



*The European Consumers' Organisation*

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## **BEUC comments on the simplification of the Cosmetics Directive 76/768/EEC**

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## Overall comments:

It remains unclear in the consultation document which elements of the new approach the European Commission wants to introduce in the field of cosmetics. In general, we do not feel confident with introducing elements of the new approach in this specific area. Such introduction often goes towards less regulation and more standardisation and is, in our view, likely to lead to a lowering of the safety standard of consumer health and the environment. We do not consider standardisation as the most appropriate tool for regulating problematic substances and products in cosmetics. Substances that can have negative health effects must be regulated by laws, based on scientific assessments. It also seems very difficult to develop standards and rule methods for assessment of the safety of finished products, as requested by the “new approach”.

Like food products, cosmetic products may have direct health effects on users. However, unlike for other products, it is difficult to prove that there is a direct correlation between the use of a cosmetic and observed adverse health effects. The principle of producer accountability that is emphasised in the consultation document seems to us necessary but very difficult to apply in this field. It should be accompanied by bare rules for the evaluation of cosmetics’ potential health effects and intensified in-market controls.

Finally, some items and related questions of the consultation document appear contradictory, e.g. item 6 is proposing to abolish the current different lists of substances in order to establish one single positive list and item 17 suggests compiling new positive lists.

## 1. Codifying and streamlining the legal provisions with a view to reducing administrative costs

### 1.1. Turning the Cosmetics Directive into a Regulation

**Item 3** considered by the Commission and submitted for public consultation:

Would it be preferable to regulate cosmetics by means of a Regulation (i.e. a directly applicable legal act, cf. Article 249(2) of the EC Treaty)? Two options could be considered:

Option 1: Turn the whole Cosmetics Directive into a Regulation;

Option 2: Turn only the annexes to the Cosmetics Directive into a Regulation.

What would be the socio-economic impact of these options?

In the converting-process, it is crucial to ensure that the current level of consumer protection is not lowered.

A European directive is usually based on the principle of minimum harmonisation, implying that Member States have the possibility to incorporate more stringent rules into their national legislation therefore often offering more protection to consumers. It is true that these rules can sometimes create problems for suppliers who want to offer their goods and services all over the European Union as he has to obey the national rules. But they are in most cases justified by reasons of general good.

The Cosmetics directive is however already quite technical and detailed and does not leave much room for Member States to apply additional stringent rules. It is also arguable that the creation of an identical legislative framework with European-wide rules for cosmetic products will be quickly and directly applicable and will decrease differences in interpretation and implementation. This is highly important when referring to consumer safety and information.

A regulation is more easily applicable and ensures similar rules in every Member States. It could foster “competition” and achieve a high level of consumer protection. It could also imply that any changes that may occur in the future will be more quickly and easy applicable without long implementation periods. A simplification process should in no case leave room for interpretation by Member States in the areas of safety and information; otherwise, it would indirectly lower the current level of protection of the consumers in the different Member States.

Guidelines have already been elaborated in order to facilitate a common interpretation and ensure a harmonised practical application of certain articles of the Cosmetics Directive by competent authorities. As these guidelines are not legally binding, we believe that minimum harmonisation of these requirements should be foreseen in the revision process. National authorities should still be allowed to keep their own prerogatives to apply the legislation in certain circumstances.

A solution for a simplification of the Cosmetics Directive could be to turn into a regulation only the rules previewed for safety and information so that consumers would benefit from the same level of protection throughout Europe. However, if the simplification leads to the suppression of the lists in the annex of the current directive, the legislative act should remain a directive that would leave Member States the possibility to achieve a higher level of consumer protection.

In any case, when deciding on the direction of the simplification of the Cosmetics Directive, it is necessary to prevent that the result will be the lowest common denominator of consumer protection as this would go against article 95 of the EC Treaty which requires the achievement of a high level of consumer protection.

#### 1.2. Introducing a set of definition

**Item 4** considered by the Commission and submitted for public consultation:

Which terms would need to be included in a set of definitions in order to make the Cosmetics Directive clearer?

The establishment of a minimum set of clear and workable definitions e.g. a set of rules or standards across Europe in the field of cosmetics could remove a significant element of uncertainty.

As a priority, a clearer general definition of “cosmetics” should be included. Indeed, more and more cosmetic products appear on the EU market every year and more and more seem to be overlapping other products’ categories (e.g. food products, drugs, detergents or even medical devices). This makes the regulation of these products very difficult to define and misleads consumers.

Commission rules about efficacy of cosmetic products have been developed in only few cases (e.g. sun protection products) and have never been made mandatory. In our view, the Commission should define what the efficacy of a cosmetic product means. Clear general standards for evaluation methods of products’ efficacy (minimum quality standards respectively for instrumental, clinical or self evaluation methods) should be established and imposed to manufacturers. Once the efficacy of products will be strictly defined in a legislative act, including strict, mandatory guidelines for conducting efficacy evaluations, the information claimed on products should be controlled. In order to avoid misleading consumers, efforts also need to be done to make this information more easily understandable.

Other definitions should be added in the Cosmetics directive for e.g.:

- producers, importers, distributors and retailers;
- adverse effects on health and on the environment;
- active ingredients and substances;
- the terms “may not cause harm”;

- the terms “damage to health”;
- efficacy of a cosmetic product, including a definition of the methods which have to be used to justify an efficacy claim;
- safety parameters with which cosmetic products and ingredients should comply;
- excipients which are used in cosmetic products (e.g. preservatives, viscosity regulators);
- the qualifications “natural”, “biological” or “organic”, which are highly misleading to consumers;
- ...

As an example, the term “damage to health” in Article 2 of the Cosmetics Directive is not legally defined so far. Manufacturers must ensure the safety of the products that they place on the market but what is exactly considered as safe is unclear. It is only inadequately commonly accepted that cosmetic products should be “safe” for the general population but that different reactions of individuals cannot be predicted or avoided (e.g. hypersensitivity to a substance). Manufacturers should make products with an intrinsically low potential to cause adverse effects e.g. use cosmetic formulation which produces “no excess” of allergic contact reactions in consumers compared with similar product types.

A set of harmonised definitions should participate to a greater openness towards consumers on the content of cosmetic products and the effects of ingredients. The definition list should be easily updated when necessary.

We would also like to address the problem of the current way in which ingredients are listed on products in the EU. The fact that the ingredients list uses internationally agreed names for ingredients makes the reading and the understanding difficult for consumers. Even though it eases comparison between products, the ingredients list is rarely meaningful to consumers and does not contribute to gain their confidence (such as in the field of chemicals). Listing ingredients in a different way could be envisaged to improve consumer comprehension and confidence. Ingredients could for instance be listed according to their properties (*ingredients*: emulsionants: A, B; preservatives: C; antioxidants: D, E; etc), in line with the labelling system of food products. We first need clear definitions of ingredients properties.

### 1.3. Streamlining regulation of substances

**Item 5** considered by the Commission and submitted for public consultation:

Do you agree that objective criteria should apply for defining groups of substances, independent of the purpose for which a substance was added to a cosmetic product?

Grouping substances according to their properties rather than to the purpose for which they were added in the product seems to be an interesting proposal. Under the current Directive, substances are grouped according to the use intentions of producers. Unfortunately, it happens that manufacturers add substances for a different purpose than the one declared. It is probably more coherent to use an objective criterion such as the properties of the substance. However, grouping substances according to their properties could also present incoherencies. As an example, a preservative has antimicrobial properties. It is often used as an “active substance” in products such as deodorants but it is also sometimes added in the sole objective of maintaining the quality of certain products. If the simplification of the Cosmetics Directive leads to grouping substances according to their properties, clear information on the concentrations should be included in the annexes and the technical dossier of each product type.

The consultation document remains unclear as to how the change would work in practice. In any case, the existing positive lists of the current Directive which group substances according to the purpose of addition should be retained anyhow.

**Item 6** considered by the Commission and submitted for public consultation:

An alternative approach could be to establish a single list of all regulated substances. (...) Would this approach be preferable?

The establishment of a single list is very difficult to achieve particularly if considering the complexities regarding the substances' properties and the function between inherent toxicity and the concentration in the product. We believe that it is more coherent and easier to perform a clear division of ingredients in different lists, such as a list of substances which are prohibited or restricted in use and a list of approved substances for specific purposes.

For example, preservatives and UV-filters are now appropriately tested for their safety and more thoroughly assessed than most of substances used in cosmetic products. Safety testing and risk assessment of ingredients is proven to significantly reduce consumers' exposure to potentially dangerous substances and the related risks. Listing separately certain problematic substances in positive lists thereby guarantees a sufficient common level of safety to consumers.

Today a number of companies circumvent the specific safety requirements and use alternative substances for their antimicrobial action, e.g. botanical extracts, solvents. By replacing well-tested and approved preservatives with ingredients with unknown effects, manufacturers reduce testing costs but may introduce unsafe products on the market. Furthermore, this strategy also allows companies to market so-called "preservative-free" cosmetic products, thereby misleading consumers. This marketing behaviour can also be avoided by having different exhaustive lists of substances.

Maintaining different lists of ingredients should however not prevent simplifying the current system by avoiding the use of asterisks and foot notes which make the provisions more difficult to understand.

#### 1.4. Facilitating updating of the inventory of ingredients

**Item 7** considered by the Commission and submitted for public consultation:

To remedy this situation the Commission could be given a more flexible mandate, which allows for establishing and updating a publicly-available inventory without legislative procedure. Would this approach be preferable?

The Cosmetics Directive specifies in Article 5a that the inventory of cosmetics ingredients is compiled "on the basis in particular of information supplied by the industry concerned". Article 8 specifies that the SCCP must be consulted prior to any amendments to the current inventory. The SCCP also works in collaboration with the Joint Research Centre (JRC) of the European Commission.

The process of updating the inventory of cosmetics ingredients by means of Commission decisions seems to us a rather transparent and balanced process leaving way for scientists' involvement, as well as Member States' experts (comitology procedure) and other stakeholders' participations. However, the current length of time needed to see an updating approved makes the new inventory already obsolete. Additionally, as the process is rather technical and does not include a safety check for new substances, we agree that the Commission should be given a more flexible mandate to ensure more efficient and regular updates of the inventory.

We deplore that the consultation paper does not give clear information as to how the updating process could possibly be adapted. In our view, the SCCP should still be consulted along the process and the new procedure should be kept transparent to Member States as well as other stakeholders. Any new scientific evidence on potential adverse effects of a substance which is notified to the Commission should be taken into account. The new procedure must be shown to gain time and cost less hereby allowing allocating more time and resources to ensure the safety of cosmetic products. We also suggest the new procedure to be made subject to a review clause of two to three years to make sure that the level of consumer safety and the communication of information are maintained or even improved.

## 2. Introducing elements of the “New Approach” in order to improve operation of the cosmetics legislation

### 2.1. Clarifying the principle of the “manufacturer’s responsibility”

**Item 8** considered by the Commission and submitted for public consultation:

The Cosmetics Directive could clearly stipulate that the person responsible for placing the product on the Community market is responsible for compliance with the Directive, i.e. for the safety of the product.

Strengthening the responsibility of industry goes hand in hand with stricter rules for the evaluation of cosmetic ingredients and improved official controls. The process of assessing and regulating single substances is still necessary.

The future legislative framework should definitely strengthen the responsibility of manufacturers, importers and distributors, in the field of cosmetics. The industry responsible for placing the cosmetic products on the market must be responsible for the safety of these products i.e. for compliance with the Cosmetics Directive and the General Product Safety Directive<sup>1</sup>. Industry must ensure that consumer health as well as the environment are not adversely affected.

However, introducing a duty of care for the cosmetic industry should in no way be considered as an alternative to assess and regulate single substances and finished products. It is crucial that potentially harmful substances and unsafe finished products are properly tested and recognized as such before entering the market.

Better controls of cosmetics can not be taken over entirely by official controls which are already overburdened with the surveillance of other products including food products. More official controls will not contribute to a higher level of consumer safety. In addition, if the detailed regulation of single substances were abolished in the Directive simplification process, official controls would need to make additional safety checks rather than concentrating on whether certain substances, which are either prohibited or restricted in use, are present in a product.

A recent Danish report<sup>2</sup> reveals that hair dyes may cause severe allergic reactions amongst consumers which may be misdiagnosed in health care system. 5,3% of 4.000 Danish hair dyes users experienced adverse skin reactions. Using QSAR, amongst the 229 substances identified in hair dying products, 75% were predicted to be strong to moderate sensitizers. This group includes the 8 ingredients which are the most used in hair dyes. In such cases, we believe that producers should be made responsible for the safety of their products.

### 2.2. Strengthening the technical documentation required

**Item 9** considered by the Commission and submitted for public consultation:

Which concrete information (including safety data) would the product information file need to contain to allow for more efficient in-market controls of the safety of the products/their substances?

Cosmetic products are everyday products for most consumers and should not be harmful in the short-term, by causing e.g. allergic reactions, or in the long-term, by causing e.g. cancers or birth defects. They need to be carefully and adequately assessed. The technical dossier should therefore be strengthened to ease controls by competent authorities.

<sup>1</sup> Directive 2001/95/EC of 3 December 2001 on General Product Safety.

<sup>2</sup> ”Allergic Contact Dermatitis to Hair Dye Ingredients”, Heidi Ssted, The National Allergy Research Center, published in Forum for Nordic Dermato-Venereology, Supplementum NO. 13, Vol. 12, January 2007 ISSN 1402-2915.

In our views, the technical dossier should contain information on:

- efficacy of the product:

The technical dossier should mention whether the efficacy claimed on the product has been developed in compliance with the specific mandatory rules included in the future legislative act on cosmetics.

- safety of the finished product:

It is not sufficient to only evaluate the safety of individual ingredients. The potential combined effects of the different ingredients within one single finished product should be assessed and the results integrated in the technical dossier.

- traceability:

Raw materials are often contaminated during e.g. the manufacturing process. A traceability system for all ingredients of products could be envisaged. This system could also help verifying common claims on products such as "without preservatives", "contains organic ingredients", "does not contain allergens".

- expiry date and PAO:

Since information about the expiry date or period after opening (PAO) is decided product by product by the manufacturer, technical and scientific data justifying this information should be also included in the technical dossier. In any case, PAO is neither practical and clear, nor effective to allow consumers to use products safely. Its definition should be re-considered.

- low volume substances and botanical extracts:

As out of the scope of the REACH regulation<sup>3</sup>, low-volume chemicals and botanical extracts should be properly assessed under the Cosmetics Directive and the results contained in the technical dossier. This dossier should also reflect the mechanisms by which "active" ingredients in cosmetic products may compromise consumer safety.

- nanosubstances

Additional safety information is needed in the case of nano-scaled substances. Their potential to cross sensitive biological barriers should be particularly assessed.

- potential environmental impacts:

Health and environmental impacts often go hand in hand. The technical dossier should address the potential effects that ingredients may have on the environment (environmental risk assessment). This would be in line with the EU Commission strategy on Environment and Health<sup>4</sup>, towards closer cooperation between the health and environment areas. Many different substances are known to have an impact on both health and the environment. As an example, Octyl-Methoxycinnamate is used in the formulation of sun protection products and produced in Europe in very high volumes (approximately 5000 tonnes annually). It is not readily biodegradable and has a high potential to bioaccumulate in the environment and is a suspected endocrine disruptor. Another example is called Musk ketone, a fragrance used in the formulation of cosmetic products. It is not readily biodegradable, has high potential to bioaccumulate in the environment and its breakdown product is an endocrine disruptor.

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<sup>3</sup> Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

<sup>4</sup> A European Environment and Health Strategy, Communication from the Commission, COM (2003) 338 final.

The SCCP has issued non-mandatory guidelines on the safety evaluation of cosmetic ingredients by European authorities, but these rules are not strictly followed, often because of the lack of accuracy of the technical dossier. A strengthened technical dossier should therefore be followed by improved in-market controls. The Commission could mandate an expert group with members of the Commission working group on cosmetics and of the SCCP that would start checking how Member States authorities perform the evaluation. On the basis of the results found, the group could work on the development on a standardised evaluation and authorization of cosmetics ingredients by the different authorities. The same guaranty should be given in the notification process of Member States.

2.3. Strengthening checks on products on the market and “cosmetovigilance”, including clarification of rules on registration

**Item 10** considered by the Commission and submitted for public consultation:

The Cosmetics Directive could provide for clear response mechanisms in the event of noncompliance with the Directive (including rules on product withdrawal). In addition, the Cosmetics Directive could contain rules on the procedure which would apply for the cases where the product information file is available in another Member State than the one where the in-market control took place. What is your view on this?

We agree that clear response mechanisms should be provided in case of non-compliance with the Directive. The notification process in every Member States needs first to be harmonised to ensure efficient in-market controls. Products should be automatically withdrawn off the market if they are shown to present a risk for consumers' health. Cosmetic products are being used everyday and often very quickly by consumers thereby making the withdrawal of dangerous products off the market sometimes too late to ensure a good level of protection.

Sufficiently demanding fines could also be envisaged in case of non-compliance. They should be high enough to avoid any company to place illegal products on the market and afford paying low fines.

Additionally, a list companies which have been fined or requested to withdraw products could be set up and made publicly available. The mere threat of ending up on a public list should make companies comply with the legislation in place. This would also allow consumer organisations to be informed about products withdrawn and rapidly warn consumers without having to check regularly the RAPEX system update.

**Item 11** considered by the Commission and submitted for public consultation:

The Cosmetics Directive could include a mandate for the Commission to assist in coordinating cooperation between the Member States in the field of “cosmetovigilance”. What is your view on this?

**Item 12** considered by the Commission and submitted for public consultation:

Would clarification of the rules on notification help to improve market surveillance?

An efficient post-marketing system, where consumer and professional awareness of potential disadvantages of cosmetic products are elicited, is timely. Most of adverse reactions are today neither reported nor recorded in a standardised way. The quality of collected data is often poor, mainly due to insufficient involvement of manufacturers, dermatologists, authorities and even affected consumers.

The Commission could certainly also play a role in the improvement and coordination of the cooperation between Member States, and between other actors, including manufacturers and consumer organisations, in the field of “cosmetovigilance”.

Primarily, a clear and harmonised definition of undesirable effects should be laid down. There must be a distinction between adverse effects occurring because of an error in the manufacturing process (e.g. contamination of raw ingredients or during production process, error in quantity or quality of ingredients) and adverse effects occurring from (new) ingredients or new formula, including rare but very serious effects. All different types of adverse effects should be notified in order to improve public safety.

Information on adverse effects should be collected along with the quantitative composition of products that is made publicly available. This should allow a better assessment of the risks posed by substances for which there is not sufficient toxicological data. However, it is true that this is easily conceivable for some biological endpoints (e.g. skin irritation) but more difficult for other endpoints reflecting acute toxicity (e.g. carcinogenic or mutagenic endpoints). For long term potential adverse effects, the time gap between exposure and the appearance of the effects requires a more complex but nevertheless crucial follow-up.

According to the European cosmetovigilance system, data on adverse effects would be sent by Member States to the Commission but harmonised rules for the collection of data and the notification must be developed to ensure the system's coherence. The Commission could then coordinate the setting up of a common database, making distinction between the different types of effects and perhaps listing them according to their level of seriousness. All adverse effects referred to in the Commission database should be subject to public disclosure.

As the cosmetic industry is global, multinational companies have the possibility to collect data from a very large number of exposed persons, providing a basis for extensive epidemiological studies and/or suspension of the use of the responsible ingredient and/or at least early indications of potential side effects. The industry should report all adverse effects in the product dossier. The industry is already obliged to collect individual consumers' complaints and provide them with an individual response in their own language and within a certain period of time (e.g. two to three weeks). We believe that companies should make publicly available all responses they give to individual customers to inform a wider public.

In parallel, the establishment of national networks of health professionals could be encouraged for reporting adverse effects back to competent authorities, including health authorities, following a standardised procedure. Harmonisation of the evaluation of reported undesirable effects and a proper aggregation of data would significantly enhance the quality of the collected information. As an example, in Sweden, health professionals are encouraged to report adverse effects from cosmetics and the competent body, the Medical Products Agency, also investigates and makes summaries of the reports.

Finally, consumer associations could encourage, by any appropriate means, affected consumers to consult health professionals and report to the manufacturer (and, ideally, also to the competent authority). They could also be allowed to play the role of mediator in certain cases, implying that any notification they would receive from consumers could be passed on to manufacturers and the authorities and taken into consideration.

#### 2.4. Addressing individual substances only in exceptional cases

**Item 13** considered by the Commission and submitted for public consultation:

The safety of ingredients in cosmetics would be assessed by the competent authorities on the basis of the product information file. Only if the competent authorities of different Member States disagree with this assessment they should refer the matter to the Commission (including the SCCP).

We disagree with Member States competent authorities being responsible for the assessment of the safety of ingredients on the sole basis of the technical dossier. It is true that the SCCP is the best competent body for a proper assessment of the risks which can be posed by substances in cosmetics.

In any case, if the Commission, the SCCP or even the competent authorities, have grounds for suspecting that a substance presents a risk for consumer health, they must have the right to require a re-assessment of the substance. If any shows that a substance presents a risk, the Commission (and the SCCP) must also be able to require a re-assessment of the substance. Any new independent scientific research or third party contribution showing new scientific evidence should be notified and taken into account.

### 3. Strengthening certain elements related to chemical safety, in particular with a view to innovative (including “active”) ingredients in cosmetics?

**Item 14** considered by the Commission and submitted for public consultation:

Which elements of the Cosmetics Directive need to be strengthened to ensure the safety of innovative products in the future?

**Item 15** considered by the Commission and submitted for public consultation: Clarification could be achieved by explaining and defining the concept of “uncompromised safety”. What is your view on this clarification?

**Item 16** considered by the Commission and submitted for public consultation:

The Cosmetics Directive could make it clear that, as a consequence of the responsibility of the manufacturer, if data are missing the substance in question will be presumed unsafe. What is your view on this clarification?

**Item 17** considered by the Commission and submitted for public consultation: Apart from a positive list for hair-dyeing substances, the Cosmetics Directive could include a mandate for the Commission, as risk-manager, to compile new positive lists for groups of substances. This would allow it to ensure that only substances which have undergone a safety assessment by the SCCP can be used as ingredients in cosmetics. What is your view on this?

The principle of “uncompromised safety” needs to be clearly reflected and explained in the future Cosmetics legislative act. It should, together with the precautionary principle, be applied in the field of cosmetics. If there is a lack of safety data, substances should not be allowed to enter the EU market (principle of “no data - no market” introduced by the REACH regulation). The SCCP should perform a safety assessment of all new substances, including active substances and nano-scaled substances, before they can be used as ingredients in cosmetics and a safety assessment of the finished products before entering on the EU market.

However, the application of these principles should not be an alternative to strict legislative rules and the responsibility of manufacturers, the Commission and governments to assess and regulate the most problematic substances.

In addition, if there is ground for suspecting that a substance used in cosmetics may present a risk for consumer health and the environment, the substance should be banned from cosmetics products and should be removed from the positive list.

**Item 18** considered by the Commission and submitted for public consultation:

The Cosmetics Directive could provide for a mechanism placing an obligation on the regulator to reconsider the listing of a substance on a “positive list”. What is your view on this?

We support a system of positive lists and approval process for certain substances. In our view, there must be an obligation on the regulator to review the listing of substances on positive lists, for example every three years. Indeed, new data, new scientific evidence or reporting data on the potential health effects of substances may always come up.

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