



European
Commission

Registrations of SMEs under **REACH**

State of play and perspectives

12th ECRN Congress
Ústí nad Labem, 22 October 2014

Mehdi Hocine
DG Enterprise and Industry
Unit F.1 : REACH

to the
1 June 2007 shall be incorporated
from 1 June 2009.

Article 138

Review

From 2019, the Commission shall
decide whether or not to extend the application of the obligation
to conduct chemical safety assessment and to document
the results of the assessment to substances not covered by this
Regulation in quantities of

The Commission shall carry out
the tasks assigned to it by 1 June 2008, with a view
to ensuring that the Commission referred to in Article 131
of the Treaty on the Functioning of the European Union
is able to perform its duties.

The Commission

number 2

Objectives of REACH

- ☑ protection of human health and the environment
- ☑ promotion of alternatives to animal testing
- ☑ free circulation of substances
- ☑ enhance competitiveness and innovation

Legal obligation to register substances

- **Registration:** one of the major elements of REACH, together with **evaluation, restrictions** and **authorisations**.
- High number of substances have to be registered (~35.000). To date more than 12,000 have been registered.
- Phase-in period with three deadlines:
 - 1 December 2010 (over 1,000 tpa),
 - 1 June 2013 (100 to 1,000 tpa),
 - 1 June 2018 (1 to 100 tpa).

What has happened so far

- Registration deadlines of **2010** and **2013** successfully completed, but limited experience with SMEs since concerned high tonnage bands.
- To date around **3,000 SMEs have registered.**
- COM has published in February 2013 a **comprehensive** review on the implementation of REACH, including on the first lessons learnt from the REACH implementation With **special attention** to:
 - attainment of its aims on human health and the environment,
 - the costs and administrative burden,
 - other impacts on innovation.

REACH review: conclusions

REACH **functions well** and delivers on all objectives that at present can be assessed.

- Too early to quantify benefits in terms of **Health and Environment** but positive initial trend.
- Less **Animal Testing**.
- **Innovation:** increased moves towards substitution of Substance of Very High Concern.
- **Internal Market & Competitiveness:** increased harmonisation but need to reduce impact on SMEs.

REACH review: conclusions

- Balanced against legislative stability and predictability, no changes to the enacting terms of REACH.
- At the same time, REACH was considered as No 1 in the TOP10 Most Burdensome EU Legislations for SMEs.

REACH review: recommendations

- The 2013 review recommends a set of actions to be taken in order to address the concerns identified. This list includes inter alia:
 - More specific guidance for SMEs,
 - Reduced fees for SMEs,
 - Improved transparency on fair cost sharing in SIEFs.

What has been achieved

- **March 2013:** further reduction of SME registration fees.
- **April 2013:** appointment of an SME Ambassador at ECHA.
Andreas Herdina 
- **December 2013:** SME workshop to identify priorities for actions.
- **April 2014:** Workshop on registration of natural essential oils.

What has been achieved (continued)

- **2014:** The Director Contacts Group, informal platform formed by Commission, ECHA and 9 associations has issued 4 important guidance documents:
 - Fair, transparent, and non-discriminatory cost sharing in SIEFs,
 - Recommendations on sound SIEF management,
 - Considerations to be made when joining an existing SIEF,
 - Checklist on how to hire a good consultant.

Priority for action in the field of registrations



- **Increasing transparency in Substance and Information Exchange Forums**
 - Perceived lack of transparency on administrative costs and cost sharing model
 - Commission is considering an implementing act to increase transparency in SIEFs
- **Development by ECHA of the 2018 Registration roadmap**
 - <http://echa.europa.eu/reach-2018>
- **Reinforcement of communication actions**

Other initiatives

- The Authorisation procedure is also a matter of concern for SMEs and downstream users.
- SVHC Roadmap: Risk Management Options
- REFIT Communication in June 2014:
 - Reduction of frequency at which substances are added on the list of substances subject to authorisation,
 - Simplified procedure for authorisation,
 - Socio-economic aspects to be taken into account at an early stage in the authorisation process.

Tips for the 2018 registration deadline

Check who else is in your SIEF:

- your substance may be already registered,
 **join existing joint submission**, identify a LR.
- your substance is not yet registered,
 **discuss in SIEF, appoint a LR.**
- Share data with others,
- LR submits the **joint part** of the dossier,
- Don't forget to submit your **individual dossier**.

Tips for 2018 registration deadline

- „In time“ means start now!
- Not only „classical“ chemical sectors are affected.
- REACH registration requires technical expertise.
- Preparing a dossier takes much time (up to 1.5 years).
- Applying data- and cost sharing reduces costs!
- SMEs have a registration fee reduction of up to 95%.
- Consider also further possible obligations (e.g. safety data sheet, obligations on articles).

Tips for the 2018 registration deadline

Where to find **REACH assistance**?

- ECHA website: REACH guidance, navigator tool, FAQs...
- National REACH/CLP helpdesks ,
→ **help for SMEs!**
- Industry associations,
- EEN/chambers of commerce.

Thank you

For further information
please visit:

- ec.europa.eu/enterprise/reach
- ec.europa.eu/environment/chemicals/reach
- echa.europa.eu

Mehdi Hocine

DG Enterprise and Industry
Unit F.1 : REACH

This presentation does not necessarily reflect the official
opinion of the Commission.