



**The activities of the Directors' Contact Group:
Results
Milano, 03/02/11**



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Directors' Contact Group



- **Directors' Contact Group on meeting the REACH registration deadline**
 - Commission
 - ECHA
 - Industry Associations
- **Objective**
 - Monitor the overall preparedness of companies as to meeting the 2010 registration deadline;
 - Identify and resolve priority issues of concern in meeting obligations relevant to the registration deadline;
 - Identify and resolve priority issues of concern for a secured supply of high-volume substances to downstream users.
- **The Directors' Contact Group will operate until 31 March 2011, but prolonged until 31 July 2013 and extended with DU**

Results - State of the art



- **Excellent cooperation to quickly find pragmatic solutions to issues identified by industry**
- **27 issues at the beginning**
 - **Issues with 1 June deadline were completed on time**
 - **1 new issue was also finalised:**
 - **implementing risk management measures**
 - **New points coming up**
- **DCG solutions presented to CARACAL**
- **Communication via ECHA website**
 - **DCG documents**
 - **Practical procedures where needed**



HOME

SIEF

REACH

DATA SHARING

ENFORCEMENT

CONSULTATIONS

ECHA CHEM

REACH-IT

CLP

GUIDANCE

LEGISLATION

HELP

Directors Contact Group

FAQ's

Documents

National Helpdesks

ECHA helpdesk

The Directors' Contact Group (DCG)

The Directors' Contact Group (DCG) was set up in January 2010 and is made up of the European Commission, ECHA and Industry Associations.

The DCG objectives are to monitor the overall preparedness of companies and to identify and resolve the priority issues of concern in meeting obligations relevant to the registration of chemical substances. Special attention is also paid to priority issues of concern for a secured supply of high volume substances to downstream users.

Since its establishment, the DCG has found solutions to 28 issues of concern for industry relating to the first REACH Registration deadline of 30 November 2010. These solutions have been shared with the Member State Competent Authorities through the CARACAL advisory body and with the EU/EEA Enforcement Authorities through the Forum for Sharing Information on Enforcement.

[The Summary Paper on 28 issues and solutions](#) (PDF)

In case you identify yourself as being in a situation described under issues 10, 15, 20 and 21 in the Summary Paper above, you are advised to contact ECHA - via a dedicated web-form - before you submit your dossier.

[Contact ECHA](#)

Issues



- **Examples of issues :**
 - **SIEF problems**
 - **Completeness of dossiers**
 - **Dependency on the lead registrant**
 - **Uses not covered by a registration**
 - **Legal entity change**
 - **Confidentiality of substance name for classification and labeling inventory (cfr. Notification of R&D substances)**
 - **Stability of guidance**

SIEF problems



- **Too long time to discuss and agree on SIEF**
 - e.g. late entries of participants in SIEFs
- **Lead Registrants can freeze the lead dossier** and the steps leading to it two months before the planned submission date. *ECHA published a recommendation on its website on 16 April 2010.*
- Industry associations will remind their members about the importance of transparency in the cost sharing:



Cefic note on transparent cost sharing published on Cefic website

Completeness of dossiers



- **Substance identity should not stop acceptance of a dossier and is part of the evaluation**
- **Data availability**
 - In the **exceptional** situation that a company has ordered tests but **not have received the results timely for the registration deadline**, they could submit dossiers that would be incomplete to an extent, providing a proof that tests have been ordered and a timeframe for resubmission. Such a dossier would fail the Technical Completeness Check but the company can continue production and will have sufficient time to complete the dossier.

Dependency on LR



1) The Lead Registrant submits his dossier in time, but subsequently fails technical completeness check

- REACH-IT allows other registrants to submit their individual dossiers immediately after the LR has submitted the dossier, i.e. even before the LR has been assigned a registration number.
- As soon as it becomes evident that the dossier of the agreed Lead Registrant will be rejected, one of the other registrants needs to take over the Lead Registrant role in REACH IT and submit a complete and valid dossier.

2) The Lead Registrant does not submit a registration dossier

One of the other registrants needs to take over the Lead Registrant role in REACH-IT and submit a complete and valid lead dossier.

Uses not covered by a registration



- **Downstream user**
 - **Use covered in the registration dossier?**
 - **Conflicts of rights**
 - **Right to communicate use**
 - **Right to stop to supply**
 - **Substances registered as intermediates used under strictly controlled conditions**
 - **No possibility for downstream user to do chemical safety assessment in that case**
 - **Only possibility is becoming importer and do the registration**
- **Remains a very important point for DCG**

Notification of C&L



- **CLP: No threshold for notification**
 - (confidentiality, workability)
- **REACH: Art 119 § 2 (g) allows claim on confidentiality IUPAC name for substances used only as:**
 - Intermediate
 - Scientific research and development
 - PPORD

Notification of C&L R&D substances



- Notification of substances still in research without information
- Quantities of substances used in R&D are by definition smaller than 1 tonne per year and are therefore not subject to registration under the REACH Regulation. If the substance used in R&D is hazardous and placed on the EU market, it, however, needs to be notified to the C&L inventory notwithstanding its volume. ...**If neither test data are available nor any other adequate information indicates that a substance should be classified, a notification to the C&L Inventory is not required.** If sufficient information is available to classify, and the substance is placed on the market, and hence when the notification to the C&L Inventory is necessary, the IUPAC name of substances used in R&D can be kept confidential

Stability of guidance



Guidance	Issuance date
Guidance on registration	
• Amendment of Annex V guidance (GMOs, glass and frits, hydrogenation)	After 1/12/ 2010
• Amendment of Guidance on monomers and polymers	After 1/12/ 2010
• Guidance on intermediates (clarification of the concept of strictly controlled conditions)	After 1/12/ 2010
Guidance IR & CSA	
• Scope of exposure assessment	After 1/12/ 2010
• Exposure based adaptation and strictly controlled conditions	After 1/12/ 2010
• Exposure scenarios for waste life cycle stage	After 1/12/ 2010
• Derivation of DNELs/DMELs from human data	After 1/12/ 2010
Guidance on substances in articles	After 1/12/ 2010
Guidance on Safety Data Sheets	After 1/12/ 2010
Guidance on the CLP Regulation - application of the CLP criteria (labelling)	After 1/12/ 2010

Looking to the future



- **Challenges:**
 - **up-date of dossiers**
 - **intermediates**
 - **evaluation,**
 - **authorisation/restrictions**
 - **Second Registration Dead-line in 2013**
 - **New challenges (more substances, less information, more and smaller companies, less existing consortia)**
- **Cefic continues to give guidance and support**

Looking to the future



Review of the Regulation in 2012

Develop industry position on the scope of the review:

- Analyse experiences and results of on-going monitoring and Commission studies
- Explore possibilities to solve identified problems for industry outside the review
- Balance threats and opportunities with opening up broad negotiations of REACH

If....

Cefic identifies and prepares positions on all possible issues



Grazie per la vostra attenzione