Registration tips: knowing ECHA IT tools

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Content of the presentation

- **The basic IT tools for registration**
    - **IUCLID and Plug-ins**
    - **REACH-IT**

- **Submitted dossiers: post-registration activities**
    - **Dissemination of data**
    - **Co-Registrants platform**
    - **targeted Compliance Check (IT screening of dossiers)**

- **Biocides and R4BP**

IUCLID

Current version: **IUCLID5.4.1**

Major changes of the format / data model:

• New mandatory section on PBT assessment (section 2.3)

• Manufacture, Use and exposure (section 3)

• Update of Endpoint Summaries in section 6 and 7

Other functionalities added e.g.:

• Bulk user creation or update

• Group of IUCLID documents / Folder structure

→ *See release notes in installation package for details on changes*

5.4.1. maintenance release in October: fixed some bugs and additional improvements (Java 7 support)

IUCLID: the future

IUCLID5.5:

- Integration of Biocidal Products Information

- Generation of hyperlinks to facilitate exchange of info between users

- Show differences between new-old dossier

- Option to reduce size of dossiers (no duplication of attachments)

- Some other minor improvements e.g. literature inventory export/print options

- Compatibility with 5.4 ensured <u>for REACH data</u>

- Final release expected by the end of Q1-2013; testing ongoing

IUCLID6:

- Different architectures for different organisations (small/medium/large)

- Collection of user requirements by OECD IUCLID Expert panel

- Release expected by the end of 2014?

IUCLID tips

→ *Plan integration with other company systems e.g. EHS*

→ *Define clear user management rules and don't use personal user names*

→ *Be careful when you share IUCLID files with other companies in the SIEF e.g. LR to provide dossier, remove company-specific data!*

→ *Be aware of new releases (migration may be unavoidable!):*
- *migration takes time and may bring errors*
- *make sure you have back-ups before migrating*
- *Test ! Use production data for testing*
- *Read FAQ*

→ *If you use servide providers: make sure you get the IUCLID datasets and users/passwords for REACH-IT*

IUCLID plug-ins

CSR plug-in to IUCLID:

- Will be updated to generate CSR from IUCLID and Chesar
- Verify consistency between Risk Assessment and substance properties
- Fill in use and exposure information in IUCLID (e.g. list of uses)
- Publication expected by the end of the year

TCC, dissemination and fee calculator: a MUST before submission:

- Ensuring your dossier will pass Business Rules and ECHA checks
- Verification that no confidential information will be disseminated
- Calculation of the fee to be paid to ECHA upon submission

→ *Tip: verify latest plug-in versions before running them*

REACH-IT

Latest update:

- 'The' submission portal to ECHA
- Developments currently focused on new legislations: Biocides, Prior Informed Consent (PIC)
- New release (end November) includes:
  - Improvement of the inquiry workflow: lower processing times expected
  - Extension of cease / restart manufacture functionality to new dossier types
  - Joint Submission Object changes e.g. possibility to leave JS before submission
  - Substance in Article Web form
  - Co-Registrants Page (CoRP) (see next)

The future:

- De-coupling from IUCLID updates
- Simplification of submission processes
- …

→ **Industry wish list for REACH-IT improvements**

→ **Discussed in the ECHA Industry users group**

REACH-IT: tips

→ *Activate option to receive mail alerts if new messages in REACH-IT (in general settings)*

→ *Decide how your company will organise access to REACH-IT and create user accounts*

→ *Fill in REACH-IT account details wisely: who will be the contact point for ECHA for each process*

→ *Be aware of 'down times' via ECHA news for your submission plan: watch out for Christmas break!*

Dissemination

- **New fields are now disseminated from the registration dossiers:** company names, registration numbers, etc.

- **Make sure you check information that will be disseminated:**
  - For new submissions
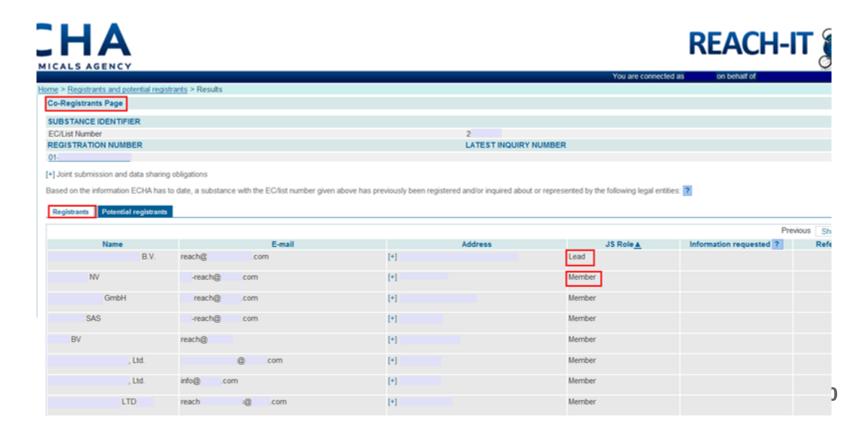 - For previously submitted dossiers including NONs

And introduce confidentiality claims if necessary!

- **Use Dissemination and Fee calculator plug-ins!**

Co-registrants page

- Puts in contact registrants and inquirers of the same substance
- Highlights who is the LR, who is outside of the Joint submission, two LRs for same substance, etc.
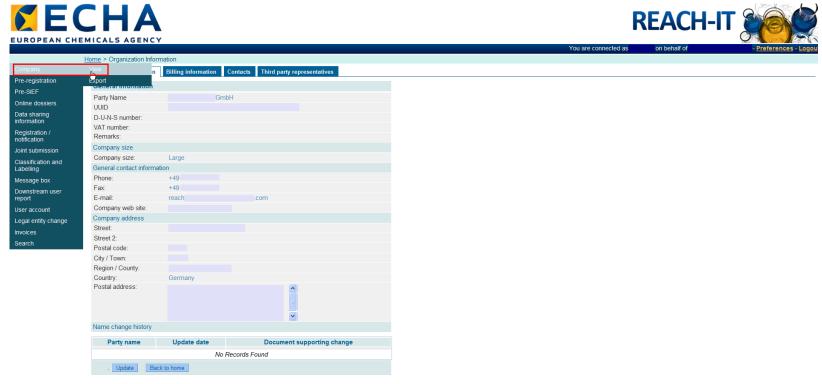- Gives real-time information on newcomers

Co-registrants page (cont.)

→ *Tip: check few of your substances to understand which email address appears on this platform and update if necessary!*

Screenshot to show where ECHA takes contact details:

→ *Tip: if you have claimed your company name confidential , check the identity is not disclosed in this page, appoint TPR!*

tCCH (IT screening of dossiers)

- ECHA has started to use IT tools to screen dossiers for quality

- These tools screen ALL dossiers

- Complements the 'normal' dossier evaluation. Outcome is manually verified, before compliance letters are sent (CCH letters have 30d to react).

- Areas of concern within dossiers will be very likely to be spotted

→ *Tip: Keep an eye on your REACH-IT mailbox, some requests have very tight deadlines!!*

→ *Tip: if you receive a communication of compliance, check if other dossiers need update too!*

See ECHA presentation for more information

Biocides

ECHA will have a central role in the implementation of BPR in 2013:

- R4BP (Register for Biocidal Products): submission portal similar to REACH-IT

- IUCLID(5.5): Format of submission of scientific dossiers in biocides

- Coordination and assistance to MS processes

- Dissemination of information

  …

Conclusions

- **Getting familiar with ECHA IT tools is essential for succesful submissions**

- **Use plug-ins before submitting**

- **Anticipating changes in e.g. IUCLID and planning accordingly may save you time and money**

- **Want to know more? Join the Cefic REACH-IT group! mvi@cefic.be**

Must-know for registrants

IUCLID news:

http://iuclid.echa.europa.eu/

ECHA Evaluation report (next one by the end of Feb.2013)

http://echa.europa.eu/web/guest/regulations/reach/evaluation

Presentations of the ECHA Lead Registrant workshop in Oct. 2012:

http://echa.europa.eu/en/web/guest/view-article/-/journal_content/2b6c9ef3-b8c8-4ee1-a15d-bee72a3b47ea

Webinars: how to bring your dossier in compliance:

http://echa.europa.eu/web/guest/support/training-material/webinars

Back-up slide: CSR plug-in

IUCLID (CSR plug-in) and Chesar