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REACH:

FOUR YEARS LATER

On June 27, 2011, Barnes Richardson associate Helena Sullivan attended a seminar hosted by the Department of Commerce on the REACH EU Chemical regime. The basics of REACH were laid out in BRC partner Rick Van Arnam's <u>A Practice Guide to REACH-The EU Chemical Classification System</u> when the regime was first enacted in 2007. However, practical issues that have come up in REACH implementation, and upcoming deadlines for registration, were discussed at the seminar.

Flavie Guerin, Commercial Specialist for REACH issues at the U.S. Mission to the EU in Brussels discussed the recent and upcoming registration deadlines. November 30, 2010 was the registration deadline for substances exported in quantities of more than 1000 tons per year, as well as certain substances which are carcinogenic, mutagenic or toxic to reproduction and chemicals used in quantities above 100 tons per year that pose long term risks to aquatic organisms. The next registration deadline is May 31, 2013 for substances exported in quantities of more than 100 tons per year.

This deadline applies to substances, substances in preparations, and substances contained in manufactured articles that are intended to be released (i.e. that are released in the normal course of usage). However the May 2013 deadline only applies if you were pre-registered in 2008. If you missed the 2008 pre-registration deadline, you can register in 2013 only if you are now exporting for the first time; otherwise you are required to register immediately. Note

that only EU manufacturers and importers can register, so if you are an exporter you must appoint a REACH "Only Representative" that is resident in the EU, or rely on the registration of your supplier's Only Representative <u>if</u> such registration covers your volumes.

Not only will there be many more substances registered in 2013 than in the last registration deadline and many more inexperienced companies participating in the Substance Information Exchange Forums (SIEF), but exporters now also have to cope with the new requirements for extended Material Safety Data Sheets in certain scenarios and compliance with the new EU regulation on classification, labeling and packaging of substances and mixtures, known as the "CLP" Regulation. CLP requirements were triggered in January 2011 for substances and in 2013 for mixtures. There is also a new United Nations initiative for CLP in the works.

Participants on the panel discussed the fact that because REACH registration is not substance-based but is based on your volume of exports to the EU, exporters relying on indirect registration (using the suppliers REACH registration number) can no longer easily switch suppliers based on price, unless the new supplier is also REACH-compliant. It was suggested that exporters have contingency plans in case the supply chain from your current supplier is interrupted. Another issue that came up is that because of REACH, it is now essential that registrants be aware of all applications of the chemical as your registration only covers those applications that are included in

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the risk assessment. If your application as confidential, you can submit your own exposure scenario confidentially. The panel also provided estimated costs per substance per company for members of a SIEF, and they were significant. However, cited benefits for SIEF participation included the ability to market products as REACH-compliant and thus environmentally sound, access to toxicology testing data at a reduced cost, and the ability to meet regulatory standards in other global markets, most of which will be less strict than REACH.

In addition, Substances of Very High Concern (SVHCs) that are potentially hazardous to the environment and/or human health were discussed. Although there are currently only 52 substances on the SVHC "Candidate List" which triggers certain requirements, the Candidate List is updated twice a year and the EU intends to expand this list significantly. Because the Candidate List status confers extra obligations, it has a 'black list' effect in the EU because that substance could eventually make it to the "Authorization List", which means it is banned. Therefore, panelists noted that exporters of such chemicals should consider alternatives.

The panel discussed the fact that the "Registry of Intentions", which is a listing of substances being considered for the Candidate List, includes some substances that are in very common usage, such as nitric acid. Note that while exporters of manufactured articles containing Candidate List substances do not have to register unless their substances have intended release or are a "container" for a substance, you still are subject to notification requirements if there is more than 0.1% of that substance in the article and export more than 1 metric ton per year (however, there are certain exemptions from notification). These requirements have sparked the growth of a new specialty, consultants specializing in REACH testing. The panel, which included such consultants, discussed the testing methodology for articles, including sampling by cryogenic milling.

The panel also discussed the fact that some EU member states, notably France, take the position that for the purpose of the 0.1% threshold, a component of an article is the "article" for the purpose of the calculation, not the finished product it is incorporated into. The panel discussed the legal obligations triggered by the presence of an SVHC in a product, including the requirement to immediately declare the presence of the SVHC to downstream users if it contains a more than 0.1% concentration. The panel noted that while Certificates of Compliance will be collected from suppliers, that does not suffice to constitute due diligence and there has been a great deal of SVHC third party verification. The panel also noted that it is expected that because of REACH, some chemicals are expected to disappear entirely from the global market, for economic reasons.

If you have further questions, please call BRC partner Rick Van Arnam at (212) 725-0200 ext 126, rvanarnam@barnesrichardson.com, or associate Helena Sullivan at (212) 725-0200 ext. 119, hsullivan@barnesrichardson.com.

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