

PUBLIC CONSULTATION
on the
SIMPLIFICATION of the COSMETICS DIRECTIVE 76/768/EEC
PROVITAL, S.A. POSITION

REMINDER :

Provital, S.A. is a Spanish company producing cosmetic ingredients.

PRELIMINARY REMARKS :

- The Cosmetics Directive 76/768/EEC implements provisions but also a spirit in terms of definition and responsibilities which are understood and recognized by all the links of the cosmetic supply chain in the EU.
- The simplification of the Cosmetics Directive 76/768/EEC is welcomed but should :
 - be primarily based upon the relevant conclusions of the SLIM Report resulting of the common work by experts from the European Commission, Member States and Industry,
 - respect the major principles and spirit of the Cosmetics Directive 76/768/EEC,
 - be an effective progress towards consumers safety and satisfaction.
- The simplification of the Cosmetics Directive 76/768/EEC should introduce provisions that will be bearable for the numerous SMEs in and upstream the cosmetic industry.
- The simplification and review of the Cosmetics Directive 76/768/EEC should take in account the search for international alignment of cosmetics legislations engaged for several years which is crucial for all stakeholders and especially for the European cosmetic industry and its whole supply chain.
- A useless or non adapted regulation could have a negative socio-economic impact leading to the disappearance of important and/or innovative ingredients.

Item 1 :

Which elements in the Cosmetics Directive have given rise to particular legal uncertainty about application ? Did this increase administrative cost, 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 ?

ANSWERS :

- 1- There are points of legal uncertainty in the Cosmetics Directive that have been considered in the SLIM Report. PROVITAL, S.A. calls the European Commission to take in account firstly the SLIM recommendations which have not been implemented yet.
- 2- Additional points of legal uncertainty are covered by specific Items in the present Consultation.
- 3- Apart from these points, the Cosmetics Directive is well known and understood by PROVITAL, S.A. in terms of spirit and provisions.
- 4- The present Consultation introduces new points of legal uncertainty that could make the Cosmetics Directive more difficult to understand and to implement. Such new points of legal uncertainty will be discussed Item by Item.
- 5- Any new regulation can constitute the risk of additional costs for companies when they have to understand it before to implement it. Such costs cannot be easily quantified, but are significant, especially in SMEs that cannot have a dedicated regulatory structure : permanent review of the regulation when facing evolutions of the market involves a significant amount of man-hours in various sections of the companies.
- 6- Within such a framework, PROVITAL, S.A. considers that clarification on identified points of uncertainty is useful if easily applicable by all types of companies, including SMEs.
- 7- More generally, PROVITAL, S.A. considers that clarification of elements of legal uncertainty can be obtained better by using tools like co-regulation, self-regulation, voluntary sectorial agreements and open cooperation and coordination between the regulatory Bodies and the industry than by additional regulations that can ever introduce more complexity.

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 European businesses ?

ANSWERS :

- 1- The European cosmetics regulation has the unique characteristic to conciliate stimulation of innovation and consumers safety. It enabled the development in Europe, upstream the cosmetic industry itself, of a strong sector of innovative companies, mainly SMEs, which are creating permanently new ingredients and new techniques and export them worldwide.
- 2- As a consequence, the European Cosmetics Directive is considered as a model which strongly contributed to the international alignment of the cosmetics regulations. This brought savings and businesses opportunities to European industries.
- 3- Some provisions of the 7th Amendment started creating distortions and confusion in this precious process of alignment as well as additional costs for the European industries.
- 4- New significant modifications in the Cosmetics Directive could enlarge the gap so created and spoil the process towards alignment which benefit to the European industries.
- 5- PROVITAL, S.A. considers that the European Commission, the European Parliament and the Council of Ministers should take strong account of this international dimension of the cosmetic industries and markets so as to avoid spoiling the competitiveness of European industries.

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 ?

ANSWERS :

- 1- National transpositions of European Directives may induce from one country to the other legal distortions which can increase legal uncertainty and unequal implementations in the countries of the EU.
- 2- PROVITAL, S.A. is favourable to turn the whole Cosmetics Directive into a Regulation, provided the Regulation :
 - respects the main principles and the spirit of the Cosmetics Directive 76/768/EEC,
 - is simplified mainly in accordance with the conclusions of the SLIM Report and clarifies points of legal uncertainty,
 - represents a progress in terms of consumers safety,
 - continues to make the European cosmetics legislation a model for other countries or areas worldwide so contributing to international harmonization of the cosmetics regulations,
 - does not alter the competitiveness of the European industry, including SMEs, by reducing its possibilities to innovate.
 - is prepared through a consensual cooperation with the industry so as to take in account its realities
- 3- They especially call for sufficient and adapted time given to the industry for implementation of the regulation.

Item 4 :

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

ANSWERS :

- 1- PROVITAL, S.A. is in favour of the introduction in the European Cosmetics Directive of a set of definitions which clarify the meaning of essential notions, unitize their understanding and avoid inadequate interpretations.
- 2- PROVITAL, S.A. also recommends that such definitions are harmonized with the ones already existing in other regulations or systems.
- 3- PROVITAL, S.A. is ready to cooperate to the creation of definitions that are related to the specialities of its members.

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.

ANSWERS :

- 1- The current concept of positive lists for specific categories of substances is one of the main pillars of the European cosmetic legislation.
- 2- It is clear and well understood by all stakeholders and contributes to the potential of innovation of the European industry.
- 3- It has been adopted as a progress by other countries and areas in the world within the framework of international alignment for harmonization of cosmetic regulations.
- 4- Moreover the replacement of the intention of the cosmetic manufacturer by a reference to properties of substances would be useless, confusing and limiting creativity and innovation :
 - Properties and technical characteristics of substances are already considered in the current process of entry in the positive lists,
 - There are many substances having multifunctional properties and their classification in one positive list according to one of their properties would make impossible to use them for their other functionalities.

The intention of the cosmetic manufacturer is consequently the clearest and most adapted reference.

- 5- Consequently, the current system of positive lists should be maintained as it is.
- 6- PROVITAL, S.A. considers however that while maintaining the current system of positive list it should be possible to improve it through :
 - Introduction in the European Cosmetics Directive of the recommendations related to Annexes made in the SLIM report and especially :
 - Correspondence tables between all annexes enabling to identify easily the substances,
 - Cross references when some ingredient is listed in several annexes.
 - Better transparency and improved time management in the process for addition of new substances in the positive lists especially through an extended cooperation between regulatory bodies and industry.

Item 6 :

An alternative approach could be to establish a single list of all regulated substances. With regards 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 a product containing these substances ? What would be the socio-economic impacts of this envisaged change ? Are there alternative approaches to consider ?

ANSWERS :

- 1- Answers concerning Item 5 are also valid for this Item 6.
- 2- Mixing all positive lists of regulated substances in one single list would not bring any simplification, advantage or progress but could create significant confusion for all users.
- 3- It has been demonstrated that in countries where such a mixed single list is in force it is not easy to interpret and use.
- 4- Such a mix of current positive lists would consist of a step back in terms of clarity.

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 envisager change ? Are there alternative approaches to consider ?

ANSWERS :

- 1- The legislative procedure governing the revision of the European cosmetic Inventory constitutes one of the weakest aspects of the European Cosmetics Directive. It does not ease innovation in the field of ingredients.
- 2- PROVITAL, S.A. strongly supports a more flexible mandate given to the Commission with the aim to establish and update a publicly-available European inventory of cosmetic ingredients and reminds that the SLIM recommendations in this field can be taken in account.
- 3- PROVITAL, S.A. is ready to cooperate to the establishment and updating of this new European Inventory of Cosmetic Ingredients in the fields of its competency, especially in the one of Botanically-derived ingredients.

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.

ANSWER :

This Item does not concern directly to PROVITAL, S.A.

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 file today ? Would this mean an increase in information as compared to today ? What would be the socio-economic impacts of these envisaged changes ?

ANSWERS :

- 1- The SCCP guidelines for safety evaluation of cosmetic ingredients already specify the extent and the content of the information to be made available in the cosmetic product information file.
- 2- The provisions of the REACH European Regulation, which primarily concern labour and environment safety but can contribute to consumer safety assessment, will be compulsory for all cosmetic ingredients suppliers so have not to be introduced in the European Cosmetics Directive. The recommendation made in the SLIM report concerning environmental effects of cosmetic ingredients become useless since the REACH Regulation includes it.
- 3- Within the framework of the implementation of the REACH Regulation, PROVITAL, S.A. considers that our primary responsibility is to supply documented characterization of the ingredients and adapted safety data resulting from their conformity to the REACH provisions.
- 4- Apart from this already enforced improvement, PROVITAL, S.A. considers that progress in the field of safety assessment can be reached through :
 - the clear confirmation of the importance of the distinction between hazard and risk,
 - the introduction in all phases of safety assessment of the principle of a case by case reasoned argument based upon the characterization of each ingredient instead of a check-box systematic approach.
 - the improvement of the definition, role and qualification of safety assessors.
- 5- PROVITAL, S.A. is ready to contribute to the introduction of these progresses in the Cosmetics Directive or in dedicated guidelines in their specific field of expertise.

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 in-market control took place.

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

ANSWER :

This Item does not concern directly to PROVITAL, S.A.

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 ?

ANSWERS :

- 1- PROVITAL, S.A. supports the introduction in the European Cosmetics Directive of a mandate to the Commission to coordinate cooperation between Members States in the field of cosmetovigilance.
- 2- PROVITAL, S.A. considers that such a mandate would have to target an harmonized system across the EU, based upon :
 - a clear and well defined objective,
 - a single model involving standardized relevant data,
 - common definitions and common tools.
- 3- PROVITAL, S.A. recommends that relevant data on cosmetovigilance are made freely and easily available for all stakeholders including :
 - cosmetic ingredients manufacturers so as to enable them taking such data in account when managing their activities,
 - independent companies involved in the safety assessment of cosmetic products and cosmetic ingredients which are primarily concerned.

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 ?**

ANSWER :

This Item does not concern directly to PROVITAL, S.A.

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 the assessment they should refer the matter to the Commission (including SCCP).

ANSWERS :

- 1- It is reminded that SCCP guidelines clearly stated that only the groups of substances listed in the annexes of the Cosmetics Directive are the responsibility of SCCP in terms of safety assessment.
- 2- PROVITAL, S.A. does not see inconvenience in an evolution of the current mechanism of ingredients review at European level.
- 3- However, PROVITAL, S.A. considers that possible modifications :
 - should have to take in account the PROVITAL, S.A. answers made for Items 9 and 17,
 - should not be such that it could lead to conclusions about use of an ingredient that would be wider than the use which is at the origin of the review.
- 4- PROVITAL, S.A. also considers that ingredients' review has to be made through a synergetic cooperation between competent authorities and the concerned industries so as to enable the best collection of knowledge about the concerned substances.

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 socio-economic impact of these additional regulatory tools ?

ANSWERS :

- 1- The European Cosmetic Directive already constitutes already a clear and well understood tool for ensuring the safety assessment of cosmetic ingredients and cosmetic products, including the numerous new innovative ingredients that have been introduced for long years.
- 2- The REACH Regulation is a new tool which will indirectly enhance the approach of ingredients safety.
- 3- There is no need for additional regulatory tools required in order to ensure this safety.
- 4- The approach of an improved safety of cosmetic ingredients including new innovations can be reached only with adapted modifications such as the ones recommended in the present position – see Items 9 and 13 – with the aim to increase the efficiency in implementation of the current European Cosmetics Directive

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 ?

ANSWERS :

- 1- The necessity of protection of consumer safety is already clearly defined in Article 2 of the European Cosmetics Directive. It is well understood by all stakeholders.
- 2- Consumer safety is consumer safety and cannot be qualified : the introduction of a new legal term qualifying consumer safety - “ uncompromised safety” or another term – would bring new risks of interpretation and consequently new legal uncertainty.
- 3- Consumer safety cannot be improved by a legal term :
 - Ingredients with risks are already considered through positive lists,
 - There is already a mechanism of ingredients review at EU level,
 - Long years of implementation shown that consumer safety has been the permanent challenge of all stakeholders.
- 4- Consumer safety can be improved again thanks to better efficiency in the implementation of the existing legal framework through recommendations included in Items 9, 13 and 14.

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 safety of products ? Do you think this clarification would have a socio-economic impact ? How ?

ANSWERS :

- 1- The European Cosmetics Directive already provides strict requirements for safety assessment of cosmetic products before marketing. Such requirements include the safety assessment of cosmetic ingredients.
- 2- Improvement can be reached through adoption of recommendations made in answers to Items 9, 13, 14 and 15.
- 3- The concept according which if data are missing the substance in question would be presumed unsafe is an extreme, unjustified and useless interpretation of the principle of precaution.
- 4- Such a concept could mean that very numerous ingredients, especially ingredients from natural origin, used for decades without any problem, would become considered as unsafe just because data are missing due to their very ancient origin and use. As a consequence it would have enormous socio-economic impacts : many interesting ingredients could disappear and many European SMEs specialized in this type of ingredients would be endangered.
- 5- Such a concept is also going against basic principles of safety assessment :
 - distinction between hazard and risk according to exposure,
 - responsibility and competency of safety assessors.
- 6- Moreover, it would go against the progress in safety assessment by promoting the concept of check-box instead of the case by case reasoned safety assessment as it is strongly recommended through answers to Item 9.

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 ?

ANSWERS :

- 1- Generalization of positive lists until the point where only substances that have undergone a safety assessment by the SCCP can be used as ingredients in cosmetics is against the spirit and major principles of the European cosmetics legislation and especially against the principle of responsibility of the person placing the cosmetic product on the market.
- 2- Such a provision would constitute a drastic step back towards the past and would make the Commission and the SCCP fully responsible of consumer safety.
- 3- It would have a very serious impact on the quest for international alignment of cosmetics legislations by creating in the EU a legislative system that have been cancelled in many countries or areas under the pressure of the EU itself.
- 4- Moreover, it would not provide progress in safety assessment : if concerns raise about a new specific group of ingredients, there is already in the European Cosmetics Directive a mechanism for creation of new specific positive lists when deemed necessary.
- 5- PROVITAL, S.A. is fully opposed to such a provision which would block all possibility of innovation en would endangered many SMEs in Europe.

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 ?

ANSWERS :

- 1- Within the framework of the current European Cosmetics Directive, re-evaluation of substances included in positive lists can be decided at any time.
- 2- PROVITAL, S.A. considers that there is no need for another or a more systematic mechanism : more systematic re-evaluation could lead to useless work and expenses and could be inefficient as the re-evaluation could be made in undue time in terms of available data.
- 3- PROVITAL, S.A. recommends that re-evaluation of ingredients listed in positives lists is engaged only when new relevant data that could affect the previous safety assessment become available.

CONCLUSION

The present consultation includes very interesting proposals which could enable a significant improvement of the European Cosmetics Directive or Regulation and its efficiency while keeping its spirit and principles.

PROVITAL, S.A. supports such proposals, as it is confirmed by its answers, comments and recommendation and makes recommendations aiming to make progresses especially in the field of safety assessment.

PROVITAL, S.A. is ready to contribute to their finalization.

However, the present consultation also includes envisaged provisions that would drastically spoil the European cosmetics legislation while drawing it back to the past, creating a strong confusion at the international level and endangering the European cosmetic industry and its whole supply chain.

PROVITAL, S.A. is clearly opposed to such provisions and especially to Items 5, 6, 14, 15, 16, 17 and 18.