



**Asia-Pacific
Economic Cooperation**

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Agenda Item: 3

APEC CD Letter to ECHA

Purpose: Information
Submitted by: CDSGA Chair



**Chemical Dialogue Steering Group Meeting
Moscow, Russia
4 February 2012**



**Asia-Pacific
Economic Cooperation
Secretariat**

Mr. Geert Dancet
Executive Director
European Chemicals Agency
Annankatu 18, P.O. Box 400
FL – 00121
Helsinki, Finland

Dear Mr. Dancet:

As co-chair of the Chemical Dialogue, a government-industry body operating under the auspices of the Asia Pacific Economic Cooperation (APEC)¹ forum, I wish to bring to your attention a number of questions raised by both APEC Chemical Dialogue members and industry stakeholders in these economies with respect to the ongoing implementation of the European Union's Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). You and your staff have been very kind to entertain previous questions from the APEC Chemical Dialogue on the implementation of REACH that have aided compliance with its requirements.

At its recent meeting in September, 2011, APEC member economies and their industry stakeholders discussed two issues arising under REACH: the application of the 0.1% threshold for substances of very high concern (SVHCs) in articles, and revisions to the REACH Annex XIII criteria for persistent, bioaccumulative, and toxic (PBT) substances. We would very much appreciate your assistance in clarifying these issues for APEC member economies and their industries.

Threshold for SVHCs in Articles

The members of the APEC Chemical Dialogue are certainly well aware that under REACH, articles containing more than 0.1% by weight of SVHC are subject to specific requirements. These requirements include the obligation to notify the European Chemicals Agency (ECHA) if the articles contain SVHCs above the threshold and if the total quantity of the SVHC exceeds 1 tonne. As we have expressed in previous communications,² how the 0.1% weight threshold is calculated has important implications for exporters of articles to the European Union.

¹ APEC's membership consists of 21 economies around the Pacific Rim: Australia; Brunei Darussalam; Canada; Chile; People's Republic of China; Hong Kong, China; Indonesia; Japan; Korea; Malaysia; Mexico; New Zealand; Papua New Guinea; Peru; Philippines; Russia; Singapore; Chinese Taipei; Thailand; United States of America; and Viet Nam.

² May, 2008 and September, 2009.

ECHA's non-binding guidance provides helpful examples to industry on calculating the 0.1% threshold.³ The Guidance further notes that not all members of the European Union have supported the guidance, and that as a result "companies may face divergent enforcement practices as to some of its aspects."

As you can imagine, the divergent practices of the Member States on this question has important implications for exporters from around the world who provide products to the European market. Virtually every product – from a simple belt to sophisticated electronics to motor vehicles – could very well require notification to the Agency. The requirement places a significant obligation on exporters, and potentially, every one of their suppliers in the value chain, to test the component parts of their products for SVHCs.

The members of the APEC Chemical Dialogue discussed that this requirement may well have the effect of discouraging imports of articles in favor of those produced in local markets, particularly in the six Member States adopting the interpretation that each component is itself to be evaluated as an article and evaluated individually against the 0.1% SVHC threshold. While some European producers may be able to change their production and supply processes to manufacture articles that meet both interpretations of the requirement, most exporters do not have the capacity to produce articles unique for the French, Austrian, Belgian, Danish, German and Swedish markets. In effect, the proposed interpretation by the six Member States has established the *de facto* European-wide standard for SVHCs in articles. That effect runs counter to the REACH objective of supporting a single European market through consistent regulation and interpretation.

We would appreciate ECHA providing additional guidance on the implementation of the 0.1% SVHC threshold in articles. In particular, we would appreciate guidance on how ECHA will treat the likely divergences in notifications.⁴ For example, ECHA may be notified by France that an article meets the SVHC threshold, while a similar product in Spain will not trigger a notification. As Article 33 of REACH also mandates communication in the supply chain when the 0.1% threshold is met, what does ECHA recommend article suppliers do when communicating with specific supply chains about the presence (or non-presence) of an SVHC when one of the six Member States requires the supply chain to notify the article to ECHA?

Revisions to Annex XIII PBT Criteria

Participants at the recent APEC Chemical Dialogue meeting also discussed the amended REACH Annex XIII "Criteria for the identification of persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances," adopted by the European Commission on March 15, 2011. The Chemical Dialogue discussed the application of the revised criteria, and would also appreciate ECHA's clarification of how the revised Annex will be applied.

The revised Annex XIII relies on a "weight of evidence" approach, aimed at ensuring all available information is considered in the identification of PBT and vPvB substances.

³ See http://www.echa.europa.eu/documents/10162/17224/articles_en.pdf

⁴ See, for example, http://echa.europa.eu/doc/sia/update_com_opinion_sia.pdf -- summary of the Commission's Legal Services opinion on the treatment of "complex articles", Document: CA/26/2011, Brussels, 4 February 2011.

The APEC Chemical Dialogue would appreciate if ECHA could help clarify how PBT and vPvB assessments under the amended Annex will be conducted, perhaps in a dialogue with European and other industry interests. In particular, some clarification is needed on how the weight of the evidence approach will be applied.

The government and industry participants in the APEC Chemical Dialogue recognize the considerable challenges you and your staff face in implementing REACH. We very much appreciate your assistance in gaining these important clarifications of key REACH elements. Your response will help the Chemical Dialogue in preparing for meetings with representatives of the APEC economies, particularly Ministers and Leaders.

A response can be sent to the attention of Mr. Steven Chen, Program Director, APEC Secretariat, 35 Heng Mui Keng Terrace, Singapore 119616; e-mail sc@apec.org.

With many thanks for your continued cooperation with the participants of the APEC Chemical Dialogue.

Sincerely,

Dr. Fumiaki Shono
Co-Chair
APEC Chemical Dialogue

A handwritten signature in black ink, appearing to read 'Fumiaki Shono', with a large, sweeping flourish underneath.

cc: The Honorable Janez Potočnik
Commissioner for Environment

The Honorable Antonio Tajani
Commissioner for Industry and Entrepreneurship
and Vice President of the Commission