



Seminar on Tips from 2010 Registration – Efficient Strategy for REACH registration in 2013/2018

- Part I REACH & CLP: New Developments in the EU -

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Agenda



Introduction

Part I - REACH & CLP: new developments in the EU

Part II - REACH: Review, lessons learnt and recommendations

Part III - CLP: Review, lessons learnt and recommendations

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Introduction: Scientific Consulting Company GmbH

- SCC was founded in 1989 and is privately owned and neutral
- SCC is one of the top three independent regulatory consultancy companies in Europe
- SCC is located one hour's drive to Frankfurt am Main, Germany



AGROCHEMICALS



REGULATORY SCIENCE



BIOCIDES



**FEED & FOOD ADDITIVES,
VETERINARY MEDICINE**



**CHEMICALS, REACH,
CONSUMER PRODUCTS**



**DATA MANAGEMENT –
GLP ARCHIVES**

Introduction: REACH expertise within SCC

■ REACH team

- ▶ REACH core team: 16 employees (increasing number)
- ▶ REACH background/ support: ~ 25 employees (regulatory science)
- ▶ ECHA and national authorities: SCC known as reliable partner; personal contacts established; pilot projects for ECHA (e.g. eSDS)

■ To this day SCC

- ▶ has pre-registered > 1,000 substances
- ▶ is active in > 100 SIEFs
- ▶ has prepared and filed ~ 100 REACH dossiers and > 100 dossiers under the old regulation (Notification of New Substances (NONS))
- ▶ provides technical support to > 20 task forces/ consortia

Introduction: Activities of SCC / SLOJ in Japan and for Japanese clients

- Business relationship with Japanese clients for more than 15 years.
- In 2007, SCC established the "SCC Liaison Office Japan (SLOJ)" to assist Japanese companies with regards to regulatory matters especially in Europe.
- But European companies also seek SCC's / SLOJ's assistance with regard to national Japanese legislation.
- SLOJ staff in Tokyo:
 - ▶ Mr. Toshiyasu Takada and Mr. Kenji Makita, each with 30 years of national and international experience in the chemical industry sector.
- Currently, SCC provides consultancy services to more than 20 companies located in Japan or in Europe with a headquarter in Japan.

I REACH - Introduction

- REACH is a European piece of legislation replacing 40 legal acts to streamline the former legislative framework for chemicals in the EU by introducing a single system for all chemical substances.
- REACH aims to improve the protection of human health and the environment through better and earlier identification of the properties of chemicals.
- REACH entered into force on 1 June 2007^{*)}
- REACH stands for the **R**egistration, **E**valuation, **A**uthorisation of Chemicals

^{*)} Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *OJ L 396*, 30.12.2006

I REACH – Introduction (continued)

- Registration of Chemicals is – if the substances have been pre-registered – phased according to the tonnage produced/imported in the EU:
 - ▶ 30 November 2010: > 1000 t/a
 - ▶ 31 May 2013: 100 - 1000 t/a
 - ▶ 31 May 2018: 1 - 100 t/a
- The main burden is being put on manufacturers and importers but all other actors in the supply chain have at least communication obligations.
- After the first registration deadline is over, the evaluation phase is getting more and more important and will lead to the control and substitution of substances with undesired properties (e.g. CMR, endocrine disruptors, persistent and bioaccumulative in the environment).

I CLP - Introduction

- The CLP Regulation^{*)} is the new European Regulation on **C**lassification, **L**abelling and **P**ackaging of chemical substances and mixtures.
- The legislation introduces throughout the EU a new system for classifying and labelling chemicals, based on the United Nations' Globally Harmonised System (UN GHS).
- The provisions of CLP will replace Council Directive 67/548/EEC (Dangerous Substances Directive, DSD) and Directive 1999/45/EC (Dangerous Preparations Directive, DPD) in a stepwise approach.

^{*)} Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, *OJ L 353, 31.12.2008*

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I New Developments in the EU

- First reviews of REACH available (Report from the Directors contact Group) and announced for summer 2012 (ECHA, general report, scope of REACH, low tonnage)
- Intention to identify/stop overlaps with other European programs (e.g. RoHS)
- New/ongoing targets like incorporation of nanomaterials into REACH (Cefic activities)
- Future of polymers still open
- Besides legal requirements: voluntary activities by industry like Global Product Strategy (GPS) safety summaries.
 - ▶ The aim of GPS is to show the safe use of chemicals in a worldwide, harmonised format.
 - ▶ Cefic has recently published a conversion template to transform REACH dossiers into GPS safety summaries.
 - ▶ Cefic and the German chemical association VCI encourage companies to prepare GPS safety summaries.

I New Developments in the EU (continued)

- The laboratory landscape in Europe underwent substantial changes (e.g. due to currency, merges)
- Testing changes
 - ▶ Adaption of tests to UN test methods
 - ▶ Extended one-generation (OECD 443) versus two-generation (OECD 416) studies
- Global player have global strategies (including testing)
- Authority shift from MSCA to ECHA
- REACH is now more in the awareness of downstream users, SME
- REACH is not only a legal obligation but also as a marketing tool:
 - ▶ REACH compliance/ availability of registration numbers versus being not compliant
 - ▶ This leads to early registrations independent on the tonnage.

I New Developments in the EU (continued)

- New/ updated tools like CHESAR, OECD toolbox
- Extended safety data sheets (eSDS) still to be standardised
- Similar trends for REACH just like for other legal programs (biocides, plant protection):
 - ▶ Submission of the dossier doesn't mean that the work is over (defence, update of dossiers)
 - ▶ Evaluation phase and authorisation impact more and more the REACH work in addition to the registration work for 2013
- Future of the C&L inventory unclear
 - ▶ Heterogenic classifications for > 100.000 substances (currently 3.2 Million notifications)
 - ▶ Processing of the generated data by ECHA?
- Increase of CLH dossiers (Annex XV) to aim for harmonised classification and labelling



ご静聴有難うございました。

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