

61. meeting of the Committee on Hazardous Substances – AGS - on 06.11.2017

Analysis of and common position on the issue of “OSH legislation and REACH - how to successfully deal with overlapping issues?”, based on the discussions at the AGS meeting in Berlin on 9 May 2017 (<https://www.baua.de/DE/Aufgaben/Geschaeftsfuehrung-von-Ausschuessen/AGS/AGS-Diskussion-2017.html>)

Context:

The practice-oriented use of REACH information for occupational safety and health (OSH) is one priority of the current work programme of the Committee on Hazardous Substances (Ausschuss für Gefahrstoffe - AGS). After having worked with REACH for ten years, it has become clear that there is need for optimisation in the overlapping area between OSH and REACH and better communication between the responsible stakeholders. The meeting helped to highlight the existing problems in the workplace and to make perspectives and experiences from both regulatory areas transparent.

The next step will be to draw the necessary lessons. At the meeting on 9 May 2017 the representatives of the AGS and of the German Ministries for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB), of Labour and Social Affairs (BMAS) and for Economic Affairs and Energy (BMWi) declared their readiness to actively coordinate OSH legislation and REACH. Therefore, the AGS Committee is asking all ministries involved to clarify where there is overlap that leads to problems of understanding in terms of workplace operations and to advocate a practical implementation of the underlying European legislation. The three topics specified in the following will serve as a starting point. The analysis-based policy recommendations should be established as a national position, which will be strongly supported by the AGS. The AGS Committee therefore recommends that at the European level the competent German ministries forward the policy recommendations specified for the three topics to the Directorates-General for Environment (DG ENV) and Industry (DG GROW) and the Directorate-General for Employment (DG EMPL). The AGS also recommends that the competent German ministries work to ensure that the German representatives in European bodies make this position their own. The AGS is ready to provide help and support for this purpose.

Topic 1: Applicability and benefits of exposure scenarios

Exposure scenarios under the REACH Regulation describe safe operational conditions for using a substance. For downstream users who, as employers, use a substance in their own workplace, the conditions for the safe handling of a substance in the exposure scenario are therefore a source of information for the risk assessment. The same applies to the safe operational conditions for using mixtures specified in the safety data sheet. In a risk assessment, not only the substances covered by the scope of the REACH Regulation but all substances and mixtures that are used and/or generated at the workplace are to be assessed with regard to the activity to be carried out. Moreover, the risk assessment must take reasonable account of additional aspects such as disposal, interactions and technical circumstances in the respective workplace.

Policy recommendation:

- The REACH Regulation stipulates that by means of the safety data sheet for substances, the exposure scenarios and thus safe operational conditions for use are communicated. Employers are required either to apply the exposure scenarios specified in the annex to the safety data sheet for a substance or to make an assessment of their own. Deviations from the operational conditions described in an exposure scenario are allowed under REACH in certain cases. It is very difficult to make use of this option in practice, however, because of very stringent guidance that is not adequately geared to workplace needs. The AGS Committee considers it necessary to draft a guide that helps employers to set up and continue to develop comprehensive risk assessment in accordance with OSH legislation while integrating / taking into account the information made available to employers by REACH.
- Under the REACH Regulation, notification must be made of scenarios that deviate from the exposure scenarios because OSH measures for the use of substances at work have been adjusted or exchanged. A waiver for this requirement should be granted in cases where the protection objective has been achieved by adopting deviating measures while taking into account the STOP principle. The AGS considers it necessary to review the obligation to make notification of such deviating scenarios. The matter should be solved by adding a clarification to the already existing guides on, for example, scaling.

Topic 2: Derivation and significance of occupational exposure limits

Under REACH, derived no-effect levels (DNEL) must be determined by the manufacturer / importer to serve as benchmark for the risk management measures (RMM). They are an important source of information but are not subject to systematic quality controls. As part of REACH authorisation and restriction questions, the European Chemicals Agency (ECHA) is increasingly publishing “reference DNELs” prepared by the Committee for Risk Assessment (RAC) for certain toxicological endpoints (SVHC properties). In the procedures established under REACH, RAC is only involved in authorisation and restriction procedures for substances of very high concern (SVHC). In contrast, the Scientific Committee on Occupational Exposure Limits (SCOEL) is currently responsible for the scientific derivation of limits for all substances relevant at the workplace.

Policy recommendation:

- The occupational exposure limits established at the national level are legally binding for employers. If there is need for action with regard to certain substances, the nationally competent AGS Committee will be charged by the German Ministry of Labour and Social Affairs (BMAS) with the derivation of legally binding occupational exposure limits, if necessary also by transferring inhalative DNELs into occupational exposure limits. In this case a qualitative review is made of the DNEL as specified in the registration documents. The AGS considers it necessary to lay down indicative occupational exposure limit values (EU IOELV) or binding occupational exposure limit values (BOELV) in the relevant EU directives on a larger scale, especially for SVHCs with identified OSH risks. The way in which these limit values are derived should be disclosed in freely accessible supporting documentation.
- Since 1995 SCOEL, a competent and experienced group of experts, has been available for the derivation of occupational exposure limits. It should be strengthened and equipped with the necessary resources and it should continue to be charged explicitly with the scientific derivation of air assessment benchmarks for the workplace. The division of work between SCOEL (OSH) and RAC (consumer and environmental protection) should be clarified. When dealing with authorisation or restriction procedures, ECHA should involve DG EMPL and entrust SCOEL with the derivation of reference DNELs and dose-effect relationships. Furthermore, measures should be taken to ensure a better technical exchange between RAC and SCOEL on matters of occupational exposure. For this purpose, the AGS Committee strongly recommends better coordination with other Member States at the European level.
- For carcinogenic substances without threshold values, exposure-risk relationships should serve as scientific basis for the assessment of exposure-related risks. This makes comparison of the risks related to the substance concentrations possible. Here, too, the AGS advocates coordination with other Member States, especially in the context of the current discussion on an extension of the Carcinogens Directive.

Topic 3: Options under REACH for substances of very high concern

Regardless of pre-existing OSH requirements, the identification of substances as SVHC may result in further regulatory activities under REACH, particularly the authorisation or restriction of such substances. This applies also if only a potential OSH risk is identified.

Policy recommendation:

- Individual substances should not be specified in Annex XIV of the REACH Regulation without further consideration solely on the basis of their SVHC properties but only if an authorisation or restriction is actually necessary and realistic. The Risk Management Option Analysis (RMOA), which is not binding, is largely used to make this assessment. In the view of the AGS Committee, it would be worthwhile to make the RMOA obligatory. The AGS considers it necessary to consistently pursue this approach and involve DG EMPL for workplace-relevant substances. Criteria for OSH requirements in the context of REACH authorisations and restrictions should be proposed with the involvement of DG EMPL.
- At EU level, DG EMPL should speedily adopt binding occupational exposure limits for workplace-relevant SVHCs. The AGS considers it necessary to speed up the procedures for laying down BOELVs while maintaining the dialogue with the social partners, if necessary also by deploying more resources.
- Substances where risks are to be expected primarily at the workplace and for which limit values and/or OSH requirements are laid down in EU OSH legislation should be suggested for an inclusion in Annex XIV (authorisation) and/or Annex XVII (restriction) only in justified individual cases. The AGS Committee recommends that the competent ministries and authorities use the RMOA for this purpose and see to it that relevant measures and occupational exposure limits for these substances are laid down in the respective EU directives.
- The implementation of tried and tested OSH measures should be taken into account in the authorisation procedure and, more specifically, when the authorisation criteria are determined. For this purpose, the relevant technical rules for hazardous substances should be translated and made available to RAC. The aim should be to coordinate the requirements for protective measures laid down in the German technical rules and at EU level in the context of authorisation.