REACH rules & OSH rules: conflicts or synergies?

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Overview

- Background info on chemicals in the EU
- Main EU legislations relevant for hazardous substances
  - Classification & Labelling – CLP regulation
  - Marketing & use of chemicals : REACH regulation
  - Occupational Safety & Health (OSH) legislation
    a. Chemical Agents Directive
    b. Carcinogens & Mutagens Directive
- Conflicts or Synergies ?
  - Risk Assessment in REACH and OSH legislation
  - Limit values: IOELs vs DNELs
  - Substitution principle
- Conclusions
Why chemicals are key for workers and their representatives?

- 1.3 million workers in the EU chemical industry
- Millions of jobs in downstream sectors (building, textile, automotive, electronic, etc...)
- Chemicals contribute to the EU economic prosperity in terms of trade and jobs

But on the other side:

- 16% of workers in Europe declare to handle hazardous products and 22% to breath in toxic vapours (Dublin Fd, 2008)
- Around 30% of all occupational diseases recognised each year in EU are related to exposure to chemicals (ETUI, 2006)
- & up to 50% according to EU-OSHA (EU-OSHA, 2012)
- Over 100 000 work-related deaths per year in EU-28 due to exposure to hazardous substances (ETUI, 2014)
Main EU legislations on chemicals?

Marketing/Use of Chemicals
- CLP
- REACH

Protection of workers exposed to Chemicals
- Chemical Agents Directive
- Carcinogens Directive

Risks prevention & reduction
Classification, Labelling & Packaging (CLP) Regulation

- For all substances & mixture *marketed* in the EU
- Industry to self-classify all substances or mixtures placed on market
- some substances with EU harmonised classification (Annex VI of CLP Regulation) managed by European Chemicals Agency (ECHA)
REACH regulation (EU 1907/2006)

- **Registration**: Manufacturers and importers of chemicals > 1 tpa are required to register their substances to demonstrate they can be used safely (no data = no market)

- **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

- **1 Jun 2007**: REACH came into force
- **1 Jun 2008**: Pre-registration for existing (phase-in) starts
- **1 Dec 2008**: Existing phase-in substances registration
  - PHASE 1 Reg: CMRs - Carcinogens, Mutagens or Reproductive toxicants (≥1 tonne/year)
  - Very toxic to aquatic organisms (R50/53) (≥100 tonnes/year)
- **30 Nov 2010**: PHASE 2 Registration: 100-1000 tonnes/year
- **31 May 2013**: PHASE 3 Registration (before deadline: 31 May 2018): 1-100 tonnes/year
- **31 May 2018**: New "non phase-in" substances registration: No Registration? No Sell!
- **Immediate Registration for existing "Phase-in" substances which have not been pre-registered**: No Registration? No EU Sell!
Chemical Agents Directive (98/24/EC)

- **Aim**: protection of workers from risks related to chemicals at work

- **Scope**: all chemicals used at the workplace (regardless of volume)

- **Obligations for employers**:
  - Determine whether any hazardous chemical agents are present in the workplace
  - Assess any risk to the H&S of workers arising from their use
  - If risks do exist, mandatory hierarchy of prevention and protection measures (substitution > exposure reduction > protective equipment)
  - Monitor the workers' health
  - Comply with existing Occupational Exposure Limit Values (OELVs); up to now 121 substances with indicative OELVs at EU level
  - Keep risk reduction measures up to date
  - Provide information and training to workers
Carcinogens Directive (2004/37/EC)

- **Aim:** protection of workers from risks related to carcinogens and mutagens at work
- **Scope:** all carcinogens and mutagens (category 1A or 1B)
- **Main obligations for employers:**
  - Eliminate/Replace with a substance which is not or less dangerous (mandatory if the alternative is available & regardless of cost)
  - If substitution is not technically feasible, use a closed system
  - Reduce workers' level of exposure as low as is technically possible
  - Comply with Binding Occupational Exposure Limit Values (BOELVs) (benzene, vinyl chloride monomer and hardwood dust + soon ~20 additional substances ?)
  - Consultation and participation of workers on the measures to minimize exposure
Conflicts or synergies between REACH and EU OSH?

Some employers say OSH directives not needed anymore, to avoid duplications we only need REACH regulation but…..

REACH, Art 4 (2) : This Regulation shall apply without prejudice to Dir 89/391, Dir 98/24, Dir 2004/37, […]
Risk Assessment under CAD/REACH are complementary tool

<table>
<thead>
<tr>
<th>Chemical Agents Directive</th>
<th>CSA under REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>All hazardous chemicals present in the workplace (= irreversible of volume)</td>
<td>Chemical Safety Assessment only for chemicals &gt; 10t/y</td>
</tr>
<tr>
<td>Including process generated substances</td>
<td>Process generated substances outside scope</td>
</tr>
<tr>
<td>Workplace specific (holistic: including multi-exposure, non-chemical hazards,...)</td>
<td>Substance specific</td>
</tr>
<tr>
<td>Obligation on Employers</td>
<td>Obligation on the Manufacturer/Importer/ DUs</td>
</tr>
<tr>
<td>Provide information &amp; training to workers</td>
<td>Information &amp; training of workers outside scope</td>
</tr>
<tr>
<td>Chemical Agents Directive</td>
<td>CSA under REACH</td>
</tr>
<tr>
<td>----------------------------</td>
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<tr>
<td>Obligation to review the effectiveness of control measures</td>
<td>Obligation to communicate up the supply chain inappropriate RMM (information can only be obtained under OSH !)</td>
</tr>
<tr>
<td>Binding hierarchy of control measures</td>
<td>Non-binding hierarchy of RMM (in guidance only)</td>
</tr>
<tr>
<td>Health surveillance in line with national laws</td>
<td>Health surveillance outside scope</td>
</tr>
<tr>
<td>Indicative Occupational Exposure Limit Values (IOELs)</td>
<td>Derived No Effect Levels-DNELs</td>
</tr>
<tr>
<td>Obligation to comply with OEL</td>
<td>Obligation to comply with Risk Management Measures -RMM</td>
</tr>
</tbody>
</table>
Limit Values under CAD/REACH still under discussion…

<table>
<thead>
<tr>
<th>Indicative Occupational Exposure Limit Values (IOELs) under CAD</th>
<th>Derived No Effect Levels (DNELs) under REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health-based</td>
<td>Health-based</td>
</tr>
<tr>
<td>Developed by a Scientific Committee (SCOEL)</td>
<td>Developed by companies for their own substances &gt; 10 tpa</td>
</tr>
<tr>
<td>Adopted by a formal legislative procedures at EU level and transposed into national legislation</td>
<td>Adopted by companies as part of their registration dossiers</td>
</tr>
<tr>
<td>Used by employers at workplaces to assess and control workers’ exposure</td>
<td>Used by companies to implement the Risk Management Measure to ensure risks are adequately controlled</td>
</tr>
<tr>
<td>Obligation for employers to comply with the OEL</td>
<td>Obligation for companies to comply with the RMMs</td>
</tr>
<tr>
<td>Available for 121 substances ( ~600 substances with national OELs) and mentioned in SDS</td>
<td>Available for more than 10 000 registered substances and mentioned in SDS</td>
</tr>
</tbody>
</table>
## Comparison of EU IOELVs with long-term worker DNELs (1)

Table adapted from Tynkkynen et al, Ann. Occup. Hyg., 2015, 1-15

<table>
<thead>
<tr>
<th>Substances</th>
<th>CAS number</th>
<th>IOELVs (TWA 8h) mg/m³</th>
<th>DNEL (workers, long-term exposure) mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloroform</td>
<td>67-66-3</td>
<td>10</td>
<td>2,5</td>
</tr>
<tr>
<td>1,2-Dichlorobenzene</td>
<td>95-50-1</td>
<td>122</td>
<td>10</td>
</tr>
<tr>
<td>2-Ethoxyethanol</td>
<td>110-80-5</td>
<td>8</td>
<td>0,083</td>
</tr>
<tr>
<td>Toluene</td>
<td>108-88-3</td>
<td>192</td>
<td>192</td>
</tr>
<tr>
<td>Cyclohexane</td>
<td>110-82-7</td>
<td>700</td>
<td>700</td>
</tr>
<tr>
<td>Ethylacrylate</td>
<td>140-88-5</td>
<td>21</td>
<td>21</td>
</tr>
<tr>
<td>Chlorobenzene</td>
<td>108-90-7</td>
<td>23</td>
<td>23/42,3*</td>
</tr>
<tr>
<td>Heptan-2-one</td>
<td>110-43-0</td>
<td>238</td>
<td>394</td>
</tr>
<tr>
<td>Oxalic acid</td>
<td>144-62-7</td>
<td>1</td>
<td>4,03</td>
</tr>
</tbody>
</table>

* Two registrations giving different DNELs
Trade union views on substance with both an OEL* and a DNEL

- **Case 1: DNEL is lower than OEL:**
  - If based on the same data, a difference is not surprising due to different methodologies (AF or expert judgment). Either the DNEL or the OEL can be used.
  - If based on different data (new data), the DNEL has to be used and the OEL has to be revised.

- **Case 2: DNEL is higher than OEL**
  - DNEL derivation should be checked for compliance by ECHA and the OEL might need to be revised.
  - If the OEL is binding at national level it has to be complied with.

(*): valid for OELs derived either at EU or national level by Scientific Cttees
REACH authorisation: main aim is substitution of SVHC

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

Candidate List
Information obligations for suppliers
161 substances

Authorisation List (Annex XIV)
Prioritisation
Substance can no more be used without authorisation
31 substances

http://www.echa.europa.eu/web/guest/candidate-list-table
Granting authorisations – The 2 routes

Application (substance & use specific)

- risks adequately controled
  - NO
  - YES Adequate control route

- socio-economic benefits > risks
  - NO
  - YES AND
    - no alternatives

Authorisation granted

Authorisation NOT granted
Possible conflict between REACH & OSH on substitution

- Under REACH, authorisations for continued use of carcinogens & mutagens can be granted despite the availability of safer alternatives (under the adequate control route or under socio-economic route when alternatives are technically feasible but economically infeasible)

- Under the Carcinogens & Mutagens Directive, there is an obligation to substitute when safer alternatives are available & technically feasible (no cost consideration)
Applications for authorisations so far (Feb 2015)?

ECHA opinions in favor of granting the authorisations:

<table>
<thead>
<tr>
<th>SVHC</th>
<th>Classification</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEHP</td>
<td>Repr 1B</td>
<td>Socio-economic</td>
</tr>
<tr>
<td>DBP</td>
<td>Repr 1B</td>
<td>Socio-economic</td>
</tr>
<tr>
<td>Diarsenic trioxide</td>
<td>Carc 1A</td>
<td>Socio-economic</td>
</tr>
<tr>
<td>Lead (sulfo)chromate</td>
<td>Carc 1A &amp; Repr 1B</td>
<td>Socio-economic</td>
</tr>
<tr>
<td>HBCDD</td>
<td>PBT</td>
<td>Socio-economic</td>
</tr>
<tr>
<td>Trichloroethylene</td>
<td>Carc 1B</td>
<td>Socio-economic</td>
</tr>
</tbody>
</table>
Conclusions

- REACH/CLP and OSH legislations share the objective of protecting workers exposed to chemicals
- Synergies between REACH/CLP and OSH are more likely than conflicts
- REACH/CLP will enhance the effectiveness of OSH legislation
- The data generated by REACH will foster a better knowledge of the properties of chemicals, their effects on human health and ways of reducing risk during their use (better quality labelling and Safety Data Sheets)
- Authorisation and Restriction procedures in REACH will progressively promote the substitution of the most harmful substances by safer alternatives
- Training of workers and employers is key for effective use of the data generated by REACH/CLP and working out synergies with OSH legislation
Thank you, further info on:

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

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