

Position paper on the extension of the generic approach to risk management in the framework of the Chemicals Strategy for Sustainability (09 June 2022)

Summary:

Verband der deutschen Lack- und Druckfarbenindustrie (VdL), Deutsche Bauchemie e.V., Industrieverband Klebstoffe e.V. (IVK), Hauptverband der Deutschen Holzindustrie (HDH), Bundesverband Farbe, Gestaltung, Bautenschutz as well as Bundesverband Korrosionsschutz e.V. (BVK) reject an extension of the generic approach to risk management for professional users. The generic approach to risk management represents a hazard-based concept which, in contrast to the science-based approach of risk assessment, is not suitable for deriving targeted regulatory measures. Accordingly, the EU Commission's plans are also critically assessed in the scientific literature. Due to the high level of vocational training and OSH in Germany, equal treatment of professional users and private end users under chemicals legislation is not sensible and discredits the vocational training and the craft sector in Germany. Deficits in European harmonisation of occupational safety and health should be addressed directly and not compensated for by chemicals law.

Background:

With the Chemicals Strategy for Sustainability, the European Commission has presented its long-term vision for the European Union's chemicals policy in the context of the Green Deal. The undersigning associations in principle support the objectives of the European Green Deal and the sustainable use of chemical products such as coatings, paints, printing inks, building materials, adhesives and adhesive tapes. With innovative products and resource-efficient applications, the member companies of the signatory associations make an important contribution to achieving the ambitious goal of a safe and sustainable economy. However, the Chemicals Strategy contains many aspects that would make this considerably more difficult in the future and are hence in conflict with the goals of the Green Deal.

One of the planned measures is the expansion of **the generic approach to risk management**. This concept¹ provides that regulatory measures, such as use bans, are automatically taken solely based on the intrinsic hazard properties of a substance. Exposure is not considered, which means that regulatory measures are implemented without a risk assessment, purely based on intrinsic properties of the substance.

The generic approach to risk management is currently already applied within the framework of Article 68, paragraph 2 of the REACH Regulation. However, it is limited to substances with CMR properties of categories 1A and 1B and to consumer uses. Otherwise, European chemicals legislation is largely based on established risk-based approaches.

¹ " In the EU legislative framework for chemicals, a 'generic approach to risk management' is an automatic trigger of pre-determined risk management measures (e.g. packaging requirements, restrictions, bans, etc.) based on the hazardous properties of the chemical and generic considerations of their exposure (e.g. widespread uses, uses in products destined to children, difficult to control exposure). It is applied in a number of pieces of legislation on the basis of specific considerations (e.g. characteristics of the hazard, vulnerability of certain population groups, non-controllable or widespread exposure).- Chemicals Strategy for Sustainability

Within the framework of the Chemicals Strategy, the generic approach to risk management is now to be expanded in two aspects:

- The intrinsic hazard properties are to be extended from CMR substances of categories 1A and 1B to endocrine disrupting substances and substances with PBT and vPvB properties. In a second step, an extension to substances with respiratory sensitising, immunotoxic and neurotoxic properties, as well as substances with specific target organ toxicity (STOT) is to be examined.
- Furthermore, the scope of the generic approach shall not only be on private end-users but is to be extended to professional users. In the context of REACH, private end consumers and professional users would thus be treated equally under chemicals legislation.

Assessment:

In the case of particularly hazardous substances, such as CMR category 1 substances and exposure to particularly vulnerable or inexperienced groups, such as the private end-user, a hazard-based approach, like the general approach to risk management, may be appropriate. Within the framework of the precautionary principle, this efficiently ensures a very high level of consumer protection. Furthermore, a specific risk assessment would generally not come to a different conclusion in these cases.

Apart from this special case, however, the assessment of chemical substances must not be based solely on intrinsic properties. Exposure during manufacture and use, and thus the actual risk, must also be considered in the assessment. Due to the many reclassifications in the CLH procedure as a result of the extension to new hazard classes, a purely hazard-based approach would not provide any planning certainty. Moreover, these criteria could change depending on the developments of the UN GHS. This makes it difficult or impossible for our industries to estimate which raw materials will be available in the future. Furthermore, this approach may lead to the paradoxical situation that a substance cannot be used in a demonstrably safe application, which would damage the credibility of chemicals legislation and may also have negative impacts on sustainability. Indeed, already today the CLH classification of chemical substances has significant and often unjustified impacts in downstream legislation that refers to the CLH classification. In contrast, the well-established science-based approach of specific risk assessment provides much more accurate results and can thus be used to derive more targeted regulatory measures. It should therefore continue to form the basis of chemicals legislation. Since the science-based concept of risk assessment allows for much more informed regulatory decisions, the expansion of the generic approach to risk management has also received criticism from the scientific community.^{2,3,4}In addition to the fundamental deficits of the generic approach to risk management, the idea of treating professional users and private end users under chemical law equally is

² "Introducing measures such as the "generic approach to risk management" or a generic MAF-in their proposed generality-will clearly result in a significant quality loss of chemical risk assessment in the EU. It is foreseeable that in the end this will lead to ill-prepared regulatory proposals, the scientific inadequacies of which will eventually have to be dealt with at the "green table" in the REACH committee or in court and might even result in an overall failure of the proposed regulation." Herzler et al, The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?, Archives of Toxicology (2021) 95:2589-2601, <https://doi.org/10.1007/s00204-021-03091-3>

³ Barile et al, The EU chemicals strategy for sustainability: in support of the BfR position, Archives of Toxicology (2021) 95:3133-3136 <https://doi.org/10.1007/s00204-021-03125-w>

⁴ "A toxicological health risk assessment approach has been established and successfully worked worldwide for decades. Some of the potential changes in chemicals legislation, e.g., for endocrine disruptors as proposed by the EU Commission, lead to an even stronger emphasis on the intrinsic hazard properties of substances as a regulatory basis (Doe et al. 2021). This would have potentially far-reaching regulatory consequences, some of which would be superfluous from a health risk perspective and without a sound toxicological basis." Batke et al., Archives of Toxicology <https://doi.org/10.1007/s00204-022-03227-z>

particularly incomprehensible. There are major differences, especially due to the profound training in Germany and the fact that personal protective equipment can be used as part of mandatory occupational safety measures. The handling of "work-specific hazardous substances" is part of the legally regulated vocational training in Germany.⁵ In addition, regular instruction on hazardous substances takes place, the respective workers compensation boards (Berufsgenossenschaften) closely monitor occupational illnesses and accidents and are also active in preventive measures at their member companies. Equating professional use with end-consumer use would both negate the immense quality of vocational training in Germany and call the high level of occupational health and safety measures into question. Squaring consumers and professional users would also be a disparagement of professions that are characterised by carrying out technically demanding work with the help of appropriate products, tools and working methods. There is no data on incidents related to occupation-specific hazardous substances that would even begin to justify this equalisation.

On the other hand, the expansion of the generic approach would entail considerable consequences for professional users. Manufacturers of coatings, paints, printing inks, building materials, adhesives, adhesive tapes and their customers depend on a broad base of chemical raw materials so that the usual variety of high-quality and specialised products remains available in the future. Especially in order to fulfil the goals of the Green Deal, a wide range of sustainability functions (e.g. corrosion protection on bridges or wind turbines, lightweight construction) of these products are required. Since the scope of the generic approach is to be extended to new hazard classes, some of which have not yet been implemented in the CLP Regulation and thus clear criteria are not yet available, it is not foreseeable at the present time which products would be affected. Another complicating factor is that the Chemicals Strategy also increasingly provides for group approaches, which would mean that larger groups of substances would be regulated at once. The economic impact analysis of the Chemicals Strategy of the European Chemical Industry Council (CEFIC), which also considers the extension of the generic approach to risk management, shows that paints, coatings and adhesives/tapes are among the most affected downstream sectors.⁶ Having a chemicals legislation framework only leaving products for professional use, which are also available for private end-users, maintaining the state of the art regarding materials used in the professional sector is at risk. Highly qualified tradesmen and master craftsmen would therefore no longer be able to differentiate themselves in their range of services from unskilled workers as they have done in the past. In any case, the effects should be examined in a comprehensive impact assessment.

It might be argued that the level of occupational safety and health (OSH) differs considerably within the EU. However, deficits in the harmonisation of OSH law should be addressed there and not be compensated for by chemicals legislation. Ultimately, this would put countries that have established a high level of vocational training and OSH measures at a disadvantage. For the above reasons, an extension of the generic approach for risk management should be rejected. Should there be a need for regulation in individual cases, even for professional users, the proven REACH regulatory instruments - such as restriction and authorisation - can be used.

⁵ e.g. Ordinance on Vocational Training for Painters and Varnishers (Maler- und Lackiererausbildungsverordnung - MalerLackAusbV)

⁶ Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability, <https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf>