

IUCLID6 & REACH-IT: key changes

Information session on updated registration process

Brussels 4 November 2015

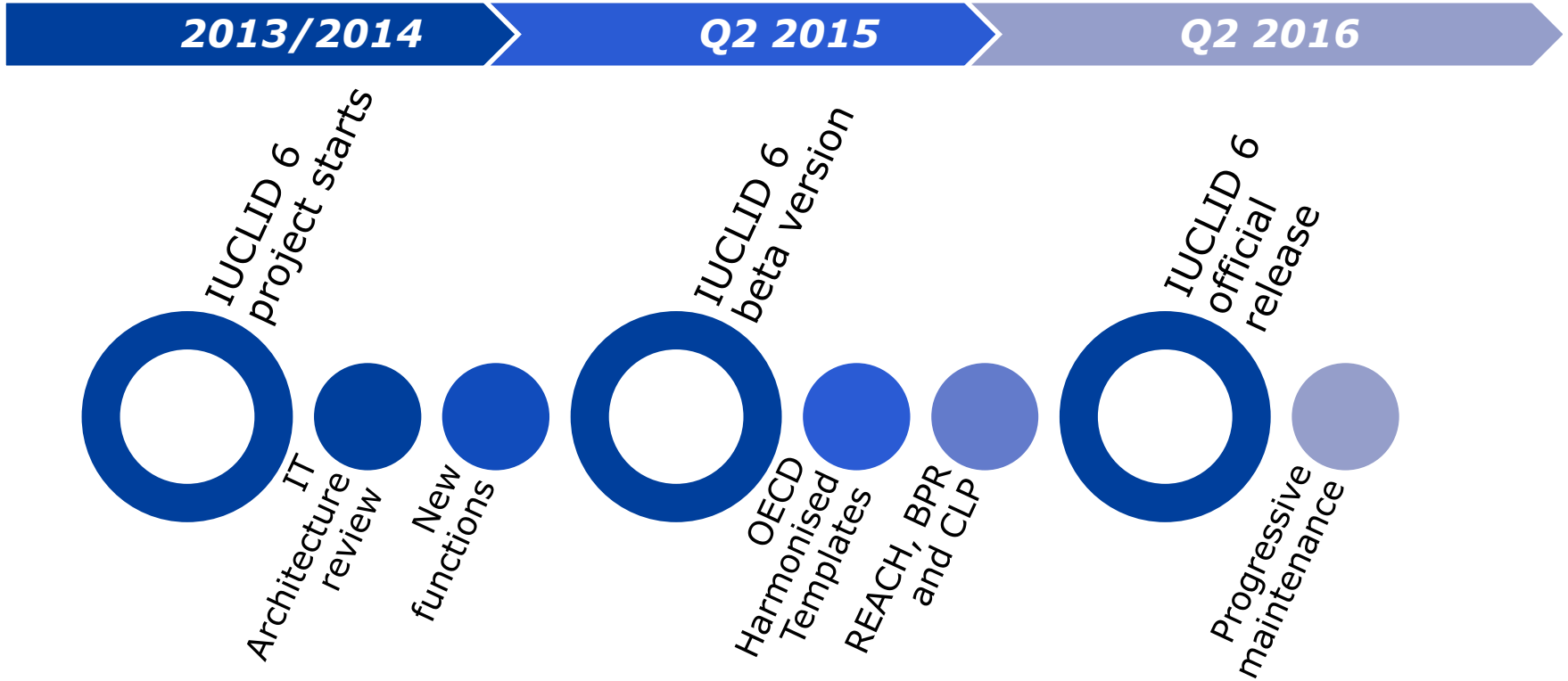
Mike Rasenberg
European Chemicals Agency

Drivers for changes

- Changes in requirements
- Feedback received
 - Interactions with the Industry IT WG (Cefic, Concawe, Eurometaux)
 - SME visits by ECHA staff and SME workshops
 - Helpdesk
- Technological upgrades

Drivers mentioned earlier today:

- Quality observations on dossiers
- Challenges of the SIEFs (for SME's)
- Needs for enhanced dissemination



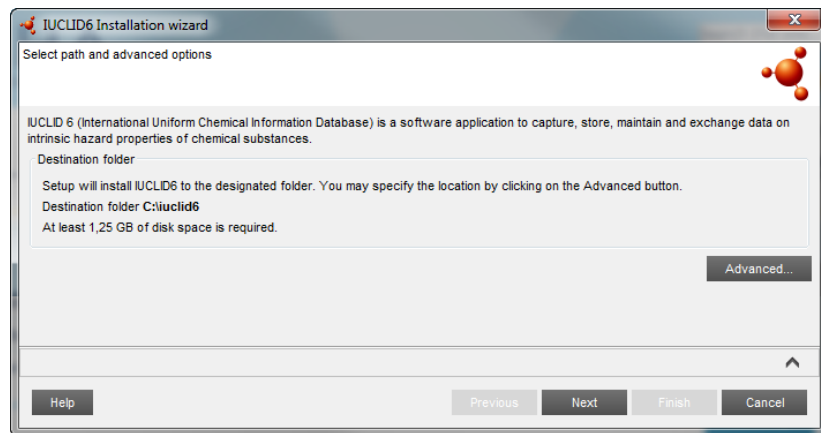
- User requirements collected, proposals presented, reviewed and approved at different levels:
 - EU Industry IUCLID User Group
 - EU MSCA IUCLID User Group
 - OECD Harmonised Templates and OECD IUCLID User Groups

New technology:

- General need to bring the technology up to date
- More possibilities for 'internationalisation', i.e. use/acceptance of IUCLID files for other programmes
- Better security model, e.g. support business unit model
- Better support for features like reporting

Desktop version
installation improved

IUCLID dossier creation
online with REACH-IT



(isononanoato-O)(isooctanoato-O)nickel EC 287-471-8 CAS 85508-46-9

Index no 028-054-00-0

Harmonized Classification

Show classified only
 Show hazard statements

Classification	Code
Health	
Skin corrosion/irritation	1A
SCL 0.01	1A
Respiratory or skin sensitisation	1
Germ cell mutagenicity	2
Carcinogenicity	1A
Reproductive toxicity	1B
Specific target organ toxicity - repeated exposure	1
SCL 0	1
SCL 1	2
Environmental	
Hazardous to the aquatic environment - chronic	x100 1

Labelling

Danger

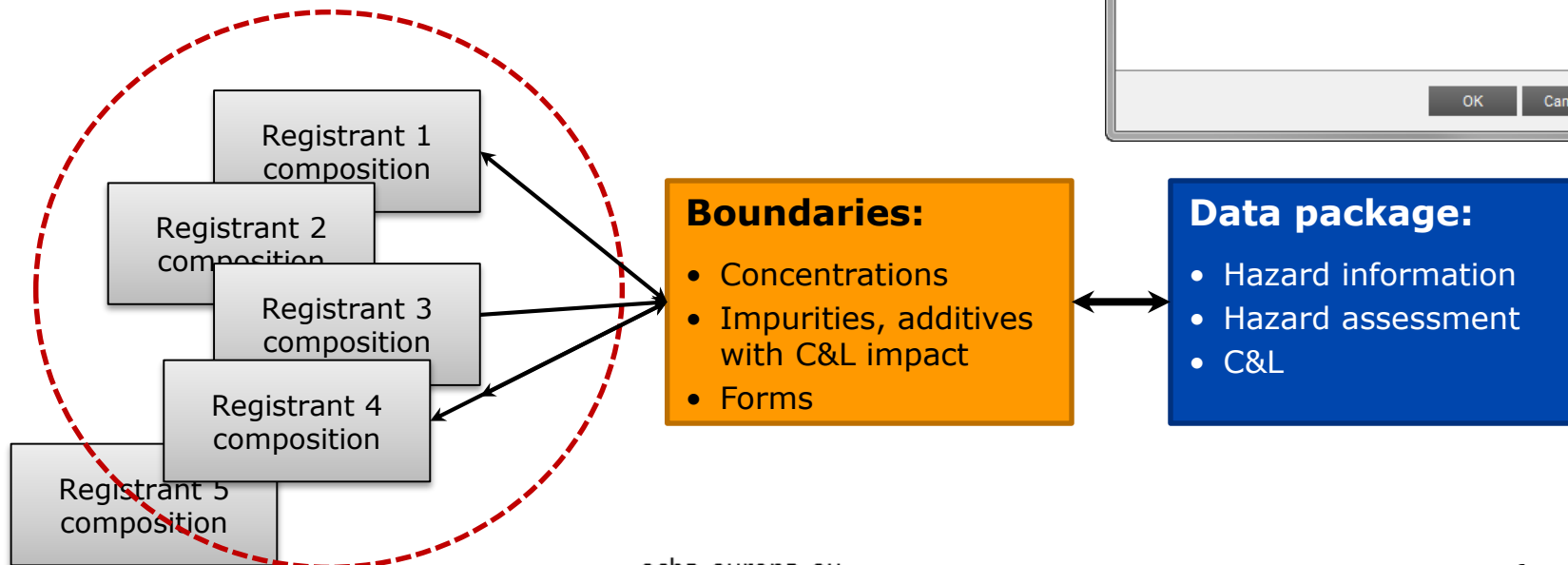
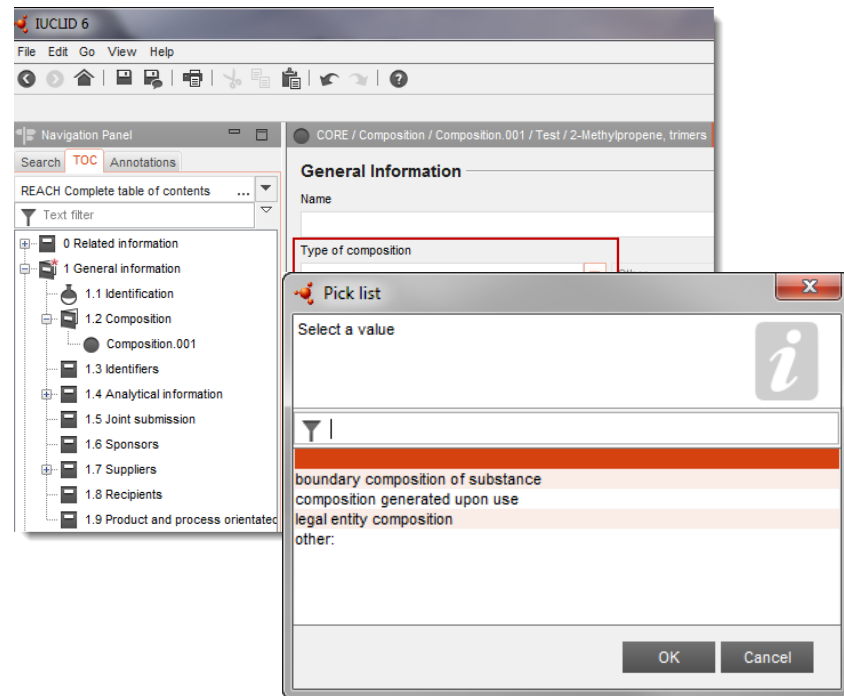
May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Suspected of causing genetic defects.
app.ghs.statements.H350I
app.ghs.statements.H360D

Causes damage to organs (heart, lungs) through prolonged or repeated exposure through inhalation.
Very toxic to aquatic life with long lasting effects.
Toxic by eye contact.

Help system reviewed and Dossier
Submission Manuals included

- Specified in the composition section (1.2) in IUCLID
- The collectively agreed boundaries of the substance in scope of a registration/notification/application
- The 'glue' between registrant-specific compositions and the jointly provided hazard data, C&L



IUCLID 6 supports more transparent data organisation for “complex cases”

If one substance needs multiple data-sets for the assessment:

- (group of) constituents behaving differently from each other
- substance transforming during use or in the environment
- different compositions (or forms) with different hazard-profile

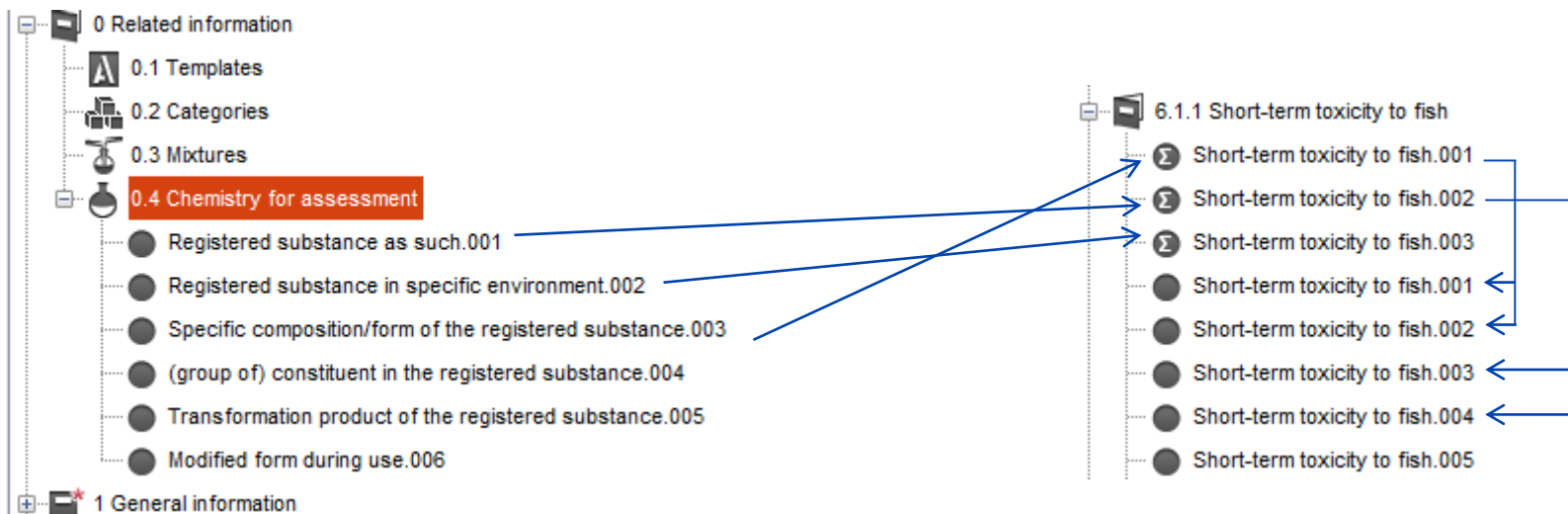
“Assessment entity” in IUCLID 6 enables

- to group substance property data-sets for the assessment
- to clearly explain the assessment approach and to improve understandability of disseminated information
- opportunities for the assessor to make his case more transparent (non mandatory)

- The Assessment Entity concept is introduced in IUCLID 6 to describe the assessment approach more transparently when needed

Assessment Entities are defined under section 0.4

They can be linked to relevant data (via endpoint summaries)



Structures for use and exposure information:

- support priority setting by the authorities for further regulatory actions:
 - identify among the (potentially) hazardous substances those which have
 - wide dispersive uses
 - uses within the scope of substance evaluation, CLH, authorisation, restriction
 - rank them for further regulatory action based on use specific tonnage information
- provide non mandatory fields supporting registrants in demonstrating low concern, for example:
 - Main tonnage used in contained system with strict control

REACH-IT 2016 and beyond...

- Set the foundation for being an innovative submission tool for REACH & CLP data
- Review of the usability of REACH-IT
 - September 2014 – December 2014: SME workshops
 - Workshops with Industry User Group
- Feedback
 - Workflow (e.g. submit a dossier) and navigation through the system not intuitive
 - Synchronisation between IUCLID and REACH-IT is problematic
 - Status of registration difficult to find/understand
 - Difficult to find co-registrants, joint submissions and the lead



Submit a dossier



Prepare online
in REACH-IT



Upload a
IUCLID
dossier
Webform
applications

View all types

Tasks

(81)



Close to
deadline

26

6

New

10

Passed
deadline

View all tasks

Substances

(48)



In progress
submissions

17

4

My
favourites

3

Failed
submissions

View all substances

a Find assignment(s): **Filters** Type: ? All

Type:

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b Select assignment(s): You may select individual and/or whole groups of

Reference Numbers [Select group](#)

<input type="checkbox"/>	01-2114083144-54-000	REGISTRATION				118283-82-4
<input type="checkbox"/>	01-2114083144-54-000	REGISTRATION	subathizone	EC 242-161-1	CAS	118283-82-4
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<input type="checkbox"/>	01-2114083144-54-000	REGISTRATION	subathizone	EC 242-161-1	CAS	118283-82-4

c Select Contact

Contact: Mr. Name Surname

Mr. Name Surname

@ email@email.com
+303253654
Big Company

Assign Cancel

Help for Contact page

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Integer nec odio. Praesent libero. Sed cursus ante dapibus diam. Sed nisi. Nulla quis sem at nibh elementum imperdiet. Duis sagittis ipsum. Praesent mauris. Fusce nec tellus sed augue semper porta. Mauris massa. Vestibulum lacinia arcu eget nulla.

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? Turn on all in-page help items

Moving towards a substance centric view

REACH-IT | Big Company Nick Vastamatis | Account | Tasks | Substances | Messages (63) | Search for Substance, Submission, Reference, Decision, EC, CAS No., etc.

Menu Home Substances

Locate: Substance ID (EC, CAS, Name):

Filters: Dossier type: Registration X CnL Notification X; Status: Active X Other X; Submission date: Last 3 years; Favorites only; Part of a JS?;

Search Clear

150 substance(s) found:

nickel(II) palmitate

EC 242-161-1 CAS 118283-82-4



citric acid, ammonium nickel salt

EC 242-161-1 CAS 118283-82-4



Dossier(s) (7): 1 Pending

DU report
Pending

Pending Submission:
UJ121618-27

Tasks
1 Passed

Pre-registration

Reference number:
#456546546456

Contact:
Name Surname

Tasks
2 Close to Deadline

Edit Pre-registration

Pre-SIEF

Registration

Reference number:
#456546546456

Pending submission:
UJ121618-27

TB registered:
> 100,000

Contact:
Name Surname

Co-registrants page

Joint Submission

Inquiry

Reference number 1:
#456546546456

Contact 1:
Name Surname

Reference number 2:
#456546546456

Contact 2:
Name Surname

Co-registrants page

External Links: Dissemination Portal

CLP platform

2-ethylhexanoic acid, nickel salt

EC 242-161-1 CAS 118283-82-4



fatty acids, C8-18 and C18-unsaturated, nickel salts

EC 242-161-1 CAS 118283-82-4



Expected benefits to REACH-IT users

- Improved learnability and memorability in order to reduce cognitive effort
- More intuitive UI preventing users from getting lost in the application
- Improved access and visibility of decisions and communications
- Central management of contact persons and TPRs
- Simplified user management (one user can manage many companies)
- Help texts integrated into the application

Enhancement SIEF experience

- Easier access to information about (potential) co-registrants and existing Joint submissions
- Clearer overview of the Joint submission information

Working with co-registrants

- Improved search for Joint submission:
 - Results clearly indicate the Substance identity, Lead Registrant contact details and type of Joint submission
- Enhanced Lead Registrant nomination scheme
 - Ensure accurate information on the candidate Lead Registrant
- Link between Co-Registrant page and Pre-SIEF:
 - From the Co-Registrant page will be possible to access the pre-SIEF page (but not from Pre-SIEF to CoRP) to get in contact with other potential registrants
- Introduction of the boundary composition (“SIP”) in the submission process
- Strengthen the OSOR principle (see: presentation earlier today)

Overview of Joint submission

- Easier, clearer and more comprehensive overview of the Joint submission page:
 - Content of the Joint submission (Substance, registration type, scope, coverage)
 - Easy access to the Lead Registrant up-to-date contact details
 - Clear summary of the own information submitted
 - Ongoing discussion on increasing transparency between all members

- Request from industry for fixed dates release in support of planning;
 - Tentative dates – confirmation by end of the year:
 - IUCLID 6: last week of April 2016
 - REACH-IT 3: last week of May 2016
- Further discussions ongoing with industry representatives (IT WG) to precise the planning and to develop support material
- Get prepared and plan ahead!

Thank you!

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