



## **Unilever Response to the Public Consultation on the 'Simplification of the Cosmetics Directive'.**

**Item 1: Which elements in the Cosmetics Directive have given rise to particular legal uncertainty about application? Did this increase administrative costs, e.g. costs to get familiar and to understand the applicable legislation? Can these costs be quantified, e.g. by assessing the necessary man-hours? How can these administrative costs be reduced without compromising the safety of cosmetics placed on the market?**

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

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

- a) fields of application in Annex IV
- b) use of Article 12 (the safeguard clause);
- c) notification requirements
- d) use of 'Frame Formulations' for Poison Centre notification;
- e) access requirements for product information
- f) threshold requirements for Annex II ingredients
- g) placing on the market.

All definitions should appear in one place within the legislation.

Typically a company such as Unilever currently incurs incremental costs associated with the use of legal and technical regulatory expertise at national level, which are in addition to the central European resources already employed in these disciplines. By changing the legislative framework from a Directive to a Regulation this would ensure a harmonised interpretation of requirements not only between Member States but also between cosmetic manufacturers.

**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?**

**It is essential to build upon the current European legislation to enhance global harmonisation.**

The European Cosmetics Directive has previously been adopted as the legislative model for ensuring the safety of cosmetic products in very many regions around the world, with the notable exceptions of the USA and Japan. This afforded enormous benefits to European exporters. More recently however, particularly with the 7<sup>th</sup> Amendment and its provisions such as the automatic ban on CMR 1 and 2 substances, we have seen that it is less and less being used as the reference text for placing safe cosmetic products on the market.

Further harmonisation of permitted ingredients, (included in Annexes III, IV, and VI), between those regulatory regimes not currently following the Cosmetics Directive approach would greatly reduce costs to those European businesses which have centralised product development and manufacturing activities.

Typically reformulating and re-labelling costs are incurred by Research and Development for a straight forward substitution of a single raw material in one product formulation, with costs increasing disproportionately if a more complex reformulation is required. In addition, also to be considered are additional manufacturing costs, loss of sales due to delayed product launches, packaging and even product right-offs etc.

**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?**

**Future legislation must facilitate a robust and harmonised interpretation and this is best achieved via a Regulation. Furthermore, such a regulation should be integrated within the REACH system.**

For an international company such as Unilever option 1 is essential to enable a robust harmonised approach to product development and marketing. By changing the legislative framework from a Directive to a Regulation this would ensure the uniformity in implementation and interpretation of requirements not only between Member States but also between cosmetic manufacturers. However in order to ensure the cosmetics industry is able to comply with new legal provisions as well as amendments to the Annexes, but without entailing unnecessary economic costs, it is essential that sufficient time for the entry into force is built into any future regulatory framework,.

In addition, considering that cosmetics are mainly chemical preparations used by consumers in their daily lives, we strongly believe that this is a unique opportunity to integrate the new regulation within the REACH system whilst addressing with appropriate tools, files and processes the specificities of the cosmetics sector.

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

**Inclusion of definitions for ‘marketing’, ‘placing on the market’, ‘responsible person’, and a number of technical terms within the legislation would be welcomed.**

There are four key topics where clear definitions are required, in addition to others of a more technical nature. The following is not an exhaustive list:-

- a) marketing
- b) ‘placing on the market’
- c) person ‘responsible’ for placing product on the market;
- d) technical terms such as use of Article 12 (the safeguard clause), ‘rinse-off, leave-on’, traces to mention a few.

In providing clarity of definitions used for cosmetics, care is needed to avoid confusion with terms used in other similar legislative texts.

The simplification of the cosmetics legislation would be a timely opportunity to update the illustrative list of cosmetics in order to take into account new innovative products.

**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.

**Unilever would wish to retain the current approach with criteria based on substance function and not its properties.**

Before pursuing any discussion about how to define groups of substances it is imperative to have a common understanding of definitions for the terms ‘properties’ and ‘functions’. Previous attempts to group substances based on objective criteria have been only partially successful as substances tend to have several biological properties underpinned by different, and sometimes multiple, chemical functionalities. A recent example of the use of an objective criteria, which highlights the limitation of the approach, has been in the selection of chemicals for the validation of studies used as alternatives to animal tests.

The difference in chemical functionality often leads to variations in product inclusion levels depending on the specific application. Using an objective approach, a decision on the ‘principal function’ for an individual substance would be necessary. This is often difficult for multi-functional substances such as benzyl alcohol which is both a fragrance ingredient (fragrance allergen) and a preservative. Other examples include calcium carbonate which is an abrasive but also a colourant in Annex IV.

It is for this reason, Unilever believes that classification based on the ‘properties’ of a substances would increase rather decrease legal uncertainty, and therefore important to retain the subjective approach to substance classification.

**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?**

**Unilever believes that there are merits in combining the current annexes into one list, as long as it is based on the ingredient function. Introduction of an electronic tool to provide clarity and ease of use would be welcomed.**

Introduction of a single list of regulated substances based on their specific properties is not a preferred option. Therefore for the reasons outlined in Item 5, any positive list of substances must be based, as currently, on the function of the substance.

Unilever would support a dual list approach based on:

1 a negative list of substances which may not be used in cosmetic products  
,(annex II)

2 a restrictive list of substances which may be used in cosmetic products, under certain conditions, and providing they do not cause damage to human health when applied under normal or reasonably foreseeable conditions of use( the current annexes III, IV, VI,VII).

We believe that it would also be beneficial to create an electronic version of the two lists, which could be organised to provide greater clarity and ease of use for all stakeholders.

**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?

**All opportunities to fast track the updating process of the European Inventory by linking to the International Nomenclature Committee updates would be welcomed.**

The proposal is preferable to the current situation where the European Inventory has only been updated once since 1993, in 2006 although the INCI names have been available since 2001. This proposal would bring the EU Inventory in line with the International Nomenclature Committee updates, particularly as the language being adopted is now very similar, for example with the recently revised labelling for botanicals. A further development would be to harmonise the EU Inventory completely and utilise the annually updated INCI Dictionary as the preferred INCI text, this in the spirit of internationalisation. However, when considering options to update the inventory, it is essential that the notion of free public access is retained.

For further clarity and consistency, it would be beneficial if all of the ingredient references, particularly in the Annexes included not only the INCI nomenclature, but the CAS number and, where appropriate, the Colour Index number which is not the case today and can lead to confusion.

**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.

**Clarification of the responsibility to comply with the requirements of the legislation by the person placing products on the market is welcomed.**

Unilever's understanding is that the person placing a product on the market is also responsible for ensuring compliance with the Directive. Therefore to ensure legal clarity a reference should be included in the legislative text confirming that the person responsible for placing a cosmetic product on the market must comply with the requirements of the cosmetics directive. In addition, robust enforcement of this requirement, via in-market control, is strongly supported. However such a clarification would also require a clear definition for 'placing on the market'.

**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.<sup>16</sup>

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?

**Recognising the differences between ingredient and finished product safety assessments, consumer health protection is best achieved via a robust and scientifically defensible risk**

**assessment of finished products, prepared by a professionally qualified and experienced safety assessor. Unilever welcomes the introduction of measures to strengthen and clarify this role. With respect to substance data collection, the REACH approach provides an opportunity to harmonise requirements.**

There needs to be a clear understanding on the difference between the two safety assessments referred to within the Cosmetics Directive. The first concerns the safety risk assessment for placing a finished product on the market conducted by the manufacturer. Whilst the second covers the full scientific review of the human safety of an individual ingredient by the SCCP, with the purpose of including new ingredients within the Annexes of the directive, which involves data from both raw material suppliers and end users in the cosmetics industry.

It is difficult to see how increasing the data requirements in the Product Information File, without introducing a simplistic 'check-list' approach for ingredient data, will improve the overall product safety. Consumer health protection is ensured by a combination of ingredient selection coupled with the formulators' skill in product development. In addition, the professional experience of the safety assessor having a clear understanding of the relationship between the ingredients present within a product, ingredient inclusion levels, and how the product will be used by the consumer, provides a robust and scientifically defensible risk assessment. It should be remembered that ultimately, the decision about cosmetic safety is not a definitive yes a product is "safe" or no it is "unsafe", but is the "risk is acceptable" or is the "risk not acceptable", as zero risk is unattainable.

It is for this reason Unilever believes that the role of the safety assessor within future legislation needs to be clarified and strengthened, and combine professional qualification along with practical experience in product safety assessment.

With respect to meeting the data requirements for ingredient evaluation by the SCCP, then Reach is very much the preferred option, permitting a harmonised approach for data collection across all industry sectors. However, harmonising data collection is only one aspect, and establishing the safety of ingredients still requires the professional risk assessment expertise described above.

**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?**

**No additional provisions over and above those already in place via the General Product Safety Directive for the withdrawal of non-compliant cosmetic products from the market place, is necessary. However, we would welcome initiatives to facilitate closer administrative co-operation between Member States.**

Unilever fully supports the concept that enforcement should be consistent across all markets, and that mutual recognition procedures should be adopted. Good administrative co-operation between competent authorities should be encouraged and would strengthen the in-market control already in place.

Product withdrawal due to non-compliance is a facility already available to Member States via the provisions of the General Product Safety Directive, so no additional requirement to establish measures specifically for cosmetics is envisaged.

Unilever would welcome initiatives from the Commission to encourage wider administrative co-operation between Member States, not only for the safety assessment of cosmetic products but to include all components of the Product Information File.

Guidelines on the appropriate use of Article 12, the so called 'safeguard clause', would ensure a consistent approach of such a facility amongst Member States.

**Item 11 :**

**The Cosmetics Directive could include a mandate for the Commission to assist in coordinating cooperation between the Member States in the field of "cosmetovigilance". What is your view on this? How would this information flow need to be organized to ensure an efficient surveillance of the safety of the products? What would be the socio-economic impact?**

**Unilever welcomes the introduction of a harmonised cosmetovigilance system for serious adverse events.**

A harmonised European system would be beneficial, but must include clear definitions on roles and responsibilities, as well as a two way dialogue between cosmetic manufacturers and Regulatory Authorities for the system to function correctly and to achieve the objective of enhancing consumer safety.

Based on the recent cosmetovigilance proposal from the Council of Europe, Unilever would support the introduction of a rapid reporting system for serious\* adverse events (\*based on the ICH definitions). In addition the company would support the provision of an annual consolidated European industry report of adverse events cases based on 'very likely' and 'likely' causality assessments.

Unilever would see a key role for the Commission to support and co-ordinate cosmetovigilance initiatives from Member States, and in particular to provide a centralised review and evaluation function to ensure that any risk management decisions emanating from cosmetovigilance alerts do not lead to unilateral action by Member States.

**Item 12 : Would clarification of the rules on notification help to improve market surveillance? What elements should notification cover? What would this mean in terms of socio-economic impact?**

**How can the registration requirement best contribute to combating importation of counterfeit goods?**

**The current divergence of notification requirements is causing confusion and therefore harmonisation of approach is welcomed. If this also included an electronic tool this would facilitate the capture of additional product information which would be beneficial to the Member States.**

Whilst Unilever sees benefits in retaining the current requirement to notify all sites of manufacture or of initial importation of cosmetic products within the European community, we welcome further clarification and harmonisation of notification requirements. For instance creation of an electronic tool to facilitate notification would be a welcome improvement on the current approach and would provide opportunities to extend the current notification requirements into the area of product identity. This could include brand and variant name as well as a full ingredient list as declared on-pack; country of sale; plus address at which the competent authority can have access to the Product Information File.

We are not however in favour of a product registration approach, as this introduces a fundamental change to the principles of the Cosmetics Directive which currently places the

responsibility of placing safe products on the market with manufacturers, where as registration places greater emphasis on the competent authorities.

It is difficult to envisage how more onerous notification requirements will assist in-market surveillance or combat counterfeiting. By the illegal nature of their activity, counterfeiters are unlikely to follow regulatory notification requirements.

**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).**

**Consumer health protection is best achieved via a robust and scientifically defensible risk assessment, prepared by a professionally qualified and experienced safety assessor.**

Unilever supports the current system of ingredient dossier review by impartial scientific experts. However the process and data requirement for assessing ingredients needs to be reviewed and streamlined. The establishment of the new Reach Chemicals Bureau in Helsinki could offer the opportunity to consider a harmonisation of such activities.

Cosmetics are mainly chemical preparations that consumers use in their daily lives. Therefore, the cosmetics sector needs to be positioned within the REACH system whilst providing the right tools and processes to address the specificities of the sector. In this context the system may request that the Agency would set up a sub-committee for cosmetics to address specific questions from the Commission as it is the case today with the SANCO committees.

Greater emphasis on the quality of the Product Information Files, and in particular product assessments, is welcomed, but not if this leads to a simple 'tick-box' approach to ingredient data to ensure product safety. Any revision in approach needs to retain responsibility of ensuring the safety of products with manufacturers and not places it with the competent authorities, and in the event of dispute, with the Commission and its expert scientific committees. Unilateral initiatives by Member States exploiting the use Article 12 must be discouraged.

Ensuring the safety of cosmetic products requires intellectual input and expert judgement, using the professional experience of the safety assessor, and based upon an intimate knowledge of the ingredients and their appropriate use in product formulations. Unilever welcomes any measures to strengthening the role and responsibility of the in-house safety assessor, which leads to the development of more robust Product Information Files.

**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?**

**Current legislation already provides satisfactory measures to ensure the safety of all cosmetic products.**

The Cosmetics Directive already offers a 'tool-box' of measures for use by both manufacture's and competent authorities to ensure the safety of cosmetics. The safety of innovative products should not be treated differently from any other cosmetic product, all need a strong legislative framework and more rigorous in-market enforcement.

**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?**

**Current legislation already provides satisfactory provisions to ensure that cosmetic products do not cause harm to human health, therefore making any new definition superfluous.**

The current legislation already includes very specific requirements that any cosmetic product placed on the market must not cause damage to human health when applied under normal or foreseeable conditions of use. Therefore the introduction of a new legal term with respect to ensuring consumer safety will simply lead to confusion. Therefore the concept of 'uncompromised safety' introduces a fundamentally different approach to product safety, by requiring a simplistic 'yes' or 'no' to the question about human safety. The reality however is about the acceptability of the risk posed by an individual product or ingredient, as zero risk is unattainable. To support this concept a clear understanding of the differences between hazard and risk is required.

**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?**

**Unilever is fully supportive of any enforcement measures taken by the competent authorities to ensure that all cosmetic products placed on the market are the subject of robust and professional risk assessments.**

Ensuring the safety of cosmetic products is not achievable by a simple 'tick box' approach to data availability. A decision on product safety is based on risk assessment which requires intellectual input and expert judgement. Whilst an understanding of the hazardous properties of an ingredient is important, a decision on safe use is made in the context of an understanding of the inclusion level of the ingredient within a product as well as how the product will be used by the consumer (its exposure). Such an assessment will not necessarily require hazard data on all toxicological endpoints. In addition, consideration needs to be given to the long term, in-market data on ingredient use otherwise many older and widely used ingredients would be lost with no benefit to consumer safety.

**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?**

**Unilever does not believe that the widespread introduction of a series of positive ingredient list would enhance the competitiveness of the European cosmetics industry or facilitate global harmonisation. Furthermore, any such requirement should be the subject of parliamentary discussion.**

The proposal to grant the Commission the scope to extend the scope of ingredient functions covered by positive lists, rather than follow the usual parliamentary process to amend the legal text of the Directive is not a preferred option, and would significantly impact upon the competitiveness of the European cosmetics industry.

Such an approach, which would permit use of only listed ingredients would limit industry's competitiveness and flexibility to meet consumer demands, increase costs and extend development timelines whilst doing nothing to enhance product safety. The development of a range of positive lists would not provide a comprehensive listing of all available ingredients, and inevitably would severely restrict the European cosmetics industry's ability to respond rapidly to consumer demands, by introducing products with more functionally active ingredients.

Other considerations, not to be underestimated, include the time taken and the practicalities of obtaining an independent expert review and approval to get new ingredients included in the appropriate positive list which will potentially be a huge issue for this fast moving consumer product sector.

Such an approach does nothing to enhance the safety of products, but removes much of the responsibility of ensuring the safety of all ingredients away from manufacturers and places it with the Commission and its expert scientific committees. In contrast it is likely to lead to a decrease in the quality of the product risk assessments, with a corresponding lowering of consumer health protection.

**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?**

**Unilever supports a process that would stimulate substitution on the basis of the availability of sustainable alternatives.**

Unilever does not agree with a reconsideration of the listing of a substance on a "positive list". There would be no benefit of a time limited inclusion on a list. Indeed, ingredient reviews should be linked to the availability of new sound scientific data or safety issues highlighted by in-market surveillance and cosmetovigilance reports.

However, Unilever would favour the establishment of a process that would stimulate the review of the list taking into account the availability of sustainable alternatives. Such a process should foster and encourage innovation in more suitable alternatives and would thus ensure the continuous improvement of the safety profile of ingredients used in cosmetics.

**March 13 2007**