Personal Care Products Council
Committed to Safety, Quality & Innovation

January 9, 2015

SUBMITTED ELECTRONICALLY

European Commission
DG Environment and Natural Resources
ENV-E2-NAGOYA-ABS@ec.europa.eu

ATTN: Anne Delvaux, Assistant Policy Officer ABS, EUTR, and FLEGT

Re: Comments Regarding the Commission's 'Discussion Paper for the Stakeholder Meeting of 9 December 2014'

In response to the Commission's call for stakeholder comments and on behalf of its member companies, the Personal Care Products Council ("PCPC") hereby submits comments regarding certain aspects of the European Commission's ("Commission") "Discussion Paper for the Stakeholder Meeting of 9 December 2014" ("Discussion Paper") on which PCPC and its members seek additional clarity. PCPC also welcomes this opportunity to provide comments regarding additional issues on which its members seek additional guidance from the Commission with respect to the implementation of the European Union's Regulation No. 511/2014 ("ABS Regulation"), whether in the form of the Implementing Act, a guidance document, or a recommendation.

PCPC is the leading U.S. trade association for the cosmetic and personal care products industry, representing more than 600 member companies. PCPC members include 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 personal care products. PCPC member companies are actively engaged in providing consumers with safe, innovative, and high quality cosmetic and personal care products in the United States and globally. The U.S. cosmetic industry has an estimated $60 billion in annual retail sales, and employs 8.5 million people, directly and indirectly, in the United States. Over 90 percent of cosmetic companies are small businesses that have 50 or fewer employees.

Given our members' global footprint, PCPC has been closely following and engaged in developments related to access and benefit sharing ("ABS") and corresponding protection of genetic resources ("GR") for years. PCPC was an active stakeholder throughout the negotiations of the Nagoya Protocol ("Protocol") and has been subsequently working closely with individual governments as they seek to implement the Protocol's commitments. In that context, PCPC, in coordination with its sister association Cosmetics Europe, has been engaged from the beginning in the EU's development of its ABS Regulation.

In that context, PCPC welcomes this opportunity to provide comments to the Commission regarding its implementation of the ABS Regulation. We also encourage the

Commission to notify this regulation and the implementation Act to the World Trade Organization (WTO) TBT notification body, so other impacted industries and governments can provide the Commission their views on how these changes will impact trade with the EU.

Per our comments, Section I below contains specific comments on the Discussion Paper and associated annexes. Section II contains additional comments regarding the ABS Regulation for the Commission's potential consideration in the Implementing Act or a future guidance document.

I. Comments on the Draft Discussion Paper

The following represent PCPC's specific comments on the Commission's proposed Discussion Paper.

A. Clarification that the Declarations Only Apply to In-Scope GR

The declaration requirement should only apply to products developed via the utilization of genetic resources that are within the scope of the ABS Regulation. The ABS Regulation's declaration requirement provides in full:

> (2) At the stage of final development of a product developed via the utilization of genetic resources or traditional knowledge associated with such resources, users shall declare to the competent authorities referred to in Article 6(1) that they have fulfilled the obligations under Article 4 and shall simultaneously submit:
>
> > (a) the relevant information from the internationally recognized certificate of compliance; or
> > (b) the related information as referred to in Article 4(3)(b)(i)-(v) and Article 4(5), including information that mutually agreed terms were established, where applicable.
>
> Users shall further provide evidence to the competent authority upon request.

ABS Regulation, Art. 7(2). The ABS Regulation applies only "to genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol." *Id*. at Art. 2(1). Access refers only to acquisition of genetic resources or associated traditional knowledge "in a party to the Nagoya Protocol." *Id*. at Art. 3(3).

Thus, the ABS Regulation does not apply to genetic resources that were accessed: (a) in states that are not parties to the Nagoya Protocol, (b) before October 12, 2014 (the date on which the Protocol entered into force for the Union, or (c) in areas not subject to the sovereign rights of states (*e.g.*, Antarctica, or marine areas beyond national jurisdiction).

The Discussion Paper and associated annexes are not however limited to products developed via the utilization of genetic resources that are within the scope of the ABS Regulation. The Discussion Paper indicates only that a declaration "will have to be made" when

any of five events occurs. Annex C provides no option for declaring that the product is out-of-scope.

This concern was raised to the Commission in person during the December 9, 2014 stakeholder session and PCPC understands that the Commission acknowledged that the declaration requirement is to apply only to in-scope GR. PCPC therefore respectfully requests that the Implementing Act contain an affirmative statement that indicates that the requirement does not apply to products developed via out-of-scope GR to which companies can refer when placing products on the EU market.

B. **Preservation of Confidentiality for Intermediate Suppliers**

Second, PCPC requests the Commission's consideration of potential mechanisms to help preserve supply chain confidentiality. Supply chains within the cosmetics and personal care industries are usually long and involve a large number of actors. Often, one entity will conduct the access, provide a GR to a second company for R&D, the results of which will then be provided to a third company for incorporation into a component (*e.g.*, a fragrance), which will be utilized by a fourth company in a final product, which may be sold by a fifth company.

These supply chains are often confidential. A company will of course know the identity of its immediate supplier and customer. Its suppliers will however often guard their own supply chains as confidential. Intermediate suppliers do not want to divulge their own suppliers and/or the entity from which they accessed the GR, out of a concern that the ultimate customer will subsequently begin transacting directly with the initial source, cutting the intermediate supplier out of the chain.

As drafted, the Commission's proposed declaration requirement would divulge the contents of this chain. Specifically, Annex C, Part (A)(4)(d) requires identification of the entity providing prior informed consent as well as the place of access.

The ABS Regulation does recognize the need to protect confidentiality and provides that it should be protected where relevant:

> The competent authorities shall take due account of the respect of confidentiality or commercial or industrial information where such confidentiality is provided for by Union or national law to protect a legitimate economic interest, in particular concerning the designation or the genetic resources and the designation of utilization.

ABS Regulation, Art. 7(5).

The issue is that, as drafted, the draft Annexes only preserve one portion of the necessary confidentiality. Draft Annex C does provide for confidentiality protection by allowing the entity completing the declaration to check a box "Confidential" and to provide an associated justification. The concern is that this only provides confidentiality from public release, it does not ensure confidentiality along the supply chain.

PCPC respectfully requests that the Commission consider implementing a mechanism whereby the entity making the declaration (*i.e.*, the entity placing the product on the EU market) can rely upon certifications from its upstream suppliers regarding compliance with the ABS Regulation, without requiring the upstream entity to divulge its suppliers and sources to the downstream customer. To the extent the Commission still required that information to confirm compliance with the ABS Regulation, the Commission could develop a mechanism for those suppliers to provide that information directly to the Commission, preserving confidentiality from their end-user customers.

PCPC's members and their supply chains are firmly committed to complying with the ABS Regulation and applicable national laws. PCPC offers this suggestion as a means to promote that compliance along the supply chains without unnecessarily undermining the legitimate economic interests of intermediate and upstream suppliers.

C. **Only a Single Declaration Should Be Made**

Third, PCPC submits that the Commission should consider a modification of how it implements the notification requirement to leverage existing EU-wide systems within the cosmetics sector rather than creating unnecessary additional burdens. The ABS Regulation requires that users submit a declaration to the competent authorities of a Member State. The Discussion Paper clarifies that the declarations are "to be made only once" and describes to whom the declarations are to be made.

PCPC supports the Discussion Paper's efforts to reduce administrative burdens by only requiring that the declaration be submitted only once. PCPC submits that this aim could be additionally furthered by creating a single portal through which notifications can be provided. Most PCPC member companies will introduce products into numerous EU Member States at the same or similar times. Having a central portal, or at a minimum having a simple process by which a notification to a single Member State is quickly and efficiently disseminated to the other members to ensure there is no delay in PCPC members' ability to quickly introduce products to market.

D. **Limiting Extraterritorial Impact**

Fourth, PCPC requests that the Commission reconsider its expansion of the ABS Regulation declaration requirement to products developed outside the EU with non-EU genetic resources solely on the basis of being ultimately imported into the EU. The ABS Regulation is intended to implement the EU's obligations under the Nagoya Protocol. Under the Protocol, the EU is only obligated to:

> [T]ake appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

Protocol, Art. 15. The focus is therefore on GR that are utilized within the EU. Article 7 of the ABS Regulation should be interpreted in this light. The focus should thus be on GR that are utilized within the EU, or at the most, products developed within in the EU based upon the utilization of GR.

To the extent the Commission is concerned that EU-based users will now be subject to different requirements than U.S.-based users as a result of the ABS Regulation, the ongoing Trans-Atlantic Trade and Investment Partnership ("T-TIP") negotiations would appear to provide a forum in which to raise the concern. Expanding the scope to products developed outside the EU, utilizing GR accessed outside of the EU, and on which R&D was conducted outside the EU through implementation of the declaration requirement appears to go beyond the scope of the intent of the ABS Regulation.

E. **Only Stakeholders in the Supply Chain Should Provide Best Practices**

Fifth, PCPC supports the comments made by other sectors at the December 9, 2014 stakeholder session that the Commission should only recognize best practice documents developed and maintained by entities with some role in the sector's supply chain. The EU recognized that the ABS Regulation would apply differently to different sectors. Through the due diligence requirement and the recognition of best practices, the EU also recognized that users in different sectors would make different choices regarding "the tools and measures to apply in order to exercise due diligence…." ABS Regulation, Preamble Para. 21.

The value of the best practice comes from the applicant's familiarity with the nuances of a sector and its suggestions regarding how the general requirements in the ABS Regulation can be made to work within the structure of that sector.

The Discussion Paper however expands the universe of potential applicants. Specifically, it provides that "other interested parties" must meet "*at least one*" of the following criteria:

> (1) they have [sic] legitimate interest in the subject matter of the basic Regulation (and provide the reasons for),
> (2) they either access, collect, transfer, or commercialize genetic resources or traditional knowledge associated with genetic resources, which must be further detailed.

Discussion Paper, p. 8. Implicitly, the Commission is therefore indicating that it would grant recognition of a best practice to an entity that was not using, accessing, collecting, transferring, or commercializing GR, if that entity could demonstrate a legitimate interest. PCPC disagrees. Broadening the universe of "interested parties" beyond the supply chain risks having unaffiliated actors attempt to impose requirements on a sector without the requisite understanding of how that sector operates.

PCPC respectfully submits that the Commission should require applicants to demonstrate that they meet both requirements before it will recognize a best practice. Only entities that are involved in some capacity in a sector's supply chain – either through utilization, or through

another stage from access to commercialization – have the requisite understanding of the sector to implement and maintain a best practice.

Additionally, PCPC requests clarification regarding how the Commission intends to treat the submission of more than one best practice covering a specific sector. For example, the Commission could receive best practices from U.S. and EU associations with overlapping memberships, from more than one specific sub-specialty within a sector, or from actors at various stages within a supply chain. Will the Commission seek to reconcile these submissions or will it consider granting recognition to more than one best practice that may overlap?

F. Process for Granting and Reviewing Best Practice Designations

Sixth, PCPC requests that the Commission clarify in the Implementing Act the procedures by which it will consider requests for recognition of best practices. The ABS Regulation provides only that the Commission is to make a determination based upon "evidence and information provided pursuant to Paragraph 1 of this Article." ABS Regulation, Art. 8(2). The Discussion Paper goes further and provides a list of information the Commission will require from any association of users seeking recognition as a best practice.

Beyond several comments regarding timing and the role of the Member States in the review, the Discussion Paper does not however provide additional clarity regarding how the Commission will make its determination. The Discussion Paper notes only that the Commission can seek additional information or documents from the applicant if needed "to carry out the assessment of the application." To ensure best practices are developed in line with the Commission's expectations, PCPC requests that the Commission provide additional guidance regarding the factors it will examine in making its determinations.

Additionally, PCPC requests additional guidance regarding whether an applicant will be authorized to seek reconsideration of any Commission determination not to grant recognition as a best practice. During the December 9 stakeholder session, the Commission noted that these determinations would be subject to a regular "appeals" process. Because of the energy that applicants will have invested in the drafting of best practices and the importance of securing recognition pursuant to the ABS Regulation, PCPC requests additional clarification regarding any review or appeal process that the Commission may be considering.

II. Additional Requests for Guidance Regarding the EU's Regulation

Additionally, PCPC and its members seek further clarification regarding several items in the ABS Regulation. To the extent these areas can be addressed in the Implementing Act, a subsequent guidance document, or a Commission recommendation, PCPC would be very appreciative.

A. Clarification on What Constitutes Research & Development (Utilization)

First, PCPC seeks additional guidance regarding the scope of the terms "user," "utilization of genetic resources," and "research and development." For example, does conducting testing on a product, potentially a product which includes a GR, for the purposes of

meeting regulatory requirements (*e.g.*, safety testing) constitute utilization and trigger obligations under the ABS Regulation?

Additionally, because these types of questions are likely to arise regularly, involve substantial amounts of capital and time investment, and require fact-specific determinations, PCPC suggests that the Commission consider developing (or recommend that Member States consider developing) resources for potential users to assist in determining whether they fall within the scope of the ABS Regulation. These could include mechanisms for users to seek proactive written (*e.g.*, in the form of an advisory opinion request) or oral (*e.g.*, in the form of an advice line) guidance from the regulators on a potential future transaction to assess their regulatory obligations in advance.

B. **Clarification on Treatment of Commodities**

Second, PCPC seeks additional clarification regarding how the ABS Regulation would apply to commodity products. Using the example that was utilized during the Nagoya Protocol negotiations, what would be the obligations if a person were to purchase an apple at a grocery store. If the person were to then conduct R&D on that apple and potentially commercialize a product based on the results, what would be its obligation under the ABS Regulation. It would be virtually impossible to trace the supply chain for the apple let alone the original provider.

PCPC therefore seeks guidance regarding whether commodity products are exempt from the scope of the ABS Regulation and, if not, what steps users should take to exercise due diligence on commodity products.

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PCPC and its members are committed to the preservation, protection, and sustainable use of biodiversity and genetic resources and welcome the opportunity to engage in a constructive dialogue with the Commission and other stakeholders to ensure the EU's implementation of the Protocol meets the Protocol's objectives in the most efficient and least burdensome way possible. Please do not hesitate to contact the undersigned with any additional questions.

Sincerely,

Tonya Kemp
Director of International Trade Policy
Personal Care Products Council