The road to REACH 2018 – how we are helping

Tenth Stakeholders' Day

27 May 2015

Christel Musset
Director of Registration
European Chemicals Agency

What are we expecting in 2018?

- Many more registration dossiers
- More small SIEFs
- More individual registrants
- Higher % of SMEs
- More SMEs as lead registrants
- Less information → need to generate new data
- Some very active sectors

Registration is hard, but it can be done

- Thousands of companies have done it
- More than 3 000 registrations already received for the 2018 deadline
- Increasing number of SMEs: 25% in 2015

We are working to make it simpler ….

- Especially for 1-10 tonnes substances

New 2018 web pages

- Advice for each phase of registration
- Targeted support with three levels of information
  - Getting started - Essential reading - Going deeper
- Practical tips, Do's and Don'ts, Checklists
- Information on events, webinars, new publications

Predictability

- IT Tools & Guidance finalised by mid-2016

Six steps to successful registration

1 Know your portfolio

2 Find your co-registrants

3 Share your data

4 Gather your data

5 Prepare your registration dossier (IUCLID)

6 Submit to ECHA (REACH-IT)

ECHA
EUROPEAN CHEMICALS AGENCY

(1) Know your portfolio

What should I register?

- Unambiguous substance identification = essential
- Ensure data can be shared and are suitable for your substance

To come

- Sector-specific substance identity guidance, fact sheets
  - Cooperation – ECHA/industry sectors
  - Commission Study – "How to identify complex substances"

Important

- Manual verification at completeness check starting in 2016 to ensure justifications are plausible

![ECHA - European Chemicals Agency]

(2) **Find your co-registrants**

Who should I work with?

- Check your pre-registrations
- Is your substance registered? Identify the lead registrant
- Is your substance not registered? Find your co-registrants
- Discuss and establish the sameness of your substance with co-registrants

Important

- Joint submission is mandatory to ensure sharing of data and no unnecessary testing on animals
- Additional verification in REACH-IT considered to prevent duplicate joint submissions

3 **Share your data**

- Organise cooperation, or get active in your SIEF
- Share data
- Negotiate costs in a fair, transparent and non-discriminatory manner
  - Practical advice on data sharing negotiations
  - Do's and Don'ts, factsheet on typical cost elements
  - What to do in case of problems

Important

- The European Commission is preparing mandatory rules – an Implementing Act on Data Sharing

![ECHA - European Chemicals Agency]

(4) **Assess hazard and risk**

- Information required depends on tonnage and uses
- 1-10 tonnes: Possible reduced data requirements for less hazardous substances
- > 10 tonnes: chemical safety report needed
- Data quality is crucial
- Some long-term studies require a testing proposal
- Animal testing is the last resort - Consider alternatives

To come in 2016

- Checklist for reduced data requirements
- List of substances likely to require a full data set

4 Use alternatives to animal testing

- Advice and practical guides on ECHA website
- Requires some expertise
- Read-across assessment framework (RAAF) on human health
  - Explains how your read-across will be assessed by ECHA
- OECD QSAR Toolbox
  - Fills data gaps by grouping chemicals, read-across and (Q)SARs
  - Helps to reduce cost and testing on animals
  - Videos and tutorials available online

To come

- Skin sensitisation: *in vitro* methods to be used in an integrated approach - Go to ECHA website
- RAAF on Environment in 2016

4 Chemical safety assessment

- Identify uses with respective volumes for all lifecycle steps
- Be precise: use information may trigger prioritisation of regulatory action
- Contact industry sectors for use maps. It can be a great help.
- Use Chesar!
  - Direct import from IUCLID for preparing the CSR
  - Keep data consistent with IUCLID for easier updates
  - Generate exposure scenarios for the safety data sheet

To come
  - Updated use description guidance
  - Chesar 3 in 2016 with more functions

5 6 Prepare/submit your dossier

As soon as possible!

BUT - in 2016..........

IUCLID 6

- One-click installation
- Integrated help
- New user interface for members
- Online access – no need to install IUCLID
- Improved substance identification

REACH-IT

- More intuitive user interface
- Easier identification of co-registrants and existing joint submissions

In summary

- Registration is challenging but manageable
- Start preparing now, even for a registration in 2018
- If you are newcomer, start now, but wait for the new IT tools in 2016 to prepare and submit
- Use all the help available
  - ECHA website http://echa.europa.eu/reach-2018
  - National helpdesks
  - Sectoral associations

7 **...and remember to keep your registration up-to-date**

Get ready!

christel.musset@echa.europa.eu

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
@EU_ECHA

Follow us on Facebook
Facebook.com/EUECHA