THE PERFUME FOUNDATION

Help us to protect your art of living

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

The Perfume Foundation's mission is to be the leading authority on health and environmental issues related to fragrances and scents, while contributing to the cultural heritage of Perfume.

- As a public organisation, we find it a must to simplify the Cosmetic Directive and to take this opportunity to take Perfume out of the Cosmetic Directive as Perfume is not a Cosmetic and should therefore be tested differently.
- Perfume is breathed. In the same time, it is not only added to cosmetics but also to household products or sprayed in the air indoors and outdoors. Consequently, it contributes to or is a part of environmental pollution.
- As a public organisation we also position ourselves as the only independent organisation expert in cosmetics and perfumes that is in a position to help the Commission in giving a label to final products, after controlling their non-toxicity in re-testing them before having them on the market.

Item 2

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?

People, organisations and governments worldwide are looking for a solid regulation. Europe could be the leader in this.
As the Perfume Foundation, we are working with associations and Health and Environmental ministries in USA, Canada, Asia... They are ready to follow Europe with their regulations if it gives the consumer the real assurance that products put on the market will be safe.
As soon as Europe will be ready with the new regulation, the Monaco Protocol launched two years ago in Monaco will bring together all concerned ministries to sign the harmonisation protocol.
This meeting in Monaco could happen every two years if needed.
The cost could be supported by the industry and the Commission.

Item 3

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?

Turn the whole Cosmetics Directive into a Regulation.

Item 4

> **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?

This could clarify the fact that perfume is not a cosmetic and should be taken out of the Cosmetic Directive.

Item 5

> **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.

Objective criteria should be applied for defining groups of substances, independent of the purpose, but only after consulting different scientists as it could be very dangerous:

Following the example in "Item 5", consumers could be assured that the product is 'anti-microbial'- a health related term used by the pharmaceutical industry. It is not a certainty that the product in which that molecule is included is safe. The property of the isolated group of 'anti-microbial' molecules will only be considered as a safe product if it is tested mixed with the rest of the product. This is: it is the final product that should be tested.

In the same line, beware of terminology that could be used as a marketing tool by the industry and could mislead the consumer. If the cosmetic industry starts to use pharmaceutical terminology, cosmetic products should be tested the same way as pharmaceutical products.

Item 6

> **Item 6 considered by the Commission and submitted for public consultation:** An alternative approach could be to establish a single list of all regulated substances. With regard to positive lists, it could be specified that substances with specific properties (e.g. anti-microbial, colouring, UV-absorbing or UV-reflecting, etc.) have to be listed in the annex before they can be used as an ingredient in cosmetics.
> Would this approach be preferable? Can you see any difficulties which this approach would pose? What would be the impact on the safety of the products containing these substances? What would be the socio-economic impacts of this envisaged change? Are there alternative approaches to consider?

Too vague. If it is not an allergen, the whole listing could be replaced by a TPF 'Seal of Approval' label, with complete guidelines available on the website and inside the packaging.
The information in the guidelines should be more precise and complete than a specific property.
If we start to consider only specific properties we will forget very quickly to consider the molecules hiding behind and this could be very dangerous for consumer health protection.

Item 7

> **Item 7 considered by the Commission and submitted for public consultation:** To remedy this situation the Commission could be given a more flexible mandate, which allows for establishing and updating a publicly-available inventory without legislative procedure. Would this approach be preferable? Can you see any difficulties with this approach? What would be the socio-economic impact of this envisaged change? Are there alternative approaches to consider?

It will be only possible if other organisations, like The Perfume Foundation will have a budget from the Commission to re-test these substances. If the substances are only tested by scientists that are paid by the industry, it is not reliable enough.

Item 8

> **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.

Not only individual substances as the means of choice to ensure that cosmetics are safe. The final product should be tested too. The product should not be put on the market if there is a single doubt about its safety.
The Cosmetics Directive should clearly stipulate that the person responsible for placing the product on the European market is responsible for the compliance with the Directive, i.e. for the safety of the product.
The consumer may not be held responsible for reading a label or not.
The Brand should be solely held responsible for putting a product on the market.

Item 9

> **Item 9 considered by the Commission and submitted for public consultation:** The Cosmetics Directive could specify more clearly the information to be made available in the product information file requested via in-market controls to prove the safety of the product. The extent and content of the information required could be based on:
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> - the SCCP guidelines for safety evaluation of cosmetic ingredients; and/or
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> - the "technical dossier" and "chemical safety report" requirements in the REACH Regulation 1907/2006 as far as human health risks are concerned.[16]
>
> Which concrete information (including safety data) would the product information file need to contain to allow for more efficient in-market controls of the safety of the products/their substances? How does this information compare with what is usually available in product information files today? Would this mean an increase in information as compared to today? What would be the socio-economic impacts of these envisaged changes?

The 'technical dossier' or 'chemical safety report' should be required.
Currently, some American products are arriving on the market with 10 ingredients that have all safe data sheets and final product testing. It demonstrates that safe products are possible.
The use of hundreds of ingredients was part of the "secret of fabrication" tradition in the sector. It is more difficult to copy a product made of 100 ingredients.
The industry could start making perfumes and cosmetics using known material with safe data sheet rather than using unknown ones.

Item 10

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

Enforcement exists but is costly to governments since many products should be tested and tests are expensive.
The industry is aware of this.
If one product is taken out of the market, the brand that puts it on the market will immediately talk about its concurrent. And tests will have to follow too.
To take off a product out of the market one has to test all the products.

The task of the Monaco Protocol will be both the international harmonization and the information of all European countries to have the same action and knowledge regarding the regulation.

Item 11

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 en efficient surveillance of the safety of the products? What would be the socio-economic impact?

Coordination could be asked to the Perfume Foundation: the 'Seal of Approval' label could again be the solution.
The actual problem regarding toxicology is the detection of allergies on people. Patches used by dermatologists should be updated regularly and follow the toxicology of the products. Every time a molecule is considered to be toxic, there should be patches related to this molecule. Or patches related to final products. The industry should finance these patches.
Our Scientific Committee could have a newsletter informing the dermatologists on new toxic substances.

Item 12

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?

The Perfume Foundation 'Seal of Approval' label is made in response to item 12

too:
Security Design, Security Inks, Optically Variable Devices – Holograms, Intaglio Printing, Latent Image Label (LIL), Laser Imaging Technology, Track and Trace Applications - Anti-Smuggling/Anti-Diversion.

Item 13

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 industry is not CSR (corporate social responsibility) compliant yet to regulate itself. The product information file given by the industry is not enough to prove the non-toxicity of the product. Products have to be re-tested and approved.

Item 14

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?

All new molecules proposed by the industry should be tested by one or several external organisations in relation with the Commission.

Item 15

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?

"Uncompromised Safety": no data. No market is not strong enough. If the industry gives a file with data sheets, these data have to be cross-checked first before having the product on the market.
The word toxic or non-toxic could easily be understood worldwide without any translation. A warning sign could be also used.
Again, a 'Seal of Approval' label could reassure the consumer and force the industry to work only with safe and good ingredients.

Item 16

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 agree on that item. But we encourage testing of the final product too. We also urge to consider the fact than an isolated molecule could react differently in a cocktail than isolated. Sometime a perfume can be mixed to a shampoo and

destroy completely the safety of the shampoo. There is actually no test on final products, which is a scientific mistake.

1. Data sheet given by the industry for each ingredient, more testing on the final product.
2. Control of the data by an independent organisation (TPF).
3. Label given to the product or interdiction to put the product on the market.

Item 17

> **Item 17 considered by the Commission and submitted for public consultation:** Apart from a positive list for hair-dying 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 Commission could ask The Perfume Foundation to help them with testing, and to classify and compile more data.
As many data we will be in a database, less money will be spend in testing isolated molecules. Final products will always have to be tested.
But at the end we hope the industry will become more aware of the importance of caring for the people and the environment.
Perfume or cosmetics could be good for them and even more profitable the day they will use the right products with the mind of 'making people feel better' for real, not only as a marketing concept to sell only.

Item 18

> **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".
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> What is your view on this? How would this impact on the safety of cosmetic products? What would be the socio-economic impact?

To reconsider "authorisation" of a substance on a positive list after a certain length of time is very important because research is evolving all the time and there is more and more communication between scientists and public opinion.
The Commission cannot afford to be 'laid back', by not updating the data following international research (and not only European research).
DEP is a good example.