

Steffen Erler

REACH Consultant, Oxford, UK

reachconsultant@btinternet.com

3/20/2007

REACH Implementation Projects: One Down, Nine to Go

Regulators and industry share uncertainty on how to implement REACH. Attaining a harmonised interpretation of the regulatory requirements is turning out to be as equally challenging as agreeing on the legislative text.

Theoretically, the REACH Implementation Projects (RIPs) should assist companies with each step of the legislation. The first of the ten projects for industry, RIP 3.1, seeks to provide an over-arching structure for companies to identify regulatory duties and obligations. However in practice some issues extend beyond the remit of technical guidance. Therefore, regulators and stakeholders are having difficulty in reaching mutual consensus on what should be contained within the guidance and on how the legal text should be implemented.

Many companies across the globe rely on the outcome of the RIPs when preparing for the legislation. Unfortunately, official guidance will not be available until after the legislation enters into force. To date, not a single Technical Guidance Document (TGD) produced by the RIPs has been finalised. One appears to be on the way to completion: RIP 3.10 on substance identification. Another nine RIP TGDs for industry may not be finished for some time.

In essence, RIP 3.10 is the most critical RIP and the starting point for regulatory compliance. Because the regulation applies at a substance-specific level, meeting requirements depends on knowing what and how much of any substance is contained within a given product. Complexities begin with the fact that different chemical naming and identification schemes exist. For instance, a substance could be a mono-constituent substance (e.g. substance A) with impurities (x and y), a multi-constituent substance (e.g. substance A, X, and Y) or a complex reaction product (e.g. reaction product of B and C). For many businesses, the chemical contents within finished products on a broad substance level prove more important than the percentage of impurities present within any substance or specific naming schemes.

RIP 3.8 on substances in articles still has to establish exactly how to determine regulatory requirements of finished goods (i.e. 'articles') that are imported into the EU. The current draft TGD appears to be the subject of significant contention and review. Unresolved questions revolve around how to calculate the chemical contents in imported goods. For instance, when importing a car into the EU, should REACH requirements be based on the percentage chemical composition of each component of the car (e.g. tire, dashboard, engine, etc.) or the entire car? Also, at what point is the chemical composition of a product more important than its physical shape? The answers to these questions prove fundamental to determining what actions a company must take to ensure REACH-compliance.

Arguably, RIP 3.2 on chemical safety assessments, RIP 3.3 on data requirements, and RIP 3.5 on downstream user obligations closely interlink and form the central axis upon which the REACH system will operate. Downstream users must supply sufficient information upstream so that manufacturers or

importers can perform chemical safety assessments to demonstrate the safe use of a given substance through the supply chain. Otherwise, a downstream user may need to perform and report its own safety assessment. A safety assessment will of course depend on both an exposure and hazard element; RIP 3.3 defines the information needed for a hazard assessment.

Another fundamental aspect of the regulation is the need to participate in consortia for the purpose of the joint submission of certain data. While RIP 3.4 on data sharing will provide invaluable advice on management strategies, forming consortia will often depend on legal contracts between parties. In turn this takes time; companies are therefore recommended to begin now.

The remaining RIPs cover the application process under the Authorisation (RIP 3.7) and performing the relevant socio-economic analyses (RIP 3.9). Given the current timeline for implementation and the small fraction of substances that will be subject to Authorisation compared to Registration, completion of the other RIPs should have priority.

Regardless of the final outcomes of the RIPs, the legislation contains some certainties. For a start, if a company wants to benefit from a phased-in implementation timeline (of up to 11 years) then each substance within the scope of REACH must be pre-registered. If a company imports an article containing a substance that is intentionally released from the article that could need to be registered, then it will probably also want to pre-register that substance. This offers a window of opportunity to check whether any other company will be supporting that particular use of the substance. Therefore, RIP 3.10 proves an important platform for many companies to begin assessing and managing some of the technical intricacies of REACH. More draft TGDs will soon follow.