



Colloque

Politiques de régulation des produits chimiques

Incidences et effets d'entraînement
du règlement européen REACH

Judi 23 juin 2011

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SESSION 2 - REACH, FIRST REVIEW ELEMENTS

REACH - Experience with implementation and 2012 review

Sebastian Gil

2010 and 2011 – eventful years for chemicals legislation

- **First REACH Registration deadline**
- **Directors' Contact Group**
- **Notification of substances in articles**
- **Dissemination of information on chemicals**
- **Evaluation kicks in**
- **The Candidate List is starting to grow**
- **Changes to REACH annexes (I, XIII, XIV, XVII)**
- **REACH review**
- **On the Road to 2020**

First REACH Registration deadline

- **24,675 dossiers on 30 November 2010**
- **Resulting in 20,175 completed registrations**
- **3,400 substances (“phase-in”)**
- **Peak towards deadline**
- **Massive effort by industry**
- **Altogether there are 4,840 substances registered as of 31 May 2011 (“phase-in” and “non-phase-in”)**

Directors Contact Group

- **Set up to help industry meet the first REACH registration deadline**
- **Directors Commission, ECHA, industry associations**
- **In 2010, it identified 28 issues and solutions all published on ECHA's website**
 - Example « Downstream user use not covered in registration »
- **It will carry on its work in 2011 under revised terms of work**

Directors Contact Group (2)

- **New terms of work started on 1 April 2011**
 - Includes participation of downstream users
 - Publication « lessons learnt from first registration deadline »
 - Follow up issues identified under 2010 mandate
 - Identify new issues
- **Particular focus**
 - Downstream Users concerns
 - SIEF issues (management and cost sharing)

Substances in Articles: Notification and Communication

- **From 1 June companies to notify presence of SVHC in articles if**
 - Substance present in those articles totalling over one tonne per producer or importer per year
 - Substance present above a concentration of 0.1% weight by weight
- **0.1% of what article?**
- **Legal opinion and guidance: whole article**
- **Consumer right to know and fight to know**
- **New guidance released on 1 April**

Dissemination of information on chemicals

- **Registration provided loads of information, so next:**
- **Dissemination on ECHA website - work in progress**
 - Aiming for user-friendly information for workers, consumers, citizens..
 - Information on 3694 substances disseminated

Evaluation kicks in

- **Compliance check**
 - General or targeted evaluation of the dossier, at least 5% of the total number of dossiers for each tonnage band
 - Priority setting: concern (3/4) and random selection (1/4)
- **Testing proposal examination**
 - Registrant seeks permission to undertake tests under Annexes IX or X
- **Substance evaluation**
 - Aims at verification whether a substance constitutes risk
 - Assessment performed by Member States picking substances from Community Rolling Action Plan (CoRAP)
 - MS drafts the decision, ECHA administrates decision-making
 - 50 evaluations in 2012, 100 evaluations per year thereafter

Candidate list starting to grow

- **53 substances of very high concern**
- **Next ECHA consultation planned for August**
- **Commission commitment for 136 SVHC by end 2012**
- **All relevant known SVHC by 2020**
- **Candidate list more than stepping stone to annex XIV**
- **Bi-annual updates of candidate list**

Changes to REACH Annex I Chemical Safety Assessment

- **How to carry out a Chemical Safety Assessment and document it in a Chemical Safety Report**
- **Annex I amendment adopted 14 March**
- **Amendment brings Annex I in line with CLP Regulation**

Changes to REACH Annex XIII PBT criteria

- **Amendment adopted 14 March**
- **Annex XIII: criteria for identification of**
 - persistent, bioaccumulative and toxic (PBT) substances,
 - very persistent and very bioaccumulative (vPvB) substances;
 - it does not apply to inorganic substances.
- **Weight of Evidence Approach**

Changes to REACH Annex XIV Authorisation list

- **Adopted on 17 February**
- **First six substances of very high concern (SVHC) on the authorisation list**
- **These SVHC can no longer be placed on market after a sunset date**
- **Ongoing process: ECHA recommended 8 more substances from Candidate List – Commission to prepare next amendment**

Changes to REACH Annex XVII Restrictions

- **Entry into force 1 June 2009**
- **Since then amendments to Annex XVII made or ongoing (examples):**
 - Cadmium and Acrylamide
 - CMR substances
 - Mercury
 - Lead
 - DMFu

Review 2012: Legal requirements

- **3 Reviews by 1 June 2012**
 - ECHA (Art 75.2)
 - Low tonnage (Art 138.3)
 - Scope of REACH (Art 138.6)
- **General report on operation of REACH by 1 June 2012 and funding of alternative test methods (Art 117.4)**
 - Member States Reports (evaluation and enforcement)
 - ECHA Reports (non-animal test methods)

Review 2012: Scope & presentation

- **COM will carry out a larger review exercise:**
 - The reviews and reporting foreseen in REACH
 - A report on first lessons learnt from REACH implementation
 - costs and administrative burden
 - other impacts on innovation
- **Reviews and reports to be presented as a package in June 2012**
- **“Chapeau” Communication for complete overview**

Review 2012: Approach

- **Thematic studies:**

- Assessment to amend scope of REACH
- Experience operation of REACH
- Nanomaterials in REACH registration dossiers
- Inspection requirements REACH and CLP
- Nominal risk caused by chemicals in 2012 compared to 2007
- Functioning of EU chemicals market
- Health and environmental benefits REACH
- Registration requirements 1-10 tonnes substances and polymers
- Review ECHA
- REACH contribution to development emerging technologies
- Implementation and enforcement of restrictions in Member States

Review 2012: Follow-up

- **COM “may, if appropriate, present a legislative proposal based on the review outcomes”**
- **Practical approaches to better implement the current legislation (e.g. guidance)**
- **After 1 June 2012 conclude whether legislative revision is needed and necessary**
 - potential impacts on the next registration deadlines (2013 and 2018)

The Road to 2020

WSSD Johannesburg 2002:

Aiming to achieve, by 2020, that chemicals that chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment.

It acknowledges the essential contribution made by chemicals to modern societies and economies while at the same time recognizing the potential threat to sustainable development if chemicals are not managed soundly.

Rio + 20 2012?

The Road to 2020 (2)

- **REACH is on its way to deliver. It is not easy, but industry, authorities and ECHA are coping**
- **The first steps towards the 2020 goal have been successfully taken and the pace is increasing**
- **We have new challenges ahead both in REACH and outside of REACH which need to be met with the same vigour**

Thank you for your Attention !