IUCLID 6

Chemical Watch Expo 2017

25 April 2017

Sandra Esteves Murras
*Dossier Submission & PIC Unit*

Tommy Hägg
*Computational Assessment & Dissemination Unit*

Directorate of Registration
Agenda

• IUCLID 6
• ECHA Cloud Services
• IUCLID 6: main functionalities
• IUCLID 6: Validation assistant
• TCC and Manual verification
• Exercise
• Guidance and support
IUCLID 6

International Uniform Chemical Information Database

- Software application to record, maintain and exchange scientific data on chemicals in a regulatory context (e.g. EU REACH and EU Biocides)
- Data is submitted via REACH-IT in IUCLID format
Drivers for changes

- Changes in requirements
- Feedback received
  - Interactions with Competent Authorities and Industry IT working groups
  - SME visits by ECHA staff and SME workshops
  - Helpdesk
- Technological upgrades
- Quality observations on dossiers
- Needs for enhanced dissemination
IUCLID 6

**IUCLID6 Desktop**
- Single machine
- One user at a time
- Easy installation
- Get from IUCLID website

**IUCLID6 Server**
- Network installation
- Accessed from within the network
- Get from IUCLID website

**IUCLID Cloud**
- Access from anywhere
- Aimed for SMEs
- Broad service
- Subscribe via ECHA Cloud Services

- Download IUCLID data, e.g. reference substances.
- FAQ, e.g. regarding installation, migration from IUCLID 5 to IUCLID 6, etc.
- Technical manuals

21 June 2016

A IUCLID 6 update is available
This update contains several fixes relevant to REACH users.

29 April 2016

IUCLID 6 is available
A new major version of IUCLID, used for managing scientific information in a regulatory context, is now online. Updated manuals and plugins are also available.

12 April 2016

A new IUCLID 6 test version is available
This test version includes bugs fixes and improvements.

05 February 2016

Test a new version of IUCLID 6
You can now download the latest IUCLID 6 test versions directly from this website.
ECHA Cloud Services

ECHA Cloud Services is a secure online platform used to distribute ECHA’s IT applications in a cloud environment.

The first services focus on IUCLID as it is crucial for the 2018 registration deadline. Their functionalities are prioritised for the needs of small and medium-sized enterprises (SMEs). The IUCLID Cloud application runs in a browser and, therefore, complements the traditional IUCLID application, which is installed on the user’s computer. SMEs are able to use these services to register their chemicals for the upcoming registration deadlines.

To access the cloud services, you need to log in using your ECHA Account credentials. These are the same credentials you use to access IUCLID. If you do not have an ECHA Account, you can register for one from the ECHA Cloud Services website.

Once you are logged in, you can access the following services:

1. IUCLID Cloud
2. IUCLID Cloud Tools

IUCLID Cloud

Try out the services in your browser without installing anything locally. This service is a new and modern cloud platform and will be automatically updated whenever there is a new release of IUCLID. As this is a trial version, there are no backups taken of the data or dedicated helpdesk support.

You can either use the IUCLID Cloud application to import and view your substance, mixture and dossier datasets or launch the IUCLID Cloud client (traditional IUCLID that stores data in the cloud) to edit datasets. However, you will not yet be able to use all IUCLID functionalities. These will be available in 2017 when the IUCLID Cloud for SMEs is launched.
What is **ECHA Cloud Services**?

- A **new** platform for delivery of Business Information systems in ECHA - Released today!

**Triggers**

1. The need to maintain an operational IUCLID version has been raised as a burden for Small and Medium size Enterprises (SMEs)

2. The usage of IUCLID for non-frequent users is seen as complex

**Solution**

- Provide IUCLID 6 as a Cloud service and simplify the usage for non-frequent users
What are the goals with ECHA Cloud Services providing IUCLID access through the cloud with the aim to:

- Significantly reduce the technical burden and costs (financial, labour) for hosting, updating and managing IUCLID locally for industry
- Ensure better protection against loss of data and ensure continuous availability of on-line IUCLID services over the internet

➢ Pave the future of the Business Information Systems delivery
Always work on the latest version of the application

Reduced risks of data loss (backups managed by ECHA)

Facilitate working anywhere (easier remote access) and delegation to consultants

Possibilities for better online support

No cost for users managing installations and hardware

Data is more secure because of reduced number of local copies
ECHA Cloud services and IUCLID Cloud Trial Go Live!

1. IUCLID Cloud Trial
   - Apr 17
   - IUCLID Cloud Trial

2. IUCLID Cloud for SMEs
   - Jul 17
   - IUCLID Cloud for SMEs

3. Full IUCLID Cloud for SMEs
   - Dec 17
   - Full IUCLID Cloud for SMEs

Full IUCLID Cloud for the REACH 2018 deadline
ECHA Cloud Services
What service are provided?

- IUCLID Cloud Trial (April 2017)
- IUCLID Cloud for SMEs (Summer 2017)
IUCLID Cloud for SMEs

- Aimed for SME users to prepare registration dossiers under REACH for 2018 deadline
- Work fully on a web browser without installing anything locally
- Automated backup and data recovery in case of data loss
- Helpdesk support during office hours
- Immediate subscription activation
- Up to 1 GB of secure data storage
- Target 24/7 availability except for pre-defined maintenance periods occurring outside the working hours
- Controlled service updates with every new release of IUCLID

- Integrated help and support for dossier preparation (End 2017)
IUCLID Cloud

Launch the IUCLID Cloud Client for full IUCLID 6 functionality

Support functionalities

Creation of new substance

Collapsible navigation menu

Quick access to Substances

Import easily IUCLID Data

Launch the IUCLID Cloud Client for full IUCLID 6 functionality

echa.europa.eu
IUCLID Cloud

Shortcuts to all sections

IUCLID Tree view with access to all documents

echa.europa.eu
## IUCLID Cloud

### Document easily readable

<table>
<thead>
<tr>
<th>General Information</th>
<th>ECHA Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>ECHA Substance</td>
</tr>
<tr>
<td>Not classified</td>
<td>false</td>
</tr>
</tbody>
</table>

### Shortcuts to sub-sections

- Classification
- Labelling
- Notes

### Open the document for editing

### Access additional information and attachments

<table>
<thead>
<tr>
<th>Related composition</th>
<th>ECHA Substance</th>
</tr>
</thead>
</table>

### Classification

- Physical Hazards
- Explosives
  - Reason for no classification: conclusive but not sufficient for classification
- Flammable gases and chemically unstable gases
  - Reason for no classification: data lacking
- Aerosols
  - Reason for no classification: data lacking

[echa.europa.eu](http://echa.europa.eu)
What to remember about ECHA Cloud Services?

- A new platform for delivery of Business Information systems, initially used for distributing IUCLID Cloud

- The cloud distribution of IUCLID is a complemented service to the downloadable versions of IUCLID

- Initial aim is to support SMEs users in their preparation for the REACH 2018 deadline – Trial release

- Security is at the heart of the ECHA Cloud Services. Global measures such as encrypted communications between the client computer and the Cloud are enforced

- SMEs can from 04/04/2017 start to get familiar with the IUCLID Cloud Trial, but the main service will be released in summer 2017
Demo

ECHA Cloud Services
Information

For today’s training, please download the IUCLID desktop version:

www.iuclid6.echa.europa.eu/
IUCLID 6 - main functionalities
Create a new or modify your existing substances

Create a template to reuse same endpoint data in different datasets

Search dossier by UUID

View your dossiers

Import files:
- legal entity;
- substance datasets;
- reference substances

View what information will be published on the ECHA website

Store chemical identifiers on particular chemicals once in the database and link it from there to any IUCLID section

Validate substance dataset AND the final dossier to minimize the risk of errors
Embedded Help System (F1)

- IUCLID 6 functionalities
- How to create specific dossiers (e.g. registration dossiers)
- Field by field help

Thank you for using IUCLID 6. This help system aims to provide, in one place, a full description of the functions of the software. In addition, it includes a set of guides on how to prepare data for submission to ECHA, under a particular set of legislations.
How to prepare registration and PPORD dossiers
IUCLID 6 – Validation assistant
Validation assistant

- Plug-in available in IUCLID.
- Assists the users in the preparation of IUCLID dossiers.
- Carries out validations on datasets and dossiers 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.
Technical completeness check (TCC) and Manual verification
Submission process

Submission process in REACH-IT
Technical Completeness Check (TCC)

According to REACH article 20 (2)

Article 20

Duties of the Agency

1. The Agency shall assign a submission number to each registration, which is to be used for all correspondence regarding the registration until the registration is deemed to be complete, and a submission date, which shall be the date of receipt of the registration at the Agency.

2. The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 or under Articles 17 or 18, as well as the registration fee referred to in Article 6(4), Article 7(1) and (5), Article 17(2) or Article 18(2), have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.
Technical Completeness Check (TCC)

Checks performed on the dossiers:

• Automated checks that can be replicated using the validation assistant.

• Manual verification by ECHA staff which cannot be replicated using the validation assistant.
Manual verification on dossiers

• As of 21 June 2016, additional manual verifications by ECHA staff on the dossiers

• The goal is to ascertain that the information required by the legislation has been included

• Scope of the manual checks is completeness, not quality or compliance; to ensure that registrants who deviate from standard requirements provide a justification that is relevant within the REACH context.
Areas of manual verification

1. Substance identification (IUPAC name, composition, manufacturing process description of UVCB substances, analytical information).

2. Justification for waiving of standard information requirements (physicochemical, environmental fate and hazard information, toxicological and ecotoxicological information).

3. Testing proposals on vertebrate animals (presence of considerations for adaptation possibilities).

4. Justification for waiving of Chemical safety report.
Areas of manual verification

Information on the areas of the additional verifications:

Summary of the exercise
Summary of the exercise

• Modifying a substance dataset

• Using the Validation assistant on the dataset and dossier

• Creating a dossier in IUCLID 6

• Correcting failing rules on the dataset and creating a new dossier
## Creating a complete dossier

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Create the dataset&lt;br&gt;Fill-in the information</td>
</tr>
<tr>
<td>2</td>
<td>Run the Validation Assistant on the dataset&lt;br&gt;Correct the failures</td>
</tr>
<tr>
<td>3</td>
<td>Create the dossier&lt;br&gt;Run the Validation Assistant on the dossier&lt;br&gt;<em>In case of failures, correct the dataset or re-create the dossier</em></td>
</tr>
</tbody>
</table>
Creating a complete dossier

1. Create the dataset
   Fill-in the information

2. Run the Validation Assistant on the dataset
   Correct the failures

3. Create the dossier
   Run the Validation Assistant on the dossier
   *In case of failures, correct the dataset or re-create the dossier*
Dataset content

Section 1:
- Substance identification
- Composition(s)

Section 2:
- 2.1 Classification and Labelling (joint or individual)
- 2.3 PBT assessment (if CSR is required)
Dataset content

Section 3:

- Section 3.2 – Estimated quantities
- Section 3.5 – Life cycle description: brief description of uses based on the REACH use descriptor system
- Section 3.7 – Exposure scenarios, exposure and risk assessment
Dataset content

Sections 4 – 7
OECD Harmonised templates

Section 11: guidance on safe use

Section 13: assessment reports
- The CSR document is attached to this section as a Word or PDF file
Create a new substance or modify an existing one.
‘TOC’ displays the dataset’s table of content. By default the view is ‘REACH Complete’.
Adapting view to submission types

Adapt the view according to your needs (e.g. registration dossier as a member of a joint submission)
Filling in a dataset: mandatory sections

- Mandatory sections are indicated with an asterisk *

- Merely indicative - the Validation Assistant should be run to verify the completeness of the dossier
Filling in a dataset: creating records

- Right-click on a section name to create a new record or an endpoint summary
- Fill-in the information
Filling in a dataset: free text templates

- Description of composition
- Attached description
- Attached document
- Justification for deviations

**Free text templates**

View / edit / insert freetext template as appropriate.
In case of several options, click the heading of the desired freetext template.
Delete/add elements and edit text set in [...] (if any) as appropriate.

1. **Option 1: Boundary composition of the substance**
2. **Option 2: Composition of a UVCB substance**

**DESCRIBE THE PROCESS BEHIND THE PARTICULAR COMPOSITION OF THE UVCB... SUBSTANCE**
- Identity of starting materials/source (and ratio):
- Reaction steps/mechanisms:
- Relevant operating parameters (e.g. temperature and pressure):
- Solvents/reagents used:
- Details on any extraction/isolation steps as appropriate:
- Details on any clean-up/purification steps as appropriate:
- Physical-chemical parameters (e.g. boiling point):

**Insert**  **Cancel**
Filling in a dataset: units

Every value must be followed by a unit:
Filling in a dataset: justifications

Values selected as *other* must be followed by a justification in the designated free text field:

The free text entry should provide similar information to the rest of the picklist.
Creating a complete dossier

1. Create the dataset
   Fill-in the information

2. Run the Validation Assistant on the dataset
   Correct the failures

3. Create the dossier
   Run the Validation Assistant on the dossier
   *In case of failures, correct the dataset or re-create the dossier*
Validation assistant

Validate substance dataset AND the final dossier to minimize the risk of errors
Validation assistant

1. Access the substance dataset

2. Right-click on the dataset and select *Validate*
Validation assistant

1. Access the substance dataset

2. Right-click on the dataset and select Validate

3. Select the submission type
Validation assistant

1. Access the substance dataset

2. Right-click on the dataset and select Validate

3. Select the submission type

4. Provide the dossier header information
Validation assistant results

Total number of failures

Rule number

Relevant section

Document name

Error message
Validation assistant results

Right-click on a failure to access the incomplete document
The incomplete document is displayed

You can (un)hide the Validation Assistant using this icon
Refreshing the Validation assistant results after correcting issues and saving

[Image of the Validation assistant wizard interface]

- **DR104**: Section 2.3 - PBT assessment
  - Message: In section 2.3 - PBT assessment, a summary document must be created, and a selection must be made in the field 'PBT status'. If the option 'PBT assessment does not apply' is selected, an explanation must be provided in the field 'Justification'. If several PBT summaries are provided, the 'Assessed composition(s)' must be indicated. Summary documents are identified with the sigma sign.
  - Rule type: Business rule
  - Rule level: Failure

- **TCC_0102_08**: Section 1.2 - Composition
  - Message: For each impurity of a legal entity composition, the full 'Concentration range' must be provided (lower and upper value), together with a unit. If declaring the absence of a specific impurity, link the appropriate reference substance and indicate the value '0', together with the unit, in the field 'Typical concentration'. Leave the 'Concentration range' fields empty.
  - Rule type: Completeness check
  - Rule level: Failure

- **TCC_0104_02**: Section 1.4 - Analytical information
  - Message: The 'Analytical information' provided in section 1.4 is incomplete. At least one row must be created in the table 'Analytical determination'. In each row, the following must be provided:
    - a selection must be made in the 'Purpose of analysis' picklist
    - at least one selection must be made in the 'Analysis type' picklist
    - either an attachment must exist in the 'Attached methods/results' field, or a reason for not providing a method/result must be indicated. To this end, make a selection in the field 'Rationale for no results' and insert an explanation in the
  - Rule type: Completeness check
  - Rule level: Failure
Creating a complete dossier

1. Create the dataset
   Fill-in the information

2. Run the Validation Assistant on the dataset
   Correct the failures

3. Create the dossier
   Run the Validation Assistant on the dossier
   *In case of failures, correct the dataset or re-create the dossier*
Dossier creation

Access your substance datasets
Dossier creation

Select the dataset for which you want to create a dossier

Right-click and create dossier
Dossier creation wizard

Select the dossier type

- REACH Downstream user report
- REACH inquiry
- REACH Notification of substance in article
- REACH IPORD
- REACH Registration 1 - 10 tonnes, physicochemical requirements
- REACH Registration 1 - 10 tonnes, standard requirements
- REACH Registration 10 - 100 tonnes
- REACH Registration 100 - 1000 tonnes
- REACH Registration above 1000 tonnes
- REACH Registration member of a joint submission - general case
- REACH Registration member of a joint submission - intermediates

Use advanced settings
Dossier creation wizard

Fill in the dossier header
Dossier creation wizard

Open the dossier

Copy and paste the dossier UUID here. Press Enter to open the dossier.
Run the Validation assistant on the dossier

Right-click on the final dossier and run the validation assistant on it before exporting the dossier.
Export the dossier

Your dossier is ready to be exported.
Exercise
Exercise

You are the Lead registrant of a joint submission of 10-100 tonnes.

Prepare your substance dataset and IUCLID dossier to submit via REACH-IT.
Exercise

Steps:

1. Log-in to IUCLID and import the substance dataset from the provided USB stick.
2. Find your substance dataset in IUCLID.
3. Run the Validation Assistant on the substance dataset and correct all the failures.
4. Create a dossier for a lead standard registration of 10-100 tonnes (own tonnage is the same). The lead provides the Guidance on safe use and CSR on behalf of the members.
5. Export your dossier.
Key messages
Key messages

• Read the IUCLID integrated help:
  - Field by field help
  - Manuals

• Prepare you dossier in advance.

• The Validation assistant does not display the manual checks.

• If your submission fails TCC, follow the advice included in Annex 1 of the communication.
Guidance and support
Useful links 1/2

• IUCLID 6 website https://iuclid6.echa.europa.eu/

• ECHA website support section https://echa.europa.eu/support

• ECHA website on 2018 deadline https://echa.europa.eu/reach-2018

• Manuals on preparing dossiers http://echa.europa.eu/manuals
Useful links 2/2


- Contact form [http://echa.europa.eu/contact](http://echa.europa.eu/contact)
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