

REACH COMPLIANCE GUIDANCE

WHAT NASF CHEMICAL SUPPLIERS NEED TO KNOW ABOUT PRE-REGISTERING UNDER THE EU REACH PROGRAM

The European Union's ("EU") Regulation on Registration, Evaluation, Authorisation and Restriction of Chemical Substances ("REACH")¹ is now in effect. If you supply the metal plating industry, this brief summary explains the basic registration aspects of the program and how REACH registration impacts you and your downstream customers.

What is REACH?

As of June 1, 2008 under REACH, EU manufacturers and EU importers have new obligations in order to continue to manufacture, import or use new and existing chemicals in the EU. Most immediately, you must determine whether the products you ship to the EU are subject to **Registration.** In addition:

- For new chemical substances, prior to registration there is now a mandatory pre-consultation period with the competent authorities to locate any test data on the substance from prior filings.
- For existing chemical substances (those listed on the European Inventory of Existing Chemical Substances (EINECS)), the time needed to register can be extended only by pre-registering by December 1, 2008. Companies that

¹ Regulation (EC) 1097/2006 (Dec. 18, 2006) (hereinafter "REACH").

manufacture or import an existing substance in quantities of 1 metric ton per year or more that fail to pre-register the chemical during this six-month window of opportunity will lose the additional time for registration that is being given to pre-registered chemicals, also referred to as the "phase-in period."²

• Substances manufactured or imported in the EU under 1 metric ton annually per EU manufacturer or importer are exempt from REACH Registration.

For pre-registered substances only, registrations are due in the following timeframes:

- December 2010 for substances > 1000 (metric) tons, Carcinogen, Mutagen, and reproductive toxicants in Categories 1 & 2, and substances in Environmental Effects Category R50/53 substances > 100 tons
- June 2013 for Substances > 100 tons
- June 2018 for Substances > 1 ton

Does REACH Apply to Ingredients and Finishes Shipped to the EU?

REACH registration applies to a substance on its own, when it is a component of a preparation, or if the substance is intended to be released from an article under normal or reasonably foreseeable conditions of use. When shipped to the EU, this means that a chemical substance alone or as an ingredient of a finish or paint is subject to registration – unless applied in advance to a part that meets the criteria for an exempt article (discussed later on below). Only substances must be registered, individual preparations or articles as such do not.

When My Ingredients or Finishes Are Shipped to the EU, Do I Need to Register?

Not directly. This is because U.S.-based companies <u>cannot</u> register under REACH. Only EU-based companies can. If you supply chemical substances either alone or as part of a formulation to the EU, each individual customer in the EU has an independent obligation

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² See REACH, Art. 7, § 1.

to register each chemical substance in the product that they are importing above 1 metric ton per year. U.S. companies may hire an "only representative" (OR) located in the EU to take on the registration burden for their EU customers though --- and this may be an option for you to assist EU customers.

What Are My Options to Assist My EU Customers?

A raw material supplier can either engage an OR in the EU to support its direct shipments and the shipments to the EU of products containing its substance by downstream customers. Optionally, a raw material supplier can work cooperatively with EU importers who want to register on their own.

To insure that your company has a market in the EU, your chemical substance and its specific use must be registered by your OR, your downstream customer in the EU, or your upstream supplier's OR. Failure to have your specific chemical and its specific use registered means no market in the EU. If you are not sure whether the registration requirement will apply to your chemical substance, you may want to submit a preregistration for your chemical and its specific use before December 31, 2008, and then make a final decision on registration at a later date.

A chemical formulator shipping to the EU has three options: Rely on pre-registrations and registrations of their upstream suppliers, engage an OR themselves to support their EU customer(s), or work cooperatively with EU importers who want to register on their own.

Will My Proprietary Formula Need to Be Disclosed for Pre-Registration?

A company is not required to provide a confidential formula by REACH. The information that must be supplied for pre-registration is as follows:

- Substance name, Chemical Abstract Services Registry Number (CASRN) and EINECS Number
- Registrant contact details
- Deadline to register/Tonnage band

Pre-registration can be done on-line at http://echa.europa.eu/reachit/pre-registration-it_en.asp; again, only an EU entity may be listed as the registrant for the filing to be accepted. Because substances must be pre-registered separately, in no set order, without specifying percentage in a composition, there is flexibility to mix and mask which substances go together. As noted, the identity of the substances in the formulation must be submitted because manufacturers and importers of a like substance will be grouped together in a Substance Information Exchange Forum. For this purpose, a list of pre-registered substances will be publicly available on the European Chemical Agency (ECHA) website as of January 2009. Additional information, however, such as reported tonnage and the names of pre-registrants, will only be available to fellow SIEF members.

How Do I Respond to Customer Requests for Information on Substances of Very High Concern Right Now?

As you are aware, the Candidate List of Substances of Very High Concern (SVHC) is under development. While the criteria for listing are known, and drafts of the Candidate list are circulating, it is still largely unknown at this time whether the list will contain the substances that you provide. Therefore, you may respond to customers that you have no knowledge currently as to whether any of the substances present at 0.1% w/w or more in your products, which would be the relevant question under Article 33 of REACH, will be added to the Candidate list of SVHCs when that list is published or later updated. You may choose to indicate that you will ask your suppliers for further information but we expect that they will await the publication of at least the draft Candidate list before responding to your inquiry.

Industry is urged to remain vigilant concerning the development of the SVHC List, specifically for proposals to add ingredients in metal finishes to this list. These listings can trigger downstream customer communication requirements, notification, the authorization process, and possible use restrictions. Substances that are exempt from registration as part of articles can be subject to these other requirements. This topic will be the subject of a future NASF briefing paper.

For more information on REACH and metal finishing operations visit the NASF website at www.nasf.org or contact Christian Richter or Jeff Hannapel at crichter@thepolicygroup.com or jhannapel@thepolicygroup.com.