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Deutsche Sozialversicherung
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Opinion from German Social Insurance issued on 17 March 2025

on the proposed revision of the REACH Regulation

I. Preliminary remarks

The registration, evaluation, authorisation, and restriction of chemicals have been regulated by the REACH Regulation in the European Union (EU) since 2007. The provisions in the Regulation are intended to protect human health and the environment from chemical hazards.

In October 2020, in its Chemicals Strategy for Sustainability, the European Commission presented initial ideas on promoting safe and sustainable chemicals and on how to better protect people and the environment from hazardous chemicals. It intends to accelerate the registration and evaluation procedures as part of the revision of the REACH Regulation. Authorisation and restriction are also to be simplified. In addition, the application of the Regulation is to be streamlined and made more user-friendly for companies. The changes under discussion are intended to contribute to the zero pollution ambition of the European Green Deal and at the same time be harmonised with the priorities of Commission President Ursula von der Leyen's second term of office for the sustainable competitiveness of the European industry.

The provisions of the REACH Regulation affect not only the manufacturers and distributors of substances but also employees who come into contact with chemicals in their everyday work. The German Social Insurance (DSV) welcomes the aims of the reform to protect people and the environment even more from the dangers of hazardous chemicals and their effects on health, while increasing the competitiveness of the European industry.

In this context, it is important that

- _ the proposed paradigm shift in the Chemicals Strategy from risk assessment to evaluation of the hazard properties of substances not only ignores the fact that proven protective measures enable the safe use of hazardous substances in the workplace, but also that consumers require a different level of protection as they have little information and skills to optimise protection.
- _ the discussion on restrictions on the use of per- and polyfluoroalkyl substances (PFAS) should also consider proposed solutions that aim to protect people and the environment based on careful assessments of the substances and their risks, while promoting the transformation of the economy.

- _ the adaptation of the mandate and the personnel and financial structure of the European Chemicals Agency (ECHA) should play a central role in the revision of the REACH Regulation, especially if the provisions relating to this agency are to be transferred from it to a new ECHA founding regulation.
- _ the evaluation of the usability of the safety data sheet as the most important means of communication within the supply chain should also play a key role in the revision of the REACH Regulation, as the information and recommendations it contains are fundamental for working with chemical substances and mixtures in the workplace.

With this Opinion, the DSV would like to make an early contribution to the discussion on the revision of the REACH Regulation.

II. Opinion

1 _ **Maintaining the risk-based approach**

As part of the REACH revision, the European Commission wants to clarify in principle what a practicable approach to the risk assessment of substances could look like in order to best protect people and the environment from the effects of hazardous chemicals. From the point of view of the DSV, it also makes sense in this respect that the European Commission – as explained in the Chemicals Strategy – is in pursuit of improving the protection of human health and the environment. The fact that it wants to adopt the strict hazard-based approach not only for consumers but also for professional users has a direct impact on the work processes in which chemicals are used.

The DSV considers it wrong to assess substances for professional use according to the hazard-based approach, without taking into account the circumstances of their use. An assessment based solely on properties could lead to substances or entire groups of substances being banned in the workplace, regardless of the actual risk associated with their use by trained specialist personnel. This is because they would be subject to the same restrictions or bans that apply to consumers.

A blanket ban on hazardous substances is also not necessary from an occupational health and safety perspective in view of the risk assessments and tried and tested protective measures in the companies. This is because risk management measures are regularly taken on the basis of the respective assessment results and employees

are protected accordingly in the workplace. This makes it possible to work safely with chemicals in the workplace.

In the DSV's view, the results of the risk assessment of a substance should rather depend on its various areas of application, such as the safety of toys, cosmetics, biocides, plant protection products and foodstuffs. Similarly, the risk assessment of carcinogens at work should be taken into account. This is because the properties of a substance should not be the sole trigger criterion for a risk assessment. Instead, the risk must be assessed on the basis of the hazard to the user during the specific use and exposure. In particular, the safe exposure of different persons (groups) and the possible safe working with the substance through prior training programmes should be taken into account here. In addition, the level of exposure and the possible use of preventive safety measures, such as detection at the point of release or respiratory protection, must be considered.

If one followed the hazard-based approach, which is solely based on the properties of a substance, surface disinfection with formaldehyde-containing cleaners or sterilisation with ethylene oxide (e.g. of medical instruments or infusion tubes) would no longer be possible in the healthcare sector, for example. Both substances are classified as carcinogenic to humans. However, the risk of damage to health can be minimised by taking appropriate protective measures. Thus, occupational exposure limits for surface disinfection with formaldehyde-containing cleaners and the use of ethylene oxide for sterilisation in closed systems make it possible for both substances to be used by employees with the help of the risk-based approach.

A similar picture emerges in the construction industry. Materials containing asbestos have been used there for many years and should be gradually removed. Asbestos is carcinogenic to humans. Safe removal can therefore only be carried out under stringent conditions and by appropriately trained professional workers. If the hazard-based approach were also to be implemented here, it would no longer be possible to remove materials containing asbestos in future. This would contradict the European Commission's intention to make Europe asbestos-free.

The DSV is therefore in favour of ensuring that the use of certain hazardous substances in the workplace by trained and adequately protected personnel is not made impossible. This could lead to prohibited activities being carried out outside the EU in future and certain sectors of the economy possibly moving to non-European countries in order to produce there under less stringent occupational health and safety regulations. In order to minimise risks to the health of employees and at the same time promote Europe as a production location and its competitiveness, the focus of occupational health and safety should also be on reducing these risks as effectively

as possible rather than on blanket bans and restrictions derived from intrinsic substance properties. The aim must be to continue working safely with hazardous substances even in the European Union.

2 _ Future use of per- and polyfluoroalkyl substances

There are currently intensive discussions at European level about restricting PFAS. These chemicals which include more than 10,000 substances are known for their long-lasting and stable properties, which also makes them attractive in many industrial applications due to their water, grease and dirt-repellent properties. They can be found in coatings for packaging or certain medical devices such as catheters, in textiles, paints, cleaning agents and adhesives and are used in many manufacturing processes, including pharmaceuticals. Future technologies that are important for the green transition cannot currently do without PFAS, as they are not only found in solar panels, heat pumps and wind turbines but also in electrolyzers, which are required for the production of clean hydrogen, and accumulators (energy storage devices), which are needed for electromobility or the storage of electrical energy.

In particular, the medical, automotive and cosmetics industries use PFAS. They are also used as an indispensable part of occupational safety, for example in personal protective equipment such as respiratory protection, gloves and numerous other textiles with a protective function, in medical devices or analytical equipment for checking maximum allowable concentrations.

PFAS and their degradation products pose a potential health risk, since they can remain in the environment for a very long time and a hazardous effect on health cannot be ruled out. For this reason, some Member States, including Germany, are endeavouring to restrict or ban PFAS. The procedure for this has been ongoing at ECHA since 2023. It is complex due to the large number of applications of PFAS. PFAS are used in areas that are important for healthcare, occupational health and safety, the competitiveness of European industry and the EU's sustainability goals. Safe alternatives will not be available for all these areas of application in the short or medium term. In addition, only a few PFAS have been researched with regard to their health effects due to accumulation in the environment and in the human body, or have been toxicologically evaluated, such as PFHxA, which is a component of fire-fighting foams, among other things.

The PFAS restriction procedure currently underway at the ECHA should provide viable solutions in terms of risk reduction relevant to prevention and the socio-economic costs associated with PFAS restriction. Orderly substitution could be helpful, for

which research into PFAS alternatives must be advanced. In addition, the PFAS restriction procedure should be used as an opportunity to further research the health effects on humans and the environment as well as the use of PFAS in the work context.

3 _ Tasks of an independent European Chemicals Agency

Title X of the REACH Regulation defines the way ECHA functions. However, this has changed since the Regulation came into force. The DSV therefore welcomes the changes proposed in the Chemicals Strategy for Sustainability to strengthen ECHA's governance, improve its funding model and clarify the legal framework of its tasks and working methods. The main focus of the adjustments should be on the independence of the agency and the expansion of adequate human resources. This is the only way ECHA can fulfil its role. In recent years, ECHA's role has been expanded through numerous amendments in various legal acts and will be further adapted in the future through the proposal of the "One substance, one assessment" reform package.¹

Close cooperation with the European Agency for Safety and Health at Work (EU-OSHA) is particularly important for the safety and health protection of employees. This ensures that the occupational health and safety perspective of this agency is included in ECHA's processes. In this way, key tasks such as the review of safety data sheets, the drafting of specifications for exposure scenarios for mixtures and the derivation of limit value proposals based on scientific data from the Member States could be implemented even better and more efficiently. The DSV is also in favour of the proposal for an ECHA founding regulation and thus the removal of ECHA-related provisions in Title X from the REACH Regulation insofar as this also goes hand in hand with the strengthening of governance, funding and clarification of tasks and the working methods.

4 _ User-friendliness of the safety data sheet

The REACH Regulation stipulates that the manufacturer, formulator or importer of a substance or mixture must record all data and recommendations for action to users of hazardous substances in a safety data sheet. This includes the classification and labelling of the substance, limit values, operating conditions and risk management measures. The safety data sheet, the requirements of which are regulated in Article 31 and Annex II of the REACH Regulation, therefore plays an important role as a

¹ [Opinion from German Social Insurance dated 25 April 2024. Chemicals assessment reform "One substance, one assessment" for faster, simplified and transparent procedures.](#)

means of communication within the supply chain. It provides users of hazardous substances with all data and recommendations for action in order to be able to take the necessary occupational health and safety measures.

In addition to the properties of the substance, mixture or articles, the hazardous properties that arise during its intended use must also be described. To protect users of chemicals, it is therefore essential to ensure that the safety data sheet includes this information on hazards. One example of this is the formation and release of fibre fragments from a woven fabric. Without the explicit labelling of these emerging hazards, different assessments can be performed and can endanger the health of employees.

As part of the REACH amendment, the evaluation of the safety data sheet should therefore be given special priority. Practical applications in recent years have shown that the user-friendliness of safety data sheets needs to be optimised, as their use in small and medium-sized companies is partly limited due to sometimes high barriers to comprehension. In order to simplify supply chain communication, the DSV believes that the experience of those who use and create extended safety data sheets should be gathered to incorporate best practices and experience into the revision of the REACH Regulation.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations of statutory health and longterm care insurance funds as well as the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance – Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e.V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union and other European institutions and advises the relevant players in the context of current legislative projects and initiatives. As part of a statutory insurance system, health and long-term care insurance with 75 million insured people, pension insurance with 57 million insured people and accident insurance with more than 70 million insured people in 5.2 million member companies, citizens in Germany are provided with effective protection against the consequences of major life risks.