REACH and CLP regulations, background information & state of play

Tony Musu
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Overview

- How does REACH work?
- State of play on REACH implementation?
- How does the CLP Regulation work?
- State of play on CLP implementation?
- Trade union's work in ECHA
- Conclusions
REACH in a nutshell

- Registration: Manufacturers and importers of chemicals > 1 tpa are required to register their substances to demonstrate they can be used safely.

- Evaluation of some substances by Member States / European Chemicals Agency.

- Authorisation only for substances of very high concern.

- Restrictions when risks are unacceptable.
Timeline for REACH registration

- **REACH came into force**
  - 1 Jun 2007

- **Pre-registration for new (non-phase-in) starts**
  - 1 Dec 2008

- **Existing phase-in substances**
  - PHASE 1 Registration (CMRs: Carcinogens, Mutagens or Reproductive toxicants) (≥1 tonne/year)
  - PHASE 2 Registration (Very toxic to aquatic organisms (R50/53)) (≥1000 tonnes/year)
  - PHASE 3 Registration (before deadline: 31 May 2018)

- **New "non phase-in" substances registration:**
  - Immediate Registration for existing "Phase-in" substances which have not been pre-registered
  - No Registration? No Sell!

- **Timeline:**
  - 30 Nov 2010
  - 31 May 2013
  - 31 May 2018

- **No Registration? No EU Sell!**
Outcome of the first registration deadline (30 Nov 2010)

- ECHA received 24,675 registration dossiers covering around 4,300 substances of which:
  - ~3,400 phase-in substances
  - ~900 non phase-in substances
  - ~80% full registration dossiers & ~20% intermediates
- only 380 CMR substances (out of 1,005 CMR cat 1A & 1B listed in CLP annex VI)
  - how many CMR illegal on the EU market?
  - how many registered CMR self-classified?

Forecast for the 2nd registration deadline (31 May 2013)

- around 15,000 registration dossiers covering substances produced in volume between 100 and 1,000 tonnes/year
Dissemination of information under REACH?

- **Article 118**: access to documents held by the ECHA (Regulation (EC) No 1049/2001)
  - Written request to access the information
  - Some data not disclosed to protect commercial interests

- **Article 119(1)**: data always available on ECHA's website

- **Article 119(2)**: data always available on ECHA's website unless:
  - The registrant has requested to keep the information confidential and
  - ECHA has accepted the justification as valid
State of play on data dissemination (20 Jan 2012)

- Data available for 4209 registered substances (out of 4300 substances) from 23 942 registration dossiers
  

- Around 1400 dossiers with confidentiality claims under Art 119 (2)

- ~ 40% of these confidentiality claims assessed by ECHA

- ECHA plans to complete the assessment of the confidentiality claims submitted for the 2010 deadline by end 2012

- Controversy initiated by ETUC and NGOs on the scope of article 119(2)d
  
  Name of the company + Registration number + PBTness will also be made publicly available unless confidentiality claims accepted by ECHA

- User-friendliness of ECHA dissemination website to be improved
Evaluation

2 types of evaluation:

- Dossier evaluation (animal testing/compliance checks) is performed by ECHA

- Substance evaluation when a substance may present a risk to human health or the environment is done by the Member States (with ECHA as coordinator)

Results of evaluation:

- No further action
- Industry can be asked for more info
- Substance needs to be regulated further
  Eg: authorisation or restriction procedures
State of play on Evaluation (end Nov 2011) ?

- **Dossier evaluation:**
  - 270 compliance checks concluded by ECHA (target 5% per tonnage band)

  **ECHA’s early findings:** one third of registration dossiers have significant quality deficiencies

  - 198 decisions taken by ECHA on testing proposals

- **Substance evaluation:**
  - ECHA and Member States have agreed prioritisation criteria
  - The first Community Rolling Action Plan for substances to be evaluated will be adopted in February 2012 (91 substances)
  - Member States capacity estimated at 30 substances/year
Authorisation

- For each use of substances of very high concern (PBTs, vPvBs, CMRs (1&2), equivalent concerns) included in the Authorisation list (= Annex XIV)

- Authorisation is granted by the Commission if
  - **Route 1**: Industry can prove the risk is adequately controlled
  - **Route 2**: Socio-economic benefits > risks and no suitable alternatives are available

- No Authorisation granted if:
  - Use is not considered to be adequately controlled
  - Benefits are smaller compared to risks
  - Suitable substitutes are available (for route 2 only)

- All authorisations will be reviewed (case-by-case)
Authorisation procedure

Substances of very high concern:
PBTs, vPvBs, CMRs (1&2), equivalent concerns

Candidate List

Information obligations for suppliers

Prioritisation

Authorisation List (Annex XIV)

Substance can no more be used without authorisation
State of play on Authorisation (Jan 2012)?

Substances of very high concern:
PBTs, vPvBs, CMRs (1&2), equivalent concerns

Candidate List
73 substances

Prioritisation

Authorisation List (Annex XIV)
6 substances

First applications for authorisation by industry expected in 2012
Restriction

Aim: safety net when risks are unacceptable

- Manufacture, use and placing on the market of substances on their own, in preparations or in articles
- Proposals for restrictions are prepared by Member States or ECHA on behalf of the European Commission
- ECHA gives opinion on each proposal
- Interested parties can comment (public consultation)
- European Commission takes final decision
- REACH takes over existing restrictions from previous EU legislation (annex XVII)
State of play on Restriction (end Jan 2012)?

- Restriction title of REACH entered into force on 1\textsuperscript{st} June 2009
- 7 dossiers for restriction submitted by Member States (NO, FR & ECHA on request from the COM)
- ECHA has adopted opinions on those 7 dossiers
  - Lead in Jewellery
  - DMFu in articles
  - 4 Phenylmercury compounds
  - mercury in measuring devices
- DK has submitted restriction dossiers for 4 Phtalates in 2011 (aim is to address potential combination effects)
- ECHA capacity to handle restrictions: 8 dossiers/year
REACH, results 3.5 years after entry into operation?

- **Registration** (after first registration deadline):
  - ~25,000 registration dossiers received by ECHA covering ~ 4,300 substances
  - Public dissemination of non-confidential data relatively slow

- **Evaluation**:
  - Dossier evaluation: one third of registration dossiers with quality deficiencies
  - Substance evaluation: starting in 2012 with ~ 30 substances/year

- **Authorisation**:
  - 73 substances on the Candidate List (out of 1500 possible SVHCs)
  - 6 substances on the Authorisation List
  - First applications for authorisation by industry expected in 2012

- **Restriction** (entry into force June 2009):
  - 7 opinions on restriction dossiers adopted by ECHA
  - Final decision by COM still pending
  - ECHA's capacity: ~ 8 dossiers/year
Classification, Labelling & Packaging (CLP) Regulation

- Criteria for C&L laid down in CLP Regulation to implement Globally Harmonised System.
- The CLP Reg (EC)1272/2008 entered into force in Jan 2009
- Industry to self-classify all substances or mixtures placed on market; some substances with EU harmonised classification (Annex VI of CLP Regulation)
- Industry to notify ECHA of all substances classified as hazardous by January 2011 (regardless of production volume)
- ECHA to maintain an inventory publicly available
- Industry to make all efforts to harmonise the C&L of substances, where there are differences
- C&L harmonisation by authorities (RAC/ECHA) required only for CMRs (cat 1,2 and 3) and respiratory sensitisers
State of play on the CLP Regulation ? (end Jan 2012)

Harmonised Classification and Labelling:
- 177 dossiers submitted by Member States
- 77 Public consultations completed
- 47 RAC opinions finalised
(i.e. White Spirit is Carc 1B, Mut 1B and neurotoxicant)
- ECHA capacity to handle CLH: 90 dossiers/year
- Annex VI of CLP planned to be updated once/year

C&L Notifications:
- 3.4 million C&L notifications received by ECHA
- covering a total of 114 000 individual substances
- Inventory of C&L available on ECHA website mid-February 2012
Timeline for transition to CLP provisions:

- **REACH entry into force:** 1 June 2007
- **Pre-registration period:** 1 June to 1 December 2008
- **First phase-in deadline:** 1 December 2010
- **Second phase-in deadline:** 1 June 2013
- **Third phase-in deadline:** 1 June 2018

### REACH timeline

- **All new substances and mixtures:**
  - 2007: Classified, labelled and packaged under DSD. If CLP is applied in full as well, no DSD labelling and packaging.
  - 2008:
  - 2009:
  - 2010:
  - 2011:
  - 2012:
  - 2013:
  - 2014:
  - 2015:
  - 2016:
  - 2017:
  - 2018:
  - **2019 onwards:** Classified, labelled and packaged under CLP.
- **Substances and mixtures ≥ 1000 tonnes per year or of very high concern:**
  - 2010:
  - 2011:
  - 2012:
  - 2013:
  - 2014:
  - 2015:
  - 2016:
  - 2017:
  - 2018:
  - **2019 onwards:** Substance and mixtures ≥ 25 tonne per year.

### CLP timeline

- **Substances:**
  - 2009:
  - 2010:
  - 2011:
  - 2012:
  - 2013:
  - 2014:
  - 2015:
  - 2016:
  - 2017:
  - 2018:
  - **2019 onwards:** Classified, labelled and packaged under DPD. If CLP is applied in full as well, no DPD labelling and packaging.

- **Mixtures:**
  - 2009:
  - 2010:
  - 2011:
  - 2012:
  - 2013:
  - 2014:
  - 2015:
  - 2016:
  - 2017:
  - 2018:
  - **2019 onwards:** Classified, labelled and packaged under CLP.

- **CLP entry into force; repeal of Annex I to DSD:**
  - 20 January 2009

- **Obligation to apply CLP to substances:**
  - 1 December 2010

- **Obligation to apply CLP to mixtures. Please note that for certain substances / mixtures the 2012 / 2017 deadline for re-labelling and re-packaging applies, cf. text above:**
  - 1 June 2015

3 January 2011: Deadline for notification to the C&L Inventory
European Chemicals Agency (ECHA)

- ECHA's main task is to manage the technical, scientific and administrative aspects of the REACH & CLP regulations
- January 2012, ECHA has a staff of ~ 500 people
- ECHA's budget 2011 was almost € 100 million
- From 2013, ECHA will also manage the implementation of
  - the new Biocides Regulation
  - the recast PIC Regulation on the export and import of dangerous chemicals
- ECHA aspires to become the world's leading regulatory authority on the safety of chemicals
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<th><strong>Trade Union representatives in ECHA's activities?</strong></th>
<th><strong>ETUI/ETUC</strong></th>
<th><strong>EMCEEF</strong></th>
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<tr>
<td>Management Board (+ dissemination AG)</td>
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<td>2011 - 2014</td>
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Trade Union Priority List for REACH Authorisation

- Constructive contribution to the choice of SVHC
- 334 high production volume chemicals
  - widely used at the workplace
  - ranked according to their eco-toxicological properties
  - linked to EU recognized occupational diseases
- If they are included in the candidate and authorisation list:
  - workers will get better information on their uses
  - development of safer alternatives will be promoted
  - occupational diseases will be reduced
- The TU list is available online: www.etuc.org/a/6023
Impact of the TU Priority List?

- 54 out of 73 substances currently on the Candidate List are also on the TU list
- 5 out of 6 SVHCs included in the Authorisation list are also on the TU list
- 131 substances in common with the Member States List
- Many inquiries from industry
Many companies still unaware of their obligations under REACH and CLP

ETUC/EMCEF awareness campaign with ECHA & EU-OSHA

Objective: use workers' reps to inform employers

“Call to action” leaflet available in 22 EU languages
Future trade union activities in 2012

- New awareness campaign ECHA/ETUC/EMCEF for workers’ reps in all sectors about next registration deadline May 2013 (foreseen in Q1 2012)

- New awareness campaign ECHA/ETUC for workers’ reps in downstream sectors about Chemical Safety Report obligations (foreseen in Q2 2012)

- ECHA’s workshop on the links between REACH and the EU Workers’ Protection Legislation (April 2012)
  - Synergies on risk assessment & substitution
  - OELs vs DNELs
  - Risk-based limit values (DMELs)
  - …
Conclusions & challenges for trade unions

REACH has the potential to improve health & safety at the workplace and reduce the number of occupational diseases and fatalities caused by hazardous chemicals provided that:

- awareness about this new legislation and its obligations
- use of the new data generated by REACH & CLP:
  - Extended Safety Data Sheets at the workplace
  - Data disseminated on ECHA’s website
  - Classification & labelling of hazardous chemicals
- synergies between OSH and REACH legislations
- substitution of the most hazardous chemicals
Thank you, further info on:

http://www.etuc.org > Our activities > REACH

http://www.etui.org/Topics/Health-Safety/Chemicals-and-REACH

http://echa.europa.eu