

Translation / Original: German

VdMi position on the introduction of a generic approach to risk management (GRA) under REACH Regulation

The Chemicals Strategy for Sustainability (CSS) published on 14 October 2020 by the European Commission is part of the European Green Deal and underlines the importance of protecting human health and the environment.¹

In the new CSS, the Commission has planned the implementation and integration of numerous legislative measures with the aim of improving the environment, health and safety and promoting innovations in the field of safe and sustainable chemicals. These include fundamental changes within the REACH and CLP Regulations.

The extension of the so-called generic approach to risk management (GRA)² in the REACH Regulation as proposed by the EU Commission would result in nothing less than a fundamental paradigm change of substance assessment. This solely hazard based approach for substances or groups of substances alone would lead to automatic bans of many substances for a huge variety of applications even though the benefit to human health is highly questionable. While the EU Commission expects simpler and faster restrictions by this fast-track system, the incredible success of the current, science-based approach which is based on a detailed risk assessment considering all means to prevent exposure would be completely neglected.

Our key messages and concerns:

- With the CLP and REACH Regulations, there have already been efficient and the world's most extensive chemicals regulations established in the EU
- The GRA contradicts the precautionary principle by focusing exclusively on the hazardous properties of a substance or groups of substances and neglecting exposure and risk
- The introduction of new terms and the departure from the tried and tested specific risk assessment would mean a change of paradigm in the entire chemicals assessment for which neither a need nor a justification is seen
- The GRA will result in many hazard classes triggering a blanket ban of substances or group of substances in many products and chemicals used by consumers and professional users
- Turning away from proven risk-based systems ignores the safe handling of chemicals in the past decades under REACH. This will result in a possible loss of essential chemicals as raw materials without any benefit to consumers /society.

¹ See also publication by the EU Commission ([link](#)).

² See also Commission Staff Working Document: Progress report on the assessment and management of combined exposures to multiple chemicals (chemical mixtures) and associated risks ([download](#) available).

Scope and purpose of the current REACH Article 68(2)

The so-called generic approach to risk management (GRA) is established in REACH Article 68(2). It allows to restrict proven CMR substances (cat. 1A or 1B) to be banned in consumer products. It is clearly restricted to these hazard classes and to substances, mixtures, or articles used by consumers. Products affected by this restriction need to bear the additional label 'Restricted to professional users'.

REACH Article 68(2) allows to implement restrictions for these substances without a detailed risk assessment³. Instead of elaborating a detailed restriction dossier and consulting the RAC and SEAC, a fast-track system⁴ may be used. In praxis, this led to general entries into REACH Annex XVII for all substances classified as CMR according to CLP Annex VI.

This way, a high level of protection was meant to be implemented in an easy and fast way for consumers which are usually not trained to handle hazardous substances and lack appropriate safety means.

However, the proposed changes of the EU Commission aim to (miss)use this system to implement generic, predetermined measures for a huge number of substances which are currently safety handled within the given regulatory frameworks. Whole groups of substances shall be banned in various applications solely based on hazardous properties. Therefore, the term of 'risk management' is misleading as the proposed new way of substance evaluation does not foresee any risk assessment and therefore neglects well-defined and proven risk approaches applied under the REACH Regulation and other European chemicals legislation.

Proposed extension of the GRA as part of a paradigm change in substance evaluation

According to the Chemicals Strategy for Sustainability, the EU commissions plans to change the fundamental principles on which substance evaluation is currently based. By implementing four separate but interlinked measures, a paradigm change is strived for. The four cornerstones are:

1. Introduction of new hazard classes in the CLP Regulation
2. Extension of the generic approach to risk management under REACH Regulation
3. Establishing a concept of "essential uses" as a loophole
4. Amplifying innovation for "safe and sustainable-by-design" chemicals

Overall, five new hazard classes are currently in discussion to be implemented in the CLP Regulation: PBT, vPvB, PMT, vPvM, and ED.⁵ Additionally, new classes for immunotoxic and neurotoxic substances are proposed for future implementations.

After introducing these new hazard classes, they – among others – shall become part of the GRA. The scope of REACH Article 68(2) shall be widened significantly. An overview of the proposed changes is given in the table below.

At the moment, 2617 substances are identified as CMR, cat. 1a or 1b.⁶ Just by extending the GRA to the five new CLP hazard classes in discussion would quadruple this number to more than 10.000 affected substances.⁶ Further extensions to more hazard classes and CMR categories 2 would further increase this number. On top of that, the expansion to professionals increases the number of affected mixtures tremendously.

³ See also REACH Article 68. Description of the restriction process incl. risk assessment in REACH Articles 69-73.

⁴ See also REACH Article 133, paragraph 4.

⁵ See also VdMi position paper on CLP Revision ([download](#) available) and on the introduction of new hazard classes ([download](#) available).

⁶ See also CEFIC Report *Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability*, Phase 1 Report ([download](#) available).

	Current GRA according to REACH Article 68(2)	Future GRA as proposed by EU Commission
Included hazard classes	<ul style="list-style-type: none"> • CMR, cat. 1A and 1B 	<ul style="list-style-type: none"> • CMR, cat. 1A and 1B • ED • PBT, vPvB • PMT, vPvM • Respiratory sensitizers • STOT RE, cat. 1 and 2 • STOT SE, cat. 1 and 2 • Immunotoxic substances • Neurotoxic substances • Skin sensitizers • Chronic aquatic toxicity • CMR, cat. 2
Affected target groups	<ul style="list-style-type: none"> • consumer 	<ul style="list-style-type: none"> • consumer • professionals

In cases where these substances are in their respective applications critical for functioning of society and there are no alternatives available, these applications shall be saved by the introduction of the so-called 'essential use' concept. This is a loophole concept. However, essentiality is a fast-changing and very individual aspect. The EU Commission still owes any explanation how this system shall be implemented: who will decide what is deemed essential, on what criteria shall this decision be based, and how shall this decision process stray flexible enough to allow timely changes in cases of urgency. If the COVID-19 pandemic taught us one thing, it is that in case of an unforeseeable emergency, we need fast and agile responses.

In parallel to the restriction of many substances, those chemicals deemed as 'safe and sustainable' shall be supported. Again, a detailed description of the criteria by the EU Commission is pending. Especially the aspect of 'sustainability' leaves room for interpretation.

Articles usually consist of a variety of substances, each with a specific task. Additives often increase the sustainability of product significantly by improving its lifetime or robustness. However, an article might also fulfil its purpose without these additives. Both, in the discussion of 'essential use' and in 'safe and sustainable' this aspect may be an important factor. Pigment and fillers do not only add color but also improve processing properties, the performance of the final article and its lifespan. Additionally, the positive impact of colors on mental health is scientifically proven. From our point of view, these are aspects that should be considered when discussing essentiality in context of sustainability.

Solely hazard-derived restrictions not appropriate, justified, or needed

The combination of the GRA and the concept of essential use constitutes a new paradigm for the assessment of chemicals. With this proposal the Commission seems to replace existing specific risk assessment by an incomplete and therefore misapplied use of the precautionary principle based only on hazard assessment and ignoring use and exposure. As a result, the current, proven

risk assessment and derived regulatory measures would become an exemption instead of the standard approach as it is nowadays. Instead, blanket bans for a high number of substances would apply resulting in a possible loss of essential chemicals as raw materials without any benefit as these are already handled safely today.

Only a detailed, specific risk assessment is the key to a proportionate and non-discriminatory set of measures, since generally there is a risk only when there is exposure to or release of a hazardous substance.

Know-how of professional users should not be ignored

The extension of the GRA to professional users would affect a huge variety of products on the market. Especially, craftsmen would be affected, losing essential working materials or having to cope with decreased performance. And again, a decrease in performance also endangers sustainability goals.

But professionals are not comparable to consumers. In most EU member states, there are training and qualification systems for all professions handling chemical substances. The know-how of professionals covers working with products that are in some cases not even available for consumers. This is one aspect, setting a professional apart from laymen and do-it-yourself craftsmen.

Additionally, professionals are usually more protected. Besides special workwear including personal safety equipment if needed, occupational safety regulations must be observed. Thereby, exposure to hazardous substances is reduced, decreasing the risk of potential effects on professionals' health. OELs and other means to reduce exposure, are the results of a detailed risk assessment and prove the success of the current system.

Proposed paradigm change does not facilitate or speed up substance assessment but only creates uncertainties

While the GRA will trigger blanket bans for all substances falling under the covered hazard classes, the substance assessment will not speed up as intended by the EU Commission. Instead of compiling scientific data on hazards and exposure to derive appropriate and proportionate measures as it is done in a risk assessment, discussions would shift towards far more complex topics which are constantly open for interpretation.

There are diverse measurement techniques available and commonly accepted to assess the hazard of a substance and to measure or estimate possible exposure. Therefore, the risk assessment is scientifically sound. However, criteria as 'essential' or 'sustainable' cannot be directly measured. Instead, arguments need to base on more general aspects, subject to constant changes. This leads to a lot of uncertainties for companies impeding innovations and does not allow for long-term planning which brings the EU's industry in disadvantage in the global perspective. Both effects would only weaken EU's industry and hamper a transition towards a resilient, innovative, and competitive economy.

Conclusion

The proposed extension of the generic approach to risk management is part of a planned paradigm change in substance assessment. The inclusion of additional hazard classes and the extension to professional uses would lead to generic, automatic, and therefore unjustified bans of a high number of chemicals. This loss of essential substances or groups of substances is not justified or reasonable and does not improve the protection of human health and the environment.

At the same time, the goal to achieve faster and easier restrictions in that way is highly questionable. Instead of the well-established risk assessment based on scientific data with precise criteria on hazard, exposure, and the resulting risk, softer arguments on essentiality and sustainability

would be in focus. The corresponding uncertainty for future innovations will bring EU's industry in disadvantage and hinder the steps necessary for the transition to a really sustainable and resilient economy.

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