Steps to a Successful REACH 2018 Registration: Q&A

1. How can I find out if there is a Lead Registrant for my substance?

If you have pre-registered your contact details (or those of your OR) will be on the SIEF page in REACH-IT. The proposed Lead Registrant will usually send out emails to all SIEF members, but if you joined late you may have missed those emails. In that case, check the message board in REACH-IT. If the message board doesn't give you any information, write to other SIEF members to inquire if anyone has taken the lead.

2. How can I change to a different SIEF if I find out my substance is not what I thought it was?

You can do this quite easily in REACH-IT by entering the other substance into the "similar substances" section. This will allow you to access selected information relating to the new SIEF. You can then contact the Lead Registrant of the other substance for data sharing. This is only allowed if there was a genuine misunderstanding about substance identity and the new substance is very similar to the original one, not if you forgot to pre-register a substance altogether.

3. Is it possible to opt out of data sharing – for example if we feel the costs are too high?

In principle yes, but you must provide robust justification and cannot opt out completely. ECHA is currently updating its systems to make it much more difficult for registrants to "go at it alone." As of 2016, submitting outside a joint submission will not be possible, so you would only be able to opt out of certain endpoints (and therefore not share in the costs of them). However, you would still need to be part of a joint registration, which means you would still have to share in the other costs.

4. What do I need to do if my substance reaches the next tonnage band threshold?

You must inform ECHA of the additional information required to update your dossier. The process is similar to that of the Inquiry. For example, if your substance is registered in the 1-10 tonnage band and you need to update to the 10-100 tonnage band you would need additional tests as required in Annex VIII (unless already submitted with the dossier) and a CSR, which is not needed for a 1-10 tonnage band registration. As a result of the Inquiry ECHA will contact the LR so you can arrange extra payment for the data sharing costs of the upgraded tonnage band.

5. Which is better: read-across or predictive toxicity software?

For unique chemistries, definitely read-across. Professional experience using read-across has helped us inform 40% of a chemical portfolio that was previously classified as "no data." Predictive toxicity software is only as good as the program's underlying data set, which is not robust for niche chemicals, UVCB, and polymer. Some software also provides read-across, but should be used with caution. For example, the US EPA program AIM gives potential read-across chemicals a percentage ranking based on similarity. The output may be Chemical A is 95% similar to your input chemical, but what if the last 5% is the functional group, which will likely drive toxicity? This "95% similarity" may be based on a shared fatty acid chain, while the 5% phenol group (i.e. the irritating functional group) is ignored.
6. Regarding interpretation of toxicological data, what are some of the GHS end points that you think are particularly hard to interpret?

There are definitely gray areas in the hazard interpretation of some GHS end points. Some of the ambiguities we've been grappling with include the following:

1. **Q:** Should all solid particles be assigned Skin, Eye, and Respiration irritants due to their inherent physical properties?
   
   **A:** GHS does not make a distinction between irritation driven by physical or chemical properties. Since both approaches are valid according to GHS criteria, ultimately this is more of a company-specific decision. We would suggest thinking of the potential SDS disclosure ramifications before settling on a company approach.

2. **Q:** Should we take pH buffering into consideration in aquatic studies of extremely acidic and basic substances?
   
   **A:** Yes, OECD protocols call for pH adjustment in aquatic testing. However, this is not always done, even if the study is reported to be adherent to OECD standards. We always prefer to classify aquatic toxicity based on studies that adjusted for pH, if available.

3. **Q:** What is considered "adverse" under specific target organ classifications?
   
   **A:** GHS has detailed criteria on what is considered clinically adverse in Section 3.9.2.7 for repeated exposure and Section 3.8.2.1.7.3 for single exposure. Essentially, the effects observed must be clinically relevant and adverse. Effects not considered clinically relevant under GHS are slight change in body weight or organ weight, changes in biochemistry, hematology, or urinalysis that do not result in adverse clinical effects, *etc.*

4. **Q:** How do we interpret acute toxicity and specific target organ studies for extremely corrosive agents?
   
   **A:** It would be inappropriate to test animals for knowingly corrosive substances for these endpoints. In fact, corrosive properties can be cited for data waiving under REACH registration, including those substances with the 2018 registration deadline. If studies already exist, focus on the non-point-of-contact effects for classification purposes. For example: we would be reluctant to classify based on gastrointestinal effects in a target organ repeated exposure study in rats following oral ingestion of a corrosive substance.

Ultimately, there's no one right answer for these questions. They depend on consistency and the level of detail available for the data at hand. Again, many of the decisions will involve a weight of evidence approach, which should be clearly documented for each endpoint and each chemical. Also, some of the decisions may relate to an individual company's risk preferences.

7. **If I am a downstream user in the US and get product from a vendor in the US or Canada who buys it from an EU producer, can I be covered under the EU producer?**

Assuming this question arises from the fact the downstream user wishes to sell the resulting product back into the EU, the answer is yes: you (and your EU customers) can be covered under the registration of the original EU producer, as this is considered a "re-import." Under Article 2(7) of REACH, substances already registered and exported from and re-imported into the EU are exempt, *i.e.* they do not have to be registered again when they re-enter the EU (otherwise there would be a duplicate registration obligation for the same substance). The conditions under which this exemption applies are as follows:

- The substance must have been registered before it was exported from the EU; and
- The substance already registered and exported must be the same as the substance being reimported; and
- The substance must not only be the same but it must actually proceed from the same supply chain in which the substance was registered.

It is important that the REACH registration number is included on all SDS that pass along the supply chain and that the importer (or Only Representative if relevant) has confirmation that this is a re-import and can be covered under the registration of the original producer.

8. Please discuss the implications of the recent European Court of Justice decision regarding articles in articles.

The ECJ ruling stated that for Article 7(2) and Article 33 applications, each component of an article must be considered as an article in its own right.

What this means in practice is that companies are much more likely to have SVHC notification obligations and Article 33 communication obligations. The REACH Centre has always advised companies to look at components rather than the whole article. This approach is often the most practical and more appropriate from a corporate responsibility point of view. From the consumer point of view, if you buy a bicycle that contains > 0.1% of an SVHC in the rubber of the handle, then you are concerned about the exposure resulting from touching the handle and the percentage as calculated based on the weight of the entire bike is irrelevant. From the company's point of view, if you are looking at a "bill of materials" or "bill of substances" or if you do some testing, then you would logically consider the material of the handle separately from the bike anyway. However, questions have arisen over what can be considered a "component part," especially in the case of very complex articles, and this is likely to cause some issues.

We expect that with regards to Article 33 there will be little difference in practice for companies in terms of how they collate their information on SVHCs.

However with respect to Article 7(2), companies will have to submit additional notifications as more substances will now be in scope of the requirement.

In cases where the substance has not already been registered for that use, this could lead to additional registration requirements, as ECHA can request that a registration be made on a case by case basis.

9. You keep mentioning that labs are busy with the increased testing requests. Do the labs that perform these tests have to be EU labs? Are there certain certification requirements that approved labs must meet?

The only requirement is that tests be performed at a laboratory that complies with recognized principles of good laboratory practices (GLP). It is not necessary that the lab be located in the EU. See the following link for more information: http://echa.europa.eu/view-article/-/journal_content/title/echa-extends-its-good-laboratory-practice-glp-policy.