

IT tools training

REACH 2018 Stakeholders' Day

30 January 2018

European Chemicals Agency



10:10

Update on IT tools



IUCLID 6



What is IUCLID? A multi-purpose tool



International Uniform Chemical Information Database

- A key application to **prepare**, **store** and **exchange data** on chemicals in a harmonised format.
- REACH Article 111: a dossier must be in IUCLID format and ECHA should work with the OECD towards the **maximum harmonisation** of the IUCLID data format

IUCLID is used by regulatory authorities and the chemical industry to fulfil their respective obligations under the REACH, CLP and the BPR regulations

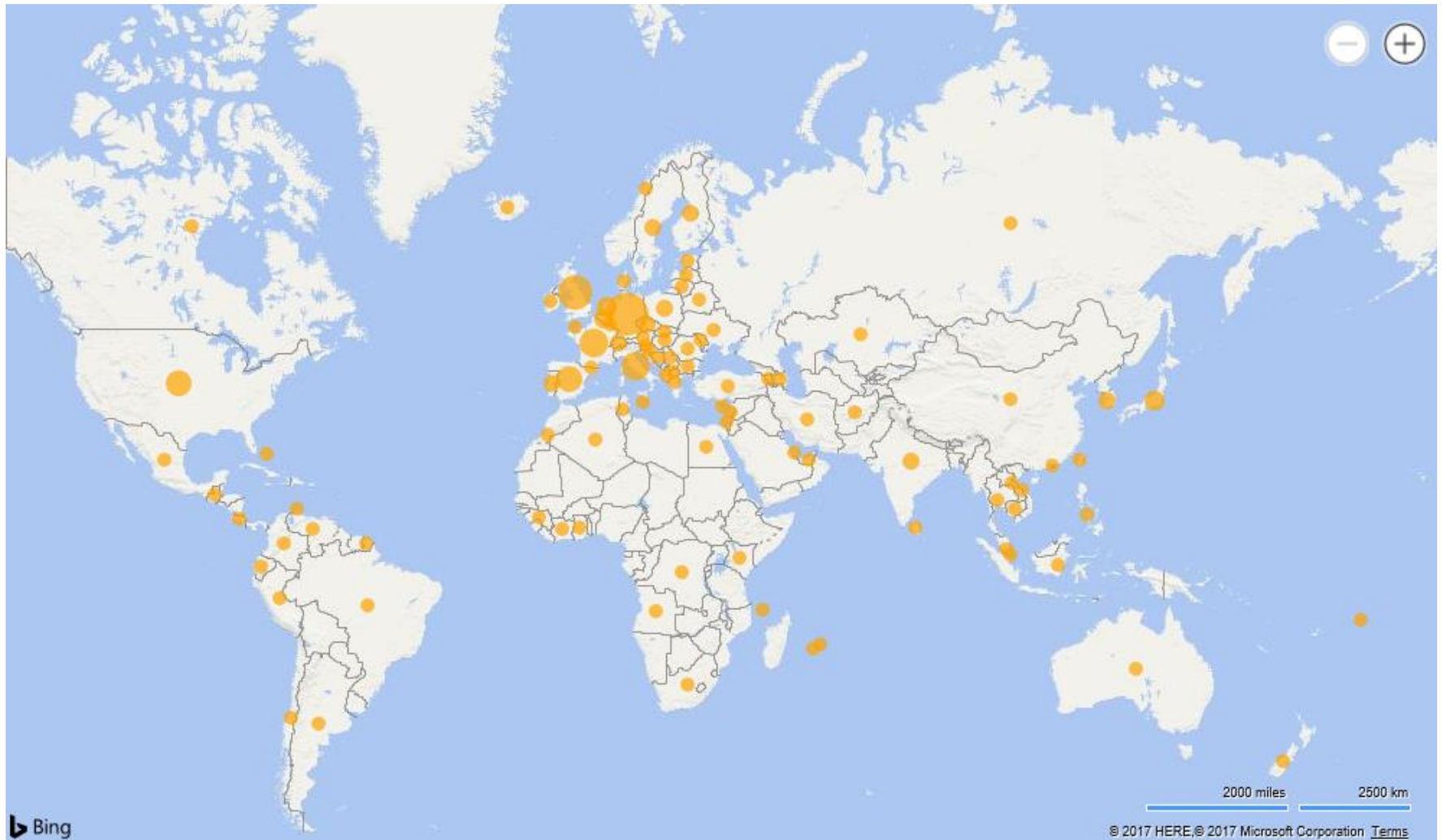
Article 111

Formats and software for submission of information to the Agency

The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency. Member States, manufacturers, importers, distributors or downstream users shall use these formats and packages in their submissions to the Agency pursuant to this Regulation. In particular, the Agency shall make available software tools to facilitate the submission of all information relating to substances registered in accordance with Article 12(1).

For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.

From where IUCLID 6 is downloaded?



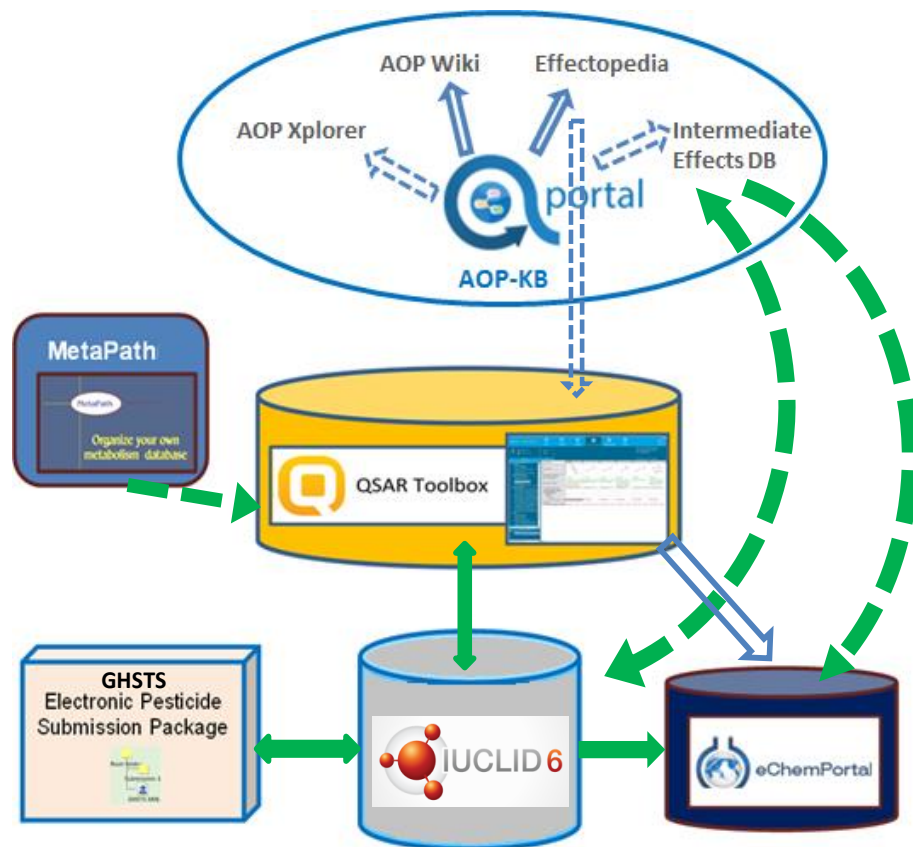
International cooperation

Organisation for Economic Co-operation and Development (OECD)

A global outreach

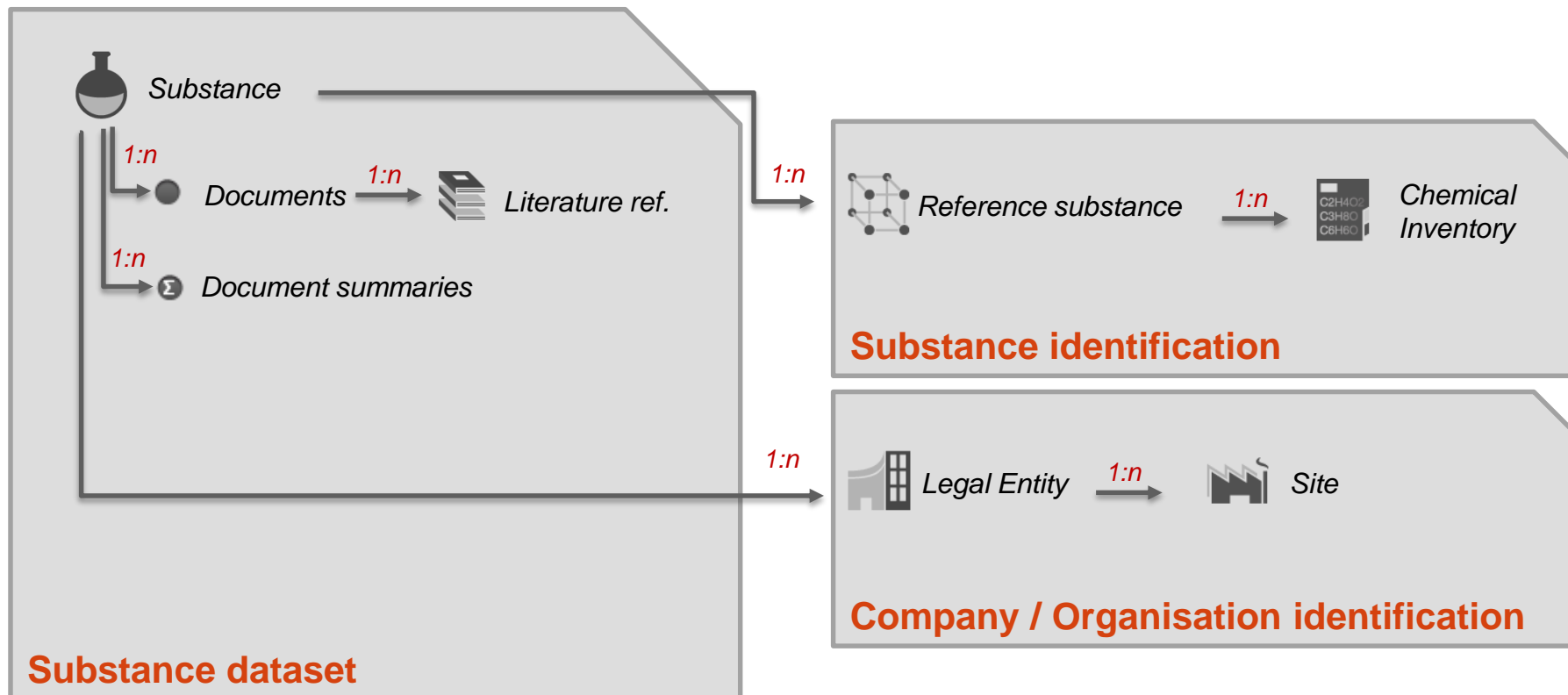


OECD 4



IUCLID entities (type of information)

Main entities and relationships (Substance)



 Attachments can be added to all entities and documents

 Annotations can be linked to all entities and documents

Information managed in IUCLID



- Substance identity

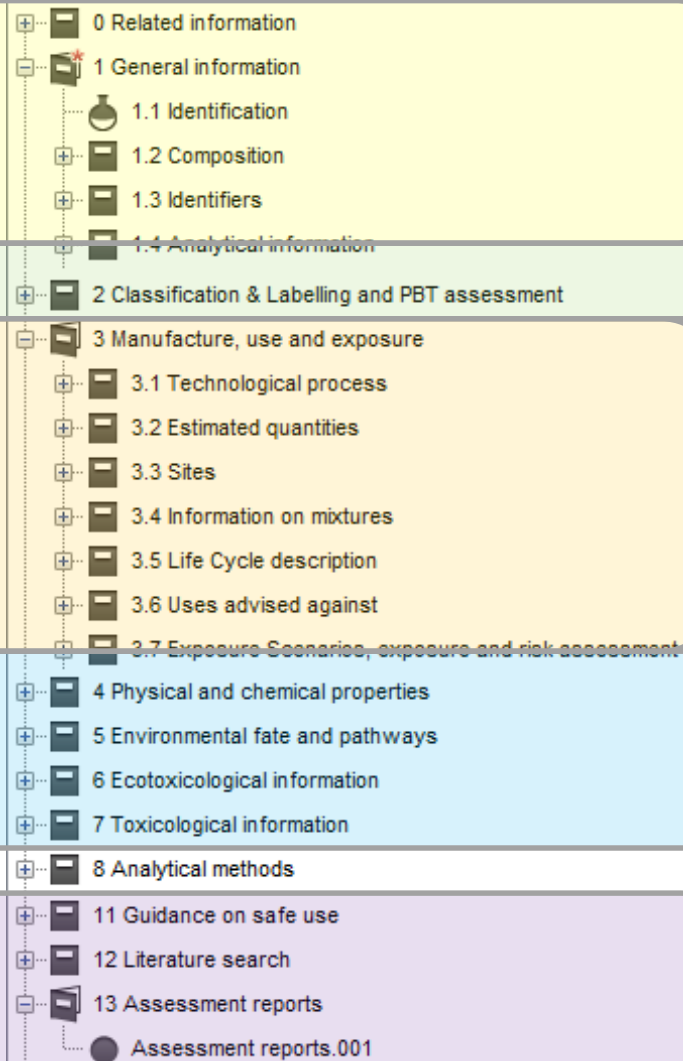
- Substance identification
- Composition(s)

- Classification and Labelling

- Use and exposure

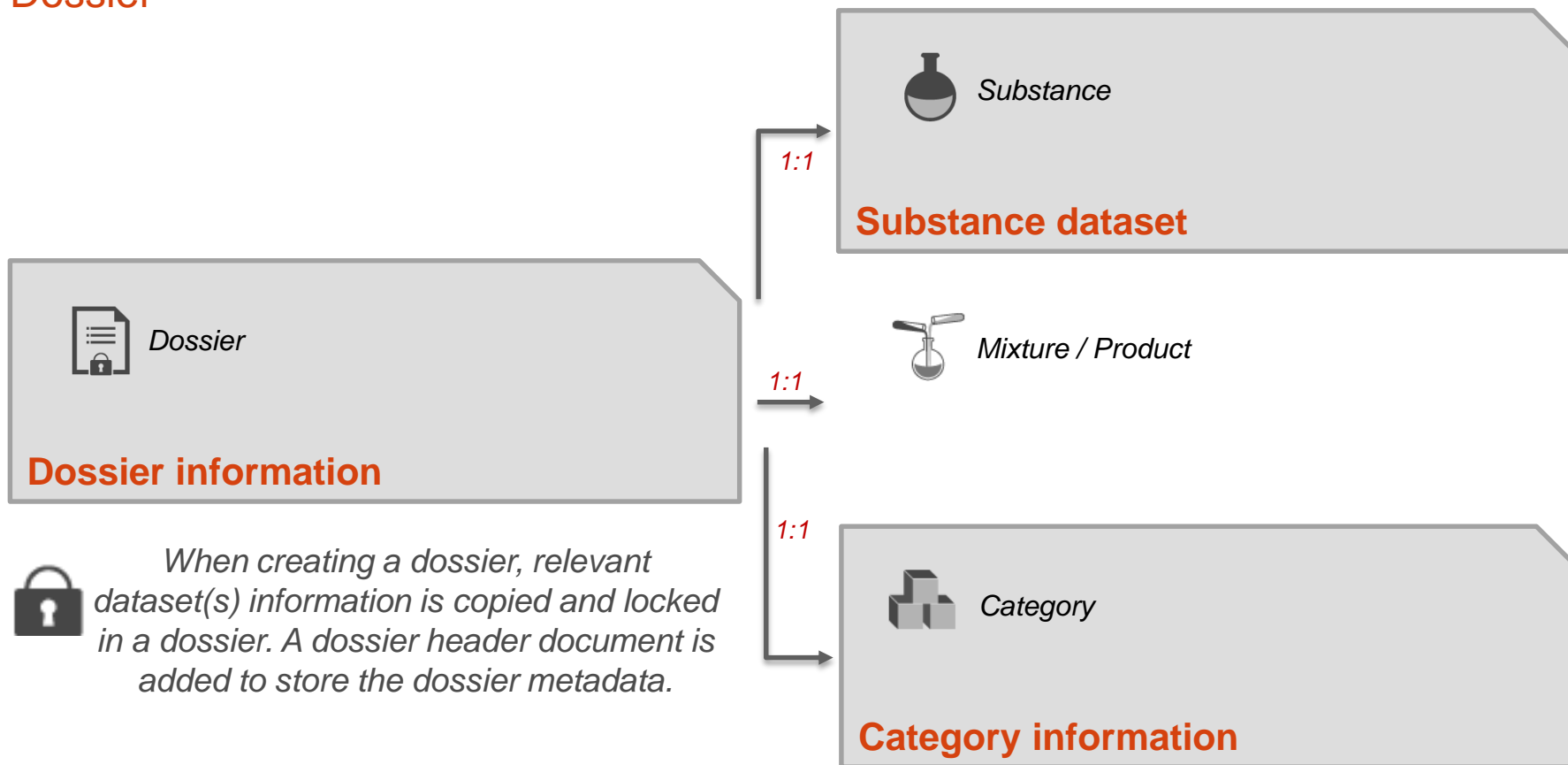
- Study and endpoint summaries

- Assessment reports

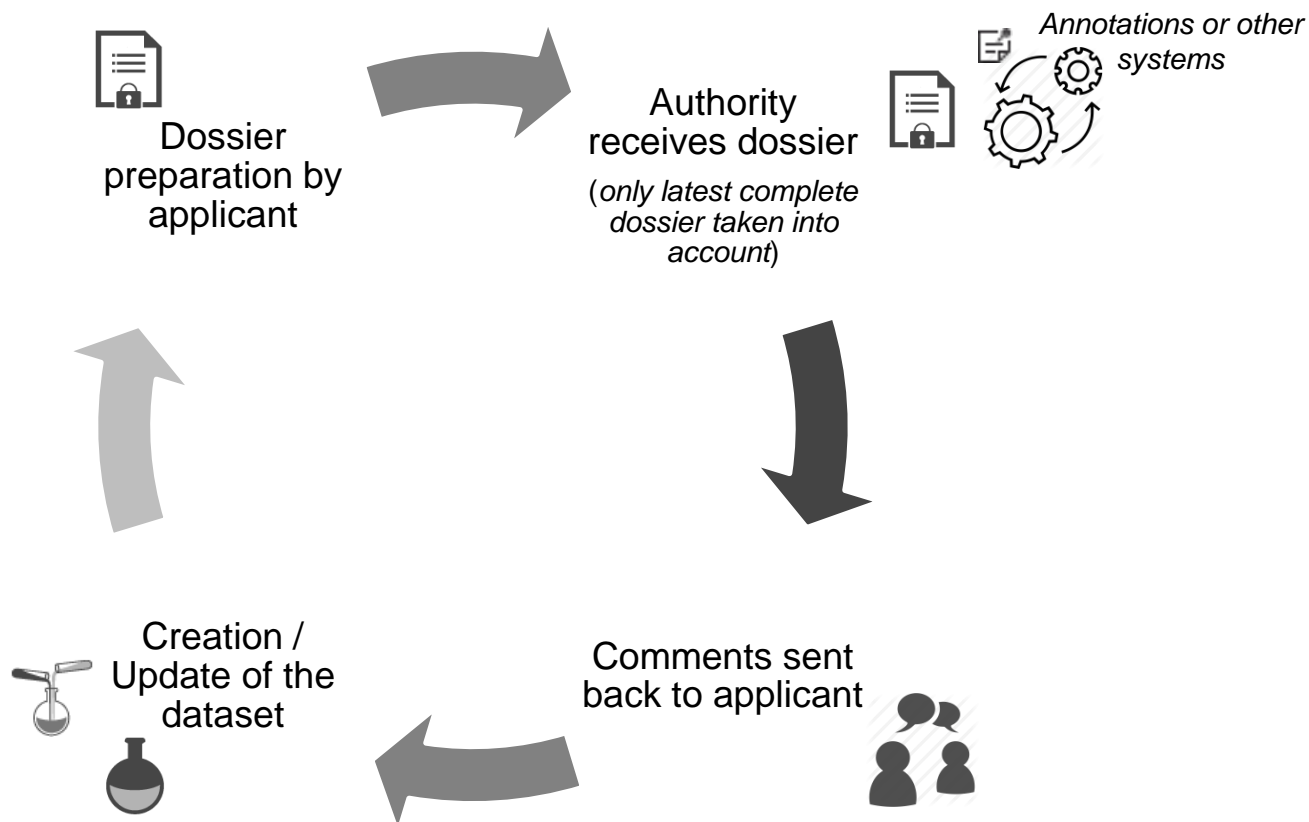


IUCLID entities (type of information)

Dossier



ECHA's approach



IUCLID 6 standard user interface



Main screen

The screenshot shows the IUCLID 6 main screen with three numbered callouts:

- 1**: Navigation panel (left side)
- 2**: Data view and entry (middle right)
- 3**: Information panel (bottom right)

The navigation panel (1) includes a search bar, result type dropdown (Substance), query type dropdown (Get all substances), and a table of search results. The data view and entry (2) shows a form for editing a substance entry, including fields for substance name, public name, legal entity flags, legal entity, and third party flags. The information panel (3) displays a list of categories and a filter section.

| Chemical name | Legal entity name/Reference subst. | Last modification |
|---------------|------------------------------------|--------------------|
| substance_1 | user_manual | 2016-08-26T18:2... |
| substance_2 | legal_entity_two | 2016-05-26T18:2... |
| substance_one | user_manual | 2016-08-30T18:1... |

1. Navigation panel
2. Data view and entry
3. Information panel

IUCLID: 3 ways to create a registration dossier



REACH-IT Online

- For members of joint submissions only
- Agree with all information submitted on your behalf by the lead registrant
- The simplified dossier creation wizard in REACH-IT guides you through this process by showing you which data you need to provide



IUCLID Cloud for SMEs

- Simplified web version of IUCLID for SME companies
- Maintained, backed-up, updated and hosted for free by ECHA
- Build all different REACH dossiers
- Easy access of data by company and consultant
- Logical choice for SMEs



IUCLID 6 Download

- For large companies or frequent users
- Full set of functionalities for data management
- Installed and maintained locally by users
- Desktop version easy to install
- Server version available for multi-user installations



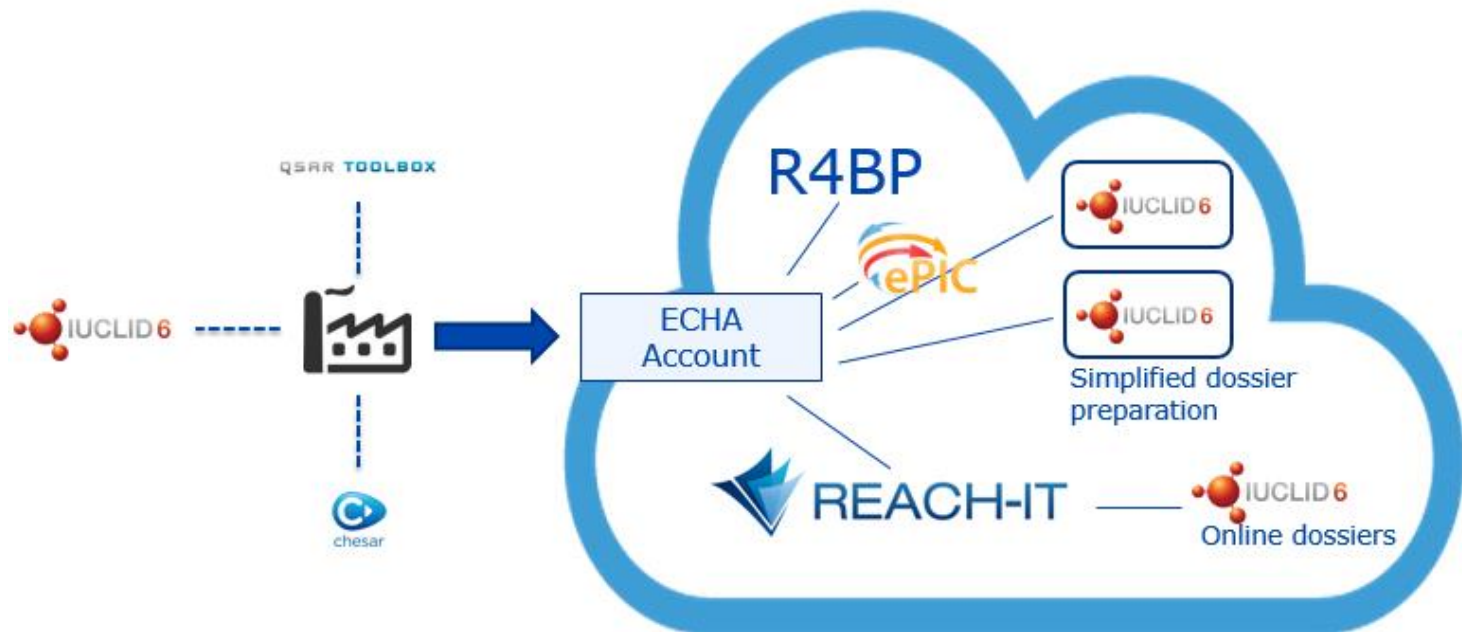
ECHA Cloud Services





What are the ECHA Cloud Services ?

The ECHA Cloud services are a new platform for delivering Business Information systems in ECHA.



What is IUCLID Cloud?

- A simpler IUCLID provided as a cloud service to prepare for the REACH 2018 deadline!
- Guided support for REACH 2018 dossier creation



SMEs and their consultants



Anyone who wants to test

| | Trial | For SMEs |
|--------------------------------------------------------|---------------|-----------------|
| Quota of data per subscription | 100 MB | 1 GB |
| Subscription terminates automatically due to non-usage | After 90 days | After 2 years |
| Backup of data | Not available | Yes |
| Helpdesk support | Limited | Fully dedicated |

IUCLID Cloud – Work with the latest version of IUCLID



**You are updated with
the latest version of
IUCLID**



**With IUCLID Cloud,
Forget about all this!**

IUCLID Cloud – Work online



IUCLID Cloud – Data security

- Private cloud built on ECHA's own infrastructure with the same infrastructure security level as any other ECHA service such as REACH-IT, R4BP and ePIC.
- encrypted communications between the client computer and the Cloud.
- Regular security audits and update on all IT components.



**Data is safe in
IUCLID Cloud!**

IUCLID Cloud – Backups and copies of data

- ECHA **backs-up the data** regularly.
- To **restore the data**, users need to contact ECHA.
- If users need to **share data**, they can grant access to the cloud to colleagues or service providers.

BACKUP



**With IUCLID Cloud,
ECHA does it for you!**



IUCLID Cloud – Helpdesk support



Having one
version of
IUCLID
allows easier
and faster
support!

What are the benefits of using IUCLID in the Cloud?

SMEs:

- ECHA takes care of the IT infrastructure
- Simpler interface, focus on the REACH Registration 2018 deadline
- Reduced risks of data loss (backup system managed by ECHA)
- Work anywhere/anytime via web browser over internet
- Easy to delegate access to consultants

Consultants:

In addition to all the advantages the SMEs have:

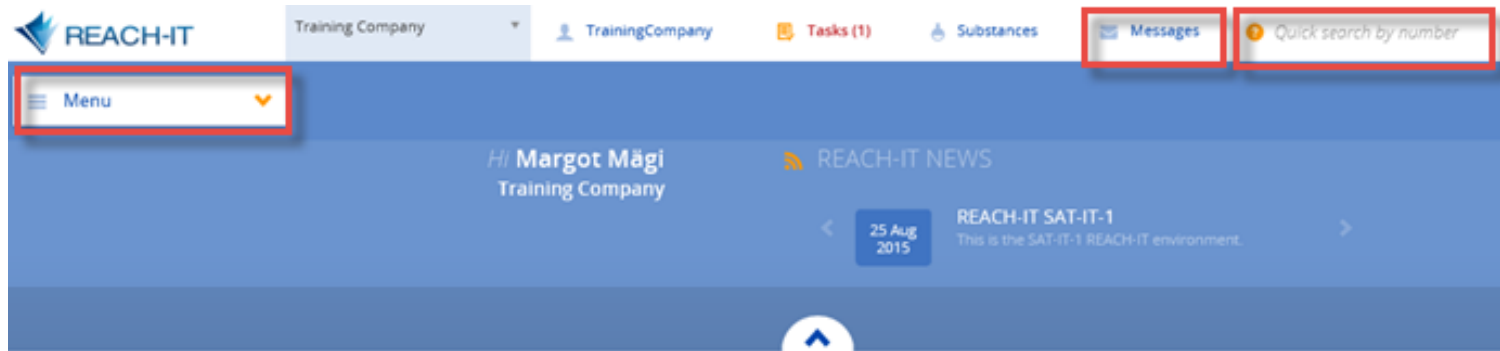
- Give your clients "more value for their money"
- Provide a more transparent and interactive service to your clients
- Opportunity to organize IUCLID trainings



Main functionalities



REACH-IT home page



Submit a dossier

Prepare online in REACH-IT

- Upload a IUCLID dossier
- Webform applications

View all types

Tasks (1)

1 New

1 Close to deadline

0 Passed deadline

View all tasks

Substances (0)

0 My favourites

0 In progress submissions

0 Failed submissions

View all substances

Menu 

 **Submit**

Submit a dossier

Alternative chemical name request

- Webform application

Application for authorisation

- Upload a IUCLID dossier

Classification and labelling notification

- Upload a IUCLID dossier
- Prepare and submit online In REACH-IT
- Manage group of manufacturers or Importers

Downstream user report – Authorisation

- Webform application

Downstream user report – Registration

- Upload a IUCLID dossier
- Webform application

Inquiry

- Upload a IUCLID dossier
- Prepare and submit online In REACH-IT

PPORD notification

- Upload a IUCLID dossier

Pre-registration

- Data holder information
- Late pre-registration

Registration

- Upload a IUCLID dossier
- Prepare and submit online In REACH-IT
- Claim notified substance

Substance in articles

- Upload a IUCLID dossier
- Webform application

 **Search**

Advanced search

Reference numbers

Submissions

Substances

Co-registrants

Pre-registrations and pre-SIEFs

Classification and labelling

Key documents

Invoices

 **Joint submission**

Create new

Join existing

Search and view

 **Manage company**

Company information

Company size

Contacts

Email notification settings

Legal entity change

- Initiate a legal entity change
- Search or finalise a legal entity change
- Create and export an assets list

Third party representatives

 **Tasks**

 **Messages**

 **Terms and Conditions**

 **Logout**

The submission process cannot be saved so ensure you have all the required information before you begin.

Dossier type: * Registration

Submission type: *

Select the option which defines the company's ownership structure. The options "Linked company" and "Partner company" can be combined. Please note that the ownership structure of a company is not covered by the ICH Q7A. You can find more information on the ECHA website (<http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/how-to-determine-the-company-size-category>). An error message will be displayed if you select an invalid option.

Topic help

Checklists in wizards

Are you ready to submit your dossier? Before continuing, make sure that:

- ✔ You are part of the **joint submission**, if one exists for your substance.
- ✔ The **company size is correct**. You can find out how to determine the company size if you are unsure.
- ✔ The **VAT number and billing address** in REACH-IT are up to date, and optionally you have a purchase order number: they will appear on the invoice.
- ✔ The **contact persons** for this dossier has been defined, and the **contact details** are up to date.

certain information from the dossier will be published on the website without further notice. Use the notification plugin in IUCLID to indicate what information will be published.

Continue to upload dossier >

Page help

Need help?

You have now launched the submission wizard for your selected submission type. The submission wizard will guide you through the steps of the submission process.

In each step of the submission process you will find customised information relevant for your submission type. Remember to refer to the checklist on each wizard step to receive detailed assistance for your submission.

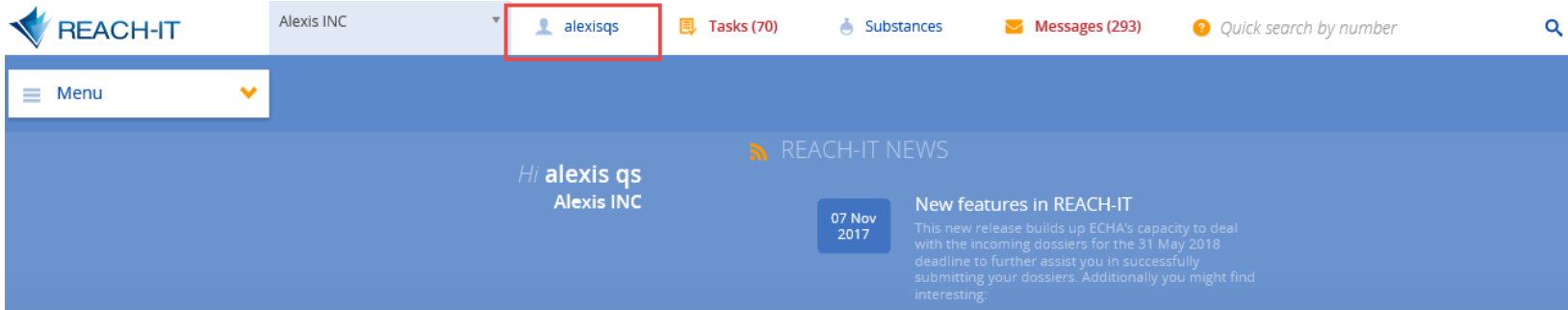
In the *Submission details* step, you will first choose the dossier type applicable to your submission: application for authorisation, classification and labelling notification, downstream user report, inquiry, PPOD notification, registration or substance in articles. If you are submitting a Registration, you will also need to specify the submission type: individual or joint submission. Remember that you will not be able to submit an individual registration if a registration for the same substance already exists. If this is the case, you need to contact your co-registrants and join the joint submission. You may search for your co-registrants and existing joint submissions on the *Advanced search* page in REACH-IT.

In the *Upload dossier* step, you can upload your IUCLID dossier. If the upload is successful, you will see an overview of your dossier details. You will also see if your IUCLID dossier are linked to your REACH-IT dossier. If you want to add details on your REACH-IT dossier that are not successful or you want to link it with another one, you need to click on *Want to upload a new file?* More information on how to prepare your dossier can be found on the [IUCLID manuals page](#).

In the *Additional details* step, you may specify and edit additional information depending on your submission type. If you are submitting an application for...

Turn on all In-page help items

Change the language of the Page help



REACH-IT Alexis INC alexisqs Tasks (70) Substances Messages (293) Quick search by number

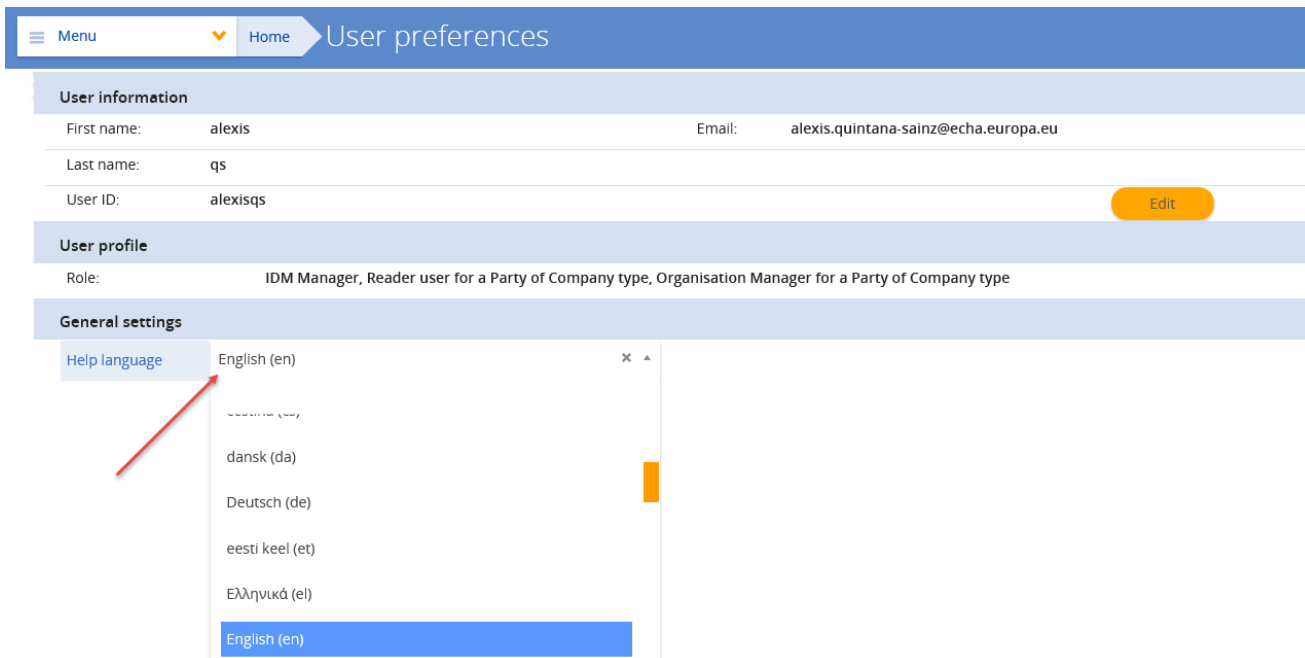
Menu

Hi alexis qs
Alexis INC

REACH-IT NEWS

07 Nov 2017

New features in REACH-IT
This new release builds up ECHA's capacity to deal with the incoming dossiers for the 31 May 2018 deadline to further assist you in successfully submitting your dossiers. Additionally you might find interesting:



Menu Home User preferences

User information

First name: alexis Email: alexis.quintana-sainz@echa.europa.eu

Last name: qs

User ID: alexisqs [Edit](#)

User profile

Role: IDM Manager, Reader user for a Party of Company type, Organisation Manager for a Party of Company type

General settings

Help language

- English (en)
- dansk (da)
- Deutsch (de)
- eesti keel (et)
- Ελληνικά (el)
- English (en)

Exercise introduction



10:30

Exercise presentation

Setting the scene



- It's Tuesday morning and you're looking out your office window at the snow fall – dreaming about the mountain hike you have planned for the next week
- Professionally you are REACH manager in a **medium** sized company in Finland
- Your company is **manufacturing** the substance **2-methoxy-1-methylethyl acetate**, but you all call it **PGMA** (propylene glycol methylether acetate). You manufacture **10-100 tonnes/year**
- Your dream about the mountain gets interrupted by your boss coming in to your office asking about the status update on **PGMA**



10:30 Exercise presentation

- You inform your boss that as we pre-registered it in 2008 we need to register it by mid 2018 and that you have done successful negotiations within the SIEF and will join the joint submission (JS) as **member**
- You additionally tell your boss that you aim at submitting your member dossier when your back from your trip, using the REACH-IT Online tool that is easy enough as we agree with everything the Lead is providing
- Your boss, who doesn't like to take risks, looks at you and asks if it wouldn't be safer that you submit the dossier before the mountain hike as one never knows if you will make it back
- In order to please him you decide to finalise the registration before the trip and decide to use an amended trip plan to help you keep track of the process

10:30

Exercise presentation

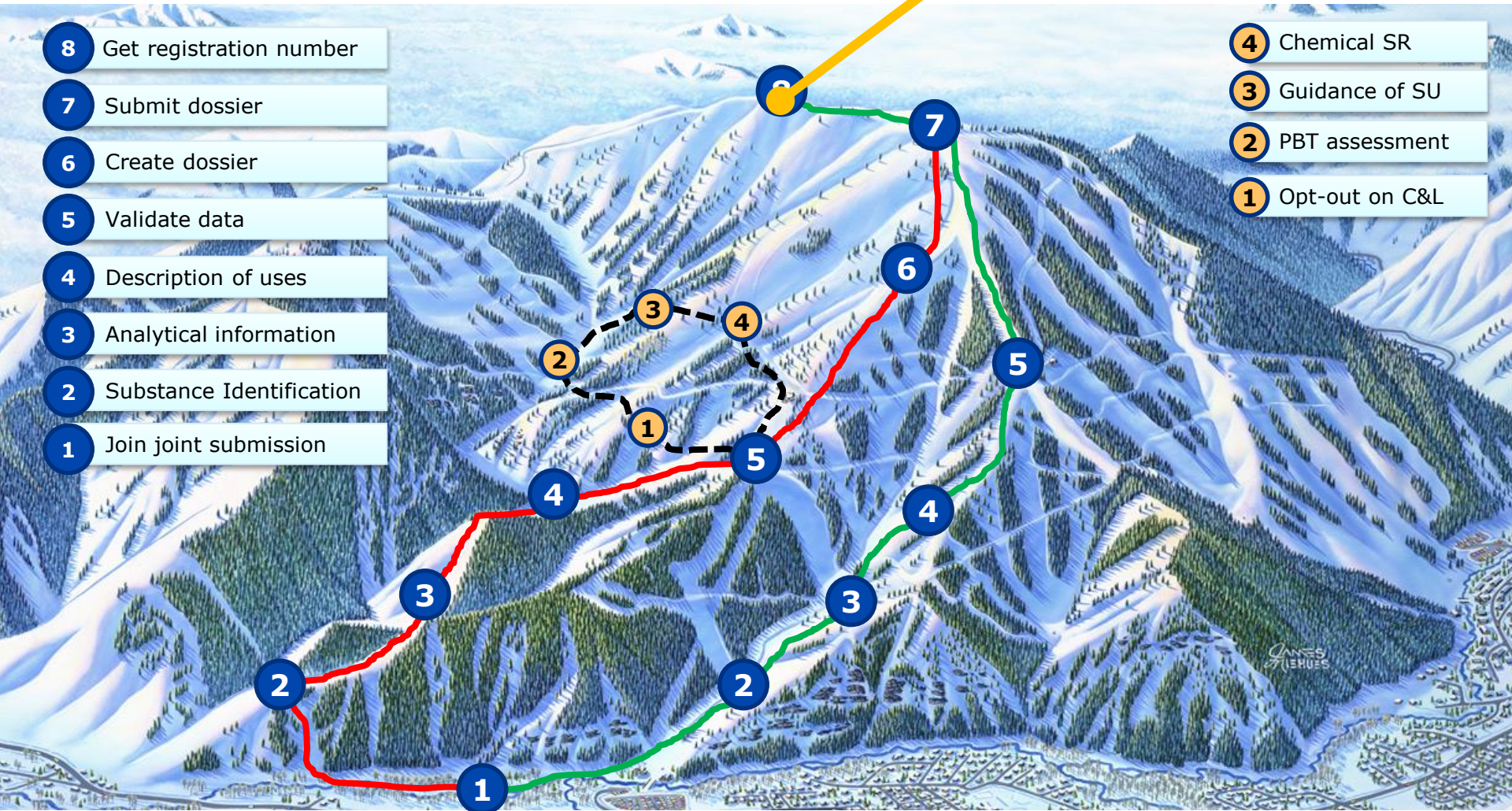


- You had just fetched a cup of coffee and rolled up your sleeves when your boss comes running back into your office
- Your boss reminds you that your company have some data which needs to be submitted outside the joint dossier...
- *"Can't share everything with our competitors"* he shouts as he leaves the office
- You adapt to the order and change your initial plan and decided to create your dossier using the IUCLID Cloud you subscribed to in the autumn. You found that to be the best option for you because it is easily accessible over the internet, it is always up-to-date, there is no need to worry about the back-up

REACH the summit

- 8 Get registration number
- 7 Submit dossier
- 6 Create dossier
- 5 Validate data
- 4 Description of uses
- 3 Analytical information
- 2 Substance Identification
- 1 Join joint submission

- 4 Chemical SR
- 3 Guidance of SU
- 2 PBT assessment
- 1 Opt-out on C&L



— REACH-IT Online path (Beginner)
— IUCLID Cloud path (Intermediate)
- - - IUCLID Cloud extended path (Advanced)

10:40 Start the work

- You have been handed an exercise script
 - REACH-IT Online member
 - IUCLID Cloud exercise
- You have been given a paper containing the username and password to be used
 - Same username to be used for both REACH-IT and ECHA Cloud Services
- Open the browser and observe the different options available




10:40

Start the work

- ADD Screenshot of Browser page and explain what they are and contain

Add Security Exception [X]

 You are about to override how Firefox identifies this site.
Legitimate banks, stores, and other public sites will not ask you to do this.

Server

Location:

Certificate Status

This site attempts to identify itself with invalid information.

Unknown Identity

The certificate is not trusted because it hasn't been verified as issued by a trusted authority using a secure signature.

Permanently store this exception



Your connection is not secure

The owner of 4fc55a85-79a8-4b82-bc16-36cad4116de0.ecs-qa.echa.eur is not the owner of this web site. The certificate is not trusted because the issuer certificate is unknown. The server might not be sending the appropriate intermediate certificates. An additional root certificate may need to be imported.

[Learn more...](#)

Report error

4fc55a85-79a8-4b82-bc16-36cad4116de0.ecs-qa.echa.eur

The certificate is not trusted because the issuer certificate is unknown.
The server might not be sending the appropriate intermediate certificates.
An additional root certificate may need to be imported.

Error code: [SEC_ERROR_UNKNOWN_ISSUER](#)

... web site

Advanced



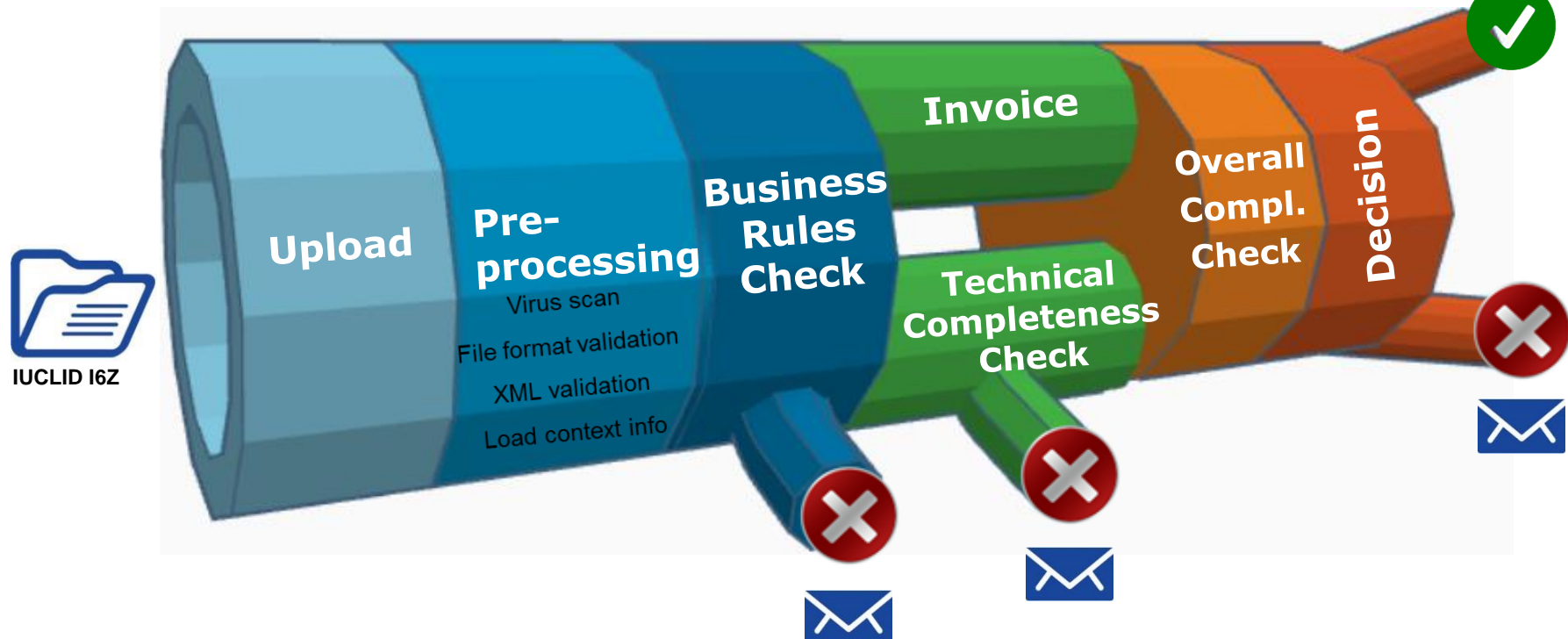
10:40

Start the work

Good luck!

...and remember to ask for help
if something is unclear!

7 Submit dossier



- Choose correct dossier type and follow the submission wizard

8 Get registration number

7 Submit dossier

6 Create dossier

5 Validate data

4 Description of uses

3 Analytical information

2 Substance Identification

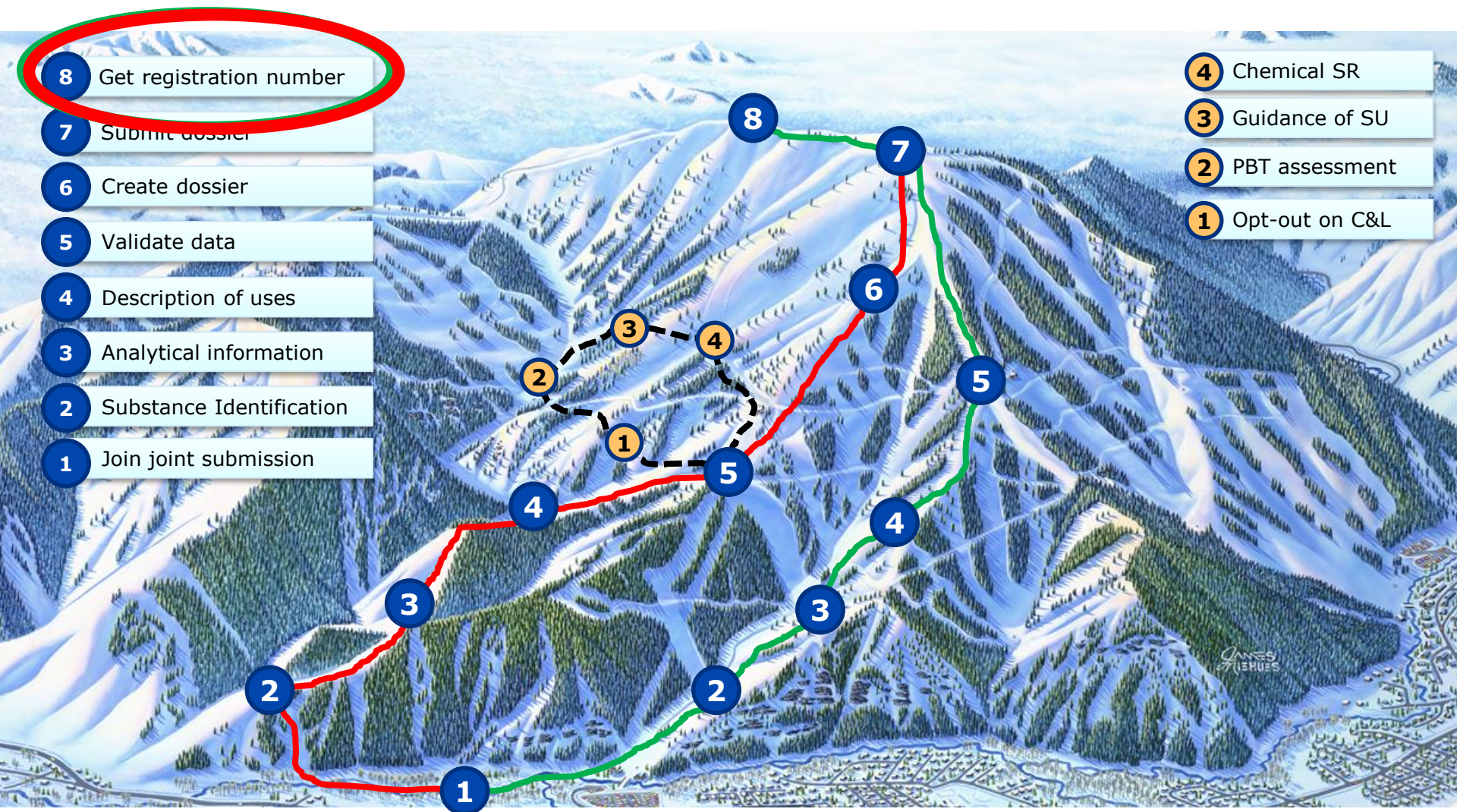
1 Join joint submission

4 Chemical SR

3 Guidance of SU

2 PBT assessment

1 Opt-out on C&L



- REACH-IT Online path (Beginner)
- IUCLID Cloud path (Intermediate)
- - - IUCLID Cloud extended path (Advanced)

8 Get registration number



- Find your invoice
- Find your registration letter
- Have a look at the Joint submission object to see what other registrants have done
- Look at your substance page, tasks and messages

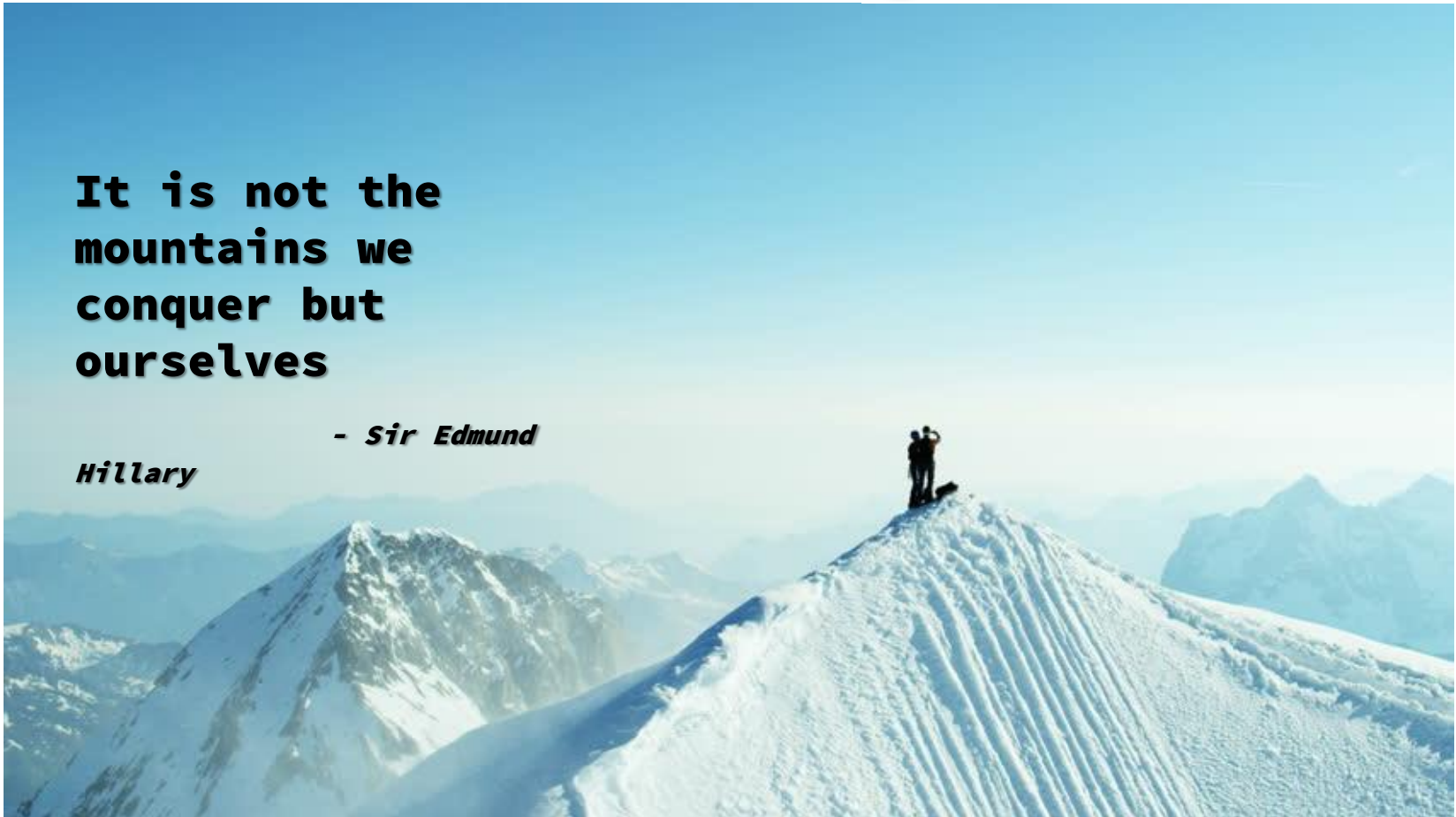
Congratulations

you REACHED IT!

**It is not the
mountains we
conquer but
ourselves**

- Sir Edmund

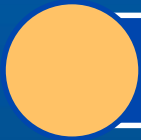
Hillary





14:55 Wrap-up of exercise

- XXX out of XXX received a registration number
- How many remembered to set your company size to medium?
- This proves that if the data is available and the process well planned it is not that hard to succeed
- We hope you seen and learnt something today that will help you succeed with your REACH 2018 deadline



15:00

Advanced Q&A on IT Tools



E-mail alerts: you got mail in REACH-IT

Here is the report for **22/02/2017**.

Party name: **Alexis4 INC**

Party UUID: **ECHA-70e62acf-09c3-4d14-bea5-** [REDACTED]

1 tasks were created since last notification.

| Subject | Type | Related to | Deadline |
|-------------------------------------------|---------|-------------|------------|
| Verify and pay your invoice - UV129882-96 | Invoice | UV129882-96 | 24/02/2017 |

4 messages were created since last notification.

| Subject | Type | Related to | Date |
|--------------------------------------------------------|------------------|-------------|------------|
| Dossier submission completed | Submission | UV129882-96 | 22/02/2017 |
| Dossier submission accepted after business rules check | Submission | UV129882-96 | 22/02/2017 |
| Confirmation of dossier submission | Submission | UV129882-96 | 22/02/2017 |
| Joint submission membership confirmed | Joint submission | | 22/02/2017 |

If you do not have a REACH-IT account, please contact your manager.

This notification was created on **01:00 23/02/2017**

- The term Cloud is often connected to negative issues with security and many do not trust cloud storages
- ECHA's Cloud is a private cloud built on ECHA's own infrastructure with the same infrastructure security level as any other ECHA service such as REACH-IT, R4BP and ePIC.
- encrypted communications between the client computer and the Cloud.
- Regular security audits and update on all IT components.



**Data is safe in
IUCLID Cloud!**

Thank you for attending!

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[Facebook.com/EUECHA](https://facebook.com/EUECHA)