March 16, 2007

To: European Commission  
Unit ENTR F/3, Cosmetics and Medical Devices

Subject: EU Public Consultation on the Simplification of the Cosmetics Directive

Dear Sirs:

On behalf of the U.S. Cosmetic, Toiletry and Fragrance Association, we are pleased to submit the following comments in response to the EU Public Consultation on the Simplification of the Cosmetics Directive.

Sincerely,

Francine Lamoriello  
Executive Vice President  
Global Strategies
On behalf of the United States Cosmetic, Toiletry and Fragrance Association (CTFA), we are pleased to submit the following comments in response to the EU Commission’s public consultation on the simplification of the Cosmetics Directive 76/768/EEC.

CTFA is the national trade association representing the U.S. cosmetics and personal care industry. CTFA has over 600 member companies, including manufacturers and distributors of finished products, as well as suppliers of ingredients, raw materials, packaging, and other services used in the production and marketing of finished products.

CTFA members include companies headquartered in the United States, Europe and other countries, and represent the vast majority of cosmetic and personal care product sales in the United States. The European Union is one of the largest markets for U.S. cosmetics products. In 2006, U.S. exports of cosmetics and personal care products to the EU approached $2 billion.

CTFA commends the EU Commission for undertaking this important work to simplify the EU Cosmetics Directive. We welcome the opportunity to participate in the public consultation process, and look forward to ongoing dialogue on trade and regulatory developments affecting our industry.

Part I: General Comments:

Cosmetics products marketed in Europe, the United States and other major markets have a strong record of safety that derives from several fundamental principles.

First, the foundation of product and ingredient safety rests on the effective integration of sound science into industry and regulatory decision-making. Regulatory authorities must have available the necessary information to allow informed decisions. The scientific information that is the basis for making far-reaching regulatory decisions must be available and assessed in an open, transparent and objective manner to ensure that the best science available is applied to the issue.

Second, in the United States, Europe and other major jurisdictions, manufacturers have the primary responsibility for placing safe products on the market. Industry commits significant resources to research and development, safety and testing, and regulatory compliance, to assure that products meet the needs and expectations of consumers and government authorities.
Finally, appropriate regulatory authority and oversight ensure effective in-market controls that provide consumers with a high level of confidence about the safety of their products.

This close partnership between industry, regulatory authorities, and scientific experts has worked to achieve a high degree of safety and has allowed the development of a vibrant and competitive industry.

The cosmetics industry and corresponding markets are truly global in nature. As with virtually all products today, the manufacturing and marketing of cosmetics is done on a global basis. Ingredients are obtained from sources all over the world and product research and development may take place in a country different from where it will be marketed.

Similar to product manufacturing, finished products, or components of finished products, may be produced and packaged and then shipped to other parts of the world. Consumers purchase from a world market through their travel to other countries, purchases through world-wide e-commerce and imports. The reality of the global market offers great challenges and opportunities for consumers, regulatory authorities and manufacturers. CTFA strongly supports international alignment of regulations as the most effective means to assure global standards for consumer safety and to support a vital and competitive cosmetics industry.

We believe that the EU Commission’s initiative to consider ways to simplify the EU Cosmetics Directive represents a unique opportunity to explore new approaches in the context of international alignment. In that regard, we offer the following comments on issues we believe are of particular importance. These are followed by responses to specific questions posed in the consultation document.

1) Scientific Consultation:

In the European Union, as in other parts of the world, the process of informed decision-making through sound and objective scientific opinion plays a critical role. Expert advisory panels both in the United States and Europe are a valued and important part of the process. The value of these programs is directly linked to the actual procedures and processes that are followed by the expert panels and committees. In order to work effectively, the expert committee must follow well defined procedures, apply predictable steps and allow ample opportunity for stakeholder participation.

The Scientific Committee on Cosmetic Products (SCCP) is the primary resource used by the European Commission (EC) in obtaining scientific opinion on the safety of ingredients. Moreover, the impact of the opinions issued by the SCCP extends beyond Europe as a result of global product formulation by industry and regulatory developments in other countries that adopt EU models.
Consequently, all stakeholders, including companies located in the United States, have a direct interest in the manner in which requests for opinions are referred to the SCCP and the identification of data needs, the collection of data, conduct of evaluations and resulting conclusions and opinions that are issued for implementation by the EC.

We believe that the EU Commission’s deliberations on the simplification of the Cosmetics Directive offer an opportunity to improve the SCCP process in ways that would contribute to greater efficiency and transparency.

The questions posed to the SCCP may be quite complex and most often rely on data provided by multiple stakeholders. Cosmetic ingredient suppliers and cosmetics companies are critical participants that contribute or develop toxicological and other data for the SCCP review and analysis. The factor that characterizes most scientific review programs is a clear understanding, by all parties, of the question to be addressed, the data required/expected for the review and the transparency of deliberations of the committee. With complex questions, the required data may not be immediately available and may change as the assessment progresses. For this reason, effective and open communication between the expert committee and stakeholders is essential to ensuring that all data needs are identified and discussed so that the appropriate data is generated in a timely manner. This includes consideration of any new and/or historical data. Effective and open communication is also essential to ensuring that there is robust discussion of scientific principles and interpretation; and the scientific basis for decisions are reviewed.

As the EU Commission considers changes to the EU Cosmetics Directive, CTFA strongly encourages the implementation of a process that ensures a high level of transparency for the deliberations of the SCCP, more effective communication with stakeholders and consideration of the impact of the program both within the EU and in other jurisdictions.

We would be pleased to discuss the specific details of our concerns and approaches to meet these important goals.

2) Assessment of Ingredient Safety

In the assessment of the safety of cosmetics products and ingredients, the identity of an ingredient, the manner in which the ingredient is used (product type and amount) and the scientific information available to describe safety are all necessary. There is a well-established scientific process that allows the safety of the use of an ingredient to be measured taking into account the conditions of use. When applied, the toxicological considerations that an ingredient might possess can be used to assess risk under conditions of use through the process of risk assessment.

In the 7th Amendment to the Cosmetics Directive, the European Union established a signification deviation from the scientifically-accepted process of hazard and risk assessment. Specifically, the 7th Amendment imposed a requirement that certain
ingredients be prohibited from use in cosmetics based solely on their hazard classification in the Dangerous Substances Directive. Under this system, the Carcinogen, Mutagen and Reproductive Toxicant (CMR) classification system automatically bans Category 1 and 2 ingredients without opportunity to consider or assess the risks associated with the level or percentage of the ingredient, the route of administration, the conditions of use, or indicated directions or warnings. This departure from accepted scientific principles is significantly out of step with regulatory treatment in other countries of the world, inconsistent with other EU legal and regulatory requirements, and, inevitably, leads to inconsistent results.

Making public health decisions based solely on hazard information results in anomalous findings that are sometimes even counter to the opinion of the SCCP. CTFA recommends that the Cosmetics Directive be amended to allow the SCCP, or other authoritative body, to consider available data on conditions of use and risk assessment. For example, the Cosmetics Directive could be amended (or associated guidelines established) to allow industry to present scientific data about the ingredient’s use in particular cosmetic products, and with a corresponding “burden of proof” of safety.

3) Requirements for Alternative Methods

While we note that the present consultation process is not intended to address the issue of rules relating to animal testing, we believe it is important to comment on certain aspects that are relevant to these deliberations.

As events over the last several years have demonstrated, the cosmetics industry and other stakeholders are committed to the development of alternatives to animal testing. Considerable advancements have been achieved as a result of strong investment in scientific research, and ongoing industry collaboration. At the same time, we recognize that the current scientific and legal paradigm is such that safety assurance is still explicitly linked to the use of animal-based toxicological tests to characterize the safety of ingredients used in products. For example, guidance is provided by the European Commission's Scientific Committee on Consumer Products (SCCP) on the use of animal-based toxicological tests to ensure the safety of cosmetics ingredients. Moreover, international markets may require adherence to specific methods to substantiate safety of cosmetics products and raw materials exported from the EU.

The lack of international consensus or alignment around the EU approach highlights the complexity of the issue. We are especially concerned that the EU requirements related to animal testing will result in new barriers and disruption of trade flows between the United States and Europe.

Within this context, we consider that the EU Commission has a duty to balance a number of factors. These include creating and maintaining an environment that will empower all manufacturers and importers of cosmetics onto the Community market to be able to assure the safety of their products, while managing the needs of animal welfare, and at the same time remaining cognizant of international requirements and the impact of EU
requirements on international trade. We encourage ongoing dialogue between the Commission and U.S. and other regulators on this important matter.

4) **Structure, Organization and Content of the Annexes to the Cosmetics Directive**

Questions concerning the organization, structure and content of annexes to the Cosmetics Directive are mentioned in several parts of the EU Public Consultation Paper. The annexes are important elements of the European cosmetics regulatory scheme and serve to provide necessary information and guidance for cosmetics manufacturers and the public.

Regulatory systems in other jurisdictions, including in the United States and Japan, incorporate structures similar to the Cosmetic Directive annexes into their regulatory programs. This shared structure serves to reinforce the importance of clear communication concerning the use or prohibition of ingredients in cosmetics. For example, in the United States, the OTC drug monograph for sunscreen drug products serves a function similar to annex VII for UV filters. A similar “positive” list exists in Japan.

CTFA strongly supports the current overall structure and organization of the annexes to the Cosmetics Directive in which the annexes are aligned with ingredient function and separate annexes identify ingredients that are banned or restricted. Consolidation of annexes will not improve clarity and may lead to misunderstanding about the use of ingredients for certain functions.

The European Commission can, through existing procedures, add new annexes or modify existing annexes. The development of specific annexes for specific purposes, such as color additives, preservatives and UV filters is a logical and well established mechanism for overseeing the safety of cosmetics.

In most cases, the ingredients that are included on a list/annex have a clear relationship to the formulation of cosmetics or controls necessary to ensure the safe use of ingredients and the formulation of products. However, the content of Annex II is a clear exception. Annex II is a list of substances which must not form part of the composition of cosmetics products. Currently, the list has over 1200 substances, and additional materials are added periodically. A comparison of the entries in Annex II with the dictionary of International Nomenclature Cosmetic Ingredients (INCI) names shows that only about 25% of those listed in Annex II have INCI names. This indicates that most of the substances included in Annex II are not used in finished cosmetic products, and historically were not likely to have been used in finished products. The inclusion of these ingredients in Annex II is thus clearly confusing, if not misleading, to cosmetics manufacturers, other regulatory authorities and the public.

CTFA strongly recommends that the information in Annex II be restructured and/or reorganized to reflect ingredients that are clearly relevant to cosmetic ingredients and products. It is further suggested that the remaining entries include:
• The International Nomenclature for Cosmetic Ingredients (INCI) name, where appropriate;
• The European Pharmocopoeia name, where appropriate; and
• The C.A.S. number.
• The source of the listing (CMR Classification, SCCP opinion, etc), and
• Date added to the list.

In addition to the comments above, we encourage the Commission to reiterate the principle that, notwithstanding the fact that ingredients included in Annex II are banned from use in cosmetics products, technically unavoidable trace levels of a banned substance in a raw material or finished product may exist. In these cases, a risk assessment of the traces and impurities can be confidently applied to assure that there is no risk to human health when applied under normal or reasonably foreseeable conditions of use. The criteria for determining acceptable levels of trace materials should be based on risk assessment principles that take into account risk and attainable levels and that are clearly and openly communicated for application throughout all Member States.

Reinforcement of this principle by the Commission would be helpful for consumers to better understand these concepts and to be better able to interpret information received through public media.

Part II: Responses to Specific Questions:

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

CTFA appreciates the Commission’s request for comment on elements of the Cosmetics Directive that give rise to legal uncertainty, and we suggest in our comments below a number of specific areas requiring more clarity. We would appreciate the opportunity to continue to examine this issue and to provide additional comment in light of any proposed revisions to the Cosmetics Directive.

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?

CTFA fully supports efforts toward international harmonization and alignment and references the recent agreement by the cosmetics industries of Japan, Europe, Canada and the United States to propose a new industry-regulators dialogue, the International
Cosmetics Alignment Process (ICAP). This initiative, which is modeled on efforts already established for drugs and medical devices, is an important and historical step that, for the first time, will bring together industry and government officials from these four jurisdictions, advancing the interests of all participants. The alignment of international policies, guidelines and regulations that are the goals of ICAP will contribute to safety of cosmetics products worldwide, and provide opportunities for more efficient global product development and marketing that will promote consumer safety and enhance the competitiveness of the worldwide cosmetics industry. CTFA looks forward to working with our European partners through this new program.

In addition to participating in the ICAP, CTFA urges the EU Commission to consider any proposed changes to its Cosmetics Directive within the context of international alignment and impacts on international trade and the EU’s obligations under the WTO, especially as relates to agreements on technical barriers to trade, and sanitary and phytosanitary measures.

In this regard, CTFA hopes that the EU Commission will continue to offer meaningful and timely opportunities for dialogue and comment by U.S. and other international trading partners on proposed revisions to the EU Cosmetics Directive and other related measures.

**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?

From its inception, the Cosmetics Directive has sought to establish a framework for the sale of cosmetics products and ensure a high level of protection to European consumers. One of its key features has been a commitment to fully harmonized rules for the labeling, composition and packaging of finished cosmetic products for the benefit of both industry and European consumers.

CTFA believes that a Regulation, instead of a Directive, would be a more effective legislative tool to achieve these objectives.

The CTFA would like to recommend in particular that:

I. *The revised regulatory framework reinforces the homogeneity of the European market by ensuring the uniform interpretation and enforcement of the EU regulations.*

Despite the high level of harmonization set forth by the Cosmetics Directive, industry still experiences some disharmony in the enforcement of certain provisions. In the CTFA’s opinion, this is due to:
(i) A lack of common understanding and/or definition of concepts that are key for the good functioning of the internal market (e.g. “placing on the market”);

(ii) A lack of clarity as to when the Member States may or may not complement the European provisions by national rules. This is notably the case for the notification provisions of Article 7a (4). On this particular issue, CTFA would like to draw the Commission’s attention to the fact that today imported cosmetic products are not accorded “national treatment” by some EU Member States.

(iii) A lack of public record of certain interpretative positions agreed among the Commission and the Member States, notably at the time of the 6th Amendment. CTFA believes that the practice of interpretative guidelines developed by the Commission following the adoption of the 7th Amendment is a useful tool which may contribute effectively to the uniform enforcement of European rules and ensure a level playing field for companies within the European Union.

II. The evaluation and regulation of cosmetics ingredients remains centralized at the European level and includes an impact assessment process.

While there is no question that the decision-making process for the regulation of ingredients must primarily aim at addressing safety issues, the economic impact of any new regulations, including the impact of the timing of implementation of any new regulation, must also be considered. The urgency of implementation should be proportional to the degree of concern associated with the underlying safety issue.

It is our understanding that the current EU legislative framework does not explicitly require the systematic performance of a business impact assessment for the regulation of cosmetic ingredients, although it should be acknowledged that internet consultations by the European Commission are increasingly becoming common practice.

More specifically, CTFA would like to stress that today industry is not systematically consulted on the timeline for the implementation and enforcement of a new ingredient regulation. However, except when the ingredient concerned is not used by industry, this is a field of regulation which generally has a significant impact on companies and raw material suppliers. Practically, the time needed by companies to implement these new regulatory requirements will vary depending on a series of factors, including the availability of alternatives and the number of products concerned. The time allowed for implementation should, except in the case of potentially serious health consequences, be set to cover at a minimum the time that is necessary to complete any necessary reformulations, safety assessments of new formulas, changes to packaging and labeling, and placing the product in the marketplace.

CTFA believes that the revised EU regulatory framework should take these considerations into account and result in an improvement to the current decision-
making processes. Our experience is that from time to time impact assessments are carried out at national level by the EU member states only after new legislation is formally adopted by the Commission. In our opinion, such process should rather take place at EU level before a mandatory decision is enacted.

1.2 Introducing a set of definitions

Item 4 considered by the Commission and submitted for public consultation: Which terms would need to be included in a set of definitions in order to make the Cosmetics Directive clearer?

CTFA agrees that there are a number of cases where terms and phrases used in the Cosmetics Directive should be defined in order to provide clarity to industry and harmonization of interpretation by member state authorities. Some initial examples where definitions should be clarified include the terms “placing on the market,” and, “person responsible for placing a product on the market.” CTFA is continuing to evaluate this question and would like to forward additional suggestions in future.

Previous EU guidance documents note that the concept of “placing on the market” refers to the first time a product is put on the Community market, and this should likewise be followed with regard to cosmetics products.

“Person responsible for placing a product on the market” should be defined as “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,” as was proposed by the SLIM-V Team reviewing EU cosmetics legislation.

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.

CTFA believes that the EU’s current approach on substance regulation, which presents reviewed and accepted materials in terms of their usual function in a cosmetic product, is appropriate, and should be maintained.

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 the envisaged change? Are there alternative approaches to consider?

CTFA notes that the present set of negative (Annex II), restrictive (Annex III) and positive lists (Annexes IV, VI and VII) may lead to some confusion, as the same ingredient may be found in more than one annex and many ingredients in Annex II are not relevant to the formulation of cosmetic products.

As noted in our opening remarks, Annex II as currently constituted includes ingredients that have been placed in the “prohibited” status through many routes over a very long period of time. Included in the Annex II list of over 1200 ingredients are those that have been added because of the CMR requirements, those that have been added based on individual assessments by authoritative reviews and others that are present based on historical reasons.

In fact, many of the ingredients listed in Annex II have never been used as cosmetic ingredients and have no history of product formulation. Most of these have arisen due to CMR requirements which resulted in several hundred ingredients being added to the annex because of their status on the Dangerous Substances Directive. The presence of these ingredients on Annex II presents a false impression that these were at one time useful in the formulation of cosmetics and were banned because of public health concerns arising from that use.

There are other ingredients that are included in Annex II arising from other actions besides the CMR requirements that should similarly be assessed and removed from the Annex if they have no history of use as cosmetic ingredients or have no value in the formulation of products.

CTFA recommends that the information in Annex II be restructured and/or reorganized to reflect ingredients that are clearly relevant to cosmetic ingredients and products. Those materials that have no history of use in cosmetics could be placed in a separate annex or identified through guidance. The simplification of Annex II would greatly enhance its use by manufacturers and more accurately reflect the true public health decisions taken by the European Union.

(2) The annexes to the Cosmetics Directive that describe the use of certain ingredients for defined purposes in a cosmetic product (as defined in Europe) should be retained and not consolidated into a single annex. For example, the ingredients listed in Annex VI for use as preservatives and in Annex VII as sunscreen ingredients should be retained. These functional ingredients are used for specific purposes in products and manufacturers must have a clear and easy reference that defines their conditions for use for that function. The use of separate annexes provides a clear focus whenever there is interest in adding new
ingredients for that function or to alter the existing conditions of use for a specific purpose.

It should be noted that the use of an ingredient for a functional purpose, such as a sunscreen ingredient to protect users of the product from the adverse effects of UV radiation, does not preclude the use of the ingredient for other purposes. It is well known that sunscreen ingredients can also be used to protect a product from degradation by UV radiation or to protect the color of the hair (or hair coloring) from fading caused by sunlight. Similarly, antimicrobial ingredients can be used to protect the product from adverse effects caused by microorganisms or to serve as an antimicrobial ingredient to minimize odor or help to inhibit the growth of bacteria.

Annex IV, which describes the list of color additives approved for use in cosmetics in the European Union, should also be retained as the defined repository for such ingredients. Typically, the color additives provide a specific functional purpose in a cosmetic product.

CTFA believes that the current format of the annexes should be retained as the most effective way to communicate to the user which ingredients are suitable for specific purposes and which may be banned or otherwise restricted. It may be possible to improve the organization of the various annexes or to more clearly define the scope of the listing in an annex. Perhaps a user’s cross reference could be prepared by the European Commission or the industry to supplement the current annexes.

Given the complexity of this issue, CTFA suggests there be further dialogue between industry and the Commission on this question.

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

CTFA strongly supports the continued use of the International Cosmetic Ingredient Dictionary (ICID) as the definitive source for cosmetic ingredient names for purposes of label declarations. The ICID is the primary reference world-wide for INCI names for cosmetic ingredients and CTFA supplies considerable resources and oversight to ensure that the process for establishment of ingredient names is transparent and technically sound and consistent with the nomenclature rules established by the Ingredient Nomenclature Committee. The International Nomenclature Committee meetings include participation by the U.S. Food and Drug Administration, the European Commission and authorities in Japan as well as representatives from the respective trade associations.

CTFA believes that the Commission should periodically update the ingredients inventory using the information supplied by CTFA and that the Commission should publish this on its website. The existing dynamic link to the International Nomenclature Committee is
advantageous and the ingredient inventory should remain the indicative list of the substances that may be used in cosmetic products.

For ingredients used in cosmetics products, the following information should be included in the Cosmetics Inventory:
- The International Nomenclature for Cosmetic Ingredients (INCI) name;
- The European Pharmacopoeia name, where appropriate;
- The E.I.N.E.C.S./E.L.I.N.C.S. number, where appropriate;
- The C.A.S. number;
- The usual function(s) of the ingredient in the final product;
- Reference to the appropriate annex for restrictions and conditions of use and warnings that may required on the label, where appropriate.

**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.

CTFA considers that the obligations of the person responsible for placing products on the Community market are understood. However, we would not be opposed to further clarifying statements, such as has been previously recommended in the SLIM-V report, noting that the person responsible for placing cosmetics products onto the EU market must assure compliance with relevant EU legislation.

**Item 9 considered by the Commission and submitted for public consultation:** The Cosmetics Directive could specify clearly the information to be made available in the product information file requested via in-market controls to prove the safety of the product. The extent and content of the information required could be based on:
- the SCCP guidelines for safety evaluation of cosmetic ingredients; and/or
- the “technical dossier” and “chemical safety report” requirements in the REACH Regulation 1907/2006 as far as human health risks are concerned.

Which concrete information (including safety data) would the product information file need to contain to allow for more efficient in-market controls of the safety of the products/their substances? How does this information compare with what is usually available in product information files today? Would this mean an increase in information as compared to today? What would be the socio-economic impacts of these envisaged changes?

Both the U.S. and EU approaches to regulation of cosmetics give industry ultimate responsibility for assuring the safety of cosmetic ingredients and products placed on the market. In both systems, the law sets broad standards that must be met regarding safety in the market place and provides authorities with the tools necessary to ensure these conditions are achieved.
The EU Cosmetics Directive distinguishes two different aspects of safety assessment which are based on different legal provisions with different primary objectives and approaches:

- Product safety assessments which are the main responsibility of the industry
- Substance evaluations for the purpose of listing in the Annexes of the Cosmetics Directive under the responsibility of the European Commission.

In describing the criteria for accomplishing these different goals, the basic legal structure defines the fundamental criteria. Specific details describing approaches to meeting these requirements are noted in guidelines and/or regulations issued under the authority of the law.

It is especially important for the cosmetics sector to have the flexibility to apply the general framework to the specific manufacturing and product situation. For example, the assessment of the safety for cosmetic products and their ingredients is a more complex process than the simple compilation of a predefined list of toxicological data on ingredients. The nature of data necessary to support the safety assessment of ingredients and combination of ingredients depends on chemical and physical properties, concentration in the finished product, product type, presentation and target population. The nature of the safety assessment may depend on whether or not the company has significant experience with the formulation or similar formulations or the ingredient and/or products are novel. Clearly, the data needs and scope of the safety assessment will be different.

Thus, product safety assessment guidance must go beyond a “check box approach” regarding the ingredient data that needs to be supplied. More detailed guidance has been developed over the past years, both by industry and regulators, to create a common understanding of the practical aspects of cosmetic safety assessment with both industry and control authorities.

We believe that, rather than detailed regulations, a more constructive approach would be for industry to propose more specific guidance for safety assessments appropriate to product information in alignment with the Commission and Member States. Moreover, as noted earlier, industry and regulators are currently considering a new process (ICAP) to foster regulatory alignment among the major jurisdictions. The proposed agenda for this important initiative includes discussion of safety assessment approaches and guidelines with a goal of achieving alignment to the fullest degree possible. The legal framework developed in the simplification of the Cosmetics Directive should provide a structure that will support such alignment.

In addition to these comments, we would like to note that some confusion seems to remain 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).
Product safety assessment (which is relevant to the issues discussed in Item 13) 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, which defines in general terms that the product risk assessment is based on the toxicological profile of the ingredients 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. As REACH has a very different scope than the specific product safety assessments required by the Cosmetics Directive, document requirements are also different.

The review of ingredients under the Cosmetics Directive rests on 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.

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 7th Amendment.

Item 10 considered by the Commission and submitted for public consultation:
The Cosmetics Directive could provide for clear response mechanisms in the event of noncompliance with the Directive (including rules on product withdrawal). In addition, the Cosmetics Directive could contain rules on the procedure which would apply for the cases where the product information file is available in another Member State than the one where the in-market control took place. What is your view on this? What would be the socio-economic impact of such an envisaged mechanism?

CTFA considers that the current legal system adequately addresses this issue. We agree that the system is dependent on effective communication and collaboration between member state authorities.

Item 11 considered by the Commission and submitted for public consultation:
The Cosmetics Directive could include a mandate for the Commission to assist in coordinating cooperation between the Member States in the field of
“cosmetovigilance”. What is your view on this? How would this information flow need to be organized to ensure an efficient surveillance of the safety of the products? What would be the socio-economic impact?

In principle, we welcome the involvement of the Commission in assisting co-operation between Member States who have the primary responsibility for cosmetovigilance efforts. This would lead to more consistency of approach (i.e. a single system), drive communication between authorities and lead to a better opportunity to view issues in the context of the entire Community market.

Industry would welcome the opportunity to work with the Commission and Member States on development of any “cosmetovigilance” process.

We believe that an efficient post market surveillance of cosmetics product safety should be based on active reporting of Serious Undesirable Events. The details of any such system should be the result of a targeted and collaborative discussion involving all key stakeholders, chaired by the Commission. However, we would stress that any system of “cosmetovigilance” must be harmonized across the EU, with balanced roles and responsibilities between the cosmetics industry, health professionals, member state health authorities and the Commission.

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

We would note that the European industry association 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 believe that this guideline should be taken into consideration.

The procedures for implementing a harmonized EU wide model of “cosmetovigilance” (i.e. fields of application, roles and responsibilities, definitions of Serious Undesirable Events, and 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 serious undesirable effects of cosmetic products in Europe in order to protect public health (ResAP(2006)1).

**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?
CTFA agrees that an EU-wide notification system could be a more efficient, and effective system, and that provisions for electronic notification may be advantageous. However, we would stress the need for any EU-wide notification to remain a simple process, with the same information requirements as in the existing system.
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).

As mentioned above in the discussion of approaches to scientific consultation, the application of systems that are open, transparent and scientifically sound is of paramount importance for ensuring safety. This principle applies at all levels of regulatory systems worldwide. It is noted that these same criteria apply both at the European Union level as well as in the Member States.

The safety of a cosmetic product, for its intended use and reasonably foreseeable use, is based on the product safety assessment, which is aimed at ensuring that the product in question does not cause damage to human health. Such product assessments are not intended to justify the use of specific ingredients in a wide variety of cosmetic products and therefore will not provide a basis for assessment of the use of a specific ingredient in cosmetics in general.

An inadequate product safety assessment, as determined by Member State in-market controls, can provide the basis for action against a particular product. However, this action should not be interpreted as a determination about safety of the ingredient across a wide range of cosmetic products.

Rather, any questions arising from the broad use of a specific ingredient or about the general safety of an ingredient should be addressed through existing mechanisms at EU and not at the national level. Relegation of such assessments to the Member States would have an obvious potential for complexity arising from differing interpretations, and would undermine the objectives of an internal EU market.

The Commission should consider approaches to ensuring that this mechanism works 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 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?

CTFA considers that the EU’s present regulatory approach for safety of cosmetics products and ingredients applies to all relevant products and is sufficiently flexible to take account of ongoing technological advancements. No special or additional regulatory tools are required.
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?

There is no higher priority for the cosmetics industry than its commitment to product
safety. The EU’s present regulatory approach mandates that cosmetics products placed
on the Community market must not cause damage to human health when applied under
normal or reasonably foreseeable conditions of use, taking account, in particular, of the
product’s presentation, its labeling, any instructions for its use and disposal as well as any
other indication or information provided by the manufacturer or his authorized agent or
by any other person responsible for placing the product on the Community market.

CTFA disagrees with the use of the terminology “uncompromised safety”. The term
“uncompromised safety” is exceptionally vague and subject to differing interpretations.
To introduce such a new, ill defined, phrase into the area of consumer products is
unnecessary and would add further confusion rather than clarification.

Indeed, any references to concepts of safety, and in particular the process involved in
achieving it, should communicate clearly that zero risk does not exist for any consumer
products, including cosmetics. This is supported by established concepts in EU
legislation and case law of the European Court of Justice, such as “high level of
consumer protection” and the difference between hazard and risk. These concepts are
further reinforced by the Communication of the Commission on the Precautionary
Principle and the relevant case law of the European Court of Justice.

As partially quoted above, Article 2 of the current legislation clearly lays down the
requirements for safety, and this is supported by existing horizontal measures. Article 2
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.

We have no reason to believe there is widespread misunderstanding of safety
responsibilities under the current phraseology. However, it may be beneficial for the
Commission to clarify the scope of the precautionary principle in order to assist in its
consistent, predictable and reasonable application.

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

- Safety assessment of the cosmetic product and its ingredients or combination of
  ingredients conducted by a qualified safety assessor.

- Reinforcement of the importance of applying risk management measures. These
  measures will usually take the form of warnings and/or instructions for use. In
  conjunction with the full ingredient labeling and information made easily
accessible to the public, this enables individual consumers to make an informed choice.

- A dynamic and collaborative post market 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 sectoral, legislation (General Product Safety Directive)

**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?

As noted above, the EU Cosmetics Directive requires that products placed on the market undergo appropriate safety assessments. CTFA strongly disagrees with the notion that an apparent data gap translate into a conclusion that the product is unsafe. The safety of ingredients and finished products can be addressed effectively by a variety of approaches. The implementation of a “data gap” test implies the use of a checklist approach and invites a subjective determination of what constitutes deviations from the checklist. This would impose an onerous and unnecessary requirement on cosmetics manufacturers that would not enhance consumer safety.

**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?

As noted above, we believe that the existing system for establishing positive lists effectively supports regulatory requirements.

**Item 18 considered by the Commission and submitted for public consultation:** The Cosmetics Directive could provide for a mechanism placing an obligation on the regulator to reconsider the listing of a substance on a “positive list”. What is your view on this? How would this impact on the safety of cosmetic products? What would be the socio-economic impact?

The current Cosmetics Directive allows systematic or case-by-case re-evaluation of substances on positive lists at any time, whether as a result of new safety information or new questions. Regulatory substance (re)-review for substances already on positive lists should be based on new and relevant safety findings that could affect the conclusions of the existing safety assessment and should not be triggered by a simple time limitation.
Any re-evaluation should follow an open, transparent and objective process as has been discussed in the general comments above.