

**L'OREAL COMMENTS TO THE
EUROPEAN COMMISSION PUBLIC CONSULTATION PAPER ON THE SIMPLIFICATION OF
COSMETICS DIRECTIVE 76/768/EEC OF 12 JANUARY 2007**

On 12 January 2007, the European Commission launched a public consultation regarding the simplification of Cosmetics Council Directive 76/768/EEC. The objectives will be reducing administration costs, strengthening the self-assessment and responsibility of individual manufacturers and maintaining a high level of safety in cosmetics without unnecessary red tape.

Stakeholders are invited to comment on three main issues:

- codifying and streamlining the legal provisions with a view to reducing administrative costs (cf. section 1);
- introducing elements of the “new approach” where useful in order to simplify and improve operation of the legislation while maintaining a high level of safety in cosmetics (cf. section 2);
- strengthening certain elements related to chemical safety, in particular with a view to innovative (including “active”) ingredients in cosmetics (cf. section 3).

1. CODIFYING AND STREAMLINING THE LEGAL PROVISIONS WITH A VIEW TO REDUCING ADMINISTRATIVE COSTS

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?

We agree that the Cosmetics Directive has given rise to particular legal uncertainties about its application and that this, in turn, has given rise to additional administrative costs:

The legal uncertainties have been mainly generated by:

1. The lack of a clear definition for certain terms and expressions within the Cosmetics Directive; and the wording in relation to the animal testing ban.
We would support the creation of a glossary as proposed in the 2nd SLIM report (see response to item 4)
2. The fact that EU Member States may have transposed the Directive differently into their national laws. Thus, an “uncertainty” exists for those companies operating across the borders of the 27 members of the EU; notably, in relation to notification and to poison centres.
3. Legal uncertainties arising from translation of the Cosmetics Directive (i.e. English word “*hair*” verses French word “*cheveux*”).

We welcome the use of explanatory guidelines, even though they are not legally binding.

We would like to now examine some key aspects of point 1 and 2 in greater detail:

Definition of a Cosmetic Product (Point 1)

We recognize that the current definition of a cosmetic product has proven to be sufficiently flexible to adequately cover the development of many cosmetic products.

However, it might be appropriate to reflect on the positive contribution of cosmetic products at both individual and societal levels and the coverage of future product innovation.

Animal Testing Ban (Point 1)

Whereas, we would not wish to re-open the debate regarding the necessity of the animal testing and marketing bans, a legal clarity regarding their scope is paramount in order to prepare for post 2009/2013 safety evaluations of cosmetic products. Notably, we believe that the phrase in Article

4a “*in order to meet the requirements of this Directive*” is unclear and requires further clarification.

Poison Centres and frame formula system (Point 2)

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, Member States have interpreted the requirements differently leading to an increase in the administrative burden to cosmetic companies. Note that not all Member States presently have a system of poison centres. Of those that do, some require information based on the EAPCCT system of frame formulae which were developed in association with the cosmetics industry. Others stipulate full formula details for all products.

Faced with the above, we believe that the frame formulae system should be adopted throughout the EU poison centres. This would be in order to provide appropriate information in an effective manner whilst at the same time reducing the administrative burden to cosmetic companies.

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?

International harmonization is a very important issue for companies operating in different geographical areas.

We acknowledge that the EU Cosmetics Directive has historically served as a model to other countries, due to its “credibility” based on the solid scientific basis for its provisions.

We would wish for this situation to continue but acknowledge that many of the provisions in the 7th amendment have not proved to be a basis for international convergence (i.e. mechanical ban of CMR 1 and 2 based on intrinsic hazard rather than on a scientifically sound risk assessment; animal testing bans, period after opening labelling requirements).

To benefit in future from the reduced costs associated with other countries harmonizing with the EU, it is vital to continue to have a cosmetics regulation centred on a robust scientific approach and based on a clear safety assessment of cosmetic products and their ingredients rather than on an ever more restrictive application of the precautionary principle.

We agree that international regulatory divergences are very costly to industry. We believe that efforts towards regulatory convergence of the following subjects would be highly beneficial:

- Harmonization of lists of regulated cosmetic ingredients
- Harmonization regarding cosmetic product classifications

- Harmonization of the nature and/or format of information required by competent authorities
- Harmonization of labelling (INCI, dates [minimum durability, expiry, manufacturing, PAO])
- Harmonization of specific methodologies (e.g. SPF, GMP)

We believe that future modifications of the EU Cosmetics Directive by the European Commission, the European Parliament and the Council of Ministers should take into consideration international repercussions for alignment of cosmetics regulations and WTO commitments.

We support the efforts of the European Commission to move towards international convergence in the field of cosmetics regulation.

1.1 Turning the Cosmetics Directive into a Regulation

Item 3 considered by the Commission and submitted for public consultation: Would it be preferable to regulate cosmetics by means of a Regulation (i.e. a directly applicable legal act, cf. Article 249(2) of the EC Treaty)? Two options could be considered:

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

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

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

We believe that a Regulation (option 1) would give advantages over a Directive as extra clarity would be introduced by having a single clear and unambiguous Regulation throughout the European Union. In addition, all elements of a Cosmetics Regulation would be obligatory.

The transposition of changes to the Cosmetics Directive (to date, 7 amendments and 40 adaptations) into 27 national laws presently gives rise to many issues:

- Additional National provisions may be added. For instance the addition of specific national notification requirements. These are permitted with the provision that they must not restrict the free circulation of goods and that they must be justified in the interests of public health.
- The transposition of the EU text into national laws may introduce errors or misunderstandings. In order to rectify this, a regulatory verification is required of the national text against the EU Cosmetics Directive and corrections to the National Law then need to be undertaken by the National Authorities.
- The EU Cosmetics Directive may be transposed into more than one National Law.

- Modifications to the articles and annexes of the EU Cosmetics Directive are transposed into National Law with delays which vary from country to country. Thus, at any one given time, labeling and ingredient restrictions could differ. Such a situation is in a way contrary to the principle of the free circulation of goods within the EU.
- A lack of harmonization of regulated ingredients within the 27 Member states

We believe that the above discrepancies could be resolved by the introduction of a single clear and unambiguous Regulation throughout the European Union.

In order for a future Cosmetics Regulation to be workable, reasonable delays would need to be introduced to enable products to be made compliant following changes to the regulation. Such delays would be as a function of any safety issue raised.

Concerning technical adaptations to the Annexes (e.g. modifications and/or introduction of single entries), these would need to follow the same principles as the Cosmetics Directive in so much that they would not require a co-decision.

1.2 Introducing a set of definitions

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?

We agree that a greater clarity would be achieved if a coherent set of definitions was included within the Cosmetics Directive.

We would therefore be in favour of following the recommendation of the 2nd SLIM report for the Cosmetics Directive to include a glossary.

In order to respond to the above item, we would like to consider:

- the Commission's proposal: *“Forward to the Elements for a Horizontalisation Legislative Approach to Technical Harmonization”*
- a list of the technical terms which we believe should form part of any future glossary

Concerning the commission's proposal *“Forward to the Elements for a Horizontalisation Legislative Approach to Technical Harmonization”*, we would like to draw your attention to the following:

1. We believe that some definitions given in the Commission's proposal are not appropriate for cosmetic products.

Placing on the market: a more adapted definition would be:

« *Initial action of making available for the first time by putting into the stocks for sale or distribution in the Community market* »

Notification: *To be defined specifically in relation to cosmetic products.*

2. We believe that several useful definitions given in the Commission's proposal are appropriate: ***Authorized Representative, Distributor and Importer***
3. We would also like to draw attention to specifically defining the following regulatory terms in the field of the Cosmetics Directive: ***Person responsible for placing the product on the Community market and Manufacturer***

We believe that it is important to include the following terms in any future glossary: ***Cosmetic Ingredient, Cosmetovigilance, Minimum Durability, Preservative, Product Information, Prototype, Small packages, and UV filter***

1.3 Streamlining regulation of substances

Item 5 considered by the Commission and submitted for public consultation: Do you agree that objective criteria should apply for defining groups of substances, independent of the purpose for which a substance was added to a cosmetic product?

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.

We agree that the present system of arranging the annexes may at times lead to a lack of clarity as substances are often regulated based on a specific purpose for which the ingredient has been added to the cosmetic product and not for all their potential cosmetic uses.

However, we believe that the proposal to regulate by the property of an ingredient (e.g. "*microbial*") instead of its function (e.g. "*preservative*") would not eliminate the problem as the same ingredient may often 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. 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.

For these reasons, we believe that this subject cannot be treated in isolation but rather should form part of a more wide ranging review of the annexes as proposed 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 YV-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 the envisaged change? Are there alternative approaches to consider?

We consider that the present set of negative (annex II), restrictive (annex III) and positive lists (annexes IV, VI and VII) may lead to a certain amount of confusion as the same ingredient may be found in more than one annex.

We also think that the fact that the positive lists are based on the purpose for which the ingredient was added may lead to a lack of clarity if the ingredient is used for a different purpose (see “*item 5*”).

We believe that the placing of an ingredient in an annex should be scientifically founded and should be preceded by a full evaluation by the SCCP or by the competent authority of an EU Member State (see item 13).

With this in mind, we would see an advantage in having two distinct annexes only:

- **A negative list** (the current annex II) which would specify those substances which may not be used as ingredients in cosmetic products
- **A restrictive list** (combining the current annexes III, IV, VI and VII) which would list those substances which may be used as cosmetic ingredients provided that:
 - The resulting product does not cause damage to human health when applied under normal or reasonably foreseeable conditions of use
 - The conditions laid down in the annex are observed.

We would see the advantages of such a system as being as follows:

- Those substances which may not be used as ingredients in cosmetic products would be listed separately as presently (annex II)
- For those substances which may be used under specific restrictions, all restrictions pertaining to all uses would be found in a single list, thus facilitating the reading of the Cosmetics Directive (note that annexes IV, VI and VII define restrictions directly related to specific functionalities of certain ingredients).
- The anomalies cited in “*item 5*” could be eliminated

In order to achieve this transformation, we would recommend to:

- Continue to classify the substances in the current positive lists according to their function and not to their specific properties
- Mention clearly in the equivalent to the present article 4 to the proposed restrictive annex that substances with specific functions (e.g. cosmetic colorants, preservatives and UV filters for skin protection) must be listed in this annex before they can be used for these functions.
- Make the listing first according to the above specific functions but also include in the same entry, restrictions for other uses. Then follow by a listing by alphabetical order for all other restricted substances (current annex III)
- Remove certain substances (traces) having a concentration limit (e.g. safrole, methyleugenol, furocoumarines) from annex II and integrate them into the global restrictive list.
- Systematically designate each substance by its INCI name and CAS number.

This rearrangement of the EU annexes will not change their essential nature and should not therefore pose problems with third countries who have adopted the EU annexes.

In order to aid all stakeholders, we would favour the creation of an electronic version of the two annexes which could be manipulated in order to provide greater clarity. This version could be placed on the Commission website. Under such a system, we can foresee great benefit in only having two annexes.

1.4 Facilitating updating of the inventory of ingredients

Item 7 considered by the Commission and submitted for public consultation: To remedy this situation, the Commission should 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?

We agree that it would be beneficial for the Commission to be given a more flexible mandate, which would allow for establishing and updating a publicly-available inventory without legislative procedure.

In particular, we would favour a simplification of the existing procedure in order to avoid the translation into EU languages. As proposed in the 2nd SLIM report, this could be achieved by linking ingredient nomenclature to the INCI dictionary and to keep a non-translated inventory on the Commission website.

As the EU Inventory is an illustrative list, we do not consider it necessary to publish an officially revised document every five years.

We believe that the conclusions of SLIM would be appropriate:

- Without passing by the procedure described in Article 10, the Commission should update periodically the inventory of ingredients employed in cosmetic products on the basis of information supplied by industry and publish it on the Commission website.
- Translation requirements could be restricted to changes to the introductory section of the inventory.
- Within this context, a dynamic link to the International Nomenclature Committee would seem advantageous.
- The inventory should stay an open indicative list of the substances used in cosmetic products.
- The information to be supplied should be limited to:
 - For ingredients used in Cosmetic Products:
 - The International Nomenclature for Cosmetic Ingredients (INCI) name;
 - The European Pharmacopoeia name, where appropriate;
 - The E.I.N.E.C.S./ E.L.I.N.C.S. number, where appropriate;
 - The C.A.S. number;
 - The Colour Index number, where appropriate;
 - The usual function(s) of the ingredient in the final product;
 - Restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes, where appropriate.
 - For perfumes and aromatic ingredients:
 - The Common name
 - The E.I.N.E.C.S/ E.L.I.N.C.S. number and name
 - The C.A.S. number
 - Restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes, where appropriate.

2. INTRODUCING ELEMENTS OF THE “NEW APPROACH” IN ORDER TO IMPROVE OPERATION OF THE COSMETICS LEGISLATION

2.1 Clarifying the principle of the “manufacturer's responsibility”

Item 8 considered by the Commission and submitted for public consultation: The Cosmetics Directive could clearly stipulate that the person responsible for placing the product on the Community market is responsible for compliance with the Directive, i.e. for the safety of the product.

We do support the responsibility of the person placing the product on the community market for product safety. We have nonetheless concerns with the wording of the question for the following reasons:

- We believe that “being in compliance with the directive” should not be limited to safety. We would therefore like to remove “i.e. for the safety of the product”. The statement “person responsible for placing the product on the Community market” is not defined in the current cosmetic regulatory framework. Clarification would therefore be needed (see Item 4)
- Moreover, we would welcome a clarification on the duties/responsibilities associated to the “person responsible for placing the product on the market”.

We believe that this item should be reworded as follows:

“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. each requirement of the Directive”.

Definition of the “*Person responsible for placing the product on the Community market*”, including a list of his/ her duties, and definition of “placing on the Community market” itself are needed to complete the above statement (see Item 4).

2.2 Strengthening the technical documentation required

Item 9 considered by the Commission and submitted for public consultation: The Cosmetics Directive could specify 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?

It is essential to distinguish between two different aspects of safety assessment addressed in the Cosmetics Directive which are based on different legal provisions, have different primary objectives and, necessarily, lead to a difference in approach :

- Ingredient safety evaluation for the purpose of listing in Annexes of the Cosmetics Directive are under the responsibility of the European Commission
- Product safety evaluation (including but not limited to the safety assessment of ingredients or combination of ingredients as used in the finished product) are under the responsibility of the industry.

Safety assessment for human health of a cosmetic product, prior to placing it on the market, aims at evaluating and ensuring that it does not cause damage to the human health under normal and reasonably foreseeable conditions of use.

Safety assessment consists of an expertise conducted by a competent professional safety assessor. It has to cover the safety assessment of ingredients or combination of ingredients based upon evaluation of their human exposure in the finished product, their chemical structure, their analytical profile, and their general toxicological profile established from all available sources of information. In its reasoning, safety assessment also includes confirmatory safety information on the finished product and post marketing safety experience with this and/or similar formulations, its presentation and mode of use.

We consider that safety assessment of cosmetic products and their ingredients is a much more complex expertise than the simple compilation of a predefined list of toxicological data on ingredients. We do not believe that the in-market control of the safety of cosmetic products and their ingredients would benefit from a rigid list of obligatory tests on each individual ingredient in the product information file. The nature of data that is necessary to conduct the safety assessment of ingredients and combination of ingredients greatly depends on chemical and physical properties, concentration in the finished product, product type, presentation and target population. In this sense, the 'technical dossier' and 'chemical safety report' under REACH are data compilations on single substances. They are not appropriate as a basis for constituting or controlling the safety assessment of cosmetic products and/or their ingredients. In addition, we strongly believe that the mandatory requirement for animal testing, as currently recommended in the SCCP guidelines, on each single ingredient would not be consistent with the bans outlined in the 7th amendment.

Consistency in the quality and standards to which safety assessments for finished products are carried out is of paramount importance. The current wording of the Cosmetics Directive in this respect is very general and does not reflect the complexity of the present expertise.

We believe that it could be beneficial for in-market control purposes:

1. to provide in the Cosmetics Directive, a more detailed description on the aim and approach for product safety assessments, setting out minimal standards (safety assessment of ingredients or combination of ingredients, confirmatory safety information on the finished product and post marketing safety experience with this and/or similar formulations) including a requirement for a reasoned scientific argument as to how the safety assessor reached his/her conclusion.
2. to provide in the Cosmetics Directive, a minimum requirement of professional experience for the safety assessor
3. to establish guidelines on safety related information, as part of the overall input to a safety assessment, is important and could be useful, but would need to go beyond a check box approach on required ingredient safety data. They should necessarily cover the safety assessment of ingredients or combination of ingredients based on evaluation of their human exposure in finished products, their structure-toxicity relationships using computer modeling, their analytical profile, their general toxicological profile established from all available sources and type of data and confirmatory in-vitro and/or clinical safety data on the finished product and/or similar formulations.

In summary, we believe that the best guarantee of safe cosmetic products is the quality, training and experience of the safety assessor in combination with more consistent and formalized safety assessments to allow for more efficient in-market controls.

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

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

The Cosmetics Directive could provide for clear response mechanisms in the event of noncompliance with the Directive (including rules on product withdrawal).

In addition, the Cosmetics Directive could contain rules on the procedure which would apply for the cases where the product information file is available in another Member State than the one where the in-market control took place.

What is your view on this? What would be the socio-economic impact of such an envisaged mechanism?

We believe this item refers to two different aspects: the first concerns non-compliance with the Cosmetics Directive and the second the cooperation between competent authorities in the EU in the in-market control of cosmetic products.

Non-compliance with the Cosmetics Directive

We believe that the Cosmetics Directive together with the General Product Safety Directive provide an appropriate regulatory framework that details general responses to products that are found to be non-compliant with the law.

Notably, the legal basis for in-market control is defined in art.3 of the Cosmetics directive: *“Member States shall take all necessary measures to ensure that only cosmetic products which conform to the provisions of the Cosmetics Directive may be put on the market”*. We are in favour of further defining response mechanisms in the event that a Member State establishes a non-compliance with the provisions of the Cosmetics Directive.

We would propose the following mechanisms:

Depending upon the severity of the infringement, appropriate and proportionate responses could include the construction of an agreed corrective action plan between the competent authority and the person responsible for placing a cosmetic product on the community market and product withdrawal.

We consider that immediate product withdrawal would be appropriate following the establishment of a serious safety concern linked to cosmetic product usage.

Product withdrawal could also be decided by a Member State if the person responsible for placing a cosmetic product on the community market failed to comply with an agreed corrective action plan within a pre-arranged timeframe.

Concerning the safety evaluation within the product information, we strongly believe that the establishment of non-compliance is not possible without a suitable reference. With this in mind, we wish to draw your attention to the need for guidelines in relation to safety assessment of cosmetic products and their ingredients as outlined in our response to item 9.

Administrative Cooperation

We strongly support the principle that access to the product information should be confined to one single location within the European Union. Whereas we acknowledge that the concept of a unique location for product information is already incorporated into article 7a(d), we believe that this concept should apply to all of article 7a. We also think that the concept of underlining of the address where the product information is held (if multiple addresses), which is already a standard practice applied throughout the EU, should be explicitly stated in article 6.1(a).

Within this context, we believe that, in the case where the product information is located in a Member State other than in the one where the control takes place, the competent authorities controlling the market should contact the concerned competent authorities having access to the product information.

Once contacted, the latter should then carry out the necessary enquiry and inform the requesting competent authority of the results obtained. Together, the two competent authorities should then agree to a corrective action, if this is thought necessary.

In the case where the findings reveal clear problems for public health, the Commission and other Member States should be alerted. However, we consider that such an action would be inappropriate when the inspection has revealed no such issues.

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?

We recognise the intention of some EU Member States to establish cosmetovigilance systems. We believe that any system of cosmetovigilance should be harmonised across the EU with balanced roles and responsibilities between cosmetic industrialists, health professionals, national health authorities and the Commission.

Such a harmonised EU wide model of cosmetovigilance would require that EU Member States implement a transparent cosmetovigilance system in order to analyse and evaluate, in consultation with health professionals and the appropriate industrialists, the serious undesirable events related to a product category and/or specific products that have been brought to their attention by consumers, cosmetic industrialists and health professionals.

Such an efficient cosmetovigilance system requires a flow of high quality data produced using a set of common definitions and tools amongst all the stakeholders. As cosmetic industrialists play a key role in collection, and analysis of Undesirable Events, Colipa has recently issued "Guidelines on Handling of Adverse Event Reports" (Colipa, 2005) as a tool for harmonizing industry practices on the management of Undesirable Events. We therefore believe that this guideline should be taken into consideration.

We believe that an efficient post market surveillance of cosmetic product safety should be based on active reporting of Serious Undesirable Events (*Undesirable events which have caused permanent or significant disability /incapacity, hospitalisation, congenital anomalies, immediate vital risk or death*) by cosmetic industrialists and health professionals but also by continuous monitoring of incidence of genuine and attributable Undesirable Events performed by the cosmetic industrialists on their respective product categories and made available to the competent Authorities when a significant signal is detected.

The procedures for implementing a harmonised EU wide model of cosmetovigilance (i.e. fields of application, roles and responsibilities, definitions of Undesirable Events and Serious Undesirable Events, rules for medical evaluation and causality assessment) should be aligned with those described in the resolution of the Council of Europe on a vigilance system for undesirable effects of cosmetic products in Europe in order to protect public health (ResAP(2006)1).

We believe that it would be desirable for the Commission to play an active role in the field of cosmetovigilance in supporting and coordinating EU Member States' initiatives but most importantly in evaluating alerts from EU Member States through a dedicated centralised entity before any risk management decision is taken at the European level.

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?

We strongly agree with the concept of **'notification'** insofar as such a system is not contradictory to the principle that the person placing the product on the market is responsible for ensuring compliance with the requirements of the Directive.

Within this context, we agree that clarification of the rules of notification would help improve market surveillance.

In order to formulate the best system to operate within the E.U., it is first necessary to examine current practices within Member States:

- The Cosmetic Directive requires notification of the address of the place of manufacture or of initial importation to the competent authority of the corresponding Member State (See Article 7a.4).
- In reality, this provision is generally transposed in national terms, which lead to the obligation of multiple notifications.
- Moreover, requirements for notification vary greatly between Member States and some of them require, in addition to the address, detailed product by product information.

Such a situation can have a considerable administrative burden which we believe is against the spirit of the single market.

We acknowledge the legitimacy of individual Member States wishing to have a trace of products on their markets and the manufacturers on their territory in order to efficiently control the market and respond to issues such as "cosmetovigilance". However, any system providing this information to Member States should be easy to operate and a further simplification would also be achieved if a single system was implemented throughout the EU.

With this in mind, we would propose the creation of an electronic tool managed by a dedicated structure within the European Commission, which would be a reference point for all Member States. Such a system could be used either on an individual Member State basis or in order to give a wider pan EU vision:

- We envisage that the person responsible for placing the product on the community market (to be defined in the Directive) would enter the following information onto a central system:
 - Full identity of the product (brand + commercial name of the product in the country where it is put for the first time on the market + shade reference if necessary, etc.);
 - The function of the product if it is not obvious from the presentation;
 - The list of ingredients as defined in article 6.1(g) of the Cosmetics Directive
 - The address at which competent authorities may have access to product information;
 - The N° of Frame-Formula;
 - The EU countries in which the product is intended to be placed on the market with the corresponding date of first commercialisation in the specified countries.
- Distinct national information, e.g. the product name in the local language(s) would be indicated within the data base and countries would be added as and when products are introduced to different Member State markets.
- A given Member State would thus be able to easily identify products that have been placed on its own national market and this system would also aid the exchange of information between Member States and/or with the European Commission.
- Details of European Manufacturing sites would also be input into the data base.

We believe that the above system would help identify those products that have been brought into the EU by parallel trade. It would also be of assistance in identifying those products which have not been notified and also help in the management of certain safety issues including the management of cosmetovigilance.

However, we believe that this system would be of little assistance in the control of counterfeit products as these products are likely to be direct copies of products legitimately placed on the EU market.

2.4 Addressing individual substances only in exceptional cases

Item 13 considered by the Commission and submitted for public consultation: The safety of ingredients in cosmetics would be assessed by the competent authorities on the basis of the product information file. Only if the competent authorities of different Member States disagree with this assessment they should refer the matter to the Commission (including the SCCP).

The product information file including the safety assessment is not intended to justify the use of a particular ingredient across a wide range of cosmetic products. Accordingly, such specific product assessments should not be the basis for evaluating the safety of ingredients in cosmetics and for decisions about a wide use of an ingredient in cosmetics.

If significant scientifically based safety concerns on a specific ingredient arise from product safety assessments, peer review scientific reports or for cosmetovigilance data, the competent authority should take into consideration all relevant data (analytical, safety) across a wide range of cosmetic products amongst the whole industry before any decisions. We consider that data collection should be handled through transparent data call up and hearing processes carried out by the competent authority.

Member state competent authority could issue an opinion following its investigation and this opinion should be shared with all the member states and discussed at the Ad Hoc Working Party. Should competent authorities of other member states disagree with the assessment, the safety of the ingredient in cosmetics should be evaluated by the SCCP. When no such disagreement is noted a decision should be taken based on the opinion of the national competent authority.

3. STRENGTHENING CERTAIN ELEMENTS RELATED TO CHEMICAL SAFETY, IN PARTICULAR WITH A VIEW TO INNOVATIVE (INCLUDING “ACTIVE”) INGREDIENTS IN COSMETICS

Item 14 considered by the Commission and submitted for public consultation: Which elements of the Cosmetics Directive need to be strengthened to ensure the safety of innovative products in the future? Are additional regulatory tools required in order to ensure this safety? If yes, what would be the socio-economic impact of these additional regulatory tools?

We believe that the scope of the question needs to be further clarified. We would like to draw your attention to the following aspects:

- Innovation should not only be associated with new ingredients but can also be the result of a change in an ingredient's concentration, delivery system or application regimen.
- We feel that the arguments introducing the question are misleading as they refer to ingredients, and in particular novel ingredients, whereas the question focuses on innovative products. We think that the safety of a cosmetic product is not only inherent to its ingredients, but also to its final formulation and intended use.
- A new ingredient in cosmetics is not necessarily a new ingredient in other sectors and safety information on ingredient may already exist for other applications.
- Innovation does not mean that concerns in terms of safety should be raised, and therefore, innovation should probably not form the basis for a product categorisation.

The principal elements of the Cosmetics Directive are well suited to ensuring the safety of all cosmetic products, including the many innovative products already introduced over the years. If these principles are complied with and enforced, cosmetic product safety is assured under the responsibility of the person responsible for placing a product on the market. No additional regulatory tools are necessary.

We believe that, the best guarantee of safe cosmetic products, including many innovative products, is the quality, training and experience of the safety assessor in combination with more consistent and formalized safety assessments to allow for more efficient in-market controls.

3.1. Stressing the principles of “uncompromised safety” and “no data – no 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?

We believe that the provisions of the Cosmetics Directive ensure a high level of consumer protection and that the introduction of the **concept** of “uncompromised safety” within the scope of the cosmetics Directive would create rather than reduce legal uncertainty without an advantage for consumers.

However we consider the appropriate level of a “high consumer protection” is capable of leading to different interpretations and therefore, we see clarification of its definition as crucial.

A high level of consumer protection, and in particular the process involved in achieving it, should be defined considering that **risk zero** does not exist for any consumer products including cosmetics. We very much agree with the risk management approach to product safety in the present EU Cosmetics Directive.

Article 2 of the Cosmetics Directive specifically relates product safety to the “normal or reasonably foreseeable conditions of use” of the product“, taking into account “the product’s presentation, its labeling, any instructions for its use and disposal”. Article 7a(1)f of the Cosmetics Directive refers to existing data on undesirable effects on human health resulting from use of the cosmetic product that should be made easily accessible to the public according to Article 7a(1)h. The present Cosmetics Directive thus acknowledges that cosmetic products may lead to undesirable events in some rare consumers resulting from individual specificities and susceptibilities.

Whereas we believe that a notion of well-being and health preservation/protection professionally evaluated through appropriate studies or quality of life questionnaires within post marketing activities should be linked to the use of cosmetic products on a collective level, we do agree that the placing on the market of cosmetic products cannot be based on the evaluation of the balance between these benefits and any risks as is the case for medicinal products.

It is now admitted that the risk assessment of a product includes two levels: the individual level, (i.e. the safety of each individual consumer) and the population level, (i.e. the safety of the community / public health level). Reaching the goal of a high level of consumer protection thus implies dynamic risk evaluation and management at individual and population levels.

In view of the above arguments, we would define a high level of consumer protection as a level of safety that drastically minimizes risk to human health when cosmetic products are applied under normal of reasonably foreseeable conditions of use.

High level of consumer protection is achieved through a global and dynamic safety evaluation and management approach which notably is at both an individual consumer level and a public/collective level and is composed of:

- A safety assessment of the cosmetic product and its ingredients or combination of ingredients conducted by a qualified safety assessor
- Risk management measures that will generally take the form of warnings and/or instructions for use. In conjunction with the Full Ingredient labeling and information made easily accessible to the public, this enables individual consumers to make an informed choice (i.e. personalized risk management).
- A dynamic post marketing surveillance system covering both a collective and individual level in order to confirm the safety of the cosmetic product at a large market scale in varied populations.

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?

We believe that the Cosmetics Directive provides a strict requirement for assessing product safety under the responsibility of a qualified safety assessor prior to marketing. Accordingly, there is already a provision in the Cosmetics Directive that places on the industry the burden of proof of the safety assessment of finished products and their ingredients and/or combinations of ingredients. The current basic principle of the Cosmetics Directive is thus “no product safety assessment – no market”.

Safety assessment of cosmetic products and their ingredients is a much more complex exercise than the simple compilation of a predefined set of toxicological data on ingredients. We believe that no guidelines are intended to define *a priori* a mandatory data set on each ingredient in a check-box approach. This would be scientifically unnecessary and unjustified as the nature of data that is necessary to conduct the safety assessment of ingredients and combination of ingredients greatly depends on the product category, chemical and physical properties, and concentration in the finished product, presentation and target population.

Safety assessment of ingredients or combination of ingredients consists of an expertise conducted by a qualified safety assessor often based on a unique combination of data in relation to human exposure in finished products under normal and foreseeable condition of use, structure-toxicity relationships using computer modeling, analytical profile, general toxicological profile

established from all available sources and type of data and confirmatory in-vitro and/or clinical safety data (i.e. data from human volunteer studies) on the finished product and/or similar formulations.

We strongly believe that there is no scientific justification to presume unsafe ingredients and/or combinations of ingredients without a predefined set of toxicological data when the safety assessment of ingredients or combination of ingredients can be supported by other relevant and valid scientific data.

We believe that the best guarantee of safe cosmetic products is through a combination of:

- the quality, training and experience of the safety assessor;
- more consistent and formalized safety assessments to allow for more efficient in-market controls;
- a robust post market safety surveillance system

3.2. Facilitating management of the “positive lists” of authorized ingredients

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?

We do not believe it necessary to change the current process for the creation of new positive lists.

Currently, there is an absolute requirement for the manufacturer to ensure product safety regardless of the ingredients in the product. If any substance raises general concerns, the present Directive allows for that substance to be evaluated by the SCCP and then discussed and regulated by the member states

If a class of substance united by function raises concerns, as did hair dyes, there already exists a mechanism by which a new positive list may be created after due discussion by Council and European Parliament; during those discussions, individual substances within that class are controlled by virtue of the existing Annex II (banned) and Annex III (restricted).

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?

The current Cosmetics Directive allows systematic or case-by-case re-evaluation of substances on positive lists at any given time, whether as a result of new safety information or new questions.

This provision could be made more explicit, also as a reminder to companies that positive listing status of a substance does not take away the responsibility to consider recent scientific findings on substances in their safety assessments.

It is important, however, that regulatory substance (re)-review on positive lists should be based on new and relevant safety findings that could affect the conclusions of the existing safety assessment and should not be triggered by a simple time limitation.

An automatic, time-triggered re-evaluation would create an unnecessary obligation to both the industry and the authorities; indeed, it might even be counter-productive in having new information shelved until some future review date instead of being considered at the appropriate time.