

The Consumer Voice in Europe

# TARGETED REVISION OF THE COSMETIC PRODUCTS REGULATION

BEUC comments to the public consultation



#### **Contact:** Pelle Moos – safety@beuc.eu

BUREAU EUROPEEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • www.beuc.eu EC register for interest representatives: identification number 9505781573-45



Co-funded by the European Union

Ref: BEUC-X-2022-050 - 26/05/2022



## Introduction

Consumers are in frequent, intimate, and often prolonged contact with cosmetic and personal care products: a survey of more than 7,000 French consumers for example found that the average adult woman uses 16 cosmetic products each day, slightly less than the 18 cosmetic products used on average by pregnant women.<sup>1</sup> The same survey also found that girls on average uses seven cosmetic products each day compared to five for boys and six for babies under three years. Cosmetic and personal care products are thus a major direct source of consumer exposure to chemicals, including ingredients of concern such as potential endocrine disruptors and fragrance allergens.

The Cosmetic Products Regulation (CPR) plays a vital role in protecting consumers against chemical risks. Still, the CPR suffers from major shortcomings, as documented for example in the Chemicals Fitness Check. Thus, BEUC welcomes the European Commission's intention to revise the CPR to achieve the goals of the Chemicals Strategy for Sustainability (CSS).

A revised CPR must contribute to minimise consumers' exposure to cosmetic ingredients of concern, including endocrine disruptors, to better protect vulnerable groups, and to address combination effects.

This paper outlines BEUC's recommendations on how the CPR revision can achieve those goals; these recommendations should be read in conjunction with our response to the open public consultation.

## The consultation omits major concerns for consumer health

We strongly regret that the public consultation does not seek feedback on options to address known concerns for consumer health, such as the need to reduce consumer exposure to skin sensitizers or to better protect consumers against dangerous cosmetic products sold online. These concerns are well-documented – and have also been discussed at length in the Cosmetic Products Working Group. As such, we insist that the revision must include options to urgently achieve the following goals:

#### **1.** Reducing consumer exposure to skin sensitisers, such as fragrance allergens.

Skin sensitisation is a severe and growing concern for consumer health: whereas the SCCS<sup>2</sup> in 2012 for example estimated that 1-3% of the European population is sensitized to one or more fragrance allergens, a more recent projection<sup>3</sup> places that number at 4-6%, indicating an urgent need to prevent exposure, especially among children and adolescent consumers.

We urge the Commission to swiftly present clear priorities for identifying relevant skin sensitisers along with adequate risk management measures, such as extending Article 15 to cover these harmful ingredients. This would ensure better consumer protection,

<sup>&</sup>lt;sup>1</sup> A. S. Ficheux *et al.* 2015. Consumption of cosmetic products by the French population. First part: Frequency data. *Food and Chemical Toxicology* 78.

<sup>&</sup>lt;sup>2</sup> SCCS. *Opinion on fragrance allergens in cosmetic products*. June 2012.

<sup>&</sup>lt;sup>3</sup> See COWI. <u>Socioeconomic consequences of fragrance allergy</u>. October 2019.



including for subgroups at particular risk of sensitization, while still allowing for limited exemptions.

#### 2. Enabling a preventive approach

The questionnaire omits questions related to the Regulation's prescriptive approach, including whether it is fit for purpose, and whether its associated constraints are reasonable and legitimate. While the current approach works reasonably well for cosmetic ingredients for which robust evidence is available, it however falls short in situations where scientific evidence is insufficient, inconclusive, or uncertain. When EU consumer groups for example raised concern over the safety of mineral oil-based cosmetics ingredients,<sup>4</sup> the Commission was unable to request an SCCS assessment due to insufficient evidence showing concern for <u>individual</u> substances in the tested ingredients. Mineral oils are however complex mixtures of thousands of different hydrocarbons, and it is doubtful whether the level of evidence required by the prescriptive approach can realistically be achieved.

In line with the CSS, we therefore recommend shifting towards a <u>preventive</u> approach to better protect consumers. Similar to the General Food Law,<sup>5</sup> the CPR revision should notably enshrine the precautionary principle in the legal text as the basis for risk identification, assessment, and management. This would help guide the regulator in those specific circumstances where there are reasonable grounds for concern for consumer health, but scientific evidence is insufficient or uncertain. Further inspiration could also come from CPR Article 16 to ensure that the revision aligns the Regulation with the fundamental principles of precaution and 'no data, no market' enshrined in EU chemicals legislation.

#### **3.** Reinforcing the control of online sales

Consumers increasingly purchase cosmetic products online, including through online marketplaces or web shops based outside of the EU. This trend presents new safety risks for consumers, as demonstrated extensively by consumer groups.<sup>6</sup> In 2020, BEUC member, Forbrugerrådet TÆNK for example found<sup>7</sup> that 7 out of 10 teeth whitening products for home use contained illegal levels of hydrogen peroxide (>0,1%). In some cases, the concentration of hydrogen peroxide were 70 times above the legal limit (6%).

As outlined in the CSS, new enforcement tools are urgently needed to address online sales and imports, including a clear definition covering the role and responsibilities of online marketplaces. The CPR revision must in particular complement and reinforce compliance with the new obligations for online marketplaces established under the Digital Services Act – and eventually under the General Product Safety Regulation.

Consequently, we recommend that a definition of `online service providers/marketplaces' is introduced in CPR Article 2, along with a possibility to hold these actors liable for non-compliance where no other responsible economic operator can be identified. This should include an obligation on online marketplaces to verify the identity of the responsible person for products sold on their sites <u>before</u> the products are being placed on the market.

<sup>&</sup>lt;sup>4</sup> BEUC. *The EU must act on problematic mineral oils in lip care products, evidence from consumer tests shows*. November 2017.

<sup>&</sup>lt;sup>5</sup> Regulation (EC) No 178/2002.

<sup>&</sup>lt;sup>6</sup> BEUC. *Illegal cosmetics on online marketplaces. Results from consumer research and testing*. Presentation to the Working Group on Cosmetic Products. June 2020. Available upon request.

<sup>&</sup>lt;sup>7</sup> Forbrugerrådet TÆNK. <u>Tandblegning: Får du hvidere tænder?</u> February 2020.



## **Extending the Generic Risk Management Approach (Q1)**

We strongly support extending Article 15 to the additional hazard properties listed in the questionnaire, including to **category 1 and 2 endocrine disruptors**. Cosmetics ingredients with endocrine-disrupting (ED) properties represent a significant, potential source of cumulative consumer exposure to these harmful chemicals, including for vulnerable groups, such as pregnant and breastfeeding women, children, and persons with compromised immune responses. As such, it is imperative that ingredients with ED properties are systematically identified and their use in cosmetic products prohibited without delay.

We disagree with the proposed exclusion of **endocrine disruptors for the environment**: if a substance is an ED for other vertebrate species, it is likely also an ED for human health, and may be identified as such in future. Therefore, EDs for the environment should be regulated as substances of equivalent concern – such as EDs for human health or CMRs – unless it can be unequivocally shown that their mode of action is not relevant to humans.

In parallel, a solution must urgently be found for the concern expressed by the SCCS that "[d]ue to the ban on animal testing for cosmetic ingredients [...] it will be extremely difficult in the future to differentiate between a potential ED and an ED, if the substance is registered solely for use in cosmetic products."<sup>8</sup> According to the SCCS,<sup>9</sup> notably, the "results obtained for a cosmetic ingredient using non-animal alternative methods (in silico, in vitro, ex vivo, omics technology, etc.), can only be indicative of endocrine activity and will not give information whether the substance can cause adverse effect(s) in an intact organism, thus whether it should be regarded as an endocrine disruptor or not. Indeed, it should be clearly noted that until today not a single validated non-animal alternative method exists for systemic toxicity." The planned update to the REACH information requirements must address this concern to ensure that sufficient evidence in future is generated to enable effective identification of all ingredients with ED properties, including cosmetic-only substances.

In line with the CSS, we further recommend extending Article 15 to include chemicals that have adverse effects on the environment, including those that are persistent, bioaccumulative, and toxic. We appreciate that the REACH revision intends to extend the generic risk management approach to such substances; and further understand that the intention is to maintain the current implementation practice, whereby the Commission adopts a restriction prohibiting the sale to consumers of substances on their own and in mixtures. This would thus in future include PBTs and vPvBs used in cosmetics. Unlike CPR Article 15, REACH however does not foresee derogation possibilities for substances used in mixtures. If this implementation route is chosen, it would therefore imply a stricter regime for cosmetic ingredients presenting a potential risk to the environment relative to those which may present a risk to human health. This hardly seems justified. We consequently encourage the Commission to explore the feasibility of regulating such substances under the CPR.

We finally support extending Article 15 to include the adverse effects of CMR substances on or via lactation.

<sup>&</sup>lt;sup>8</sup> SCCS. <u>Memorandum on Endocrine Disruptors</u>. December 2014.

<sup>&</sup>lt;sup>9</sup> SCCS. Feedback on "Harmful chemicals – endocrine disruptors, review of EU rules". July 2019.



## Streamlining the exemption procedure (Q2)

Article 15 ensures that exemptions for **CMR category 1 substances** can only in exceptional circumstances be considered. We support extending this strict approach to the most harmful chemicals. We however insist that this should include <u>all</u> the derogation criteria laid down in Article 15.2, and not just <u>some</u> as indicated in Question 2, i.e. the answer options omit criteria b) and c) in Article 15.2. Further, we recommend introducing additional derogation criteria for **category 2 substances** – such as a lack of alternatives and applications for a particular use with a known exposure, cf. Article 15.2, criteria b) and c). This would greatly contribute to reduce consumer exposure to ingredients of concern, while also providing clearer incentives for substitution to economic operators.

While we support maintaining the current derogation criteria, their practical application however also demonstrates a need for further clarification to facilitate easier, faster, and more predictable decision-making on the situations where use of the most harmful chemicals can exceptionally be considered. We in particular recommend that the CPR revision:

- Clarifies the meaning of compliance with EU food safety requirements. Diverging interpretations of the criterion have been advanced in the past including during the negotiations leading to the adoption of the current CPR. These ambiguities should be addressed to ensure faster, and more predictable decision-making in future. As observed in the 2008 Commission proposal,<sup>10</sup> this criterion however also serves an important 'gatekeeper' function which ensures derogations for category 1 substances can only exceptionally be considered. We insist that this limitation is maintained in future.
- Clarifies the meaning of **available suitable alternatives** and introduces an obligation to also consider **available alternative technologies** similar to REACH Article 60.4. This would further ensure that derogations for the most harmful chemicals are only considered in exceptional situations.

We finally support the introduction of a new criterion inspired by the **essential use concept** to ensure that only those uses society deems necessary for health, safety or for the functioning of critical sectors can be allowed in future. Whereas today continued use of a category 1A/1B CMR substances can be authorised provided the criteria in Article 15.2 are satisfied, the practical application of these criteria fails to consider whether society really needs the function in question (i.e. 'need-to-have', rather than 'nice-to-have'). We recommend taking inspiration from the Food Additives Regulation in this regard, notably the requirement laid down in Article 6.2 that food additives must provide benefits to consumers, such as for example preserving food's nutritional quality or meeting special dietary needs.

A new essential use criterion should limit potential exemptions to those uses that are crucial for society and to particular uses that are necessary for consumer health and safety. Whereas for example sun (UV) protection (the function) is essential, UV filters are today also used in products where the justification for consumer health may not be obvious (specific use). In contrast to the current situation, an essential use criterion should thus enable the regulator to consider whether the specific use for which an exemption is requested in fact is necessary from a health and safety perspective; and to reject an exemption application where this is not the case.

<sup>&</sup>lt;sup>10</sup> European Commission. *Proposal for a Regulation of the European Parliament and of the Council on cosmetic products*. February 2008.



#### Clarifying the nature of the automatic ban

Article 15 prohibits the use in cosmetic products of substances classified as CMR of category 1A, 1B and 2. This ban applies <u>automatically</u> to CMR substances as from the date of application of their classification under Part 3 of Annex VI to Regulation 1272/2008. Consequently, the Commission only needs to adopt implementing measures in those exceptional situations where amendments to the relevant Annexes (III-VI) are necessary to authorise the use in cosmetic products of CMR substances that fulfil the conditions laid down in Article 15. This automatic ban nonetheless does not preclude the Commission from amending the Annexes – including Annex II – when new CMR classifications become applicable, as illustrated by the 'omnibus' procedure.

Regrettably, the Commission's proposal<sup>11</sup> for a revised implementation approach has however resulted in legal uncertainty over the correct interpretation – and therefore enforcement – of Article 15. We reiterate<sup>12</sup> our concern that this situation may in future create unnecessary and unacceptable risks for consumers. While we support the intention behind the 'omnibus' procedure established by the Commission, one of the main rationales for the automatic ban is thus also to prevent that procedural delays will weaken consumer protection.<sup>13</sup> The Commission notably confirmed this rationale in a 2010 working document,<sup>14</sup> observing that "[a] different interpretation, which would imply the need to adopt implementing measures for CMR [...] substances in order to ban them, would mean that these substances are allowed in cosmetic products as long as the Commission has not adopted specific measures to ban them."

As previously observed,<sup>15</sup> the Commission appears to base its opinion on a perceived ambiguity in the English language version of Article 15; this ambiguity is however not found in other language versions which explicitly refers to an active ban (e.g. the French "est interdite" or the German "ist verboten"). We maintain that the ban is automatic both from a <u>substantial</u> and <u>procedural</u> perspective. Indeed, an automatic ban combined with regular amendments to the relevant Annexes represent in our view the most effective and efficient route to achieve a high level of consumer protection, while also ensuring legal certainty for economic operators and enforcement authorities. Given the ongoing disagreement over the correct interpretation of Article 15, we however urge the Commission to revise the legal text to clarify the automatic nature of the ban.

This should also include clarifying the 15-month timeframe prescribed by Article 15.2 to establish that 'inclusion in Part 3 of Annex VI to Regulation (EC) No 1272/2008' refers to the date of entry into force of the implementing measures amending the Annexes to the CLP Regulation, not to the date of application. In parallel, we recommend introducing in Article 15.1 a timeframe, and corresponding obligation for the Commission to amend the relevant Annexes to avoid uncertainty on whether continued use of a category 2 substance will be authorised. Such a timeframe would prevent doubts that could result in unnecessary health risks for consumers, while also providing legal certainty for national enforcement authorities and economic operators. Article 15 finally precludes the Commission from granting longer transition periods for CMR substances. We insist that this approach must be maintained in future.

<sup>&</sup>lt;sup>11</sup> Working Group on Cosmetic Products. Minutes. September 2016.

<sup>&</sup>lt;sup>12</sup> See further BEUC. *The EU Commission's revised approach to toxic cosmetic ingredients*. April 2018.

<sup>&</sup>lt;sup>13</sup> When the European Parliament and Council enacted the Cosmetics Regulation in 2009, the Legislator indeed deliberately sought to strengthen the protection of consumers through an automatic ban to guarantee that a lack of full scientific certainty would not prevent or delay protective action; this automatic ban also expresses a consensus on the need to mitigate any negative implications for consumer safety arising from the new exemption possibility for CMR 1A and 1B substances which did not exist under the old EU Cosmetics Directive.

<sup>&</sup>lt;sup>14</sup> European Commission. *Working document on the implementation of Article 15 of Regulation 1223/2009 on CMR substances*. October 2010.

<sup>&</sup>lt;sup>15</sup> See further BEUC. <u>The EU Commission's revised approach to toxic cosmetic ingredients</u>. April 2018.



## Protecting consumers against combination effects (Q3)

Consumers are simultaneously exposed to chemicals released from products as well as through other media such as food, water, soil, and air – a fact sadly ignored by most EU laws, including the Cosmetics Regulation. As a result, risks to human health may be systematically underestimated.<sup>16</sup>

We therefore welcome the proposal to introduce new legal provisions to take account of consumers' combined exposure to ingredients of concern from all sources, including water, food, and other consumer goods. It is imperative that this requirement addresses non-intentional co-exposure to <u>all</u> substances used in cosmetics along with <u>any other</u> <u>substances</u> that the consumer may be exposed to. Limiting the requirement to only the most harmful chemicals would be insufficient.

We agree that introducing a mixture assessment factor (MAF) is in the short- and mediumterm the most suitable approach to reduce the risks associated with the unintentional exposure to chemical mixtures. A future MAF value must be large enough to account both for the contributions of a substance to overall mixture toxicity as well as for the contributions to multiple chemicals from multiple sources.<sup>17</sup>

### **Improving consumer access to product information (Q5)**

Clear, reliable, and readily accessible information about cosmetic products and their characteristics is an essential safeguard of consumer health, rights, and interests. Therefore, it is imperative that the means of communicating this information to consumers is continuously improved. Digital technologies hold significant potential to increase both the available product information and the effective capacity to communicate it to consumers. Smartphone apps, e-labels and other digital information tools must however not replace on-pack labels or paper leaflets as the means of communicating essential product information to consumers, such as safety warnings, minimum durability, ingredient lists, etc.

A shift towards digital labelling as an alternative to on-product labels would indeed risk undermining, rather than enabling, informed consumer choices, e.g., by making access to information more time consuming and burdensome or by outright excluding some consumers from information essential to their health and well-being.<sup>18</sup> Requiring consumers to access information through a QR code or a weblink would likewise extend the time needed to take corrective action in an emergency situation and could ultimately endanger their health, e.g. if a connected device is not at hand.

On-pack labelling in contrast ensures that all consumers have access to information at the point of sale, without the use of additional devices or internet connectivity. This approach thus ensures a high level of consumer protection, as observed in the judgment in Case C-667/19. Notably, the Court found<sup>19</sup> that "[p]rotection of health cannot in fact be fully guaranteed if consumers are not in a position to familiarise themselves fully with, and to

<sup>&</sup>lt;sup>16</sup> See e.g. EDC-MixRisk. *Policy brief*. March 2019.

<sup>&</sup>lt;sup>17</sup> See further CHEM Trust. <u>Chemical cocktails – The neglected threat of toxic mixtures and how to fix it</u>. March 2022.

<sup>&</sup>lt;sup>18</sup> See further BEUC. <u>Why moving essential product information online is a no-go</u>. February 2021.

<sup>&</sup>lt;sup>19</sup> Court of Justice of the European Union. <u>Press release No 165/20: Judgment in Case C-667/19</u>. December 2020.



understand, in particular, the information concerning the function of the cosmetic product concerned and the particular precautions to be observed when using it."

Digital tools could instead play an important complementary role by e.g. improving legibility for visually impaired consumers or by helping to translate mandatory on-pack information to useful advice for consumers. The popular smartphone apps<sup>20</sup> launched by several BEUC members offer an instructive example: these apps provide advice based on widely accepted lists of ingredients of concern, such as the EU list of potential endocrine disruptors. Hence, rather than replace the mandatory ingredient list, the apps complement it, helping to translate ingredient names into meaningful recommendations for consumers.

Given the increasing voluntary use of digital information tools, we encourage the Commission to establish a common EU framework for digital labelling to ensure that information provided through digital means is relevant, reliable, and accurate. A future EU framework for digital labelling as a <u>complement</u> to on-product labels must:

- **Promote access for all consumers to complementary product information**, including those without internet or those who lack the necessary digital skills. Alternative means of providing this information to consumers who do not wish to use digital tools even if they have access to them must also be identified.
- **Establish quality criteria** to ensure that the digital information is relevant, reliable, and verifiable. Safeguards are also needed to prevent rogue traders from exploiting digital labelling for advertising purposes, e.g. by linking to commercial content hosted on other parts of the trader's website.
- **Implement privacy and security by design and by default solutions**. Full compliance with the GDPR must be ensured, while an adequate security architecture is needed to prevent digital risks for consumers related e.g. to user identification, misleading information, or hacker attacks.
- **Facilitate enforcement** by increasing the information available to authorities to perform market surveillance. Inspiration could come from the compliance approach developed under the European Product Database for Energy Labelling.

To further improve product labels, we recommend that the **CPR revision introduces clear legibility criteria** in relation to e.g. minimum font size, letter spacing, material surface and text/background contrast. Inspiration could in this regard come from the existing CLP criteria for hazard pictograms. Given the readability and noticeability challenges observed in the impact assessment study on fragrance allergens,<sup>21</sup> we further recommend introducing an obligation to highlight within the ingredient list the presence of fragrance allergens – for example by means of the font, style, or background colour – consistent with the approach to substances or products causing food allergies or intolerances.

Finally, the CPR revision should **improve transparency for cosmetic products purchased online**. In line with Regulation (EU) No 1169/2011, traders should in particular be obliged to prominently display all mandatory labelling information on the webpage or online marketplace where a product is made available for purchase by EU consumers. This would enable consumers to make informed purchasing choices, while also facilitating market surveillance of online sales.

ENDS

<sup>&</sup>lt;sup>20</sup> For example, <u>Kemiluppen</u> by Forbrugerrådet TÆNK or <u>QuelProduit</u> by UFC-Que Choisir.

<sup>&</sup>lt;sup>21</sup> VVA et at. <u>Impact assessment study on fragrance labelling on cosmetic products</u>. Final Report. November 2020.





*Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or EISMEA. Neither the European Union nor the granting authority can be held responsible for them.* 

BEUC would like to thank the European Environment and Health Initiative (EEHI) for providing funding for the development of this publication.