

# Position on the reform of REACH

## Key messages

- BASF supports the objectives and aims of the Green Deal and of the Chemical Strategy for Sustainability (CSS) including the targeted revision of the REACH Regulation to further strengthen protection of human health and the environment.
- Chemistry is essential for achieving the objectives of the EU Green Deal and for maintaining the wellbeing of people. Consequently, the most appropriate and proportionate regulatory measures have to be identified and implemented in order to adequately control exposure to hazardous chemicals and their emissions.
- The revision of the REACH Regulation which strengthens the EU's chemicals management must continue to be based on scientific principles, clear definitions and an ambitious but clearly defined scope which prioritizes substances for regulatory action. At the same time, development of safer and more sustainable alternatives should be incentivized. BASF stands ready to support policymakers based on its expertise as the largest registrant in the chemical industry.

## About the topic

1. The CSS is a key element of the EU Green Deal. It will lead to a fundamental change of the current chemicals legislation and will have major implications for the chemical industry, for downstream users of chemicals and finally for society.
2. The CSS entails a revision of the REACH Regulation, one of the EU's legislative cornerstones for regulating chemicals. The revision plans include the extension of a Generic Risk Management Approach (GRA), the introduction of a concept for "essential use", a reform of the authorisation and restriction processes, and the introduction of (a) Mixture Assessment Factor(s) (MAF), to name a few. The revision should take place "in the most targeted way possible, limited to achieving the objectives of the Strategy" as was stated in the CSS.

## What does BASF offer?

1. BASF supports the objectives of the Green Deal and CSS to protect human health and the environment. We continue our investment and commitment in research and innovation for supporting the development of safer and more sustainable chemicals. E.g., we steer our product portfolio based on sustainability criteria using our Sustainable Solution Steering method. We advocate for a science-based and innovation-driven regulatory framework to maintain the competitiveness of the European industry.
2. As largest registrant in the chemical industry, BASF has provided safety data in more than 2,000 REACH registration files and is working on improving the quality of dossiers. Since 2007, we have conducted about 4,000 ecotoxicological studies.
3. Keeping the quality of registration dossiers up to date is key to maintain the validity and credibility of risk assessment. In addition to complying to our legal obligation, BASF has been actively contributing to the improvement of dossier quality through the Cefic REACH Dossier Improvement Action Plan. BASF supports the "no data, no market" principle and welcomes a tightened compliance check and stricter enforcement.
4. To reduce our reliance on animal testing, we want to contribute to the development of New Approach Methodologies (NAMs) that are well validated and harmonised with international standards. BASF is already developing alternative test methods and achieved the OECD's approval for the world's first testing strategy for skin sensitization without animal testing in 2021.
5. We continuously train our employees, customers and logistics partners on the proper handling and optimal use of products with a particular hazard potential.

## Our position

1. **We propose the prioritization of substances for regulatory action** in a transparent process. The EU already has a comprehensive and protective regulatory framework comprising approximately 40 legislative instruments for regulating chemicals. However, a process to screen the best legislative instrument, including REACH as one of many, has not been formally established. Therefore, in order to achieve the goals of the EU Green Deal and CSS, we believe that the most appropriate regulatory action should be selected through an analysis of the regulatory management options at the start of a regulatory process; this may be REACH, but also others including the Industrial Emission Directive (IED) or the Occupational Safety and Health legislation (OSH).

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2. BASF supports further **improvements in the existing REACH framework with the aim to close potential gaps, with the following recommendations:**
  - a. The **information requirements for substances manufactured/imported in low tonnage (1-10 tonnes)** should be proportionate, based on exposure considerations where needs for hazard identification arises, avoid unnecessary animal testing and potential hurdles to innovation.
  - b. The current hazard assessment rules should be made more flexible to allow for a stepwise transition to a testing scheme that is based on **NAMs**. The resulting integrated assessment strategy must aim at reducing the reliance on animal testing in particular when there is limited exposure to human health and the environment. We support and actively contribute to the development of NAMs that are well validated and adhere to international standards.
  - c. **Downstream Users (DU)** should continue to support the registrants in collecting use and exposure information when necessary for specific cases. Any new reporting requirements on DU to ECHA should focus on substances considered for regulatory actions where data gaps are identified in developing regulatory measures, in the shape of call for evidence or questionnaire.
  - d. The assessment of risks may require an additional safety factor to account for toxicity of chemicals coexisting unintentionally. Solutions might include a targeted **Mixture Assessment Factor (MAF)**. There is scientific evidence, that the need for applying a MAF arises only in very exceptional cases, which can be identified based on the hazard properties of the substances, its use pattern and its potential for environmental releases. For more detailed information see Annex 1.
  - e. For **polymer registration**, a targeted, risk-based approach is essential, aligned with international registration schemes and reflecting the differences to low molecular weight substances. Registration and notification obligations need to be purposeful, proportionate, and value-adding towards the protection goals of REACH.
  - f. To assess a substance's potential to act as **Endocrine disruptor (ED)** more data need to be generated by applying validated OECD test guidelines in a tiered approach. Therefore, more OECD Guidelines especially on in-vitro methods (NAMs) need to be developed.
  - g. The REACH revision will include a proposal for a new definition of **intermediates**. The current intermediate concept is designed to keep information requirements and data generation proportional with the potential risk of exposure for substances which are fully transformed into other substances by a so-called "synthesis", and which are handled under strictly controlled conditions. This is an important element of the REACH framework and should be retained in the current form, which is fit for purpose.
3. **A holistic chemicals management strategy should be developed building on the strengths of complementary legislation.** Assessing the potential exposure to hazardous chemicals is required under different complementary legislation, such as OSH legislation, IED and sector-specific legislation targeting specific products (e.g., toys, cosmetics, biocides, plant protection products).
  - a. The **GRA** is an integral part of REACH which bans products classified as Carcinogenic, Mutagenic and Reprotoxic (CMR) from the consumer market. Under the CSS, the Commission aims to extend GRA to professional users to improve worker safety. As a result, the chemical toolbox for professional users will become significantly limited. Many substances will be banned from key applications and technologies in daily life and in business. Although a safe use can be demonstrated, and the well-established OSH regulation mandates workplace-specific risk assessments and risk management measures are in place. We rather recommend strengthening the available OSH regulations, e.g., by providing of technical guidance documents, introducing a EU training passport and extending OSH regulations to self-employed workers. EU-wide occupational exposure limits should be set for all substances of very high concern. For more detailed information see Annex 2.
4. Only if all other regulatory options are fully exhausted and the remaining risk is still deemed unacceptable, restricting the use of a chemical, including full or partial bans, under the REACH Regulation should be considered. BASF proposes the following:
  - a. **The restriction process should remain independent from authorisation** to focus on unacceptable risk on specific uses via case-by-case assessments. Authorisation should continue being granted when risks can be adequately controlled, or the advantages of the use of the substance outweigh the risks to human health or the environment and no suitable alternatives are available.



- b. In both restriction and authorisation processes, it should be possible for the industry to request derogations where a safe use is demonstrated, or the use is considered essential for society and/or to achieve the objectives of the EU Green Deal. The “**Essential use**” concept should be applied at the end of the restriction and authorization processes as a way to harmonize the derogation mechanism. Decisions on essentiality should be done on a case-by-case basis, linked to scientific assessments and be taken by a newly formed Essential Use Committee with a rather political mandate that should also include industry stakeholders.
- c. To protect consumers and the environment the already existing **GRA** for CMR substances for consumer uses could be extended to known endocrine disruptors (ED) and persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances as proposed by the Commission. Prerequisite for this extension is a timeline that allows for the development of scientifically sound criteria as well as validated testing methods for the identification of EDs. A further generic extension of GRA to other hazard classes, such as specific target organ toxicity, respiratory sensitization, immunotoxicity, or neurotoxicity, is not justified without additional rigorous scientific assessment. For more detailed information see Annex 3.
- d. The Authorisation process should remain focused on substances that need to be phased-out from the market, by incentivizing industry to replace the most hazardous substances with **Safe-and-Sustainable-by-Design (SSbD)** substitutes, particularly for consumer use. SSbD should consider the full lifecycle of a chemical in its application and end-of-life. Hazardous substances may be needed and essential for very sustainable products - with proper risk management measures they can improve the sustainability through their specific function. Clear definitions of safe use are already provided within the REACH regulation.
- e. The **Product Environmental Footprint (PEF)** can complement REACH as it considers, among many other impact categories of life-cycle assessment (LCA), the human-/eco-toxicity potential of all materials/chemicals with a scope covering the complete life cycle (cradle-to-grave) and can support a balanced assessment, also providing sustainability information of products in their specific use. The voluntary use of the PEF and the further development of the methodology is welcomed, but it should be introduced in other regulatory frameworks than REACH, because REACH is a substance- not a product-specific legislation. The human-/eco-toxicity information of REACH can be used as a basis for the lifecycle-based assessments with ProScale<sup>1</sup> as an impact category of adopted PEF.

<sup>1</sup> ProScale addresses the need to identify and quantify hazards and exposures from chemical constituents within products or otherwise used during their lifecycle. It proposes a performance-based indicator that can consolidate hazard and direct exposure potentials from chemicals along their life cycle, that can be applied and communicated within LCAs, Environmental Product Declarations (“EPDs”) and Product Environmental Footprints. It focuses on direct human exposure to chemicals along product value chains by (i) using life cycle thinking, (ii) using a hazard and exposure-based approach for product assessments, (iii) aggregating from single chemical to a complete product and (iv) using existing, systematic and readily available data. The ProScale method enables LCA practitioners to factor in hazard and exposure data in a simple and efficient way, based on established methods.