ECHA contribution to OSH regulation

Roadmap on Carcinogens Conference
“Working together to eliminate occupational cancer”

27-28 November 2019
Helsinki

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Carcinogens under REACH and CLP

- REACH generates data on chemicals, e.g., mutagenicity, reproductive toxicity and carcinogenicity
- CLP classifies substances which have data as mutagens, reproductive toxins and carcinogens
- OSH uses the data and classification to protect workers
Integrated regulatory strategy

from ECHA’s Integrated Regulatory Strategy Annual Report
Integrated regulatory strategy

~400 registered; all scrutinised, further action taken or ongoing
Also covered:
- Substances containing carcinogenic impurities.
- Structurally similar substances.

28 require authorisation

1245 harmonised classification
83 in Candidate List of substances of very high concern
The chemical universe
- mapping the REACH chemical space

A mapping tool to support the Integrated Regulatory Strategy (snapshot from May 2018)

ECHA. europa.eu
The chemical universe
- mapping the REACH chemical space

Where we want to be in 2020!

echa.europa.eu
Grouping of substances

- Objectives
  - *Accelerate* data generation and *intensify* identification of substances of concern and
  - *Accelerate* regulatory action of substances of concern.
    - The time from identification of concern to (final) regulatory risk management as short as possible.
ECHA’s contribution to OEL

- DG EMPL decides on substances, consulting WPC, other services and ECHA
- ECHA secretariat develops scientific base for OEL
- ECHA RAC develops opinion
- Package handed to DG EMPL for WPC discussion
Processing OELs (Commission)

Setting of OELs for carcinogens at EU level follows the ordinary legislative procedure
(For Indicative OELs a lighter legislative procedure applies)

1. Selection of chemicals for Scientific Evaluation
   DG EMPL establishes lists of priorities for scientific evaluation based on inputs from various sources and application of priority criteria.

2. Scientific Recommendation
   DG EMPL issues mandates to scientific committee, who will deliver as a rule the exposure-risk-relationships (ERR) for non-threshold carcinogens, or a practical threshold when possible. Scientific Recs are subject to external consultation before adoption.

3. WPC - ACSH
   The Working Party on Chemicals (WPC) discusses the scientific Recommendation and various feasibility issues and comes up with a consensus based suggestion for the OEL value. This is integrated in a draft opinion for adoption by the Plenary of ACSH.

4. Impact Assessment (IA)
   DG EMPL drafts IA containing policy options and associated impacts. IA is discussed within an Interservice Steering Group and submitted to the Regulatory Scrutiny Board (RSB). A positive reply is required.

5. Draft legislative proposal
   DG EMPL prepares the draft legislative proposal and submits it to inter-service consultation. Thereafter, a final draft legislative proposal is prepared.

6. College of Commissioners
   The College of Commissioners adopts the proposal and sends it to Council and Parliament for negotiation and subsequent adoption. As a Directive.

   MSs will transpose the legal text into national legislation by the date set in the Directive.

*2 stages of social partners' consultation have to be carried out in accordance with Article 154 of TFEU
ECHA process for OELs

Steps in ECHA’s process:

a. Request from the EU Commission
b. Call for evidence
c. ECHA Scientific Report
d. Public consultation
e. Risk Assessment Committee opinion

This process is equivalent to steps 1 and 2 in the EU Commission process

Next step:

⇒ Commission Decision process
ECHA process - timeline

- Request from EC
- Call for evidence: Optional call for evidence to collect additional literature and evidence for the preparation of the scientific report
- Submission of the scientific report
  - Public consultation: Mandatory 60-day public consultation on the scientific report
  - Preparation of the scientific report
- 12-24 months
  - RAC develops opinion
  - The scientific report becomes background document for RAC
- Draft RAC opinion
- Final opinion published
- Publication in the Official Journal

* When a substance is evaluated under the Chemical Agents Directive (CAD) and the occupational exposure limit is indicative, the decision is made by the European Commission

** When a substance is evaluated under the Carcinogens and Mutagens Directive (CMD), the decision is made in agreement between the Council and the European Parliament based on a proposal put forward by the European Commission
Pilot Project - 5 substances in 2018
• Arsenic acid and its salts
• 4,4'-methylene-bis(2-chloroaniline) – MOCA
OELs adopted & published June 2019: Dir 2019/983
• Nickel and its salts
• Benzene
• Acrylonitrile
OELs adopted by ACSH June 2019; Draft legislation proposed to Council and Parliament

Under Service Level Agreement (SLA) between Commission and ECHA
• The requests/substances are decided by Commission/DG EMPL.
• 2 substances in 2019:
  • Lead and its compounds
  • Diisocyanates
• Proposed 2 substances for 2020:
  • Cadmium and its inorganic compounds
  • Asbestos
• SLA to be reviewed/renewed in 2021/2022.
REACH Authorisation and Restrictions in promoting substitution of carcinogens

- REACH Authorisation implements OSH substitution of mutagens, reproductive toxins and carcinogens by mandatory analysis of alternatives and proper control of risks
- REACH Restrictions sets timelines for substitution where workers are at risk
REACH Authorisation and Restriction

- REACH Authorisation and Restriction processes are powerful tools to promote substitution of substances of concern, including carcinogens.

  - E.g. **Applications for Authorisation: Cr(VI)**
    Innovative alternative developed: **RotoHybrid**: a Diamond-Like Carbon coating process for press gravure printing cylinders.

  - E.g. **Restrictions: 1,4-dichlorobenzene** in air fresheners and toilet blocks.
    Safer alternatives: existing safer consumer products, technical alternatives such as more frequent cleaning, automatic flush toilets, greater ventilation.
Hexavalent chromium (Cr(VI)): Exposure reduction in surface treatment supporting the attainment of OEL

Based on CrVI compounds in 97 samples in 11 sites in France 2010-13 (Vincent et al. 2015)

- Applicants committed to reduce exposure to 2 μg/m³ or even lower (current OEL is 10 μg/m³ going to 5 μg/m³)
- Authorisation requirement clearly supports the attainment of the OEL
Safe use in the supply chain

- REACH requires a chemical safety assessment, incl. maximum exposure levels for workers: What risk management is needed beyond C&L?
- REACH requires this info be communicated to employers in a Safety Data Sheet
- OSH uses the info for employer risk management
Basic pillars of chemicals legislation

Safe use of chemicals

Knowledge

Regulatory action
“10%” of substances

Communication in supply chain
Information on uses
Hazard
Use restrictions
Safe use advice
From fulfilling information requirements to safe use

4200 substances
~ 34,000 ext SDS

Safe use

ext-SDS mixture

REACH Annex II

ext-SDS substance

REACH Annex I

Exposure/Risk Assessment

REACH Annex I
CLP

Hazard Assessment

Classification
DNEL; PNEC

Substance use & property Info

REACH Annex VI-X

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What to do?

• Demonstrate concretely how REACH can satisfy OSH employer information needs => Make system effective.
• Develop minimum requirements for exposure scenarios
  • Commission open to make them binding.
  • Supports one holistic [coherent] system for generation and communication by all actors in the supply chain => Synchronise the system.
• Prepare the ground for digitalisation of safety data => Make system efficient.
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