



Richard N. Holwill ♦ Vice President – Public Policy ♦ 419 New Jersey Avenue, SE ♦ Washington, DC 20003
202.547.0300 ♦ Fax 616.682.4076 ♦ richard.holwill@Alticor.com

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The Honorable Ron Kirk
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

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Re: Promoting U.S.- EU Regulatory Compatibility: Request for Comment from the Public; Docket Number USTR-2012-0028

Dear Ambassador Kirk:

On behalf of Amway, we would like to express our strong support for the idea of an economic agreement between the United States (U.S.) and the European Union (EU), particularly if the agreement succeeds in promoting regulatory compatibility and reducing technical barriers to trade.

Amway is a global company operating in many countries, including the EU and is a worldwide leader in direct selling. Amway is best known for our health and beauty products; including the NUTRILITE™ brand of vitamins and dietary supplements and our ARTISTRY™ skincare line, among other exclusive, high quality brands. NUTRILITE is the world's No. 1 selling vitamins and dietary supplements brand;*ARTISTRY is among the world's top five, largest selling, premium skincare brands.*

We believe that a meaningful agreement could be beneficial in terms of trans-Atlantic trade and that it would have a catalytic impact on the negotiations toward liberalized trade in the context of the various agreements of the World Trade Organization (WTO). We want to stress the term “meaningful agreement” both because we believe that a superficial agreement does nothing to enhance trade and because we contend that it will not influence the other participants in the WTO negotiations.

Distribution Services

With regard to Distribution Services, direct selling companies are quite concerned about restrictions on the types of products that can be distributed in the EU through the direct selling channel. Some EU Member States prohibit or limit the ability of companies to sell vitamins and dietary supplements, including botanical and herbal products through this channel even though they are sold on an over-the-counter basis in retail shops. We believe that these restrictions should be lifted as a matter of right.

*Source: Euromonitor International Limited, www.euromonitor.com/amway-claims.

Supplements and Related Products

We also believe that the European Food Safety Agency (EFSA) has imposed unreasonable restrictions on information that may be associated (for regulatory approvals, acceptances, etc.) with many products. In many cases, respected universities and scientific investigators have published peer-reviewed studies on the efficacy of non-pharmaceutical products. The EFSA will not allow companies to list these studies in materials explaining the potential benefits of those products that are designed to help maintain health. Instead, the EFSA has demanded that these health-maintenance products be accepted only after positive outcomes from randomized controlled clinical trials (RCTs) that are normally required only for pharmaceuticals and other products that are designed to fight diseases. We hope to see an agreement between the U.S. and EU that establishes standards for these submissions that allow companies to utilize scientific studies related to products.

REACH

In addition, we contend that the chemical registration regime for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) creates unreasonable burdens on U.S. exporters to the EU. Because REACH classifies all importers as chemical producers, the regulation creates substantial barriers to the importing of finished product even though comparable “downstream users” are not similarly subject to REACH registration if their products are manufactured in the EU. This bias toward EU production disadvantages U.S. companies that distribute any product in the EU--even if they use chemically identical substances. We believe strongly that any U.S.-EU agreement on regulatory harmonization should allow for a greater degree of reciprocity than is now the case. In other words, if a product containing a chemical compound is freely offered for sale in the U.S., it should be authorized for sale in the EU without additional chemical ingredient registration.

Sectoral Approach

In general, we strongly support a sectoral approach as a way to promote greater transatlantic regulatory compatibility. As such, we appreciate your openness to that approach, as indicated in the above-referenced notice: “Concrete ideas on how greater compatibility could be achieved in a particular economic sector are also requested.” USTR is proposing a sectoral approach to the cosmetics sector in the Trans-Pacific Partnership negotiations and we would support a similar approach for cosmetics in a U.S. –EU agreement. In addition, a sectoral approach would yield results in the vitamins and dietary supplement sector, and we would like to work with you on such an initiative.

Very truly yours,



Richard Holwill