REACH and OSH Legislation: Advancing Safe Chemical Handling Through Occupational Hygiene Expertise

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Executive Summary

Both REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) and the traditional Occupational Health and Safety (OSH) legislation deal with the control of hazardous chemicals in the workplace. This document explores the interaction between these two key pieces of legislation from the prospective of EPOH, the European Platform for Occupational Hygiene.

Occupational hygiene (OH) is the science and art of anticipation, recognition, evaluation, control of risks associated with exposures to health hazards in, or arising from, the workplace.

REACH had a positive impact on Occupational Hygiene thanks to several achievements, including comprehensive toxicological assessments, improved access to information, generation of health data for previously unstudied chemicals, and effective elimination of hazardous substances through restrictions and authorizations.

However, there are also areas that could be improved. This document provides recommendations for improving the effectiveness of REACH and its impact on health risk reduction:

- Experts in occupational hygiene should be involved both in the preparation of the exposure scenarios and in their implementation from downstream users. Expert involvement is of the uttermost importance to avoid putting at risk workers health. When experts are involved, and provided that certain conditions are respected, the chemical risk assessment compliant with Occupational Health and Safety legislation should be formally recognized as an acceptable alternative to REACH scaling and exposure scenario compliance checks.
- Health and safety professionals would benefit from additional guidance on some of the REACH concepts. Among other, it appears necessary to provide clarifications on how end-users can assess the quality of some of the REACH data such as DNELs and DMELs, for instance when these values have not been reviewed by ECHA or are thought to be outdated. Clarifications should also specify what action can be undertaken in case some data is

considered unreliable. Occupational Hygiene professional Associations may play a role in REACH education if adequately supported by authorities.

Introduction

The European Platform for Occupational Hygiene (EPOH) is an exchange board for all European associations of Occupational Hygiene professionals.

EPOH aims at:

- Creating more visibility of OH as a profession at European level;
- Promoting the harmonization of OH related methods, standards, guidelines;
- Serving as a contact point and discussion partner for European institutions;
- Contributing to schemes of training, qualification or certification in OH in the context of a common EU regulation;
- Exchanging OH knowledge and practical field experiences;
- Strengthening the communication and cooperation between the different European associations.

Occupational Hygienists are experts in the assessment and control of chemical risks. Occupational hygienists are therefore the best placed to provide feedback on the effectiveness of the legislation in controlling the risks to workers' health.

This document focuses on the interaction of two co-existing pieces of legislation:

- REACH, the European regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals;
- Occupational Health and Safety (OSH) legislation, particularly the CAD and CMRD directives: these directives date from before REACH, and have defined the legal framework and main obligations for controlling health hazards at work; these directives have been and are being frequently updated.

The REACH regulation addresses the safe use of chemicals not only in the workplace, but in every context, from consumers use to environmental impact. The two pieces of legislation, REACH and OSH, interact mainly in the control of hazardous chemicals in the workplace, which is the focus of this position paper. Because of that, this document will not cover consumer risk and other REACH aspect not related to workplace hazards. In addition, this document will not address REACH and OSH implications in terms of environmental risk control.

REACH main achievements for the OH discipline

The objectives of the REACH regulation are to:

- ensure a high level of protection of human health and the environment against harmful chemicals;
- assess the safety of chemical substances in use in the EU;
- promote innovation and competitiveness;
- promote alternative (non-animal) methods for the assessment of the hazards of substances (1).

REACH entered into force in 2007, and it has been progressively implemented over the subsequent years. Some 15 years later, EPOH believes that most of the original objectives have been achieved, although experience also shows that some elements could deserve to be better addressed or clarified.

The following successes of REACH have been the most important for the safe use of chemicals in the workplace, according to the EPOH:

- The leading principle "no data no market" has led to comprehensive toxicological assessments of chemicals. Many formerly unknown hazards could be identified and consequently many more evaluation criteria were set (mainly DNEL[1]). These are essential in conducting objective risk assessments. Furthermore DNEL/DMEL were also derived for skin exposure, providing for the first time a large data set of criteria for this exposure route.
- REACH, mainly through the ECHA portal, enabled the easy access to a broad range of information; this includes data that are required in the risk assessment process and can help improving workers' health protection;
- REACH co-exists with and complements the CLP (Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging). Together, these regulations support and significantly enhance the harmonization of hazard identification[2];
- The REACH restrictions and authorisation processes have played a major role in strengthening the risk management practices and enhanced the overall effectiveness of risk assessment. As part of the restriction process, the ban of certain hazardous substances effectively minimized risks (8).
- The implementation of strictly controlled conditions for granted exemptions has contributed to improved worker safety when these chemicals are used, though challenges remain in ensuring consistent application.

[1] DNEL (Derived No Effect Level): The maximum level of exposure to a chemical substance below which no adverse health effects are expected for humans. It is a key parameter used in REACH risk assessments to ensure worker and consumer safety.
DMEL (Derived Minimal Effect Level): Similar to DNEL, but applied to substances that are genotoxic carcinogens. It represents a level of exposure associated with a low, but measurable, risk of adverse effects.

[2] However inconsistencies still persist for chemicals that are out of scope or due to self-classifications of manufacturers

Recommendation for improvement

Expert involvement and Priority to OSH risk assessment

An exposure scenario is a set of conditions that describes how the substance is manufactured or used during its life-cycle and how the manufacturer or importer recommends to control exposures of humans and the environment. Risk Assessment for each exposure scenarios must be generated for chemicals that meet certain criteria, particularly the higher tonnages.

Users of chemicals that receive an extended safety data sheet (e-SDS) with exposure scenarios need to verify whether their intended use and conditions of use match the conditions described in the exposure scenarios. If that is not the case, users have several options, that range from substitution to modifying the way the substance is used and to submitting their own Chemical Safety Assessment (CSA).

When executed properly, this process is, however, complex and resources consuming.

At the same time the control of compliance with the REACH exposure scenarios, does not exempt neither a formulator nor the end user from the obligations of the OSH risk assessment.

In the present state, the OSH risk assessment and compliance check against Exposure Scenarios may yield to different conclusions for the same chemicals and uses, because:

a) different risk assessment tools are used and
b) different standards are used to judge the acceptability of risk; notably, REACH uses DNEL/ DMEL whereas OSH uses OEL. Both are levels of exposure to a substance above which humans should not be exposed, but they are derived at different times through separate processes; even though the derivation steps are similar, the actual values may differ significantly, depending on when and how well the values were derived. Furthermore OELs take into account feasibility and socio-economic factors, which are not considered in REACH. The assessment of the quality of both values should be the subject of advice.

The REACH directive does not seem to clarify how to handle these differences, at least not entirely.

OSH risk assessments have structurally a wider scope than REACH risk assessments, because some elements covered by OSH are out of scope of REACH or only partially in scope:

- Some chemicals (such as pharmaceutics or cosmetics) are exempted from REACH as they are in scope of separate pieces of legislation.
- Natural occurring chemicals are exempted from REACH.
- REACH only partially deal with substances released during chemical processes[3] (such as welding fumes and wood dust) or formed in an accidental or uncontrolled manner.
- REACH currently does not deal with risks that are simultaneously present on the workplace, such as exposures to combinations of chemicals with synergistic effects. Likewise, the

[3] Substances released during normal uses are covered bur limited information is available in the safety data sheet

simultaneous presence of chemicals and physical hazards is not taken into account, although in some cases it may be relevant (e.g.: ototoxic substances).

- The so-called SUMIs (Safe Use of Mixtures Information) are an alternative to exposure scenarios for mixtures of chemicals placed on the market. However, SUMIs are seldom available. Due to the challenges posed by upstream communication, they tend to be too generic.
- REACH does not require confirmation of the effectiveness of the control measure in place over time (e.g.: with exposure measurements).
- REACH does not provide sufficient information on what is exactly required as exposure control for substances under strictly controlled conditions.
- OSH regulation put a higher emphasis on the hierarchy of controls compared to REACH (7).
- Above all, REACH assessments are, by their nature, generic risk assessments by the manufacturer, that need to be adapted to actual workplaces. Exposure scenarios do not and cannot take into account the specificities of each individual workplace nor the interaction of humans with the workplace. Human behaviour may substantially modify the exposure levels.

Some law enforcers accept the OSH risk assessment as an alternative to the REACH compliance checks. For instance (6) states:

> *If you can demonstrate that your existing control measures, derived according to your CAD risk assessment, are sufficient to achieve the DNEL communicated in the extended safety data sheet, you do not need to apply the risk management measures recommended therein where they differ from your own measures.*

The EPOH recommends formal recognition that the chemical risk assessment compliant with the OSH legislation is a sufficient and acceptable alternative to REACH scaling and exposure scenario compliance check[4], provided it demonstrates that the risk is controlled.

For that to be possible, a number of conditions would need to apply:

1) the OSH assessment would need to be specific to the workplace chemicals and conditions;
2) an expert in chemical risk assessment such as an occupational hygienist has to be involved. the expert must be also familiar with the REACH approach;
3) the OSH risk assessment follows good occupational hygiene practices, including hazard identification for each chemical and targeted exposure assessment for each relevant task, using a combination of modelling and measurement techniques;
4) the OSH assessment shall consider all information provided by the supplier;
5) the assessment must show compliance with all applicable occupational exposure limits (OEL, DNEL/DMEL).

While we suggest that the OSH assessment can replace REACH compliance checks under the conditions discussed above, this would not exempt from compliance with other REACH

[4] It is reminded that environment as well as exposure of general population are out of scope of this paper. Hence this statement should be read as applicable only to the scaling and compliance check related to exposures to chemicals of the working population.

obligations, such as authorisation, restrictions, checking for uses advised against, and ensuring effective upstream communication.

The involvement of sufficiently skilled and knowledgeable risk assessors appears fundamental for ensuring that health hazards are correctly identified and controlled both in editing and verifying compliance with exposure scenarios. Errors in the exposure scenarios can lead to insufficient risk management measures, directly endangering workers' health. Occupational hygienists, with their specialized expertise, play a pivotal role in identifying such errors and taking appropriate actions, including contacting the manufacturer.

Likewise, errors in implementing exposure scenarios may lead to serious consequences in workers' health. Occupational hygienists help preventing such mistakes by applying robust and evidence-based methodologies to risk assessment.

Collaboration with other stakeholders, such as labour inspectorates, industry associations, academic institutions, and trade unions, further strengthens the overall effectiveness of risk management practices. Occupational hygienists are the best positioned to facilitate these exchanges due to their technical background and risk communication skills.

A workplace risk assessor dealing with chemicals has to apply traditional occupational hygiene methods as well as to be familiar with REACH and the information provided though that channel; the assessor needs to be familiar with and be able to utilise all risk assessment methods, ranging from exposure measurement to modelling – as for many substances there are no validated measurement options.

In some cases, it may be necessary to apply "expert judgement" to assess the acceptability of exposures. Examples include substances without sufficient toxicological data, or situation which are obviously not a concern and do not need to be assessed.

The primary aim is to ensure that exposure assessment is carried out in all situations that are critical to the health of workers, and that sufficient protective measures are in place to control the risks of the hazardous chemicals handled in the workplace. This is the core task of an occupational hygienist and requires extensive training to be mastered.

Competency certificates, such as those provided by national occupational hygiene associations, would be a way to demonstrate sufficient skill and knowledge.

Increased Education and Guidance

The amount, quality and importance of data available in REACH dossiers has not been fully recognised by many health and safety professionals. These professionals would benefit from trainings on how to use the available information.

Experience also suggests that many downstream users, including many health and safety professionals, have a rather limited awareness of some of the REACH obligations. This concerns mainly a) the exposure scenarios, b) the need for upstream communication, c) the general requirements related to DNELs/DMELs. Guidance and education of health and safety professionals

would be greatly beneficial in achieving a better implementation of these requirements and ultimately a better protection of workers.

At the same time, it should be recognised that for many occasional end users of chemicals, these obligations are too complex to understand and comply with. Nonetheless the health and safety managers of end users would benefit from basic trainings on the key concepts of REACH, such as what is a DNEL/DMEL and why it is important for them.

In that respect, several needs for education and guidance were identified:

- need for clarity in the enforcement rules and topics from labour inspectorates;
- need for guidance and/or IT-tools for the application of all the information available at the workplace;
- need to relaunch and enforce the electronic SDS (machine readable SDS);
- need for guidance on what REACH and OSH data can be trusted; for instance, OELs and DNELs/DMELs could be evaluated based on criteria such as the date of their last update, the involvement of experts and the review from the ECHA, the underlining studies and the application of assumptions and assessment factors.
- EPOH also welcomes further discussion between REACH experts and OSH experts on synergies and opportunities for improvement. Health and Safety professionals, particularly occupational hygienists, can contribute significantly to the discussion.

EPOH members consider that additional guidance and, more broadly, education would be beneficial to address some of the issues identified.

Health and safety professional associations such as national occupational hygiene associations may play a major role in educating the community. These associations regularly arrange initiatives for continuous professional development, and a share of those could be dedicated to REACH literacy.

Authorities (European and national) would however need to support these initiatives via a “train the trainer” approach, by providing material and access to support resources, as well as via a recognition of the role that would be played by professional associations.

Acronyms

- CAD: Chemical Agents Directive
- CLP: Classification, Labelling and Packaging
- CMRD: Carcinogens, Mutagens and toxic for Reproduction Directive
- CSR: Chemical Safety Report
- DMEL: Derived minimal effect level
- DNEL: Derived No Effect Level
- DU CSR: Downstream User Chemical Safety Report
- ECHA: European Chemicals Agency
- EPOH: European Platform for Occupational Hygiene
- ES: Exposure Scenario
- eSDS: extended SDS
- EU: European Union
- OEL: Occupational Exposure Limit
- OH: Occupational Hygiene
- OSH: Occupational Health and Safety
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- SDS: Safety Data Sheet
- SUMI: Safe Use of Mixtures Information

References

(1) REACH Regulation – description by the EC: https://environment.ec.europa.eu/topics/chemicals/reach-regulation_en#:~:text=The%20REACH%20Regulation%20aims%20to,promote%20innovation%20and%20competitiveness, accessed on 13th April 2023.

(2) How to prepare a downstream user chemical safety report – Guidance by ECHA: https://echa.europa.eu/documents/10162/13655/pg17_du_csr_final_en.pdf/03aeab25-405a-45a4-9a66-5fa5c2dbfcb2, accessed on 14th April 2023.

(3) GUIDANCE for National Labour Inspectors on the interaction of the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) (Regulation (EC) No. 1907/2006), the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD), Senior Labour Inspector's Committee (SLIC), November 2013

(4) ECHA yearly Progress in Evaluation reports, accessed on 16th April 2023 and available here: https://echa.europa.eu/progress-in-dossier-evaluation

(5) EPOH position paper "REACH and Occupational Hygiene", October 2018

(6) "Guidance for employers on controlling risks from chemicals - Interface between Chemicals Agents Directive and REACH at the workplace" developed by the Advisory Committee for Safety and Health at Work (ACSH): https://osha.europa.eu/en/legislation/guidelines/guidance-employers-controlling-risks-chemicals-interface-between-chemicals-agents-directive-and-reach-workplace

(7) See directives 2004/37/EC, 89/656/EEC, 98/24/EC, 89/391/EEC

(8) See Holger-Lars Deubner, Gudrun Walendzik, Andreas Lüdeke, Urs Schlüter, Assessing the impact of authorisation process as a regulatory tool in the European REACH regulation: A study on improving occupational safety for applying companies, Annals of Work Exposures and Health, Volume 68, Issue 6, July 2024, Pages 617–625 and Dumke and Schlüter 2021; ECHA SOI 2021; Engel and Hanschmidt 2021; Reihlen et al. 2021; Reihlen, Jepsen and Wirth 2021; Schlüter, U. 2021; ECHA REF-9 2023.