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## **Expert Q&A: James Calder, Intertek**

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Do you have questions about Substances of Very High Concern (SVHC)? Inside Cosmeceuticals (IC) did, too, so we connected with James Calder, manager - global regulatory services of Intertek Health & Environment and asked him to give us some insights on SVHC.

### **IC: What are SVHC and/or what qualifies an ingredient as a SVHC under REACH?**

**Calder:** The term SVHC comes from the Authorization portion of the EU's Registration Evaluation Authorization of Chemicals (REACH) Regulation (EC) No 1907/2006. As described by the European Chemical Agency (ECHA), the two first steps of the authorization procedure are the identification and inclusion in the "Candidate List" of SVHC, and the prioritization of substances to be included in Annex XIV of REACH (the Authorization List). EU Member States Competent Authorities (MSCAs) / the European Chemicals Agency (ECHA) on request by the European Commission (EC) may prepare Annex XV dossiers for identification of SVHC. An SVHC is substances such as carcinogen, mutagen, reproductive toxin (CMRs), persistent bioaccumulative toxic (PBTs), very persistent very bioaccumulative (vPvBs) and endocrine disruptors that are dangerous to human health and/or the environment. SVHC are not determined by their use as an ingredient, but on much broader criteria defined by their hazard classification.

### **IC: Once an ingredient is proposed as a SVHC, what's required to add it to the restricted list?**

**Calder:** The REACH Regulation requires ECHA identifies from the "Candidate List" priority substances to be included in Annex XIV of REACH and recommends Annex XIV entries (i.e., transitional arrangements and, where relevant, exemptions and review periods) for these substances to the EC, taking into account the opinion of the Member State Committee. The EC finally decides, by "comitology" procedure (with scrutiny), which substances will be included in Annex XIV and with which entries.

This new list of substances requiring Authorization (Annex XIV) is separate from substances that are restricted under REACH (Annex XVII).

On Feb. 17, 2011, the ECHA published the first Annex XIV listing six substances. Substances on the Authorization List (Annex XIV) cannot be placed on the market or used after the so called "sunset date". Unless specific exceptions apply, these substances may be placed on the market only if an authorization has been granted for a specific use, or the use has been exempted from authorization. The EC decides on the granting or refusing of authorizations. This has a large impact if manufacturers in Europe wish to use substances on the Authorization list in the manufacturing of their products after the sunset date.

Restrictions under REACH (Annex XVII) are contained in more than 20 pages of the Regulation, listing specific applications restricting the use of substances. For example, nonylphenol is restricted in cosmetic products equal to or greater than 0.1 percent by weight.

### **IC: What types of suppliers are responsible for testing their products for SVHC? How do they go about testing for SVHC?**

**Calder:** SVHCs have impact on three types of products defined under REACH Regulation as Substances, Mixtures (of two or more substances) and Articles. Articles are products that do not meet the definition of a Substance or a Mixture (i.e., packaging, computer, furniture, etc.) Suppliers of Substances defined as an SVHC must provide recipients an updated and compliant Safety Data Sheet (SDS).

Suppliers of Mixtures containing an SVHC greater than or equal to 0.1 percent (w/w) must also provide recipients an updated and compliant SDS.

Suppliers of Articles that contain substances on the Candidate List in a concentration above 0.1 percent (w/w) have to provide sufficient information to allow safe use of the article to their customers or upon request, to a consumer within 45 days of the receipt of the request. In addition, suppliers will have to notify the ECHA if the same SVHCs are present in the Articles greater than 1 ton/annum by either production or import.

These three product-specific requirements do not mandate testing. If a supplier provides any of these products and does not identify SVHCs then they are taking the assumption that no SVHCs are present at a level requiring communication.

On the other hand, without sufficient due diligence to manage SVHCs, the risk of enforcement or market loss due to enforcement action is greatly increased. This due-diligence process should include typical substance management protocol of upstream supplier communication, product risk assessment and testing. For example, a Supplier of Mixtures may not consider themselves at too high of risk if the substances can be identified to 100 percent of its known components (or at least any greater than 0.1 percent). To do this may require some analytical testing to support this consideration.

For Articles, this becomes much more complicated dependant on the complexity of the Article. The due-diligence approach requires the supplier of an Article assess the risk of SVHC contained in their product that could breach the 0.1 percent weight by weight measurement. The supplier of the Article should then perform analytical testing on the Article or any parts of the Article to identify any SVHCs determined to be a risk based on educated assessment. For all parts covered or not covered by risk-based approached testing, the supplier should document upstream declaration of conformity to the presence of SVHCs.

**IC: If Company A tests higher than 0.1 percent by weight, what's the next step? What notifications are necessary to ensure compliance?**

**Calder:** For Mixtures, if tests identify an SVHC greater than 0.1 percent by weight, then the supplier of that mixture must provide an SDS. For Articles, the supplier must provide sufficient information to allow safe use of the Article to their customers or upon request, to a consumer within 45 days of the receipt of the request. This information must contain, as a minimum, the name of the substance. Beginning in June 2011, suppliers also will have to submit formal notification to the ECHA if those same SVHC greater than 0.1 percent by weight are contained in the Articles at a volume of 1 ton or more per annum.

**IC: What happens when one ingredient is OK by itself, but once mixed with other ingredients it may be toxic, possibly categorizing it as a SVHC? How are these situations handled, prevented, etc.?**

**Calder:** Simply mixing two ingredients without chemical reaction turns it into one product (Mixture) with its relevant responsibilities to REACH. If there is a chemical reaction, this has the potential to create a risk of an SVHC without intent. To properly manage this risk, one needs to have proper process controls in place that apply the due-diligence aspect related to earlier. In relation to Mixtures, SVHC are just a part of what needs to be address in relation to REACH. Suppliers of Mixtures need to know the hazards of their product and SVHC are one of those potential hazards. Testing the final product is one way to determine the presence of SVHC or any other substances that need to be identified because of their hazardous characteristics.