Getting An A grade in Authorisation

For the companies it affects, Authorisation is likely to be the biggest REACH challenge. But there’s no reason why it has to be – provided you stick to a few simple rules.

Applications for Authorisation are on the rise. Eight were submitted last year and ECHA expects 20 more during 2014. With 151 substances on the candidate list, and new substances appearing all the time, this is really just the start.

So it is no surprise that many companies are already investigating this relatively unknown part of the regulation. It is an intimidating prospect. An Application for Authorisation is both complex and costly, and most companies do not have the relevant expertise to call on. What is more, a failed Application will result in the inability to continue using the substance. So if your products are dependent on this use, you could suffer a significant blow to your business.

“The Authorisation process was always designed to be challenging,” says Meg Postle, Director at RPA, a UK chemical hazard consultancy. “The idea is to push companies towards substitution. They have to submit in-depth studies of the alternatives that should, to a large extent, pre-empt third party objections. For many companies, it will be much bigger than anything they’ve previously had to do for REACH.”

RPA is working on a wide range of Applications, including six of the eight Applications relating to phthalates DEHP and DBP. In February, the company took part in the Trilogue meetings for these phthalates, which included discussion of the more than 120 comments received during the public consultation period and additional questions from the RAC and SEAC Committees. But there are encouraging signs. ECHA has said that companies can improve their Applications are of a high standard. As an Application can take several years to put together, early preparation is essential. It is also important to pre-know your supply chain. If it is not possible to ‘adequately control’ the risks associated with your substance, perhaps because there is no safe threshold exposure, you will need to accurately determine the impacts of a non-use scenario. Such an analysis is difficult, if not impossible, without the cooperation of downstream users.

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According to the study, Impact of REACH on SMEs in the Netherlands,1 commissioned by the Dutch Ministry for Infrastructure and the Environment, 23% of SMEs belonging to the chemical industry are not aware that they do, in fact, have obligations under REACH. A company does not need to be an SME, however, to have the false impression that it has no obligations under REACH. This article outlines frequent misconceptions regarding REACH obligations and provides guidance to help confirm whether companies have responsibilities under REACH.

“We have already pre-registered our substances.” Remember, submitting a pre-registration is an administrative task that allows for potential REACH registrants to benefit from extended registration deadlines. With the final deadline fast approaching, the expected number of unique substance registrations is estimated at 25,000 to 50,000.2 Many companies may find themselves in non-functioning SIEFs with no Lead Registrant, or with Lead Registrants who themselves are SME companies with limited regulatory and financial resources.

If your company has pre-registered a substance, it is essential to check REACH-IT regularly for new information on the progress of the SIEF and appointment of the Lead Registrant. If substances are considered essential within your business, now is the time to evaluate your ability to take the Lead Registrant role. It is also possible for your company to evaluate its business and determine if it wishes to continue to place its substances on the EU market. This activity should begin now so that your company can ensure compliance with REACH by the respective deadline.

Think REACH Does Not Apply to Your Company? Are You Certain? Read On

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Even if you pre-registered your substances as a precaution, you should communicate with your supplier to request details on a substance’s registration status. More importantly, you should confirm with your supplier that your tonnage is covered by its, or its supplier’s, registration. A request for a REACH conformity/confimation letter would suffice in this case. Remember, it does not matter where your company falls within the supply chain of a substance, confirmation of how these substances are addressed under REACH is essential. If a pre-registration or registration is not confirmed for your substances placed on the EU market at >1 tonne, you may have to consider an alternative supply to ensure compliance for your company.

“The SDS is the registrant’s responsibility.” The quality of SDSs has improved with significant increases in available hazard data. As a user of chemical substances, mixtures, or end products, you must understand and comply with the PNECs and DNELs/DNELs, Risk Management Measures, and Exposure Scenarios provided in the SDS within 12 months of receipt. It is essential to understand which Exposure Scenario refers specifically to your activities, potentially performing scaling calculations to ensure exposure is not higher than allowed. ECHA has recently updated its guidance on these processes.3

“We import articles; substance registration is not our concern.” Producers and importers of articles, defined at REACH Article 3, must ensure a pre-registration or registration for substances intended for release in the article (>1 tonne) is in place and addresses the specific uses. If the substance is listed on the candidate list, ECHA must be notified of concentrations exceeding 0.1% and ≥1 tonne. Communication obligations along the supply chain, however, are not restricted by tonnage thresholds. Producers and importers of articles will find themselves facing decisions on whether it meets the REACH “article” definition, whether there are substances intended for release, or if it is registered upstream in the supply chain for the same use. Understanding your obligations can seem overwhelming at first, but it does not need to be a long or complicated process. A good starting place is the Navigator application4 where, by answering a couple of simple questions, the system helps to identify obligations under REACH. If you have any concerns of your substance’s status or are unfamiliar with REACH expressions, a qualified consultant can assist in determining your compliance obligations. The only unacceptable option is to do nothing. REACH non-compliance can cause serious business disruption or a fine being issued by your local Competent Authority. Take the steps recommended here so you can answer with certainty whether REACH applies to your business.

The Acta Group is a scientific and regulatory consulting firm with offices in England, China and the United States, provides strategic, comprehensive support for global chemical registration, regulation, and sustained compliance.

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2. Industry submitted 3,400 substances during the 2010 registration, and 3,000 more in 2013.

References: