Streamlining the interface between REACH and OSH

Working together to eliminate occupational cancer

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II REACH Review

Legal obligation for the Commission to review the functioning of REACH every 5 years

Information sources

- Member States reports – June 2015
- ECHA reports – June 2016 (functioning of REACH), 2014 and 2017 (alternatives to animal testing)
- 16 thematic studies carried out between 2014 and 2017
- Stakeholder views
- Experience gained through implementation
II REACH Review. Key findings

After 10 years REACH is fully operational and delivers results:

- A comprehensive data set on substances
- Progress in phasing out SVHC
- Improvement of the RMM at the workplace
- Improvement of communication in the supply chain
- ECHA plays a key role on REACH implementation
Interface REACH and OSH legislation

- The use of substances’ information through the supply chain
- The authorisation and restriction processes vs the principles of OSH
- The establishment of DNELs and OELs
- The enforcement obligations of REACH and OSH at national level
RRA 12. REACH and OSH interface

(1) How to use REACH tools to enhance the effectiveness of OSH legislation.

(2) Improve the coordination of national enforcement authorities of REACH and OSH legislation.

(3) Align methodologies to establish safe levels of exposure to chemicals at the workplace by first quarter 2019.

(4) Enhance the role of RAC, involving also social partners, to provide scientific opinions under the OSH legislation while respecting the role of the ACSH.
RRA 12.1. REACH tools enhancing OSH effectiveness

- SDS: Improving the workability and quality of SDS through RRA3
- ES: COM will set minimum requirements for ES
- SMEs: RRA 14: Supports SMEs compliance
- SVHC: RRA 5: Promote substitution of SVHCs
- RMOA: A case-by-case substance analysis carried out by MS or ECHA
RRA 3. Improving workability and quality of eSDS

Why?

Information is too lengthy and technical for SMEs

Difficulties for formulators responsible of mixtures’ SDS

Need of harmonised formats

Need of IT tools to facilitate dissemination
RRA 3. Improving workability and quality of eSDS

(1) COM, ECHA and stakeholders are developing harmonized formats and IT tools to provide more user-targeted information and to facilitate the SDS’s preparation and distribution.

(2) COM will set minimum requirements for ES in SDS and request ECHA to develop a methodology for mxSDS.
RRA 3. Improving workability and quality of eSDS. Way forward

I. Scoping phase. To collect potential solutions to improve eSDS

II. Development phase. To develop the basis for the potential new, more efficient and workable solutions

III. Consultation phase. Formal consultation on selected solutions
RRA 3. Improving workability and quality of eSDS. Scoping phase

- Strong need for digitalisation
- Requests for mandatory regulatory requirements for exposure scenarios in eSDSs
- No alternatives identified for the proposed holistic approach
- Need to match better information with end user needs
RRA 12.2. Improving the coordination of National Enforcement Authorities

- A Forum WG Survey on OSH-REACH enforcement interactions was established at the Forum 31 with a mandate to prepare, send and process such survey.

- To support COM in understanding how enforcement is coordinated in MS when there are interactions.
- To determine if further actions are needed (i.e. joint training).

- 31 countries have sent their contribution.
- The report is under preparation and will be submitted soon to the Forum, SLIC WG CHEMEX and COM for consultation.
RRA 12.2. Improving the coordination of NEAs. Survey on enforcement.

Main challenges at national level

- lack of resources (e.g. lack of inspectors or time)
- lack of knowledge of the other piece of legislation
- different priorities for each authority
- lack of availability of training on REACH/OSH interactions

Good practices for cooperation between inspectors

- joint inspections
- trainings on REACH/OSH interactions
- regular meetings between enforcement authorities
- mentoring between REACH/OSH inspectors
RRA 12.3. Alignment of methodologies

- In 2015, COM requested RAC and SCOEL to make a comparative assessment of the scientific methodologies for delivering OELs and DNELs

- As part of the RRA12, COM requested ECHA to align its methodology accordingly.

- Guidance for preparing a scientific report for health-based exposure limits at the workplace
RRA 12.3. Alignment of methodologies
Part I. Findings of the ECHA/RAC-SCOEL Joint Task Force on alignment of methodologies related to the exposure of chemicals at the workplace, including the inhalation and dermal routes, and in particular carcinogens with or without a threshold.

Part II. How to prepare a scientific report for health based exposure limits at the workplace in accordance with the Joint Task Force reports.
RRA 12.3. Alignment of methodologies. Synergies found in the JTF

The use of human data in setting workplace limits

The use of uncertainty or assessment factors (UF, AF)

Sensory irritation

Dermal risk assessment and skin notation

Mode of Action based thresholds for genotoxic carcinogens
DG EMPL and ECHA have signed a Service Level Agreement for the Agency to provide scientific evaluations of selected substances under OSH.

These scientific evaluations shall, where appropriate, include proposals for OELs, BLV and/or notations.

The agreement requires ECHA to assess four to five substances per year from 2020 onwards.

ECHA has recently strengthened RAC’s expertise on OSH with newly co-opted members.
RRA 12.4. RAC to prepare OSH recommendations

- **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
- **12-24 months**
  - Preparation of the scientific report
  - The scientific report becomes background document for RAC
  - RAC develops opinion
  - RAC finalises opinion
- **Draft RAC opinion**
- **Final opinion published**
- **Publication in the Official Journal**

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Conclusions and way forward

The **challenges on communication** of safe use of chemicals in the **supply chain** will be tackled by an holistic approach.

The **enforcement interactions** could be tackled at national level by following the recommendations of the Forum WG.

Having **one common source for scientific advice** under REACH and OSH will ensure coherence and transparency.

**ECHA** will continue playing a key role in the implementation of the two sets of EU legislation ensuring worker’s protection to chemicals.
90
Thorium
232.03806

79
Gold
196.966569

7
Nitrogen
14.0067

19
Potassium
39.0983

39
Yttrium
88.90585

8
Oxygen
15.9994

92
Uranium
238.02891