

SIMPLIFICATION of the COSMETICS DIRECTIVE 76/768/EEC

PSVAK RESPONSE

16 March 2007

What is PSVAK?

The Hellenic Cosmetic Toiletry and Perfumery Association (PSVAK) is a trade association founded in 1964 and represent the interests of the Greek Cosmetic Industry. PSVAK has 70 members, covering about the 80% of the total Greek cosmetic market, most of them medium and small enterprises (SME's).

General remarks

PSVAK (the Greek Cosmetics Association, a member of COLIPA) is pleased to provide its input in the public consultation on the simplification of the Cosmetics Directive 76/768/EEC, launched by the European Commission on 12 January 2007.

PSVAK fully supports the main concepts which characterize the Cosmetics Directive and would like to see them prevailing in the simplification scheme:

- In-market inspections instead of pre-market registration/approval.
- The responsibility of the person/company 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.
- Risk based approach in assessing a cosmetic product safety aspects.

The vast majority of PSVAK members are of SME nature. It is thus essential that the regulatory framework to-be allows them to operate successfully and be competitive (without of course compromising consumer safety).

RESPONSE TO THE SPECIFIC ITEMS

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?

There is a need for clarification of definitions in order to remove legal uncertainty.

The recommendations from the 2nd SLIM report should be adopted in the area of clarification of definitions to remove the legal uncertainty and ambiguity around terms such as:

1. Definition of a cosmetic product

Article 1 of the Cosmetics Directive specifies the “*application sites*” and the “*functions*” of cosmetic products but neither the intended “*action sites*” nor the “*purposes*”, for which cosmetic products are developed, are specified. This can lead to an incomplete understanding of the modes of action and associated benefits of cosmetic products. Under such circumstances, the classification of certain products as cosmetic products, which nevertheless have been formulated for truly “cosmetic purposes”, may be questioned.

In order to minimise this legal uncertainty, it should be specified that the application site of a cosmetic product is “*the skin (i.e. the biological organ) and its appendages, the lips and external genital organs, or the teeth and the mucous membranes of the oral cavity*”.

The “*purposes*” for which cosmetic products are developed should also be specified in the legal text.

The European Commission guidance document on the demarcation between cosmetics and medicinal products describes “cleaning”, “perfuming” etc. as being the principal purposes of a cosmetic product. However, it is Colipa’s assessment that these describe rather the “functions” of individual products. The “purposes” of cosmetic products, as described above, are to maintain in good condition and to improve well-being.

Against this background, Colipa proposes the following slightly revised definition of a cosmetic product with the aim of clarifying the “application site” and “purpose” of cosmetic products:

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

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

2. Poison control centers & frame formulae system

Whereas Article 7[3] of the Cosmetics Directive requires that appropriate and adequate information on substances used in cosmetic products be made available to the competent authorities for purposes of prompt and appropriate medical treatment in the event of difficulties, EU Member States have interpreted the

requirements differently, leading to an increase in the administrative burden to cosmetic companies.

Not all Member States presently have a system of poison control centres. Of those that do, some require 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. Others require the submission of full formula details for all products.

Faced with the above, Colipa considers that the poison control centre requirements should be harmonized across the EU. Colipa therefore calls on the European Commission to include in its legislative proposal a reference to the above-mentioned EAPCCT frame formulation system.

This clarification would ensure that the adequate information is provided to the poison control centers in an effective manner, while at the same time reducing the administrative burden to cosmetic companies.

3. Interpretation of the “fields of application” colorants

This element, not part of the SLIM report and not covered either by other items of the public consultation document, is related to the lack of harmonised interpretation of the “fields of application” used in Annex IV of the Cosmetics Directive (use categories of colorants). Colipa has raised this issue with the European Commission in the past and is ready to share again its proposal.

4. Notification requirements

Variability across countries. There is need to harmonise and simplify requirements.

5. Definition of placing on the market

Need to include in the legislation the definition adopted by most MS during the application of 7th Amendment. In general, all definitions should appear in one place within the legislation.

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?

The revision of the Cosmetics Directive must enhance international alignment, not hinder it.

The Cosmetics Directive, as indicated in the RPA study¹, “*combines a wide definition of cosmetics with clear and comprehensive requirements on safety testing, ingredients and labelling, provides a good basis for achieving further alignment, demonstrated by the number of countries and regions already modelling their approach upon it*”.

It is important that the proposed changes to the EU legislation should be viewed in a wider reality.

The European Cosmetics Directive has previously been adopted as the legislative model for ensuring the safety of cosmetic products in very many regions around the world. The later has produced major benefits to PSVAK exporters who, despite their SME size, have seized the opportunities given in international markets. More recently however, particularly with the 7th Amendment and its provisions such as the automatic ban on CMR 1 and 2 substances, we have seen that it is less and less being used as the reference text for placing safe cosmetic products on the market.

Typically, reformulating and relabelling costs are incurred by R&D for a substitution of a single raw material in one product formulation, with costs increasing disproportionately if a more complex reformulation is required. In addition, also to be considered are additional manufacturing costs, loss of sales due to delayed product launches etc.

Therefore, it is essential to safeguard European export activities by keeping the new legislation scheme adhered to the principles prevailing up to the 6th Amendment.

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?

A 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.

PSVAK believes that the transposition of changes to the Cosmetic Directive (7 amendments and 40 adaptations to the Technical Progress) into 27 national legislations give rise to additional national provisions (i.e. notification requirements),

¹ “*Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products*”, prepared for the EC by RPA. August 2004.

differences through errors or misunderstanding, delays from country to country and even transposition into more than one pieces of national legislation.

By changing the legislative framework from a Directive to a Regulation this would ensure the uniformity in implementation and interpretation of requirements not only between Member States but also between cosmetic manufacturers. However in order to ensure the cosmetics industry are able to comply with new legal provisions as well as amendments to the Annexes, but without entailing unnecessary economic costs, it is essential that **sufficient time for the entry into force is built into any future regulatory framework.**

PSVAK has quite an experience with discrepancies at local level and, although the considerable level of cooperation and understanding between Industry and local authority helped alleviate major problems, we think that it is the Regulation scheme that will ensure the proper and harmonised application of future legislation.

Item 4

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

Placing on the (Community) market:

PSVAK 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.

The date of putting a product into the stocks and thus making it physically available, in most cases corresponds closely with the production date, which can be easily identified through the batch number. Therefore the interpretation that “placing on the market” means “putting into the stocks for sale” is practicable and easy to control.

Any other system based on the date of receipt by the retailer/point of sale, can not be supported, as it would require 100% traceability in the retail market, something that not even large retailer chains can not guarantee.

Linking the moment of placing on the market to the act of storage for the purpose of sale in the Community market, also covers situations where other approaches would not be consistent. In the case of direct marketing (catalogue sales) or outlet stores, products are offered to the public in a direct way out of the stocks, without being handed over to any retailers.

Person responsible for placing the product on the (Community) market

Recommendation n.6 of the SLIM report proposes adding a clear definition concerning the person(s) responsible for placing a cosmetic product on the Community market. For reasons of a harmonised interpretation of the Directive, it is necessary to clarify that “person” may not only refer to a physical person but also to a company.

Other terms

PSVAK considers there is also a need to introduce definitions of certain other terms in the future EU cosmetics regulations, which would make its implementation easier and more harmonised (e.g. manufacturer, importer, authorised representative, distributor, cosmetovigilance, notification, cosmetic ingredient, minimum durability, product information, preservative, UV filter, leave-on, rinse-off, traces, place of 1st importation to Community market).

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.

It is proposed to continue the current principle approach on specific substance lists as the simplest and most effective way of presenting reviewed and accepted materials in terms of their usual function in a cosmetic product. In particular, SMEs and control authorities in the EU as well as third countries are more likely to find the listing easier to use, and to be able to monitor changes effectively.

One substance may have distinct properties for which it can be used in a cosmetic product. It may even have more than one property for which it is used in the same product. As way of an example, salicylic acid may be added to cosmetic products as a preservative, as an antidandruff agent (microbial property) or as an exfoliant (keratolytic property). In other cosmetic products, it may exhibit other distinct properties/functions.

Furthermore, the current form of listing is in keeping with similar EU legislation (e.g. biocides, a much more austere legislation than cosmetics, explicitly stating that biocidal ingredients are those which are ***intended*** to exercise a biocidal activity) as well as with most international regulations on cosmetics, some of which were themselves developed based on the current EU structure. With such a system the possibility always exists for international alignment on ingredients and subsequent benefits to trade. If major changes are made to the structure the opposite effect, and subsequent costs to Industry, are possible.

Previous attempts to group substances based on objective criteria have been only partially successful as substances tend to have several biological properties underpinned by different, and sometimes multiple, chemical functionalities.

The difference in chemical functionality often leads to variations in product inclusion levels depending on the specific application. Using an objective approach,

a decision on the 'principal function' for an individual substance would be necessary. This is often difficult for multi-functional ingredients.

It is for this reason that PSVAK believes that classification based on the 'properties' of a substances would increase rather decrease legal uncertainty; therefore it is important to retain the "subjective" approach to substance classification, i.e. depending on its actual function in the product.

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?

The present approach of negative (annex II), restrictive (annex III) and positive lists (annexes IV, VI, VII) 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

It is proposed to continue the regulation of specific substances in Annexes to the Cosmetics Directive. The simplest and most effective way of presenting reviewed and accepted materials is in terms of their usual **function** in a cosmetic product.

This fundamental approach is transparent and well understood by both industry and competent authorities and creates an appropriate basis for consumer confidence. This form of listing is also in line with similar EU legislation (e.g. biocides) as well as with most international regulations on cosmetics, some of which were themselves developed based on the current EU structure.

However, the present set of negative (annex II), restrictive (annex III) and positive lists (annexes IV, VI and VII) should be reviewed and clarified for readability and accessibility.

Confusion may arise in some cases from the fact that the same substance can be regulated simultaneously in several Annexes of the Cosmetics Directive. Indeed, one substance may exhibit different distinct properties for which it can be used in a

cosmetic product. It may even have more than one property for which it is used in the same product.

However, It should be considered to regroup and edit the existing restrictive and positive annexes in a manner that for substances that may be used only under specific restrictions, all relevant information can be found in a single place. Such rearrangement of the annexes would not change their essential nature and should not therefore pose problems with third countries who have adopted the EU annexes.

The development and use of an electronic version of substance lists must be considered. Industry and control authorities in the EU as well as third countries are likely to find electronic listing easier to use, in particular for monitoring changes effectively.

Placing of an ingredient in an annex should remain to be scientifically founded and should be preceded by a full evaluation by the SCCP. To make the current system more effective, the system for addition or revision of new entries to Annexes should be enhanced. Proposals for this would include:

- Greater transparency and commitment to timings where applications are currently in the review process.
- A more collaborative system that allows for interaction with SCCP and key stakeholders (including Industry) to better resolve developing issues at an earlier stage. This will help to ensure that concerns for human safety are resolved with the minimum of confusion and eliminate unnecessary testing which is key considering the restrictions included in the 7th Amendment.

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. 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?

PSVAK supports the simplification of the existing procedure linked to the EU Inventory updating.

Industry agrees to a simplification of the existing procedure to ensure availability of up-to-date information on INCI names to all involved parties.

The existing Cosmetics Directive requires administrative steps, such as the whole text translation (except for the INCI names) and publication in paper format in all national languages, which are time consuming procedures without any added value to the information.

Therefore, PSVAK suggests a full revision of the Cosmetics Directive requirements concerning the Inventory and its subsequent updates.

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.

The Greek Cosmetics Association considers that the current framework is quiet clear and workable, and does not lead to possible misunderstandings in its application.

However, as it is important to be more explicit that the person placing the products on the market is responsible for compliance with the requirements of the Cosmetics Directive, PSVAK supports the clarification of Article 3 of the Directive, in line with Recommendation n. 7 of the SLIM report, which reads: *“A new sentence stipulating that the person(s) responsible for placing a cosmetic product on the EU market has to ensure that the products he puts on the market comply with the provisions of the directive should be inserted in Article 3”*.

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?

PSVAK considers it is important to clarify that there are two different aspects of safety assessment addressed in the Cosmetics Directive:

- **product safety assessment, under the main responsibility of the industry**

- **Ingredient evaluation for the purpose of listing in the Annexes of the Cosmetics Directive, under the responsibility of the SCCP/ European Commission.**

Product safety assessment aims at ensuring that the product does not cause damage to human health when it is applied under reasonably foreseeable conditions of use.

So each one safety assessment is an intellectual exercise having two parts. In the first part the likelihood of causing damage to human health, when the cosmetic product is applied under reasonably foreseeable conditions of use, has to be assessed. The safety assessor comes to a conclusion based on knowledge of the ingredients alone and in combination with knowledge of the product, its presentation and mode of use (exposure), as well as on experience with similar formulations. In this part the “technical dossier” and “chemical safety report” under REACH can be useful.

In the second part, maybe the more significant one, the safety assessor, having assessed that likelihood, has to decide whether the likelihood or risk is acceptable, as zero risk is unachievable. This is a much more complex procedure than the simple compilation of a list of data on ingredients and it must be undertaken by a competent professional person.

This is why the safety of the product is guaranteed through the knowledge and the experience of the safety assessor

PSVAK considers the best guarantee of developing safe cosmetic products is the knowledge, experience and training of the safety assessor.

Therefore, the role and the qualification of this person should be described more clearly in the Directive.

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?

PSVAK believes this question refers to two different aspects: the first concerns the situations of non-compliance with the Directive and the second relates to the cooperation between competent authorities in the EU in the in-market control of cosmetic products.

Concerning the first aspect, when products put on the market are not compliant with the Cosmetics Directive, PSVAK believes that the existing regulatory framework is sufficiently clear as of the consequences including the imposition of

fines even the prohibition of placing on the market non-compliant products (General Product Safety Directive).

Concerning the second aspect, cases where the product information file is available in another Member State, PSVAK, instead of new rules, supports a better administrative cooperation between the EU Member States on this issue.

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?

PSVAK supports the Colipa “Guidelines on Handling of Adverse Event Reports”, as a tool for harmonizing industry practice with regard to 6th Amendment Product Information requirements regarding the collection of adverse event reports and believes that under Cosmetovigilance field a system may be applied for reporting to the authorities cases of serious adverse effects.

PSVAK is ready to collaborate with the Commission and the Member States, for any realistic cosmetovigilance system harmonized across the EU.

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?

The rules of notification in the Cosmetic Directive are clear and sufficient.

Any simplification on that issue could be achieved by introducing a single and simple system of notification at EU level, in order to overcome any administrative burdens have been created by the current situation, such as multiple notifications and different requirements for notification between Member States.

PSVAK fully supports the efforts by the European Commission to fight against counterfeiting of cosmetic products; a world-wide phenomenon that has socio-economic impact.

However PSVAK believes that further notification systems and rules will not help to solve the problem of counterfeit goods. An effective control of these goods could

only be done through an effective control and collaboration between custom authorities, police and right-holders.

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).

PSVAK's proposal on this Item is to use or further modify the existing mechanisms at EU level to work more effectively.

Product safety assessment aims at ensuring that the product does not cause damage to human health when it is applied under reasonably foreseeable conditions of use as determined in Article 2. Appropriate action should be taken when a specific product safety assessment is found inadequate. However, decisions about the wider use of an ingredient should not be made based on that, either at a European or national level.

So, some clarification is needed in the interpretation this Item.

PSVAK would be in agreement, if the suggested procedure to be followed is the following:

- Member States review safety on basis of safety assessment
- Only when unsatisfied with this and the use of an ingredient, they should raise it to SCCP.

PSVAK would not be in agreement, if the suggested procedure to be followed is the following:

- Member States review and take decisions on ingredient safety
- SCCP is only involved if Member States disagree.

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?

Provided that the existing elements of the Cosmetic Directive are properly implemented, no modification or additional regulatory tools are needed in order to ensure the safety of innovative products.

The current system seems to be very efficient and working well, taking into account the fact that the cases of safety issues with cosmetics in the market are extremely

rare. PSVAK believes that the challenge lies in the efficient implementation of the regulation rather than in the creation of new requirements.

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?

There is no need for the legal term “uncompromised safety”, as this would also probably raise rather than reduce legal uncertainty.

Article 2 of the Cosmetic Directive states that *“a product must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use”*.

This Article of the current legislation could be a benchmark safety clause in clarifying the need for safety.

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?

Lack of data should not be taken as an indication of health risks and therefore should never be the reason for a formal ban of a substance. This should be restricted to those cases where there is evidence of health issues.

Provided that the safety assessment of a product is carried out professionally, there can be justifiable reasons why specific data on ingredients is waived or replaced.

Also, the process suggested in this Item leads to a check list approach and ignores the central pillars of risk assessment by a qualified safety assessor and the more holistic approach to safety, necessary to protect the consumer.

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?

There is no need for additional positive lists.

A mechanism for creation of new positive lists (when necessary) already exists in the Cosmetics Directive. Until the constitution of the new list is formal, the substances or groups of substances under review can be handled with the help of existing Annexes.

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?

There is no need for a specific mechanism.

A substance or a group of substances on a “positive list” can be re-evaluated at any time based on the current Cosmetic Directive.

It is important though to agree on the review of any ingredient, based on specific and data supported concerns and not due to time limitations.

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