browser window that contains it, from the right, as shown below.
3.3.7.2. **Column width**

The distribution of column widths within a table is set by hovering in the table header until the icon appears, as shown below, and then moving it side to side.

![Column width adjustment](image)

3.3.8. **Dynamic content rules**

To help users to enter data in a logically consistent way, the values that can be entered into some fields are dependent on the values that are already in other fields. If it is illogical for a field to contain a value, entering data into the field is disabled, which is indicated by a lighter colour for the field label. If the value of a field is changed so that it breaks the rules for dynamic content, a warning message is displayed, and the data cannot be saved. The user must change what has been entered until it is logically consistent.

**Examples**

In the example shown below, on the left, the field *Hazard assessment conclusion* has the value *no hazard identified*. Due to the lack of hazard, there is no meaningful value for the PNEC. Therefore, the field *PNEC value* is shown with a lighter field label, and no value can be entered. On the right, the field *Hazard assessment conclusion* has the value *PNEC aqua freshwater*. Therefore, the fields relevant to PNEC are shown with a darker field label, and can be edited.

![Dynamic content rules example](image)
In the example shown below, whilst the field *Hazard assessment conclusion* had a value of *PNEC aqua (freshwater)*, the value of the field *PNEC value* was set to 23 micrograms per litre. Then, the value of the field *Hazard assessment conclusion* was changed to *insufficient hazard data available*…, without deleting the value of *PNEC value*. This results in the error message “This field is expected to be empty”, and the *Save* button is inactivated. Under the red question mark icon there is a tip on how to proceed.
The rules for dynamic fields are applied to data that has been imported in to IUCLID and/or migrated from a previous version. If a rule has been broken, the data can still be imported but on editing, it can be saved only when the rules are obeyed.

**Example of dynamic content rules for imported migrated data**

In the example shown below, the values for data waving are inconsistent with the value for *Adequacy of study* (1). All the fields involved in the application of the dynamic rule are shown with an error message, and the data cannot be saved (2). Removing the inconsistency (3) clears the error message from all the affected fields, even if the field itself is not edited. The data can now be saved (4).
3.3.9. **Table of contents**

The *Table of contents* is shown for entities of type *Substance*, *Mixture/Product* and *Template*. The *Table of contents* does the following:

1. Provides access to specific documents in an entity;
2. Shows the structure of the documents in an entity in a particular regulatory context;

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3. Indicates whether a document is mandatory for a particular type of data submission made for regulatory purposes. This is done using a red asterisk to the right of the name of the section.

4. Indicates how many documents are in each section.

The general structure of the table on contents, and aspects of how it can be viewed are indicated in the figure below.

**Figure 39: General structure of the table of contents**

---

**Legend for Figure 39:**

1. *Submissions type* is used to set the display of the table of contents so that it suits a particular regulatory context;

2. All of the top-level tree structure of the table of contents for the submission type is shown on the left. Clicking on a top-level section opens it on the right, from where subsections can be accessed, scrolling down if necessary;

3. The view of subsections can be expanded and contracted using the arrowhead icons;

4. Documents can be ordered within a section or subsection by dragging and dropping;

5. The number of documents in a section or subsection is shown in a round icon to the right of the section name. Empty sections have no numbered icon;

6. A link to a document. When this is clicked, the document is opened and the table of contents expands to show the location of the document. See the next figure;

7. This button scrolls the window to the top of the table of contents;
Figure 40: Navigating by subsection in the table of contents

Legend for Figure 40

1. This figure follows on from (6) in the previous figure, where a document named Basic.toxicokinetics.001 has been opened;

2. The table of contents has automatically expanded to show the location of the open document;

3. The table of contents can be navigated by clicking on the section headings, and documents can be opened by clicking on the names of the documents;

4. Where the title of a field is in bold and blue, the field can be edited by clicking on the title.

The submission type is selected from a drop-down menu, as shown ringed in red in the figure below.
If the required submission type is not on the menu, add it by first clicking on *New submission type*, and then by selecting it from the predefined values. These include options that correspond to various dossier types for submission under a range of different regulatory programmes. In the example shown below, *BPR Active substance information* is being added to the menu.

The submission type typically corresponds to a specific type of *Dossier* uses to submit information under a regulatory programme. An example of an exception is *REACH Complete*, which shows all the documents that have any relevance to the REACH regulation. It uses the structure that is common to all *Dossiers* submitted under REACH. Also, it refers to no specific type of *Dossier*, so no document is marked as mandatory.

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Whilst entering data intended for submission in a particular type of Dossier, it is recommended to keep the Submission type set to that type of Dossier.

### 3.3.9.1. Complete table of contents

For the Submission type of Complete table of contents, documents are displayed in sections that are determined by the origin of their definitions. Documents that are not specific to a legislation are displayed in a section referred to as CORE. An example is Composition, as shown in the example below.

**Figure 43: Complete table of contents**

*DOMAIN* contains a link to the record of the dataset. Sections defined by OECD harmonised templates are in a section named *OECD*. In addition, IUCLID 6 is supplied with sections dedicated to documents that are defined under the legislations: *AU Industrial Chemicals*, *EU BPR*, *EU CLP* and *REACH*.

Documents that are shown in the same section under a particular legislation, may be shown under different sections for Complete table of contents, because they can be defined from either that legislation, CORE or OECD.

For example, for a submission type of REACH Registration 10 – 100 tonnes, if a Site is added to section 3.3 Sites, it appears under Complete table of contents in CORE / section 3.3 Sites. Similarly, for a submission type of REACH Registration 10 – 100 tonnes, if an endpoint study summary is added to section 6.1.1 Short-term toxicity to fish, when using Complete table of contents it appears under OECD in the harmonised template C Effects on biotic systems, section 41 Short-term toxicity to fish. The difference is shown in the figures below.
3.3.9.2. **New / Copy from existing**

To create a document there are two options, both of which are accessed from the link labelled *New* at the right of a section in the table of contents. *New document* opens a wizard into which data is
Functionalities of IUCLID in the web interface

entered, whereas Copy from existing creates a copy of a document that is in the same section of a different entity of the same type. An example is shown below for an endpoint summary in the section named Short-term toxicity to fish. To copy an item, click anywhere on its record in the list.

Figure 46: Creating documents using New / Copy from existing

3.3.9.3. Endpoint study record

An endpoint study record provides a template with predefined fields in which data is entered to describe a study carried out within the subject area defined by the title of the section. All entries under the OECD harmonised templates are endpoint study records.

An example of an endpoint study record is Long-term toxicity to fish.

3.3.9.4. Endpoint summary

An endpoint summary provides a means of grouping endpoint study records from within the same subsection, and of providing further information about the grouping. An endpoint summary contains links to endpoint study records in the field Link to relevant study records(s).
If an endpoint study record is created under OECD, and an endpoint summary is created under CORE for the same section, when that section is viewed for a particular legislation, both are shown.

3.3.9.5. Record

If a record contains data that cannot be described as an endpoint study record, it is referred to as just, a record.

E.g. under REACH, section 1.2 Composition, section 1.6 Sponsors.

3.3.9.6. Summary

A summary as opposed to an endpoint summary refers to only records, not endpoint study records.

E.g. under BPR section 13 Summary and evaluation.

3.3.9.7. Fixed record

A fixed record is created in a section where there can be only one record.

E.g. under REACH, section 14 Information requirements > Downstream user report.

3.3.10. Hide empty fields

Empty fields can be hidden in the document data view. An example is shown below.
Figure 47: Hide empty fields

Legend for Figure 47
1. *Hide empty fields* is selected;
2. No flag is set, so its icon becomes hidden;
3. The field *Used for classification* is empty so it becomes hidden.

3.3.11. Save

After editing a document, click on the Save button at the bottom right of the interface:

Figure 48: Save
For a few seconds after clicking on Save, an option to view the record page of what was saved is presented in a green box, as shown below.

Figure 49: Option to view a document that has just been saved

3.3.12. Modification History

The modification history for a document is available whilst the document is open in the data window. It is accessed via a button at the top right of the data window, as shown in the example below:

Figure 50: Access to the modification history

For each event, the history shows a timestamp, the IUCLID User that carried out the action, and for some cases, a description of the event. The example below shows the modification history of an Endpoint study record immediately after it has been created. Note that the document is open in the data window.

Figure 51: Modification history of an Endpoint study record
The modification history of a top-level entity such as a Substance or Mixture/Product is accessible from the document that defines its name. For example, the document that defines the name of a Substance under REACH is section 1.1 Identification, as shown in the example below.

**Figure 52: Access to the modification history of a Substance**

When the content inside a IUCLID document is edited, the edit does not appear in the modification history of a IUCLID document or entity that refers to it. For example, when the value of a field is changed inside an Endpoint study record, the event does not appear in the modification history of a Substance dataset that contains it.

Each import action is recorded as an event, even where the import did not result in a change to the data as a result of migration from a previous version. If the modification history does not start with a Creation event, but Import instead, it means that the document had been exported from IUCLID with the modification history excluded.

A description for an event is given, in a grey box below the timestamp, if a reference to a IUCLID document is changed, or the action was an import. If only the value of a field is changed in a document, no description is given.

An example of the modification histories for a Substance and an Endpoint study record inside it is given below.
Figure 53: Example modification histories for a Substance and an Endpoint study record inside it

Legend for Figure 53

1. 13:22 Substance was imported from an i6z file;
2. 13:24 An Endpoint study record was created with the default name, Short-term toxicity to fish.001;
3. 13:27 The value of a field was changed in Short-term toxicity to fish.001. Note that it is not shown in the history of the Substance;
4. 13:29 Name of the Substance was changed. Note that it is not shown in the history of the Endpoint study record named Short-term toxicity to fish.001;

3.3.13. Bookmarks, hyperlinks, and the sharing of entities and documents

The web technology behind the interface means that it is possible to create a hyperlink that points to any document or entity. Such links can be saved as bookmarks, and shared between colleagues.

The information required to create a bookmark or link can be obtained by right-clicking on a link to the document in the web interface. The exact steps depend on the browser, but typical options are Copy link location (Chrome) and Copy shortcut (IE). In the browser Firefox, a bookmark can be created directly, as shown in the example below.
Remember that you must take into consideration the address of the instance of IUCLID. For example, links can be shared without modification between any two default instances of IUCLID 6 Desktop. The same goes for colleagues sharing access to a single instance of IUCLID 6 Server.

If the addresses of the instances of IUCLID differ, modifying the link is a simple matter of changing the first part of the link up until the start of the following code:

```
/iuclid6-web/...
```

The part of the address to change is indicated in the screenshot below, underlined in a wavy red line.
Figure 55: The part of a link to an entity or document that depends on the instance of IUCLID

![Image of IUCLID interface]

A link to a Dossier is of the form:

```
http://<server>/iuclid6-web/browser/dossier/<dossier uuid>/DOSSIER/<dossier uuid>
```

**Example 1**

An address from a default instance of IUCLID 6 Desktop is adapted to an instance of IUCLID 6 Server.

Default instance of IUCLID 6 Desktop:

```
http://localhost:8080/iuclid6-web/browser/raw/SUBSTANCE/...
```

Changes to:

```
```

**Example 2**

A link to a Dossier. This requires the Dossier UUID, and the location of the installation of IUCLID. The Dossier UUID can be copied from the record page of the Dossier, where it is stated just under the name. The location of the UUID and the link are given below.
3.4. Attachments

An attachment is an external file that has been included in a IUCLID document. This is done either for convenience, or because the data cannot be entered directly in to a IUCLID field. An attachment can be attached either to a whole document, or within a field. After attaching a document, click on "Save." A remark can be added for each attachment by clicking on the icon .

An example of attachment to a whole document is shown below.
Functionalities of IUCLID in the web interface

Figure 56: Attaching an attachment to a whole document

An example of adding an attachment within a field is shown below for a the attachment of a Chemical Safety Report in section 13 Assessment reports, under REACH.

Figure 57: Attaching an attachment within a field

The name of an attachment in the data window is a link to the file, from which it can be downloaded.

An Attachment attached to a whole Substance dataset is accessible from only the section Identification. An Attachment attached to a whole Mixture/Product dataset is accessible from only the first section under the identity of the mixture.

https://iuclid6.echa.europa.eu
If a migration of data across different versions of IUCLID involves the transfer of data into a version of IUCLID that has no equivalent field in which to place it, the data is not lost, but is automatically placed in to a new text file that is then attached to the document. The file name of such attachments is of the form:

...<source version>-to-<destination version>_migration_<date>.txt
4. Substance

A Substance is a type of entity in IUCLID that is used to store information about something that, in a regulatory context, is considered a single chemical substance.

The fields in a Substance are designed to allow the recording of the identity of the chemical substance and a broad range of different types of information relevant to its regulation. The fields are organised in a Table of contents. For more information see 3.3.9 Table of contents.

In the table of contents, the identity of the Substance is defined in section 1 General information. In section 1.1 Identification, there are two mandatory fields: Substance name and Legal entity.

More detail can be provided about the Substance identity in section 1.2 Composition, where one or more compositions can be defined. A composition may contain the identities of constituents, additives and impurities, and their relative proportions. To define the identity of a Substance properly for a specific legislation, and to know how to enter sufficient data into the Substance entity, see the guidance for that legislation, such as the manuals provided on the ECHA website at the following link.

http://echa.europa.eu/manuals

A Dossier used to submit information on a chemical substance to a regulatory authority contains a read-only copy of a Substance dataset. IUCLID can be used to create such Dossiers directly from a Substance dataset. A read-only copy of a Substance dataset within a Dossier is indicated in the IUCLID interface by placing a lock icon next to the Substance icon, as shown below:

![Lock icon next to Substance icon]

The list of Substances can be accessed from the Dashboard and the Main menu. The viewing of Dossiers that refer to Substances is described in section 8.3 Viewing the Dossier header of a completed Dossier

A link to the Dossier header is provided within the record of the Dossier, under View complete information, as shown in the example below.
In the header there is a link to the subject of the Dossier. If a Legal entity were included in the Dossier, there is a link to it under Submitting Legal Entity. An example header is shown below.
Following the link to the subject of a Dossier, opens a window that contains links as described below.

Legend for Figure 81

1. A link to the read-only copy of the entity that is the subject inside the Dossier. The subject can be either a Substance or a Mixture/Product.

2. If the source dataset for the subject of the Dossier is present in the IUCLID database, a link to it is provided here.

https://iuclid6.echa.europa.eu
4.1. The Assessment entity

An Assessment entity can be thought of as 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).

The Assessment entity aims to provide a tool to assist users in documenting complex assessment cases in IUCLID. When the assessment is straightforward, there is no need to define Assessment entities.

Each Assessment entity consists of a name, a composition and a list of related endpoint summaries. To ensure consistency, all endpoint study records that are relevant for the summary of a specific endpoint, are to be actively linked by the assessor to the summary itself.

Assessment entity is under section 1.10 of the tables of contents for REACH. There is a fixed record for the whole section, and four subsections under which multiple records can be created.

4.1.1. Assessment approach (assessment entities)

The fixed section under Assessment approach (assessment entities) has a default name of Assessment approach. It contains the following two fields.

4.1.1.1. Approach to fate/hazard assessment

Approach to fate/hazard assessment contains a description of the set(s) of properties of the Substance used for the assessment considering the chemical behaviour of the substance in the different foreseen uses. Such a description provides the overall reasoning used in the creation of the Assessment entities.

4.1.1.2. Approach to fate/hazard assessment - public information

This is a specific field to provide a public description of the approach to fate/hazard assessment.

4.1.2. Types of assessment entity

The types of assessment entity that can be created are listed below:

1. Registered substance as such
2. Specific composition/form of the registered substance
3. (group of) constituent in the registered substance
4. Transformation of the registered substance

The following fields are displayed for the various types of Assessment entity.
4.1.2.1. **Assessment entity confidentiality claim**

A flag can be set that applies to all of an individual assessment entity document. A flag is set by clicking on the flag icon to the left of the name in the application bar. For a full description of flags, see section 3.3.5 Flag.

4.1.2.2. **Assessment entity name**

The user should indicate the name of the Assessment entity. As this name will not be displayed in the tree view, it is suggested to re-name the Assessment entity in the tree view accordingly.

4.1.2.3. **Relation to the registered substance**

This depends on the type of Assessment entity. It is read-only.

4.1.2.4. **Assessment entity composition**

In this table, the user defines the composition of the Assessment entity, to support the understanding of the Assessment entity definition. Depending on the type of Assessment entity, the user creates link to one of the following:

- an available composition in section 1.2 [Specific composition/form of the registered substance];
- a list of Reference substances that are part of the compositions in section 1.2 [(group of) constituent in the registered substance];
- one of the Reference substances available in IUCLID [transformation of the registered substance]

4.1.2.5. **Related Composition**

A link to compositions reported in section 1.2 can be made to indicate that the Assessment entity is expected to be used for the assessment of those compositions. Such a link is useful for the understanding of the assessment approach. See the manual titled *How to prepare Registration and PPORD Dossiers*.

4.1.2.6. **Additional information**

Report specific information not already stated in the overall explanations on why Assessment entity has been created (in the field Approach to fate/hazard assessment). For example one could use this field to explain the reasoning for grouping constituents as part of a (group of) constituents.

4.1.2.7. **Endpoint summary linked**

To enable transparency and sorting of the information in the IUCLID dataset, all study records and endpoint summaries relevant to an Assessment entity should be linked to it. This will for example enable them to be sorted in the view of the IUCLID data set, and to report them in a sorted way in the CSR when using the Report generator. From this table, the user can link all endpoint summaries that are relevant for the Assessment entity. An explanation of the relevancy of one or several endpoint summary(-ies) for the Assessment entity can be provided, when needed, in the
field Notes when linking it to the Assessment entity. In case one or several summaries have a different explanation, a new repeatable block can be added. In each endpoint summary linked, users are invited to provide the link to all study records relevant for the summary itself. In this way, the Assessment entity is indirectly linked to the endpoint studies.

4.1.2.8. Reaction schema

Upload the image of the reaction schema when needed [for Transformation of the registered substance].
5. Mixture/Product

A Mixture/Product is a type of entity in IUCLID that is used to store information on a chemical substance that is considered to be in a regulatory context, either a mixture, or a product, or both. An example is the concept of Mixture/Product under the BPR regulation.

The structure of the entity Mixture/Product is similar to that for Substance, which is described in section 4 Substance, but there are important differences in section 1.2 Composition. There is an additional field named Formulation type which is relevant to Products. In addition, the Mixture/Product can contain components instead of constituents. There can be multiple components, impurities and additives, all of which can refer not just to a Reference substance, but also to either a Substance or a Mixture/Product. Thus, where a link is made to define the identity of a component, impurity or additive, the type of entity must be selected. An example is shown below in which a component of type Mixture/Product is being added.

Figure 58: Adding a Mixture/Product as a component in a Mixture/Product

Components, impurities and additives are given a two digit number that indicates the order in which they were added, per type. In the example shown above, the fourth component is being added.

Mixture/Product can be accessed from the Dashboard and the Main menu. The way they are viewed is linked to the viewing of Dossiers that refer to them, as described in section 8.3 Viewing the Dossier header of a completed Dossier

A link to the Dossier header is provided within the record of the Dossier, under View complete information, as shown in the example below.

https://iuclid6.echa.europa.eu
In the header there is a link to the subject of the Dossier. If a Legal entity were included in the Dossier, there is a link to it under Submitting Legal Entity. An example header is shown below.
Following the link to the subject of a Dossier, opens a window that contains links as described below.

**Figure 81: Links to the subject of a Dossier and its source dataset**

Legend for Figure 81

5. A link to the read-only copy of the entity that is the subject inside the Dossier. The subject can be either a Substance or a Mixture/Product.

6. If the source dataset for the subject of the Dossier is present in the IUCLID database, a link to it is provided here.

https://iuclid6.echa.europa.eu
Viewing Dossiers and Substances or Mixture/Products.

6. Annotation

An Annotation is a type of entity in IUCLID 6 that is used as a container for information that relates to the evaluation of data in a particular regulatory context, for example, by a regulatory body. It provides more functionality than using an attachment because the data is structured within IUCLID.

An Annotation is applied to an individual document. A document can have more than one Annotation applied to it, and an Annotation can be applied to more than one document.

The Annotation(s) applied to a document are accessed and managed via a link at the top right of the record of the document, as indicated in the figure below.

Figure 59: Viewing and managing the Annotations applied to a document

Legend for Figure 59

7. Open a list of Annotations applied to the document by clicking on the Annotation icon;
8. Create an Annotation for the current document;
9. The value of the status field for the Annotation is shown with a colour code;
10. Actions that apply to only the specific Annotation are accessed via the three dot icon.

There are two sections in an Annotation, as described below.

6.1. Annotation - Basic data

Enter a name for the Annotation and the organisation carrying out the work. The field Annotation status may be used to record whether the Annotation is still being worked on or whether it has been finalised. An evaluation may be uploaded as an attached file to the field Attached regulatory authorities’ evaluation.

6.2. Annotation - Dataset data

This section contains fields into which details about the evaluation process may be recorded. The field Remarks, is a free-text field that has a free-text template. Suggestions as to what to enter are provided in a free-text template. To open the free-text template, click on the icon that shows the letter A with an arrow at the bottom right, 𝐀. To copy the text from the template to the field, click on the button labelled Insert… . Next, edit the text in square brackets, as required.
7. Template

A Template is a type of entity that allows data from multiple sections to be inserted into a Substance or Mixture/Product dataset all at once, without having to manually recreate all the sections individually, and re-enter the data. Templates can be managed from their list view, which is accessible via the main menu, as shown below.

Figure 60: Manage Templates – E.g. delete
7.1. Attaching a Template to a Substance or a Mixture/Product

A Template is inserted in to a Substance or Mixture/Product dataset via the Information pane in its opened record. There are two options, Inherit and Copy, as shown in the example below:

Figure 61: Inserting a Template in to a Substance or Mixture/Product

Selecting either Inherit or Copy opens a list of the available Templates.

The same Templates are presented for either option, but a Template can be inherited only once. The Legal entity in the Template is neither inherited by, nor copied to, the Substance or Mixture/Product.

In the example shown below, a Template named section_4_template is being copied to a Substance dataset.
7.2. Inherit a Template

Inherit creates a dynamic link from the Substance or Mixture/Product to the Template. The data can be modified only from within the Template, not from within the Substance or Mixture/Product. Modifications made in the Template are available immediately in the Substance or Mixture/Product.

The Templates that have been inserted using Inherit, are shown in lower part of the Information panel of the Substance or Mixture/Product, as shown in the example below where there are two Templates: common_data and section_11_template.
Documents inherited from a Template are added to the table of contents alongside existing documents, and marked out by an icon that has a box surrounding the standard icon, as shown below.

**Figure 64: A document within an inherited Template in the table of contents**

Note how the inherited documents do not have delete buttons. They can be removed only by removing the whole inherited Template, which is done from the list of inherited Templates in the record of the dataset.

### 7.3. Copy a Template

*Copy* adds a copy of the documents in the Template to the Substance or the Mixture/Product. There is no link. A document copied in this way can be modified in the Substance or Mixture/Product to which it was copied. Changes to the data in the Template do not affect the Substance or Mixture/Product to which it was copied. All the documents from a Template are copied. There is no way to make a limited selection during the copy process. If a Template is copied more than once to the same Substance or Mixture/Product, new extra copies of the documents are added to the table of contents, without over-writing data. Documents copied from a Template are added to the table of contents alongside existing documents. The document icon is the standard icon because there is no link to the data from the Template, and the data can be modified.
8. Dossier

A Dossier is used to submit data to a regulatory authority to satisfy a legal obligation arising from a legislation, for example REACH.

A Dossier contains a read-only copy of a header for storing administrative data, and a read-only copy of either a Substance or a Mixture/Product dataset. Dossiers are created starting from the Substance or Mixture/Product dataset which they will contain. The functionality described in this section applies to both Substances and Mixture/Products.

8.1. Dossier header

A Dossier header is a set of fields used to store administrative information that is relevant to the submission of data under a particular regulation. The fields present are determined by the Submission type. Each Substance dataset has a Dossier header associated with it which can be edited at any time, including at the start of Dossier creation. When a Dossier is created, a read-only copy of the Dossier header is placed in to the Dossier.

The Dossier header can be accessed independently of Dossier creation via the link Submission type details, as shown in the figure below.

**Figure 65: Editing the Dossier header independently of Dossier creation**

During Dossier creation, the first step is to review and/or edit the Dossier header. See the section on Dossier creation for more information.
8.2. Creating a Dossier

Before creating a Dossier, a Submission type must be selected. This allows the IUCLID interface to present to the user at the start of Dossier creation, either a pre-filled or blank Dossier header of the correct type. Entering data in to the Dossier header is an essential part of creating a Dossier, for the reasons described in section 8.1 Dossier header.

Dossier creation is started by clicking on the button labelled Create dossier, which is shown at the upper right of the record of a dataset. If the button is dimmed and cannot be clicked on, select a Submission type. An example where to find the Create dossier button is shown below for a Substance dataset.

**Figure 66:** Start Dossier creation for a Substance dataset

![Image of Create dossier button](https://iuclid6.echa.europa.eu)

Enter values and/or check the values already entered in to the Dossier header. The values to be entered in to the Dossier header depend on the specific circumstances under which data is to be submitted to a regulatory authority. For example, for advice on how to fill out the header under the REACH regulation, see the manual How to prepare registration and PPORD dossiers, which is available on the ECHA website here. Translated versions of that manual, and other manuals on Dossier preparation under the REACH and CLP regulations are available on the ECHA website at the following address:

http://echa.europa.eu/manuals

To create a Dossier with default settings, click on Create dossier, in which case you can skip the next section. To use advanced settings, click on the button labelled with three dots. The settings are described in the next section.
8.2.1. Advanced settings for excluding and including data from the Dossier

The filtering rules that are set in the following fields are applied cumulatively such that if any rule excludes a type of document or a field, it is excluded from the Dossier. To use advanced settings, click on the button labelled with three dots, as ringed in red in the screenshot below.

After editing the advanced settings, click on Create dossier.
8.2.1.1. Include legal entity

Either exclude or include the Legal entity that is attached to the Substance or Mixture/Product. Unlike the other fields, the default is to exclude, which is the setting shown in the screenshot below.

**Figure 69: Include/Exclude legal entity from a Dossier**

8.2.1.2. Detail level of document fields

Unticking the box labelled Detailed fields, excludes from a Dossier the fields that are labelled as being confidential by having the text (confidential) appended to their names. Note that these fields are handled completely separately from fields for which flags may be set.

**Figure 70: Detail level of document fields, to be included in a Dossier**

Example

The figure below shows an example of a field that can be excluded. It is part of Test materials.
8.2.1.3. Flags for confidentiality

Flags for confidentiality relates to flags, which are described in section 3.3.5 Flag. By default, all the flagged data is included. Inclusion is indicated by the presence of a grey box that contains the name of the type of the flag. To exclude data that has a particular type of flag, remove its box by ticking the cross icon on its right. An example is shown below in which data flagged as being confidential business data (CBI) will be excluded.
To add an option that is not shown on the list, open the drop-down menu, and then click on the item, as shown in the example below.

Figure 73: Include or exclude data from a Dossier according to confidentiality flags
8.2.1.4. Flags for regulatory programme

Flags for regulatory programme relates to flags, which are described in section 3.3.5 Flag. By default, all the flagged data is included. Inclusion is indicated by the presence of a grey box that contains the name of the type of the flag. To exclude data that has a particular type of flag, remove its box by ticking the cross icon on its right. The options for regulatory programme are shown below. The field other is a free-text field.

Figure 74: Flags for regulatory programme

![Flags for regulatory programme](https://iuclid6.echa.europa.eu)
To add an option that is not shown on the list, open the drop-down menu, and then click on the item, as shown in the example below.

Figure 75: Include or exclude data from a Dossier according to regulatory programme flags

8.2.1.5. **Included Annotations**

This step in the wizard allows Annotation entities to be excluded. The default is to include them all, as shown below.

Figure 76: Exclusion of Annotation entities

8.2.2. **Validation during creation of a Dossier**

Next, the Validation assistant is run automatically in the background. If any Submission checks fail that would prevent the Dossier from being submitted to the relevant regulatory authority, an option is given to go straight in to the Validation assistant to try to start fixing the problems in the dataset before actually creating a Dossier. It is also possible to ignore the warning and create a Dossier, but bear in mind it will not be possible to submit the Dossier.
Figure 77: Dossier creation – Option to use the Validation assistant

Clicking on View/fix errors opens the report of the Validation assistant, which is described in section 16 Validation assistant.

8.2.3. Finishing the creation of a Dossier

If you click on Continue with dossier creation, or if the Dossier creation passes all the Submission checks, the Dossier is created and the following message is shown.

Figure 78: Successful Dossier creation

8.3. Viewing the Dossier header of a completed Dossier

A link to the Dossier header is provided within the record of the Dossier, under View complete information, as shown in the example below.
In the header there is a link to the subject of the Dossier. If a Legal entity were included in the Dossier, there is a link to it under Submitting Legal Entity. An example header is shown below.
Functionalities of IUCLID in the web interface

Figure 80: Viewing the header in a Dossier

![Figure 80: Viewing the header in a Dossier](image1)

Following the link to the subject of a Dossier, opens a window that contains links as described below.

Figure 81: Links to the subject of a Dossier and its source dataset

![Figure 81: Links to the subject of a Dossier and its source dataset](image2)

Legend for Figure 81

11. A link to the read-only copy of the entity that is the subject inside the Dossier. The subject can be either a Substance or a Mixture/Product.

12. If the source dataset for the subject of the Dossier is present in the IUCLID database, a link to it is provided here.

https://iuclid6.echa.europa.eu
8.4. Viewing Dossiers and Substances or Mixture/Products

The icons on the Dashboard for Substance and Mixture/Product lead to lists of either Dossiers or datasets. To switch between the two, click on the button shown in the example below:

**Figure 82: Show a list of datasets**

![Datasets and Dossiers button](image)

The type of entity in a record is indicated by an icon on its right-hand side, as shown below.

**Figure 83: Substance versus Dossier**

![Table salt record](image)

There is link from a Dossier to the Substance or a Mixture/Product from which it was created. There are also links in the opposite direction, from the record page of a dataset to the Dossiers created from it.

Where multiple Dossiers have been created for a Substance, they can all be accessed via either the Substance or the Dossier record.

To get to a Dossier from a Substance dataset, click on the link View Dossiers at the top right of Substance information. This opens a list of all the Dossiers that refer to the Substance, as shown in the example below. To open a Dossier, click on its entry in the list.
To go in the opposite direction, from a Dossier to a Substance dataset, click on the link Go to source at the top right of Substance information. An example is shown below.

If Go to source is not visible, the source Substance dataset is not in the IUCLID database.
8.5. Compare Dossiers

*Compare* produces a comparison of every value in any two *Dossiers*. The output is an HTML file that can be viewed in a browser, for example by opening it in a tab alongside the web interface. To compare two *Dossiers*, start by viewing the record of the source *Dossier* against which the comparison will be made, and then select *Compare*, from the menu labelled with three dots, as shown below.

**Figure 86: Start the comparison of two Dossiers**

This opens a page from where the other, or target, *Dossier* is selected, as described in the figure below.
Figure 87: Select the second, or target, Dossier in a comparison

Legend for Figure 87
1. Search for a target Dossier by Dossier name, Substance name and Submission type all at the same time;
2. Tick the box to limit the Dossiers shown to only those that were created from the same dataset as the source Dossier;
3. Click on a target Dossier to generate the comparison report.

The comparison report is an HTML file with a name of the form:

<name of source Dossier>_<name of target Dossier>_<comparison.html>

E.g. Dossier_one_ts_Dossier_two_ts_comparison.html

Section 1 of the comparison report, Dossiers, contains some basic information about the content of the source and the target Dossiers, as shown in the example below:
The second level of the comparison report, *Dossier contents*, contains a side by side comparison of the *Dossier* header and the entities, grouped by type of entity, for example *Substance*, as shown below.

**Figure 89: Comparison report – Second level: Dossier contents**

At the second level, the entity level, where the column *Comparison* contains the value *Different*, there is an internal hyperlink down to the corresponding entry at the third-level, which is the document level, *Section Document comparison*, as shown below.

**Figure 90: Comparison report – Third level: Section document comparison**
Section Document comparison is arranged and numbered as per the table of contents (TOC) for the Dossier type of the source Dossier. Therefore, choose as the source Dossier the one with the numbering and structure that you prefer to see in the comparison report. An example is the difference between a REACH Dossier, and one for OECD harmonised templates.

At the third level, the document level, where the column Comparison contains the value Different, there is an internal hyperlink down to the corresponding entry at the lowest level in the report, which is Field-level content differences. On this level, there is a row for each field in which a difference was found. The field name and the values for the field are given. An example is shown below for an endpoint study record named EP3 in the section Short-term toxicity to fish.

![Field-level content differences](https://example.com/image.png)

The possible values of the column Comparison on levels two and three are described in the table below.

### Table 3: Key for the icons in the Dossier comparison report

<table>
<thead>
<tr>
<th>Icon</th>
<th>Label in interface</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📜</td>
<td>Identical</td>
<td>The entity or document is exactly the same in both Dossiers. This is based on UUID and content.</td>
</tr>
</tbody>
</table>

https://iuclid6.echa.europa.eu
### Functionalities of IUCLID in the web interface

#### Icon | Label in interface | Description
--- | --- | ---
[ ] | Different | The entity or document has the same UUID in both Dossiers, but different content. For example, this could happen for an endpoint study record if the Dossiers being compared were created from the same Substance that contained it, and the endpoint study record were edited after the creation of the first dossier. This can occur during the process of providing updated data under a regulation, for example under REACH. The word Different is a hyperlink to the fourth level of the comparison report, where the differing field(s) and their values are shown.

[ ] | Only in source | The entity or document is in the source Dossier, but not the target Dossier. This is based on UUID.

[ ] | Only in target | The entity or document is in the target Dossier, but not the source Dossier. This is based on UUID.

[ ] | Only in source, same content | The entity or document is in the source Dossier, but not the target Dossier. This is based on UUID. There is a another document in the source Dossier with the same content.

[ ] | Only in target, same content | The entity or document is in the target Dossier, but not the source Dossier. This is based on UUID. There is a another document in the target Dossier with the same content.

#### 8.5.1. References in the comparison report

Where the same content is found in a different document, a link is created to the first instance of the content. The first instance is shown with a label (content reference: <RefN>) where N is its sequence number throughout the whole comparison. Links can be across the two Dossiers compared, or inside the same Dossier. Hovering over a link or its anchor, highlights the anchor and the reference(s) to it. An example is shown below in which there are two reference anchors, Ref2 and Ref4. Ref3 is in a difference section, and so cannot be seen in this view.

**Figure 92: Links to duplicate content in the comparison report**

![Image of comparison report with links to duplicate content](https://iuclid6.echa.europa.eu)
Legend for Figure 92

1. The direction of the links to Ref2 are shown as red arrows. One link to Ref2 is in the source Dossier, and one is in the target Dossier. EP1 and EP1-copy in the source Dossier have identical content. Their UUIDs must be different otherwise they could not exist in the same dataset;

2. The cursor is hovering over the content reference Ref4, causing it and its links to be highlighted. EP2 is in both the source Dossier and the target Dossier. There is also a copy of it in the target Dossier, hence the two links.
8.6. Calculate Fee

The *Fee calculator* assists users in calculating the fees for submission of data according to the [REACH Fee Regulation](https://europa.eu) (No 340/2008 of 16 April 2008, and subsequent amendments). The *Fee calculator* takes a *Dossier* as its input, and outputs a list of the expected fees. It works for all types of *Dossier* that industry users can submit to the European Chemicals Agency (ECHA) under the REACH regulation.

8.6.1. Running the Fee calculator

The *Fee calculator* is run from the top level of the record for a *Dossier*. Click on the button labelled with three dots, and then select *Fee calculator*, as shown ringed in red in the example below.

Figure 93: Run the Fee calculator

8.6.2. Selecting the company size

First, select the size of the company from the drop-down menu, as shown in the example below.
8.6.3. The Indicators needed for the fee calculation

Some indicators appear when there are confidentiality claims in the dossier, or when the fee waiver has been claimed.

For calculating the fees of some confidentiality claims, you will need to indicate whether:

1. the substance is hazardous as defined in the amended Articles 119(2) (f) or (g) and 14(4) of the REACH Regulation and if the substance is assessed to be PBT/vPvB;

2. a safety data sheet is required for the substance.

The indicators will appear only if they are relevant for calculating the fee, and if the required information is not included in the dossier. For example, if there are no confidentiality claim flags set in the dossier, the indicators will not appear.

For calculating the fees of Dossiers with tonnage band 1 – 10 tonnes/year where the fee waiver has been claimed, you will need to indicate whether the substance fulfils the Annex III criteria.

8.6.3.1. Hazardous Substance indicator

If the substance is classified as hazardous and is assessed to be PBT/vPvB according to Articles 119(2) (f) or (g) and 14(4) of REACH Regulation, tick the box next to the “Hazardous Substance indicator”.

This indicator is shown when the required information is not included in the dossier.
Functionalties of IUCLID in the web interface

Figure 95: Hazardous substance indicator

For more information, check the manual Dissemination and confidentiality under the REACH Regulation: https://echa.europa.eu/manuals.

8.6.3.2. Safety Data Sheet indicator

If the safety data sheet is required for the substance according to Article 31 of the REACH Regulation, tick the box next to the Safety Data Sheet indicator. A safety data sheet is required when the substance is classified under the CLP regulation, is PBT/vPvB, and/or is on the Candidate list.

This indicator is shown when the required information is not included in the dossier.

Figure 96: Safety Data Sheet indicator

For more information, check the manual Dissemination and confidentiality under the REACH Regulation: https://echa.europa.eu/manuals.

8.6.3.3. PBT/vPvB indicator

If the substance is assessed to be PBT/vPvB according to Annex XIII of REACH Regulation, tick the box next to the text PBT / vPvB indicator.

This indicator is shown when the required information is not included in the dossier.

Figure 97: PBT/vPvB indicator

https://iuclid6.echa.europa.eu
For more information, check the manual *Dissemination and confidentiality under the REACH Regulation*: [https://echa.europa.eu/manuals](https://echa.europa.eu/manuals).

### 8.6.3.4. Annex III criteria indicator

If the substance does not fulfil the Annex III criteria according to REACH Regulation, and the full Annex VII is voluntarily provided, tick the box next to the "Annex III criteria indicator".

The Annex III criteria is not fulfilled when:

1. there is no indication that the substance has carcinogenic, mutagenic or toxic to reproduction (CMR, category 1A or 1B), persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) properties, OR

2. there is no indication that a substance with dispersive or diffuse uses would be classified as hazardous for human health or as an environmental hazard under the CLP Regulation.

This indicator is shown when the fee waiver is claimed in dossiers with standard tonnage band 1 - 10 tonnes/year.

**Figure 98: Annex III criteria indicator**

![Annex III criteria indicator](image)
8.6.4. Dossier is for an update to a previous submission

If the dossier is an update, select the tonnage range of the previous submission, and tick the appropriate box(es) if the onsite or transported intermediate use has been paid for previously.

Figure 99: Select the tonnage band of the previous submission, and information on intermediates
8.6.5. Fee calculator results window

Clicking on the button labelled *Calculate* at the foot of the page generates an itemised list of the fees calculated according to the *Dossier* information, and the information inserted manually into the *Fee calculator*. An example is shown below.

**Figure 100: Fee calculator results window – example showing intermediates and confidentiality claims**

![Fee calculator results window – example showing intermediates and confidentiality claims](image)

8.6.6. Version of the Fee calculator

It is important to use the latest version of the *Fee calculator*. New versions are made available either as part of a new release of the IUCLID application, or through an update to an individual component. To be informed of changes, sign up to the general newsletter of IUCLID by logging in to the IUCLID website, opening *My account*, and then ticking the relevant box.

8.6.7. Disclaimer

The fees calculated by the *Fee calculator* are only estimates, and do not replace the fees specified in the actual invoice you will receive in REACH-IT after the submission of your registration dossier. It is the responsibility of the submitter to ensure that the dossier fulfills the appropriate data requirements and to monitor the receipt of the invoice in REACH-IT.
8.7. Dissemination preview

The Dissemination preview allows you to simulate which information from your Dossier is likely to be made publicly available by ECHA in the process known as dissemination.

The output of the Dissemination preview is a file in the format of Microsoft Excel (XLSX).

The output contains an indication of the information which would be, if submitted to ECHA, be made publicly available over the internet.

The Filtering Process in the tool, that prescribes the output, uses the same Filtering Rules as used by ECHA for publication of information on the ECHA website. Information on these Filtering Rules can be found in a dedicated manual titled Dissemination and Confidentiality under the REACH Regulation, which is available in PDF format on the ECHA website at: https://echa.europa.eu/manuals.

The Dissemination preview is for information purposes only, and the resulting output may not be identical to the actual dissemination that will be performed by ECHA in accordance with Article 119 of REACH.

In particular, as the Dissemination preview cannot assess confidentiality claim(s); so by default, it will remove information claimed confidential. Note however, that ECHA will perform an assessment of each confidentiality claim falling under REACH Article 119(2). Should ECHA reject any such confidentiality claim(s) the information claimed confidential will be disclosed at a later stage after consultation with the registrant, in accordance with REACH Article 119(2).

In addition, the information that will be disseminated for each Substance on the ECHA website will be aggregated from multiple registration Dossiers at different tonnage bands, and therefore may contain additional information to that indicated in the output of the Dissemination preview.

The following subsections describe how to run the Dissemination preview, and how to understand its output.

Note: It is recommended to always use the latest version of the Dissemination preview, which in practice means using the latest version of IUCLID.

8.7.1. Running the Dissemination preview

The Dissemination preview is run from the top level of the record for a Dossier. Click on the button labelled with three dots, and then select Dissemination preview, as shown ringed in red in the example below.
8.7.2. Output of the Dissemination preview

The output is a file in the format of Microsoft Excel (XLSX).

There is a row per field that states the location of the data within IUCLID, and whether data in that field is published publicly on the ECHA website. The publication is indicated in the column named *Outcome*. If a field is empty, there is no row for it in the output of the Dissemination preview.

8.7.2.1. Fields for which there is a reference within IUCLID

In IUCLID, an entity or a document can refer to another entity. The types of entity that can be referred to are: *Reference substance*, *Test material*, *Contact*, *Legal entity*, *Literature reference*, and *Category*. For example, a *Substance* can refer to a *Reference substance*.

Where data exists in cases such as this, there are rows in the output of the Dissemination preview for the fields at both ends of the reference. For example the field in a *Substance* where it refers to a *Reference substance* has a row. Also, the fields in the *Reference substance* have their own rows. If the row in the *Substance* has an outcome of “Published” this does not necessarily mean that all the fields for the *Reference substance* are published.

Where a reference exists from the field in a row, the row contains a value in the column named *referencedDocumentKey*. This value is present in the column *sourceDocumentKey* for the rows to which the reference points. Thus the values can be used to find the rows to which a reference points. An example is shown below.
The outcomes for referenced entities are at the bottom of the report, but they can be seen more clearly using the filter function of Excel, as described in the example below.

Example

A substance contains a link in section 1.1 Identification to a Reference substance.

Open the Dissemination report and then find the field required, using the column named field. In this example it is:

**Substance / Identification of substance / Reference substance**

From the screenshot below it can be seen that the Reference substance will be published, but what about the individual fields inside the Reference substance? Their values for Outcome can be viewed as follows.

Copy the value of referencedDocumentKey (Column G) for the row to the clipboard, for example by selecting it, and then using right-click Copy. It is displayed by selecting the cell, as shown below.
Figure 104: The identifier of a Reference substance in `referencedDocumentKey` (Column G)

In this example the value is:

```
a1c82b2f-4552-4670-90bc-019bb478ce06/59c5101c-87bc-4c3e-93c7-3c03bd98c480
```

Apply a filter in MS Excel to the column `sourceDocumentKey` (F) as shown in the figure below.

In this example the value is:

```
a1c82b2f-4552-4670-90bc-019bb478ce06/59c5101c-87bc-4c3e-93c7-3c03bd98c480
```
Figure 105: Apply a filter to *sourceDocumentKey* in MS Excel

Legend for Figure 105
1. With the column *sourceDocumentKey* (F) selected, click on DATA > Filter;
2. Open the filter window;
3. Paste the value of *referencedDocumentKey* copied earlier, into the box Text Filters;
4. Click OK;

The result shows the predicted outcome for all the fields in the Reference substance, as shown below. Note that even though the outcome for the link to the Reference substance is “Published”, not all the fields in the Reference substance itself are published.
Figure 106: Output of the Dissemination preview filtered for a single reference to a Reference substance

<table>
<thead>
<tr>
<th>Field</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference substance / General information / Reference substance name</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Inventory / Inventory number</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Reference substance information / IUPAC name</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Reference substance information / Description</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Not published (ineligible for display)</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Reference substance information / Synonyms / 1 / Identifier</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Not published (ineligible for display)</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Reference substance information / Synonyms / 1 / Remarks</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Reference substance information / CAS Information / CAS number</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Reference substance information / CAS Information / CAS name</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Reference substance information / Related substances / Group / CAS</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Molecular and structural information / Molecular formula</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Molecular and structural information / Molecular weight</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Molecular and structural information / SMILES notation</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Molecular and structural information / InChI</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Molecular and structural information / Structural formula</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
</tr>
<tr>
<td>Reference substance / Molecular and structural information / Remarks</td>
<td>Not published</td>
<td>e1c82b2f-4552-4670-90bc-0195b478ec0</td>
<td>Published</td>
<td>e1c82b2f-4670-90bc-0195b478ec0</td>
</tr>
</tbody>
</table>
9. Guided dossier preparation

A Guided dossier preparation is a type of extended wizard for data entry that helps a user to create a Dossier that can be submitted to a regulatory authority. The idea is to simplify Dossier preparation by providing only the information and options required to create a specific type of Dossier.

On creating a Guided dossier preparation the user enters the type of Dossier to be created. Based on that choice, the Guided dossier preparation presents the user with only the required fields, functionalities, and help texts.

A Guided dossier preparation is a discrete software entity in IUCLID in that there is a list page that shows all the Guided dossier preparations in the system, from which they can be created and deleted. Each Guided dossier preparation refers to a specific dataset. It is possible to edit the dataset completely independently of the Guided dossier preparation that refers to it, and to switch in and out of the Guided dossier preparation whilst working on the dataset. Deleting a Guided dossier preparation has no effect on the dataset to which it refers, nor on any Dossiers it was used to create.

In the list of Guided dossier preparations, each entry in the list is identified by the name of the dataset to which it refers. The list of Guided dossier preparations is accessed via either the Dashboard or the Main menu, as shown in the figure below.

Figure 107: Open the list of Guided dossier preparations

An example of the list of Guided dossier preparations is shown below.
Figure 108: The list page of Guided dossier preparations

Legend for Figure 108
1. This button is used to create a new Guided dossier preparation;
2. The name and some identifiers of the dataset to which the Guided dossier preparation refers;
3. The Submission type that will be used for the Dossier created from the Guided dossier preparation;
4. A colour-coded indicator of the legislation or the regulatory programme.

9.1. Creating a Guided dossier preparation

A Guided dossier preparation is first created using a two-page wizard, after which data is entered in to it via a set of tasks. The information entered in to the creation wizard enables the Guided dossier preparation to define which dataset is included in a Dossier, to select the appropriate Dossier type, to decide which specific tasks to present to the user, and to begin filling out the Dossier header.

The creation wizard for Guided dossier preparation is opened by clicking on the button labelled + New. First, a legislation or regulatory programme selected. Then, on the first page, a dataset is associated with the Guided dossier preparation. Either select an existing dataset, or create a new one. Note that the current page number within the data entry wizard is indicated on the left of the window.

An example is shown below for the REACH regulation, which uses a dataset of type Substance.
Figure 109: Page one of the wizard to create a Guided dossier preparation – example of REACH

Legend for Figure 109
1. This indicates the current page number within the data entry wizard;
2. From here you can select an existing dataset, e.g. a Substance to which the Guided dossier preparation will refer;
3. As an alternative to referring to an existing dataset, here you can enter the name of a new dataset that the Guided dossier preparation will create. The rest of the identity information about the dataset can be entered later.

Click on Next to go to page two of the wizard. The specific fields presented here depend on the legislation that was selected at the start of the wizard. For mandatory fields, see the legislation specific help. If you do not know what to enter in to an optional field, you can leave it empty, and enter a value later as part of the tasks that come later.

Continuing with the same example shown above for REACH, on the second page, the type of registrant and the tonnage band information are entered, as shown below:
Legend for Figure 110

1. This indicates the current page number within the data entry wizard;
2. Fill out at least the mandatory fields;
3. In this example for REACH, the tonnage band information is mandatory, so a red warning is given until a value is entered.
4. The Finish button. Here, it is inactive because a mandatory field has not yet been filled out.

When all mandatory fields have been filled out, the Finish button becomes active. Note that once Finish has been clicked, the particular dataset entity associated with the Guided Dossier Preparation cannot be changed, although the data within the dataset can be edited. The ability to edit the data on the second page of the creation wizard depends on the legislation selected for the Guided Dossier Preparation. Legislation specific guidance is provided in help texts available from the task pages described in the next section.

Click on Finish to go to the record page of the newly created Guided dossier preparation, where its tasks are presented.
9.2. The record page of a Guided Dossier Preparation

The record page of a *Guided dossier preparation* presents a list of tasks that must be carried out to obtain the final *Dossier*, ready for submission to a regulatory body. More information about the tasks is provided in the next section. Links to regulatory specific guidance are supplied on the right under *Useful information*, and detailed help is provided within the tasks themselves.

The features of the record page, which are common to all legislations, are described in the figures below. The record page is shown divided up in to its upper and lower parts. The example shown is for REACH.

**Figure 111: An example of the record page of a Guided dossier preparation – upper part**

![Figure 111: An example of the record page of a Guided dossier preparation – upper part](image)

**Legend for Figure 111**

1. The *Submission* type that will be used when a *Dossier* is created;
2. Switch to the dataset to which the *Guided dossier preparation* refers. It is possible to edit the dataset completely independently of the *Guided dossier preparation* that refers to it, and to switch in and out of the *Guided dossier preparation* whilst working on the dataset;
3. Delete the *Guided dossier preparation*. Deleting a *Guided dossier preparation* affects neither the dataset to which it refers, nor on any *Dossiers* it was used to create;
4. This is an introduction to the *Guided dossier preparation*. It may contain links, for example, to the website that is used to submit the *Dossier* to the relevant regulatory authority;

https://iuclid6.echa.europa.eu
5. These are tasks that show which data must be entered, in accordance with the information supplied when creating the *Guided dossier preparation*. Each box is a link to a list of locations in the table of contents of the dataset where data can be entered;

6. This is a list of links to documents that provide general background information on the regulation for the *Guided dossier preparation*. More specific guidance is given from within the tasks listed in (5).

**Figure 112: An example of the record page of a Guided dossier preparation – lower part**

---

**Legend for Figure 112**

1. These are tasks that show which data can be entered optionally, in accordance with the information supplied when creating the *Guided dossier preparation*. Each box is a link to a list of locations in the table of contents of the dataset where data can be entered;

2. The *Validation assistant* can be run from here. The functionality is the same as when the *Validation assistant* is opened from inside a dataset, as described in section 16 *Validation assistant*. The links in the validation report lead to the dataset that is associated with the *Guided dossier preparation*. On closing the validation report, the record page of the *Guided dossier preparation* is opened;

3. *Dossier* creation can be started from here. The functionality is the same as described in section 8.2 *Creating a Dossier*. Note that creation of a *Dossier* started from *Guided dossier preparation* overwrites the *Dossier* header that is accessible in the dataset view.
9.3. The task hierarchy in a Guided Dossier Preparation

The tasks are presented on two levels, both represented by icons of a clip-board. The upper task level icon has three dots in it to symbolise the presence of sub-tasks. The sub-task level is usually, but not always a section in the dataset. Where a section number exists, it is stated on the right of the name of the subtask. Below a subtask there are the documents/records in that section of the dataset. It is possible to add and delete documents/records. Under a document/record there is direct access to the data fields, grouped by section. An example of the appearance of the hierarchy in the interface is shown in the figure below:

**Figure 113: Hierarchy in a Guided Dossier Preparation – example for REACH**

Legend for Figure 113

1. The top level of a *Guided dossier preparation* contains tasks, indicated by an icon of a clip-board with three dots inside it;

2. At the next level down there are sub-tasks, indicated by an empty icon of a clip-board. The sub-task level is usually, but not always a section in the dataset. Where a section number exists, it is stated on the right of the name of the sub-task;
3. Below a subtask there are the documents/records in that section of the dataset. Where the dataset and dossier type allow it, it is possible to add and to delete documents/records using (+ Additional record) and (X) respectively;

4. This level provides direct access to the fields in to which data is entered. The fields are presented on a separate page for each section. To move through the sections there are buttons labelled Next and Back, at the foot of the page. The number of the current section is indicated on the left of the page. In this example it is General Information;

5. This is a field in to which data can be entered. In this example it is the field Name.

The hierarchy can be viewed and navigated from the breadcrumbs shown at the top of the page. An example is shown in the figure below for the same data as shown in the previous figure. The labels in blue are active links upwards in the hierarchy, whilst the grey one is the current level.

Figure 114: The breadcrumbs in a Guided dossier preparation – example for REACH

9.4. Entering data in to a Guided Dossier Preparation

A task contains a list of sub-tasks, and some links to help text. An example is shown below for Substance identity.
Legend for Figure 115

1. The name of the task;
2. Each box is a substask, which is a link to a section in the table of contents of the dataset;
3. The number of the section in the table of contents of the dataset. This is not always available;
4. The quantity of records/documents in the section of the dataset. Remember that if the section is a so-called fixed section, this number can be only one, as is the case for section 1.1 shown in the example. If no number is shown, the section contains no document/records;
5. This link leads to detailed context and legislation specific help on how to enter data;
6. These links lead to higher-level more general information relevant to the task.

A Guided dossier preparation expects there to be at least one record/document in each substask. If the cursor is hovered over a substask that contains no documents/records, the interface gives the options shown below.
Figure 116: Options to add a record to an empty section in Guided dossier preparation – example for REACH

The option *Provide information* creates a record/document, and opens a wizard in to which data can be entered. An example is shown below.
Figure 117: Data entry wizard under Guided dossier preparation – example for REACH

Legend for Figure 117
1. The sub-task;
2. This indicates the page number within the data entry wizard;
3. This type of field allows more than one of the same type of item to be entered. In this example there can be one or more Analytical determinations;
4. In this type of field, the value is selected from predefined options;
5. This is a free-text field;
6. The Next button goes forwards a page in the wizard. At the end of the wizard, this button becomes Finish. Clicking on Finish saves the data and then goes back to the view of all the documents/records in the sub-task;

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7. The *Back* button goes back a page in the wizard. Before *Finish* is clicked, the user can navigate back and forwards in the wizard editing the data freely;

8. This icon leads to the flag functionality. For more information see section 3.3.5 Flag.

The option *Use existing information*, allows an existing document/record of the appropriate type to be included in the section. In the example shown below, a document/record named *Analytical information A* is selected. Any document/record of the appropriate type can be selected, so long as the user has access to the data in the installation of IUCLID. The search function applies only to the name of the document/record. At least three characters must be entered in to the search field.

**Figure 118: Add an existing document/record to a Guided dossier preparation – example for REACH**

Clicking on a subtask that contains one or more documents/records, opens it and displays a list of the documents/records it contains. In the example shown below, the subsection *Composition (section 1.2)* has been opened.
Figure 119: A subtask (section in a dataset) in a Guided dossier preparation – example for REACH

Legend for Figure 119

1. The subtask, which in this example is a section Composition in a Substance dataset;
2. This is a list of the sub-tasks in the task. The currently displayed sub-task is indicated by having no dot on the vertical line. The names of the other sub-tasks are links to them. In this example, Composition is being displayed;
3. Each document/record in the section has a box that links to a data entry wizard from where it can be edited;
4. The option Provide additional information allows a new document/record to be created. The option Use existing information, allows an existing document/record of the same type to be included in the section. These functions are the same as those accessible from the task, as described above;
5. The cross icon is used to delete a document/record.

When you have entered data in to all the subsections presented by the Guided dossier preparation, run the Validation assistant. A link is provided on the top level record of the Guided

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dossier preparation. Follow the instructions provided by the Validation report, until the dataset passes all the rules. You can then create a Dossier, run the Validation assistant on it, Export it, and then submit it to the relevant regulatory authority.
10. Legal entity

In IUCLID, a Legal entity is used to store information about a party or person that is involved in the life-cycle of a chemical substance, mixture or product. A Legal entity can be used to identify the party that is responsible for a certain activity, such as the manufacturing or import of a substance. The Legal entity does not have to be created by the person or party it represents. For example, a manufacturer can create a Legal entity to store information on a third party representative of the substance, or an only representative can create Legal entities to identify their suppliers.

The creation and editing of a Legal entity is done from the point where the Legal entity is referred to in a dataset.

A Legal entity can be associated with various entities, such as Substance. When a User creates an entity, by default, the working legal entity for the User is assigned to the entity. This can subsequently be changed to any of the Legal entities to which the User has access, not just the working one. The working legal entity is indicated at the top right of the interface, as shown below circled in red. The working legal entity may be changed via the client interface.

**Figure 120: The working legal entity**

10.1. General information

The name of the Legal entity must be entered, but the other fields are optional. The type of the Legal entity and other names are for information purposes.

10.2. Identifiers

The identifiers can be recorded of type Legal entity, Regulatory programme, and Other IT system. Each type contains a menu from which relevant sub-types of identifier can be selected. For example, Legal entity has an option for DUNS.

10.3. Contact information

An address can be defined for a contact of the Legal entity and links can be made to one or more entities of type Contact.

11. Legal entity site

A Legal entity site is an entity that is used to associate a Legal entity, and therefore its associated entities, with a physical location. This can have important legal implications, especially where the
country is concerned. A Legal entity site must have a name, a value in the field Site to indicate the physical location, and be associated with a Legal entity. The creation and editing of a Legal entity site is done from the point where the Legal entity site is referred to in a dataset.

12. Reference substance

A Reference substance is an entity that is used to define a particular molecular structure, or narrow range of molecular structures in such a way that the definition may be re-used. A Reference substance contains chemical identifiers and structural information. For example, there is typically a one to one relationship between Reference substance and EC number. A single Reference substance can be referred to from multiple entities wherever a chemical identity needs to be defined, for example in a constituent of a Substance.

The use of Reference substances is efficient because some chemical substances appear frequently across multiple Substances and Mixture/products. In addition, Reference substances can be shared and exchanged among instances and users of IUCLID. A collection of Reference substance entities are available to download free of charge from the IUCLID web site under the section Support / Get Reference Substances. If the required Reference substance is not available on the web site, or if you otherwise prefer, it is possible to create a Reference substance within IUCLID. This can be done from the point where the Reference substance is referred to in a dataset, or from the list page of Reference substances, from where deletion and editing are also available. The list page is opened from the main menu, as shown below.
The list page for *Reference substance* is shown below. It has the same navigation and search features as the list pages for *Substance* and *Mixture/Product*. *Delete* is under the button, with the three dots that is on the right of an entry in the list.
An example of a reference to a Reference substance is given below for the section Identification of substance. To enter a Reference substance in to the field, click on Select, as shown below.

A windows opens that allows a Reference substance to either be created (1), or selected from those already in the database (2, 3), as shown below.
Figure 124: Create a Reference substance, or select one from the IUCLID database

Clicking on Create, opens a window in to which the values are entered for the Reference substance, as described in the subsections that follow.

After editing or creating a Reference substance or the entity or document that refers to it, click on the Save button at the bottom right of the interface:

Figure 125: Save

12.1. General information

A Reference substance must at least have a name defined. The name is often the same as an entry in an inventory such as the EC Inventory, but it does not have to be.

12.2. Inventory

The field Inventory allows substance identity information to be retrieved from an Inventory. The EC Inventory is supplied with IUCLID. The field contains a dynamic search feature that tries to find a match between the value entered, and the values in the EC Inventory supplied with IUCLID. The matches are offered as selectable options, but they do not have to be selected. An example is shown below where the text “butanone” has been entered.
If no link is made to an inventory, a reason and a justification can be supplied under *No inventory information available*.

### 12.3. Reference substance information

*Reference substance information* is a collection of fields that contain identifiers for the *Reference substance* and related substances. In the field *Identifiers of related substances*, there is a field *Relation*, where the relationship can be described.

A single flag can be applied to all of *Reference substance information*, *CAS information* and *Related substances*.

### 12.4. Molecular and structural information

In *Molecular and structural information*, enter the molecular formula, the molecular weight, and upload an image that shows the structure in either JPEG, GIF, or PNG format. The field *Molecular formula* accepts text but no characters in subscript, so for example ethane would be C2H4.

A single flag can be applied to all of *Molecular and structural information*.

### 13. Contacts

A *Contact* is an entity that is used to record the contact details for a particular person. It can also be used to record something about a person’s role in a process, for example, as the competent person who is responsible for a safety data sheet (SDS). Links can be made from various other entities to a *Contact*, for example from a *Legal entity*.

Using *Contacts* removes the need to re-enter details where a particular person is involved across multiple processes and *Substances*. The built-in types of contact are *competent person responsible for the SDS, emergency contact, substance manager, toxicologist* and *other*.

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A *Contact* can be either edited or created from the place within a document or entity that links to it. Typically, a link can be made to more than one *Contact* from the same place. An example of a field that refers to two *Contacts* is given below for *General information > Identification of substance > Contact persons*, which is section 1.1 under REACH. Note that the cursor is hovering over the second contact, causing a highlighted box to be displayed.

**Figure 127: Contacts in the identification of a substance dataset**

A *Contact* in a field is actually a link to a *Contact*, not the *Contact* itself. A link can be removed by clicking on the red delete icon ✗. This does not delete the *Contact*. Clicking on the highlighted blue box for a link to a *Contact* opens the linked *Contact* for editing.

A link can be created by clicking on + *New item*. A newly created link contains no *Contact*, as shown below:

**Figure 128: A newly created link to a Contact**
To place a Contact in a new link, edit the link by clicking on the blue highlighted box. Either link to an existing Contact, or create one, as shown below.

**Figure 129: Place a Contact in an empty link**

Legend for Figure 129

6. To place a Contact in a newly created empty link, first click on *Select item* within the link;

7. To place an existing Contact in the link, first search for it by entering a search term to match the name or organisation, then click on its entry in the search results;

8. To create a Contact and place it in the link, click *Create*.

After editing or creating a link to a Contact, click on the *Save* button at the bottom right of the interface.

**Figure 130: Save**

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14. Test materials

Test materials is an entity used to describe the material on which a physical test has been performed. A link can be made to a Test material entity from within an endpoint study record.

A Test material entity consists of a composition, similar to that used for a Substance, a description of the physical form, and some extra information that may be considered confidential, such as a batch number. The creation and editing of a Test material is done from the point where the Test material is referred to in a dataset.

The composition can have components of type constituent, impurity or additive. Each component should be linked to a Reference substance and given a concentration range. The field Composition / purity: other information is provided to record more qualitative information about the purity. The field Test material form is provided to record information about the physical state and characteristics of the material used in the test.

Finally, there are two free-text fields where more details can be added. Suggestions as to what to enter are provided in free-text templates. To open a free-text template, click on the icon that shows the letter A with an arrow at the bottom right. To copy the text from the template to the field, click on the button labelled Insert… . Next, edit the text in square brackets, as required.

The value of the field Confidential details on test material can be excluded during Dossier creation, and during Export of data that is outside a Dossier. A value that has been included in a Dossier cannot be excluded during Export of the Dossier.

14.1. Test material for a Mixture/Product

A Test material can be created for a Mixture/Product. In that case, there is no need to enter values for the fields Type, Reference substance, Concentration and Remarks, because in this context those values are relevant only for a Substance. Instead, the composition is indicated by referring to a composition in a Mixture/Product dataset. Usually this is the composition of the Mixture/Product in which the Test material is located, which for example in BPR is in section 2.3.

To make the reference to the composition, first set the field Composition/purity to 'other:' . This causes a text field to appear. Then, enter the name of the composition and the name of its dataset. An example is shown below.
Figure 131: Test material in a Mixture/Product – example where the Test material refers to the composition of the Mixture/product

Legend for Figure 131
1. No value is required here;
2. Select ‘other’;
3. State to which composition document the Text material refers.

Any information about the batch number, expiry date, and other information should be entered in to the fields Details on test material, and/or Confidential details on test material.
15. Literature reference

A Literature reference is an entity that identifies a particular document that contains information on a Substance or a Mixture/Product. The creation and editing of a Literature reference is done from the point where the Literature reference is referred to in a dataset. The only mandatory field is the title, but there are also various other fields that allow a reader to find the document outside IUCLID. A link may be made to a Literature reference from an endpoint study record in a harmonised template. The link is made from the field data source. An example is shown below.

Figure 132: Literature references in the field Data source
16. Validation assistant

The aim of the Validation assistant is to assist users in the preparation of IUCLID Dossiers so that they can be successfully submitted to and processed by the relevant authority. To this end, the Validation assistant carries out validations on the data provided in a Substance dataset or Dossier according to a set of pre-defined rules to verify that the information was provided as expected. The outcome of the validation is a report, which lists all the rules for which the validation failed.

The Validation assistant currently supports the validation of all submission types that industry can submit to the European Chemicals Agency (ECHA) under the REACH and CLP regulations. It can be customised to validate other types of dossiers, as needed.

The following chapters describe the principles of the Validation assistant, and how it is used.

16.1. Structure

The Validation assistant is based on the following components:

1. **Scenarios.** A scenario refers to a specific submission type. For simple submission types, a scenario equals a dossier template, but for more complex types, additional parameters are calculated.

2. **Rules.** A rule carries out a specific validation on certain content in the dataset or dossier. Each rule is identified by a unique rule ID.

3. **Rule sets.** The rule sets are used to configure which rules should be run for each scenario.

4. **Messages.** The messages are displayed to the user when a rule is not fulfilled. They inform the user of what caused the failure.

For the IUCLID user, it is not necessary to understand this structure in detail. However, it may be useful if in doubt about the outcome of the validation, to verify that the validation scenario was the intended one.

16.2. Supported validations

The current version of the Validation assistant allows the users to perform the following checks on their dossiers or substance datasets:

1. The completeness check on the technical dossier (TCC), for REACH registrations and PPORD notifications;

2. The verification of those business rules that do not rely on information from the ECHA database (e.g. submission history), for all supported dossier types;

3. In addition, the current version of the Validation assistant includes a subset of quality checks to support users in improving consistent reporting of information. Further quality checks are under development and will be added in future versions.

16.2.1. Completeness check

According to Articles 9(3) and 20(2) of the REACH regulation, registration dossiers and PPORD notifications are subject to a completeness check. This completeness check consists of two parts:

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the financial completeness check (FCC) and the completeness check on the technical dossier (TCC). The Validation assistant enables registrants and PPORD notifiers to check within their IUCLID installation the completeness (TCC) of their Substance datasets and Dossiers prior to submission to ECHA via REACH-IT.

While the Validation assistant largely simulates the completeness check carried out by ECHA, it does not capture exhaustively all possible situations in which a dossier may be found incomplete. This includes situations where the registrant deviates from the standard information and needs to provide a justification for the deviation, or when a joint submission member registers a higher tonnage band than the tonnage band of the joint submission and needs to provide the additional study information in his dossier. In such cases, completeness of the dossier will be ensured by manual verification of the information by ECHA staff. The responsibility remains with the registrant to ensure that their submission fulfils all the relevant legal requirements.

Please refer to the manual How to prepare Registration and PPORD Dossiers for detailed information on how to fill in the information for these dossier types in the IUCLID format. Furthermore, we recommend that all registrants get familiar with the document Information on manual verification at completeness check. Both the manual and the document are available at:

http://echa.europa.eu/manuals

16.2.2. Business rules

The Validation assistant also incorporates several of the business rules (BR) checked at ECHA.

As some of the business rules depend on contextual information that is stored within the REACH-IT database (e.g. submission history), the Validation assistant cannot simulate all the business rules checked at ECHA.

Please refer to the dossier preparation manuals for detailed information on how to fill in the information. The manuals are available at:

http://echa.europa.eu/manuals

16.2.3. Quality checks

The quality check feature enables users to check their IUCLID datasets and dossiers for common shortcomings and inconsistencies before submitting them to ECHA. The quality rule set is updated on a regular basis with experience from ECHA’s different evaluation and assessment activities.

The quality checks have been designed to assist the user in detecting inconsistencies in the information provided. The Validation assistant does not offer an exhaustive verification of the quality of the entire Dossier or dataset, and there may be special circumstances in which some of the quality warnings can be ignored. The responsibility remains with the user of the tool to ensure that the information submitted is adequate under the relevant regulation.

16.3. Run the Validation assistant on a Substance or Mixture/Product

The Validation assistant is run from the top level of the record for a Substance or Mixture/Product. This can be displayed either from the list of Substance, Dossier, or Mixture/Product, or by clicking on the name of the entity in the breadcrumbs. The latter approach is useful if you have just edited a
document, and you want to see the effect the edit has had on the validation. An example is shown in the figure below in which a tonnage per year has just been edited. The user clicks on the name of the Substance in the breadcrumbs, which is `table_salt`. The same example is used in the next figure.

**Figure 133: Navigate to the top level of an entity's record via the breadcrumbs**

Before running the **Validation assistant** on a dataset, a **Submission type** must be selected. This allows the IUCLID interface to present to the user, either a pre-filled or blank **Dossier** header of the correct type, before carrying out the actual validation. The **Dossier** header provides the information that allow the checks applied to fit the regulatory context in which the data will be submitted to an authority.

The **Validation assistant** is run by clicking on the button labelled **Validate**, which is shown at the upper right of the record of a dataset. If the button is dimmed and cannot be clicked on, select a **Submission type**.

An example where to find the **Validate** button is shown for a **Substance** dataset.

**Figure 134: Run the Validation assistant on a Substance dataset**

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Fill out the Dossier header, and then click on the Validate button at the bottom right of the window. The Validation assistant produces a report. There are two tabs in the report: one named Submission checks which contains the Business rules and the Completeness check rules, and another for the Quality checks. Annotated examples of the report are shown in the figures below.

**Figure 135: The Validation assistant report: Submission checks**

**Legend for Figure 135**

1. Information is provided about the validation;
2. Click here to run the Validation assistant again;
3. This link opens the Dossier header for editing;
4. Here are two tabs: Submission checks, and Quality checks. The selected tab is shown with a coloured bar under its title. By default, the tab Submission checks is selected, which contains Business rules and Completeness check rules. Under the other tab, failing Quality checks are shown. The number to the right is the total number of rules currently failing under that tab;
5. On the left there is the number of rules failing under the selected tab, by type. On the right there is the total number of rules failing under both tabs;
6. A list of the rules currently failing for the entity. For each rule there is a statement of why the entity fails the rule, and instructions on how to edit the data to pass the rule. A link in the name of the rule leads to the specific document that failed the rule. If the name does not have a link it means that the required document does not exist, and must therefore be created;
7. The type of rule and its identifying code.

Following a link in the Validation report opens the document that fails the rule, so that it can be edited. The rule is presented at the top of the document page. An example is shown below.
Functionalities of IUCLID in the web interface

Figure 136: The link back to the validation report from a document being edited

Legend for Figure 136

1. To edit the document click on Edit;
2. To help the user edit the document, instructions on how to pass the rule are shown. Clicking on hide closes the blue area in which the instructions are shown to give the user more vertical space in the data entry window. Clicking on Show re-opens the instructions. Save changes by clicking on the Save button;
3. To go back without saving unsaved changes, click on the cross icon, or the greyed-out area to the left of the data window.

16.4. Run the Validation assistant on a Dossier

The Validation assistant is run on a Dossier from the top level of the record for the Dossier. An example is shown below.

Figure 137: Run the Validation assistant on a Dossier

Links in the Validation report lead to the read-only copies of documents within the dataset. To obtain a Dossier that passes all the Validation checks, edit the dataset upon which the Dossier is based until it passes all the checks, and then re-create the Dossier.

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16.5. Update a registration - reduced information requirements

When updating a registration that was previously a notification under Directive 67/548/EEC for another reason than a tonnage band update, or to become the lead registrant of a joint submission, less information is required than for a standard registration dossier. The minimum information to be provided in this case is described in Annex 4 (Minimum information required for updating a registration under previous Directive) of the manual How to prepare Registration and PPORD Dossiers available at http://echa.europa.eu/manuals.

The Validation assistant does not offer the possibility to verify the completeness of only these reduced information requirements (especially, since all new and updated information needs to be checked for completeness), but will check the full requirements for the selected submission type. Consequently, the Validation assistant can be used to check the completeness of these datasets and dossiers but only the TCC failures related to the information requirements indicated in the manual should be considered in the result.

16.6. Disclaimer

The checks performed by the Validation assistant do not cover all of the verifications carried out on a dossier submitted to ECHA. It is the responsibility of the submitter to ensure that the Dossier fulfils the appropriate data requirements, and to monitor the outcome of the submission process in REACH-IT.
17. Export to i6z

This exports the entity currently being viewed to a file in the standard data exchange format of IUCLID, which has an extension i6z. This works for entities of type Dossier, Substance, Mixture/Product and Template. Documents within these entities cannot be exported individually.

By default, entities and documents referred to directly by an entity are also exported. For example, by default, a Reference substance linked to a Substance is exported. The default behaviour can be over-ridden using settings in the export process, as described below. Export is accessed from the menu under the three-dot button in the application window.

![Figure 138: Selecting Export to i6z for a Substance dataset](image)

This opens the Export settings, as shown below.

![Figure 139: The settings for Export to i6z](image)
Note that the current submission type is stated at the top of the settings, which can determine the sections of the table of contents that are exported. To see which sections are included, use the function *Set documents to be included*; as described later.

17.1. Export to previous major version

In each major release of IUCLID 6, changes are made to the underlying way that data is stored in IUCLID. In other words, the IUCLID format changes. This may be seen, for example, in changes to the way that data is organised across fields. When this happens, the version number after the 6 goes up by one: for example from IUCLID 6.3 to IUCLID 6.4. Data exported from IUCLID can be imported in to the same version, and optionally in to the previous major release. This latter option is switched on using *Export to previous major version*. Data cannot be exported to be compatible with a major release that was two or more releases in the past. For example, data cannot be exported from IUCLID 6.4 in to the format for IUCLID 6.2.

If you need to send data to a IUCLID user who is using IUCLID from the previous major version, and you know that the data is not critically affected by the most recent format changes, export the data with *Export to previous major version* enabled. This will allow the data to be imported. However, it is always recommended to use the latest version of IUCLID.

Be aware that *Export to previous major version* does not reverse all the actions that can occur on migration forwards between major versions, e.g. from IUCLID 6.3 to IUCLID 6.4.

The differences between major versions of IUCLID 6 are documented on the IUCLID website under the section *IUCLID format*.

Example

In some cases, migration of data between major versions involves the merging of the text from two text fields in to a single text field. The migration process appends the text from the second field to the text from the first field, and then attempts to write all the text in to the destination field. If the text does not fit in to the destination field, only the text from the first field is written, and the text from the second field is saved as an attachment to the document. That way, at least no text is lost on migration. This process is not reversed on export, even when *Export to a previous major version* is enabled. However, any text that was placed in an attachment is available in the IUCLID from which data is being exported, so if required, it can be pasted back in to the original field.

An attachment created during migration begins with the name and path of the field from which it originated, followed by a brief statement of why the attachment was created. An example is shown below:

```plaintext
Not migrated field "Distribution of residues" (Path: ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.DistributionOfResidues):
  value of distribution field ...
```

17.2. Detail level of document fields

See section 8.2.1.2 *Detail level of document fields*. 

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17.3. Flags for confidentiality
See section 8.2.1.3 Flags for confidentiality.

17.4. Flags for regulatory programmes
See section 8.2.1.4 Flags for regulatory programme.

17.5. Included annotations
See section 8.2.1.5 Included Annotations.

17.6. Included attachments
If the box is ticked, attachments will be exported.

17.7. Select documents to be included
This allows entities and documents to be excluded individually. It over-rides exclusion for other reasons. If this box is ticked, the button to the right changes to Next. Clicking on Next, opens a selection panel that has Entities on the left and Documents on the right. On the left, entities can be excluded individually by unticking their boxes. In the example shown below, this has been done for the Reference substance ethanol. There are no documents in the Reference substance, so the right-hand side remains unchanged.
The dependencies of excluded Documents are excluded. In the example shown below, all Documents in section 1.2 Composition have been excluded by unticking the box adjacent to the section name. This has automatically unticked the Documents in the section 1.2 on the right. It has also excluded the Reference substances on the left that are referred to only in section 1.2.
18. Create PDF

The entity currently being viewed is output in portable document format (PDF). It is accessed from the three dot icon in the application bar, as shown below.

The exclusion of data works in the same way as for Export to i6z file, which is described in the previous chapter. For more structured and tailored output from datasets and Dossiers, see the section on Generate Report, below.
19. Generate Report

The function Generate report exports data from a dataset or a Dossier to an external file that can be downloaded from the browser used to view the web interface. It is accessed from the menu under the three dot button in the application bar. Select the required type of report and its output format from the menu. An example is shown below for a Chemical safety report (CSR) in rich text format (RTF).

Figure 143: Generate report – example of Chemical Safety Report (CSR)

![Image showing the selection of a Chemical safety report (CSR) in RTF format]

Reports are defined per dossier submission type. If Generate report is greyed out and cannot be selected, there are no reports available for the current dossier submission type.

For more information about reports, see the IUCLID website at the address: https://iuclid6.echa.europa.eu/reports.
20. Sharing and Ownership - Instance based security (IBS)

*Instance based security* (IBS) is intended for use with only IUCLID 6 Server, and not with IUCLID 6 Desktop. The full management of IBS is done via the client interface of IUCLID 6 Server.

When IBS is in use, users of the web interface of IUCLID 6 Server have access to the options *Share* and *Change ownership* for the entities of type *Substance*, *Mixture/Product* and *Assessment entity*.

Instance based security allows access within IUCLID 6 to be controlled per entity per *User*. *Users* can be organised in to *Groups*. Access to an entity can be defined per *Group* using the *Share* functionality. When a *User* creates an entity, the *User* becomes the owner of the entity. Ownership allows the *User* to *Share* an entity to the members of any *Group* to which it belongs. The system can be set up to *Share* entities automatically on creation, or to allow *Users* to decide to which *Group(s)* they share the entities they create. Contact your system administrator for details on how your system is set up. If you are unsure of the behaviour, it is always possible to view how an entity is currently being shared, as described later in this section.

An example of how IBS may be used is where members of a particular team in an organisation need the same exclusive access to a subset of the data in a centralised database. The team members are given personal *Users* which are placed in a *Group* for the team. The administrator sets the system so that entities created by any member of the group are automatically shared to the whole *Group*. *Users* in the system who are not in the team *Group* may be given restricted access to its entities, or none at all.

### 20.1. Common Group

Common can be considered to be a *Group* to which all *Users* belong. In that sense, common has the same meaning as public. In contrast, a *Group* created within IUCLID 6 is inherently private, because only members of the *Group* have access to the data shared within the *Group*.

### 20.2. Share

*Share* is an action in which the *Users* in a *Group* are granted access to an entity with one of the four permissions shown in the table below:

<table>
<thead>
<tr>
<th>Permissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Shared</td>
</tr>
<tr>
<td>Read</td>
</tr>
<tr>
<td>Read/Write</td>
</tr>
<tr>
<td>Read/Write/Delete</td>
</tr>
</tbody>
</table>

To view the permissions for an entity, click on the three dot icon to the right of its entry in the list of entities, and then select the option *Share*. This opens a list of the *Groups* of which the *User* is a member. For each *Group*, the current permissions are stated, as shown in the example below.
To change a permission for a Group, click on the arrowhead icon for a Group, and select the required option. Thus, a share can be applied by the owner of an entity to any of the Groups of which the User is a member.

If a User is in more than one Group, the combined effect of a Share is additive. Thus, the combination of Not Shared and Read/Write is Read/Write. If a User has a permission for an entity only because the document has been Shared, the User cannot pass that permission on to another User via Share.
Example of Share

Figure 145: Example of sharing a Substance dataset

The options presented show that the current user is in group 1 and group 2, both of which were created by the administrator. The value of Read for group Common means that by default, all users can read the dataset. The value of Not shared for group 1 means that the data is not explicitly shared with group 1. However, members of group 1, can read the data because they are in the group Common. For group 2, the permissions are being changed from Not shared, to Read/Write/Delete. The data could be accessible by users in other groups not shown above, but the user cannot see whether that is the case because users can see only the groups of which they are a member.

20.3. Change ownership

When an entity is created or imported, its ownership is set to that of the current User. Ownership is transferable, but a document can have only one owner at a time. Ownership can be transferred only within the group of the owner, and only by an administrator User.

Ownership of an entity is viewed and changed from a window opened via the three dot icon accessible from the list of entities, as shown in the example below.
Figure 146: Viewing and changing the ownership of an entity, e.g. a Substance dataset
21. Shutting down IUCLID

Before shutting down the IUCLID application, ensure that all processes have been completed. For example, if data is being imported, a rotating icon ( ) is shown on the home page next to the process. The import will be cancelled if IUCLID is shut down before the green tick icon appears.

**Figure 147: Data is being imported**

![Import IUCLID file(s)](image)

To shut down the IUCLID application, close the window that opened when the application started, as shown below.

**Figure 148: Shut down the IUCLID application**

![Shut down the IUCLID application](image)
22. Getting help

Links to help are provided in the interface under icons that contain a question mark. There are three types, as described below.

**Figure 149: Sources of help in the web interface**

**Legend for Figure 149**

1. Links to external sources of help;
2. This manual in PDF format;
3. Help for a specific field or point of data entry.

The external sources of help include, for example, a link to a Q&A on the IUCLID website, and manuals hosted at ECHA on how to prepare a Dossier for a specific legislation. If you still need help after checking these sources, you can submit a request for help directly to ECHA via the link Create support request, as indicated below.
Figure 150: External sources of help: The option highlighted is to request help directly from the IUCLID helpdesk at ECHA
## 23. Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D structure</td>
<td>2 dimensional structure formula of a chemical molecule</td>
</tr>
<tr>
<td>ATP</td>
<td>Adaptation to Technical Progress</td>
</tr>
<tr>
<td>BMC</td>
<td>Benchmark Concentration</td>
</tr>
<tr>
<td>BMD</td>
<td>Benchmark Dose</td>
</tr>
<tr>
<td>BPD</td>
<td>Biocidal Products Directive (98/8/EC)</td>
</tr>
<tr>
<td>BPR</td>
<td>EU Biocidal Products Regulation (528/2012/EC)</td>
</tr>
<tr>
<td>C&amp;L</td>
<td>Classification &amp; Labelling</td>
</tr>
<tr>
<td>CA</td>
<td>Competent Authority</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service</td>
</tr>
<tr>
<td>CBI</td>
<td>Confidential Business Information</td>
</tr>
<tr>
<td>CCOHS</td>
<td>Canadian Centre for Occupational Health and Safety</td>
</tr>
<tr>
<td>CEFIC</td>
<td>Conseil Européen de l'Industrie Chimique / European Chemical Industry Council</td>
</tr>
<tr>
<td>CMR</td>
<td>Substances which present at least one of the following properties: Carcinogen, Mutagen, Reprotoxic (Toxic to reproduction)</td>
</tr>
<tr>
<td>CSA</td>
<td>Chemical Safety Assessment</td>
</tr>
<tr>
<td>CSF</td>
<td>R-Phrases Chemicals Stakeholder Forum - risk phrases</td>
</tr>
<tr>
<td>CSR</td>
<td>Chemical Safety Report</td>
</tr>
<tr>
<td>DMEL</td>
<td>Derived Minimal Effect Level</td>
</tr>
<tr>
<td>DNEL</td>
<td>Derived No-Effect Level</td>
</tr>
<tr>
<td>DU</td>
<td>Downstream User</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EC number</td>
<td>European Chemical number: EINECS, ELINCS or NLP</td>
</tr>
<tr>
<td>ECB</td>
<td>European Chemicals Bureau</td>
</tr>
<tr>
<td>ECHA</td>
<td>European Chemicals Agency</td>
</tr>
<tr>
<td>EFSA</td>
<td>European Food Safety Authority</td>
</tr>
<tr>
<td>EINECS</td>
<td>European Inventory of Existing Commercial Chemical Substances</td>
</tr>
<tr>
<td>ELINCS</td>
<td>European List of Notified Chemical Substances</td>
</tr>
<tr>
<td>EPA</td>
<td>Environment Protection Agency (United States)</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonised System for classification and labelling of chemicals</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practice</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>HPV</td>
<td>High Production Volume</td>
</tr>
<tr>
<td>HPVC</td>
<td>High Production Volume Chemicals</td>
</tr>
<tr>
<td>HTML</td>
<td>HyperText Markup Language</td>
</tr>
<tr>
<td>i5z</td>
<td>The file format of IUCLID 5</td>
</tr>
<tr>
<td>i6z</td>
<td>The file format of IUCLID 6</td>
</tr>
<tr>
<td>ICCA</td>
<td>International Council of Chemical Associations</td>
</tr>
<tr>
<td>IFCS</td>
<td>Intergovernmental Forum on Chemical Safety</td>
</tr>
<tr>
<td>IP</td>
<td>Intellectual Property</td>
</tr>
<tr>
<td>IRPTC</td>
<td>International Register of Potentially Toxic Chemicals</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standards Organisation</td>
</tr>
<tr>
<td>IUCLID</td>
<td>International Uniform Chemical Information Database</td>
</tr>
<tr>
<td>IUPAC</td>
<td>International Union of Pure and Applied Chemistry</td>
</tr>
<tr>
<td>JRC</td>
<td>Joint Research Centre</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Lowest Observed Adverse Effect Level</td>
</tr>
<tr>
<td>LOEL</td>
<td>Lowest Observed Effect Level</td>
</tr>
<tr>
<td>MS</td>
<td>Member State</td>
</tr>
<tr>
<td>MSCA</td>
<td>Member State Competent Authority</td>
</tr>
<tr>
<td>NCD</td>
<td>New Chemicals Database</td>
</tr>
<tr>
<td>NLP</td>
<td>No-Longer Polymer</td>
</tr>
<tr>
<td>NOAEL</td>
<td>No Observed Adverse Effect Level</td>
</tr>
<tr>
<td>NOEL</td>
<td>No Observed Effect Level</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Cooperation and Development</td>
</tr>
<tr>
<td>OECD TG</td>
<td>OECD Test Guidelines</td>
</tr>
<tr>
<td>OSOR</td>
<td>One Substance One Registration</td>
</tr>
<tr>
<td>PBT</td>
<td>Substances which are Persistent, Bioaccumulative and Toxic</td>
</tr>
<tr>
<td>PIC</td>
<td>Prior Informed Consent (The Rotterdam Convention on Prior Informed Consent sets up a system to control international trade in certain hazardous substances)</td>
</tr>
<tr>
<td>PNEC</td>
<td>Predicted No-Effect Concentration</td>
</tr>
<tr>
<td>POP</td>
<td>Persistent Organic Pollutant</td>
</tr>
<tr>
<td>PPORD</td>
<td>Product and Process Orientated Research and Development</td>
</tr>
<tr>
<td>PPP</td>
<td>Plant Protection Product</td>
</tr>
<tr>
<td>QSAR</td>
<td>Quantitative Structure Activity Relationship</td>
</tr>
<tr>
<td>RA</td>
<td>Risk Assessment</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>RAR</td>
<td>Risk Assessment Report</td>
</tr>
<tr>
<td>REACH</td>
<td>Registration, Evaluation and Authorisation of CHemicals</td>
</tr>
<tr>
<td>RIP</td>
<td>REACH Implementation Project</td>
</tr>
<tr>
<td>SAR</td>
<td>Structure Activity Relationship</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety Data Sheet</td>
</tr>
<tr>
<td>SIDS</td>
<td>Screening Information Data Set (OECD Existing Chemicals Programme)</td>
</tr>
<tr>
<td>SIEF</td>
<td>Substance Information Exchange Forum</td>
</tr>
<tr>
<td>SME</td>
<td>Small and Medium Sized Enterprises</td>
</tr>
<tr>
<td>SVHC</td>
<td>Substance of Very High Concern</td>
</tr>
<tr>
<td>TGD</td>
<td>Technical Guidance Document</td>
</tr>
<tr>
<td>TNsG</td>
<td>Technical Notes for Guidance</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act Inventory in the USA</td>
</tr>
<tr>
<td>UI</td>
<td>User interface</td>
</tr>
<tr>
<td>US-EPA</td>
<td>United States Environment Protection Agency</td>
</tr>
<tr>
<td>UUID</td>
<td>Universal Unique IDentifier</td>
</tr>
<tr>
<td>vPvB</td>
<td>Very Persistent Very Bio-accumulative substance</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organisation</td>
</tr>
<tr>
<td>XML</td>
<td>eXtensible Markup Language</td>
</tr>
<tr>
<td>XSD</td>
<td>XML Schema Definition</td>
</tr>
</tbody>
</table>