

**PUBLIC CONSULTATION PAPER ON THE SIMPLIFICATION OF COSMETICS DIRECTIVE
76/768/EEC**

1. Which elements in the Cosmetics Directive have given rise to particular legal uncertainty about application? Did this increase administrative costs, e.g. costs to get familiar and to understand the applicable legislation? Can these costs be quantified, e.g. by assessing the necessary man-hours? How can these administrative costs be reduced without compromising the safety of cosmetics placed on the market?

The Polish Association of Cosmetics and Home Care Products Producers considers that several elements have given rise to legal uncertainty, some of them already covered under specific items of the present consultations. One of them is term ‘placing on the market’ that needs to be clarified. What should be also taken into account is the lack of clear regulations concerning in-market control in the field of cosmetics. We consider that international legislation should be introduced as an instrument that will determine general in-market control standards.

2. Can you (roughly) estimate the costs stemming from international regulatory divergences? Which elements in the Cosmetics Directive should be reviewed in order to reach better international alignment? Can you estimate the savings this would bring about for European businesses?

The Association takes the view that the revision of the Cosmetics Directive should improve international alignment instead of hinder it. Matters that need to be simplified and clearly explained are terms interpretation, notification and annexes harmonization. A clear interpretation of these issues will improve trade flow. A lot of solutions introduced in The Cosmetics Directive have been also put into effect in many other non-EU countries. Therefore, all proposed modifications to the EU Directive should take into account external, non-European regulations that have impact on trade flows.

3. 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?*

The Association considers that the legislative form is not as essential as unambiguous interpretation of terms, sufficient implementation time and the way the act will be enforced. The needs of the cosmetic industry of sufficient time for the implementation of new legal provisions should be taken into account. It is also important to improve the information flow between legislators and the cosmetic industry at early stage in order to develop industry awareness of proposed changes as early as possible.

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

The Association recommends that the following terms should be included in a set of definitions in the Cosmetics Directive:

- placing on the market

It is important to clarify that this term refers to the first time a product is put into the stocks for the purpose of sale. In practice, this date usually corresponds with the production date that can be easily checked by identifying the batch number. Therefore, the interpretation that links “placing on the market” with putting into the stocks for sale is the most practicable and easy to control.

- person responsible for placing the product on the market

We consider there is a need to clarify the term “person responsible for placing the product on the market”.

- product

The Association considers that the problem of double meaning of the term “product” should be also taken into account.

The first meaning is a single unit of a cosmetic which can be bought by a consumer e.g. jar, bottle. The second one is a batch – a group of products creating a line (SKU). The double meaning of the term “product” can generate misunderstandings – in articles that concern notification, the term product means a line (a group of products) but taking into account the definition of placing on the market one single product is considered. The interpretation of this term should be unambiguous and make no doubts what “product” means.

5. 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? One example is the term “preservative”. At present, the definition of “preservative” refers to the intention of the manufacturer (“substances [...] added [...] for the primary purpose of inhibiting the development of micro-organisms in such products”, cf. preamble to Annex VI to the Cosmetics Directive). In order to avoid legal uncertainty it might be preferable to define a substance by referring to its *properties* (e.g. anti-microbial), independent of the *reason* why this substance was added to a cosmetic product.

The new criteria for defining groups of substances according their properties will not simplify The Cosmetics Directive. The current approach that takes into account usual function of raw materials in a cosmetic product is the simplest and the most effective because it creates easy access to regulatory information and allows to monitor changes effectively.

What is more, a similar method for defining groups of substances functions in other EU legislation e.g. biocides and in international regulations based on the current EU structure. Changing criteria for defining groups of substances in cosmetic legislation can make the interpretation of terms more sophisticated and subsequently generate more costs for industry.

What should be reviewed and clarified are the current annexes to make them more understandable. Therefore, to achieve this effect we recommend to harmonize the columns and titles as well as terms used in the annexes (e.g. shampoo versus rinse off product).

6. An alternative approach could be to establish a single list of all regulated substances. With regard to positive lists, it could be specified that substances with specific properties (e.g. anti-microbial, colouring, UV-absorbing or UV-reflecting, etc.) have to be listed in the annex before they can be used as an ingredient in cosmetics. Would this approach be preferable? Can you see any difficulties which this approach would pose? What would be the impact on the safety of the products containing these substances? What would be the socio-economic impacts of this envisaged change? Are there alternative approaches to consider?

We consider that current system of positive and negative lists functions effectively and is well understood by industry and authorities. Introducing a single list will not cause more benefit than the present system. On the contrary, such a large list can generate misunderstandings and wrong interpretation. Therefore, a better solution would be the

improvement of the present lists by e.g. removing annex 5 and introducing a system of better cooperation between SCCP and the most important stakeholders. Such modification could lead as well to better and earlier information flow.

7. 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? Can you see any difficulties with this approach? What would be the socio-economic impact of this envisaged change? Are there alternative approaches to consider?

The Association supports simplification of the present procedures for updating of the EU inventory. We recommend introducing an updated electronic publishing which could eliminate delay caused by requirement of inventory translation and its publication in paper format.

8. 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.

We consider that the present form of The Cosmetics Directive guarantees that the person placing the products on the market is responsible for their safety. However, a new sentence determining that the person responsible for placing a cosmetic product on the EU market has to ensure that this product comply with the provisions of the Directive, should be inserted in Article 3.

9. The Cosmetics Directive could specify more clearly the information to be made available in the product information file requested via in-market controls to prove the safety of the product. The extent and content of the information required could be based on: - the SCCP guidelines for safety evaluation of cosmetic ingredients; and/or - the “technical dossier” and “chemical safety report” requirements in the REACH Regulation 1907/2006 as far as human health risks are concerned. 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? How does this information compare with what is usually available in product information files today? Would this mean an increase in information as compared to today? What would be the socio-economic impacts of these envisaged changes?

We take the view that it is essential to provide in the Directive more detailed definition on the role and qualification of the safety assessor and explanation how the assessor reached his/her conclusion. What is more, the safety assessment should not be based only on necessary ingredients information but mainly on assessor’s experience and knowledge. Experience shows that the best guarantee of safe cosmetics products is the quality, training and experience of the safety assessor. Therefore, providing the uniform definition would improve consistent interpretation.

10. The Cosmetics Directive could provide for clear response mechanisms in the event of non compliance 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? What would be the socio-economic impact of such an envisaged mechanism?

The changing of the present system is not as important as the improvement and harmonization of control system. The person responsible for the products should take responsibility for it at every stage of production and placing on the market. It is important to eliminate the situation in which other people taking part in this process must take responsibility for a product they sell.

The matter of control system concerns especially the new EU member states markets where control rules need to be harmonized for trade flow improvement.

11. 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? How would this information flow need to be organized to ensure an efficient surveillance of the safety of the products? What would be the socio-economic impact?

The Association considers that The European Commission should continue co-ordination over national activities in the field of cosmetovigilance to ensure better harmonization of the system in the EU.

12. Would clarification of the rules on notification help to improve market surveillance? What elements should notification cover? What would this mean in terms of socio-economic impact? How can the registration requirement best contribute to combating importation of counterfeit goods?

The Association considers that Polish system of notification doesn't need clarification. Therefore we would like to maintain the current state that requires following data from the producer before placing the product on the market:

- trade name of the cosmetics and its category

- a name and address of the producer who notify a product
- the address where the product dossier is placed

The registration requirement will not cause the decrease in importation of counterfeit goods.

13. 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).

The safety of cosmetics is the very essential aspect of The Cosmetics Directive and should be widely discussed. However, The Association wants to underline that product safety cannot be just assessed on the basis of the safety of particular ingredients but should concern cosmetic product as a whole.

The Association considers that such modification could lead to pre-market control. Our experience indicates that a solution you propose disperses full responsibility for product safety and could hinder trade flow significantly.

14. Which elements of the Cosmetics Directive need to be strengthened to ensure the safety of innovative products in the future? Are additional regulatory tools required in order to ensure this safety? If yes, what would be the socioeconomic impact of these additional regulatory tools?

We consider that The Cosmetics Directive in an adequate way ensure safety of all cosmetic products on the EU market including the many innovative products. Therefore, no additional regulatory tools are necessary to ensure safety. At the present time the challenge to the industry is rather efficient enforcement of existing regulations than introducing a new one.

15. Clarification could be achieved by explaining and defining the concept of “uncompromised safety”. What is your view on this clarification? What would be the socio-economic impact?

The Association take the view that there is no need for a new legal term because the products safety has been already ensured in Article 2 that reads “a product must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use”. Introducing a new term will probably make regulation less understandable for the producers and consumers as well. The meaning of word “safety” includes a term “full safety”, hence adding a word “uncompromised” does not broaden “safety”.

16. 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? Are there alternative approaches to ensure the safety of products? Do you think this clarification would have a socio-economic impact? How?

The current Cosmetics Directive in a clear and unambiguous way requires mandatory product safety assessments. Without it placing product on the market is impossible. Therefore, a complete data set on each ingredient is not necessary to ensure product safety because product safety cannot be guaranteed only by data but first of all, by company experience, knowledge, trainings and experience required from a safety assessor.

17. 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? How would this impact on the safety of cosmetic products? What would be the socio-economic impact?

The Association considers that The Cosmetics Directive already provides a mechanism for the creation of new positive lists if it is necessary. Besides, if there are any doubts that a substance can cause damage to human health the current regulation provides legal instruments for assessment of the substance function by SCCP.

18. 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? How would this impact on the safety of cosmetic products? What would be the socio-economic impact?

There is no need for creation a specific mechanism. The current regulation allows to re-evaluate substances at any time as a result of new information or questions. What is more, a time-triggered re-evaluation will not provide benefit because it can even lead to having new information shelved until some future review data instead of being considered at the time.