

REACH: Confidentiality and the Only Representative Provision

Preserving company confidential business information (CBI) is one of the most perplexing and challenging aspects of the European Union's (EU) new chemicals regulation -- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).¹ The "only representative" provision, which enables a non-EU manufacturer to appoint an EU-based company or individual to fulfill the registration obligations that would otherwise fall on the EU importer of record, is an avenue that may offer relief to many U.S. and non-EU chemical manufacturers that export chemicals, mixtures, and articles to the EU, and to the EU importers of these materials.² One example of the need to protect CBI is the highly complex area of polymer composition and formulation, which is of significant interest to many of our clients and explained in some detail in this paper.

Polymer Confidentiality Issues

Under REACH Article 2(9), polymers are exempt from the registration and evaluation processes, although they ultimately may be subject to authorisation and restriction.³ The monomers

¹ Council Regulation (EC) No. 1907/2006, O.J. (L 296) 1 (Dec. 18, 2006) amending Directive 1999/45/EC, repealing Council Regulation (EEC) No. 793/93, Commission Regulation (EC) No. 1488/94, Council Directive 76/769/EEC, and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC, available at http://ec.europa.eu/enterprise/reach/index_en.htm.

² See REACH Article 8.

³ REACH Article 3(5) defines a polymer as follows:

[A] substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

- (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

REACH: Confidentiality and the Only Representative Provision

Page 2

employed in the manufacture of polymers are, however, subject to the full rigors of REACH, including registration, even if the monomers are imported into the EU in reacted form as a component of the polymers that are imported.⁴ This means that the importer must know the identity of the monomeric components of a polymer that the non-EU supplier may consider CBI.

Further, the importer must know the exact quantity of each monomer used in the polymer to be able to determine whether the REACH Article 6(3) conditions have been met and whether a registration volume trigger, which dictates the timing of registration, has been exceeded. Custom design by polymer architects is the lifeblood of the polymer manufacturing industry. The precise quantities of common monomers are one part of the technology, while the use of specialty monomers to provide unique properties is another. In the latter case, identifying the specialty monomer may be highly detrimental to preserving a competitive position. The following example illustrates these points.

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- (b) less than a simple weight majority of molecules of the same molecular weight.

⁴ REACH Article 6(3) provides in full:

Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

- (a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
- (b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

Hence, monomers (and other substances) for which both of the above conditions are satisfied must be registered under REACH.

Pre-registration and Registration of Polymers: The Acrylate Example

The design and manufacture of acrylate polymers represents a versatile technology for polymers used in a wide variety of applications. The ratios of such commonly used acrylate monomers as butyl acrylate (BA), ethyl acrylate (EA), and methyl methacrylate (MMA) in a given polymer will result in widely diverse products: for example, a polymer made using 90% BA and 10% MMA will be a soft, sticky glue-like material, while a polymer made using 90% MMA and 10% BA will be a hard plastic such as Plexiglas™. Due to the unique convention commonly utilized for naming polymers (*i.e.*, using only the identity of the monomers on a qualitative basis), these dramatically different polymers in terms of performance have identical chemical names.

The specific example we will use to demonstrate the degree to which confidentiality might be lost is that of an acrylate polymer consisting of five monomers in reacted form: 50% BA/40% MMA/6% EA/2.5% PM1/1.5% PM2. PM1 and PM2 are proprietary monomers, the first of which is used as an adhesion promoter and the second as a cross-linker. The major components of this polymer are commodity items and could probably be identified through common spectroscopic techniques, although the exact ratio would require a trial and error analysis in order to match properties. The proprietary monomers, on the other hand, would be extremely difficult to analyze as to both their identities and the levels at which they are used, and therefore they represent the heart of the confidential information. The following examples represent various levels of importation into the EU of the polymer described above and what the importer must know to be able to fulfill its registration obligation under REACH, even for pre-registration in 2008.

- **Scenario 1** -- The polymer is imported at a level of 2.2 metric tons (MT) per year: only monomer BA would have to be registered by the polymer importer because it is the only one that exceeds both the 2% weight condition and the threshold level of 1 MT per year.
- **Scenario 2** -- The polymer is imported at a level of 3 MT per year: both BA and MMA meet the conditions and must be registered.
- **Scenario 3** -- The polymer is imported at a level of 20 MT per year: BA, MMA, and EA all meet the conditions and must be registered.
- **Scenario 4** -- The polymer is imported at a level of 55 MT per year: BA, MMA, EA, and PM1 all meet the conditions and must be registered.

REACH: Confidentiality and the Only Representative Provision
Page 4

- **Scenario 5** -- The polymer is imported at a level of 100 MT per year: BA, MMA, EA, and PM1 all meet the conditions and must be registered; although the final monomer PM2 now also exceeds the 1 MT per year condition, it does not have to be registered because it is used in the polymer at a level below 2%.

In reality, the business relationship described above is overly simplistic. For example, the polymer manufacturer in the U.S. might sell its product to a polymer formulator in the U.S. who adds to its colorants, stabilizers, and surfactants, among other substances. Each of these additives must be considered for registration under REACH as well, so the importing company will have to know the identity and quantity of each in order to determine pre-registration and registration requirements. For these additive substances, the 2% condition in REACH Article 6(3)(a) would not apply because the additives are not “chemically bound” to the polymer, but an additive used at less than 2% would nevertheless have to be registered if it is imported into the EU, in this case as part of a mixture, in quantities of at least 1 MT per year. The exceptions to this rule are unbound heat stabilizers, light stabilizers, and/or antioxidants which do not need to be registered because they are considered to be part of the polymer substance. Although formulators know the components of their formulation, they will not typically know the composition of the polymer with which they start.

Summary

This paper summarizes only a few of the issues involving the critical and sensitive area of confidentiality under REACH with a focus on polymers. Some polymer manufacturers and formulators in the U.S. may choose to cease supplying proprietary substances to Europe and simply give up that business to maintain the confidential information inherent in the products in the rest of the world. The use of a REACH Article 8 “only representative” provides a way of dealing with confidentiality issues without giving up business interests in Europe.

The Acta Group, EU Ltd (Acta EU), Bergeson & Campbell, P.C.’s U.K.-based consulting affiliate, offers REACH Article 8 “only representative” services. Please call Steven Green at 011-44-1928-500056 or e-mail him at sgreen@actagroupeu.com to obtain more specific information on the services Acta EU can provide.