Personal Care Products Council
Committed to Safety, Quality & Innovation

May 10, 2013

Mr. Douglas Bell
Chairman, Trade Policy Staff Committee
Office of the US Trade Representative
Executive Office of the President
600 17th Street NW
Washington, DC 20508

Re: Request for Comments Concerning the Proposed Transatlantic Trade and Investment Partnership, 78 Fed. Reg. 19566 (April 1, 2013)

On behalf of the Personal Care Products Council, we are pleased to submit comments on how the Transatlantic Trade and Investment Partnership (TTIP) can contribute to our industry's goals of providing global consumers with safe, innovative products and expanding international trade and market growth. We believe the TTIP offers a unique opportunity to resolve long-standing regulatory divergences between the United States and the European Union that do not contribute to health and safety, but merely serve as barriers to innovation and trade.

The elimination of regulatory divergences between the United States and the European Union through alignment and mutual recognition of regulations, would significantly reduce industry costs related to formulation, marketing, labeling, and supply chain management, and facilitate market access and trade, especially for small and medium-sized companies. Consumers would enjoy access to a wider array of safe and effective products, and regulators would be positioned to conserve resources for product categories and regions that may pose greater risks to public health and safety.

Greater alignment of US and EU regulations would also facilitate future regulatory cooperation between our two jurisdictions and other countries, and serve as a model for other bilateral and multilateral trade initiatives.

Therefore, we support an ambitious agenda for the TTIP that eliminates existing regulatory barriers for cosmetics and personal care products and also establishes new models for cooperation that will allow US and EU regulators to address emerging science and technological issues affecting our industry with a view toward promoting innovation, and avoiding future regulatory divergences.

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The Cosmetic and Personal Care Products Industry

The Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, our more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. Our members continually strive to uphold and surpass the most stringent regulatory and product integrity standards worldwide.

The cosmetics and personal care products industry is a truly global industry, dependent on open markets and transparent, consistent regulatory environments around the world. International trade is a critical component to the success of our industry, and significantly contributes to our ability to expand manufacturing and employment both here and abroad, and to achieve scientific and technological innovations that benefit consumers around the world.

The US and European industries are highly integrated, with robust trade and investment flows, and enjoying growing markets domestically and abroad. In 2011 the combined US-EU market for cosmetics exceeded $150 billion in retail sales. Two-way trade in cosmetics and personal care products approached $6.5 billion in 2011, with EU exports to the United States of $4.2 billion and US exports to the European Union of $2.2 billion. We believe that achievement of industry's TTIP objectives would create new opportunities for US exporters and could lead to closer trade balance in our sector.

US-EU Regulatory Approaches and Cooperation

In considering industry's objectives for the TTIP, it is important to note that US and EU regulatory approaches toward cosmetics and personal care products are fundamentally similar, assure equally high standards of safety and quality, and, in fact, are aligned on most, but not all, requirements.

In the United States, the Food & Drug Administration (FDA) has long expressed interest in regulatory alignment. FDA's 1995 Policy on International Harmonization (60 FR 53078-53084) described a number of overarching goals, including:

- Facilitate international trade & promote mutual understanding
- Accept equivalent standards, compliance activities and enforcement programs of other countries if such programs meet FDA's level of public health protection.

And, in its 2011 "Global Engagement" strategy, FDA also addresses the importance of harmonizing standards as a way to ensure public health protection. We expect the EU has similar interests and intentions.

Moreover, long-standing, and ongoing, exchanges of information and cooperation between the FDA and the EU Commission, including a *Memorandum of Cooperation*, and participation in fora such as the Cosmetics Harmonization and International

Cooperation (CHIC) meetings and the International Cooperation for Cosmetics Regulation (ICCR) have served to build understanding and confidence in each other's regulatory systems and practices.

These shared interests in regulatory harmonization, joint strategies for global engagement and experience with regulatory cooperation, should facilitate positive outcomes in the TTIP for mutual recognition and acceptance of US and EU standards and regulatory requirements for cosmetics.

Commitment to Good Regulatory Practices

To a large extent, progress in eliminating regulatory barriers in our sector can be achieved by a renewed commitment on both sides to well-established regulatory principles and practices, including:

- Regulatory decision-making grounded in sound science, and risk--not hazard--based principles;
- Transparent regulatory decision-making processes, allowing meaningful participation by stakeholders, and opportunity for scientific/technical dialogue with industry and other stakeholders (for example in FDA rulemaking and reviews by the EU Scientific Committee on Consumer Safety);
- Consideration of costs/benefits of regulatory decisions; alternative regulatory approaches and non-regulatory options;
- Consistency of national regulations and/or enforcement measures with those of sub-national entities (for example to resolve long-standing issues related to differing EU member states interpretation and enforcement of so-called "borderline products.");
- Development and acceptance of international standards.

In addition to changes that would result from renewed commitment to these "best regulatory practices," we request consideration of the following additional specific objectives for the TTIP:

Harmonized Definition of Cosmetics:

The most obvious, and significant, area of divergence between US and EU cosmetic regulations arises from differences in the definition of cosmetic products. In the United States, certain cosmetic products are also regulated as "over the counter (OTC) drugs." These include sunscreens, antiperspirants, anti-dandruff shampoos, and skin protectants.

Such products are inherently low-risk, and are far more like cosmetics than drugs, but nonetheless are subject to burdensome requirements, such as ingredient pre-approval; OTC labeling requirements ("Drug Facts Box"); GMP requirements that are applicable to pharmaceuticals; and other requirements. As a result, products that are marketed in the

European Union as cosmetics cannot be placed on the market in the same way in the United States, adding unnecessary costs and denying consumers access to innovative products..

Therefore, as part of the TTIP negotiation, we seek a harmonization of US and EU definitions of cosmetics, which, in the United States would be adjusted to include "non-dosage" products that are currently considered as OTC drug products.[1]

Mutual Recognition of Cosmetic Ingredients

As noted above, US and EU regulatory systems for cosmetics are fundamentally similar. Neither system requires licensing or pre market approvals, with few exceptions. Both systems use independent expert scientific review for safety assessments and employ in market controls and enforcement. And both systems identify conditions of use for certain ingredients and ban other, harmful, ingredients.

US and EU regulatory systems assure an equivalent high degree of safety and quality for cosmetic products, and the risk of these products to consumer health and safety is acknowledged by both regulators to be very low. Divergent regulations related to the acceptability and conditions of use for certain ingredients do, however, negatively impact industry, consumers and regulators.

Therefore, a key industry objective for the TTIP is the mutual recognition of cosmetic ingredients and conditions of use. In particular, the United States should recognize ingredients and their conditions of use that are allowed in the European Union, including colors and UV filters. (Although FDA has established the TEA process as a mechanism that potentially would lead to approval of EU UV filters, the process is slow and has not yielded an approved UV filter.) In turn, the European Union should accept products formulated in compliance with US regulations.

Another significant deterrent to US-EU regulatory alignment relates to Annex II of the EU Cosmetic Regulation, which is a list of substances which must not form part of the composition of cosmetics products. Currently, Annex II lists nearly 1400 substances, and additional materials are added periodically. A comparison of the entries in Annex II with the dictionary of International Nomenclature Cosmetic Ingredients (INCI) shows that only about 25% of ingredients 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.

[1] In comments to the FDA's proposed regulations on over-the-counter drug labeling (62 Federal Register 9024, February 27, 1997) our industry has defined "dosage limitation" as meaning "a set of limitations on the size, frequency, and number of doses required in the labeling of a product either pursuant to a Tentative Final Monograph, where applicable, or Final OTC Drug Monograph or an approved New Drug Application."

The inclusion of irrelevant ingredients in Annex II is thus clearly confusing, if not misleading, to cosmetic manufacturers, other international regulatory authorities and the public, and undermines the ability to achieve US-EU regulatory alignment.

This issue arises from what we view to be a deviation from the scientifically-accepted process of hazard and risk assessment. The EU requires that ingredients be listed on Annex II as prohibited from use in cosmetics based solely on a classification in the EU regulation on the Classification, Labeling and Packaging of Substances and Mixtures (EC 1272/2008) whether or not they are ever intended to be used in cosmetics and without assessment of the risks associated with their use, for example the level or percentage of the ingredient in the formulation, the route of administration, the conditions of use, or indicated directions or warnings.

Moreover, the EU Commission's decision to consider ingredients listed in the Classification & Labeling Inventory as carcinogens, mutagens or reproductive toxicants as added to Annex II without recourse to the Scientific Committee for Consumer Safety review process and an "Adaptation to Technical Progress" procedure further reduces the level of transparency and ability for global stakeholders to react appropriately in matters of reformulation or timely ingredient defense activities. This will be most seriously felt by SMEs and importers who rely on the transparency of regulations for compliance and fair market access.

US industry therefore seeks an amended process for ingredients to be placed on Annex II of the EU Cosmetic Regulation, in which industry would have a meaningful opportunity to present scientific data about an ingredient's use in particular cosmetic products, and with a corresponding "burden of proof" of safety, that could lead to its acceptability in cosmetic products.

Industry also seeks a commitment from the EU to restructure Annex II of the EU Cosmetic Regulation to clearly and accurately reflect ingredients that are relevant to cosmetic and personal care products. The EU should further commit to the ongoing maintenance of this and other EU annexes.

Harmonization and/or Mutual Recognition of Testing Requirements

In a number of cases, the United States and the European Union require different test methods and protocols to achieve the same goal, i.e., safety of cosmetics products and ingredients, and do not utilize internationally agreed methods. Divergent testing requirements add considerable costs to manufacturing and marketing processes, restrict implementation of the latest scientific and technological advances, and do not result in added safety or health benefits to consumers.

US and EU regulators should harmonize required test methods and/or agree on mutual recognition of each other's methods for use in safety assessments. In particular:

Alternatives to Animal Testing: The United States and the European Union should promote alternative test methods that do not use animals. For nearly thirty years, the cosmetics industry has been a leader in the development of alternative methods that reduce or eliminate the need to use animals in safety testing. Today in Europe and the United States, more than 99% of all safety evaluations are conducted without testing on animals. Enhanced US and EU cooperation on alternative test methods would promote further scientific advances, align regulatory requirements with modern societal norms, and provide impetus for acceptance of alternative methods in other countries.

We therefore seek specific commitments from both sides to devote necessary resources to develop alternative test methods, to achieve timely and efficient validation of alternatives, and to promote the use of validated methods. In addition, the FDA should issue a regulatory guidance document clarifying its acceptance of validated alternative methods. At the same time, we urge the EU Commission to take all necessary steps to assure that the EU animal test ban is implemented in a way that avoids trade barriers and allows for the continued marketing of new and innovative cosmetics products in the European Union.

International SPF Test Methods: US and European test methods for sun protection factor (SPF) should be harmonized on the basis of the International Standards Organization (ISO) standard (ISO 24445).

Testing Requirements for Colors: The United States imposes unique and overly burdensome requirements for colors used in cosmetics. All color additives must be approved by the FDA and, for certain colors, FDA must "certify" each production batch of the color. In the European Union, colors are permitted if approved and listed in the relevant Annex to the EU Cosmetics Regulation. There is no requirement to "batch certify" colors. US requirements are not based on any special or heightened risk profile of colors, and undermine the overall approach of the FDA (and EU) regulatory system which relies on manufacturers' responsibility to assure safety of products and ingredients.

In order to promote greater alignment of regulatory approaches towards cosmetic colors, the FDA should eliminate its requirement for specific batch testing. In addition, the United States and the European Union should harmonize purity specifications for cosmetics colors.

Harmonization of Labeling Requirements

In today's global marketplace, consumers are increasingly purchasing cosmetic products over the internet and through other non-traditional distribution channels, often away from their local retail outlets. Greater alignment of US and EU labeling requirements has the potential for significant improvements in supply chain efficiencies, reductions in manufacturing costs, and enhanced consumer understanding and product recognition. Therefore, industry seeks harmonization of EU and US labeling requirements. In particular:

INCI "trivial names:" US and EU regulations require full labeling of cosmetic ingredients, based on technical nomenclature agreed in the International Nomenclature of Cosmetic Ingredients (INCI). The near-universal acceptance of INCI nomenclature around the world provides benefits to consumers, health care professionals, governments, and industry alike. While a single INCI name exists for the vast majority of cosmetic ingredients, for common or "trivial" names, FDA does not accept the INCI technical name, but requires an English word.

For example, FDA does not accept "aqua," as the term for water, causing further difficulties in EU and other countries that require national language labeling. As a practical result, industry would have three labels for US-EU-Canada trade (if English is used, Canada requires French). In 2008, industry sponsored a comprehensive consumer survey which demonstrated that over 80% of US consumers recognized "aqua" as equivalent to the word "water." We believe that consumers would, similarly, understand that "parfum" is equivalent to the term "fragrance."

We therefore seek acceptance by the FDA of INCI trivial names. Especially in light of the lack of risk related to water, FDA should immediately acknowledge acceptance of "aqua," and then take steps to systematically review and accept all INCI trivial names that are widely understood and do not pose risk.

Sunscreens: The United States and the European Union should accept each other's labeling of sunscreen protection factor (SPF) based on common test methods (ISO) as discussed above. This would provide consumers with increased choice and knowledge of product benefits.

Net content: The United States and the European Union should accept each other's expressions of net content (metric/ounces) and harmonize the criteria for net content labeling. Presently, the US and EU have different approaches regarding whether the net content needs to be labeled based on weight or volume.

Warning Statements: The United States and the European Union should harmonize requirements for warning statements, avoiding duplicative warnings on packages. For example, the EU requires unnecessary or duplicative, statements for hair-dyes; sunscreen use, etc. In some cases, these warning statements "contain XYZ" are redundant, as the ingredient is already declared on the ingredient list.

Labeling of Color Ingredients: The United States and the European Union should agree on mutual recognition of each other's system for the labeling of color ingredients. Presently the FDA requires INCI names for colors, while the EU regulations stipulate the use of a "Color Index" number.

Ongoing Regulatory Cooperation

As US and EU regulations for cosmetic and personal care products become more closely aligned, it will remain important to establish commitments for ongoing cooperation and

adherence to good regulatory practices on emerging issues. As an innovation-based industry, cosmetic and personal care products companies continually strive to make scientific advances, to stay current on the latest science with respect to safety, and to apply new technologies.

Nanotechnology: In our view EU requirements for notification and labeling are not consistent with a risk-based regulatory approach and are harmful to innovation and consumer confidence. We support the principle that regulation should be technology-neutral. EU and US regulations incorporate well-established safety assessment principles that are fully adequate to account for emerging technologies such as nano-scale materials. Current science does not support the suggestion that the mere use of nanotechnology affects the safety or effectiveness of a product, and there is no basis for requiring special labeling, which in effect amounts to a "warning label" of nano-scale ingredients.

Therefore, our industry seeks the removal of EU requirements for notification and labeling of nano-scale ingredients used in cosmetic products.

International Cooperation on Cosmetics Regulation

Since 2007, the USFDA and the EU Commission have been actively engaged, along with their counterparts from Canada and Japan, in the International Cooperation on Cosmetics Regulation (ICCR). The purpose of the multilateral framework of ICCR is to maintain the highest level of global consumer protection, while minimizing barriers to international trade. ICCR is modeled on similar efforts in the drug and medical device sectors, and provides an opportunity for the participating countries to consider common approaches to existing and emerging issues.

As noted in the ICCR Terms of Reference, "representatives of the members agree to take appropriate steps to implement the items that have reached consensus within the boundaries of their legal and institutional constraints. In this respect they agree to promote the documents reflecting the consensus within their own jurisdictions and to seek convergence of regulatory policies and practices."

We believe that the ICCR can serve as an important forum for alignment of regulations, polices and guidelines affecting our industry and as a resource for other countries looking to model their regulatory approaches around such common guidelines.

As such, we urge US and EU regulators to strengthen their cooperation within the ICCR, and to seek any necessary mandates that would allow the formal adoption of ICCR decisions. US and EU regulators should agree to issue specific guidance documents and regulations as appropriate to implement ICCR decisions. This would include implementation of existing ICCR decisions, such as cosmetics Good Manufacturing Practices based on ISO standards; principles of safety assessment; handling of trace contaminants in cosmetics ingredients, as well as future ICCR decisions.

Going forward, US and EU regulators should commit to addressing common regulatory issues and challenges arising from nanotechnology and other emerging issues within the ICCR, and in other bilateral and multilateral trade, scientific and regulatory fora.

The United States and the European Union should also commit to consult each other and seek to coordinate positions on, and implementation of, global treaties impacting the cosmetics industry, including treaties on environmental/sustainability, for example, the UN Convention on Biodiversity, and the UN Convention on International Trade in Endangered Species.

Conclusion

The Personal Care Products Council appreciates this opportunity to present our industry's objectives for the Transatlantic Trade and Investment Partnership. We believe that the fundamental similarity of US and EU regulatory systems, together with the high degree of trust and confidence by US and EU policymakers and consumers in each other's regulations and products, should serve as a favorable foundation to achieve further regulatory alignment and mutual recognition in the area of cosmetics.

To summarize, our key objectives for TTIP are:

- Risk-not hazard-based regulations that would eliminate automatic EU bans of ingredients and EU requirements for nanotechnology notification and labeling;
- Harmonization of US and EU definitions for cosmetics, the US definition to include non-dosage OTC products;
- Mutual recognition of cosmetic ingredients and conditions of use;
- Harmonization of testing requirements;
- Harmonization or mutual recognition of labeling requirements;
- Enhanced cooperation through the ICCR and implementation of ICCR decisions

We look forward to continuing to support US and EU negotiators with additional information and insight on how US-EU cosmetics regulatory alignment and cooperation can benefit our industries, consumers and policymakers.

Sincerely,

Francine Lamoriello

Francine Lamoriello
Executive Vice President, Global Strategies

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