The role of the EU directive REACH in health protection of workers

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What is REACH?

**Registration, Evaluation, Authorisation and Restriction of Chemicals**

- A regulation of the EU → to improve the protection of human health and the environment from the risks that can be posed by chemicals
  - enhancing EU chemical industry competitiveness
  - promotes alternative methods for the hazard assessment → to reduce animal testing
- Entered into force in 2007
Why REACH?

- Large number of substances manufactured and placed on the market in Europe for many years
  - ...sometimes in very high amounts
- Yet, insufficient information on hazards for human health and environment!

A need to fill these information gaps → industry has to:
- assess hazards and risks
- identify and implement the risk management measures to protect humans and the environment
“No data, no market!”
REACH processes

- Registration
- Evaluation
- Authorisation
- Restriction …of chemicals

The central point in the REACH system

- co-ordinates evaluation of chemicals
- Committees:
  - Risk Assessment Committee (RAC)
  - Socio-Economic Analysis Committee (SEAC)
REACH processes - Registration

- Manufacturers and importers of substances → obligation to submit a registration to ECHA (Registration dossier) for substances manufactured or imported in ≥1 tonne / year

- Registration dossier → ECHA and Member States evaluate:
  - quality of Registration dossier
  - justification for additional testing
  - risk to human health or environment

REACH principle:
Manufacturers, importers and downstream users have to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or environment
What to do with substances hazardous for human health or environment?
- Substance of Very High Concern (SVHC)

RESTRICTION OR AUTHORISATION
What to do with substances hazardous for human health or environment?
- Substance of Very High Concern (SVHC)

RESTRICTION
Limit or ban for manufacture, placing on market or use of a substance on EU level

OR

AUTHORISATION
REACH processes - Authorisation

- Industry applies for authorisation for placing on the market or use of SVHC substance:
  - chemical safety report
  - analysis of the possible alternatives and substitution plan
  - (SEA)
Authorisations granted if:

- applicant demonstrates adequately controlled risk
- socio-economic benefits of using the substance outweigh the risks and there are no suitable alternatives, even if the risk is not adequately controlled

<table>
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<th>Year</th>
<th>Received notifications to submit</th>
<th>Pre-submission information sessions held</th>
<th>Received(^1) applications (applicants)</th>
<th>Number of uses</th>
<th>RAC-SEAC opinions per use(^2)</th>
<th>RAC-SEAC opinions per use and per applicant(^3)</th>
<th>Commission decisions per use and per applicant(^4)</th>
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*) Situation as of 23 September 2015.

Bis(2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP), Diarsenic trioxide
REACH in health protection of workers

REACH

- Encourages/ensures that substances of high concern are eventually replaced by less dangerous substances or technologies

- Improves quality of risk assessment
  - higher quantity and quality of data used in assessment
  - review process of registration dossier in ECHA

- Improves quantity and quality of information on chemicals which are employers obliged to give to the employees
REACH in health protection of workers

EU to date set only a limited number of OELs

E.g. among recognised occupational carcinogens…

- Carcinogens with binding values
  - inorganic lead and its compounds
  - benzene
  - vinyl-chloride monomer (VCM)
  - hardwood dust
  - asbestos
REACH in health protection of workers

Very often no workplace measurements are performed

In Germany

1-2%

Workplaces with air monitoring
REACH: Exposure assessment in authorisation process

Exposure assessment

Applicant’s information

Databases, published data...

Air monitoring data

Computer models
Efforts to ensure high level of protection!

**NOAEL** = no adverse effect level
- Lowest value in the most sensitive species

**Assessment factor:** default **50**
- 10 for interspecies differences (e.g. rodents to humans)
- 5 for intraspecies differences (for workers)

Substances without threshold = no NOAEL, but…

**Highest acceptable risk** → disease probability: 1 per 10,000 workers
- **REACH** = continuously evolving legislation…
- **REACH processes** (Registration, Evaluation, Restriction, Authorisation) → learning through experience
  - improved efficacy of the processes
  - new guidances → more consistent approach
  - greater transparency to Industry representatives…
Hvala Vam na pažnji!

There is only one thing more painful than learning from experience, and that is not learning from experience.

Laurence J. Peter