Downstream Users of Chemicals Co-ordination group

DUCC comments GRA

DUCC wishes to support a future regulatory framework that is protective of human health, focuses resources on what matters, is workable and enforceable.

In this context DUCC wishes to comment on the *generic approach to risk management* (GRA). 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 workable procedure, that focusses on what matters, and will have a workable derogation process.**

The *generic approach to risk management* is based on the principle that the intrinsic properties of substances alone are determinant for regulatory measures, such as ban of certain uses. In this case, no risk assessment takes place, and therefore nor are the conditions and risk management measures determined for ensuring safe use. The risk approach which is otherwise usual under the REACH Regulation and in European chemicals legislation is not applied with the GRA.

The extensive package of measures under the Chemicals Strategy for Sustainability (CSS) includes a fundamental revision of the REACH Regulation. In this context, the application of the generic approach to risk management is intended to be extended in two directions, empowering the Commission to take action on:

i) Possibly expanding the applicability of the GRA beyond substances with CMR properties of Categories 1A and 1B, as is currently the case, to endocrine disrupters and substances with PBT and vPvB properties. In a second step, a further extension is to be examined to substances which are respiratory sensitisers, and which are immunotoxic and neurotoxic, as well as to substances with specific target organ toxicity (STOT).

ii) Broaden the scope of application to risk management to products for use in the professional sector.

DUCC supports the objectives of the Chemical Strategy for Sustainability in encouraging innovation towards safe and sustainable alternatives. We acknowledge this to be the aim of the GRA approach.

Formulation Chemistry

A note on formulation chemistry.

Formulation chemistry is the branch of 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 different ingredients e.g. flour, oil, cocoa powder, milk and eggs are mixed together as specific quantities to make a final product. In this case, chocolate cake. The different ratio and quality of each ingredient allow to make different formulations to best please consumers. Tastes vary depending on consumers, regions, cultures, hence different formulations based on the same ingredients are necessary to satisfy the market.

There are different recipes that will result in chocolate cakes with slightly different results, similarly there can be different formulations that result in products of similar effects. Sometimes the order of bringing together different ingredients is of major importance. This is the principle behind formulation**. Re-formulation** is needed when customers require other properties or if the properties of the raw materials change. This is a continuous process in formulating industries where R&D departments work to find better recipes to products. In a similar way that a baker may find that their cake had a poor rise and was therefore dense. In order to overcome this our baker bakes the same cake or "formulation" again but this time they increase the amount of raising agent they use by a few grams. The resulting cake has a better rise. However, reformulation is not always a linear process. The baker may use a different brand of eggs than usual, which are bigger and have more liquid egg than a previous time. Therefore, as the batter is more liquid, the baker may need to compensate with more flour and then find their cake to be dense once more.

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 greater during industrial research. In a manufacturing setting there are increased complexities to be considered.
A company needs to ensure they have sufficient ingredients to continue running. Therefore, they need to ensure access to different suppliers of raw materials and there may be slight reformulations needs as suppliers change (refer to the egg example above).
However, a company cannot have as much variability between batches. Consumers expect products to always have consistent texture, pourability, colour.
Companies cannot only consider the mixing step of the single product but need to make sure other aspects:

- That the product can go through the pipes of the manufacturing plant,
- It will remain 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: Restrictions on ingredients thus have a specific impact on formulators. Returning to the backing example we imagine a restriction of one ingredient: like 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 on a large class of products – like all animal derived ingredients or restriction on animal 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. What are the implications on the subsequent availability of plant-based milk? Is there enough being produced in the world for this sudden shift?

A blanket restrictions for a substance to all its uses may not be proportional or could lead to too many unexpected consequences. Depending on the objective of the restriction, forbidding the use of certain ingredients in specific products (only in cakes?) may be more proportionate that doing it in all foods.

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[1]. One of the targeted groups is salicylic esters[2] 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. One of these substances would be methyl salicylate which has been found to be safe for cosmetics by the SCCS[3] (Scientific Committee on Consumer Safety). Moreover, this substance is a constituent of several essential oils (Natural Complex Substances) 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, therefore the only possibility would be to stop using them. 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

[1] https://echa.europa.eu/-/first-assessments-of-regulatory-needs-for-groups-of-chemicals-published
[2] https://echa.europa.eu/documents/10162/c1a1f586-cfda-e5b4-61b9-2ac473d953c5
[3] https://ec.europa.eu/health/system/files/2021-11/sccs_o_255_0.pdf

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 that safe use of methyl salicylate in the products. **There is thus precendent 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[4].

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. Enzymes are proteins, thereby they are readily biodegradable. 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. These ingredient have enabled significant environmental savings for detergent and maintenance products: washing at low termperatues, innovative compact products, alternative technologies to replace phoshates[5].

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 environmenal and technological benefits.

However, safety is of utmost importance for the enzyme, cleaning, and hygiene industry. The industry have 50+ years of experience on the safety of enzymes regarding 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, posters for professional worker[6].

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

[4] https://www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/LCAs/CradletogateenvironmentalassessmentofenzymeproductsproducedindustriallyinDenmarkbyNovozymesAS.pdf?la=en
[5] AISE-AMFEP-HCPA-ACI Enzyme Factsheet https://aise.eu/cust/documentrequest.aspx?UID=ecaa311b-701c-4a50-83ea-f66963f04d87
[6] SAFE HANDLING OF ENZYMES - AISE ACIConsumerEnzymeProductRiskAssessmentGuide.pdf (cleaninginstitute.org)

toxicity and carcinogenicity are not endpoints of concern[7].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[8].

Derived Minimal Effect Levels (DMEL) have been set at 60 ng/m^3 for workers and at 15 ng/m^3 for consumers[9] based on the data generated over decades of years. Published data from the detergent industry[10] and the enzyme manufacturing industry[11,12,13] 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[14].

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)[15].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 regulation, to manage the risk 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.

FEICA, in coordination 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 producers and professional users all over Europe. In

[7] : 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
[8] Basketter et al,
Enzymes and sensitization via skin exposure: A critical analysis, Regulatory Toxicology and Pharmacology 129 (2022) 105112
[9] Basketter et al., 2010. Defining occupational and consumer exposure limits for enzyme protein respiratory allergens under REACH. Toxicology 268: 165-170.
[10]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.
[11] Johnsen C.R., Sorensen T.B., Larsen A.I., Secher A.B., Andreasen 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
[12] 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.
[13] 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
[14] 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).
[15] 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.

this way, FEICA also ensures that all end-users of PU containing adhesives and sealants across Europe continue to handle diisocyanates safely. 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.[16]

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 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 instread lead to a more targeted approach.

DUCC supports an **early screening process** for determining 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**

[16] https://www.feica.eu/our-projects/safe-use-diisocyanates

limit the need for authorities to assess (possibly 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 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.**

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About DUCC

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 focuses on the downstream users' needs, rights, duties and specificities under **REACH** and **CLP**.

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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