

P&G COMMENTS TO THE COMMISSION CONSULTATION DOCUMENT ON THE SIMPLIFICATION OF THE COSMETICS DIRECTIVE

This document presents comments from Procter & Gamble on the public consultation on proposals for the simplification of the Cosmetics Directive

About P&G:

P&G employs 138,000 employees in over 80 countries worldwide. Our European business dates back to 1930 when we opened a subsidiary in the UK. Since then we have expanded. Today, P&G has a presence in every country in Europe and the region represents about a quarter of our total business. Of 138,000 global employees, about 25% work in Western Europe.

25 years ago, P&G had a beauty business which generated \$1 Billion in global sales. Since that time, P&G Beauty has become a global leader with over \$20 Billion in sales, offering consumers in more than 180 countries over 100 brands they turn to everyday.

General Comments

We welcome the opportunity to comment on the consultation paper from the Commission on this key topic of Community and International importance. Furthermore we offer our availability, with the rest of Industry, for ongoing collaboration for the development of cosmetic regulation in the European Community that protects the consumer, upholds the principle of free movement of goods and provides an environment where the cosmetic industry can continue to prosper.

The fundamental principles of the current Cosmetics Directive (including principles of risk assessment, the responsibilities of manufacturers and importers, combined with strong in-market control) have been an international gold standard and it is our hope that this continues to be the case in the future.

We regret that the timeline imposed for feedback on this consultation does not allow for the collection of meaningful data that the Commission requests. This emphasises the need for a continuing process of dialogue between the Commission and stakeholders such as Industry to ensure that the eventual outcome of this process is a practical and effective legislative instrument.

Background: A simplification of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (the “Cosmetics Directive”) was announced in the Commission Communication “Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment” and in the Commission’s Annual Policy Strategy for 2007.

The aim is to simplify the legal framework for economic activities in the EU which was identified as one of the key issues on the better regulation agenda

in the Commission Communication “Better regulation for growth and jobs in the European Union”.

The Commission intends to simplify the Cosmetics Directive in the form of a recast, i.e. a legislative technique which enables codification of a legislative text and its amendments and to introduce substantive improvements.

Stakeholders were 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

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?

We agree that there are some parts that could be clarified. The annexes to the Cosmetics Directive should be made consistent with the recommendations made in the SLIM discussions in 2002, for example:

- A clear definition concerning the person(s) responsible for placing a cosmetic product on the EU market should be adopted and where appropriate, used throughout the directive. The following definition is proposed: “the manufacturer, or his authorized agent, or the person to whose order a cosmetic product is manufactured or the person responsible for its first importation into the Community”.
- A new subparagraph in Article 5a.1 providing a definition of “perfume and aromatic ingredients and compositions” should be added.
- The information contained in the inventory concerning the identity of the cosmetic ingredients should be restricted to: their International Nomenclature for Cosmetic Ingredients (INCI) name - which replaces the previous CTFA name – and when appropriate, their European Pharmacopoeia name, their EINECS/ELINCS number, their CAS number and the Colour Index Number.
- Article 6.1 point (g) should be updated by making reference to cosmetic ingredients by their INCI names, in accordance with the European Inventory of Cosmetic Ingredients, the use of the INCI term “INGREDIENTS”, “Parfum” & “Aroma”, and providing the possibility to replace the terms “may contain” by the symbol “+/-“. These points can assist International trade as well as clarity within the EU by formally confirming existing best practice.
- The safety assessment should be signed by the assessor and be more precise with respect to the criteria used in the assessment process.
- More details on the point of access to the information and where the product information should be practically accessible should be provided. This can be used to reinforce the principle of mutual recognition between member state authorities

In addition to conclusions from the SIMPL process, it is proposed that requirements on period after opening (Article 6.1(c)) are adapted in line with the Commission guidelines published to give clarification on this point, most

notably in the indication of categories of product where the concept of period after opening has no meaning (e.g. products intended for single use).

Some of these points are dealt with in more detail later in the consultation. The object of clarification should be to build on practical experience with the existing legislation and to introduce practical improvements that add clarity and transparency. The intention should be to deliver revised legislation that holds to the successful pillars that have operated to date, enhancing consumer protection both in terms of actuality and perception.

At the same time measures should be chosen that make responsibilities and technical requirements clear to all persons placing cosmetic products on the Community market, whatever their size, and give those bodies involved in enforcement clear rules to help with in market control procedures

We encourage the Commission to enter into a transparent and collaborative process of discussion with stakeholders in the ongoing development of changes

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 EU Directive was a model internationally for the regulation of cosmetics, leading to alignment in many countries and advantages for Industry prior to the publication of the 7th Amendment

After this legislation, there is now increasing divergence from the EU positions. However, Europe is still seen as a Global leader in the area of consumer protection and Industry legislation. Therefore, changes in legislation in the European Union have far reaching impact well beyond the borders of the EU. This in turn has impact on the European Industry in terms of exports.

We recommend that the Commission should not initiate any unnecessary changes that result in further divergence from the key principles of the Directive and continue to monitor the effect the elements of the 7th Amendment have on the European cosmetics Industry in terms of International trade.

Further we ask the Commission to support the process of alignment in cosmetic regulations in their discussion with other markets and to seek opportunities for increased trade between these markets and the European Industry

Elements that would benefit all European Industry in the context of International alignment include:

- Advocacy of INCI nomenclature, the EU definition of a cosmetic product and the system of effective in market control
- Support, and have a flexible approach to, activities that lead to international alignment of labelling provisions, for example application of dual unit weight declarations or aligned warnings/symbols where these are applicable
- Encourage alignment on approaches to key activities, in particular safety assessment of cosmetic products and the importance of risk assessment in this activity.
- In the context of changes introduced by the seventh amendment to the Cosmetics Directive, reassurance to third countries of the quality and safety of European products
- Encourage alignment of positive and negative lists of ingredients where this is possible

Where the matters of International trade are not considered, the consequences are potentially very high. The exact figures will depend on the size of businesses and the relationship between production for and in the Community market, and the amount of import or export business.

Changes in technical requirements can lead to the need for European specific formulations and/or labels which add complexity to any business and may not be of any relevance to the safety or benefit of the consumer in the Community. Other changes may have an effect of shaking the confidence that other regulatory authorities may have over the safety of the products that originate from within the Community.

Simplification and clarification of existing legislation should be welcomed and well considered measures will continue to influence legislation in other markets.

Cosmetics form a Global market and all changes should be considered in the light of WTO requirements and in terms of their actual benefit to the consumer and should not be pursued unless a benefit can be shown

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?

We have two considerations that must be considered when determining the best legislative instrument for the future regulation of cosmetics in the Community

First, the instrument must allow for consistent requirements and enforcement of those requirements across all Member States.

Secondly, that reasonable timelines are given for compliance with changes in the legislation. These timelines could vary in line with the type and extent of the change

There is no need to split the form of legislation for articles and annexes. In most cases, lack of clarity/inconsistency in the existing legislation has come from transposition of the articles (e.g. notification requirements) so to split the legislation as proposed in Option 2 may not achieve the goal of consistency.

The recommendations from the SLIM process of 2002, indicated a Regulation as the most efficient way of adapting the legislation to technical progress, and such a change would not be of concern to us providing the principles above were adhered to.

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

We agree with the Commission that the inclusion of definitions of key terms in the future EU cosmetics regulations would facilitate the interpretation of its provisions and the free movement of cosmetic products within the EU Community Market.

Where possible, definitions that are present in horizontal legislation and are of wider application should be reapplied. Discussion should focus on those specific terms unique to cosmetics

However, there are some terms that require comment and should be included.

Placing on the (Community) market:

It is 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.

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

There are a number of technical terms that could be clarified in future cosmetic regulation. These can be considered, with input from stakeholders, including Industry, as part of a transparent and collaborative process after the consultation.

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.

Substances have multiple properties and could theoretically have multiple functions within a cosmetic product

To be of any practical use, ingredients in a positive list(s) should be arranged in a clear and transparent manner for both the manufacturer/importer (to use) and the authority (to monitor).

In this case, the primary intended use is the clearest parameter, rather than property. Any properties shown by a substance should rightly be reviewed in the process of adding any material to the annex and so are in no way excluded from the review.

It is acknowledged that the current listing by function could be considered an over simplification, but then so is the proposal made in this consultation for arrangement by property.

Small and medium sized enterprises and other stakeholders need to be able to find the listing of reviewed and accepted materials. A listing in terms of their usual function in a cosmetic product is easier to use and easier for them to monitor changes effectively

Therefore, while there can be enhancement of the current approach, the listing by function is still the best, most practical way of presenting the conclusions on SCCP reviewed materials in the annexes of the Cosmetics legislation

The basic concept of the current annexes should be retained, although they could be reordered and possibly combined into a well indexed single positive list. Certainly they must be clarified. The conclusions of the 2002 SLIM process should be considered. These recommendations were:

- Due to the fact that the cosmetic ingredients and the perfume and aromatic ingredients are designated by their INCI name, CAS and EINECS/ELINCS number in the inventory, all annexes (including Annex II) should have correspondence tables thus allowing the ingredients to be easily identified.

- If separate annexes are maintained, whenever a same ingredient is listed in Annexes III, IV, VI and VII, there should be cross references specifying the annexes in question and the corresponding reference numbers in the annexes.
- Columns and titles in the different annexes should be harmonised.

In addition, to make the current system more effective, the system for addition or revision of new entries to positive lists should be enhanced. Proposals for this would include

- Greater transparency on commitment to timings and 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 seventh amendment

The current principles seen in the Directive listing are consistent with most international regulations on cosmetics, some of which were themselves developed based on the current EU format. With such a system the possibility always exists for International alignment on ingredients and subsequent benefits to trade.

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?

One potential option would be the combination of existing positive lists in to a single annex. However, care should be taken not to make this large and unwieldy, considering it has great practical use. An example of what can go wrong can be clearly seen in the form of the current Annex II where the lack of organised listing and large number of ingredients makes it extremely hard to review materials in the context of this list.

The current annex principles should be retained and clarified, and expanded. If the lists are combined, this combined listing should have clear sections covering the existing functional categories. Practical considerations, such as making these searchable, making them consistent in terms of the wording of entries, the format of entries and use of recognised identification such as CAS, EC Number and INCI name are essential.

As indicated in the answer to Item 5, the success of a list system is defined by the process that supports the system as well as its form,

The Industry should play a key role in assisting the Commission in this effort.

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?

We are fully aligned with the Commission comments that intervention should be made on the cosmetic ingredient inventory to make this important reference more effective

An inventory of names that are to be considered as applicable on an International basis must be is up to date with new cosmetic ingredients, available and easy to use. In addition, the vision for the Inventory is that the names should be acceptable on an international basis. To achieve these aims several areas need to be examined.

There should be full involvement of the European Commission or appointed European institution in the process to grant INCI names, although this may continue to be led by the current organisations.

The management of the Inventory within the EU structure should be in a form where the Commission may update it regularly without excessive bureaucracy.

This could be delivered by annual updates of the Inventory, based on information compiled by Industry and provided to the Commission in a transparent and agreed process

There should be consideration of improvements to the form of the Inventory to allow stakeholders to easily find names. The existence of the Inventory as the endorsed repository of INCI names, including advocacy of this Inventory as an element of International harmonisation of cosmetics legislation should also be considered.

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 approach of authorities and Industry to date has that the person responsible for placing the product on the Community market is responsible for compliance with the Cosmetics Directive. We would note that this extends to all elements of the Directive, not only safety.

Further, horizontal legislation such as the General Product Safety Directive reinforce the underlying responsibilities for products to be safe for their function.

If, however, a more explicit text is required, a simple solution is the addition of an explanatory sentence as recommended in the SLIM proposals of 2002 into Article 3, namely

“The person responsible for placing a cosmetic product on the Community market (the manufacturer or his authorized agent, or the person to whose order a cosmetic is manufactured, or the person responsible for its first importation into the Community) must ensure that products put on the market comply with the provisions of this Directive and its Annexes.”

As well as the proposed clarification, such a statement will also make those responsibilities under EU law explicit for non European Union countries that are, or might in future, want to adopt a similar model to the Cosmetics Directive. This has in the past been an area of confusion for markets unused to the principles of in market control and manufacturer/importer responsibility.

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?

We note that Product safety assessment is the primary responsibility of the manufacturer/importer of cosmetic products and is a key pillar of the Cosmetics Directive.

Product safety assessment guidance has to go beyond a check box approach on the ingredient data that needs to be supplied. It will need to include additional sources of information to fill any data gaps, i.e. where ingredients are felt not to have a full safety package to current standards. Rather than requiring new testing and new data, such gaps could be filled by

- Using existing human exposure data (obtained from years of monitoring products on the market)
- Data from other sources such as the food or drug sectors where relevant
- Historical data (e.g. generated from studies which although undertaken several years ago can still be used as a solid basis)
- Computer-based programs used for the review of structure-activity relationships of similar compounds where additional reassurance of safety is required
- Understanding toxicological risk assessments in which the actual exposure to ingredients is negligible (potential exposures as well a potential hazard being key elements in this risk assessment process).

More detailed guidance has been developed over time, both by industry and regulators, to create a common understanding of the practical aspects of cosmetic safety assessment with both industry and control authorities.

A more constructive approach is for Industry to propose more specific guidance for safety assessments appropriate to product information in alignment with the Commission and member states

Confusion seems to remain, however, over two distinctly different aspects of safety assessment addressed in the Cosmetics Directive: product safety

assessments (these are the responsibility of the industry) and ingredient evaluations for the purpose of listing in the Annexes of the Cosmetics Directive (under the responsibility of the SCCP/ European Commission).

These two aspects are based on different legal provisions, have different primary objectives and, necessarily, lead to a difference in approach.

Product safety assessment (which is relevant here) 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.

Article 7 (a) states that for control purposes information on safety assessment of the finished product for human health has to be kept readily available

This article defines that the product risk assessment has to cover the general toxicological profile of the ingredients, their chemical structure and their level of exposure.

In this context, the example of documentation needed for compliance with the REACH regulation does not correlate with the needs of article 2. The requirements defined under REACH are for a different piece of legislation that has a very different scope than the specific product Human safety assessments required by the Cosmetics Directive

Regarding the review of ingredients this rests under the provisions of articles 8.2 and 10 which lay the legal framework for the SCCP ingredient assessments aimed primarily at adapting the annexes to technical progress. SCCP therefore covers new developments regarding the general safety profile of an ingredient when used in different product types (and is not necessarily relevant to a specific marketed product).

The SCCP has published clear guidelines for data requirements and updates them on a regular basis. There does not appear to be a need for further guidance on data needs. However, there can be improvements in this area in terms of the process for the assessment of ingredients with respect to all stakeholders involved, for example:

- Greater transparency on commitment to timings and 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 seventh amendment

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?

We fully agree that in a system where the responsibility for compliance rests with the person placing the product on the Community market there must be strong and clear mechanisms to deal with non compliance

However, inclusion of such measures in the text of the cosmetics law could be counter productive, and lead to the potential for inconsistency with mechanisms covering other consumer products.

We believe that there are sufficient horizontal measures for dealing with product that may cause damage to Human health existing under the General Product Safety Directive and in member state legislation. The co-ordination of issues on non compliance through the RAPEX system seems to work well.

We would support continued use of these tools rather than the introduction of new provisions under one piece of vertical legislation.

If considered necessary, a reference to existing legislative tools could be made in a future version of the cosmetic legislation

Regarding Product Information availability

We welcome the suggestion to clarify and reinforce existing best practice on the procedure for examination of product information files.

Embracing the principle of mutual recognition fully, Member States should be encouraged to co-operate with their respective colleagues where the address where product information is held is in another member state. This helps to facilitate sharing of information between Member States, and reduces unnecessary cost and administration for all organisations placing product on Community market. The presence of product information at one Community address is of key importance to SME companies who may not have an appropriate size operation in each of the 27 member states of the Community

Item 11: The Cosmetics Directive could include a mandate for the Commission to assist in coordinating co-operation 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?

In principle, we welcome the involvement of the Commission in assisting co-operation between Member States in the field of cosmetovigilance.

This will lead to consistency of approach (i.e. a single system), drive communication between authorities and lead to a better opportunity to understand the bigger picture across the Community market.

In addition, Industry would welcome the opportunity of working with the Commission and Member States on development of any “cosmetovigilance” process.

In terms of reference to this consultation we must emphasise that any system of “cosmetovigilance” should be harmonised across the EU with balanced roles and responsibilities between cosmetic Industry, health professionals, Member State health authorities and the Commission. It is not of use to any stakeholder to have separate systems in different Member States

Once in place a harmonised EU wide model of “cosmetovigilance” would allow analysis and evaluation, in consultation with health professionals and the cosmetics Industry of any serious undesirable events related to a product category and/or specific products that have been brought to their attention by consumers, cosmetic Industry and health professionals.

An effective “cosmetovigilance” system requires a flow of high quality data produced using a set of common definitions and tools amongst all the stakeholders.

As the cosmetic Industry plays 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 Industry and health professionals but also by continuous monitoring of incidence of genuine and attributable Undesirable Events performed by the cosmetic industry 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).

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?

In a system based on in-market control, enforced through effective inspection of product on the shelf in combination with product information requirements, it is not clear the benefit that notification requirements can bring to the consumer

In addition, information on any product can be obtained through the address in the Community that is required on every cosmetic package

However, recognising that there are key stakeholders for whom notification is of use we would suggest improvements of the current system. The revised system would need to be simple, consistent, and ideally relate only to the country of manufacture or first import into the Community, or to the address declared as the location within the Community where the product information file is held. This would be in keeping with the concept of free movement of goods with the Community.

This could be a notification sent to a member state in an agreed and consistent format or to a central European body. The data would have to be available to all member states whoever the initial recipient. It could be foreseen that this notification would include the product name, identity and the Member States in which the product will be introduced

Considering the complexity of the current notifications requirements between the Member States, this simplification process is an ideal time to reduce administrative burden to industry and Member State authorities and introduce a streamlined system that still serves to indicate that a product has been placed on the Community market.

Such a revised system could be developed by a stakeholder discussion involving the Commission, interested Member States and representatives of Industry

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).

The Product safety assessment is the key tool that the person that places a product on the Community uses to support the safety of that product for intended and reasonably foreseeable use.

Product safety assessments ensure that the product in question does not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. Such specific product assessments are not intended to justify the use of a particular ingredient across a wide range of cosmetic products. Indeed, they cover a far wider area than just a review of the safety of individual ingredients.

Inadequacy of a specific product safety assessment can justify appropriate action against this product. It should not, however, be the basis for decisions, either at national or EU level, about the wider use of an ingredient in cosmetics.

If wider questions on the safety of a specific ingredient arise from controls of product safety assessments, there is already a mechanism at EU level to handle this. We believe this current mechanism should continue to be used.

We would be pleased discuss how this mechanism can be modified to work more effectively, and to ensure that the scientific review process at the European Commission is reserved for consumer safety matters that are significant from an EU perspective.

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?

We would note that 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. Furthermore, a new ingredient in cosmetics is not necessarily a new ingredient in other sectors (e.g. active substance in a medicinal product) and adequate safety information may already exist from these uses.

Most importantly the safety of a cosmetic product, innovative or long established, is not only determined by the intrinsic properties of its ingredients but also by the final formulation and intended use.

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

The principal elements of the Cosmetics Directive are well suited to ensuring the safety of all cosmetic products, including the many innovative products already introduced over the years. If they are clearly described, complied with and enforced, cosmetic product safety is assured.

No additional regulatory tools are necessary. Currently, the person responsible for placing a product on the market has the duty to ensure product safety as described in Art. 2 of the Cosmetics Directive and cannot pass that responsibility on to another party or authority.

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?

The Commission wishes to emphasise that, unlike medicinal products, the concept of risk/benefit analysis, where potential health risks are considered against the benefits of the medicinal product, does not apply in the case of cosmetics.

Any cosmetic product placed on the Community market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, as defined in the current Article 2.

The concept of “uncompromised safety”, and in particular the process involved in achieving it, should be defined considering that zero risk does not exist for any consumer product including cosmetics. This is supported by established concepts in EU legislation and case law of the European Court of Justice. Concepts such as “high level of consumer protection”, the difference between hazard and risk, and the acknowledgement that that “risk zero” does not exist for any consumer product are all relevant. Many of these are laid down by the Communication of the Commission on the Precautionary Principle and the relevant case law of the European Court of Justice

However, the actual proposed phrase “uncompromised safety” is not well known or well used in EU law. Nor does this phrase enshrine clearly the point that the Commission intends. To introduce such a new, ill defined, phrase into the area of consumer products is unnecessary and adds further confusion rather than clarification

As partially quoted above, Article 2 of the current legislation clearly lays down the requirements for safety, and this is backed up by existing horizontal measures. Indeed, Article 2 could be a benchmark in clarifying the need for safety as not only does it make requirements clear, it also indicates specific areas (such as presentation of the product) that need to be considered by the person placing the product on the Community market when making an assessment of safety

The Commission makes reference to differences in the phrases used in the Directive in reference to safety. It is our opinion that any inconsistencies in reference to safety in the text can be easily managed by aligning to one form of words (for example “damage to human health”) rather than resorting to a new term.

It should be noted that no evidence is presented to suggest that there is widespread misunderstanding of safety responsibilities under the current phraseology.

To conclude, the person placing a cosmetic product on the Community market must not compromise on safety at any point. To do so is of detriment to the

consumer and no benefit to the person placing the product on the Community market, as the health and safety of the consumers of our products a fundamental principle of the cosmetic Industry

Instead of introducing new elements of unproven effectiveness, there should be reinforcement of existing structures, namely

- Greater emphasis on the safety assessment of the cosmetic product and its ingredients or combination of ingredients conducted by a qualified safety assessor, with clear and transparent expectations on minimum requirements
- There should be reinforcement of the important use of risk management measures. These measures will usually take the form of warnings and/or instructions for use. In conjunction with the Full Ingredient labelling and information made easily accessible to the public, this enables individual consumers to make an informed choice
- A dynamic and collaborative post marketing surveillance system to monitor and resolve issues if they occur in the market, making use of existing structures (RAPEX and mutual recognition and co-operation between Member State authorities) and horizontal as well as sector legislation (General Product Safety Directive)

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?

Data gaps may lead to non-listing or de-listing on a positive list, but should not be taken as an indication of health risks. This should be restricted to those cases, where there is evidence of health issues. Lack of data should not be the reason for a formal ban of a substance

The precautionary principle should not be misinterpreted and/or abused in this manner.

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 including their ingredients and/or combinations of ingredients

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. 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 for a specific use 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 modelling, 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.

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 surveillance system by companies.

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?

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 including their ingredients and/or combinations of ingredients

If a class of substances united by function raises concerns, such as 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: 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?

For the re-review of any ingredient, specific and data supported concerns must first be raised. This will allow for a Commission mandate to SCCP and the call for information from stakeholders

Where no specific data exists leading to the raising of a concern, to re-open the listing of a material is inappropriate.

It will lead to Industry and the authorities to do work of no benefit to the consumer. There will be unnecessary cost to the industry and valuable time will be taken up at SCCP that could be used for review of new substances. Finally, such a provision would require studies without clear concern of risk, and could lead to the prohibition of a substance due to conflict with the provisions of the 7th Amendment.

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