

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

1.0 General comment on requests for cost estimates for all items

Costs of compliance with legislation vary greatly, depending on the specific substances and on their intended uses. Also, where general chemical notification costs are applicable (particularly for new ingredients), it would be a very onerous and time-consuming exercise to separate these costs from those arising solely from use in cosmetics. Therefore we will only address the cost issue in a general way in the comments that follow.

Item 1 considered by the Commission and submitted for public consultation: 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?

Item 1 - EFfCI Comment:

1.1 Cross-References to 67/548/EEC and other legislation

The Cosmetics Directive in Article 7a (1) (h) requires "without prejudice to the protection, in particular of commercial secrecy and of intellectual property rights, Member States shall ensure that any information required under (a) and (f) shall be made accessible to the public by any appropriate means, including electronic means. The quantitative information required under 9a) to be made publicly accessible shall be limited to dangerous substances covered by Directive 67/548/EEC." This obligation to make information accessible to the public for dangerous substances covered by Directive 67/548/EEC has led to uncertainty in relation to the adaptation made to Directive 67/548/EEC and whether the obligation is strictly conditional on the date of adoption of the adaptation to 67/548/EEC or the date of implementation in any one of the Member States.

The Cosmetics Directive continues to refer to Directive 67/548/EEC and other legal instruments such as Council Regulation 1777/2002 and subsequent amendments but has no formal and workable mechanism in place too ensure consistency with changes made to these other legislative texts.

Most notably, the Cosmetics Directive will continue to refer to Directive 67/548/EEC even though this Directive has been amended under Directive 2006/121/EC in order to adapt for the entry into force of REACH Regulation 1907/2006.

Equally, the reference in Directive 2006/76/EC to the measures implemented in Regulation 1774/2002 on the management and use of animal by-products does fail to have a formal process in place to make further adaptation of the Cosmetics Directive when changes are made in Regulation 1774/2002. This does lead to inconsistency and legal uncertainty.

1.2 “In order to meet the requirements of this Directive”

In our view the interpretation of the correct intended scope of the phrase “*in order to meet the requirements of this Directive*” as used throughout Article 4(a) [4(a) 1(a), (b), (c), (d)] of the Directive as amended with respect to potential banning of products tested on animals has given rise to more particular legal uncertainty about application than all other issues in the entire history of the Directive (going back to its inception in 1976) combined. We therefore feel that it is this issue which should be the absolute priority for **any** review of the text for the purposes of simplification. Without this, in our view, the whole exercise is pointless. In particular clarification of the scope of the phrase before testing of phase-in substances for the purposes of REACH is seen as essential to the continuity of the EU cosmetics ingredient industries in their present form.

Item 2 considered by the Commission and submitted for public consultation: 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?

Item 2 - EFfCI Comment:

The regulatory framework of cosmetic ingredients on an international basis varies from country to country. The major legislative regimes include e.g. those of Europe, the USA and Japan. There are several significant differences to be found within these legislations, for example:

2.1. Categorization and definition of products

The definitions of a cosmetic product in general may vary from country to country (or economic area in the case of e.g. the EU and South American Comunidad Andina and Mercosur groups) due to differing national or regional regulations. Even for special product categories the definition varies, e.g. in Europe UV filters are considered to be substances contained in cosmetic sunscreen products specifically intended to filter certain UV rays to protect the skin from harmful effects. By contrast in the USA the following definition is used: "Sunscreen active ingredient. An active ingredient listed in § 352.10 that absorbs, reflects, or scatters radiation in the UV range at wavelengths from 290 to 400 nanometers". Different definitions make it difficult for uniform claims to be made in an international market. Questions about the use of UV filters in products other than sunscreen products remain unanswered.

2.2 Specification of colorants

Colorants are more or less regulated in positive lists in nearly all countries/regions. However how is a colorant defined? Because a clear definition is not available in all regulations the listing or non-listing of special substances gives rise to uncertainties. Furthermore the specifications are not harmonized. In many cases the analytical methods which in principle make a specified parameter comparable are missing or different - leading to additional analytical costs.

Four fields of application were created in the Annex IV, part 1 listing the permitted colorants in the Cosmetic Directive 76/768. There have been various interpretations about the proper meaning of these 4 categories.

A note of guidance published by the Commission in December 2006 does not appear sufficient to ensure a uniform interpretation in all member States.

A possible simplification of the future Cosmetic Directive could be that the permitted colorants would be classified in only two fields of application

Field nr 1 = colorants permitted for all cosmetic products

Field nr 2 = colorants permitted for all cosmetic products excepted those who are specifically intended to be applied to mucous membranes or in the eye area.

2.3. Chemical compliance - requirements and control

In Europe a cosmetic ingredient is basically also considered a chemical substance and therefore has not only to comply with the Cosmetics Directive but also with general chemicals legislation. This means that the substance has to fulfil all requirements for a notification (in the case of a new chemical substance) or in future to comply with REACH. The requirements in other countries are sometimes different. Quite often compliance with just the requirements under the national cosmetic regulations is sufficient. This means that cosmetic raw materials can be used under the responsibility of the cosmetic manufacturer without being subject to a chemical legislation (e.g. the INCI listing is sometimes sufficient as an authorization for cosmetic use together with the self responsibility of industry). This means that placing a (new) cosmetic raw material on the market is much more complicated in Europe than in many other countries.

The requirement for compliance of a chemical substance with not only the Cosmetics Directive but also with EU REACH and other regulations such as cosmetic regulations in countries outside the EU or even the use of the substance in totally different fields of application make it nearly impossible to restrict and to control animal testing for non-EU or non-cosmetics purposes. In order to comply with increasing safety requirements all over the world, substances used outside the European cosmetic market have often to be tested on animals to comply with other regulations. As a consequence the existing range of cosmetic ingredients will potentially dramatically decrease over the years unless the text of EU cosmetics legislation is clarified with respect to testing for other purposes than cosmetics use or for the purposes of non-EU legislation. This could lead to problems which cannot be foreseen at this stage (e.g. potential increase of sensitization reactions due to increasing total exposure to a more limited range of preservative products as some alternative products are forced off the market because they have been animal tested).

2.4. RPA Report August 2004

This report already specifies numerous divergences between the international cosmetic legislation systems and can be used as a sound basis for harmonization efforts and thus for cost reduction and simplification.

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?

Item 3 - EFfCI Comment:

We agree that it would be preferable to regulate cosmetics by means of a Regulation. We would prefer Option 1 – i.e. to change the whole Cosmetics Directive into a Regulation – this means that it should become more transparently consistent in application throughout Member States. Implementation should be easier and more cost-effective thanks to the removal of uncertainty and absence of future need for individual Member States to prepare individual national legislation i.e. a Regulation would define exactly when and how it is applicable in all Member States

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?

Item 4 - EFfCI Comment:

We agree that there is a need for a coherent list of definitions (c.f. Article 3 of the REACH Regulation). We should like to refer to our comments under Item 1 regarding the need to define legal terms such as “*for the purposes of this Directive*” in addition to specific technical terms.

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?

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.

Item 5 - EFfCI Comment:

In our view this proposal is not practicable and in any case would not lead to simplification. Who would define the criteria? Who would define the criteria for defining criteria? This would be an extremely complex exercise and the decision as to whether it is “objective” would itself be subjective.

Even in the case of the example given for preservatives would every cosmetic ingredient need to be tested for its anti-microbial properties even when the product has not been used for this function? In any case, most chemical substances have multiple properties – in some cases performance of the intended function may involve a combination of these properties. There is no simplification or removal of uncertainty by assigning substances to multiple categories according to properties independently of whether they are used in this function.

We would prefer to retain the concept of intended function of the substance.

There is other EU legislation which post-dates the Cosmetics Directive that nevertheless retains the concept of intended function (Biocidal Products Directive, REACH etc.).

The proposed change would also be less compatible with the structure of other international cosmetics legislation globally.

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. 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?

Item 6 - EFfCI Comment:

We foresee no advantage in establishing a single list of all regulated substances. Mixture of negative list substances with those that have positive approvals within the same list is likely to increase confusion, not reduce it. Improved clarity could be achieved by simply including assigned INCI names for substances in all lists wherever possible. Addition of CAS registry numbers to the negative list substances would also facilitate identification of banned substances (in many cases INCI names will not have been assigned to these materials since they are by definition not suitable for use in cosmetic products).

In cases where the same substance appears in more than one of the lists it would be helpful and improve transparency to make cross-references within each of the lists to other occurrences of the same substance within the same Directive/Regulation.

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? 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?

Item 7 - EFfCI Comment:

INCI Names are assigned by the International Nomenclature Committee of the USA's Cosmetics, Toiletries and Fragrance Association (CTFA) in US. This process can take several months to complete and is essentially outside the scope of any EU legislation. After assignment (and/or amendment) by the CTFA, the adoption of the INCI names into the EU Inventory is currently via Commission Decisions and this process can add further time delays to their incorporation into the updated EU inventory either on-line or in other forms. The EU inventory of common nomenclature is therefore easily and constantly out of date.

The term "CTFA name" is already redundant even in the US CTFA's usage. Reference should be made to "INCI" names throughout the Directive.

We would therefore propose the following:

* Direct Adoption of INCI Names "as soon as reasonably practicable" in the form assigned by the CTFA's International Nomenclature Committee into the EU inventory (or even directly into labelling in practice) without need for a separate EU legal process would significantly decrease the overall time delay, remove the need for separate EU activity, promote global harmonization and remove significant uncertainty and ambiguity.

* Where valid reasons for different approaches to nomenclature of certain classes of compounds arise (e.g. EU use of Linnaean names for plants instead of USA use of trivial English-language-specific names) these should be resolved **at source** i.e. by increased participation of EU-based regulators, finished cosmetic product and ingredient associations (e.g. COLIPA, EFfCI) and European companies in the activities of the International Nomenclature Committee. We do not foresee any objections to this from the US CTFA, on the contrary it should be welcomed as it would significantly improve the efficiency and effectiveness on the nomenclature assignment process. (Creation of an EU Agency to create "EU INCI Names" would also not necessarily improve timing of publications and would duplicate an existing process with no added or perceived benefit.)

Therefore we propose removal of the reference to the inventory from the Directive and its replacement throughout by reference to INCI nomenclature as the common nomenclature where necessary. This would remove any link between the mechanism/procedure for creation of CTFA/INCI names and compliance with the Directive with regard to creation of an inventory. Product labelling transparency is still a key aim of the Directive, and to retain this we propose simple reference to the INCI names as and when they become available for use on finished cosmetic product labels.

The issue of how and when an “INCI” name is assigned and recognised by the EU and when changes should be implemented could then be addressed more effectively by Technical Guidance Documents or other appropriate legal instruments if deemed necessary.

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.

Item 8 - EFfCI Comment:

No comment as this is an issue specifically for those placing finished cosmetic products on the market.

Item 9 considered by the Commission and submitted for public consultation: 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.¹⁶

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?

Item 9 - EFfCI Comment:

No comment as this item is under separate discussion.

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? What would be the socio-economic impact of such an envisaged mechanism?

Item 10 - EFfCI Comment:

We have no comment to make as this is an issue specifically for those placing finished cosmetic products on the market.

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? 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?

Item 11 - EFfCI Comment:

No comment as this is an issue specifically for those placing finished cosmetic products on the market.

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

Item 12 - EFfCI Comment:

No comment as this is an issue specifically for those placing finished cosmetic products on the market.

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).

Item 13 - EFfCI Comment:

We agree. In fact it is our interpretation that this procedure should already be in place now under the current provisions of the Directive.

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? Are additional regulatory tools required in order to ensure this safety? If yes, what would be the socioeconomic impact of these additional regulatory tools?

Item 14 - EFfCI Comment:

In our opinion it is difficult to answer the questions posed in this item without discussion of animal testing or at least clarification as proposed in comments above for Item 1. If the status of substances subjected to animal tests as a consequence of REACH and other chemicals control legislation (including that outside the EU) is not addressed it will be very difficult to launch innovative products in the future on the EU market.

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? What would be the socio-economic impact?

Item 15 - EFfCI Comment:

We agree on the basic principle that “safety is a crucial concept for cosmetic products”, and that no risk-benefit analysis should be applied in the case of cosmetic products.

We find that the concept of consumer safety is already quite clearly defined in the current wording of Article 2 of the Directive:

“...must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer...”

This Article clearly outlines the basic requirement of Directive 76/768/EEC for safety of cosmetic products with respect to human health, reflecting the principle that safety is not an absolute concept, but has rather to be assessed in each individual case by the Safety Assessor, on the basis of relevant and adequate information needed to make a Risk Assessment of the product.

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

Item 16 - EFfCI Comment:

It should be emphasised that “valid information”, rather than “data”, is needed for conducting a product’s risk assessment. Such information goes beyond a simple list of required data, and notably includes the adoption of *alternative* risk assessment approaches (existing human exposure data, computer based programs, approaches based on actual exposure to ingredients) to fill any possible gaps. Maintenance of this approach is essential to the avoidance of unnecessary animal tests for cosmetic ingredients.

It is therefore the relevance, validity and adequacy of the existing available information which should be evaluated to judge the safety of a cosmetic product, rather than simply trying to identify imprecisely defined “missing data” based on a tick-box or other pre-defined list.

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

Item 17 - EFfCI Comment:

This proposal appears to be in contradiction with the principle of self-responsibility. In any case it is difficult to see how this proposal can be interpreted as part of a “simplification” proposal when it involves generating additional lists that have not been necessary for the Directive to function over the past 31 years.



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

Item 18 - EFfCI Comment:

In our view this procedure should be implemented only on a case-by-case basis and only when there is a specific reason for concern identified. Otherwise there will be unnecessary work for the SCCP. Experience indicates that it is difficult for the regulators to comply with deadlines even with their current workload. Any delay in evaluation of dossiers at SCCP has direct financial consequences for the manufacturer of the cosmetic ingredient since he has already invested heavily in R&D and will not be able to commercialize his material without approval of the SCCP. Resources should not be diverted from products of genuine concern to products that are simply due for review for arbitrary reasons.