BAuA position paper

Ensure safe-to-use chemicals, materials and products

A contribution of occupational safety and health to "safe and sustainable by design"

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baua: Focus

With the Chemicals Strategy for Sustainability the European Union provides an important basis for the implementation of the United Nations Global Development Goals. A main focus is a safe and sustainable design of chemicals and materials. The German Federal Institute for Occupational Safety and Health (BAuA) contributes to this with its long-term strategic goal "Ensure safe-to-use chemicals and products". Although the focus of this discussion paper is on safe work, simultaneous consumer and environmental protection is strongly desired.

Content

1 Introduction

"Ensure safe-to-use chemicals and products" is one of 4 strategic fields of action in the work and research programme 2022 - 25 of the German Federal Institute for Occupational Safety and Health (BAuA). It is underpinned by a large number of activities in legal tasks, policy advice, research and development [1]. With reference to chemical risks, the idea of "safe-to-use chemicals" goes back to the initiative "New Quality of Work" of the German Federal Ministry of Labour started in 2002. The focus was on a vision that chemicals should be placed on the market by manufacturers and importers in a form that largely excludes risks to humans and the environment. However, the insight going back to Paracelsus that "it is the dose alone that makes a thing not a poison" also means that a chemical cannot be safe in general. Exposure, e. g. at the workplace, has to be taken into account as well. A reliable statement for "safe" therefore must consider conditions of use and the persons applying it. Therefore, we have used "safe-to-use chemicals and products". The three different paths to "safe-to-use" were defined based on the occupational safety and health and chemicals legislation 20 years ago [2]. Additional consideration to materials was given in 2016 with the joint research strategy of the German higher federal authorities for safe and environmentally compatible nanomaterials [3], leading to an overall picture outlined in fig. 1.

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Fig. 1 Three pathways to safe-to-use chemicals, materials and products

With the Chemicals Strategy for Sustainability [4], the European Union will provide an important contribution to the United Nations Global Developments Goals for 2030. In this context, "safe and sustainable by design" (SSbD) is a central starting point for the future development of new chemicals, materials and related products. There is currently an intensive discussion on the criteria for SSbD. The next sections will describe how robust criteria can be derived on the basis of current EU legislation on chemical safety and occupational safety and health. These also open up the possibility of a link with further criteria to cover consumer and environmental protection as well.

2 Conditions for safe-to-use chemicals, materials and products

2.1 Safe-to-use chemicals, materials and products are designed in such a way that they pose only a low risk to workers´ safety and health during their entire life cycle: production, use, recycling and disposal.

The requirements for a safe-to-use design are directed at developers, manufacturers and importers of chemicals, materials and corresponding products. They should place their products on the market with a design that excludes unacceptable risks to workers health during the whole life-cycle. The adjusting screws to reach save-to-use are, as outlined in fig. 1, the hazardous properties, the potential for inhalation and dermal exposure as well as the active support of low-risk working procedures.

2.2 Low risk to workers safety and health means, that inhalative and dermal exposure at work as well as risks for fire and explosion are minimised to a broadly acceptable level.

Legislation in occupational safety and health has a long tradition of setting levels for a broadly accepted risk. This is done, for example, with legally binding health-based exposure limits for chemicals in the workplace and corresponding measures to comply with them. For chemical substances without a toxicological threshold, e.g. for many carcinogens, "acceptance thresholds" can be set. They are based on a socially generally accepted risk level that is oriented towards other everyday life risks. In order to meet the requirement of a "broadly accepted risk", a balanced participation of social groups is necessary, which has with tripartite bodies and decisions also a long tradition in occupational safety and health. Such risk-based approaches have already been successfully implemented in the Netherlands and in Germany [5, 6].

2.3 "Safe-to-use" solutions only provide safety and health at work if the minimum standards of a good working practice are consequently applied.

According to Paracelsus, any chemical agent can harm the safety and health of workers at high levels of exposure. For this reason, the legal requirements on occupational safety and health contain a package of basic measures with which - irrespective of the result of a risk assessment - exposure to chemical agents at work is basically reduced and peaks are cut off. These minimum standards of a good working practice are laid down in Article 5 of the "Chemical Agents Directive" (CAD) [7] as "general principles for the prevention of risks". Further-reaching "specific protective and preventive measures" are then decided by the "determination and assessment of risk of hazardous chemical agents" according to CAD Article 4. The “general principles” do not include source-related technical measures, e. g. local exhaust ventilation (LEV) or closed working systems, and the use of specific personal protective equipment (PPE) against chemical risks. In control banding tools for risk assessment in small and medium enterprises, these measures are often characterized as “control strategy 1” [8]. Please note, that for a "supported safe use" additional technical and organizational measures requirements are necessary, actively supported by the supplier. But here, too, the minimum standards must be ensured in order for them to be sufficiently effective.

3 Three pathways to safe-to-use solutions

Fig. 1 has demonstrated the three pathways to a safe design of chemicals, materials and corresponding products. What is special about the system described here is that the underlying criteria are based on the EU chemical safety and occupational health legislation. This should make it possible to use safety testing and assessments carried out to fulfil legal obligations for a reliable and legally sound communication on safe-to-use solutions in the supply chain.

3.1 Direct safe-to-use - target on no or weak hazardous properties

“Direct safe-to-use” follows the main idea of “green chemistry”, to design chemicals and materials in a way, that their hazardous properties - according to the classification under the EU CLP Regulation [9] - lead to only a low risk to safety and health for the intended uses and in compliance with the minimum standards for occupational hygiene. Sufficient physico-chemical and toxicological data must be available. In terms of the European Chemicals Regulation REACH [10], for chemical substances the data submitted with a complete, quality-assured registration should normally be considered sufficient.

3.2 Integrated safe-to-use - target on low exposure forms and techniques

“Integrated safe-to-use” covers a design of low-emission forms for chemicals, materials or products, including application techniques, which reduce the potential for inhalation and dermal exposure to a broadly accepted low risk level. In this case, too, robust evidence must be

provided, that occupational health or risk-based exposure limits are safely complied under the conditions of the "general principles" acc. to CAD Art. 5. Integrated safe-to-use offers practical solutions for chemical substances, mixtures or materials with non-avoidable hazardous properties, which may also be necessary for the application, e. g. in biocidal products. Examples are granulates, pastes or binding oils for highly dust evolving chemicals and materials, but also the safe inclusion into a matrix or the use of a "lost packaging".

3.3 Supported safe-to-use – target on ambitious suppliers

"Supported safe-to-use" is a third pathway, if the other two are not applicable: manufacturers and suppliers design low-risk application equipment and practices for hazardous chemicals, materials or products and market them as a complete system. This support must go beyond the basic legal requirements for communication in the supply chain (labelling, safety data sheet, exposure scenarios). It can include user training, accompanying workplace measurements or technical solutions, e. g. chemical leasing [11].

4 Building a bridge from occupational safety and health to sustainability

The best way is to think about safe-to-use solutions at an early stage in the development of chemical, material and product innovations. This offers the greatest possibilities for modifications in the interests of human health and environmental protection [12]. The advantage of the safe-to-use concept described here is the orientation towards legal enforceable criteria. This is not the case with many other systems of safety and sustainability assessment [13]. Therefore, these system also offers for developers, producers and suppliers the advantage of a good preparation for the legal requirements on European chemical safety and occupational safety and health. This applies in particular to the determination of exposure scenarios for the registration of chemical substances under REACH. Low-emission design can also significantly facilitate the authorisation of products under the EU Biocides Regulation [14].
The three pathways to safe-to-use solutions are primarily directed at manufacturers and importers of chemicals and materials, but also at actors in the supply chains who place them on the market as "products" - if necessary, in a modified form. On the other hand, purchasers and users also profit in their role as OSH managers. For chemical agents that offer safe-to-use solutions, compliance with the legal demand for substitution is considerably facilitated. According to CAD Art. 6 substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, pose no or a lower risk to workers' safety and health. The Technical Rule TRGS 600, which supports the implementation of these requirements in Germany, also defines in this context "low-emission uses of a substance or mixture" [15]. The "integrated safe-to-use" refers to this definition.

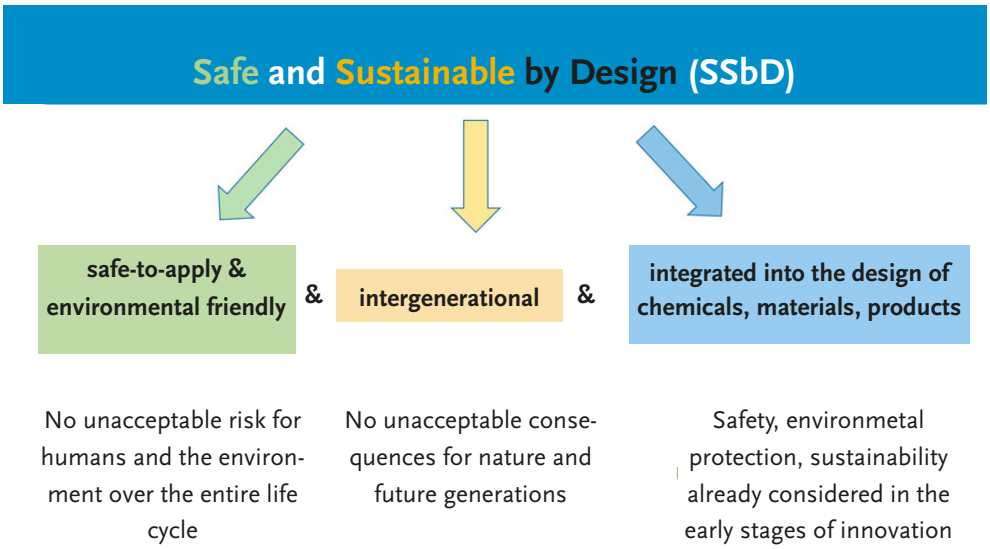

Fig.2 Integration of safe-to-use into a comprehensive concept for safe and sustainable by design of chemicals, materials and related products [16]

Fig. 2 demonstrates, how a safe-to-use approach in the workplace can be integrated into a more comprehensive approach to a safe and sustainable design (SSbD) of chemicals, materials and related products. A current focus are advanced materials, which play an important role for the challenges of climate change mitigation and a more resilient economy in the European Union. In co-operation with the German Federal Environment Agency and the Federal Institute for Risk Assessment, the conditions for risk governance of advanced materials were described [17]. Under the lead of the Netherlands National Institute for Public Health and the Environment (RIVM) detailed SSbD criteria for advanced nanomaterials have recently been published in a joint brochure [18]. In a running BAuA research project integrated safe-to-use solutions for chemicals are collected, categorised and evaluated on selected examples at model workplaces with regard to their protective effect [19]. These examples should contribute to a better understanding and promotion of safe-to-use chemicals, materials and products.

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