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# *COSMETICS EUROPE'S RESPONSE TO THE CONSULTATION ON THE DRAFT SEAC OPINION TO SUPPORT ANNEX XV RESTRICTION REPORT*

In this submission, we respond to the arguments raised in the draft SEAC opinion of 11 June 2020, on an Annex XV dossier proposing restrictions on intentionally-added microplastics.

This submission also incorporates our response to the issues raised in the questions accompanying the consultation.

In the annex we provide technical evidence in response to questions raised by ECHA.

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## Executive Summary

Cosmetics Europe shares the concern over the serious issue of plastic pollution and as such, considers it essential that the proposed REACH restriction delivers a tangible and meaningful benefit to the environment. However, as the SEAC draft opinion highlights, the proposed measures for leave-on cosmetic products will provide an insignificant reduction in microplastic emissions yet will incur huge costs. In fact, the potential emissions from leave-on cosmetic products to intentionally added microplastics represent <2% of all intentionally added microplastics, yet these products will bear 80% of the costs of the whole restriction, all sectors included. This response to the SEAC opinion aims to bring a constructive demonstration of how the desired result of the restriction, i.e. the reduction of microplastic emissions, can be achieved without incurring such high impacts in term of social and economic costs, and therefore representing a proportionate approach. This is further explained in the section IV on proportionality.

Cosmetic and personal care products provide essential societal benefits. Cosmetics Europe has surveyed European consumers[1] and found that 80% of consumers identify them as important in building self-esteem, and 71% as important in their daily lives, and 72% feel the cosmetics and personal care products they use improve the quality of life. The study demonstrated that cosmetic and personal care products improve the quality of life across society. They are considered as an essential part of people's daily lives, and contribute to their self-confidence, well-being, and a healthy lifestyle for all generations.

[1] Consumer Insights 2017 https://cosmeticseurope.eu/cosmetic-products/consumer-insigths/

We are pleased that some of the input provided by Cosmetics Europe during the public consultation in 2019 has been taken into account by SEAC in preparing its draft Opinion. For example, the cost-effectiveness ratios for make-up, lip and nail products are now larger, and so more accurate, than previously assessed. Nevertheless, we are strongly convinced that several parts of the draft opinion could be further improved in order to provide accurate information to the risk managers, thus leading to more proportionate measures for the cosmetics sector. The following issues should be addressed:

- Under-consideration of the specificities of the cosmetics sector: the large product portfolio has been developed to meet an increasing demand from consumers for greater variety of products, corresponding to demographic and other societal changes. Therefore, ECHA's assumption that 50% of formulations will not be reformulated does not reflect the reality of consumer expectations and needs
- Assumption that there are alternatives for microplastics in all cosmetics products, without consideration of technical performance or economic availability.
- Under-estimation of the complexity of reformulation in the absence of suitable alternatives.
- Under-estimation of reformulation costs by SEAC on the basis of a confidential contribution with no indication of representativeness / weight of evidence.
- Under–estimation of the impact on the competitiveness of the EU industry.
- Under consideration of costs vs environmental impacts for product categories such as make-up, including lip and nail products, which are not directly released into the environment.
- Under-estimation of technical and timing issues regarding the out of scope criteria.

Cosmetics Europe considers that the evaluation by SEAC does not fully reflect the extent of socio-economic impact of the restriction on the cosmetics sector, which would be far greater than suggested in the draft SEAC opinion.

SEAC should therefore, when assessing the complexity of the proposed restriction for the cosmetics sector, reflect in its Opinion the **different factors of complexity**:

> **1. Number of formulations:** A first factor is the **complexity** of the reformulation related to the **number of formulations, and not only the number of ingredients but also the number of ingredients per formulation** and their **function**. Our conservative estimation, based on 2018 survey of Cosmetics Europe, shows that 13,381 leave on formulations[2] will be impacted, a large majority of them containing up to 6 different microplastics, whose function is critical for the

[2] 13,381 formulations refers to the number of leave-on formulations reported in the dataset of the Cosmetics Europe Survey from 2018 (based on replies from 56 companies covering over 50% of the cosmetic sector). This survey was based on a sample approach of 19 ingredients. Considering that the number of ingredients is larger than 19, the total economic impact (including for example increased reformulation) will be greater than the one calculated based on the sample.

product architecture. One to one substitution in this case is not possible; the whole architecture of the formula needs to be reviewed. Cosmetics Europe is performing additional survey in respect of the make-up lip and nail and preliminary results indicate a much larger number of ingredients and in turn a larger number of formulations. The results will be made available to SEAC.

**2. Lack of availability of suitable alternatives:** A second factor is the **availability of alternatives** for the cosmetics sector and their suitability (technical performance, stability, consumer satisfaction, etc.). Natural alternatives, which can be suitable in very specific applications only, have already been utilized where possible by the cosmetics industry. For 85.5% of formulations[3], there are no suitable alternatives due to unsatisfactory performance or quality.

**3. Reformulation capacity:** A third factor to be taken into account is the **ability of cosmetic companies to reformulate thousands of products within a short time period.** The need to replace simultaneously several raw materials for one reformulation extends significantly the time needed for research of raw materials, designing of technologies, and ultimately products. In addition, it will be impossible to work simultaneously on all the technologies used to formulate thousands of products and deviate R&D resources to focus exclusively on product redesign.

**4. Impact on SMEs:** The impact of the restriction on **SMEs** will be significant.

**5. Competitiveness:** Wide economic impacts on the **competitiveness of the EU cosmetics industry** (required differentiation of production and duplication of production lines) also need to be included in the analysis.

These complexity factors should be given greater consideration in SEAC's assessment of the cost of the restriction for the cosmetics sector, especially in view of the limited release of certain leave-on products in the environment and overall disproportionality of the restriction regarding cosmetics products.

**Cosmetic Europe calls on SEAC to reassess the socio-economic impact of the restriction on the cosmetics sector taking into consideration the submitted evidence, which in our view clearly demonstrates the economic and social impact of the proposed restriction - with limited benefit for the environment.**

[3] Cosmetics Europe Survey 2018

**Cosmetics Europe's Position for a Proportionate Restriction**

Cosmetics Europe considers that a more proportionate and efficient way to address the concerns around the emissions of microplastics in the environment from leave-on cosmetics products is to adjust the proposed REACH restriction as follows:

1. A **derogation for make-up**, including lip and nail products, on the basis that these products are predominantly disposed of in the trash, not the water system, yet the cost-effectiveness ratio for the restriction on make-up is extremely high. To avoid any residual emissions, clear instructions for use and disposal of these products could be provided.
2. An **eight-year transition period for sunscreen products.**
3. A **twelve-year transition period for skin care products**.
4. A **ten-year transition period for other leave-on products**.
5. The transition period extensions are required for technical reasons and will also improve the proportionality of the restriction.

The arguments set out in this paper in response to SEAC's opinion on the proposed restriction on intentionally added microplastics support this approach.

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## Comments specific to the cosmetics sector

**Preliminary Remarks on the Cosmetics sector:**

As a preliminary note, it is important to understand the drivers behind the innovation in the cosmetic sector and the recent trends leading to the development of a large portfolio of products.

The European cosmetics and personal care market contributed €79.8 billion[4] by value at retail sales price to the European economy in 2019. Over the past 30-40 years, the Cosmetics sector has significantly increased its offer by diversifying its products to better meet consumers' expectations and needs. The emergence of the modern cosmetics industry and the subsequent surge in the product portfolio go hand in hand with changing demographics, notably:

- **An increasingly ageing population**. While in 2015 19% of the European population was aged 65 and above, it is projected to reach 32% of the European population by 2060.
- **Migration and growing ethnic minorities** also seem to influence the industry. **Continuously increasing mobility** has led to more mixed populations. The cosmetics industry has responded to a changing ethnic composition by developing products that take into account the needs of all citizens of the EU.
- **Changing gender perceptions** also seem to impact trends in the cosmetic industry. Studies have shown that the usage of cosmetics among men has become more acceptable, and the cosmetics industry has developed products based on specific formulas to meet this increasing demand.

There are still underrepresented groups in the cosmetic sector. Hence there are **calls for an even greater expansion of the cosmetic product range and the implementation of new product lines for these groups.**

The cosmetics sector is an innovative and scientific industry. Science and innovation is essential for the industry to be able to continuously improve its products to best meet consumer expectations and contribute to consumer welfare. The industry also takes into account a range of age, cultural demands, ethical demands, preferences in terms of sourcing of raw materials, etc. A major factor behind the improvement in the performance of cosmetic and personal care products, and a more diverse product portfolio, was the introduction of polymer ingredients like microplastics in the 1970s-1980s. These ingredients brought improved technical performance in almost all cosmetic product categories at an affordable cost. This innovation process is on-going, and cosmetics products are regularly reviewed

[4] https://cosmeticseurope.eu/

and improved. However, microplastics are an integral part of the architecture of cosmetic products and cannot be easily replaced.

We would like to highlight the following characteristics and specificity of the cosmetic sector, which should be taken into account by SEAC:

- High-mix active products in portfolio and significant volumes to meet consumer demands and respond to growing diversity of needs, related to social, demographic, economic trends, etc.
- The number of products on the market in constantly growing to better suit the diversity of needs of the population
- Infrequent redesign of products – the innovation often protected by patents, creates the architecture of the product. While upgrading of product performance is frequent and requires minor adaptations to the formulations, the basic architecture of the products is not subject to frequent redesign. Microplastics, as defined by ECHA, form part of the basic architecture.
- Limited number of highly qualified specialists involved in product redesign– for instance regarding color matching, it is impossible to redesign many formulations in a short period of time as these experts cannot be multiplied overnight. This argument has been taken on board in previous regulatory decisions.
- Cosmetics products have to undergo a number of evaluations and tests for human health and environmental safety, stability, performance, efficacy, packaging compatibility, consumer testing for acceptance of product, and shelf-life to ensure compliance with EU regulations

## Reminder of the scope and the representativeness of the Cosmetics Europe SEA

The Socio-Economic Assessment ( hereafter the 'SEA') prepared by the independent consultancy EPPA on behalf of Cosmetics Europe for the ECHA Call for Evidence (CFE) in 2018, is based on a highly representative industry survey, including 56 companies covering over 50% of the cosmetic sector, both in terms of total revenue for the European Economic Area (EEA) and workforce. The dataset contains data from 36 producers of skin-care products, 25 producers of make-up products, 36 producers of rinse-off products, and 42 producers of leave-on products.

This survey was based on a sample approach of 19 polymers (note that for Cosmetics Europe, these 19 materials are not all considered microplastics). Please see footnote 2.

It should also be noted that the SEA is based on a dataset of formulas rather than products. On the basis of a representative dataset of 19,200 formulations provided by participating companies, the availability of alternatives could therefore be assessed at the level of ingredients rather than products, providing a more refined and reliable analysis.

## I. Recognition of limited release in the environment of leave-on cosmetics

**Key points:**

- There is a **limited environmental risk of release from certain categories of leave-on cosmetics products** (make-up, lip and nail care products) as consumers dispose of used products to the trash and not the aquatic environment.
- A **proportionate risk management measure**, i.e. a derogation for these products, should be explicitly recommended by SEAC.
- For other categories of leave-on cosmetics given the complexity of the product, essential function of the microplastic ingredients, lack of availability of suitable alternatives, vast number of formulations which will be impacted and in the case of sun screen the public health consequences, **longer transition periods should be explicitly recommended by SEAC**.

In its draft Opinion, SEAC has refined its approach by recognizing that there is a limited environmental release from certain categories of leave-on cosmetic products. Cosmetics Europe acknowledges this recognition and is satisfied that this has been considered by SEAC. However, Cosmetics Europe considers that SEAC does not push this argument sufficiently far, as it does not explicitly recommend a more proportionate risk management measure, i.e. a derogation for make-up, including lip and nail products, taking into account that residual releases in the environment could be avoided through additional measures such as clear instructions for use. In 2018, on behalf of Cosmetics Europe, market research

company Kantar TNS conducted a survey of 8,000 consumers in 8 European Union member states (UK, France, Germany, Italy, Netherlands, Poland, Spain and Sweden) to gain insights into consumer removal and disposal habits of leave-on cosmetics products. The survey gives specific insights into the final stages of the consumer use of the life cycle of the leave-on cosmetic product i.e. at the point of removal and disposal.

The key findings of the survey for the different sub-categories of leave -on for which CE is seeking a derogation are as follows:

- **Make-up category:** 75% of make-up users used both removal methods involving cotton pads or wipes only or cotton-pads/wipes and then water. Of the make- up users that use cotton-pads or wipes, 93% throw the cotton pads or wipes in the bin.
- **Nail-varnish and nail-varnish remover category**: 76% of nail varnish/remover users remove nail varnish/remover using cotton pads only or both wipes cotton pads/ wipes and water. 95% of nail varnish/remover users who have used removal methods using cotton pads/ wipes throw them in the bin[5].
- **Lipstick category**: 69% of lipstick users remove their lip stick using cotton pads/wipes only or both removal methods cotton pads/wipes and water. 94% of lip stick users who have used removal methods using cotton pads /wipes throw them in the bin [6]

The conclusions of the KANTAR consumer study were therefore that the majority of consumers surveyed dispose of their **make- up, lip and nail care products** to the trash and not to the aquatic environment.

These findings were applied to the tonnages of microplastics and (in our view) non-microplastics ingredients gathered in an industry survey for the purposes of the SEA. These tonnages were used in the SEA to give an indication of the potential release*. The SEA estimates – based on extrapolation – that 861 plus 1,310 i.e. 2,171 tons*/year of microplastics and non-microplastics ingredients[7] as identified for the purposes of the SEA are used in all leave-on products.

Our survey for the SEA found that the estimated tonnage of microplastics used in leave-on products corresponds to **13,381 leave-on formulations[8] representing 93.5% of all formulations impacted by the**

[5] Note that nail varnish cannot be properly removed with water alone if a nail varnish remover product is not used, the assumption that could be drawn from findings that consumers remove using methods other than cotton/wipes only or cotton wipes and water, is that the consumers were referring to nail varnish remover or perhaps that they washed their hands after having removed the nail -varnish with a nail- varnish remover or used some other method.

[6] In the lip care category: 37% of lip balm users removed their lip balm with cotton / wipes only or involving cotton pads/wipes and water. 93% who have used removal methods using cotton pads or wipes throw them in the bin. The usage of Microplastics and non-Microplastics ingredients used reported for the CE SEA submitted for the ECHA CFE is however is in the kilogrammes which must be taken into account when considering the environmental fate and socio-economic impact.

[7] Cosmetics Europe took a pragmatic approach to its SEA submitted to the ECHA CFE and this included substances which Cosmetics Europe considers are not Microplastics within its definitions (see Cosmetics Europe definitions document and SEA submitted for the purposes of the ECHA CFE.)

[8] 13,381 formulations refers to the number of leave-on formulations reported in the dataset of the Cosmetics Europe Survey from 2018 (based on replies from 56 companies covering over 50% of the cosmetic sector).

**restriction overall** across all cosmetics products, rinse-off and leave-on. Thus, the relatively small tonnages actually translate into a very large number of products impacted**, of which 89% is make-up**.

The analysis of the 19 materials is therefore a sample approach. Please see footnote 2.

Following ECHA's proposal for a derogation for film-formers in leave-on products, Cosmetics Europe's analysis has been refined for the leave on category by removing the tonnage of film-former ingredients as well as the number of formulations concerned. Consequently, the number of leave on formulations has been reduced by 21.19% and the tonnage by 22.05%. The adjustment related to film-formers does not have an impact the cost-effectiveness ratio estimated for the leave on products

**The table below is taken from the Cosmetics Europe SEA based on the 19-materials sample approach (please see footnote 2):**

| Product categories | Releases (tons)/y from the formulas in the Cosmetics Europe database (rounded to the closest unity) | Pathway to the environment (% derived for all leave-on categories from by ECHA estimates in the restriction proposal; 100% assumed for sunscreen) | Formulas impacted in the Cosmetics Europe database |
|---|---|---|---|
| Make up (including lipstick products & nail products) | 134 | 24% | 15,207 |
| Sunscreen | 191 | 100% | 297 |
| Skin care | 85 | 24% | 1,125 |
| | | | |
| Other leave-on Products | 54 | 24% | 414 |

## II. Key factors to assess the complexity of the proposed restriction for the cosmetics sector

**Key factors:**

- The voluntary phase-out of microbeads initiated in October 2015 was a simple one-to-one replacement of ingredients for which alternatives existed and for which reformulation was easy because such ingredients do not blend with the formulation. However, there are **key**

**differences with the case of microbeads the broader microplastics restriction** and the related reformulations have to be highlighted: in the case of microbeads, there was **availability of suitable alternatives**, low number of ingredients to be substituted and number of formulations concerned, lower possibilities of differentiation within product category.

- To date, there are **no confirmed suitable alternative solutions to most microplastics in leave-on products**. Natural alternatives are limited in terms of technical performance and general suitability (stability, sensorial performance, micro contamination).
- Formulas, the core technologies of cosmetics companies, are not commodities but complex mixtures of a number of raw materials. Reformulating the products means **completely redesigning the architecture of these core technologies as a "one-on-one" substitution of microplastics is not possible**. The equation "alternative product = alternative ingredient" is therefore too simplistic and completely inappropriate, especially for leave-on products.
- Cosmetic products are **an essential part of people's life**, and contribute to their self-confidence, well-being, and healthy lifestyle for all generations. There is a clear link between cosmetic and personal care products, and quality of life. Some of the key characteristics of cosmetics (e.g. ease of application, technical performance, stability) are **linked to microplastics in the formulation.**
- Thus, significantly longer transitional periods are necessary for the reformulation of leave-on cosmetic products (sun care, skin care and other leave on cosmetics (for make- up lip and nail a derogation is sought) containing microplastics (as defined by ECHA), as further explained in section VI.

SEAC evaluates the impact assessment done by the Dossier Submitter, e.g. in a cost-benefit, cost effectiveness, or compliance cost analysis or other appropriate method, as well as the likely economic impacts (i.e. socio-economic costs) to the society if a restriction enters into force. For SEAC, the cost of moving to alternatives is often the most important part of the overall cost of the proposal. Other factors are also taken into account to assess the complexity and cost of the process in addition to the availability of alternatives, such as the number of ingredients, the number of formulations, the number of ingredients per formulation, and the function and whether it is a critical function. These key factors can be perfectly illustrated by the experience of the cosmetics industry with the voluntary phase-out of microbeads, to provide a contrast with the microplastics restriction. It should be understood however that the microbeads case, while providing a relevant case study of the process, is fundamentally different to the broader microplastics restriction and should not create wrong expectations or underestimations in this case.

- **CASE STUDY: VOLUNTARY PHASE OUT OF MICROBEADS**

In October 2015, Cosmetics Europe announced a voluntary initiative[9] to phase out microbeads by 2020, which built on the voluntary actions that individual member companies had taken before national regulatory restriction in the EEA were adopted.

The substitution of microbeads followed the typical reformulation process that has an approximate duration of 5 years. This timing assumes that suitable alternatives are readily available and no fundamental research is needed by the suppliers to create alternatives since the substances to phase out mostly did not have critical function in the architecture of the formula. The key reformulation steps are described below:


The substitution took over **5 years** (some companies started and finished earlier)**.** This data demonstrates that even in a situation where suitable alternatives to microbeads were available, the reformulation costs were substantial and 7 out of 14 companies (50%) had discontinued some of their formulations, and **56% of the formulations were discontinued** (166 out of 296). This rationalization was possible because microbeads were only contained in one type of products: wash-off personal care cleansing and exfoliating products. The **possibilities of differentiation within this category of products are limited**, so it was possible to reduce significantly the number of formulations across the industry. **However, the same considerations regarding formulations discontinuations would not be applicable to the broad category of leave-on products**, which include categories like sunscreen products, skin care products and make-up products**, which have a much greater level of differentiation within each sub-category**, e.g. there are many different types of lipsticks (stick, liquid, shiny, matte, long stay) and each type corresponds to specific consumers' preferences.

We would like to stress that phasing out of microbeads (essentially beads of polyethylene) was **significantly less challenging** compared with potential substitution of microplastics, according to the proposed REACH restriction, as the **substitutions only concerned exfoliating and cleansing products** (simple rinse-off formulations), **alternatives were available** and the **number of ingredients** to be substituted and the **number of formulations** concerned was low. With the knowledge of the physical parameters of the microbeads (e.g. density, physical size) and the knowledge of the stabilizing gel system, it was a relatively easy exchange as microbeads are inert and do not interact with any of the other formula ingredients, as only physical properties matter.

[9] https://cosmeticseurope.eu/how-we-take-action/leading-voluntary-actions/all-about-plastic-microbeads/

The possible alternatives to microbeads used for exfoliating and cleansing were available. Therefore, companies did not have to invest significantly in the research of alternatives. Those alternatives included, for example, apricot kernel, perlite, cellulose beads, jojoba esters beads, and silica. In some cases, the substitution of inert plastic microbeads, which do not interact with and change the structure of the formula, could be achieved with a "one-by-one" substitution. For many ingredients which may potentially be included within the scope of the REACH restriction, there are no alternatives, and "one-by-one" substitution is not possible.

**The results presented in the next table are based on the CE SEA which covered a sample based on 19 substances. The analysis of the 19 ingredients is therefore a sample approach (please see footnote 2).**

| Key factors | Phase out of microbeads | Ban of Microplastics |
|---|---|---|
| Number of ingredients | 2 | Minimum 19 (CE Survey) |
| Number of ingredients per formulation | 1 | More than 1 and up to 6 in the majority of the cases* |
| Function | 2 (exfoliating and cleansing) | 11 (or more) |
| Critical function in the architecture of the formula | No, in majority of the cases | Yes, affects product architecture |
| Number of formulations | 130 out of 296 | Minimum 30,000 |
| Availability of alternatives | Easy to identify, available in majority of the cases. 1:1 substitution possible. | Alternatives do not exist in 85, 5% of cases. 1:1 substitution is not possible. * |

*NB: 30,000 formulations refers to the extrapolated total number of formulations, rinse-off and leave-on (EEA industry), based on Cosmetics Europe survey dataset 2018[10]. The data on alternatives also comes from this survey.*

SEAC accepts that the assumptions made by the Dossier Submitter are underpinned by experiences from the phase out of microbeads, but does not take into account the specific information provided and summarized above, which demonstrates that the reformulation of leave-on cosmetic products, a very broad and heterogeneous category of products, containing microplastics, is a completely different undertaking from the reformulation of the exfoliating and cleansing products containing plastic microbeads. Leave-on products include very diverse categories of products, like skin care, sunscreen products and make-up. These products are significantly more complex than exfoliating and cleansing products, and they often contain more than one microplastic raw material. **Therefore, significantly longer transition periods are required for the reformulation of leave-on cosmetic products containing microplastics (as defined by ECHA), as further explained in section VI.**

- **LACK OF AVAILABILITY OF SUITABLE ALTERNATIVES FOR THE COSMETICS SECTOR**

Cosmetics Europe provided data in previous consultations, which SEAC has not sufficiently integrated in its draft opinion. The SEA highlighted that there are no alternative ingredients in 85.5% of formulations, close to 100% in the case of leave-on products.

The 11 June 2020 Draft Opinion states **"***SEAC agrees that the investments needed to develop and use alternatives instead of microplastics are likely to be substantial, but also notes that in principal there seem to be alternatives to replace microplastics in all cosmetic products categories."* (p.66)

SEAC also comments that "i*n general, the existence of microplastic-free products within a product category suggests that the performance of alternatives is acceptable to replace microplastics*" (p46)

The Fraunhofer September 2018 study[11], referenced by SEAC in the annexes to the Background Document, mentions the use of natural plant and animal-based polymers, such as proteins, polysaccharides, natural rubber or resins, as alternatives to the use of microplastics (other than microbeads) in cosmetics. These natural polymers are then either used directly, or semi-synthetically after chemical modification (distillates, powders, oils, waxes, gels, gums or resins).

However, it is important to make a distinction between these natural and semi-synthetic alternatives:

[10] 13,381 formulations refers to the number of leave-on formulations reported in the dataset of the Cosmetics Europe Survey from 2018 (based on replies from 56 companies covering over 50% of the cosmetic sector). The figure of 30,000 formulations is extrapolated from this survey dataset.

[11] https://www.nabu.de/imperia/md/content/nabude/konsumressourcenmuell/20181004_mikroplastikstudie.pdf

- **Natural alternatives as currently defined by the restriction proposal** have important performance limitations and could be suitable alternatives in very specific applications only, mainly as thickeners, emulsifiers, and adhesives – but they usually cannot reach the expected level of product performance on their own. Accordingly, the contribution of these natural substances is known and has been utlized already, where possible, by the cosmetic industry. Tonnages of native and hydrolysed cellulose, starch, polysaccharides etc. entering in the composition of raw materials used already by the cosmetic industry are very high. Where possible, those have already been used, especially for exfoliating, scrubbing and cleansing rinse -off cosmetics.
- **Semi-synthetic "alternatives"** would likely fall under the "microplastics" definition, and therefore do not constitute valid alternatives.

In addition, the study does not address whether these suggested alternatives achieve the technical functions related to the specific applications in leave-on cosmetic products. The study does not contain any reference to technical and functioning performance tests nor does it compare the performance of the suggested alternatives with the materials currently used by the cosmetics industry. It is important to understand that finding a "suitable alternative" in leave-on cosmetics products does not mean finding a new substance to replace a microplastic substance, but inventing new core technologies providing the same level of performance with an original combination of raw materials free of microplastic components.

Starch, xanthan, guar gum, carrageenan, alginates, polysaccharides, pectin, natural gums, have been subject to a **number of tests to assess their suitability for broader rinse-off and leave-on applications**. These tests include rheology tests (viscosity, shear, yield value), physical performance tests, stability tests (cold temperature, room temperature, elevated temperature, shear stability), sensory panel tests, and consumer studies. In addition, ingredients of natural origin do not meet shelf life expectations, which for cosmetic product ranges between of 30 to 36 months. Also, natural substances have far greater variability in quality of the materials throughout the supply chain. Micro contamination in the raw material can also be experienced using starch, with an unpredictable behaviour over time leading to stability issues. Natural substances indeed have much higher concentrations of natural contaminants, such as heavy metals, which potentially decrease overall product safety.

As per Cosmetics Europe's previous comments in public consultations, the Kantar consumer survey confirms that the performance and quality of the products is a key criterion of choice for consumers.

One should also take into account that **with the broad definition of MPs and scope of the restriction proposal, the only other alternatives are biodegradable polymers**, which, as far as Cosmetics Europe knows, are not readily available yet. A realistic transition period should take into account the time needed by suppliers to develop such materials, prove their biodegradability according to the approach proposed by RAC (this, too, will have to be factored into the transitional period), and the time for scaling up to provide all the raw materials needed (viz., suppliers could need to build new factories to supply the market and substances would need to be registered).

The fact that other products from the same category exist on the market and do not contain microplastics (as defined by ECHA) certainly does not mean that these products can directly replace products containing microplastics. Within a cosmetic product category, many different technologies and formulations are used in order to target different concerns to reach a high level of performance. For example, a shampoo for oily hair and a shampoo for dry hair will require different formulations and ingredients.

Cosmetics Europe therefore strongly disagrees with SEAC's statement regarding the availability of suitable alternatives for all cosmetic products categories. This conclusion is not supported by any evidence nor is it accompanied by a comparative assessment of the technical performance of alternatives. The SEAC opinion does not elaborate on the relevance, availability and representativeness of this information for the entire sector.

***Alternatives, Raw Materials and Reformulation***

Reformulation of products other than exfoliants means the cosmetics industry has to reformulate tens of thousands of products by completely redesigning the architecture of the formula itself as the substitution would not be possible on a "one-by-one" basis like for the exfoliating products.

Replacing microplastics means replacing multiple raw materials in a core technology, which represents one of the building blocks for a formula and has to be entirely redesigned to achieve the same level of performance. Cosmetics formulations generally are complex mixtures of a number of raw materials pre-blended by the raw material manufacturer, these are then mixed together by the cosmetic company in their facilities when creating the formula. These core technologies are specific to the company that develops them and are often protected by patents and exclusivity contracts with suppliers for certain raw materials. As polymers contain the building blocks of a formulation, replacing these materials generally requires working with various raw material suppliers to get their mixtures to react together in the cosmetics mixture. All of the substances, raw material mixtures, and formulations will need to be completely redesigned to achieve the same level of performance. This shows cosmetic raw materials are not commodities that will become available to the whole industry when they are found, and that the companies which discover the best core technologies create a competitive advantage. As a result, finding "suitable alternative solutions" in leave-on products does not mean finding a new substance to replace a microplastic substance, but inventing alternative solutions, i.e. new core technologies providing the same level of performance with an original combination of raw materials free of Microplastics components.

In addition, leave-on cosmetic products may contain up to six microplastic ingredients (only taking into the SEA sample approach, maybe more given the broader scope of ECHA's definition,) where one of the components could be defined as a substance covered by the proposed restriction.

The R&D efforts required to identify the alternative solutions and to redesign the architecture of products to achieve an equivalent level of performance, given the number of products to be reformulated, will have a huge impact on the functioning of companies' R&D department. These are not "tweaks" of the formulation, but a complete rethinking of it.

Additionally, replacing microplastic-containing raw materials requires **suppliers** to be able to propose alternative solutions. Taking into consideration the broad spectrum of substances covered by the proposed definition chosen by ECHA, those alternative solutions will likely involve non-polymeric, natural or biodegradable in order to be outside the scope of the proposed restriction.

Suppliers usually specialize in specific chemistry domains. This means that most likely current suppliers who produce certain raw materials containing polymers covered by the proposed restriction will be replaced by other suppliers or vendors who will be able, for example, to propose non polymeric or biodegradable solutions (not available to this day).These proposed new raw materials free of microplastic components will be taken up by expert formulators of cosmetic products and combined with many others in order to assess if these new core technologies are able to deliver the expected level of cosmetic performance.

Once the suppliers get confirmation that these new raw materials have the potential to contribute to the targeted product performance, they need to scale-up and industrialize their process and production of the new raw material to be prepared to supply their client, at an affordable price for the relevant product category.

**Note that such solutions will not necessarily be accessible to other companies, because of exclusivity contracts, patents, and the specific know-how deployed to achieve the result**. Furthermore, formulation core technologies rely strongly on the complementarity and compatibility of raw materials, which depends on the formulation type, and needs to take into account the presence of some proprietary raw materials, which means, once again, that solutions are unique to an individual company and cannot be shared across the industry.

All these factors mean that finding suitable alternative technologies will require time and significant investments both for suppliers of raw materials and for manufacturers of cosmetic products.

According the SEA, **when there are no suitable alternatives, the first step in the reformulation process (research prior to reformulation/redesign) will be extended to 8-10 years**, if alternatives can be found at all.

To ensure a seamless transition, appropriate transition periods need to be defined, taking into account the time needed for both the supply chain and cosmetic manufacturers to adapt and find new solutions.

**The considerations on product performance characteristics, complexity of the raw materials and of the process that leads to the validation of an alternative solution, market demand and supply chains have not been properly reflected and addressed by the Dossier Submitter.** The idea (assumed by SEAC) that consumers would accept a loss in quality does not imply that this loss will not affect the total costs of the restriction. And those additional costs, only listed in a qualitative way, have not been included in the calculation of the cost-effectiveness ratios.

It should be stressed that as long as uncertainties related to the exact scope of the substances under restriction remain[12], it will be very difficult to make sure that substances that could be alternatives are not actually falling under the scope of the restriction.

- **ECONOMIC FEASIBILITY AND MARKET DYNAMICS**

According to SEAC, many alternative products (in terms of variability) are in the market. However, we are concerned that SEAC may not have assessed the available quantities (tonnage) of the formulations for these alternative products that would be able to satisfy *the whole EEA demand*. **ECHA clarified that the 520 polymers database do not show the tonnage of the formulas of the alternatives products available in the market.** This is key to understanding the economic feasibility and sustainability of the Annex XV restriction report's potential impacts. In addition to the available quantities, and perhaps more importantly, **the equation "alternative product = alternative ingredient" is too simplistic, especially for leave-on products.** The fact that within the same category both products with microplastics and without microplastics exist does not mean that these two types of products are interchangeable. They each respond to a different consumer need, and therefore a different performance category. For example, mascaras claiming increased length of the lashes contain microplastics fibers, and the same result cannot be achieved with natural ingredients. As alternative ingredients achieving the same function do not exist, the needs of a particular group of consumers may no longer be satisfied. Another example is that there are many different types of lipsticks (e.g. stick, liquid, shiny, matte, long stay), each with a different expected performance and where microplastics will fulfill different functions. The fact that alternative products without microplastics exist within the category does not mean that they will be able to satisfy all the consumers' needs within the category. Indeed, according to the Dossier Submitter and based on the data from the CosmEthics database, for the following categories of leave-on products the share of products not containing microplastics is below 50%:

- Make-up: concealer, blush/bronzer, eyeshadow, eyebrow pen/gel/powder, eyeliner liquid/gel/pen, foundation/BB cream, highlighter, lipstick, lip gloss, lip liner, mascara, nail polish, pressed powder,
- Skin care: body lotion/balm/cream/gel, eye gel and moisturizer, facial care/moisturizer, Moisturizer/face cream,
- Sunscreen[13]

These are indeed the products where alternatives are not available. Therefore, ECHA's reasoning based on the data provided through the application CosmEthics is flawed.

[12] This issue will be addressed in greater detail in the section of this document dedicated to "General comments".
[13] See table 53 on page 188 et ss. of the Annex to Background Document.

**Economic availability, price affordability, quality of products meeting consumers' expectation has not been taken into account.** Differentiation within product categories, where different types of products are not interchangeable, and competitiveness within the cosmetics sector (different formulation impacts performance and allows a company to differentiate its products) should also be considered. In case of a lack of alternatives, the disruption for certain categories and the business loss incurred have not been considered.

**The proposal does not foresee sufficient time for the supply chain to find and to transition to alternatives**. The assumptions made that are related to the percentages of reformulations (viz., dividing the formulas portfolio among the groups 0-30%, 30%-70%, and 70%-100%) based on the availability of alternative products according to CosmEthics database is incorrect as it assumes that products are interchangeable within a category and that there is no differentiation. Also, ECHA does not take into account the socio-economic costs associated with the loss of the formulas that would not be reformulated under these circumstances.

**SEAC has assumed that the net effect from the restriction on the suppliers of microplastics will be zero because they are likely to produce both MPs and the alternative ingredients.** This assumption is not correct as some suppliers do not have the current infrastructures for new methodologies and may even renounce to supply the cosmetics sector. Some suppliers will produce alternatives, while others, faced with too many uncertainties and potential high investments**,** will stop supplying the cosmetics industry or be forced to remove products and technologies from the EEA market. In that case, the cosmetics industry will have to find new suppliers. Market dynamics is not a simple process as depicted in Annex XV restriction report. The incentive for companies to invest in alternatives depends on the legal certainty and predictability of the regulatory environment. The assumption for increasing the demand for microplastics-free ingredients in some products and providing income for their suppliers is not well substantiated.

The lack of proper assessment of the impact of the restriction on suppliers of ingredients and their ability to innovate is a major gap in the Microplastics restriction dossier and this has not been sufficiently reflected in the SEAC draft opinion.

- **FUNCTIONAL AND EMOTIONAL BENEFITS OF COSMETICS AND ESSENTIAL ROLE OF MICROPLASTICS**

Cosmetics Europe has surveyed European consumers of cosmetics products[14], finding that cosmetics and personal care products are essential in people's daily lives, and contribute to their self-confidence, well-being, and healthy lifestyle for all generations.[15]

[14] As defined in the Cosmetic Products Regulation EC 1223/2009
[15] Cosmetics Europe, 2016. "Socio-economic contribution of the European Cosmetics Industry".

The survey revealed consumers make a clear link between cosmetics and personal care products and quality of life. In particular, 72% of consumers said that cosmetics and personal care products improve the quality of life, even above financial stability or a rewarding job – which reflects an emerging emphasis on well-being across society. In addition, 80% of consumers identified cosmetics and personal care products as important or very important in building up self-esteem and enhancing their social interactions.

A strong link exists between how confident we feel about our appearance and our level of self-esteem. Feeling confident about one's appearance rated as the most important factor for building up self-esteem, above having a large group of friends, being financially successful and even having a supportive family. [16]

The European population is ageing and cosmetics vastly improve their way of living among others. A research survey conducted in hospitals on patients receiving treatment for cancer shows that beauty care experience helps patients live through the period of treatment better or less difficultly, giving rise to approbation and satisfaction.[17]

The cosmetics industry charity "Look Good Feel Better (LGFB)", which is the only international cancer support charity that helps women and teenagers manage the visible side effects of cancer treatment offers confidence boosting skincare and make-up workshops and masterclasses across the world for women undergoing treatment for any type of cancer[18]. Since 1989, the program has empowered 2 million women in 27 countries around the world to reclaim the sense of control, confidence and self-esteem that are so central to wellbeing.

**Cosmetics therefore should be considered as essential for well-being, and they reflect consumers' preferences.**

**Some of their key characteristics, such as ease of application or technical performance are linked to microplastics in the formulation.**

There are many different types of **essential functions** performed by "microplastics" ingredients in leave-on cosmetic products. Cosmetics Europe provided a detailed inventory in its previous contributions.

For example:

- In **sunscreen products**, some polymers have been shown to boost the performance of sunscreen formulations, yielding higher SPF levels from a given combination of UV actives; others reduce the stickiness of the formula, increasing the spreadability, easing the use of the product, and increasing reapplication of the product. Sunscreen is important for its consumer protection and public health benefits, i.e. to prevent skin cancer. Better performance means a higher level of

[16] CTPA 2012. Annual Report
[17] Amiel, P., Dauchy S., Bodin, J., Cerf, C., Zenasni, F., Pezant, E., Teller, A., André, F., DiPalma, M., 2009. Evaluating Beauty Care Provided by the Hospital to Women Suffering from Breast Cancer: Qualitative Aspects. Supportive Care in Cancer 17, 839-845.
[18] https://lookgoodfeelbetter.org/about/about-the-program/

consumer protection. With the proposed ECHA definition of microplastics, these polymers would be considered as microplastics and fall within the scope of the Restriction. A ban on the use of microplastics with this specific function in suncare products would lead to an increase in the amounts of UV Filters used in the product to achieve a similar level of SPF.

- In **make-up products**, microplastics have been key for the industry's innovation. For example, for the past 30 years, foundation products have evolved tremendously, thanks to microplastics. With these ingredients, it was possible to create very light and fluid textures, with greatly improved spreadability, which led to a more homogenous and natural-looking make-up, which is more resistant, luminous and long-lasting, while providing shine control. Without microplastics, that level of performance will be lost, and consumers will be left with the old foundations, which were heavy, greasy, shiny, and difficult to apply.
- **In skincare products**, microplastics offer a combination of benefits to skin care formulations that is not duplicated by any other ingredient or technology today. Specific benefits of these materials include:
  - **Skin Feel** – providing a superior soft, cushiony, silky, smooth feel on the skin that consumers find delightful. Importantly, this feel is not greasy like typical liquid emollients nor dry like typical hard powders;
  - **Skin Appearance** – providing very strong "soft focus" benefits, optically blurring the appearance of skin texture, fine lines, wrinkles, and pores. Additionally, they also are capable of absorbing sebum, hence providing shine control benefits over time after application.

**Recommendations to appropriately consider the complexity of the proposed restriction for the cosmetics sector**:

- Recommendation for SEAC to take into account the fact that for close to 100% of leave-on formulas on the market there are no known suitable alternatives to Microplastics
- Recommendation for SEAC to take into account when assessing alternatives: product performance characteristics, consumer benefits and expectations, complexity of the raw materials which are not commodities but proprietary to individual companies, market demand and supply chains
- Recommendation for SEAC to substantiate better assumptions for the possibility for suppliers of raw materials to innovate and supply microplastic-free ingredients to the cosmetic sector, within the short timelines foreseen for reformulation and in sufficient quantities to meet the market demand.
- Recommendations to set longer transitional periods

## III. Cost Assessment for the Cosmetics sector

**Key points:**

- The **average cost of reformulations is estimated at 820,000 EUR** per company where alternatives are available, based on the steps of the reformulation process. Where alternatives are not available, the reformulation costs are **substantially higher** as they include heavy investment of resources to find new raw materials and new core technologies.
- The broad scope of the microplastics restriction will force the cosmetics sector **to reformulate and redesign more than 30,000 formulations at the same time,** covering many types of different functions, types of microplastics and types of products.
- The **number of ingredients to substitute per formulation** will also have an impact on reformulation costs.
- The **overall reformulation capacity of the sector is limited**: reformulation will require the re-deployment and monopolization of the resources of R&D departments for years, at the expense of innovation beyond compliance.

The plausibility of the cost estimates presented in the dossier is always evaluated by SEAC. If the SEAC receives little information on costs and technical feasibility of alternatives during public consultation, it will assume that the proposed restriction can be considered proportionate or has little impact on the relevant sector. In the 11 June 2020 Draft Opinion, "*SEAC considers the estimates used by the Dossier Submitter to be overall appropriate to reflect the average reformulation costs to be expected.*" (p.49)

However, Cosmetics Europe submitted detailed information on the costs to be expected for the sector, reflecting the key factors detailed above including the availability of alternative ingredients. This contribution was not sufficiently taken into account by SEAC in its Draft Opinion, which is aligned with the cost estimates of the restriction dossier including for reformulation costs. Cosmetics Europe disagrees with these cost estimates. Revised estimates, based on conservative data obtained from industry, are provided below.

- **REFORMULATION COSTS AND AFFORDABILITY**

The reformulation process covers a range of steps, detailed below:

| Key reformulation Process Steps | Key activities |
|---|---|
| | Identification and Testing of the raw material |
| **R&D** | Laboratory Bench Testing |
| | Pilot Plant Testing |
| | Raw Material Documentation Request/Sample Coordination |
| | Formulary Database Entry / Management |
| | Formula Stability Testing |
| | Plant Trial Stability Testing |
| | Safety Data Review |
| | Coordinate Safety Testing |
| | Safety Testing |
| | Regulatory Assessment |
| | Product Review |
| | Claims Study(s) |
| | Fragrance Evaluation |
| | Formulation by Labs |
| | Packaging Compatibility Assessment |
| **Redesign** | Design/ IP |
| | Validation by Marketing |
| **Assessment of Safety and Environmental Impacts** | Safety Studies |
| | Environmental Studies, including tests to evaluate biodegradability |
| **Testing & Validation** | Stability Tests |
| | Consumer Tests |
| **Regulatory Compliance** | Re-Notification in the EU CPNP Database |
| | Updating of the PIF and of the Safety Report |
| | Updating of the Labelling |
| **Packaging & Labeling** | Packaging Compatibility Assessment |
| | Claims Study(s) |
| **Manufacturing** | Plant Testing, including Pilot |
| | Plant Trials, including shade matching for make-up |
| | Modification of Production Process<br>Adaption of Good Manufacturing Practice Aspects |
| **Information to Customers** | Post-Market Consumer Studies |
| | Material Master # Set up in SAP |
| | Vendor # Creation in SAP |
| | Update of IT Tools |

| | |
|---|---|
| **Post-Launch and In-Market Costs** | Product Withdrawal with Switch in Formula |

According to the Dossier submitter's estimates which are supported by SEAC, the average reformulation costs for international companies are estimated at 365 000 euros, while for SMEs the average cost of a reformulation is 42 000 euros. These values are derived by using the UK 2015 proposal for restricting D4/D5 in rinse-off products. The case of D4/D5 is not comparable as the average reformulation cost is related to the substitution of only two substances in a limited number of categories of products. In reality, the reformulation cost in the context of the proposed restriction will be much higher. The AMEC study reports that the high value for re-formulation is 820,000 euro, where alternatives are available. In the case of Microplastics restriction, alternatives are not available in 85.5% of the cases (close to 100% in the case of leave-on products), therefore a reformulation will require fundamental research to find new raw materials and new core technologies, which implies heavy investments of resources.

Moreover, companies would face the situation in which they have to reformulate thousands of formulations at the same time, replacing up to 6 ingredients (or more) in the same formula in some cases; this task will monopolize the resources of R&D departments for years, at the expense of innovation beyond compliance. Therefore, the **average reformulation costs will be substantially higher than 820,000 euro.** We strongly recommend that SEAC applies this value as a minimum and considers this as a conservative approach to estimate the reformulation costs. SEAC points out that for some product groups (e.g. cosmetics) the proposed restriction will not create a need to reformulate *per se*, because they are currently reformulated at regular intervals, but will bring reformulation efforts, and the associated costs, forward to an earlier point in time (i.e. during the transition period). Therefore, it can be expected that the reformulation efforts triggered by the proposed restriction will be coordinated with baseline reformulations (p.44). This is not realistic, because baseline reformulations are usually "tweaks" in the formulation that bring incremental improvements and not radical redesigns that require inventing new core technologies, with a different level of resources and investment needed. Instead, for leave-on products, the proposed restriction of microplastics will directly create a need to radically reformulate many thousands of products in a short period of time (6 years), which will mean that entire segments of products will disappear, especially as far as make-up is concerned, because their reformulation will simply not be possible in such timing.

- **NUMBER OF FORMULATIONS**

Voluntary phasing out of microbeads required the reformulation of **130 formulations** (estimation from the data gathered for the Call for Evidence on the use on microplastics submitted in May 2018). Phasing out

of microplastics will force the **reformulation and redesign of more than 30,000 formulations**[19] (conservatively estimated). The fact that the substitution of microbeads was made in one single category of products (exfoliating and cleansing ones) allowed an "economy of scale approach" and a brutal rationalization of the number of products that were all very similar to one another. This is why only 130 out of 296 exfoliating and cleansing products were reformulated. Companies could group the reformulation of similar products and extrapolate certain test results across products. This will certainly not be the case for the compliance with the ban of microplastics because companies will have to deal with many different functions, many types of microplastics, and many types of products, given the current wide definition.

According to SEAC the number of formulations is over estimated, as high number of products are "characterised by small differences, e.g. on the basis of colour, within the same brand name and product series" (p 49 of the SEAC draft opinion). The number of formulas surveyed by Cosmetics Europe reflects the full range of products, however, an adjustment has been made to the reformulation costs to take into account the similarity between certain formulations. The cost of reformulation for similar formulas, like make-up, however, remains high, because of the delicate balance represented by each color nuance, which will have to be reworked to integrate the new technologies while maintaining the desired nuance of color. For instance, the number of formulations includes the number of color nuances, however the dimension of "duplication of formulas" is taken into account in the cost per reformulation, which considers the cost to find the alternatives, redo the architecture of the formula (which is basically only counted once as spread over all the nuances), the associated "cascading" to each of the nuances, that have to be adjusted, and the packs and labelling that also have to be updated. Therefore, the cost estimates presented by the survey of Cosmetics Europe correctly reflect the above-mentioned concern.

In addition, SEAC accepts ECHA's assumption that high numbers of reformulations allow to reduce the cost of individual reformulation. This is not generally true, because economies of scale are not always possible, as sometimes within the same company it is not possible to reuse the same technology in all the products of the same category (e.g. a specific type of skin care) or across brands. In addition, SMEs are unlikely to have a sufficiently big portfolio to rely on economies of scale.

Finally, SEAC wrongly assumes that *"not all cosmetic products containing microplastics are likely to be reformulated in response to the restriction, for some it is likely that production will be discontinued instead"* (p.47 of the draft opinion). It refers to the information presented by Cosmetics Europe regarding the

[19] 13,381 formulations refers to the number of leave-on formulations reported in the dataset of the Cosmetics Europe Survey from 2018 (based on replies from 56 companies covering over 50% of the cosmetic sector). The figure of 30,000 formulations is extrapolated from this survey dataset. The CE SEA was based on a sample 19 substances. The analysis of the 19 ingredients is therefore a sample approach. Please see footnote 2.

experience related to phasing out of microbeads where 56% of the formulations had to be discontinued (166 out of 296), based on which ECHA assumes the discontinuation of 50% of leave-on products. As already indicated, the discontinuation of formulations in the case of microbeads concerned a very limited number of functions and product categories. However, the same considerations would not be applicable to the broad category of leave-on products. The broad definition of microplastics and very large scope indeed impacts dramatically the product portfolio of companies. It is unrealistic to assume that companies will discontinue formulations in the same proportions as in the case of microbeads for all leave-on cosmetic products, including make-up, as these products respond to a very broad range of consumers' needs. The business decision whether or not to reformulate a product, even if the reformulation is particularly challenging, is driven by many parameters, such as profit margins, shares in company/brand's portfolio, share of the company in the product market segment, consumer trends etc. Endorsing the conclusion made by ECHA in the present report would implicitly mean accepting to eliminate from the marketplace many existing leave-on product categories, especially make-up. In turn, this may also reduce the number of shades, colours and textures on the market, therefore drastically impacting minority consumers and making the marketplace less inclusive. Given the limited contribution of leave-on cosmetics, and especially make-up, to the emissions of microplastics in the environment, a restriction that does not allow the reformulation of all the impacted products, for example by providing appropriate transition periods, is obviously disproportionate.

- **NUMBER OF INGREDIENTS PER FORMULATION**

The time needed to reformulate as well as the reformulation costs depend on the number of ingredients to substitute in a single formulation. For leave-on products, and make-up in particular, a substantial number of formulations contain more than one and up to 6 different microplastic compounds (or more, given the broad scope of the restriction). Replacing more than one ingredient requires in the majority of the cases complete re-design of the formula, including several individual core technologies, after identifying new raw materials capable of providing a certain type of functionality and a specific level of performance. This task is of an extremely high complexity.

- **REFORMULATION CAPACITY**

It is assumed that companies will anticipate all reformulations that would happen up to 5 years after the end of the proposed transition periods (4 and 6 years), so as to make them within the transition periods. This implies assuming that companies are able to at least double their reformulation capacity and that all alternatives are available, which is not the case in reality. In addition, the majority of reformulations are not simply one-to-one replacement, as thoroughly explained above and in previous submissions of Cosmetics Europe in the ECHA stakeholder consultation, therefore increasing the complexity for the reformulation processes. This requires **re-deploying R&D qualified workforce to focus on redesign instead on innovation**. In a majority of cases, the substitution of the 19 substances (see footnote 2) will

require a fundamental redesign of the formula architecture. This is often linked to fundamental research which can take up to 8-10 years due to the lack of alternatives and require millions of euros investments. In reality, many products would have to be discontinued solely because the company did not have the capacity to reformulate all the products in the transition period allocated.

This is going to be extremely impactful for **make-up**, including lip and nail products. In these products, the numerous and diverse functions of microplastics, combined with the additional level of complexity brought by the broad palette of color shades make it impossible to reformulate in a limited period of time. In the proposed transition period of 6 years, industry will only be able to reformulate a fraction of the thousands of impacted products, due to a combination of factors: absence of viable or validated alternative solutions, huge number of raw materials, suppliers and formulations, lack of reformulation capacity within the R&D departments, lack of industrial pilots, lack of capacity to perform shade matching in the factories (equipment and specialized staff). The loss of about 70% of the make-up formulations would not only have a huge impact on companies, including SME's, turnover, but the impact on society will be very significant, as consumers will lose many products they know and love, without being able to satisfy their specific needs (e.g. matte lipsticks, fluid foundations, lengthening mascaras) on the EEA market.

Similar concerns are raised for **skin care products**, where the high number of formulations also suggests that the lack of alternatives and the current capacity of the industry's R&I will not allow to reformulate all the impacted products in the proposed six-year transition period.

- **COST ESTIMATES**

**SEAC considers that the estimate provided by industry is likely to be overestimated and may reflect the marginal, but not the average cost to reformulate. This is based in particular on the following assumptions:**

1. alternatives are on the market already for most functions of Microplastics
2. number of reformulations that require extensive initial R&D to develop alternatives is likely to be limited
3. cost for reformulating raw material mixture to be allocated among final products
4. confidential submission stating that the reformulation cost is lower, and as a consequence, the industry cost estimates are considered likely over-estimates and the dossier submitters cost estimates are considered within the appropriate range.

As far as **Statement 1** is concerned, the previous paragraphs indicate that it is not accurate. Additionally, as new technologies are developed, patent protections will not necessarily allow for large scale application of this.

**Statement 2** is incorrect, because the core technologies used to formulate cosmetic products are very numerous and they are combined in many different ways, therefore one cannot assume that only a limited number of formulations require extensive initial R&D efforts. Where an alternative exists, it is necessary to find the right way to integrate it in a formulation, so that it yields a comparable level of performance to the initial product. That also requires significant resources. In addition, several attempts will be required before finding the right alternative and validating it.

**Statement 3** is only true within individual companies, who will be able to use a certain raw material or a certain core technology in several products. Each company will have to invest to research raw materials and formulate them.

Regarding **Statement 4**, to **properly determine the correct cost estimation on the basis of differing submissions**, a number of possible variables need to be considered to determine the representativeness of each contribution. We appreciate the need to ensure that **submissions made confidentially are kept confidential**. Whilst Cosmetics Europe is unable to directly scrutinise confidential submissions, ECHA can legitimately disclose the basis of the differing costs calculations without infringing the requested confidentiality. This will better allow to assess the **approach taken by SEAC to the weight of evidence and will help make for an informed response to the SEAC opinion public consultation**. Accordingly, we request ECHA to provide the following information in relation to the contradictory submissions on the costs of reformulation of cosmetics products whose data was used for the purposes of the SEAC draft Opinion:

1. The product categories assessed
2. The number of formulations assessed
3. The steps in the reformulation process assessed
4. How many formulations with only 1 microplastic? How many formulations with 2? How many with 3? How many with 4? How many with 5? how many with 6? etc
5. The proportion of the EEA market represented by the data
6. Is the conflicting submission evidence from one single company or from several (if so, how many?) companies with aggregated data?
7. Is the company or are the companies SME(s)?
8. Are the company or companies based in the EEA, if not where are they based?

**Recommendations on cost assessment for the Cosmetics sector**:

- Recommendation for SEAC to apply value of reformulation costs at 820,000 euro.
- Recommendation for SEAC to take into account reformulation capacity, number of formulations and number of ingredients per formulations, and need for R&D resources redeployment.
- Recommendation for SEAC to weigh evidence contained in confidential conflicting cost estimate

- **CONSUMER AWARENESS**

In our view, two conditions are necessary for Instructions for Use and Disposal [IFUD] to be effective. First, IFUD needs to be genuinely consumer orientated and fully consistent with the objectives of the EU Green agenda aiming at reducing packaging and packaging waste. Second, industry needs freedom to adopt suitable approaches which optimise both accessibility to, and quality of, information. We recognise that for certain applications, release into the environment is dependent upon appropriate use and disposal by the consumer. In such circumstances, IFUD may play a useful role in, ultimately, completely eliminating such emissions. This is potentially the case with the Derogation requested by Cosmetics Europe in respect of Make Up, including Lip and Nail Products for which data show (see Kantar study above) that, although a vast majority of users use and dispose properly these products, there is still a minority of users who could benefit from being advised how to use and dispose these products.

However, Cosmetics Europe doubts whether the imposition of IFUD for some derogated uses serves any useful purpose in terms of environmental protection. This is evidently, in our view, excessive regulation, and therefore cost, to no clear purpose.

In this context, we welcome the indications given in Section 2.2.1.4 of the Background Document that some flexibility should be encouraged to address IFUD challenges, including online and/or digital solutions. Should the Derogation for Make Up, including Lip and Nail products be granted, the Cosmetics and Personal Care industry is strongly committed to working with the Commission and other stakeholders to develop a genuinely effective, consumer orientated, future proof and flexible approach to IFUD which will help ensure that any remaining microplastic emissions are eliminated.

## IV. Overall proportionality for the Cosmetics sector

**Key points:**

- For leave-on cosmetics, the cost-effectiveness ratio is calculated at 7,790 EUR/kg. Adjusting to include other factors highlighting in previous contributions, it is not implausible that the real **cost-effectiveness ratio for the restriction of leave-on products is more than 8,000 EUR/kg.**
- The Dossier submitter recognizes that the leave-on cosmetics sector has one of the **lowest contributions to the emissions** of intentionally added microplastics to the environment, while it would have to face the **highest cost per kg of emissions reduced**.
- **The transition periods should therefore be adjusted to improve the proportionality of the restriction.**
- **The impact of the microplastics restriction on SMEs should not be under-estimated**, as many cosmetics SMEs manufacture or use microplastics ingredients. Depending on products segments, SMEs would not necessarily take advantage of the restriction.

- **APPROACH TO THE PROPORTIONALITY ASSESSMENT**

The proportionality assessment needs to investigate whether the benefits are proportionate to the costs. By considering only the cost-effectiveness (the cost per emission abatement), proportionality has not been fully assessed. Consumer willingness to pay should also be taken into account.

For example, a Consumer Willingness to Pay (WTP) study[20] was conducted on behalf of the UK Environment Agency in April 2020. The study was conducted on a representative sample of 670 UK adults and elicited WTP for three different measures to control the loss of intentionally added microplastics to the terrestrial and marine environments. The Choice Experiment section of the Stated Preference survey asks respondents about their preferences for the price, performance, and reduction of microplastics from their personal care products. Amongst other findings, the study found that *"the sample WTP ... is £0.036 for a one percentage point decrease in the number of microplastics lost per product, and Willingness To Accept (WTA) of £0.048 for a one percentage point loss of product performance. Although the two values cannot easily be aggregated and scaled, the comparison of the two shows that respondents value product performance highly, as expected."*

[20] "Economic Valuation of Benefits from the Proposed REACH Restriction of Intentionally Added Microplastics" UK Environment Agency, August 2020, available to view as a submission to the SEAC consultation at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22921/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=-&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

By considering only the cost-effectiveness, it is assumed that if costs are similar to previous measures then they are acceptable, because it is assumed that previous measures were proportionate. However, this assumption cannot be made, as explained below.

- **COST-EFFECTIVENESS RATIO FOR THE COSMETICS SECTOR**

The Dossier Submitter and SEAC (and Cosmetics Europe as well) are in a position to say, with a high likelihood, that the **cost-effectiveness ratios are less than 50,000 EUR/kg for all product categories.**

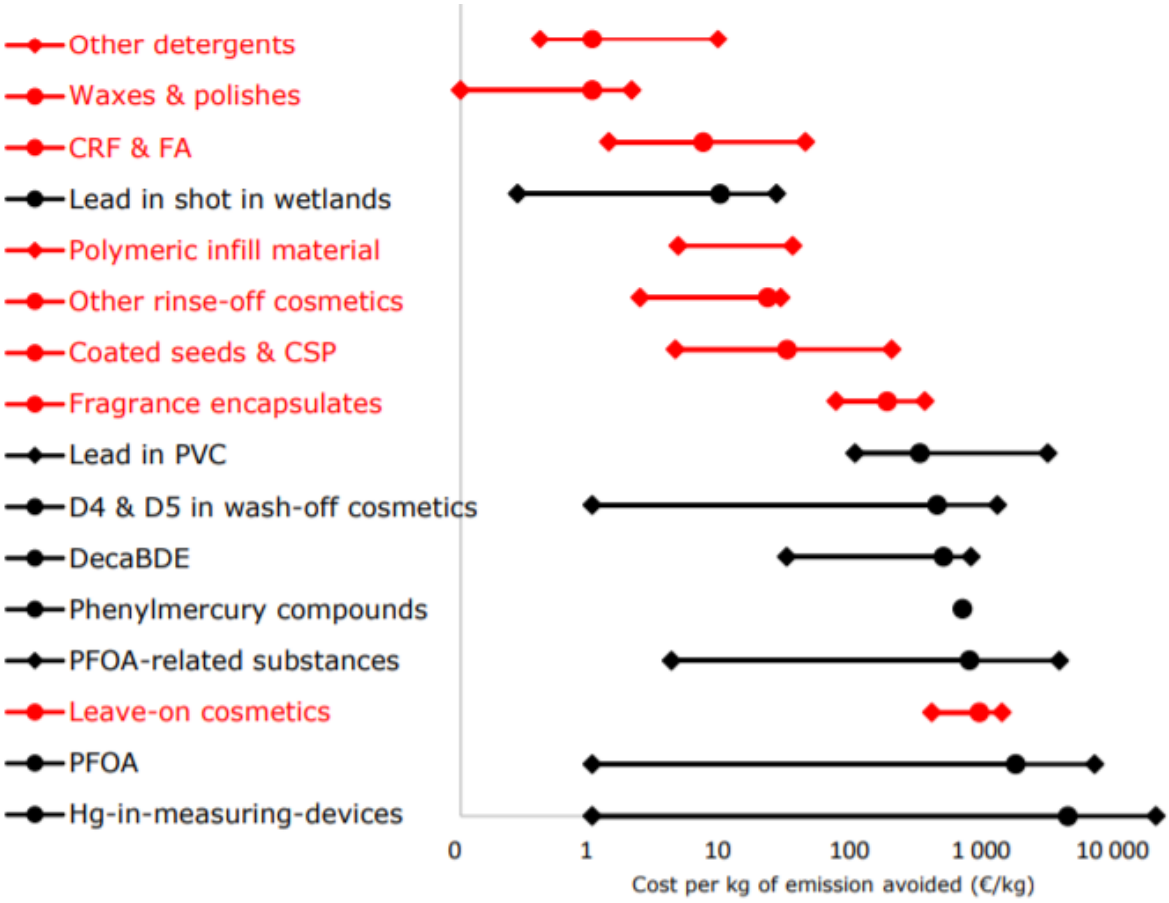
It is worth recalling here the reference used by the Dossier Submitter (and SEAC) in judging, in general terms, the cost effectiveness of a given restriction:

*"The study concludes that, although cost estimates of previously adopted actions do not allow deriving a value for society's willingness to pay to reduce PBT presence, use, and emissions, the available evidence suggested that* ***measures costing less than €1 000 per kilogram of emission reduction would usually not be rejected for reasons of disproportionate costs****, whereas for measures with costs above €50 000 per kilogram PBT such a rejection is likely (Oosterhuis et al., 2017)."*

This is a misunderstanding of the Oosterhuis study. The Oosterhuis study sought to provide information that could be used to develop a benchmark for assessing the proportionality of measures to control PFOA, PFOS and other POP-like substances, and it looked at the cost-effectiveness estimates for regulatory measures that have been applied or considered. The available evidence suggests that in the past, regulatory measures costing less than 1,000€/kg substance use or emission reduction have usually not been rejected, whereas for measures with costs above 50,000 €/kg substance such a rejection is likely. However, the study did not assess whether the measures were justified in terms of benefits and costs, so **it cannot be said that the measures were rejected for proportionality reasons**. This is summarised by the following statement from the Oosterhuis study:

*"Decisions on PBT measures appear to be rarely explicitly motivated by cost effectiveness arguments. In particular, it is hard to find clear statements that a restriction or ban on the use of a PBT or the clean-up of a site polluted by a PBT should be abandoned due to disproportionate or excessive costs per kg."*

Cosmetics Europe rejects the basis of making cost-effectiveness comparisons because this does not provide any information about proportionality. However, even if such a comparison were made between leave-on cosmetic products and other previous measures, it highlights how expensive the restriction is for leave-on cosmetic products. The background document to RAC and SEAC gives the following table (p.162), showing the high cost per kg of emissions avoided for leave-on cosmetics as compared to other comparable restrictions, as it is only exceeded by two specific substances with a limited scope as shown below:




Setting a reference threshold for assessing the cost effectiveness is arbitrary, as there is no meaningful comparison. It does not set a realistic criterion that can be used by the regulator. It is in fact over 5 times higher than the highest cost effectiveness estimated for cosmetics products and 50 times higher than the ratios derived in the REACH restriction decisions over the last decade.

Unfortunately, ECHA does not provide sufficient transparency regarding the information on the approach, background calculations and detailed tables used to derive its estimates in the restriction proposal. Therefore, it is not possible to refine the estimates by directly challenging or changing values in those tables/equations. The final adjusted **cost-effectiveness ratio can be calculated for the leave-on cosmetics** according to the socio-economic analysis of the cosmetics sector and has already been shared with ECHA by Cosmetics Europe during previous consultations. In addition, cost effectiveness ratios for individual categories of leave-on products are provided further in this document below.

- **STEP 1:**

For the calculation of the tonnages, ECHA takes into account the CosmEthics dataset which includes both liquid/dissolved polymers (50%) and film formers (19% of the remaining solid part). This is inconsistent with the proposed definition of MP and scope of the restriction proposal. When correcting this inconsistency, we conclude that 40.5% of tonnage is relevant: (100%-50%)x(100%-19%).

The annual tonnage (used MP) of the central scenario should be equal to 40.5% times 4,262 tons/year (which is the tonnage of High Scenario) = 1,726.11 ton/year instead of the current 2,689 ton/year (See Table 47 of Annexes, p. 146). This is equivalent to a reduction in the used tonnage of approximately 36% with respect to that derived by ECHA estimations. Therefore, the releases should be reduced by this same proportion.

We take now the estimate of the cost-effectiveness ratio derived by ECHA for the restriction of leave-on products (820 EUR/kg) and multiplying it by 2,689/1,726.11 we derive the adjusted cost-effectiveness ratio of 1,277 EUR/kg.

- **STEP 2:**

ECHA has assumed that there are alternatives for all formulations but we reported in our initial SEA that 85.5% of current formulas on the market have no alternatives to MP.

ECHA has also reported that in the current restriction proposal about 95% of the restriction costs are for the reformulation.

In the Annex to the restriction proposal ECHA has used the value to reformulate of 547,500 EUR for large companies and 63,000 EUR for SMEs (accounting for 50% of estimated formulations; see Table 54 of Annex to the restriction proposal). A much higher value should be used for both large companies and SMEs: at least 820,000 EUR.

This means that one should adjust as follow:

- Large companies: 820,000/547,500 = 1.4977 times (accounting for 50% of the impact of adjustment)
- SMEs: 820,000/63,000 = 13.0159 times (accounting for 50% of the impact of adjustment)
- Taking the weighted average: (50% x 1.4977) + (50% 13.0159) = 7.2568 times.
- Accounting for the % of formulas with no alternative (85.5%) and the proportion of restriction costs (95%), we derive an estimated adjustment factor of: 85.5% x 95% x 7.2568 times = 5.8943358.

This value should be used to multiply the cost-effectiveness as adjusted in STEP 1: 1,277 EUR/kg times 5.8943358 = 7,527 EUR/kg. To this we should be added to the remaining 14.5% times 95% times 1,277

EUR/kg = about 176 EUR/kg. Hence the final adjusted cost-effectiveness ratio is 7,527 EUR/kg + 176 EUR/kg = 7,703 EUR/kg.

- **STEP 3:**

One can derive the additional value to be added to the cost-effectiveness ratio, highlighting that the loss in EBIT from exports is equal to 150 million/year for each year after the transition period.

150 million EUR/year divided by 1,726.11 ton/year of releases (see STEP 1 above): 87 EUR/kg to be added to the cost-effectiveness ratio derived in STEP 2: 7,703 EUR/kg + 87 EUR/kg = **7,790 EUR/kg.**

- **Conclusions**

The adjustment in the cost-effectiveness ratio as derived above does not take into account the other points highlighted in previous contributions of Cosmetics Europe to the public consultation, which would be likely to strongly increase further the "real" cost-effectiveness ratio for the restriction for leave-on products.

It is not implausible that the real cost-effectiveness ratio for the restriction of leave-on products is more than 8,000 EUR/kg.

As ECHA itself notes in its proposal report, the potential emissions from leave-on cosmetic products to intentionally added microplastics represent 2% of all intentionally added microplastics, yet these products will bear 80% of the costs of the whole restriction. This is evidently disproportionate. Further it should be stressed again, a vast number of complex formulations would be impacted; the estimated tonnage used in leave-on corresponds to 13,381 leave-on formulations representing 93.5% of all formulations[21].

It is clear from the cost-benefit analysis above that a restriction including leave-on products in the scope of the restriction will have a huge negative impact on the EEA society.

Cosmetics Europe has since the submission of our dossier to ECHA developed further analyses. The data set Cosmetics Europe used for its socio-economic assessment was based on a survey of our members and the real data extracted from the resulting data set. That data set had some gaps.

**Cosmetics Europe has therefore performed an extrapolation to "fill" those data gaps. According to this extrapolation the following assessment has been made per leave-on product category showing the potential tonnages used, the potential risk of exposure, the number of formulas impacted and the cost effectiveness ratio per product category** – this is set out in the table below:

[21] 13,381 formulations refers to the number of leave-on formulations reported in the dataset of the Cosmetics Europe Survey from 2018 (based on replies from 56 companies covering over 50% of the cosmetic sector).

| Product categories | Releases (tons)/y from the formulas in the Cosmetics Europe database (rounded to the closest unity) | Pathway to the environment (% derived for all leave-on categories from by ECHA estimates in the restriction proposal; 100% assumed for sunscreen) | Formulas impacted in the Cosmetics Europe database | Cost-effectiveness ratio |
|---|---|---|---|---|
| Make up (including lipstick products & nail products) | 134 | 24% | 15,207 | 8,556 EUR/kg |
| Sunscreen | 191 | 100% | 297 | 117 EUR/kg |
| Skin care | 85 | 24% | 1,125 | 994 EUR/kg |
| | | | | |
| Other leave-on Products | 54 | 24% | 414 | 582 EUR/kg |

- **PROPORTIONALITY OF THE PROPOSAL FOR THE COSMETICS SECTOR**

Both the Dossier Submitter and the SEAC in its draft opinion have recognised that the proposed restriction would have **substantial impacts on the cosmetics industry**, in particular leave-on cosmetics sector and some products with much lower emission potential/rate (i.e. make-up, lip and nail products) than some other products in the scope of restriction.

As ECHA itself notes in its proposal report, **the potential emissions from leave-on cosmetic products to intentionally added Microplastics represent 2% of all intentionally added Microplastics, yet these products will bear 80% of the costs of the whole restriction.** This is evidently disproportionate. Further it should be stressed again, a vast number of complex formulations would be impacted; the estimated tonnage used in leave-on corresponds to 13,381 leave-on formulations representing 93.5% of all formulations[22].

**The Dossier Submitter recognized in its analysis that the leave-on cosmetics sector has one of the lowest contributions to the emissions of intentionally added Microplastics to the environment, while it would have to face the highest cost per kg of emissions reduced.** The Dossier Submitter also highlighted that some groups of leave-on cosmetics (make-up, lip and nail leave-on products) **could bear a much larger cost than other product groups** while they contribute much less emissions to the environment than some of the other sectors in the scope of the proposed restriction. The cost-effectiveness of leave-on cosmetics is higher than the other sectors in scope as the proposed measure would lead to the highest share of the total restriction costs, while it is estimated to account for about 2% of the emissions anticipated to be

[22] 13,381 formulations refers to the number of leave-on formulations reported in the dataset of the Cosmetics Europe Survey from 2018 (based on replies from 56 companies covering over 50% of the cosmetic sector).

reduced as a result of the proposed restriction. ECHA's Annex XV dossier (Figure 14, p126) contains a comparison of the cost vs emissions of the proposed restriction between the different sectors concerned.

This comparison clearly demonstrates that leave-on cosmetics dramatically increase the cost of the restriction whilst barely impacting the emissions to the environment. The desired result of the restriction, a reduction in microplastic emissions to the environment, can be achieved with far less cost if leave-on cosmetics, specifically make-up, lip and nail products, are derogated.

For leave-on cosmetics that are mainly disposed via solid waste, i.e. make-up, lip and nail products, SEAC finds that other measures to manage microplastics emissions from these uses, such as informing consumers on proper use and disposal, or a longer transitional period (> 6 years) could also be considered proportionate taking into account the low contribution to overall emissions as well as the possible impact on SMEs of a ban of microplastics in these products (p. 64). If a similar result (reducing emissions from make-up products) can be achieved with a less impactful and more proportionate measure, then the more proportionate option should be pursued. The arguments developed above show clearly that despite the difficulty in precisely identifying the materials covered by the restriction, conclusions can be drawn using the available data, and such conclusions clearly indicate that the cosmetics sector, and in particular make-up products, is disproportionately impacted in absolute terms ( cfr. Cost-effectiveness ratio).

- **IMPACT ON SMEs**

**ECHA's assumption that SMEs do not use Microplastics does not reflect the reality. Many SMEs are producing leave on products containing microplastics, because microplastics (as defined by ECHA) are a fundamental part of the architecture of very many cosmetic products, whichever company has produced them. The impacts on SMEs are underestimated as Cosmetics Europe indicated in its input to the ECHA consultation:**

- **Many large companies outsource the production of certain products to SMEs and thus SMEs produce the products using microplastics ingredients**. For example, in Italy, 126 out of 135 Italian contract manufacturers are SMEs. 98 out of 135 Italian contract manufacturers are members of Cosmetica Italia, the Italian Cosmetics industry trade association. The total turnover of the 126 SMEs is 736 mio/€. The remaining 9 bigger companies (8 of them are members of Cosmetica Italia) have a total turnover of about 853 mio/€. Thus, as far as cosmetic SMEs are concerned, a distinction can be made between those who manufacture for others (they sell B2B), who will brand the products, and those who place on the market their own branded product (they sell B2C).

  Following a survey of Cosmetics Europe association members conducted in February 2019, just 123 out of 2,082 small and medium sized companies represented in the survey (based on responses from 16 of our national association members – over half our association members) produced only natural and organic products; therefore approximately **only 5.9% of the small and**

**medium sized companies represented in the survey produce only natural and organic products**. Cosmetics Europe is of the view that this is a solid representative sample, especially as the biggest national markets in Europe were represented in the survey[23].

- **The assumption that there are SMEs which could take advantage of the restriction does not imply that the net effect across all SMEs is zero**. This depends on the product categories in which the SMEs are involved, as the product segment needs to be considered. This should be highlighted not to take into account the net profit losses SMEs would face in the cosmetics industry and to derive larger cost-effectiveness ratios per se.

Overall, more precise information is needed on the SMEs and their role in the supply chain. Some key elements to consider for the public consultation in support of longer transition periods related to the SMEs:

- SME manufacturers which would be unable to secure contracts for microplastics-free alternatives;
- SME suppliers of microplastics containing ingredients;
- SME manufacturing proprietary cosmetics products containing microplastics;
- overall net effect expected from the restriction for this supply chain segment;
- estimation of SME's turnover and typical R&D investments
- prediction/estimation of the average number of products per company that would require reformulation.

**Recommendations**:

- Recommendation for SEAC to take into account the disproportionate impact on the cosmetics sector and consider a fairer and more consistent approach, by proposing a derogation for make-up, including lip and nail products, and more appropriate transition periods for sunscreen, skin care and other leave-on products to put more emphasis on the contribution ratio/estimations of the emissions of the environment of individual product types in the scope of the Microplastics restriction, the complexity and the number of reformulations.
- Recommendation for SEAC to take into account cost-effectiveness ratio for different cosmetics product categories on the basis of Cosmetics Europe's further analyses when considering the scope of the restriction and the length of transitional periods.
- Recommendation for SEAC to adjust its analysis on SME impact and collect more precise information on SMEs and their role in the supply chain

[23] Poland, Netherlands, Finland, Hungary, Bulgaria, Italy, Germany, Greece, Romania, Lithuania, Switzerland, Norway, Sweden, Spain, Belgium and France.

## V. Wider economic impacts on the competitiveness of the EU Cosmetics industry

**Key points:**

- Exports to non-EEA countries account for more than 18 billion EUR per year. The majority of exports (in value) is of leave-on products. In the main export markets' jurisdiction there are no restrictions of microplastics in leave-on cosmetics products. European companies may therefore have to **differentiate production between the EEA market and the export markets**.
- This would result in a **considerable loss of competitiveness**: duplication of production lines, different raw materials, increased excess and obsoletes. Many production plants would be made unviable.

The information provided by Cosmetics Europe relation to the impact on competitiveness of the EU industry was insufficiently taken into account both by the Dossier Submitter and SEAC.

As per the data submitted by Cosmetics Europe, the exports to non-EEA countries account for more than 18 billion euro, with France and Germany covering 51% of global exports. There recent export statistics (2014-2017) show a stable increase in exports (Cosmetics Europe) reaching 20.1 billion euro in 2017.

However, both Dossier Submitter and SEAC considered that "while it is possible that in the worst-case scenario these impacts may materialise for microplastics-containing products, it is also possible that value-added and exports of microplastics-free products may increase."

ECHA does not consider the asymmetry in the market dynamics between MP-containing products, which cover a large market share, and MP-free products which today represent a small percentage of the market, and this is especially true for leave-on products. Indeed, it is essential to refine by sub-category of products when making such assumptions. MP-free products do not have the same quality performance as MP–containing products, they respond to different consumers' expectations, and are available in insufficient quantity. Therefore, MP-free products cannot immediately take over the market share of MP containing products, this could be only possible if sufficiently long period of time is given to industry to reformulate their products. The real market dynamics is not like a Neo-classical economic model in which a new equilibrium is established immediately after any shock (as the narrative in the current restriction proposal would suggest). If the European companies cannot maintain the performance of their products, they will lose market shares internationally. European consumers could look for supply outside the EU, which is facilitated by e-commerce.

The main non-EEA export markets for the EEA cosmetics industry are USA, Singapore, China, United Arab Emirates, Russia, Hong Kong, Switzerland, South Korea, Japan, Canada, Australia, Mexico, Thailand, India, Indonesia, Brazil and Turkey. The majority of the exports (in value) of the EEA cosmetic industry to non-EEA markets is of leave-on products.

In these jurisdictions, there are no restrictions of MP, equivalent in scope to the restriction proposed by ECHA. None of these countries includes leave-on in their restriction. This means that companies may have to differentiate production between the one destined to the EEA market and the rest of the world to avoid placing on markets outside of Europe products with diminished performance, as this would result in a considerable loss of competitiveness. In addition, this would have important costs, notably to duplicate production lines, buy different raw materials, manage increased excess and obsoletes. Duplicating production lines to differentiate productions for the EU and for third countries would make many production plants unviable.

The proposed by ECHA restriction of Microplastics will therefore **negatively affect the international competitiveness of the EEA cosmetics sector**, as the scope of proposed the ban is very broad.

**Without proper transitional periods and derogations,** the EEA economy will face every year (after the ECHA's transitional periods) at least 150 million of loss in EBIT (assuming EBIT = 25% sales value; considering approximately 20 billion of exported sales per year, as stated above; applying the estimate of 3% for in-scope products).

## VI. Transitional periods for the Cosmetics sector

**Key points:**

- Cosmetics Europe welcomes the longer transitional periods based on information provided by industry in certain sectors.
- Equally, we would like to emphasise our arguments relating to the **time needed for reformulation for different categories of leave-on cosmetics products,** and in this light adopt adapted transition periods for sunscreen cosmetic products (8 years), skincare cosmetic products (12 years) and other leave-on cosmetic products (10 years).

- **COHERENCE ACROSS SECTORS**

**According to the Dossier submitter and SEAC no sufficient information is available to support longer transitional periods for cosmetics products or a time/progress-limited derogation** (the reported reformulation costs are deemed to be overestimated based on potential double counting) (RCOM to the public consultations on Annex XV restriction proposal; Sections D.5.4 and D.5.5 in the Annex to the Background Document).

We welcome that SEAC has concluded in favour of longer transitional periods for several sectors, based on information provided by industry in the public consultations on the tonnage and estimated reformulation costs. Equally, we would ask that SEAC reconsiders the argumentation provided by Cosmetic Europe's for longer transition periods for skin care, sun care and other leave on products in section VI.

Lastly, as indicated, in the SEAC opinion another sector far less impacted in terms of number of formulations, but which represent a major source of direct emissions of Microplastics in the environment has a similar transition period to leave-on cosmetic products where close to 30,000 formulas are impacted representing only 2% of the potential emissions.

**Recommendations**:

- Recommendation for SEAC to use a transparent and coherent approach across industry sectors when assessing and recommending transitional periods.

- **COMPARISON WITH D4 AND D5**

According to the response of ECHA to the comments provided by the cosmetic sector in the public consultation, *"the stakeholders do not take into account any coordination with baseline reformulations similar to the approach agreed by SEAC in the D4/5 opinion (ECHA 2016b) and recently reflected in the SEAC D4/5/6 opinion. As this is an approach agreed by SEAC, the Dossier Submitter is not proposing changes at this stage".*

- The analysis regarding potential overlaps between proposed restrictions on microplastics and D4, D5, D6 in cosmetics products in support of the Annex XV restriction report on intentionally added microplastics to products should be based upon 1) a robust dataset of product and ingredient use and potential overlaps between the two proposed restrictions; and 2) should take into consideration additional magnitude of complexity of reformulation programs when more than one ingredient is involved.

- The main area of uncertainty for the many cosmetic manufacturers is the identification of the materials impacted by the proposed restriction on intentionally added microplastics to products. As long as uncertainty remains on the product portfolio impacted by the definition, scope and restriction on microplastics, it is almost impossible to establish adequately and accurately the potential overlap with other ingredients.

- The proposed restriction on D4, D5 and D6 for leave-on cosmetic products clearly identifies the actual substances and exact scope covered by the restriction. Accordingly, the raw material portfolio used by each cosmetic company and the leave-on cosmetic product range impacted by the proposed restriction on D4, D5 and D6 have been clearly identified as early as 2017. Therefore, research programs 1) to develop alternative raw materials to D4, D5 and D6 with specific targeted functionalities for leave-on cosmetic products in collaboration with our suppliers and full-buy vendors and 2) to redesign relevant core technologies across leave-on categories have been initiated already by most of the actors of the cosmetic industry. These current research programs across the cosmetic industry do not include at all in their scope and specifications the need to cover in parallel the functional loss of unique cosmetic properties coming from many additional raw materials containing microplastics. Incorporating an additional layer of constraints in relation to the microplastics restriction in leave-on products adds a layer of complexity and may lead to abandoning or reshaping many on-going research projects solely focused on D4, D5 and D6 functional replacement. This socio-economic impact has not been properly evaluated.

- **TIME TO REFORMULATE AND TRANSITION PERIODS**

**Information required by ECHA regarding stability testing for cosmetics products**

**ECHA - Annex to Background Document to the Opinion on the Annex XV dossier proposing restrictions on intentionally added microplastics – 11 June 2020**

**P.216**

*"As stated above, the Dossier Submitter considered **6-12 months stability testing** in the setting of the review period. […] The Dossier Submitter hence concludes that, while **there may be an argument to extend the transitional period by an additional two years to reflect the total time needed for stability testing**, **none of the stakeholders requesting such extension provided sufficient justification**, **including information on the required tests, their duration, whether this considers the possibility for accelerated testing, and why accelerated testing is not appropriate for microplastics when it is recommended for other ingredients**."*

**Stability testing**

**Stability is the ability of a cosmetic product to resist change or variation of its initial properties over time under stated or reasonably foreseeable conditions of storage and use.** Considering the wide variety of cosmetic products, storage and use conditions, **it is not possible to define a single way to assess product stability**. Therefore, it is up to the manufacturer to specify and justify the stability protocol to cover test methods, specifications and conditions at which products will be tested. **The ISO/TR 18811:2018 standard provides guidelines for the stability testing of cosmetic products (formulas, manufacturing processes, packaging)**, as a helpful starting point to evaluate new products and technologies.

The stability test will **address several aspects of the product** (formula, manufacturing process, packaging):

- **Temperature and humidity testing**: regular storage conditions (controlled room temperature – for long term evaluation) and stress conditions (elevated temperature – for accelerated evaluation). Low temperatures may also be tested if appropriate. Similarly, tests at low or elevated relative humidity may be ambient or controlled (usually tests for the packaging).
- **Cycling of temperature and/or humidity**: tests in which the temperature and/or humidity are changed at regular intervals with variations other than static stresses. These tests provide evidence of emulsion stability, tendency to crystallization, deposition or clouding, and whether the reaction is reversible. Freeze/thaw tests are applicable for certain products. The number of cycles may vary.

- **Vibration**: these tests are needed to determine if emulsions or powders are going to break or collapse during transport. Vibration tests are carried out on a suitable vibrator of known frequency and amplitude for a specific period of time and temperature.
- **Centrifugation** increases gravity force action on product constituents of different density to test the vulnerability of emulsions and suspensions to destabilization phenomena like separation caking, bleeding and segregation.
- **Exposure to light (photostability):** use of lighting to simulate the intensity to which the product and packaging will likely be exposed (natural sunlight, artificial light). Continuous expose may be done with photostability testing equipment.
- **Interactions with packaging** will also be assessed depending on the type of packing material (cellulosic, metallic, plastic, glass) with specific conditions for pressure vessels / aerosols.

In addition, the **microbiological stability** also needs to be tested. **Microbiological tests** are critical to consumer safety and product shelf life. These tests will assess microbiological parameters (microbial count and preservation efficacy testing (challenge-test)) to evaluate the growth of microorganisms and change in the efficiency of the antimicrobial preservation, which in turn has an impact on the safety and integrity of the final product. International Standards on cosmetics microbiology are in place, in addition to which some countries or regions can have legal requirements on microbiological content for cosmetics.

These tests will assess through direct instrumental methods and correlative instrumental methods **physical, physico-chemical and chemical alterations**:

- **Physical destabilization phenomena** of different product types: dispersions (emulsions and suspensions), pressed and loose powders, semi-solid and waxed-based products, solutions, gels and fragrances formulations.
- **Chemical destabilization processes**: oxidation, light alterations, hydrolysis, transesterification, interactions between ingredients

The following **physical properties and chemical alterations** will be measured: pH value (as an indication of chemical and microbiological changes), viscosity, rheology (steady or dynamic shear rate), density (change in homogeneity and/or incorporation or loss of air or volatile compounds), mean/median particle size or size distribution, penetration or texture, thermal analysis of melting point, drop melting point, softening point and/or solidification/crystallization temperature, weight, etc. **Organoleptic properties** will also be assessed: changes in odour/taste and colour, appearance, texture/consistency, etc.

**<u>Regarding accelerated stability testing</u>**

After determination of the **stability metrics** *(properties/parameters of the state or behaviour of a cosmetic product which should be monitored according to demanded, specific product qualities),* the manufacturer will select appropriate stability test methods to monitor the alteration of the product over time. This can be done under:

- **Real time stability evaluation** (often called "**long term test**" or "**standard stability test**"): study that monitors the state of a product to determine the time course of any alteration to it under reasonably expected conditions of storage and use
- **Accelerated stability evaluation**: study designed to speed up naturally occurring destabilization processes due to intrinsic or extrinsic factors and which predicts the behaviour over the long term. Typically, physico-chemical, mechanical or thermal procedures are employed.

Accelerated testing may trigger additional further destabilization phenomena which would not typically be observed under normal conditions of storage and use. Test results based on accelerated stability testing should therefore be verified by real time stability testing under normal conditions.

**Stability testing for reformulations in the context of the microplastics restriction**

Regarding microplastics specifically, there is no simple 1:1 substitution, and the entire architecture of the formula will need to be reevaluated. The question of reformulating cosmetics products would therefore entail **restructuring entire formulation bases**, based on **no previous market experience with these new bases**. Contrary to situations where innovation builds on an existing base with historical market experience, in the case of microplastics reformulations, there will be **no historical experience to be reused in the assessment**. There are many unknowns, for instance, how will the new formula will be preserved, will the fragrance remain in solution, are the new polymers impacted by temperature changes, what is the safety profile of the new raw materials and formula, will it interact with the existing package, will it remain stable on shelf up to two years, are the new raw materials legal to sell in the EU, etc.

This has an impact on the **duration of the stability testing**.

- In cases of reformulations based on prior historical experience, these stability tests are done in parallel which leads to shorter overall durations.
- However, in the case of new chemistries, sometimes all of the product testing may have to be done in tandem.
    - When dealing with new bases, companies traditionally conduct **the stability tests and micro tests on just the base** and leave out the fragrance and colorants.
    - Once a stable base is identified (using accelerated stability) then the research for a stable fragrance and colorant begins. Only then will the stability tests and micro tests be conducted with the fragrances and colorants. So there is research that happens along the way and in between these **two sets of stability evaluations (on the base and on fragrance/colorants).** Assuming no failures and everything goes perfectly along the way, this work could easily be **10-14 months on its own**.
    - Only once there is some level of confidence in the stability and safety, consumer testing will be needed to understand the **acceptability of this new formula** with the current product users in the market.
    - At minimum companies need a **6 month preservative efficacy test** to go to market and again, assumes no failures along the way.

- With these new technologies, there is no institutional knowledge as to the success of the various product tests so there is a **high likelihood things could go wrong**. If there is **even one single failure along the way**, then companies have to go back and restart the entire process.

The **estimated period of 6-12 months for the stability testing by the Dossier Submitter** is therefore not appropriate for the cosmetics sector in the framework of the microplastics restriction because:

- This length is given for "typical" reformulations that usually **need to replace one raw material**. As demonstrated, microplastics are not a typical reformulation with a 1:1 substitution.
- It does not allow for these **different steps of the stability evaluation** to be completed
- It **assumes no iteration in the process**, which is however quite common with these new technologies.

**Accelerated stability testing is typically used after there is experience with the new technologies and demonstrated real-time stability and shelf-life**. If the formula has a completely new base, there is a risk to consumer safety going to market with only accelerated stability data. In the case of microplastics, entire formulation bases would need to be restructured, hence need for real-time stability testing.

**Reformulation process**

**Reformulation process lasts on average 4.5 year, only if suitable alternatives are available.** In the case of microbeads, the substitution took 5 years, as described above.

In the microplastics restriction, the proposed restriction forces companies to **reformulate thousands of formulas *at the same time.*** However, this restriction (according to the definition of MPs) is not only on one polymer; potentially it is on hundreds polymers *at the same time*. The lack of alternatives and the fact that reformulations where key technologies have to be replaced are major reformulations mean that the above-mentioned 4.5/5 years reformulation period is grossly insufficient. **In addition, SEAC has not acknowledged the technical time Cosmetics Europe highlighted in the SEA, related to the shelf life test**, which requires between 30 and 36 months (between 2.5 and 3 years: average 2.75 years), to be added to the 3-5 years for the baseline reformulation, which, as already mentioned, is a smaller undertaking as no radical redesign of the product will be required.

SEAC's current calculation assumes that no time is needed for suppliers to develop and produce new alternatives. Also not considered is the time needed for companies to work on how to formulate these new materials, which is unrealistic. Therefore, this supports the need for longer transition times.

The table below summarises the challenges & time needed to reformulate leave-on products:

| Key factors | Microbeads | Make up, lip, nail | Skincare | Other leave on | Sunscreen |
|---|---|---|---|---|---|
| Number of ingredients per formulation | 1 | Up to 6 | Up to 6 | Up to 6 | Up to 6 |
| Critical function | No | Yes | Yes | Yes | Yes |
| **Number of formulations** | **130** | **15,207** | **1,125** | **414** | **297** |
| Availability of alternatives | Yes | No | No | No | No |
| **Time needed** | **Completed in 5 y** | **Derogation**<br>**CER*: 8,556 EUR/kg** | **12 y** | **10 y** | **8 y** |

*NB: CER: cost effectiveness ratio*

**Cosmetics Europe proposes as transitional period 8, 10, and 12 years for sunscreen, other products, and skin care, respectively.**

- 4.5 x 125% + 2.75 = 5.625 + 2.75 = 8.375 years -> 8 years
- 4.5 x 150% + 2.75 = 6.75 + 2.75 = 9.5 years -> 10 years
- 4.5 x 200% + 2.75 = 9 + 2.75 = 11.75 years -> 12 years

The three adjusting factors 125%, 150%, 200% have been chosen by considering the high number of required reformulations and the lack of alternatives.

**For make-up, including lip and nail products**, taking into account the absence of viable or validated alternative solutions, an enormous workload would be required to launch a campaign to reformulate the

thousands of make-up formulas, which represent a limited source of emissions of microplastics. This would include specificities associated with the development and industrialization of make-up products (huge number of raw materials, suppliers and formulations, shade matching specificity, patent portfolio, industrial pilots, etc.) and, consequently, Cosmetics Europe considers that, regrettably, its members would not be able, even after an extended transition period of 15 years, to reformulate 100% of its make-up products impacted by the proposed Restriction. Instead, Cosmetics Europe proposes a derogation accompanied by appropriate solutions to minimize the risk of emissions and change consumer behavior to wipe off not wash off make up, lip and nail cosmetic products to be included in the instructions for use and disposal. This solution would be more proportionate and it would achieve the same result.

**Recommendations:**

Given the elements outlined above: characteristics of the leave-on cosmetic products and specific leave-on cosmetics product categories, consumer preferences, essential functions of the microplastics in the products, limited risk of emissions, socio-economic impact and cost effectiveness:

**Make-up cosmetic products (including lip and nail cosmetic products) should be derogated from the scope of the ban.** In this context we are committed **to developing appropriate consumer information solutions to minimize the risk of emissions and change consumer behavior to wipe off not wash off make up, lip and nail cosmetic products.**

- **Sunscreen cosmetic products:** the transition period for suncare products should be extended **to 8 years** to allow for research and innovation to ensure the same high level of performance and high-level consumer protection.

- **Skincare cosmetic products**: the transition period for skincare should be extended **to 12 years** to allow for research and innovation to reformulate a high number of products.

- **Other leave-on cosmetic product:** the transition period for all other leave-on cosmetic products should be extended **to 10 years** to allow for research and innovation and reformulation.

## Conclusions

Given the elements outlined above: characteristics of the leave-on cosmetic products and specific leave-on cosmetics products categories, consumer preferences, essential functions of the microplastics in the products, risk of emissions, socio-economic impact and cost effectiveness:

- **Make-up cosmetic products, including lip and nail cosmetics products, should be derogated from the scope of the ban.**

A restriction by way of a ban on microplastics in make-up including lip and nail cosmetic products is wholly disproportionate. The risk of emissions is low and can be minimized with labelling and consumer information. The socio-economic impact is severe with a huge number of formulations impacted.

In this context we are committed to developing appropriate labelling solutions to minimize the risk of emissions and change consumer behavior to wipe off not wash off make up, lip and nail cosmetic products.

- **The transition period for sunscreen products should be extended to 8 years to allow for research and innovation to ensure the same high level of performance and high-level consumer protection.**

A restriction by way of a ban of microplastics in sunscreen products with the proposed 6 year transition period may pose a risk to consumer protection and public health if the same level of performance cannot be achieved without microplastics.

It is essential that sufficient time is given to allow for research and innovation to develop products with the same level of performance and consumer protection as the sunscreen products today using the microplastics ingredients with the booster functionality.

- **The transition period for skincare should be extended to 12 years to allow for research and innovation to identify appropriate alternatives and reformulate a large number of products.**

A restriction by way of a ban of microplastics in skin care products with a proposed 6 year transition period would be wholly disproportionate in particular given the pre- requisite for product performance in this category, the complexity of the products and high number of formulas impacted.

It is essential that sufficient time is given to allow for research and development to enable innovation to ensure the same level of performance in skincare products.

Note that for skincare, thousands of products need to be reformulated within the transition period.

- **The transition period for all other leave-on cosmetic products should be extended to 10 years to allow for research and innovation and reformulation.**

A restriction by way of a ban with a proposed transition period of 6 years for all other leave-on cosmetic product categories would be disproportionate.

# General comments

## VII. Scope and definitions[24]

SEAC supports the approach to build the restriction on microplastics on a generic definition of polymers which is too broad to target the issue specifically. It is therefore key that appropriate relevant, workable and enforceable criteria are included in the definition of microplastics to identify precisely a list of eligible materials. This would be the only way to establish **technical and legal certainty for all the stakeholders including suppliers, cosmetic manufacturers as well as control authorities of the Member States**. A clear identification of substances subject to restrictions is also required by REACH, according to which substances must be clearly identified (Article 67.1 and Annex XV). In addition, a scope that is too broad is not consistent with the guidance on the application of the precautionary principle, i.e. that it has to be applied restrictively.

**The most essential criterion is the solid state of the particles, which should remain unchanged over time,** i.e. during use and at the time of disposal. These criteria should be measured by using relevant and robust analytical methods.

Moreover, the **threshold of application of the ban on Microplastics in products** needs to be increased to 0.1%, as the proposed 0.01% threshold is arbitrary, inadequate, and disproportionate; and not in line with the regulatory best practices under REACH.

The proposed approach to regulate a generic group of substances based on a broad definition is not in line with REACH and with the way the precautionary principle should be applied. Therefore, it is necessary to identify a list of materials eligible to the restriction through relevant, workable and enforceable criteria, which are the only way to guarantee the legal certainty that economic operators and control authorities need.

Industry, and particular SMEs, are facing serious issues with understanding the definition of Microplastics and evaluating the presence of Microplastics in their products. This creates a serious lack of legal certainty, confusion over the impact of the restriction and it is the main reason why Cosmetics Europe has been (and

[24] Please note the comments in the Annex on technical aspects on out of scope criteria

still is) unable to provide updated data on the number of materials covered by the proposed restriction. Cosmetics Europe's SEA prepared in 2018 for the CFE was based on a pragmatic and non-exhaustive list of 19 ingredients (including some film formers); see footnote 2.

**Recommendations**:

- Recommendation to SEAC to recommend a clear identification of materials subject to the microplastics restriction to provide legal certainty to economic operators and control authorities.
- Take into account the current technical limitations regarding out of the scope criteria.

## IX. Practicality, including enforceability

RAC and SEAC support the Dossier Submitter's view that the proposed restriction is practical and enforceable, but they consider that flanking measures (i.e. implementing guidelines) are needed to guide industry and control authorities in the implementation process.

**The broad scope of the proposed restriction, the uncertainties surrounding the complex definition of microplastics**, including the proposed tiered approach for assessing if a given product contains microplastics particles covered by the definition and the scope of the restriction, as well as the lack of harmonized analytical methods to detect microplastics[25] and easily accessible accredited labs, will definitely create significant **enforcement** and **interpretation issues** both for the industry and control authorities. **This will hamper the enforceability and effectiveness of the restriction.** Cosmetics Europe doubts whether implementing guidelines, which will take time to develop, will be sufficient to respond to these challenges and to ensure a smooth implementation of the proposed restriction, taking into account the proposed transition periods.

The value reported in Table 25 of ECHA's Annex XV restriction report for the enforcement costs (55,000 EURO) is based primarily on the assumption that compliance with the proposed restriction can be controlled solely by checking the **ingredients list on the labelling** and might be highly underestimated. Indeed, the ingredients list on the labelling does not provide information on the physical state of the substance and the process of formulation, therefore it cannot be used to determine whether any ingredient is a microplastic.

[25] The Canadian method mentioned by the Dossier Submitter does not allow to differentiate Microplastics from polymers.

In order to control the market, analytical methods to identify microplastics in complex cosmetics matrices will have to be developed. No standardized method exists to date; therefore, it is necessary to take into account the time to develop those methods in the determination of the appropriate transition periods.

**Recommendations**:

- Recommendation to provide clarity on definition of microplastics and analytical methods ahead of the adoption of the restriction
- Recommendation to consider the time necessary to develop appropriate harmonized detection methods for microplastics

*  *  *

# ANNEX

## Derogation and Out of Scope Criteria

Key points:

- A pragmatic water solubility criteria could be set at 100 mg/L.
- Suitable longer transitional period are needed considering necessary studies, research and alternatives development.
- Natural polymers definition should be clarified

### 1. Solubility

The Dossier Submitter proposes not to apply the restriction to polymers with a water solubility > 2 g/L.

The rational is that "*microplastics particles that would inevitably and immediately lose their particle form once in the environment are different from microplastics that would retain their particle form once released to the environment*." We fully support such a criterion as what matters for protecting the environment from microplastics pollution is the form of these compounds when they are released in the environment.

However, the value itself was chosen based on the concentration used when conducting ISO biodegradation standards, in order to optimise the test conditions, and does not relate to the threshold defining solubility. The consequence when setting such a high value is that many materials will be included in the scope of the restriction even if they lose their particle form when placed on the market and entering the environment in low concentrations (i.e. well below2 g/L).

OECD, in the framework of the assessment of polymers of low concern, concluded that polymer water solubility ranged from 10 to 10,000 mg/L. The OECD website refers to extractability in water as polymers of low concern criterion, stating that "*10 mg/L was seen as acceptable, provided that test conditions were standardized*"[26]. In other words**, OECD considers polymers as soluble when water solubility is > 10 mg/L**.

It should as well be noticed that poorly water-soluble substances are defined in **CLP (1272/2008/CE) when solubility is < 1 mg/L**, and in **REACh (1907/2006/CE) when solubility is < 0.1 mg/L**.

**In order to take a margin of safety considering the molecular weight of polymers, the water solubility limit could be set at 100 mg/L as a reasonable worst case.**

## 2. Biodegradability

The Dossier Submitter proposes not to apply the restriction to microplastics that are biodegradable. RAC proposes a tiered approach to assess biodegradability, starting with screening tests (test methods from groups 1, 2 and 3), followed by group 4 ISO standard or group 5 OECD guideline methods when screening step fails.

### a. Screening tests

Screening tests were not designed for compounds such as microplastics but they can be applied to evaluate their biodegradability. Limited experience exists with regards to applying these methods to microplastics. As experience is gained there may be scientific value in adapting the existing screening methods in order to obtain a more realistic view of microplastic persistence. **Longer transition periods, would allow industry to gain more technical experience applying screening methods to evaluate microplastic biodegradation and identify any changes that can be used to better evaluate persistence of microplastics.**

[26] http://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm

We also suggest to make use of every standard that is available to assess the biodegradation potential of polymers. In this regard we welcome the option to conduct inherent tests (group 3). However, the proposal only considers the inherent test that offers the least capacity of the OECD 302 tests for biodegradation according to OECD[27]. RAC has considered the OECD 302B not suitable to test microplastics due to a lack of measurement of mineralization and excluded the test from Appendix X, although this test has a higher capacity as the proposed OECD 302C. It should be noted that the OECD 302B can be easily adapted to mineralization parameter[28]. We therefore suggest, this test to be reconsidered in its modified form in the restriction proposal.

### b. Group 4 - ISO standards

ISO standards listed in RAC's opinion were indeed developed to assess the biodegradability of plastics. We therefore welcome RAC's proposal, and confirm the relevance of those methods to assess the biodegradability of microplastics.

As RAC mentioned, it has however to be highlighted that the test duration of these tests may vary from 6 months in aqueous tests to at least 24 months in soil/sediment, even 48 months to reach a plateau. The duration of these tests is therefore not compatible with the entry into force of the restriction, as there is not sufficient time to find alternatives that 1) are suitable in terms of efficiency, and 2) have a good environmental profile. **A longer transition period, at least for products with the lowest environmental impact considering their volumes of use (e.g. make-up cosmetic products), would allow industry to conduct the necessary studies and/or find suitable alternatives.**

### c. Group 5 - OECD guidelines

#### *i. Applicability*

OECD guidelines are indeed suitable methods to determine DT50s in the different environmental compartments. They were however developed for single chemicals, and not designed for mixtures, as microplastics might be. Their applicability to microplastics may rely on the need to develop novel approaches to radiolabel polymeric components of microplastics. Synthesis chemists and encapsulate experts have raised major concerns regarding the technical feasibility of radiolabelling encapsulate walls.

[27] OECD 2006. Section 3 Introduction PART 1: PRINCIPLES AND STRATEGIES RELATED TO THE TESTING OF DEGRADATION OF ORGANIC CHEMICALS

[28] Strothman, U.J., Schwarz, H., Pagga, U.. 1995. The combined $CO_2$/DOC Test – a new Method to determine the Biodegradability of Organic Compounds. Chemosphere. 30, 3, 525-538

Significant research would be needed if radiolabelling is at all possible. RAC's opinion highlights some of these limitations.

#### *ii. Costs*

These methods need to be conducted with radiolabelled test items and require suitable analytical methods that can quantify the test item and its degradation products formed during the test. Because of frequent analytical measurements necessary to determine robust DT50s, these studies are costly (aprox. 300 k€ per compound and compartment), and therefore represent a non-negligible economic impact, as tests in 3 compartments are required. These costs should be taken into account in the socio-economic analysis. External labs will modify and adapt their service portfolio only depending on the demand and under aspects of cost-efficiency and profit. The number of laboratories providing studies with radiolabelled material is limited.

In addition, if these tests are considered too expensive by some suppliers, they may choose not to conduct these tests. As a result, the related microplastics will by default be considered non-biodegradable and fall into the restriction. This may lead to a loss of compounds of technical interest for cosmetics industry and induce additional costs to find suitable alternatives and reformulate the related final products.

### d. Conclusion

**As mentioned above, group 4 ISO standards or group 5 OECD methods are proposed to be conducted when the microplastics fail the criteria after the screening tests. Considering the above limits: especially test duration of ISO standards and applicability and cost of OECD guidelines, the cost-benefit ratio needs to be weighed when setting the transition periods.**

## 3. Natural polymers

For natural polymers, the Dossier Submitter initially proposed to refer in the definition to chemical modification "other than hydrolysis". This precision was removed in the new restriction proposal. Instead, reference is made to REACH guidance and REACh Article 3(40).

Cosmetics Europe agrees to a derogation for "natural polymer" based on a clear definition and precision on the restrictive conditions. Technical elements that are listed in REACh Guidance and Article 3 are indeed suitable. However, we regard it beneficial to **clarify in the current restriction what is meant by "natural polymers", i.e. "*polymers which are the result of a polymerisation process that has taken***

***place in nature, independently of the extraction process with which they have been extracted, and whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation***".

The natural polymer definition should include natural native polymer and natural identical polymer as they will present similar water solubility and biodegradability profile. Therefore:

- A natural polymer (end product) should be a polymer which has a chemical composition identical to the one of a polymer existing in the nature (like cellulose, polysaccharide, xanthan gum) independently of the physical characteristics like molecular weight distribution of the end product.
- The natural polymer is the result of a polymerization process that exists in the nature: could have taken place in the nature or mimic polymerization process existing in nature (fermentation, hydrolysis, ...) as long as the starting materials and final polymer exist in nature.
- Natural polymers are the result of a polymerization process that exist in the nature independently of the extraction process with which they have been extracted and whose organic chemical composition remains unchanged even if it has undergone a chemical process (hydrolysis, ion exchange, salification) or treatment, or a physical mineralogical transformation.

**END**