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**The Advisory Committee on Safety and Health at Work**

**OPINION**

**Interface between EU OSH Legislation and REACH restrictions**

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## **Introduction**

In its Council conclusions “A New EU Strategic Framework on Health and Safety at Work: Enhancing the implementation of Occupational Safety and Health in the EU” (10.12.2019), the Council invited the Commission to clarify the interface between the OSH and REACH legislations and to improve coordination by developing transparent procedures and criteria to be used when selecting the most appropriate substance specific regulatory options. ACSH hereby provides an analysis why there is the need to reach clarity at the interplay between REACH and OSH and when, if and how REACH and OSH regulation can complement each other.

EU OSH requirements primarily come from EU directives adopted in the field of social policy where social partners and governments play an important role in decision making via the tri-partite ACSH. Limit values for priority chemicals are routinely set under OSH legislation and this paper seeks to explain where it may be appropriate, under certain specified conditions, to use Restrictions under REACH to complement the requirements under EU OSH legislation.

For OSH-related REACH restrictions, the proof of an unacceptable level of risk for workers is an essential prerequisite for demonstrating that action is necessary beyond any measures already in place, quoted from REACH Art. 69. Therefore, there is a need to agree on criteria that should be considered when determining when OSH-related REACH restrictions are expedient or not.

Whilst this paper concerns REACH Restrictions, the ACSH acknowledges that there are other aspects of the OSH/REACH interface that would benefit from common guidance.<sup>1</sup> However, the current need appears to be most prominent in relation to the restrictions under REACH annex XVII.

The tri-partite Advisory Committee on Safety and Health (ACSH) is of the opinion, that whenever a national competent body for REACH considers the necessity to replace, pre-empt or complement OSH regulation, the assessment regarding subsidiarity and coherence should take place before initiating any regulatory action.

## **Development of OSH and REACH regulations**

The primary source of EU OSH requirements are directives set in the field of social policy. It is recognised that, in certain situations, benefits can arise when OSH and REACH requirements can work together to ensure added value at EU level for the safety and health of workers.

This document evaluates one such situation, namely the relationship between EU Occupational Safety and Health (OSH) legislation and restrictions under the chemical regulation REACH or a combination of both. The ACSH provides its perspective to identify ways and principles for using REACH-restrictions as a means for complementing the protection of workers handling hazardous substances or reinforcing OSH provisions (especially with a new OEL or a revised OEL).

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<sup>1</sup> For example, OSH legislation can work in synergy with REACH authorisations to make sure all exposure situations are covered (e.g., the binding OEL for chrome VI under the OSH legislation complement the REACH authorisation as it covers all exposure situations including welding processes which are out of REACH authorisation scope.

REACH and OSH legislation are different but complementary. In order to promote synergies, actions in both areas need to be well coordinated and it has to be ensured that the specific legal requirements of the EU Treaty pertaining to that policy area are adequately respected.

OSH directives regulate duties and responsibilities of the employer and workers. According to the EU Treaty (Art. 153 of the treaty), Social Partners at European level have to be consulted before the Commission makes a proposal to amend an OSH directive. OSH directives are based on the co-decision legislative procedure and have to be adopted by the EP and the Council. According to the EU Treaty, OSH directives regulate minimum requirements. This is due to the specific nature of EU social legislation and the strict division of competences between the EU institutions and Member States, as well as the need to respect the autonomy of social partners. Member states can impose more strict national OSH regulations.

REACH regulates duties of manufacturers, importers, downstream users, in relation to substances (manufactured/imported or placed on the market). REACH as a single market regulation applies directly and provides for a harmonised maximum EU approach (Art. 114 of the treaty). REACH restrictions are based on a decision of the Commission in a comitology procedure with scrutiny involving Council and EP.

Above all, existing OSH principles (the hierarchy of controls) provide for sufficient protection against chemical risks at the workplace since the basis of OSH legislation is that those risks shall be eliminated or reduced to a minimum. The employer is responsible for elimination or substitution and for introducing preventive and protective measures to ensure risk reduction while considering the specific conditions of use at the workplace. To further support those objectives, OSH legislation (98/24/EC (CAD), 2004/37/EC (CMD)) sets limit values and minimum standards that must be transposed into national legislation.

The Advisory Committee on Health and Safety at Work (ACSH) and its Working Party on Chemicals (WPC) is effectively and necessarily involved in the limit setting process. The tripartite dialogue between employee representatives, employer organisations and national governments is required specifically to address the feasibility of proposals as well as socioeconomic issues and thus to provide for input from national governments and social partners, as required by the Treaty.

In 2007, the REACH Regulation came into force. With REACH, tailor-made approaches addressing specific risks can be brought forward and the introduction of a restriction including worker protection is in principle processed in a structured and transparent way. Setting up restrictions under REACH however does not involve the consultation and participation of social partners. This is a significant difference compared to the procedures foreseen for OSH legislation. Additionally, the principle of not prejudicing other regulations (OSH here) has not always been comprehensively assessed in the past and the ACSH provides thoughts on how a comprehensive and thorough analysis could be performed in the future.

REACH restrictions may offer a valuable instrument to complement OSH legislation in specific and duly justified cases. For the vast majority of chemicals and applications, OSH legislation already ensures safe use and adequate worker protection. An analysis as to whether OSH-restrictions under

REACH are actually necessary should be carried out taking into account the proposed criteria presented in this paper.

### **Criteria for a restriction under REACH addressing work-related issues**

A pre-requisite for every restriction is evaluating practicability and feasibility beforehand, ensuring that all affected parties can comply with the conditions of the restriction. Whether a restriction under REACH is an option to address OSH issues could be checked further against the following considerations (non-exhaustive list):

- Is there a relevant health-risk and a significant difference in protection levels in EU Member States that requires EU regulation to assure a comparable and adequately high level of protection?
- Is there a need to enhance the existing EU OSH-instruments to reduce risks in a situation where application of the general OSH requirements including an OEL is not sufficient? This could be the situation in individual cases where e.g. occupational diseases have been demonstrated to remain at high level due to specific properties of the substances and/or how exposure occurs e.g. sensitisers or dermal exposure.
- Are - for technical reasons - sufficient risk management measures and operational conditions not achievable? Does that lead to unacceptable high risks of severe effects for a significant number of workers across EU member states?
- Due to an unacceptable risk for workers, is the most efficient regulatory approach to prevent the substance from being placed on the market (e.g.: total ban of asbestos fibres)?
- Are there particular advantages of introducing a restriction by REACH in order to e.g. deliver specific descriptions of particular measures that will ensure adequate protection of workers? Or could a similar or higher level of protection be obtained by the implementation of a BOELV?
- Where there is an identified unacceptable health risk, is this due to a lack of effective practical implementation of the EU OSH requirements or a weakness of actual legal requirements. Where this can be identified, can this be addressed by improvements to the EU OSH legislation or providing guidance to facilitate better compliance?

To tackle these issues, a cooperation of the relevant REACH Committees with the ACSH/WPC before a project of restriction concerning OSH under REACH is highly recommended by ACSH.

Restrictions can be generic or targeted with regard to many aspects (e.g. coverage, efficiency and proportionality). They can be flexible and address principally any substance-related risk. The following non-exhaustive list focusses on OSH-related issues that are addressed by REACH restrictions already:

- **Ban**: A substance as such, in mixtures or in articles could be totally banned (e.g. Annex XVII, entry 1: Polychlorinated terphenyles; Annex XVII, entry 6: Asbestos fibres) or restricted for specific ways of use or areas of use. In particular, the latter is an option in case alternative solutions are available and a restriction would force the use of those alternatives.
- **Minimisation in mixtures or articles**: The concentration or the release of a substance could be limited for certain mixtures or articles (e.g. Annex XVII, entry 60: Acrylamide).
- **Harmonised technical measure**: quality-assured, harmonised EU-wide installation of technical measures (e.g. Annex XVII, entry 59: Dichloromethane)
- **Harmonised training**: quality-assured, harmonised EU-wide introduction of tailor-made organisational risk reduction strategies (training material for the employer and employee, e.g. restriction for Diisocyanates)
- **Harmonised limit values**, combined with guidance (e.g. NMP)

The last two types of restriction are novel approaches, which clearly need thorough reflection between Member States and Commission since they serve as precedents to address similar risks cases.

In general, it is the opinion of the ACSH that setting of detailed **harmonized workplace training requirements** for individual substances under REACH should be a well-founded exception and used only where well justified. OSH instruments already include requirements for training that apply in the general sense and also to the use of individual substances. The use of a REACH restriction may be appropriate in some very specific situations where training is demonstrated to reduce significantly an identified unacceptable risk for workers.

Regarding **harmonized limit values**, the ACSH considers, that for substances regulated by the CMD, limit values should always be set as BOELVs pursuant to the CMD and not by way of a REACH restriction. Similarly, BOELVs can be set for substances, which are regulated by the CAD. The need to set harmonized limit values can be fulfilled using OSH instruments. If in addition to OSH legislation, occupational limit values are in practice set also by REACH restrictions, the coherence of the legislation is disrupted. These risks causing confusion, administrative burden and legal uncertainty.

Also, in the perspective of this interface between REACH and OSH, the case of substances generated during a production process and other agents occurring at the workplace (e.g. wood dust) should be seen as always relevant for (B)OELVs, taking into account that they are not in the scope of REACH.

## **Conclusion**

The ACSH, being the appointed tripartite advisory body for occupational safety and health, urges the Commission's conclude its assessment on the interface between REACH and OSH in general, with a focus on the future relationship of restrictions under REACH and OSH measures like BOELVs or IOELVs under CAD or/and BOELVs under CMD. This is necessary, as there remains a lack of adequate progress in this respect since the ACSH's statements in 2013 (Doc. 01903/13) and 2017 (3.3 Doc.789-18-EN) addressing this topic.

The ACSH would welcome the adoption and communication of common guidance that presents the agreed view of the relevant services of the Commission who are responsible for REACH and OSH policy.

The ACSH would welcome to continue working with DG EMPL to agree on prioritizing substances for limit value setting, including OELs setting. To enhance transparency the ACSH suggests communicating the list of priority substances and to make them available in an Opinion.

In general, the selection of regulatory measures should be assessed within a transparent process without prejudice to either policy area. Thus, an analysis or screening of potential options should be mandatory and harmonised and OSH legislation (e.g. setting of BOELV) must be considered as a relevant option and equal before law within this process (for instance at the stage of the regulatory management option analysis (RMOA)). Such early analysis and discussion should enable a focus of regulatory action, achieve an earlier consensus and might significantly reduce discussion at a later stage, thus accelerating action. All relevant stakeholders should be actively engaged in this process.

ACSH insists on the need to develop a binding list of criteria to be used in this procedure and suggest that this be developed by appointed representatives from WPC (all IGs) and ECHA/ENV/GROW/EMPL and agreed by the three policy Directorates General (EMPL/ENV/GROW). The ACSH invite the Commission services to jointly publish guidance based on the outcome of this work. This will provide clarity, transparency and predictability of future substance specific policy initiatives relevant for workers protection.

The ACSH supports that whenever ECHA/MSCA under REACH discuss regulatory options during the RMOA process this set of criteria should be used and the ACSH should be actively engaged. Further, it is of the opinion that only with a set of agreed and binding criteria, all stakeholders will be able to acknowledge and enforce REACH and OSH measures synergistically.