IT tools training

REACH 2018 Stakeholders' Day

30 January 2018

European Chemicals Agency

10:10 Update on IT tools

IUCLID 6

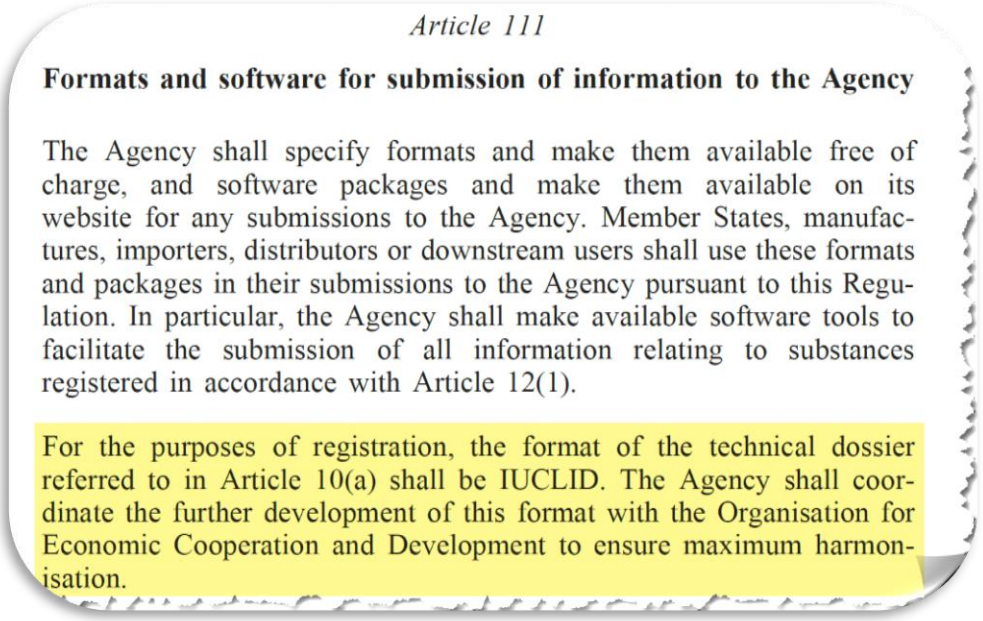
What is IUCLID? A multi-purpose tool

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



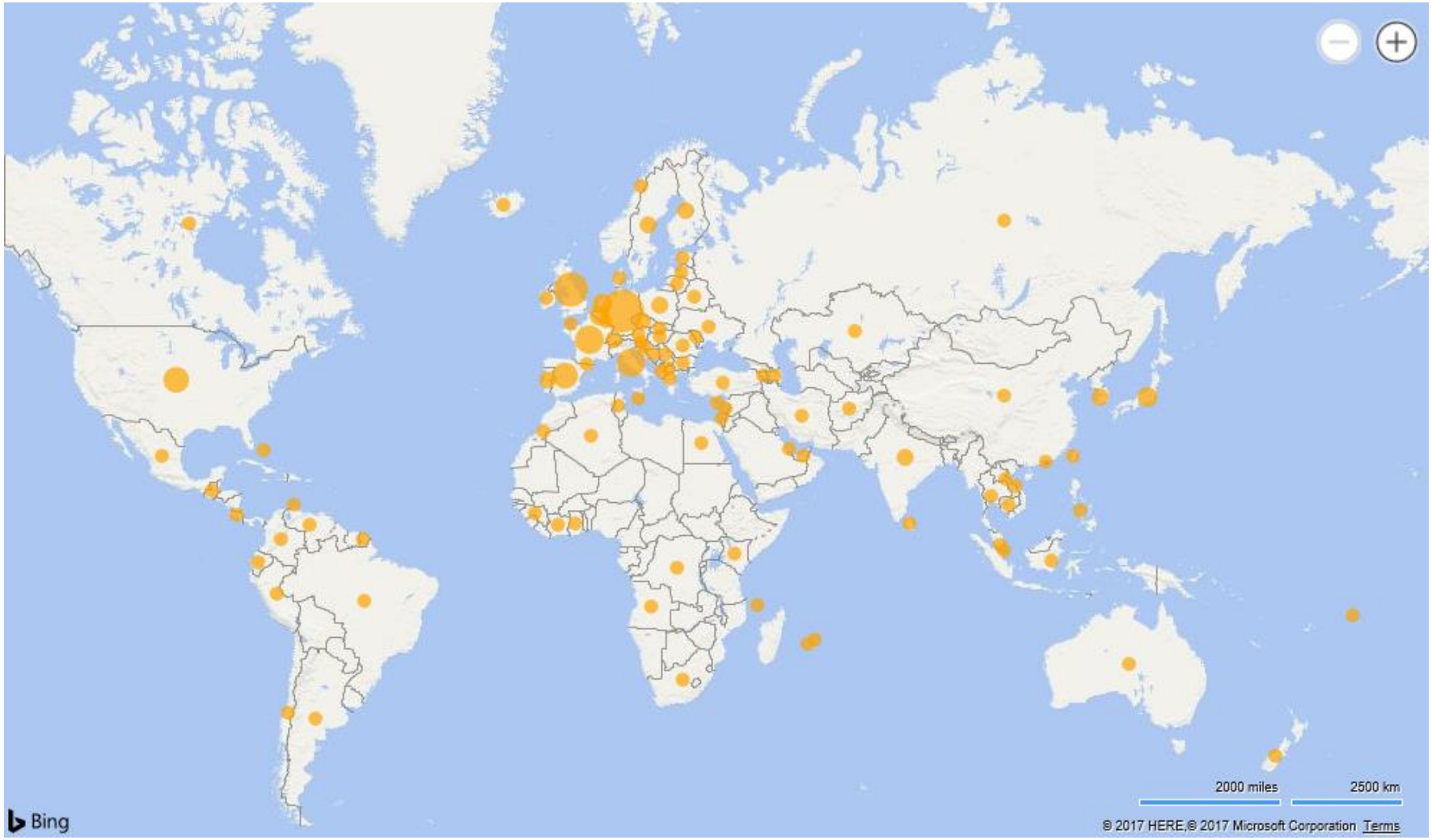
Article 111

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, manufactures, 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).

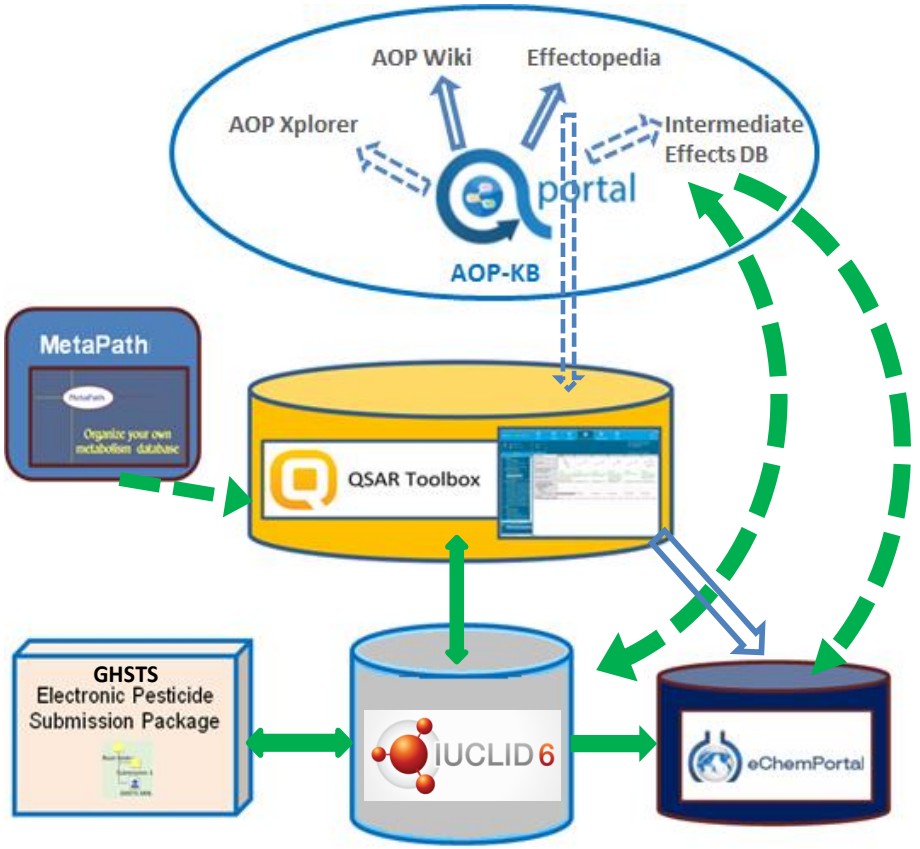
For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.

From where IUCLID 6 is downloaded?



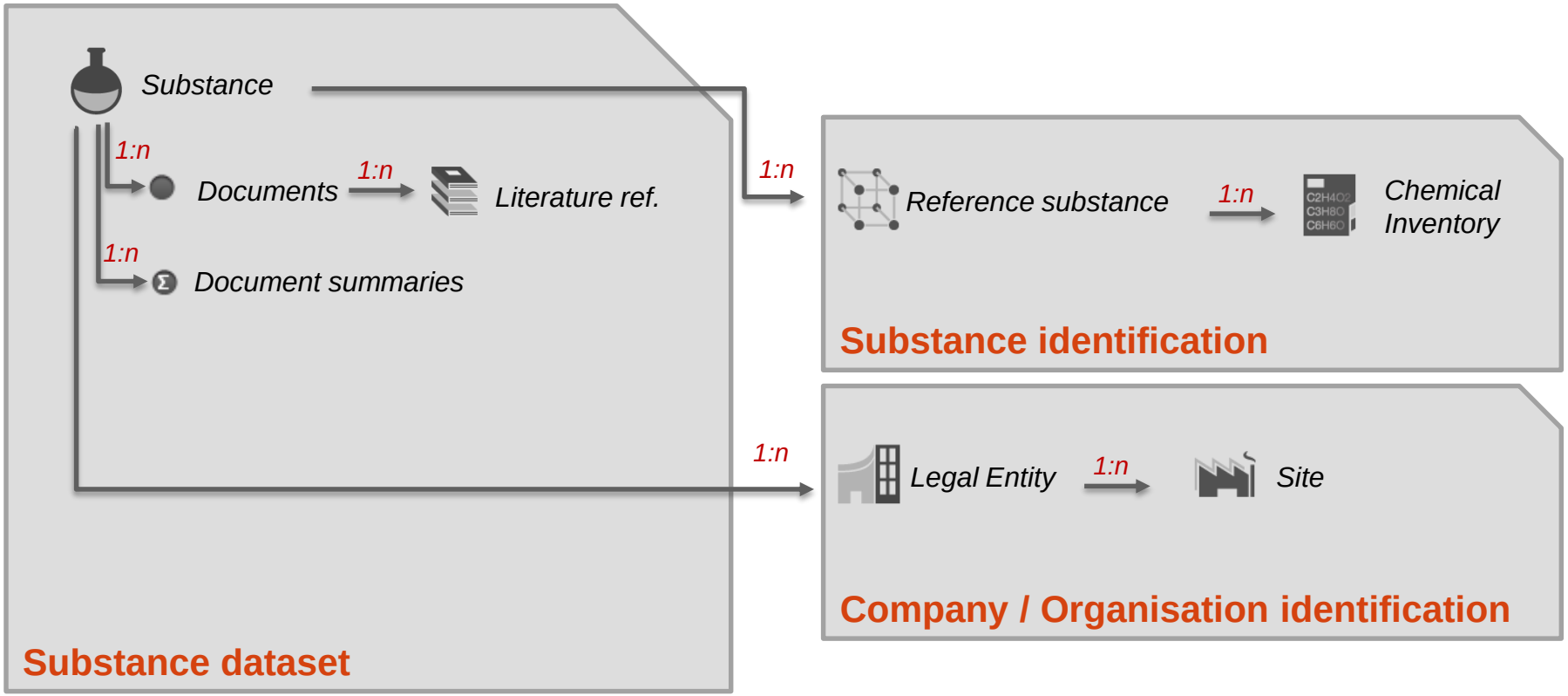
International cooperation

Organisation for Economic Co-operation and Development (OECD)



IUCLID entities (type of information)

Main entities and relationships (Substance)

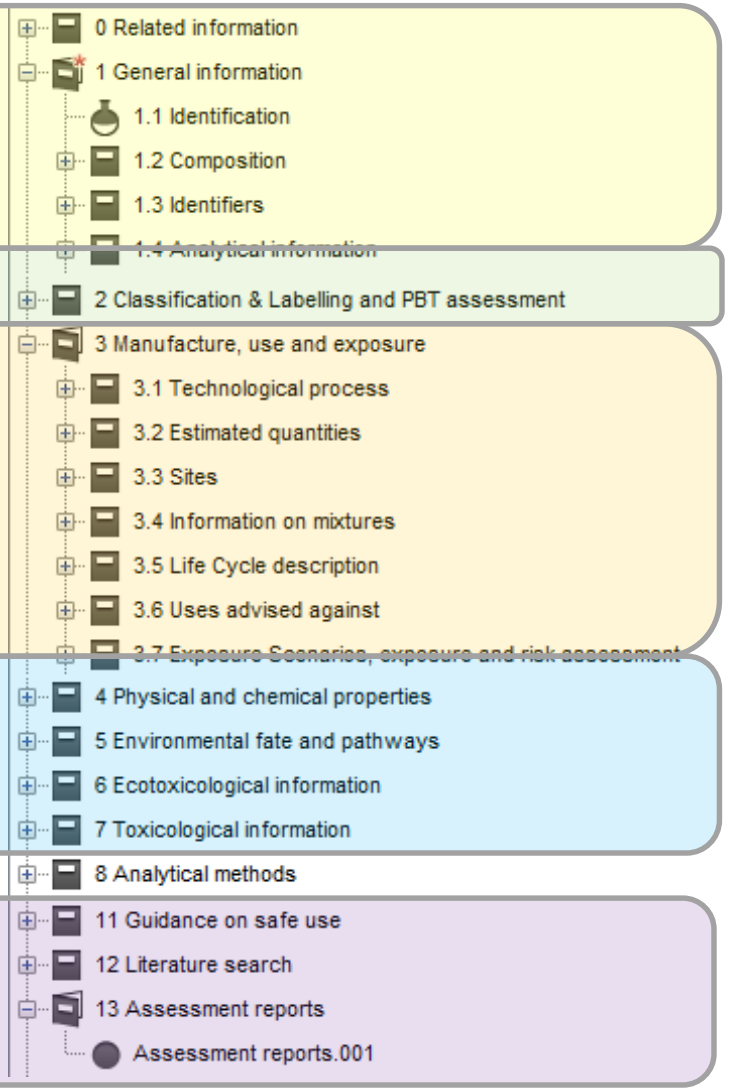


Attachments can be added to all entities and documents

Annotations can be linked to all entities and documents

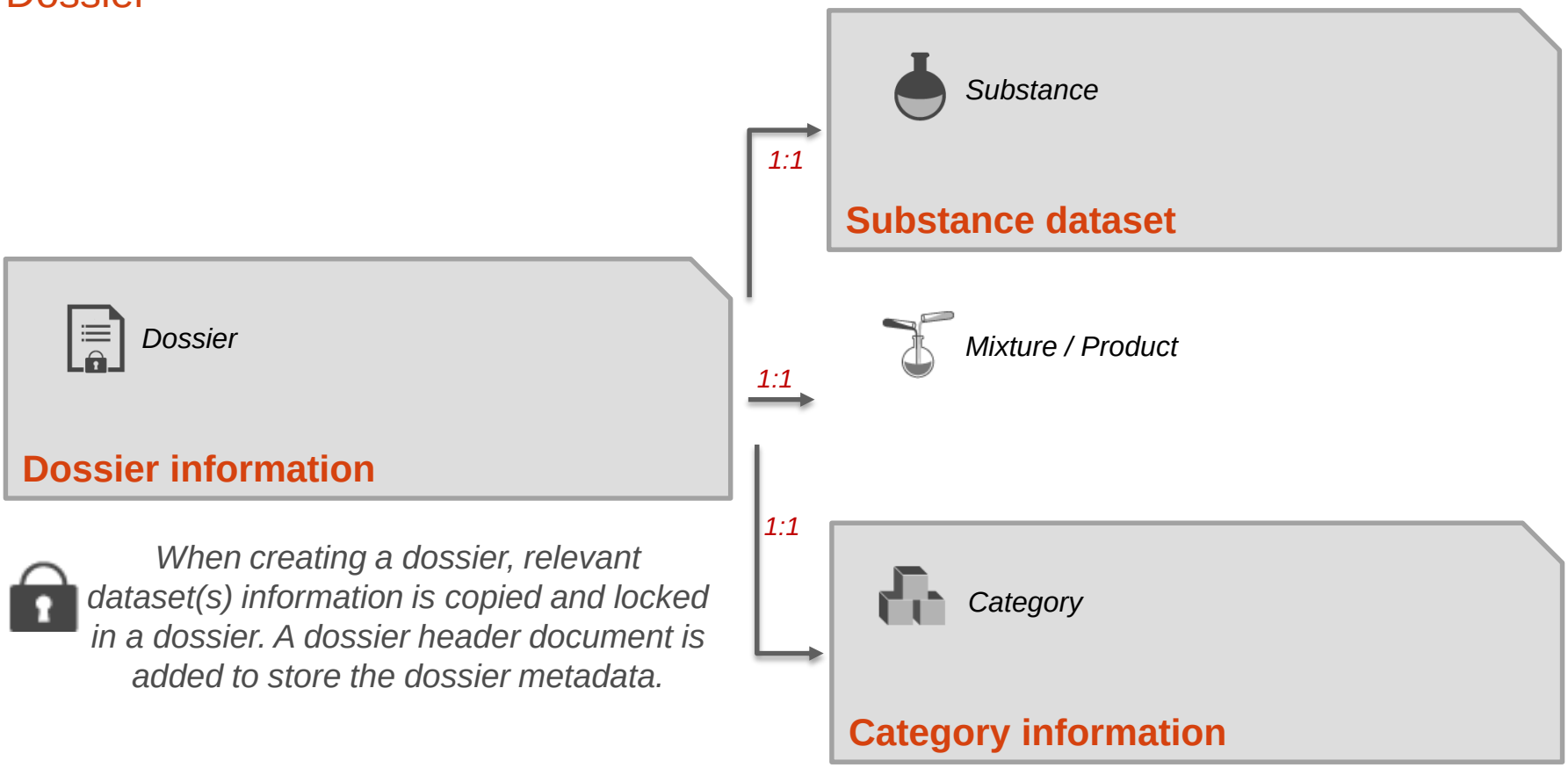
Information managed in IUCLID

- Substance identity
  - Substance identification
  - Composition(s)
- Classification and Labelling
- Use and exposure
- Study and endpoint summaries
- Assessment reports



IUCLID entities (type of information)

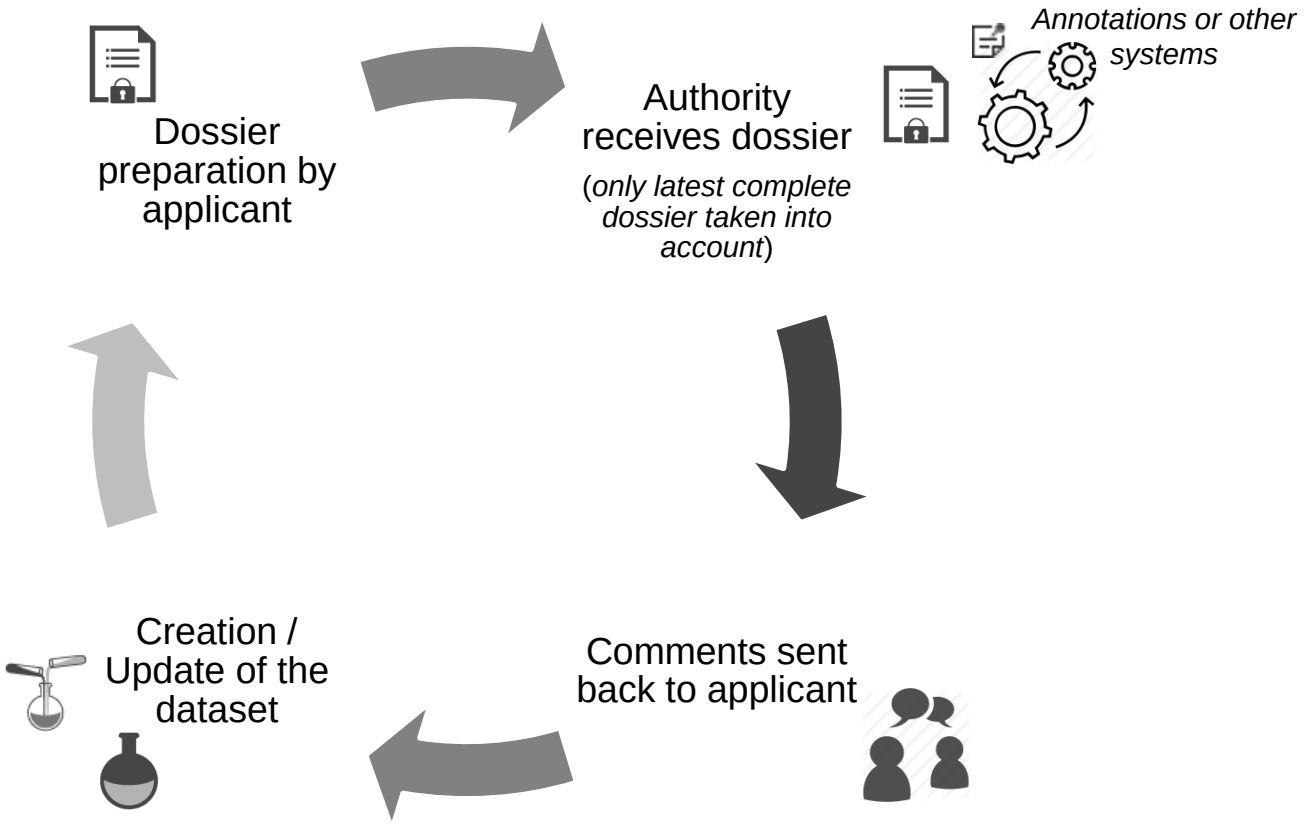
Dossier



When creating a dossier, relevant dataset(s) information is copied and locked in a dossier. A dossier header document is added to store the dossier metadata.

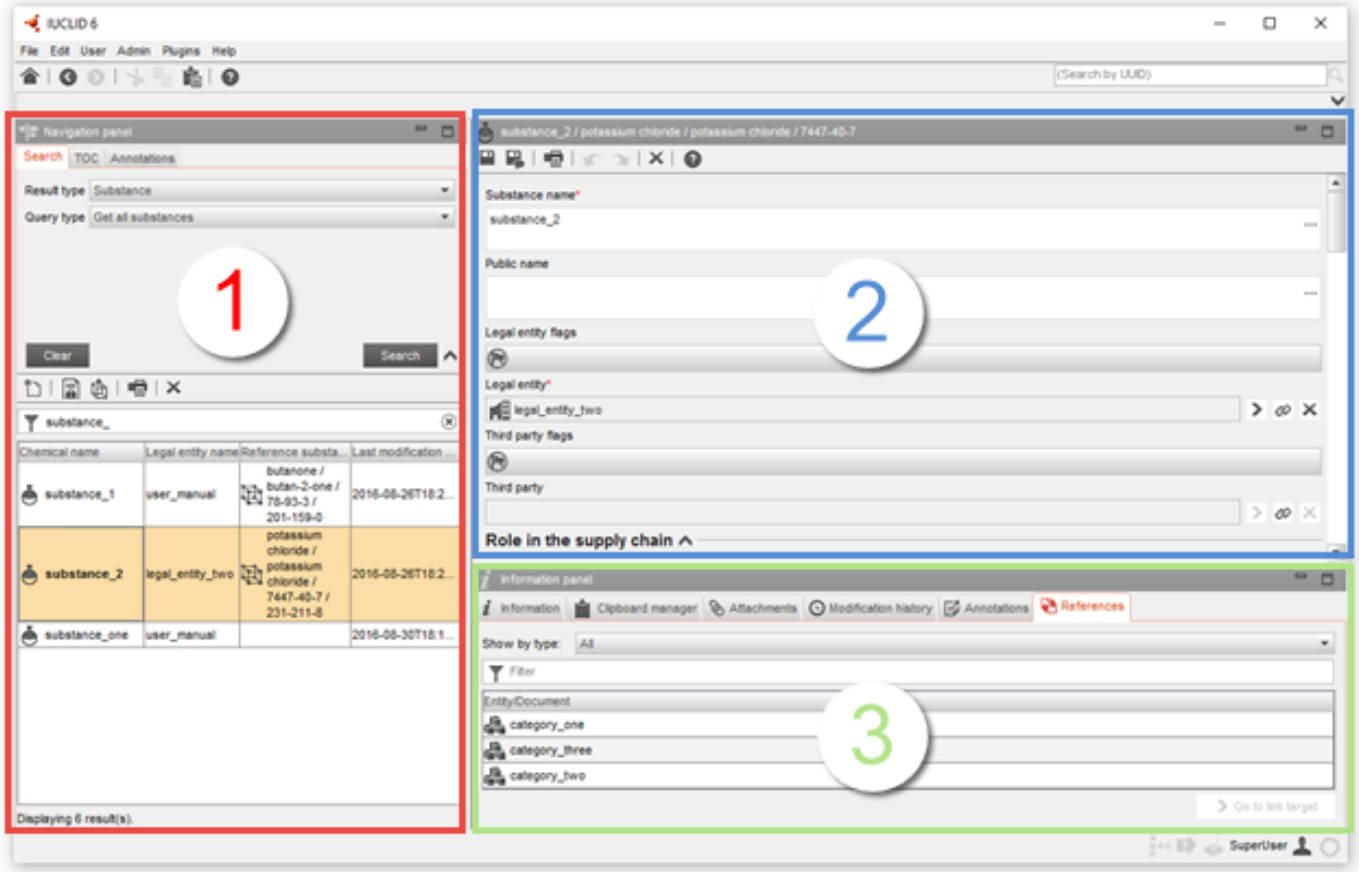
IUCLID and regulatory data submission

ECHA's approach



IUCLID 6 standard user interface

Main screen



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

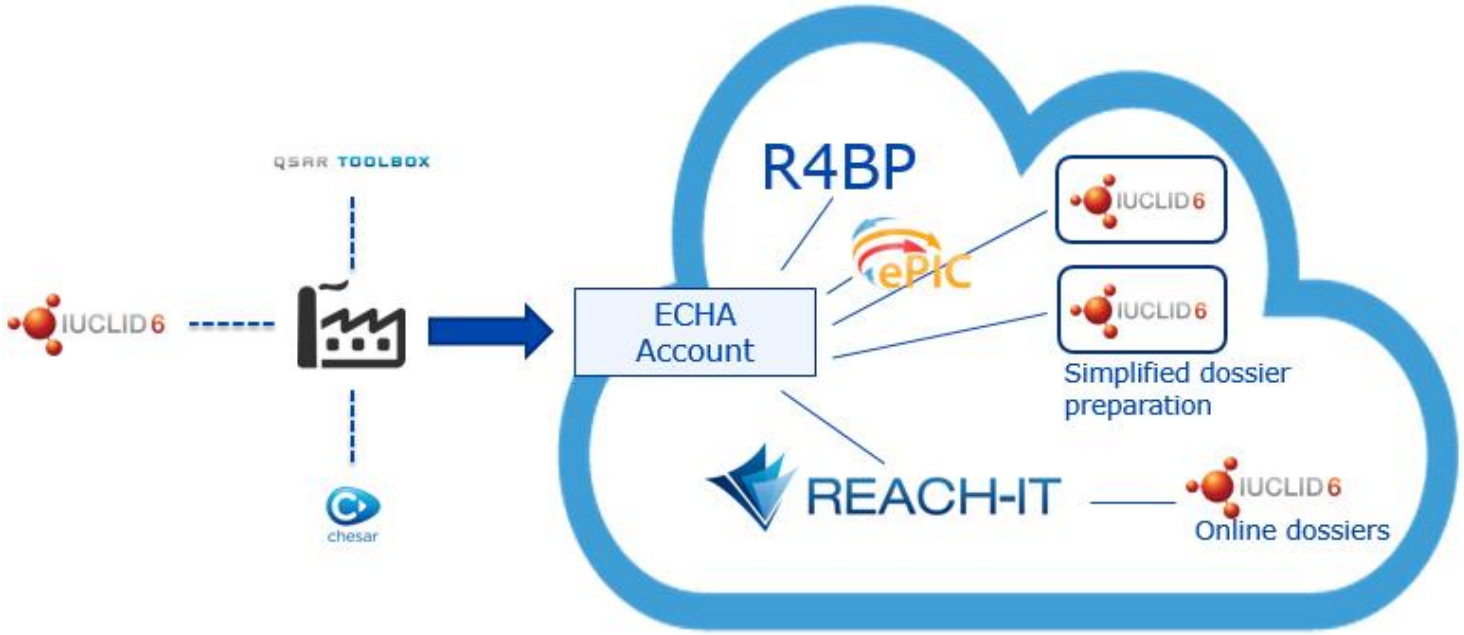
- For large companies or frequent users
- Full set of functionalities for data management
- Installed and maintained locally by users
- Desktop version easy to install
- Server version available for multi-user installations

ECHA Cloud Services

IUCLID 6
SME

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?

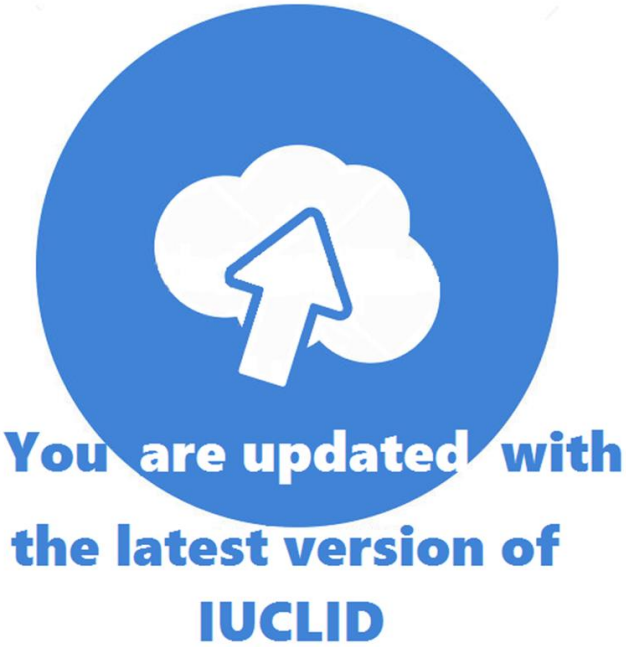
- A simpler IUCLID provided as a cloud service to prepare for the REACH 2018 deadline!
- Guided support for REACH 2018 dossier creation

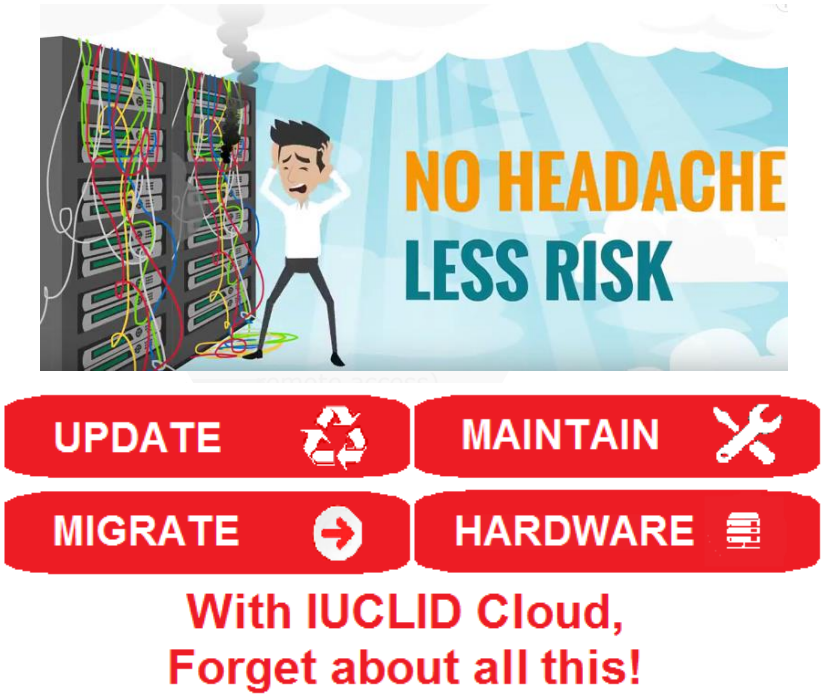
SMEs and their consultants

Anyone who wants to test

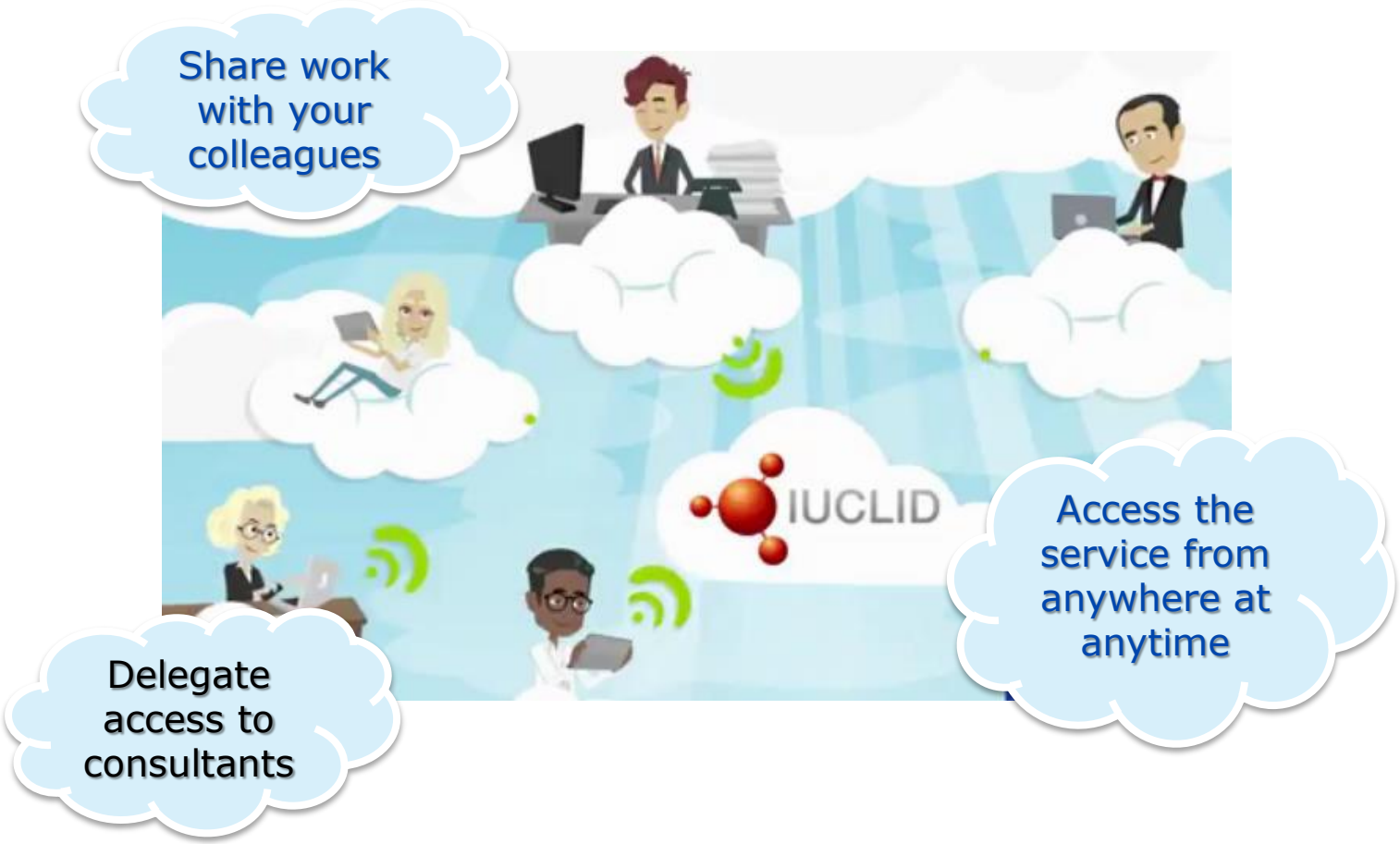
	Trial	For SMEs
Quota of data per subscription	100 MB	1 GB
Subscription terminates automatically due to non-usage	After 90 days	After 2 years
Backup of data	Not available	Yes
Helpdesk support	Limited	Fully dedicated

IUCLID Cloud – Work with the latest version of IUCLID





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.

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:

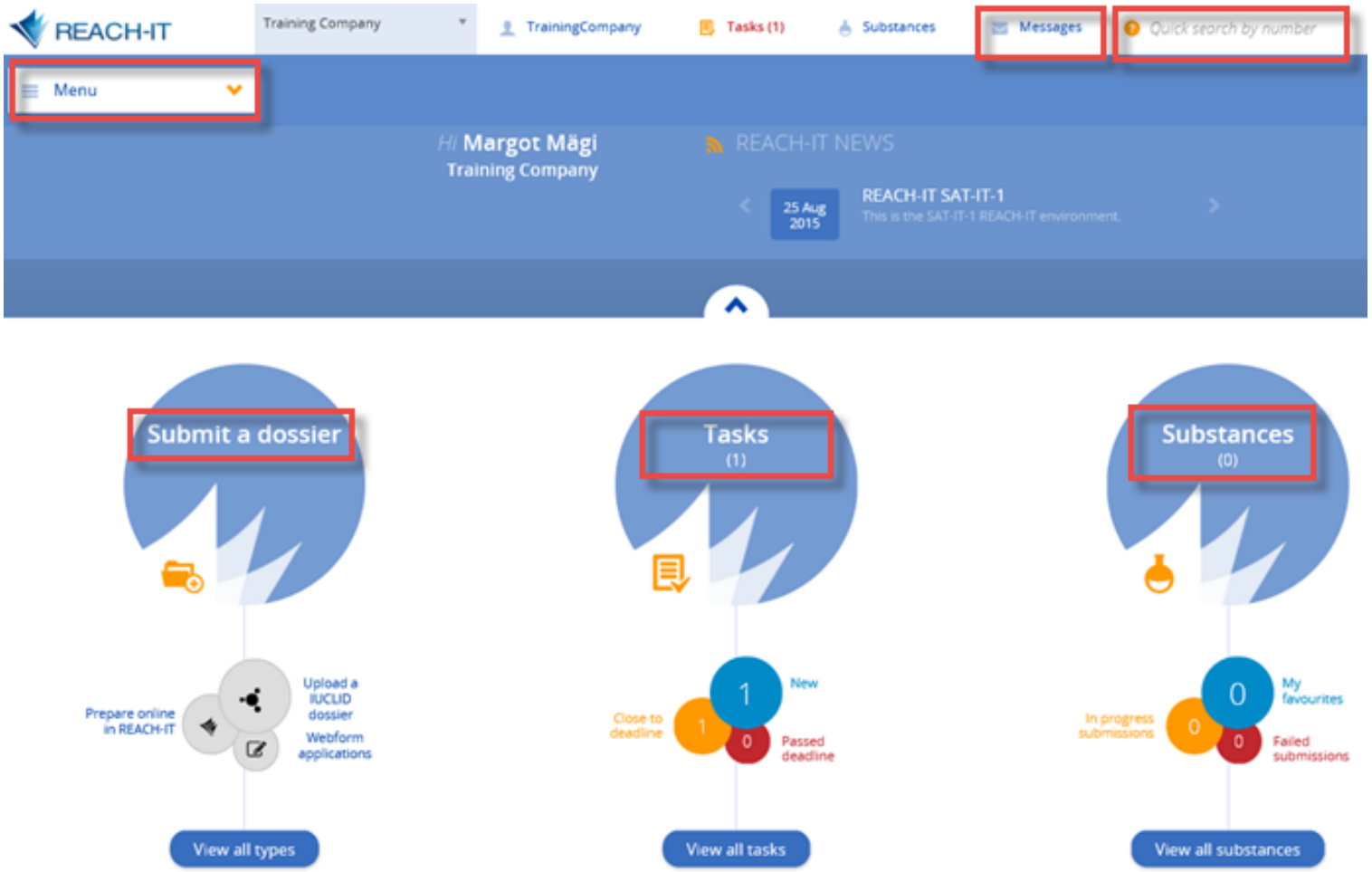
In addition to all the advantages the SMEs have:

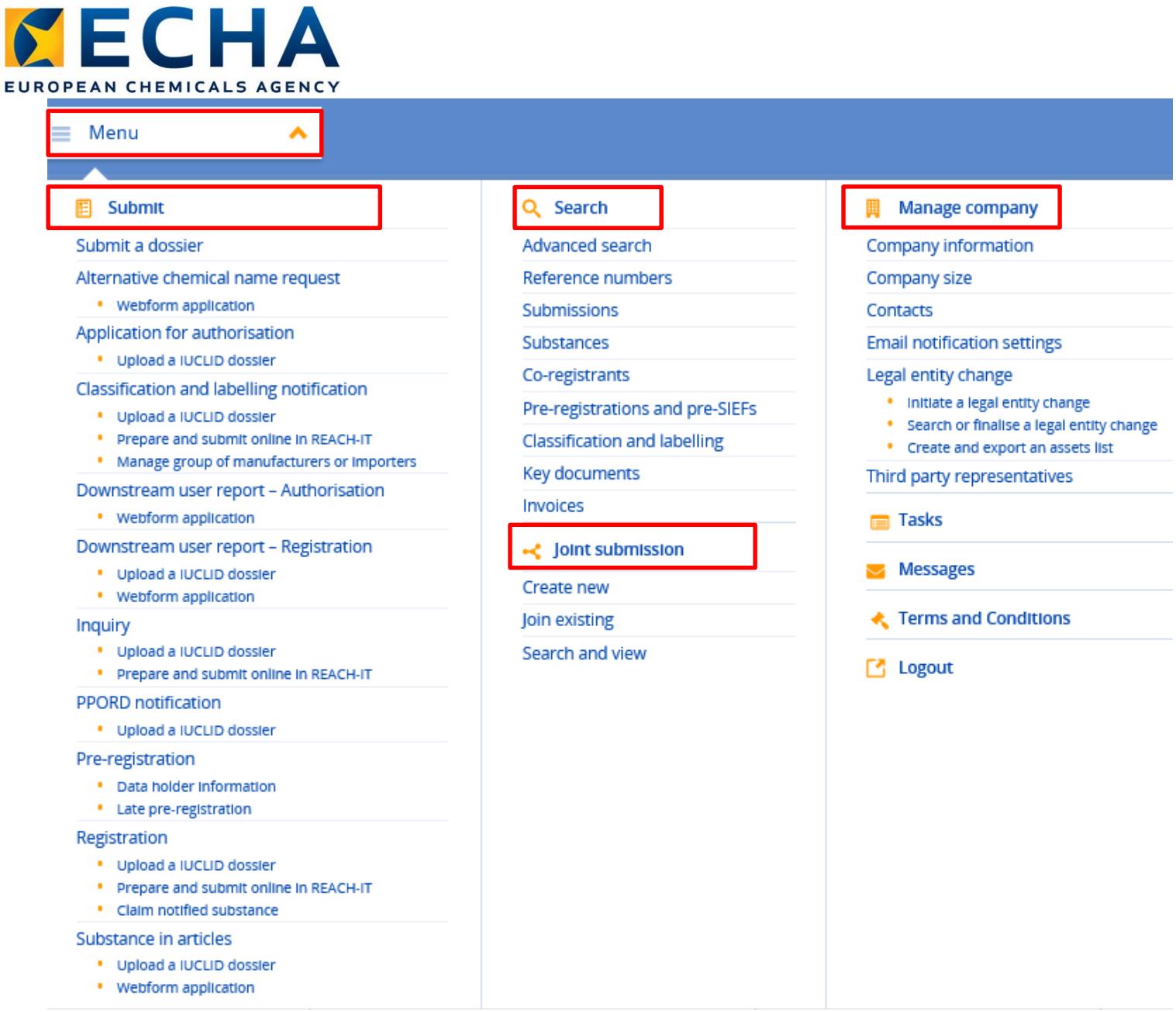
- Give your clients "more value for their money”
- Provide a more transparent and interactive service to your clients
- Opportunity to organize IUCLID trainings

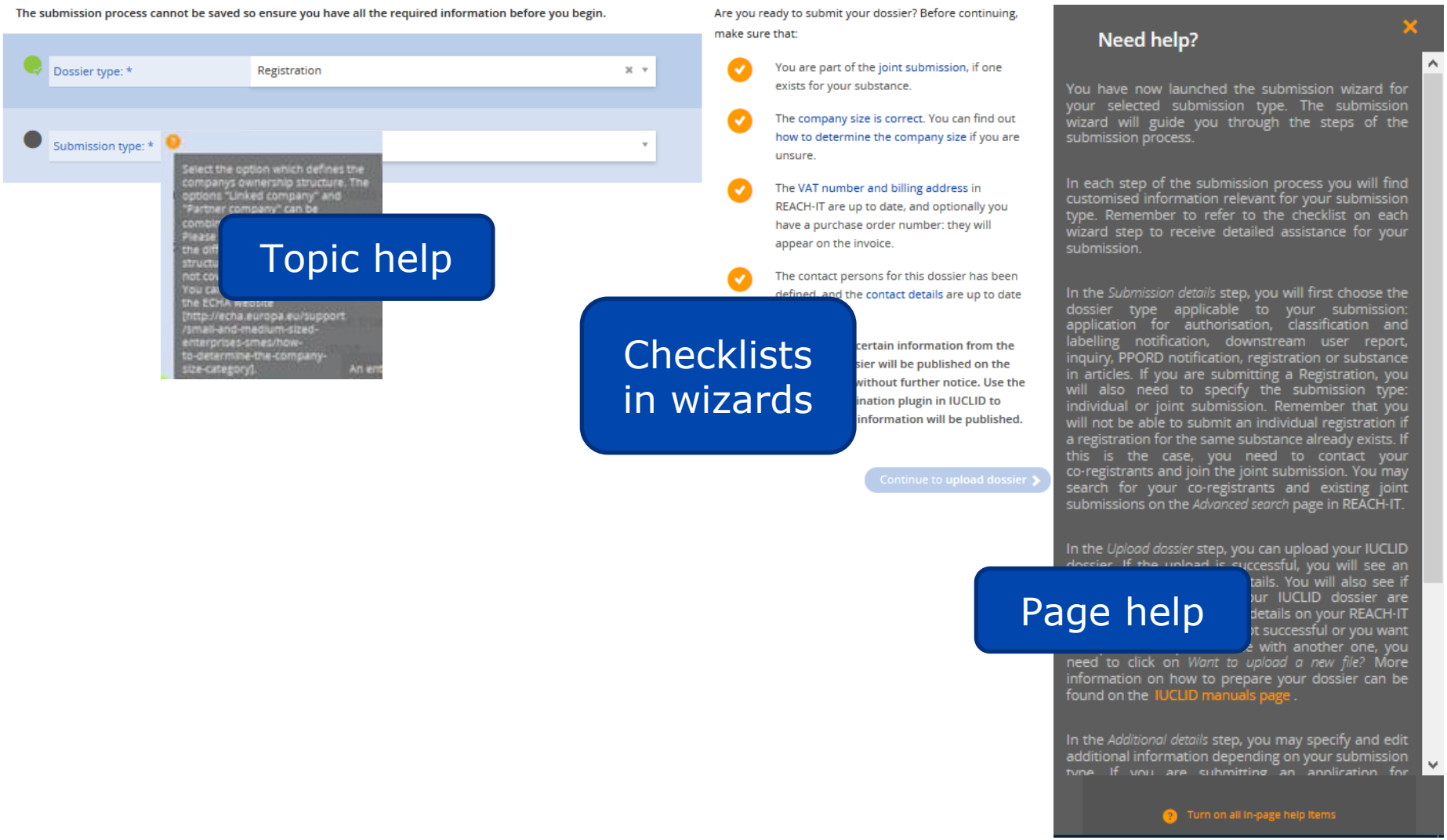
REACH-IT

Main functionalities

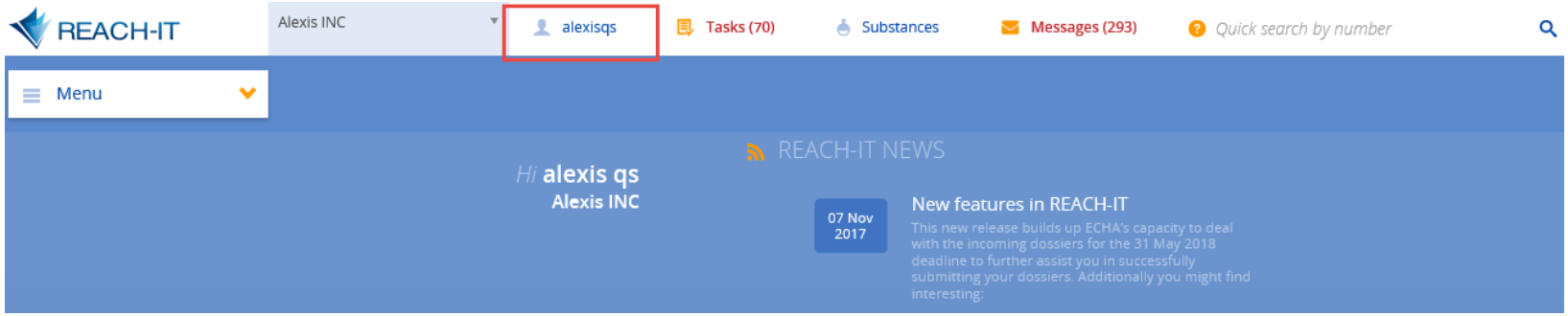
REACH-IT home page

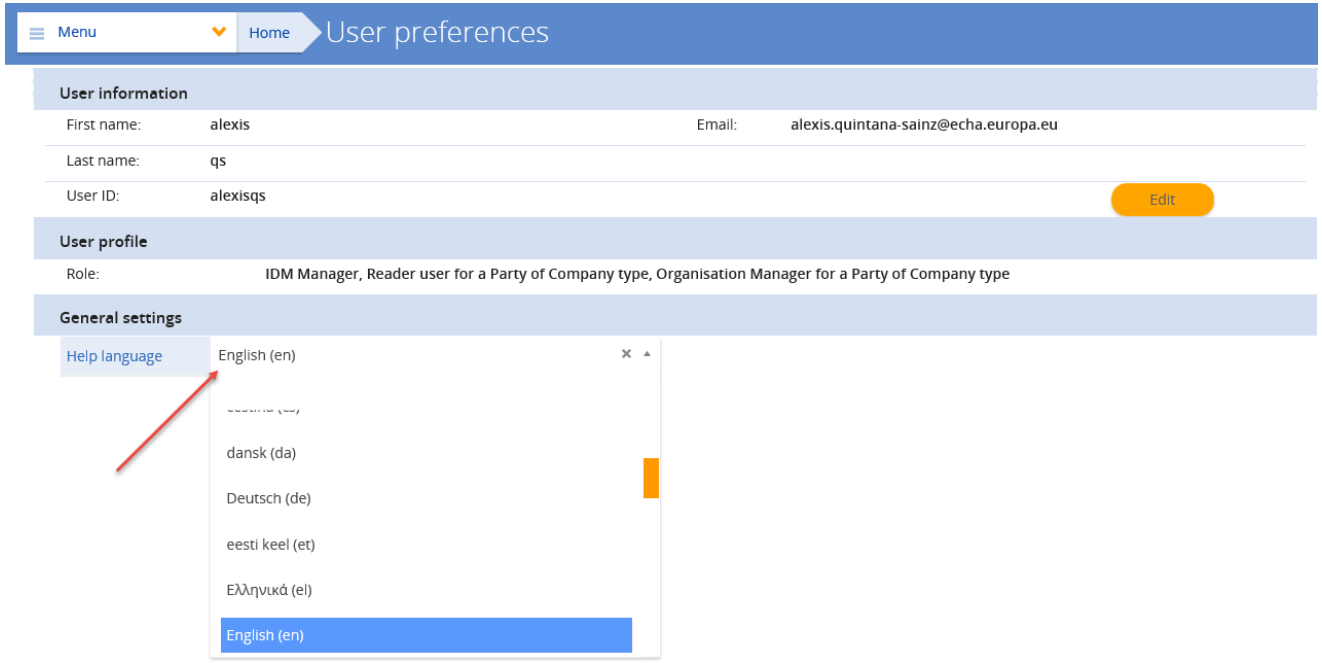



ECHA
EUROPEAN CHEMICALS AGENCY
Menu
Submit
Submit a dossier
Alternative chemical name request
Webform application
Application for authorisation
Upload a IUCLID dossier
Classification and labelling notification
Upload a IUCLID dossier
Prepare and submit online in REACH-IT
Manage group of manufacturers 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 companys ownership structure. The options "Linked company" and "Partner company" can be
Topic help
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
Checklists in wizards
Continue to upload dossier
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, PPORD 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
Page help
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
Turn on all in-page help items

Change the language of the Page help





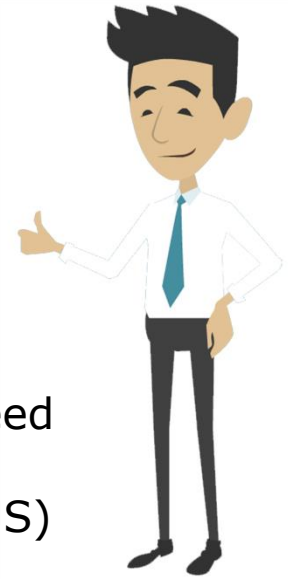
Exercise introduction

10:30 Exercise presentation

Setting the scene

- It’s Tuesday morning and your 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

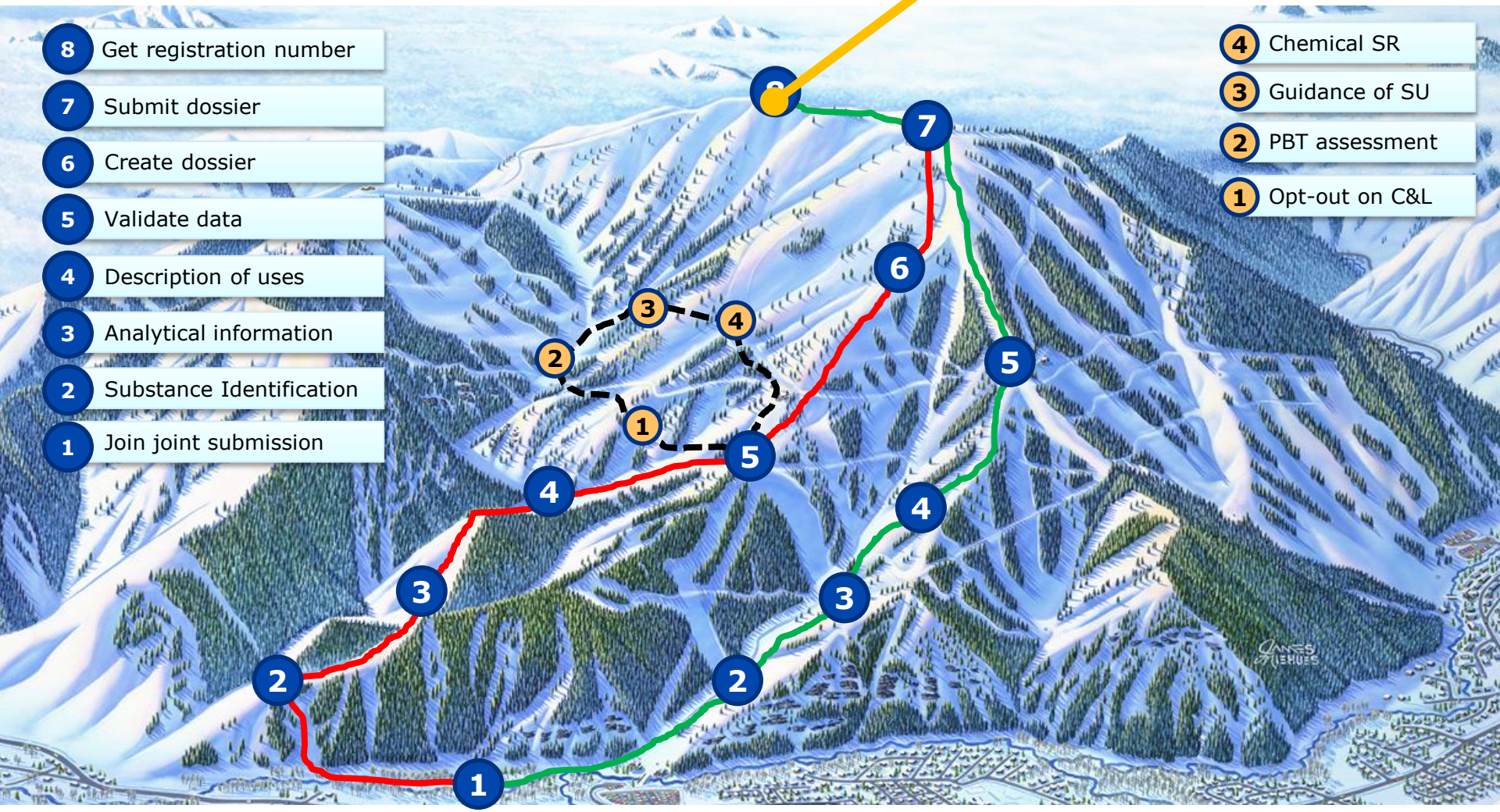
- Your boss, who doesn't like to take risks, looks at you and asks if it wouldn't be safer that you submit the dossier before the mountain hike as one never knows if you will make it back

- 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



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

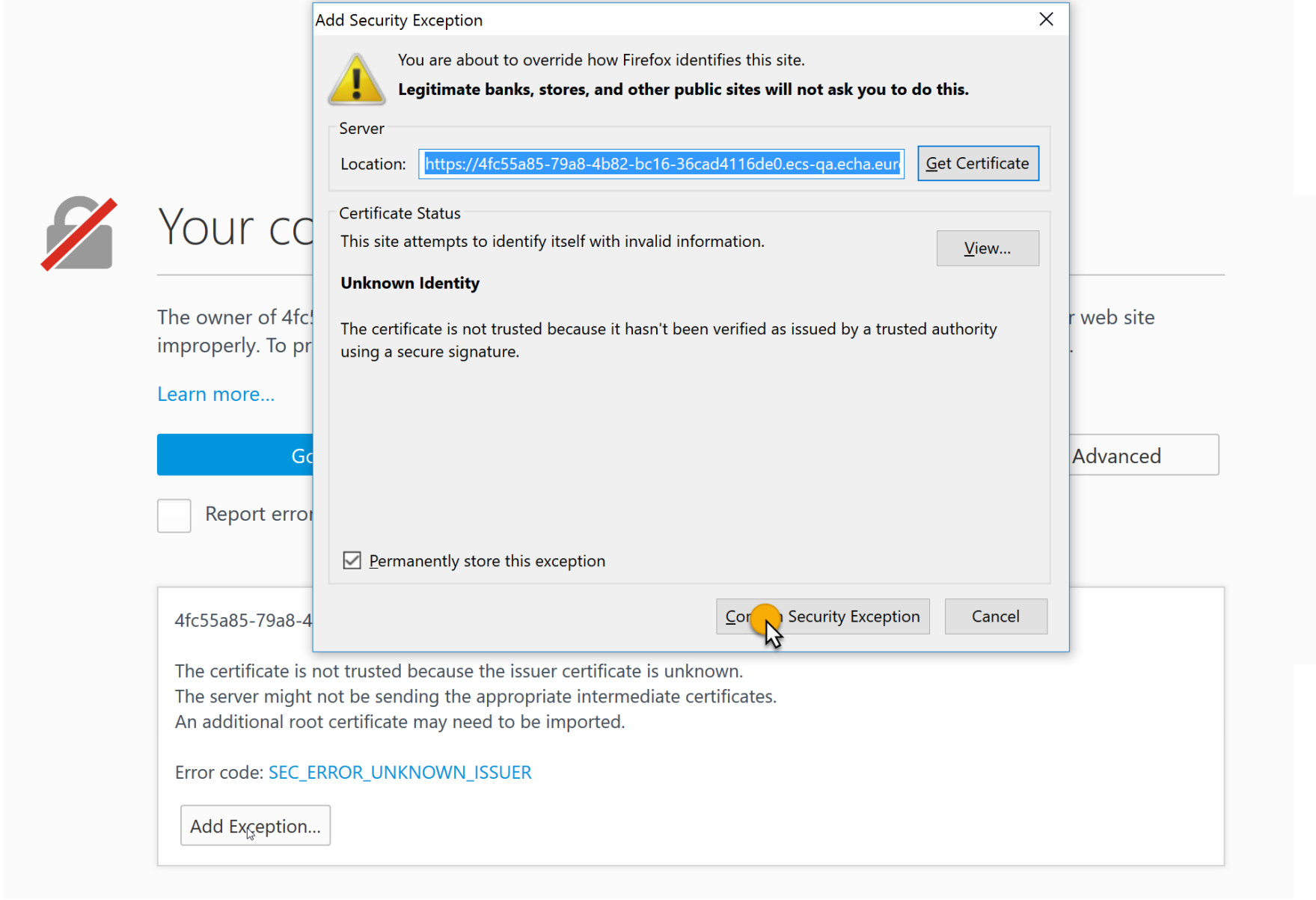
10:40 Start the work

- 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

Training environment warning



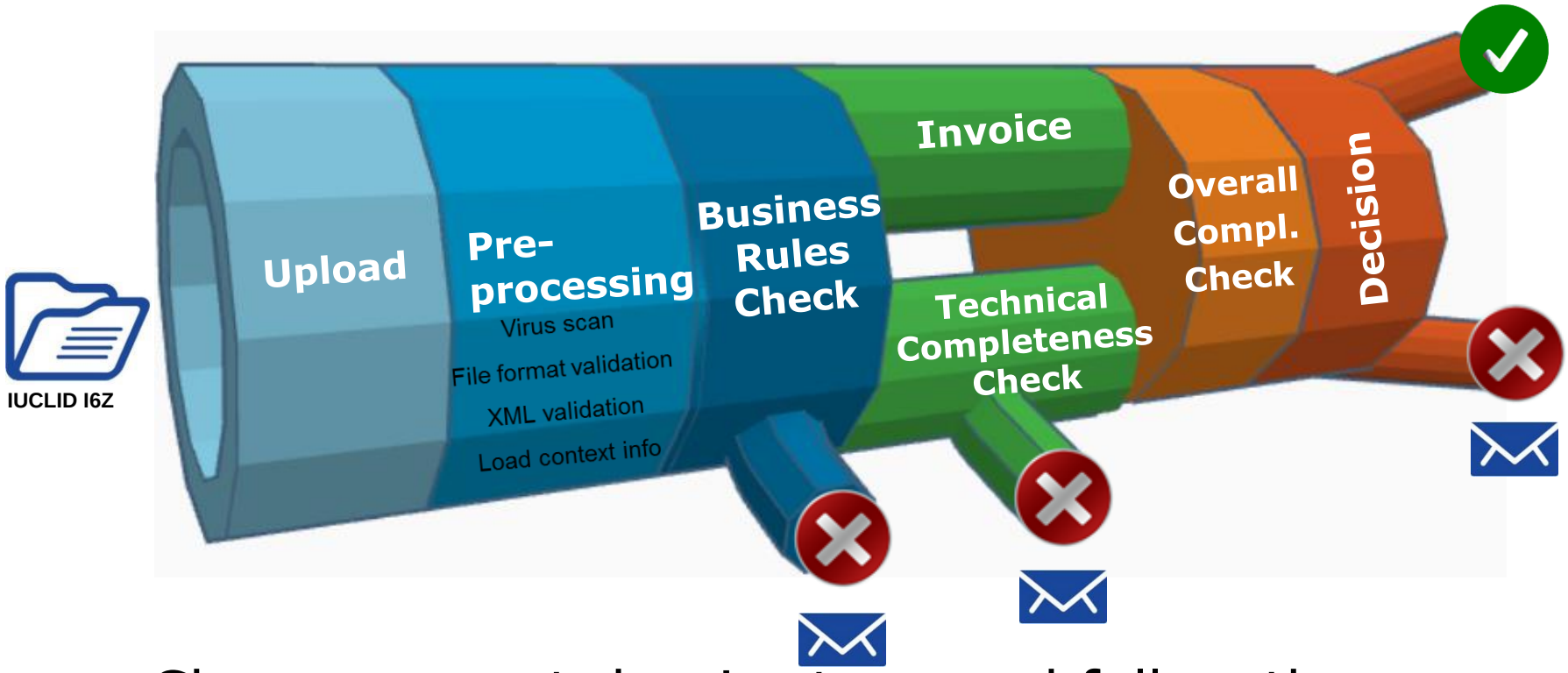
10:40 Start the work

Good luck!

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

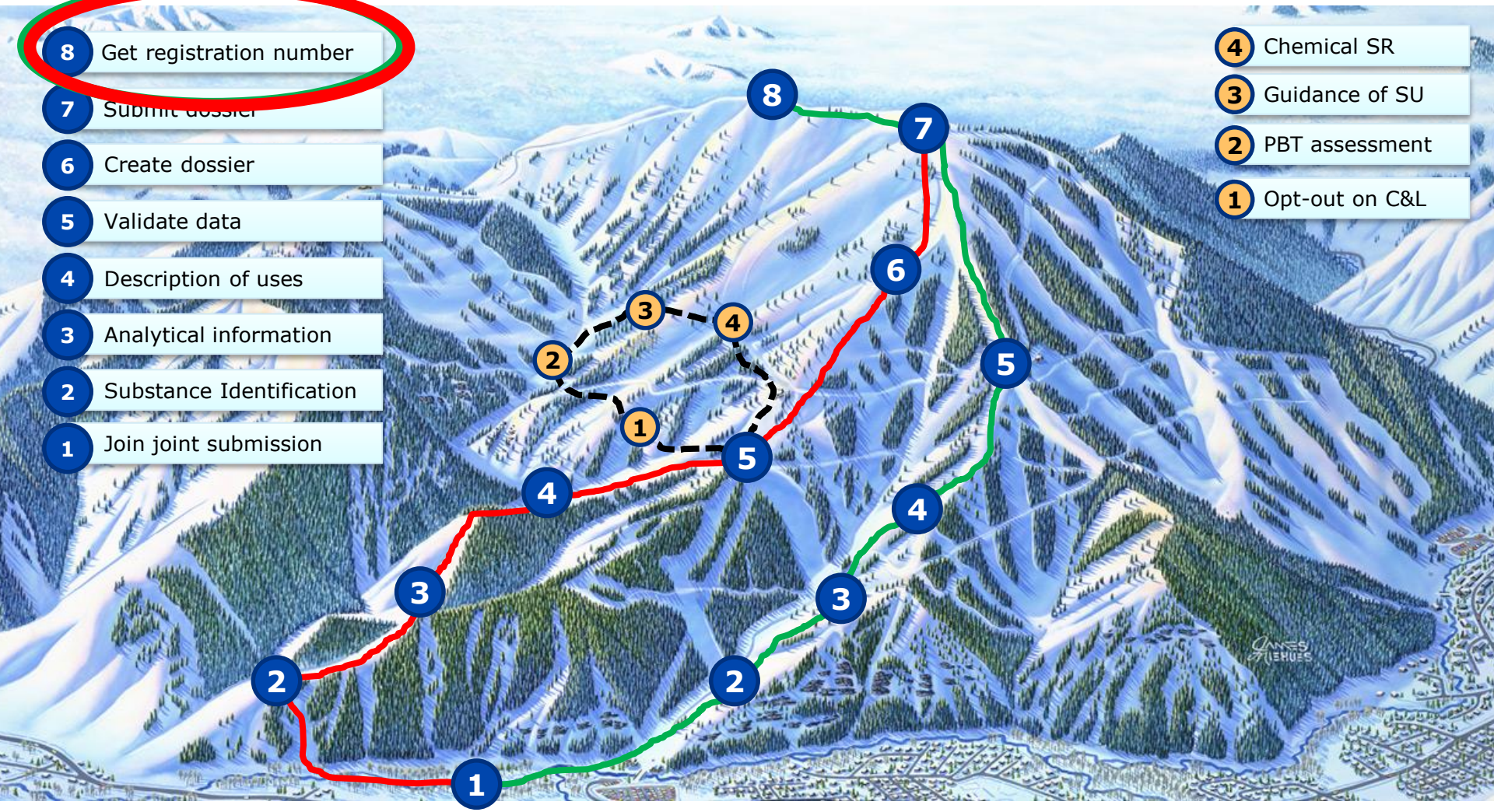
REACH-IT Online path (Beginner)
IUCLID Cloud path (Intermediate)

7 Submit dossier



- Choose correct dossier type and follow the submission wizard

REACH the summit

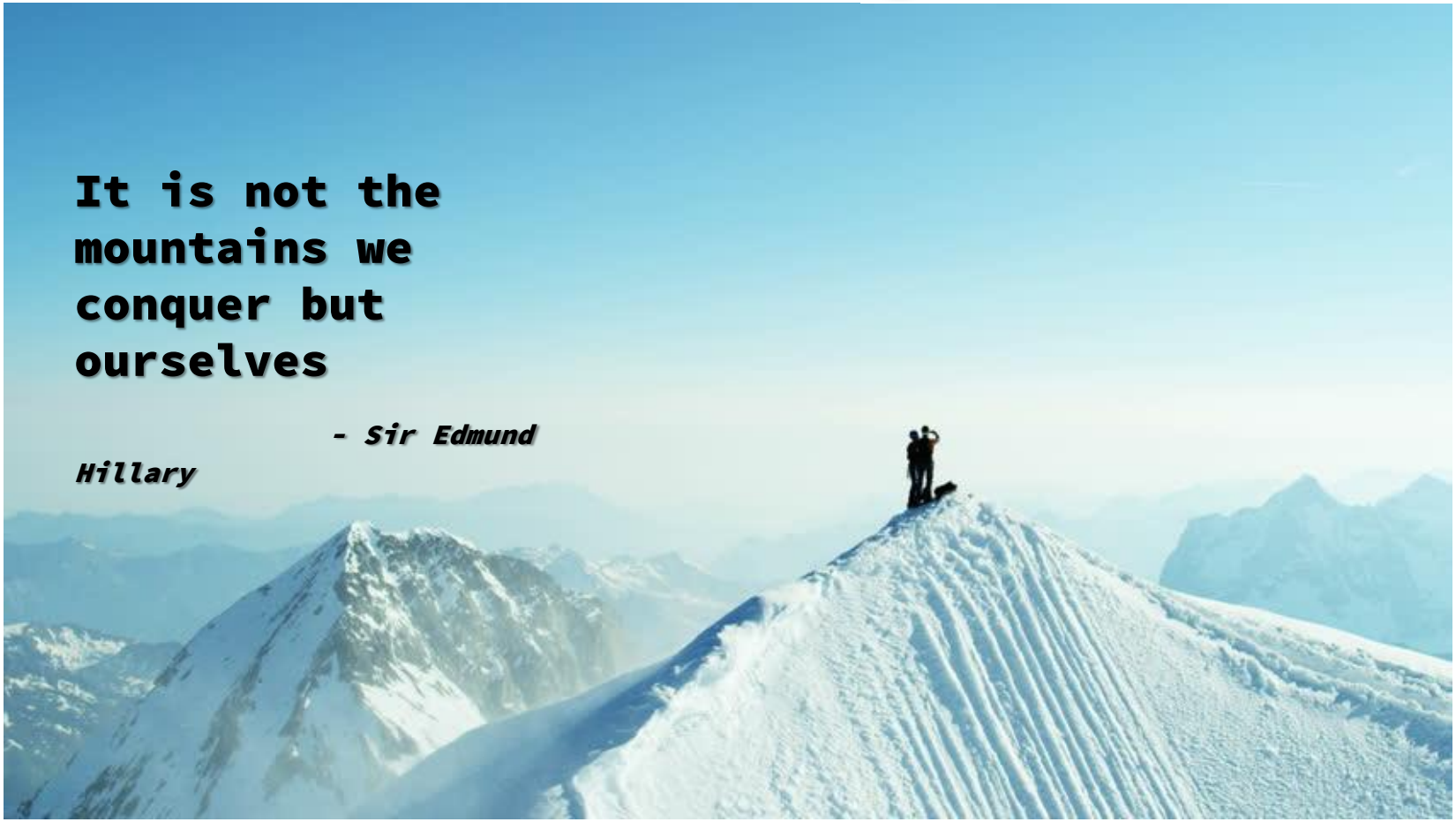


8 Get registration number

- Find you 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!



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-**

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**

IUCLID Cloud – Data security

- The term Cloud is often connected to negative issues with security and many do not trust cloud storages
- ECHAs Clound 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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