



Reach compliance with REACH requirements- the registrants' perspective



REACH Compliance – WS on data quality in registration dossiers

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ECHA and Cefic sign joint statement to work on effective implementation of REACH



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JOINT STATEMENT

Helsinki, 14 June 2018

With the completion of the third registration deadline, REACH now regulates all chemicals on the EU market.

Recognising that the 2018 Commission General Report on REACH calls on all actors to further improve REACH implementation and, in particular, on industry and ECHA to further improve the safety information and its communication in the supply chain,

Acknowledging that the assessment of some substances or groups of substances has been scientifically challenging, and believing that early stage cooperation between industry and ECHA experts will contribute to this further improvement,

In this context of co-operation:

ECHA and Cefic sign joint statement to work on effective implementation of REACH



Cefic will:

- Make further endeavours to promote a gradual and planned improvement of the compliance, quality and understanding of the registration dossiers.
- ...

Cefic continues to help REACH work



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Guidances and Tools

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Cefic has developed a number of guidances and tools, available for free for the entire industry, to support companies in the implementation of REACH as well as to enhance harmonisation.

Having a harmonised approach, and using standard tools, are key for a successful and efficient implementation of REACH requirements.

Discover our newsletter on Information on REACH registration process: [Issue 1 \(January - April 2017\)](#)

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Substance Identification Profile (SIP) template

18 August 2009

This Substance Identification Profile (SIP) template can be used to support the substance sameness discussions in SIEFs. The intention is to use this

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REACH Registrations



- Companies have been making major efforts to register in time, believing they made good quality dossiers according to their experience from the previous legislation
- Companies took animal testing as last resort very seriously
- The German studies, the first and second REACH Review reveal the « alarming figures » on the data quality, which are heard during many meetings as well
- The gaps in the CSR have been leading to the creation of the CSR/ES roadmap and the ENES community, developing tools that were not available

REACH Registrations – hazard properties



- As the project(s) « REACH Compliance » run by BfR show, we can distinguish 4 categories
 - Compliant
 - **Complex**
 - Non-compliant
 - Testing proposal
- **Annex XI** was and is part of the REACH legal text, but the expectations on what is an acceptable justification for using Annex XI differs from authorities to industry – a more intensive collaboration may be a step forward

Article 22



- Article 22 is rather clear, but here again different interpretations are given by different stakeholders
- Any change in composition or any change in composition leading to a different classification (interesting in view of the CLP Annex VIII discussions).
- New knowledge of the risks of the substance to human health and/or the environment
 - Many companies do a regular literature review, but are not taking up studies that are not done according to OECD approved test methods or are not GLP approved

Article 22



- Is requesting for updates
 - Of the lead registrants for the joint parts
 - Of the joint submitters for legal entity individual information
- Industry believes that it remains a case-by-case decision whether an update is needed according to Article 22 and hence doesn't see an need for an Implementing Act.

Data quality



Which one are you?



1/2 FULL?



1/2 EMPTY?

Industry shows goodwill



- Cefic works on recommendations on updating of dossiers, in line with the joint Helsinki declaration
- Industry has been participating in the COLLA process. Despite the resource intensive activity, industry believes that we should look how we can improve this, essentially in view of more grouping in future from the perspective of authorities for regulatory risk management

Industry shows goodwill



- Chemical industry is active in the joint ECHA – Cefic – EUPC activities on mapping the chemical universe on plastic additives. We strongly believe that these kind of interactions will be of help for updating dossier quality
- Eurometaux engaged with ECHA in the MISA project, Metals and Inorganics Sectorial approach

Industry shows goodwill



- Industry is continuing to engage further to understand what is considered to be needed to be of good quality
- The grouping approach that has been followed by registering companies (resulting in Annex XI use by industry as alternative information sources for hazard properties) is now as well clearly mentioned in the ECHA strategic plan 2019 – 2013.
- A more in depth discussion between different stakeholders in the process will be needed to sort this out, in order to get the quality right and to use animal testing as last resort as mentioned in the legal text.

How to progress?



- More targetted figures related to dossier quality
 - Distinguish between LR and joint submitters
 - Distinguish between the different registrant roles
- Let's find improved ways to create joint clarity on
 - Use of Annex XI to close the data gaps
 - Use of grouping in an appropriate way and how to choose the substances for testing
 - ...

