



KEMISK-TEKNISKA LEVERANTÖRFÖRBUNDET
THE SWEDISH COSMETIC, TOILETRY AND DETERGENT ASSOCIATION

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EUROPEAN COMMISSION PUBLIC CONSULTATION on the SIMPLIFICATION of the COSMETICS DIRECTIVE 76/768/EEC, 12 January 2007

Comments From KTF, The Swedish Cosmetic, Toiletry and Detergent Association

General remarks

KTF is thankful that it has been given the opportunity to give its input in the public consultation on the simplification of the Cosmetics Directive 76/768/EEC.

Overall, KTF considers that the main pillars of the Cosmetics Directive remain valid regulatory concepts for the regulation of cosmetic products, namely:

- System of in-market control by EU Member States, as opposed to pre-market approval.
- The responsibility of the person placing a cosmetic product on the EU market for the compliance with the provisions of the Cosmetics Directive.
- System of regulation of specific substances by ingredients lists.

Fundamentally, legislation must be based and subsequent regulatory decisions must be taken on the basis of risk and not hazard. Such an approach must allow for proportionate regulatory decisions on the basis of scientific assessments on the safety of cosmetic products.

Item 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?

KTF - There is a need to clarify certain concepts in order to minimise legal uncertainty, i.e.

Proposal of New Definition for Cosmetic Products:

- "A "cosmetic product" shall mean any substance or preparation intended to be placed in contact with the skin and its appendages (Application), the lips and external genital organs, or the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to maintaining them in good condition and/or contributing to well-being (Purpose).



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This may be achieved (Function) by cleaning them, perfuming them, changing their appearance and/or correcting body odours and/ or protecting them”

Poison control centres & frame formulae system:

- Harmonisation within the EU is needed. Information based on the EAPCCT system of frame formulae of the European Association of Poison Control Centers and Clinical Toxicologists (EAPCCT), which was developed in association with the cosmetics industry is accepted by the Swedish competent authorities and given the low number of alerts, this information should be sufficient for all authorities across the EU.

Animal Testing Ban:

- Animal testing provisions need further clarification both in the framework of the cosmetics legislation and in relation to the new chemicals legislation, REACH.

Item 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?

KTF - The revision of the Cosmetics Directive must enhance international alignment. Many Swedish cosmetics companies today have business relations in the US, Russia and countries in Asia.

Item 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?

KTF - An equal high level of consumer protection, a smooth functioning of the EU Single Market and the facilitation of international trade can be better ensured by the introduction of a clear and unambiguous Regulation. Regardless of the legal instrument chosen, sufficient timelines for placing on the market of products are necessary to ensure effective implementation of new requirements.

The different Nordic competent bodies have different views on what to focus on concerning the surveillance of cosmetics. Without the national implementation the legislative reality would be more equal if turning the directive into a regulation for Swedish companies that often act on the whole Nordic market.

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



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KTF - “Placing on the market”, “person responsible for placing a product on the market” and other terms should be defined in the Cosmetics Directive.

Placing on the (Community) market:

- KTF considers it important to clarify that this concept refers to the first time a product is put on the Community market, and links it to the act of storage for the purpose of sale in the Community market.

A common interpretation of the term should, if possible, be used in all EU legislations.

Item 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.

KTF: The current principle approach on substance regulation is the simplest and most effective way of presenting reviewed and accepted materials in terms of their usual function in a cosmetic product. It enables stakeholders easy access to relevant regulatory information and allows to monitor changes effectively.

The proposal to regulate by property (e.g. « anti-microbial ») instead of function (e.g. « preservative ») would not eliminate the described problem. The problem could though be solved via proposal as described in Item 6.

Item 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?

KTF: The fundamental approach of specific substance regulation is well understood by industry and authorities and has proven its effectiveness. Rearranging and editing of the current Annexes to the Cosmetics Directive will increase clarity and user-friendliness and will facilitate substance management by companies as well as control activities by competent authorities.

KTF favours one negative list and a list for other restrictions and provisions.

The new simplified annex on restrictions/provisions should be presented as an easily browsed Internet interface annexed to a consolidated cosmetics legislation.

Item 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.



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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?

KTF supports simplification of the existing procedures for regular updating of the EU Inventory. A user friendly, easily browsed database would make handling of administration as well as information easier.

Item 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.*

KTF: The current framework works but can be clarified. The underlined sentence above makes the whole sentence more unclear. The responsibility should go beyond safety, including for example labelling etc.

Item 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?*

KTF proposes to provide a more detailed description on the aim and approach for product safety assessments, setting out of minimum standards, including a requirement for a reasoned argument as to how the safety assessor reached his/her conclusion.

Clearer definitions on the role and qualification of the safety assessor would improve consistent interpretation.

It is important to distinguish between the role of the safety assessor (assessing the safety of ingredients in products) and the SCCP (evaluation of substances for the purpose of listing in annexes).

Item 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?*



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KTF: The current legal system, supported by good administrative cooperation, already provides adequate tools.

KTF supports:

- principle of unique location for PIF
- clear response mechanisms in event of non-compliance
- simplification to specify mechanisms for administrative cooperation

Item 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?*

KTF supports that the Commission should co-ordinate national activities in the area of “cosmetovigilance” to ensure any system is harmonised across the EU. This includes the Commission to evaluate alerts from EU Member States through a dedicated centralised entity before any risk management decision is taken at the European level.

Item 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?*

A simple EU notification system would be more effective than current practice and could include information to poison centres.

The notification technically speaking should be in a digital format.

Item 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).*

KTF: A specific product assessment is not intended to justify the use of a particular ingredient across a wide range of cosmetic products. Inadequacy of a specific product safety assessment can justify appropriate action against this product. It should not, however, be the basis for decisions, either at national or EU level, about the wider use of an ingredient in cosmetics.

Item 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?*

KTF: Innovation as such does not indicate concerns for safety and should not form the basis for product categorisation.

The principal elements of the Cosmetics Directive (general and specific safety provisions), if clearly described, complied with and enforced, are well suited to ensuring the safety of all



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cosmetic products, including the many innovative products already introduced over the years.

Item 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?

KTF: The implementation of the safety provisions of the Cosmetics Directive already ensures a high level of consumer protection. The legal concept of “high level of consumer protection” is enshrined in the EC Treaty¹⁰ and defined in case law. Hence there is no need of a new legal concept.

If a new definition is still the way forward it should take into account that risk zero does not exist for any consumer product including cosmetics and the wording “uncompromised safety” must be clarified.

Item 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?

KTF: Best guarantee of safe cosmetic products is through a combination of: a) The quality, training and experience of the safety assessor, b) more consistent and formalised safety assessments to allow for more efficient in-market controls and c) a robust post market surveillance system.

The safety assessment of cosmetic products and their ingredients is a much more complex issue than the simple compilation of a predefined set of toxicological data on ingredients.

Item 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?

KTF: The Cosmetics Directive already provides a mechanism for the creation of new positive lists when deemed necessary. In the interim, until a new list is formally constituted, substances / groups of substances can be managed by virtue of the existing Annex II (banned) and Annex III (restricted).

Every new positive list diminishes the responsibility and reliability of the safety assessor. If a “safe” substance, i.e. positive listed substances turns out “unsafe”, the positive listing and the work done by the legislators becomes questionable.

Item 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?



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KTF: There is no need for a specific mechanism. Re-evaluation of substances can already now be decided at any time. Such action should however be triggered by new relevant safety information rather than by time limitations.