

## Position paper of Deutsche Bauchemie on the revision of the REACH Regulation

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**Deutsche Bauchemie and its member companies** support the goals of the **European Green Deal** and, with their products, make an **active contribution to achieving climate neutrality and greater resource efficiency**.

However, there is a **trade-off** between sustainable technical solutions to **increase energy, carbon and resource efficiency** on the one hand, and avoiding the **use of substances with certain hazard characteristics** on the other. The **risk-based approach used by REACH** is the best way of striking the right balance.

**Deutsche Bauchemie adopts the following position on the individual aspects of the revised REACH regulation:**

- **Extending the *Generic Approach to Risk Management (GRA)* to professional uses and additional hazard classes**

There is a serious **risk that sustainable, technical solutions will be abandoned** if the generic approach to risk management is expanded and strengthened as planned. **Although safe use has been demonstrated**, following a purely hazard-based approach, as represented by the generic risk approach, would prohibit these uses of certain substances and thus **jeopardise the current state of the art**.

Specifically, extending the **generic approach to risk management (GRA)** to **additional hazard classes** would **significantly increase** the number of relevant raw materials and thus the number of **construction chemicals affected**. In some cases, the criteria for new hazard classes, such as for endocrine disruptors, have not yet been defined, making it difficult to assess their potential effects and creating legal uncertainty. However, it is foreseeable that **reactive resins based on polyurethane, epoxy and MMA resins, which are widely used in the construction sector due to their excellent properties, could be among the candidates whose use would be prohibited by the GRA**.

The proposed **extension to products for professional use** is viewed **particularly critically and seen as disproportionate**. This would place products sold to private consumers through DIY markets on an equal footing with products processed in the commercial sector by trained professionals and subject them to the same prohibitions. Unlike private individuals, trained workers take appropriate risk management measures such as using technical and personal protective equipment. Under European and national law, employers are already obliged to assess potential hazards when handling chemical substances, as well as to instruct their employees accordingly, define and implement appropriate protective measures and, if necessary, provide personal protective equipment. Therefore, the conditions that apply to professional users are completely different from those that apply to private consumers, which should be taken into account when applying the GRA.

A substance- and application-specific risk assessment is required to identify safe conditions of use and any necessary risk management measures. Adopting the generic approach to risk management means that this risk assessment would cease to apply, and prohibitions would be laid down directly. This would eliminate products that are essential for maintaining the state of the art, even though the safe use of these products has been demonstrated with the procedures specified in the REACH Regulation.

**It is possible that only products that are also offered to private consumers in DIY stores would be available for professional uses in the construction and building industry.** Skilled craftsmen and construction workers would no longer be able to differentiate themselves from unskilled workers and private consumers through the special features and performance of their professional products.

Deutsche Bauchemie advocates the **retention of best practice**: If there is a need for regulatory action for professional uses in specific cases, then – in a **restriction procedure** – certain conditions of use and risk management measures for certain substances and their uses could be selectively regulated. This has recently been done in the case of diisocyanates.

- **Concept of essential use**

The “concept of essential use” entails a serious risk that decisions will be made for the whole of the EU in the course of a regulatory process and that regional, cultural, economic and social factors will not be considered adequately. Excluding products from the European single market based on such a decision, which cannot be objectified, seems inappropriate and should be reconsidered. It is also questionable whether the concept originally developed solely for the use of greenhouse gases is suitable for transfer to general chemicals law and to multi-stage value chains.

The “concept of essential use” is, among other things, intended to identify exceptions to “GRA restrictions” under Article 68(2). While developing “GRA restrictions” under Article 68(2), a risk-based approach to identifying exceptions should be applied in addition to the concept of essential use. Uses of substances that have been deemed safe by established methods must not be restricted or *de facto* banned.

- **Mixture Assessment Factors (MAF)**

The European Commission proposes including a *Mixture Assessment Factor* (MAF) in the REACH Regulation to account for combined exposures to unintentionally occurring mixtures.

Deutsche Bauchemie believes the **application of a blanket MAF for all substances and all uses will not contribute to protecting the environment and human health**. Instead, specific MAFs should be applied only to those substances that actually occur in the environment and for which appreciable combination effects can be assumed. The current debate has shown that this may only be the case for a small number of substances. Accordingly, the application of a **MAF** should be **limited** and specified to **relevant cases**.

If various MAFs are included in the REACH Regulation, they should only be applied to substances that, due to their properties, may result in an unintentional mixture and, if so, contribute to the toxicity of the mixture. Because the likelihood of potential unintentional co-exposure to chemicals in the environment is greatest for substances that can bioaccumulate and for persistent substances, the **focus of a potential MAF approach** should be on **bioaccumulative and persistent substances** that are **used in large quantities and in widely dispersed applications**.

A MAF should not be applied to DNEL/PNEC levels (derived no-effect level/predicted no-effect concentration) because it would then also apply to the risk assessment of intended mixtures and would not take into account different, use-specific exposure scenarios. It could be appropriate to apply a MAF to specific **risk characterisation ratios (RCRs)** derived for specific uses that are assessed as critical.

- **Reporting obligations for downstream users (DU)**

Various options are being considered regarding additional information requirements relating to the use and exposure of substances. These include the **introduction of mandatory reporting requirements for downstream users**. Accordingly, after receipt of a safety data sheet for a registered substance, downstream users (particularly formulators) could be required to provide ECHA with information on the uses, the technical function of the substance, and the quantity used.

It is imperative that the **following aspects be considered** when potentially establishing mandatory reporting requirements for formulators (downstream users).

- The technical function of substances in mixtures is often part of the **confidential business information of formulators** and must therefore be protected at all costs.
- Furthermore, it must be **noted that the specification of the technical function of substances is always to some extent generic**, and it would be a fallacy to assume that substances with an identical technical function could simply be substituted for each other.
- In the current debate, it has been rightly noted that the necessary effort depends heavily on whether the relevant information is available in digital form and is communicated digitally in the supply chains. **The introduction of digital communication standards is, therefore, a prerequisite for keeping the effort required within acceptable limits.**
- It has been alarming to see the amount of effort that affected companies have had to expend in order to implement the notification requirements according to Annex VIII of the CLP Regulation. Against this backdrop, it is vital to ensure that **binding reporting obligations for downstream users are avoided as far as possible or, if necessary, limited to what is absolutely necessary**. The burden on downstream users should be examined and assessed in detail in the impact assessment. **The One-in-One-out Rule should be applied in a targeted way during the implementation of the standards.**
- It is standard for formulators of mixtures using classified substances to participate in the **consultations conducted prior to the establishment of regulatory risk management measures** (e.g. restrictions, CLH, EU OEL). Input from the sectors concerned is frequently organised through the relevant industry associations. This best practice ensures that the respective authorities and agencies are not confronted with a flood of non-validated and, in the worst case, contradictory information, but receive information that is already validated. This procedure should continue to be possible and should not be replaced by a reporting requirement for each individual downstream user.

- **Environmental Footprint**

There is already considerable demand for environmental product declarations for construction chemicals (mixtures) used as construction products. In the wake of the imminent revision of the Construction Products Regulation, the upcoming Ecodesign for Sustainable Products Regulation, and the legislative proposal to substantiate environmental claims, the demand for *environmental footprints* for products will continue to grow. LCA data on the substances used is required to determine the environmental footprint of products. Substance-based LCA data should be limited to a “cradle-to-gate” assessment so that downstream users can add their specific uses and relevant end-of-life scenarios. Although the need for substance-specific LCA data exists and will continue to grow, Deutsche Bauchemie believes that REACH is not the appropriate legal framework for determining and communicating the *environmental footprints* (cradle-to-gate) of substances. Another European framework should be found in which the required substance-related data is provided using uniform methods. For the implementation of the above-mentioned product-related regulations, a European database with the necessary

background data on the relevant substances would be required, which has already been partially discussed in the context of the above-mentioned initiatives.

- **Registration requirement for certain polymers of concern**

It is common to produce or modify polymers for specific applications or according to customer requirements in the construction chemicals industry. In the process, new polymers are created that could become subject to registration in the course of a possible obligation to register polymers. The number of polymers produced in this way is quite high, although the quantities of individual polymers are fairly low. Due to this ratio, data requirements should be staggered by volume bands and registration should only be required for volume thresholds significantly above 1 tonne/year. In addition, pragmatic grouping rules should be established to ensure the necessary practicability. This is the only way that companies in the construction chemicals sector (often SMEs), which have so far mainly acted as downstream users under REACH, will have a chance to meet their new obligations as polymer registrants.

The following are additional comments on specific aspects of a potential polymer registration

- Notification of polymer status

It is envisaged that manufacturers will have to report polymer status to the ECHA for all polymers, including those not subject to registration. If this reporting requirement is introduced, it must be limited to a minimum of already existing data. It would be disproportionate for manufacturers to have to generate previously unavailable data for polymers not subject to registration in order to comply with the new reporting requirement. Even without the generation of new data, the implementation of the reporting obligation would be very burdensome for the companies concerned and this burden should be examined and assessed in detail in the course of the impact assessment. **The one-in-one-out rule should also be applied here.**

- Exception for polymeric precursors under appropriately controlled conditions

The list of criteria for identifying polymers that are subject to registration contains an exception for **polymeric precursors**. The discussed restriction to “**strictly controlled conditions**” – **analogous to the conditions for intermediate products – serves no purpose and is unnecessary**. Polymeric precursors have different hazard characteristics to intermediates and should not be equated with them under any circumstances. Other criteria for appropriately-controlled conditions of use must be established for polymeric precursors as a prerequisite for the application of this exemption. If “strictly controlled conditions” were to be established as a requirement for polymer precursors, this exemption could not be applied in the construction chemicals industry.

- EU criteria for polymers of low concern (PLC)

Another exemption from polymer registration is provided for polymers that meet the criteria of “**polymers of low concern**” (PLC). When setting European PLC criteria (e.g., maximum oligomer content), it is essential to adopt existing PLC criteria from other jurisdictions outside the EU (e.g., Australia, Canada, USA).

*As an industry association, Deutsche Bauchemie represents the entire construction chemicals industry in Germany. In 2021, the more than 130 member companies with around 32.000 employees generated sales of 8.9 billion euros. This corresponds to half of the European market volume and about a quarter of the world market. Under the umbrella of the German Chemical Industry Association (VCI), Deutsche Bauchemie has been representing the interests of its member companies for over 70 years, to the public, political actors, authorities, other industry sectors, science and the press.*