April 2022

REACH REVISION – PUBLIC CONSULTATION

Cosmetics Europe represents the cosmetics and personal care industry in Europe. The vast majority of Europe's 500 million consumers use cosmetic and personal care products every day. Ranging from dermo-cosmetics, antiperspirants, fragrances, make-up and shampoos, to soaps, sunscreens and toothpastes, these products play an essential role in all stages of our life. European citizens use cosmetic products as part of their daily lives. Our industry provides choice for all consumers whoever they are, wherever they are from, that serve their needs and expectations. These needs and expectations drive our industry as well as delivering innovative products that enhance consumers' well-being and quality of life and boost their self-esteem. The European cosmetics and personal care market is the largest in the world, with a value of €79.841billion (retail sales) in 2019.

Cosmetics Europe welcomes the opportunity to engage with the European Commission on the revision of REACH.

EXECUTIVE SUMMARY

Introduction of GRA and essential use concept and/or its application under REACH

- Cosmetics Europe supports a proportionate GRA approach that triggers an automatic restriction of substances classified as (CMR Cat. 1, ED Cat. 1, PBT, vPvB), whilst allowing for exceptional derogations based on demonstrated safety or essentiality, with the burden of proof resting on the industry.
- A well-functioning model for such GRA approach already exists under the Cosmetic Products Regulation and similar principles should be considered for REACH.

Information in the supply chain, including on use and exposure

- In justified cases, it may be useful that downstream users provide specific information on use and exposure. However, systematic provision by downstream users of detailed use and exposure information on all substances would impose significant and unnecessary burden on the industry.
- Under the Cosmetic Products Regulation, a functioning system is in place, ensuring provision of detailed use and exposure information to the Scientific Committee on Consumer Safety (SCCS) when human-safety concerns for a specific substance require a regulation. This sector-specific approach for human-safety should be maintained not be replaced by a future general mechanism under REACH.

Mixture Assessment Factor (MAF)

- Application of one blanket MAF for all chemicals will lead to unnecessary restrictions/bans of safe chemicals and to unnecessary animal testing.
- The MAF concept should only apply to the substances of highest concern and the actual MAF values be tailored to different types of use and different types of effects. MAFs should be considered as a 'tier 1' approach that can be replaced by more specific scientific approaches when more detailed data is available.

Accelerating the acceptance and use of NAMs through the revision of REACH

- The REACH revision is a unique opportunity to recognize the state of the science on New Approach Methods (NAMs) and enable their widespread use and regulatory acceptance for hazard identification and risk management of chemical substances.
- Shifting towards a risk-based approach drawing on use-specific exposure data and NAMs would ensure an equally high level of safety, while avoiding unnecessary animal testing.
- It is crucial that REACH facilitates scientific progress and regulatory acceptance of NAMs to ensure everyone fulfils their legal obligations to uphold animal testing as a last resort.

1. INTRODUCTION OF GRA AND ESSENTIAL USE CONCEPT AND/OR ITS APPLICATION UNDER REACH

Cosmetics Europe understands that classification of a substance as CMR Cat. 1, ED Cat. 1, PBT, or vPvB is an alert that requires efficient and effective risk management. We also understand the authorities' wish for speed and simplicity of the risk management process. A 'Generic Risk Management approach (GRA)' and the concept of 'essential use' can help to achieve the original objective of REACH, i.e., 'a high level of protection of human health and the environment'[1].

However, it is important that any regulatory measure remains proportionate and not more restrictive than necessary to reach the objective. This is not only a firm principle of EU legislation[2] but also an obligation under international trade agreements[3]. The primary objective of chemical legislation is to ensure that the use of chemicals is safe. A GRA that unconditionally puts 'essentiality' over 'demonstrated safety' would go beyond the legitimate safety objective and lead to disproportionate bans of safe uses of chemicals[4] and possibly to regrettable substitutions.

Demonstrated safety of a use of a chemical substance should be allowed to override hazard based GRA bans, and chemicals legislation must give interested parties the possibility for a demonstration of such safety. We fully acknowledge that the burden of proof is mainly with the industry applicant.

Consequently, we strongly advocate for the inclusion of an additional, exceptional derogation mechanism from GRA under REACH that is based on 'demonstrated safe use'. Indeed, if the use of a chemical is unambiguously shown to be safe, the question of whether it is 'essential' is no longer relevant and the ban of the substance is no longer justified in order to reach the safety objective of REACH. As explained below on the example of the Cosmetic Products Regulation, such application for derogation would not be the 'default option' but rather reserved to a limited number of key substances.

Essential use criteria: Cosmetics Europe acknowledges that the concept of 'essential use' can be used to prioritise and speed up the management of GRA substances, guiding the decision making on GRA derogations where an unambiguous demonstration of safe use is not carried out or not possible.

Essential use of chemicals will go through constant change following societal needs, and innovative and technical development, therefore this concept should not be considered as permanent and harmonised. COVID-19 crisis is a good example of changes in societal need. Consequently, any concept should be future proof and allow for innovation. The notion of essentiality remains subjective, and it is important to ensure that the concept is objective and allows for change and innovation.

Essentiality should be assessed on a case-by-case basis through a set of criteria assigned after careful evaluation of all possible impacts and benefits to human health, environment, and the society. Similarly, it should not be used to compare different sectors with each other and only be used in an intra-sectorial manner, if considered at all.

The concept of 'essential use' already exists in the Montreal Protocol. However, we believe it is not a solution that can ensure sufficient clarity and predictability to the industry and consumers as the

[1] REACH Article 1.1: "The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."
[2] Treaty of the European Union, Article 54: 4. Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.
[3] Article 2.2 of TBT Agreement: Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.
[4] Application of a GRA approach to ethanol (proposed for classification as CMR Cat 1) would destroy the fine fragrance industry, although the safety of use of alcohol in fragrance is undisputed.

Montreal Protocol applies to a very limited number of specific chemicals with limited set of uses. Translating it to a much broader scope, covering the whole universe of chemical substances and any potential use, would lead to arbitrary and non-proportionate decisions.

Therefore, essentiality for health and safety or the functioning of the society must be interpreted wider than just 'necessity for bare survival' and 'absence of disease'. Cosmetics and personal care products bring important functional and emotional benefits to consumers, contributing to well-being, hygiene and mental health, thus providing essential societal benefits. In a survey, 71% of consumers said cosmetics and personal care products are important or very important in their daily lives. Their positive perception extended across a range of cosmetic and personal care products. Consumers made a clear link between cosmetics and personal care products and quality of life; 72% of consumers said that the cosmetic and personal care products they use improve their quality of life.[5] Therefore, any concept of essential use of chemicals should take a holistic approach, including the value to the society.

The chemicals used in cosmetic and personal care products perform functions in the product that make the product what it is. These are essential for the product performance, both decisive factors in the purchasing choice of consumers. If one chemical substance is to be removed, it is not always possible to simply replace it by another substance performing the same function and the product needs to be completely reformulated. Even in the case of reformulation, it may be impossible to achieve the required level of performance.

The critical elements when considering the essentiality of a chemical substance for cosmetics products should be the type of function, the number of different functions and the availability of suitable alternatives.

Example of a functioning GRA/essentiality approach under the Cosmetic Products Regulation: For 20 years, the Cosmetic Products Regulation (Article 15) has implemented a GRA ban of CMR chemicals (classified in Annex VI of Regulation 1272/2008). The approach recognises that the main driver of chemicals legislation is to ensure safe use.

The approach implements:

- A ban of substances classified as CMR;
- An exceptional derogation mechanism based on demonstrated safety (burden of proof on the industry, confirmation of safety by the Scientific Committee on Consumer Safety);
- 'Essential use', in terms of availability of suitable alternatives, as an additional derogation criterion for CMR Cat. 1 substances;
- Strict and fixed timelines by which the substance is either derogated or banned for use in cosmetics.

Experience under the Cosmetic Products Regulation shows that derogations are applied for in exceptional cases and do not become a resource-intensive, slow system. A similar process under REACH would bring the whole GRA/essential use concept in line with principles of Good Regulatory Practice and with the EU's obligations under international trade agreements.

Potential extension of GRA to professional uses: The public consultation suggests an application of GRA bans to professional uses, mentioning in particular hairdressers and cleaning staff as examples. In line with the position expressed above, GRA under REACH should only be applied for professional uses if/when safety of such uses is not unambiguously demonstrated.

[5] Cosmetics Europe (2017). Consumer Insights, https://www.cosmeticseurope.eu/files/6114/9738/2777/CE_Consumer_Insights_2017.pdf

As regards to human safety, the Cosmetic Products Regulation addresses the safety of the 'end user' which is defined as "*either a consumer or professional using the cosmetic product*". The Regulation - including its existing GRA mechanism for CMR substances – fully covers human safety aspects of professional use of cosmetic products (e.g. by hairdressers or beauticians). Safety assessments of cosmetic products must be carried out on the basis of 'reasonably foreseeable conditions of use' taking into account the targeted population(s) and potential exposure of a specific population. Similarly, ingredient safety evaluations by the Scientific Committee on Consumer Safety (SCCS) are based on comprehensive and detailed exposure information. Where necessary to achieve a high level of human safety, the Annexes of the Cosmetic Products Regulation specifically distinguish between consumer use and professional use.

Given the clear regulatory framework of the Cosmetic Products Regulation, there is no reason to address under REACH the human safety aspects of professional uses of cosmetic products.

2. INFORMATION IN THE SUPPLY CHAIN, INCLUDING ON USE AND EXPOSURE

Cosmetics Europe supports that adequate information on use and exposure is available for regulatory decisions that are based on sound risk assessments. Information requirements should be focussed and relevant to the regulatory purpose. The type of information, level of detail and supply chain actor providing the information may be different according to the regulatory objective, e.g., REACH registration/evaluation, authorisation/restriction or information required by the downstream users for establishing Digital Product Passports.

The current approach under REACH, based on general/generic use and exposure models, works is well implemented and works for the vast majority of regulatory needs. Systematic provision by downstream users of detailed use and exposure information on all substances would impose significant and unnecessary burden on the industry, especially for SMEs. Furthermore, such data would not be of any use for authorities for substances that are of low concern.

We agree, however, that in some cases, especially in the area of restriction/authorisation/derogation procedures, it may be useful that downstream users provide specific information on use and exposure that allow specific risk assessments, both for an individual use or – after aggregation – for overall use across sectors.

Under the Cosmetic Products Regulation, a functioning system is in place, ensuring provision of detailed use and exposure information to the Scientific Committee on Consumer Safety (SCCS) when human-safety concerns for a specific substance require a regulation. The data are used by the SCCS in the context of a (human safety) risk assessment which is the basis for restriction/authorisation/derogation of the substance under the Cosmetic Products Regulation. The information is typically collected and aggregated by consortia or the trade association, thus reducing the necessary work and resources spent by authorities. This approach ensures direct and timely information flow from the downstream user industry to the scientific body who ultimately makes use of the information. This approach, in the context of human safety, should be maintained at the cosmetic-sector level and not be replaced by a future general mechanism under REACH.

3. MIXTURE ASSESSMENT FACTOR (MAF)

Cosmetics Europe supports the European Commission's intention to evaluate and handle adverse mixture effects not covered by the existing regulatory system. However, it is important to emphasise that the EU framework already provides one of the most advanced regulatory chemical safety systems worldwide. Risk assessments under REACH are built on conservatism, already incorporating various safety factors.

A weight of evidence assessment does not support the presence of increased toxicity due to combination effects of substances at common human and environmental exposure levels[6]. Additive[7] or synergetic[8] adverse effects from exposure to combinations of substances are rarely reported outside of pharmacologically active drugs. Humans are continuously exposed to millions of substances via food, environment, and consumer or personal care products without tangible evidence of adverse health effects. Thus, the human organism permanently deals with combinations of substances during its life span.

For an adverse effect to occur from unintentional chemical mixtures, all following aspects would need to be met[9]:

1. The hazard posed by the individual mixture components must be of very high concern.
2. The individual mixture components must have a common/interlinked modes of action to act additively in a mixture.
3. Each individual mixture component must be present in the environment below their individual regulatory thresholds (otherwise the scenario is already covered with the existing system), and in combination a toxic level must be reached.
4. These levels have to remain more or less constant (not above the individual thresholds, not below an overall toxic level of the mixture) over the whole time-window relevant for the effect.

Evaluating above, it is apparent that not yet regulated adverse mixture effects only occur in very rare occasions connected to very specific scenarios. This is supported by recent study[10] findings where ca. 90% of all monitored unintentional mixtures presented no concern. Where potential concerns arose, these were partially already tackled by the existing legislative framework (ca. 5% such as through authorisation lists, prioritisation list of the Waste Framework Directive), only leaving ca. 5% of identified mixtures posing a potential risk which is not yet handled within the current legislative framework. When such rare adverse mixture effects occur, they are typically i) limited to a specific temporal and local scenario, (ii) occur when a combination of agrochemicals, pharmaceutical, industrial and household chemicals are present, and (iii) are typically driven by a few well-known problem chemicals.

Consequently, a safety factor under REACH for adverse mixture effects such as the mixture assessment factor (MAF) needs to be designed to tackle the above very specific cases of concern by encapsulating below fundamental principles of safe chemical management:

1. **Develop the MAF application based on sound science, driven by data.**
2. **Apply the MAF only to substances of highest concern.**
3. **Apply different MAFs for different scenarios.** Tailor the size of the safety factor MAF applied to substances based on their different types of use and different types of effects.
4. **Apply the MAF to the risk characterisation ratio and not the hazard or exposure component.** The MAF is not the reflection of the inherent (eco)toxicity of a substance but rather the intention of the MAF (if applied) is to address additive risks resulting from the mixture in the environment.

[6] Boobis, A., Budinsky, R., Collie, S., Crofton, K., Embry, M., Felter, S., Hertzberg, R., Kopp, D., Mihlan, G., Mumtaz, M., Price, P., Solomon, K., Teuschler, L., Yang, R., & Zaleski, R. (2011). Critical analysis of literature on low-dose synergy for use in screening chemical mixtures for risk assessment. *Critical Reviews in Toxicology*, *41*(5), 369–383. https://doi.org/10.3109/10408444.2010.543655

[7] Additive effect: Combined effect of two or more chemicals is equal to the sum of the effect of each chemical alone; They do not interact in a direct way.

[8] Synergetic effect: Combined effect of two or more chemicals is much greater than the sum of the effects of each chemical alone.

[9] Herzler, M., Marx-Stoelting, P., Pirow, R., Riebeling, C., Luch, A., Tralau, T., Schwerdtle, T., & Hensel, A. (2021). The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence? *Archives of Toxicology*, *95*(7), 2589–2601. https://doi.org/10.1007/s00204-021-03091-3

10 Arche, Vito, 2021. Characterising chemical co-exposures in EU to support a combined exposure assessment strategy." https://www.arche-consulting.be/wp-content/uploads/2022/03/CEFIC-CoExposure_ARCHEfinal.pdf

5. **Allow more accurate higher tier data to refine the simplistic first tier MAF approach.**

The application of a single generic MAF not based on sound science will have detrimental consequences. It will lead to unnecessary restrictions/bans of safe chemicals as well as unnecessary animal testing to refine assessments under REACH that have been shown to be sufficiently protective of both human and environmental health. This is contradictory to the other pieces of legislations and is in stark contrast to the European Commission's objective to reduce animal testing in Europe. The current risk assessment approach for the vast majority of individual substances is sufficiently conservative and thus, does not underestimate the risk from combined exposure to substances[11]. The current knowledge on combined exposure suggests that concerns about synergistic (exceeding additive) effects are unfounded.

4. ACCELERATING THE ACCEPTANCE AND USE OF NAMS THROUGH THE REVISION OF REACH

Risk assessment and animal welfare: Cosmetics Europe believes that the questions on animal testing/New Approach Methods (NAMs) included in the REACH public consultation make it difficult to provide meaningful and accurate input that would feed into the EU policy-making process. Several questions suggest that there is an inevitable need to balance human health and environmental protection with animal welfare. Safety should always be the first criterion for any assessment, but there is nothing inevitable about the balance between human and environmental protection and animal welfare when we consider the progress of alternatives to animal testing. Other questions make the assumptions that NAMs are less protective and reliable. The cosmetics and personal care industry's collective experience and growing consensus within the scientific literature supports the proposal that by using human relevant NAMs, we can progress towards an equally or even higher level of human health and environmental protection while avoiding unnecessary animal testing.

The cosmetics industry as a pioneer in research and development of alternatives to animal testing: The EU banned the testing of cosmetic products on animals in 2004, banned animal tests for cosmetics ingredients in 2009, and prohibited the sale of cosmetics relying on newly generated animal test data in 2013. Cosmetics Europe fully supports the ban on animal testing for cosmetics under the Cosmetic Products Regulation and is supporting sister cosmetics industry associations as similar bans are implemented globally. Because of animal testing bans, it remains imperative that requests for additional information on registered ingredients under REACH can, wherever feasible, be addressed by NAM-based approaches to ensure animal testing is only used as a last resort. The cosmetics and personal care industry has therefore been at the forefront of developing and applying alternatives to animal testing for regulatory safety assessment for more than 30 years and believes the only way forward for the EU is to focus on the development and regulatory acceptance of non-animal testing methods. In addition to pioneering the application of NAMs through Next Generation Risk Assessment (NGRA) frameworks, cosmetics industry-funded research has directly contributed to the replacement of skin irritation, eye irritation, genotoxicity and skin sensitisation endpoints in partnership with EURL-ECVAM and OECD. Furthermore, Cosmetics Europe is a member of the European Partnership for Alternative Approaches to Animal Testing (EPAA) and supports cross-sector industry collaboration with the European Commission to ensure we continue to share our experience of applying alternatives to animal testing, as well as learning from others.

Optimising the use of NAMs under REACH: The current REACH legislative framework requires many animal tests, which are time and resource consuming and are mostly based on outdated assumptions. The Chemicals Strategy for Sustainability (CSS) is likely to increase the number of requests for animal tests because of the proposed extension of GRA to new hazard classes, additional information requirements for chemicals, and polymer registration.

[11] Herzler, M., Marx-Stoelting, P., Pirow, R., Riebeling, C., Luch, A., Tralau, T., Schwerdtle, T., & Hensel, A. (2021). The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence? *Archives of Toxicology*, *95*(7), 2589–2601. https://doi.org/10.1007/s00204-021-03091-3

The cosmetics and personal care industry could be very significantly impacted by the continued and increasing requests for animal tests under REACH, resulting in a reduced palette of cosmetic ingredients that remain available.

New cosmetic ingredients are not only the lifeblood of innovation in our consumer-driven industry but are also key to help achieve the objectives of the European Green Deal, i.e. better environmental footprint, circularity, resource efficiency. In order to satisfy consumers' expectations of no animal testing, NAMs will increasingly need to be used, including in registrations, supported by growing confidence in their application, non withstanding the legal obligation on registrants to only use animal testing as a last resort.

Building on its experience of the application of the animal testing ban under the Cosmetic Products Regulation and its significant involvement in developing NAMs, Cosmetics Europe firmly believes there are opportunities to optimise the use of NAMs under REACH on two levels.

Firstly, we as the European cosmetics and personal care industry will continue to play a central role in the global scientific development and application of NAMs, building on progress achieved so far, identifying areas for further development, to achieve a NAMs-based paradigm of chemical safety assessment.

Secondly, we need to ensure that ECHA and other relevant stakeholders accept and deploy NAMs in the light of a full appreciation of the state of the science. Safety assessments should not simply rely on data from conventional toxicology studies but should rather focus on providing robust information to establish whether chemicals can be used safely. NAMs and NGRA should be combined in a flexible way (e.g., using defined approaches (DAs) and Integrated Approaches to Testing and Assessment (IATA)) with exposure information to ensure that decisions on the use of chemicals are fit-for-purpose and based on the best available science. Shifting towards a risk-based approach drawing on use-specific exposure data and NAMs would ensure an equally high level of safety, while avoiding unnecessary animal testing. For cosmetics, the application of NAMs through exposure driven, tiered NGRA frameworks is now an integral part of the principles and guidance published by the International Cooperation on Cosmetics Regulation (ICCR) and the Scientific Committee on Consumer Safety (SCCS). Similarly, Health Canada is already paving the way in the use of NAMs for priority setting and screening of chemicals.

In this respect, it is crucial that REACH facilitates scientific progress and regulatory acceptance of NAMs to ensure everyone fulfils their legal obligations to uphold animal testing as a last resort.

The REACH revision is a unique opportunity to apply the insights gained from the cosmetics and personal care industry investment in NAMs to enable their widespread use and regulatory acceptance for hazard identification and risk management of chemical substances.

To achieve the above objective of optimising the use of NAMs under REACH, Cosmetics Europe would like to suggest the following policy options:

- For the REACH revision:
    - Ensure the REACH Impact Assessment looks at the impact of animal testing both at the upstream chemicals producer level and for the cosmetics and personal care industry.
    - Explore opportunities to evolve the REACH framework to ensure those chemicals most likely to cause adverse effects and those with the highest level of exposure would be the chemicals for which most information was generated. This strategy has enabled NAMs to be applied under NGRA approaches to assess cosmetics products and can be translated to accelerate NAM use under REACH.

- Amend REACH Annexes VII–X to enable a flexible, science-driven substance-tailored approach to addressing information requirements. We foresee that a 'test agnostic' approach would remove specific test requirements from REACH Annexes and instead define an information requirement to be fulfilled (e.g. information on acute oral toxicity, carcinogenicity etc) with associated technical notes of guidance outlining a weight of evidence, tiered approach where animal testing is a last resort. Such notes of guidance for addressing information requirements would be more easily updated as new science emerges.
- Amend REACH Annex XI, Article 25 to ensure that an independent scientific expert group assesses whether information requirements can be met through NAMS, then requesting animal testing as a last resort. This expert group should regularly report its findings, including animal testing justifications, to enable full transparency and scientific peer review.

- Adopt, at the level of the European Commission, an EU NAM strategy to increase their regulatory acceptance in the chemicals legislation, including REACH. Such strategy should be implemented in partnership with EPAA and should include a transition roadmap with key milestones and a reporting mechanism.
- Create a mechanism to allow meaningful scientific dialogue between REACH registrants and an independent scientific committee (i.e., similar to SCCS role relative to the Cosmetic Products Regulation), empowered by ECHA, to ensure NAMs are applied in a robust and fit-for purpose way. The opinions and statements of this committee would be considered as legally binding.
- Continue dedicated funding at the European Commission and Member States' level to invest in the development and deployment of NAMs/NGRA.

ENDS