



The Chemical Company

## REACH – North American Specific issues (Rev 3 - July 2008)

### Insert to accompany BASF brochure "REACH – What it means for company practice"

If you are in the chemical manufacturing or processing industry - you've been complying with chemical control regulations for a very long time. In the US, we have the TSCA Inventory. In Canada we have the Domestic Substance List. Both involve filing application to the respective government to ultimately obtain a listing of a substance on the applicable inventory. Once on the inventory, all other manufacturers and importers can utilize this listing for their own use.

**REACH is different.** REACH is not an inventory listing type regulation. Though a list of substances will be generated from

the process of registration<sup>1</sup> – every substance imported by every importer will be required to "sign up" or register for their share of the volumes and downstream uses in the EU market. In other words, a registration under REACH **does NOT constitute** a general legal status for a substance in the EU, but is always linked to a manufacturer or importer and a specific supply chain. This makes for a very complex regulation.

The purpose of this communication is to inform you of the key concepts of REACH specific to the North American landscape to assist you in your planning and preparations.

### REGISTRATION ISSUES and CONSIDERATIONS

REACH requires that only legal entities of the EU can register. Importers into the EU are obliged to register. To do so, importers must know the compositions of the products they are importing. Management of confidential business information needs to be considered and may preclude registration by the EU importer if the non-EU supplier isn't willing to disclose. In addition, some EU importers may prefer to be considered as "downstream users" (DUs) by pushing the registration obligation back to the supplier - because DUs have no obligation to register.

To solve these issues, the non-EU manufacturer can establish an Only Representative (OR) in Europe to register the substance on the importer's behalf. However, an EU entity importing substances from non-EU countries can only waive its obligation to register if the EU importer has been informed of the appointment of an OR by the appointing non-EU supplier/manufacturer and agrees to provide the information necessary for the OR to fulfil its obligations.

The OR is the only option available to non-EU companies needing to register substances. The OR party must be a legal entity of the EU and is tasked with the responsibility of fulfilling the obligations of the importer :

- OR must be "technically" competent in chemical handling and related information
- OR must have access to the imported volumes, customers and uses of the substance(s) they are representing
- Obligations of the OR start immediately upon pre-registration

The REACH regulation itself leaves open questions regarding how an OR can operate. The European Chemical Agency (EChA) through various technical guidance documents is attempting to clarify the issues of registration via an OR. You should keep a watchful eye for new guidance and interpretation via the EChA website given below.

### POLYMER/MONOMER

Substances that meet with the REACH definition of "polymer" are not required to be registered. However, all monomers or other substances that make up the polymer's "chemically-bound structure" are required to be registered if >2 wt%.

One should also pay close attention to the definition of a polymer under REACH. This definition is different than the definition used in the U.S. Careful analysis should be undertaken to deter-

mine how the polymer you are manufacturing or using as a formulant qualifies under REACH. For formulations containing polymers, you must look at the polymeric substance(s) separately from the other non-chemically bound additives/ingredients.

The final guidance on polymers and monomers can be found at the EChA website given below.

### RE-IMPORTS

REACH Article 7(c)(i) exempts substances in your supply chain from re-registration if it can be shown that these substances are already registered by the EU source manufacturer. At least one official interpretation by an EU member state national authority confirmed that full registration is required for substances before the re-import exclusion would apply. EChA has not officially ruled.

Currently this means that pre-registration is still necessary by importers regardless of the fact the substance is a re-import. Therefore during the pre-registration phase, all importers or OR's representing exporters should plan to pre-register until full registration of the substance(s) has been realized.

<sup>1</sup> The term "registration" utilized throughout this document is intended to include the pre-registration process.

## MANUFACTURED ARTICLES

Many of BASF's customers manufacture "articles". Article producers that are exporting their finished goods to the EU need to become very familiar with the REACH guidance on articles. A copy of the guidance document can be obtained at the ECHA weblink below (follow to REACH > guidance documents) or visit <http://reach.jrc.it/> directly.

### **Substances requiring registration**

REACH makes a clear distinction between

- substances in containers/carriers and
- substances as part of articles with "*intended release under normal or reasonably foreseeable conditions of use*".

The distinction is not necessarily the same as other determinations you may have made in the past under other laws, but one that should be closely scrutinized for future EU exports of these items.

Items like ink cartridges or ink pen housings are considered containers under REACH and any ink contained in them is to be registered per Article 6 if >1mt/yr. Wet cleaning wipes also fit into this category in which the tissue/cloth is considered as a carrier and the liquid cleaning solution is "contained" and requires registration.

Items like scented erasers are considered articles and the aromatic substance(s) intended to be released are required to be registered according to Article 7.1.

### **Substances requiring notification**

Though your articles may not contain substances that are intended to be released, they might also be subject to another requirement under REACH whereby you must **notify**. Notification is triggered for any of the substances that may be an integral part of the article at >0.1 wt%, >1 mt/yr and identified as a "substance of very high concern" or "SVHC" (Art. 57).

Potential SVHC's will initially be added to a "candidate list". The candidate listing will initiate a public comment period but will also trigger the obligation of article suppliers to notify downstream article users that the article contains one or more of the SVHC's at >0.1 wt%. Suppliers must provide safe use instructions and the substance identity to the users (Art. 33). The first candidate list of SVHC's is expected mid-2008.

A finalized list of SVHC's will become REACH Annex XIV. Addition to Annex XIV triggers additional notification requirements - this time to ECHA. Articles containing >0.1 wt% of an Annex XIV listed substance will have 6 months from date of addition to Annex XIV to notify (Art. 7). Annex XIV is scheduled to begin population in mid-2009.

Exporters of article to the EU need to thoroughly understand the REACH article definitions and provisions in order to properly assess obligations!

## WHAT SHOULD YOU BE DOING?

### ***Get educated on REACH***

Trade and industry associations are well educated on the provisions of REACH and can provide you with guidance on how you might be affected and the information you'll need to comply. You'll also gain a network of other similar companies to exchange ideas with.

### ***Assess your EU market/ vulnerability***

Do you have exports going to the EU? Discuss these with the EU customers to determine their plans under REACH. Will they be handling registrations or are they expecting you to handle it? Remember – for them to do it they must have full product composition information for the products they import.

### ***Prepare for pre-registration***

If you are currently in the EU market and intend to stay then you must prepare for pre-registration. Pre-registration begins June 1, 2008 and only lasts 6 months until December 1, 2008. Once this window closes, you will not be able to export without fulfilling the full set of registration requirements. Appoint an OR or enable EU customers to complete pre-registration obligations.

### ***Do not "wait to see what happens"***

Deciding to hold off on pre-registration and get back in at a later time may not be a wise strategic decision - particularly if your customers have already adjusted their supply chains.

***Engage in discussions with BASF on the products you purchase from us that are part of your EU exports!***

## RESOURCES / LINKS

To get a copy of the REACH legislation or various guidance documents – please visit the European Chemicals Agency (ECHA) website:

<http://echa.europa.eu>

You may also obtain information about BASF's preparations and REACH overview information from BASF's REACH website:

<http://reach.basf.com>