

8-Feb-2011

## **Chemical industry concern over application of 0.1% SVHC threshold in REACH**

### **Japan Chemical Industry Association**

The Guidance on Requirements for Substances in Articles in REACH regulation states that a 0.1% threshold for SVHC, which, if exceeded, requires an SVHC notification to be made to ECHA and relevant information to be communicated to the supply chain, should apply to an “article as produced or imported,” and has been applied to whole articles as produced or imported. However, more than six member states, including Denmark, are opposing this interpretation of the threshold, insisting that the 0.1% threshold should be applied to the parts of complex articles based on the “once an article—always an article” concept. To the extent of our knowledge, an agreement has not been reached yet on the issue.

As the Japanese chemical industry, we express the following concerns regarding the above opinions, which will change the current application of the guidance.

- 1) Because of the unclear definition of the term “article” used in the phrase “once an article—always an article,” proposed in the October 2010 CARACAL Meeting, it is ambiguous as to exactly what the threshold applies; therefore, it is feared that in actual operation confusion will be created in supply chains both inside and outside the EU. In addition, to ensure the information of component levels are managed, it is expected that downstream users will increasingly demand the disclosure of information on the mixtures used, which are not even substances that are subject to the notification/communication requirements, and also will demand the disclosure of compositional information necessary for process management purposes, which may lead to the compromise of confidential business information of suppliers. Also, as a large number of information disclosure requests will need to be handled, workload is also expected to increase.
- 2) For importers or trade companies in Europe, keeping track of the use information of SVHC at final product levels is simple, however, at parts levels, there will certainly be an increased number of notifications to ECHA and of communications of information to the supply chain, and in addition keeping track of the use information of SVHC and user information will cover a broader spectrum, which is expected in practice to cause extreme difficulty.  
Parts and mixture manufacturers are typically subcontractors and there are many small-to-medium-sized businesses for those, and in some cases a third country is involved. Further, REACH regulations do not require the manufacturers in third countries or elsewhere to

provide information legally. With respect to export of final products from outside the EU, if the above elements are taken into account, it is practically impossible to provide information on substances and concentration directly to importers, and it is close to impossible to trace the final amount of substances and their final uses after export.