



Downstream Users of Chemicals Co-ordination group

## DUCC comments: AP4\_1\_CA\_19\_2022\_GRA

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The Downstream Users of Chemicals Co-ordination group (DUCC) thanks the European Commission for the opportunity to provide comments on the aforementioned document on the extension of the generic approach to risk management in the REACH Regulation.

In addition to responding to the Commission's questions below, DUCC wishes to supplement its contribution with an annex outlining three examples to support our points, as well as a more extensive explanation of formulation chemistry and the intricacies faced by formulators in the case of a restriction.

1. *Do you support the overall approach sketched out for the implementation of the generic approach to risk management or do you think that there are key elements not taken into account? In particular, do you agree with the gradual implementation of restrictions under Article 68(2) according to a work plan?*

DUCC has the following comments on the approach:

- DUCC does not support the extension of the generic approach to risk management (GRA) to professional uses.
- Implementing the GRA at once for all hazard classes and scenarios foreseen in the CSS would create an unmanageable workload, for both economic operators and authorities. Therefore, DUCC finds value in the proposal of a work plan for gradual implementation, which identifies where such restrictions may be appropriate, e.g. where risks are not demonstrated to be adequately controlled, and would be effective to improve protection of human health and the environment, i.e. focusing on what matters most.
- It is important that any regulatory measure remains proportionate and not more restrictive than necessary to reach the objectives (in the case of REACH: a high level of human and environmental protection). This is not only a firm principle of EU legislation but also an obligation under international trade agreements.
- DUCC stresses the importance of including an additional derogation procedure, that is practical, and also considers "demonstrated safe use" – i.e., if the use of a chemical is unambiguously shown to be safe, a ban is not justified nor necessary to reach the legitimate safety objective of REACH.

2. *What is your view on the possibility to differentiate between different types of articles? What should be the criteria for such differentiation?*

The vast majority of products placed on the market by DUCC members are mixtures, however articles may still be of some relevance in the context of packaging or delivery systems. DUCC believes that restriction proposals for articles should be decided on a case-by-case basis, as is currently the case for CMRs, and based on consideration of the potential for exposure to, or emission of, the substance.

3. *What is your view on the possibility to differentiate between types of professional uses? What should be the criteria for such differentiation?*

DUCC does not support the extension of the GRA to professional users:

- Professional workers are not consumers and should therefore not be subject to the same restrictions or prohibitions.
- Professional workers are subject to a comprehensive set of occupational health and safety rules (established in OSH legislation) aimed at protecting them from the risks posed by the chemical substances they handle.
- Lack of compliance with existing OSH requirements should not be a reason to automatically compare professionals with consumers but rather OSH legislation should be improved and harmonised to protect all professional users.



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- Professional workers perform tasks that are important for the society and circular economy and they need chemical products to perform those tasks.
- The current legal framework already provides an appropriate set of tools. For example, targeted and specific restrictions could be established under Article 68(1) or harmonised classification and labelling (CLH) could be established in combination with substance-specific limits

4. *Which elements should be taken into account in defining the terms 'consumer use' and 'professional use' in REACH for the purposes of the implementation of GRA?*

'Consumer use' applies to any product which is available to the general public, for use outside the context of paid work. This would also apply to products that are in principle intended for professional use, but their supply is not restricted or controlled such that they are only available to professionals.

'Professional use' by contrast relates to use in the conduct of an occupation or any paid work, but not in an industrial facility/setting. Professional users are subject to occupation health and safety regulations and therefore trained to safely handle chemical products. This is also the main difference with consumers.

5. *Do you have other suggestions to structure GRA restrictions, limit or extend their scope, and on the implementation scenarios?*

A crucial point for downstream users, for a future regulatory process that will not result in an unworkable number of requests for derogations, is the importance of a practical, effective procedure, that focusses on what matters, and has a workable derogation process.

To substantiate safe use, more information can be provided by DU, but the level of detail to be provided for any screening process should be case specific, depending on the level of concern, available data etc. to ensure a workable system.

Voluntary industry actions to manage the risk of specific ingredient classes and ensure safe use should also be considered before taking a regulatory decision purely based on hazard.



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## ANNEX

### DUCC comments GRA\_EXAMPLES

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#### Impact of the GRA and possible solutions

DUCC wishes to bring forward three examples of the possible impact of the GRA and use these as case studies to propose alternative solutions.

#### *Salicylic Esters in Cosmetics*

In December 2021, ECHA published the substances/groups for which further regulatory actions would be needed<sup>1</sup>. One of the targeted groups is salicylic esters<sup>2</sup> comprising 27 individual substances. ECHA stated that ...*"the need for restriction for skin sensitisation and reprotoxicity is due to potential for prolonged consumer exposure during scented article service life. Only two substances, ECs 201-732-5 and 228-408-6 are reported to be used for this purpose, however it is suggested to cover all salicylates in the proposed restriction due to structural similarity of the substances and potential for substitution"*. Without questioning the scientific approach taken for the grouping, if the group of salicylic esters would fall under the GRA, it is DUCC's understanding that all these substances would be banned without any risk and safe use considerations.

The potential to act via substitution cited by ECHA, is in this case not-existent. Banning all salicylates through a group approach cannot be 'fixed' by using other fragrance ingredients, simply because there are very few other substances with a similar olfactive profile in existence. The result of such a regulatory measure would effectively be the decimation of an entire family of scents (Floral, Balsamic), something unprecedented in the fragrance industry. The impact on perfumers would be similar to removing the colour light green from a painter's palette.

One of these substances in the group of salicylic esters would be methyl salicylate which has been found to be safe for cosmetics by the SCCS<sup>3</sup> (Scientific Committee on Consumer Safety). Moreover, this substance is a constituent of several essential oils (e.g. *wintergreen*, *spearmint*, *peppermint*) which would also be forbidden because of the presence of methyl salicylate given that there is no possibility to remove this constituent from the NCSs (Natural Complex Substances). Therefore, the only possibility would be to ban the use of any natural substance containing methyl salicylate. This situation would have a huge impact for the sector without a science-based justification.

Conversely, for cosmetics, industry reported the use of methyl salicylate as: a flavouring agent, smoothing agent in oral hygiene products such as toothpastes, mouthwashes and breath fresheners, perfumery, bathing products such as soaps, detergents and oils, body and hand preparations and mud packs, skin care preparations, foot powders and hair products such as

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<sup>1</sup> <https://echa.europa.eu/-/first-assessments-of-regulatory-needs-for-groups-of-chemicals-published>

<sup>2</sup> <https://echa.europa.eu/documents/10162/c1a1f586-cfda-e5b4-61b9-2ac473d953c5>

<sup>3</sup> [https://ec.europa.eu/health/system/files/2021-11/sccs\\_o\\_255\\_0.pdf](https://ec.europa.eu/health/system/files/2021-11/sccs_o_255_0.pdf)



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shampoo and conditioners and pharmaceutical application with respective use concentrations. Following an exposure assessment, toxicological evaluation and evaluation of safety, the SCCS opinion concluded Methyl salicylate safe, when used in cosmetic products up to the maximum concentrations cited.

The cosmetics industry provided an extensive dossier to demonstrate the safe use of methyl salicylate in the products. **There is thus precedent for situations where concerns arise from authorities and more detailed descriptions on use can be provided to substantiate safety.**

### *Enzymes in Detergents*

Enzymes are protein-based catalysts speeding up biological processes. These ingredients exist abundantly in nature from microorganisms to our own bodies. Enzymes used in detergent products are produced by microorganisms in fermentation processes. The fermentation process uses carbohydrates, protein, mineral salts and vitamins including sugar and other agricultural products as feedstock for organisms<sup>4</sup>.

Enzymes are used in detergent products to enhance cleaning performance while decreasing environmental impact. They help the breakdown of larger molecules into smaller fragments, that then can be removed easily by other ingredients in the formulation. In general, each enzyme is good at targeting a certain type of stain removal from surfaces. In the detergent industry, commercial enzymes are used to provide a higher degree of stain removal, whiteness, fabric and colour care and overall cleaning performance. Enzymes have minimal environmental impact as they are proteins, thereby they are readily biodegradable. These ingredients have enabled significant environmental savings for detergent and maintenance products: washing at low temperatures, innovative compact products, alternative technologies to replace phosphates<sup>5</sup>.

Enzymes are classified as Respiratory Sensitizer Category 1 under CLP regulation. If a blanket ban was placed on these ingredients simply due to their hazard, this would lead to a loss in important environmental and technological benefits.

However, safety is of utmost importance for the enzyme, cleaning, and hygiene industry. The industry has 50+ years of experience on the safety of enzymes under both occupational and consumer conditions and focusing on product design and guidance to obtain exposures below the respective DMELs. Ample material on the safe use of these ingredients have been co-created, including guidance, webinars and posters for professional workers<sup>6</sup>.

Industrial enzymes have an excellent safety profile with little ability to cause adverse responses in humans. Enzymes pose no risk of acute toxicity, repeat dose toxicity, genotoxicity, carcinogenicity or reproductive and developmental toxicity. Reproductive

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<sup>4</sup> <https://www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/LCAs/CradletogateenvironmentalassessmentofenzymeproductsproducedindustriallyinDenmarkbyNovozymesAS.pdf?la=en>

<sup>5</sup> AISE-AMFEP-HCPA-ACI Enzyme Factsheet <https://aise.eu/cust/documentrequest.aspx?UID=ecaa311b-701c-4a50-83ea-f66963f04d87>

<sup>6</sup> [SAFE HANDLING OF ENZYMES - AISE](#)  
[ACIConsumerEnzymeProductRiskAssessmentGuide.pdf \(cleaninginstitute.org\)](#)



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toxicity and carcinogenicity are not endpoints of concern<sup>7</sup>. The important exception is the intrinsic potential of enzymes, like other proteins, to act as respiratory sensitizers. Repeated inhalation exposure to a high dosage of the same enzyme may eventually cause a sensitised person to develop allergy symptoms. Sensitization by itself does not cause symptoms, but repeated high dosage exposure to the same enzyme can cause a sensitized person to develop allergy symptoms at a later point in time<sup>8</sup>.

Derived Minimal Effect Levels (DMEL) have been set at 60 ng/m<sup>3</sup> for workers and at 15 ng/m<sup>3</sup> for consumers<sup>9</sup> based on the data generated over decades. Published data from the detergent industry<sup>10</sup> and the enzyme manufacturing industry<sup>11-12-13</sup> shows that controlling airborne exposure using the DMEL as a target leads to a safe working environment with a very limited number of allergies. Incidents of enzyme allergy have been reported in cases where risk mitigation and the DMEL have not been applied or have failed for technical reasons<sup>14</sup>.

Allergy to enzymes among consumers of enzyme containing laundry and cleaning products has not been reported since the late 1960's. Clinical evidence showed that the prevalence of enzyme specific sensitization in the population is very rare (0.126% in the 1977 –2010 period)<sup>15</sup>. This demonstrates that sensitisation due to exposure to enzymes via laundry and cleaning products is not an issue among the general population.

**Voluntary industry actions, as well as regulations, to manage the risks of specific ingredient classes and ensure safe use should also be considered before taking a regulatory decision based on hazard.**

#### *Safe use of diisocyanates - Professional Users in an Industrial Setting*

As of 24 August 2023, training is required for all professional and industrial users of products with a total monomeric diisocyanate concentration of > 0.1%. Details of this restriction can be found in all EU languages via EUR-Lex, the European Union's website offering access to EU law.

DUCC members, such as FEICA, EFCC and CEPE, in close cooperation with the European Diisocyanate & Polyol Producers Association (ISOPA), the European Aliphatic Isocyanates Producer Association (ALIPA), and several other industries in the polyurethane industry, launched a comprehensive training programme to ensure the safe use of diisocyanates for

<sup>7</sup> : Basketter D et al, Enzymes in cleaning products: An overview of toxicological properties and risk assessment/management Regulatory Toxicology and Pharmacology 64 (2012) 117–123. <http://dx.doi.org/10.1016/j.yrtph.2012.06.016>

<sup>8</sup> Basketter et al,

Enzymes and sensitization via skin exposure: A critical analysis, Regulatory Toxicology and Pharmacology 129 (2022) 105112

<sup>9</sup> Basketter et al., 2010. Defining occupational and consumer exposure limits for enzyme protein respiratory allergens under REACH. Toxicology 268: 165-170.

<sup>10</sup> Cullinan P., J.M. Harris, A.J. Newman-Taylor et al. (2000). An outbreak of asthma in a modern detergent factory. *Lancet* 356:1899–1900.

<sup>11</sup> Johnsen C.R., Sorensen T.B., Larsen A.I., Secher A.B., Andreassen E., Kofoed G.S., Nielsen L.F., Gyntelberg F. (1997) Allergy risk in an enzyme producing plant: a retrospective follow up study. *Occupational and Environmental Medicine* ;54:671-675

<sup>12</sup> A I Larsen, C R Johnsen, J Frickmann, et al. (2007) Incidence of respiratory sensitisation and allergy to enzymes among employees in an enzyme producing plant and the relation to exposure and host factors. *Occup Environ Med*;64:763–768. doi: 10.1136/oem.2005.025304.

<sup>13</sup> A. I. Larsen, L. Cederkvist, A M Lykke, P Wagner, C. R. Johnsen, L. K. Poulsen, (2020) Allergy Development in Adulthood: An Occupational Cohort Study of the Manufacturing of Industrial Enzymes. *J ALLERGY CLIN IMMUNOL PRACT VOLUME 8, NUMBER 1*

<sup>14</sup> Cullinan P., J.M. Harris, A.J. Newman-Taylor et al.: An outbreak of asthma in a modern detergent factory. *Lancet* 356:1899–1900 (2000).

<sup>15</sup> Sarlo, K., Kirchner, D.B., Troyano, E., Smith, L.A., Carr, G.J., Rodriguez, C., 2010. Assessing the risk of type 1 allergy to enzymes present in laundry and cleaning products: evidence from the clinical data. *Toxicology* 271, 87-93.



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producers and professional users all over Europe. In this way, these Downstream Users ensure that all end-users of PU containing products across Europe continue to handle diisocyanates safely across Europe. From 24 February 2022 at the latest, all PU products for which safety training is required can be identified by the following statement: 'As of 24 August 2023, adequate training is required before industrial or professional use of this product.'<sup>16</sup>

The example of the diisocyanates is brought forward to show that **industrial or professional users operating in a setting similar to industrial use can be expected to apply the appropriate risk management measures, such as specific workplace conditions, training of workers, proper work instructions and supervision as set up under OSH.**

While DUCC acknowledges that some workers, e.g. self-employed, will have less knowledge on the risks of chemicals and chemical mixtures, regulatory actions should play a role to improve such knowledge to increase the protection of human health and avoid a systematic ban.

We refer to the publication of ECHA on the 1st of December 2020, i.e. '*A thought starter how to better regulate professional users border-lining with industrial and consumer users under REACH restriction*', which aims, amongst others, to help define the approach for adequate protection of professional users from exposure to chemicals.

DUCC would support actions aiming to increase the protection of professional workers that should thus first focus on increasing the level of safe use knowledge, via mandatory training, education, simplified communication or other tools. Consequentially, the GRA should focus on what matters most amongst non-trained people or uses still identified as not safe.

#### Conclusions from the DUCC examples

A future regulatory framework that acts through a blanket approach and does not focus resources on what matters, will result in unintended/unexpected consequences of the disappearance of useful products from the EU market without strong justification that this was absolutely necessary for the protection of Human health or the environment. A prioritization process could instead lead to a more targeted approach.

DUCC supports an **early screening process** to determine the appropriate way forward before any regulatory action is taken. Creating such a screening procedure that accounts for information provided by industry at an early stage, would allow authorities to have an option of targeting risk management to where risks occur or where concerns have not been addressed. **The level of detail to be provided for this screening process should be case specific, depending on the level of concern, available data etc. to ensure a workable system.**

Possibilities of derogations for safe uses should be envisaged. The 'screening procedure' suggested above could be used as an opportunity to properly scope the proposed risk management measure **including relevant upfront exemptions or derogations, which would**

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<sup>16</sup> <https://www.feica.eu/our-projects/safe-use-diisocyanates>





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**limit the need for authorities to assess, likely very granular, derogation applications from restrictions after these have been decided with a generic or all-encompassing scope.**

**GRA would be envisaged only when no other practical and appropriate risk reduction measures can be applied.**

Finally, for professional users we support for a definition and for requirements that **distinguish between the level of training of different professional user categories and where the GRA should focus on what matters most amongst non-trained people or uses still identified as not safe.**

### Formulation Chemistry

A note on formulation chemistry.

Formulation chemistry is a branch of chemicals manufacturing that deals with substances that typically don't react with each other, but contribute to the final product in some way. For example, a paint may be made of pigment (to provide the desired colour), binder (to stick all together on the surface), solvent (carrier, dissolver), etc. These don't react with each other, but all play a role in the final product.

A good analogy to formulation is that of baking where ingredients in different ratios are added to make the final products, however with considerable, additional complexity:

- **Manufacturing:** in industry, a formulation is likely to be made many more times than any professional or amateur baker might make at home. Also, the level of precision in weighing, analysing and recording observations will be much higher during industrial research. A formulation cannot have significant variability between batches. Customers expect paints, detergents, adhesives and other formulations to always have consistent texture, pourability, colour.
- Companies cannot only consider the mixing step of the single product but also need to ensure other aspects, such as:
  - The product must go through the pipes of the manufacturing plant,
  - It remains in the container in a way that it can be functionally used by an end user,
  - To reduce the amount of product that remains as waste inside packaging,
  - Don't want your product to spoil.
  - Etc.
- **Restrictions:** Remaining on baking, we imagine a restriction of one ingredient: like (ethyl)alcohol. This would impact the production of certain kinds of cakes, but could be replaced with alcohol-like flavourings (e.g. alcohol-free rum flavour). For restriction of a large class of products – such as all animal derived ingredients or of milk. It may be possible to do this on large scale, but what are the impacts of the whole supply chain moving in that direction? E.g. an entire industry moves towards plant-based milk.



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What are the implications on the subsequent availability of plant-based milk? Is there enough being produced in the world for this sudden shift?

Even if no reaction chemistry takes place within such a complex product, it needs to be ensured that all ingredients do not negatively affect the overall performance of the product (stability, miscibility, colour, odour, etc.). As a consequence, there is no easy way of replacing a given ingredient by another within any given mixture.

Hence, a blanket prohibition of any given substance for all its uses based on an intrinsic hazard is disproportionate and has too many unintended consequences. Instead, a more tailored approach should be adopted.





DUCC is a joint platform of **11 European associations** whose member companies use chemicals to **formulate mixtures** (as finished or intermediary products) for professional and industrial users, as well as for consumers.

DUCC's membership represents several important industry sectors, ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, disinfectants, lubricants, crop protection, and chemical distributors industries. Altogether, their membership comprises more than **9.000 companies** across the respective sectors in Europe, **the vast majority being SMEs**. The calculated turnover of these companies is more than 215 billion euros in Europe.

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DUCC's public ID number in the **Transparency Register of the European Commission** is:  
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