



**Asia-Pacific  
Economic Cooperation**

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**2012/SOM1/CDSG/IPM/018**

Agenda item: 3

## **Response Letter from ECHA**

Purpose: Information  
Submitted by: Industry Co-Chair



**Chemical Dialogue Steering Group Industry  
Pre-Meeting  
Moscow, Russia  
3 February 2012**

Helsinki, 27. 01. 2012

APEC Chemical Dialogue  
Dr Fumiaki Shono  
Co-Chair  
35 Heng Mui Keng Terrace  
SINGAPORE 119616

Dear Dr Shono,

Thank you for sharing with us the APEC member economies' and their industry stakeholders' considerations regarding the application of the 0.1% threshold for SVHCs in articles and the revision of the REACH Annex XIII criteria for PBT substances.

Regarding the application of the 0.1% threshold for SVHCs in articles we concur that the current situation with differing approaches to implementation is unfortunate. We recognise that this may result in a situation where companies need to be prepared to face different enforcement approaches with regard to communication obligations in different EU member states.

However, we would like to clarify that the provisions under Articles 7(2) and 33 of the REACH Regulation do not regulate the placing on the market of articles in the EU. Articles containing more than 0.1% of a SVHC can be placed on the EU market in all Member States unless there are specific restrictions on the substance in REACH or other EU legislation. The 0.1% threshold requirements relate to the duty of importers and producers of articles to notify to ECHA and to communicate in the supply chain whether the articles they place on the market contain SVHCs included in the Candidate list. The relevance of the difference in interpretation of the communication obligations depends on the case. We do consider that in many cases companies will have to have content information available on parts anyway in order to fulfil the requirements if also spare parts are provided. This situation is reflected in ECHA's updated Guidance on requirements for substances in articles that was issued in April 2011<sup>1</sup>.

In ECHA we will use the aggregated notification information on different SVHCs to support our own work, for instance identifying further needs for regulatory risk management. ECHA has no intention to check single notifications to see which interpretation of the 0.1% threshold has been used. The EU member states are responsible for the enforcement of REACH, including the notification requirement.

We believe that the key to successful compliance with Article 33 and Article 7(2) of REACH is well organised supply chain communication on the substances used and the content of the articles. We see chemical analyses as last resort to obtain necessary information. This is because these analyses are often difficult to conduct in a way that provides reliable and representative results. Furthermore

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<sup>1</sup> [http://echa.europa.eu/documents/10162/17224/articles\\_en.pdf](http://echa.europa.eu/documents/10162/17224/articles_en.pdf)

they can be time consuming and costly. These aspects are further reflected in the Guidance.

Regarding the revision of the REACH Annex XIII criteria for PBT/vPvB substances adopted by the European Commission on 15 March, 2011 ECHA intends to update the current "*Guidance on information requirements and chemical safety assessment, : PBT assessment(Chapter R.11)*". However, the current guidance<sup>2</sup> already discusses most of the criteria newly introduced in the revised Annex XIII as well as how to apply the weight of evidence approach. This is because the current guidance provided major scientific elements for the updating Annex XIII as the approach it describes is commonly used when dealing with PBT/vPvB substances.

I trust this provides your colleagues involved in the Chemical Dialogue the answers they were looking for. If you receive any further requests for explanation we would be pleased to provide further support. In that context I would like to inform you that your members can always send specific queries on REACH implementation to the ECHA helpdesk which you can access via our (new) website.

Yours sincerely,



Geert Dancet  
Executive Director

cc. Gustaaf Borchardt, DG Environment, European Commission  
Gwen Cozigou, DG Enterprise and Industry, European Commission

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[http://echa.europa.eu/documents/10162/17224/information\\_requirements\\_r11\\_en.pdf](http://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf)