EU REACH Chemicals Law: Challenges For American General Counsel

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Last year we advised you on the challenges posed by the draft EU REACH legislation. Now that the law is finalised, we update you on the position.

Essential REACH Overview

REACH is the acronym for a new European Union (EU) chemicals law that has finally been agreed after a long period of debate and lobbying in Europe. REACH stands for the Registration, Evaluation and Authorisation of Chemicals. There is a further stage, Restriction, which certain substances will also have to go through. It will be in force in all EU member states on 1 June 2007, with the first obligations coming into effect in June 2008.

In very broad terms, REACH affects companies which operate in, or import products into, the EU. It will therefore have an impact upon trade worldwide. REACH affects a wide range of sectors to differing degrees; from the obvious large chemical and raw material manufacturing companies; to sectors as diverse as automotives, paints, detergents and clothing. The main obligations are on manufacturers and importers, but there are a number of requirements on product re-formulators and professional users further down the supply chain. Distributors and retailers may be affected by product changes or the ceasing of production of certain products. Affected manufacturers and importers have to register with a new European Chemicals Agency in Helsinki, Finland and will be prevented from operating in the EU market if they fail to register by the relevant deadlines. Infringements will result in sanctions. Consumers have no obligations under REACH and can obtain a significant amount of information regarding substances from the new European Chemicals Agency.

Fundamentally, REACH has completely reversed the burden of responsibility for the risk assessment process governing the use of substances. As a market pre-requisite, industry must now prove that their chemicals are safe for human health and the environment. The cost impact of this on business will be significant. REACH raises a number of issues that General Counsel will have to face as set out below.

What Does REACH cover?

REACH covers both existing substances that are on the market now (estimated at 30,000) and new substances as they are introduced by industry. It is important to note that REACH applies to substances, not products. Substances can be on their own, within preparations (mixtures of substances), or in articles (items that have a particular shape or design which determines function).

A small number of substances are totally excluded from REACH, such as radioactive substances and waste. A larger group of substances are excluded from the Registration and/or Authorisation processes, notably, food additives, cosmetics, medicinal products, biocides, pesticides and polymers (monomers are not excluded). Therefore, the first step for General Counsel is to determine whether their company's chemicals and/or articles will fall under REACH.

Is There A Duty Of Care?

Industry will be pleased to hear that the final text of REACH does not include a specific legal duty of care, which was present in earlier versions of the legislation. However, there is still a general obligation to ensure that the manufacturing, placing on the market, importation or use of chemicals does not adversely affect human health or the environment. General Counsel will need to consider the impact on the company's risk management strategy and put in place mechanisms to deal with this. For example, by considering contractual mechanisms with suppliers and customers.

What Is Registration?

Companies that manufacture or import substances caught by REACH, in quantities of 1 tonne or more per year, must register with the new European Chemicals Agency. Failure to comply will mean exclusion from the EU market. Registration requires detailed technical dossiers to be compiled (requirements increase with tonnage and/or hazardous nature). Users of chemicals further down the supply chain will also need to ensure that their specific uses are registered and provide additional information back up the supply chain.

Due to the large numbers of substances and sectors affected by REACH, there is a transitional period for registration of substances already on the market. To facilitate this process, there is a pre-registration period in 2008. If a company takes advantage of this, it will have much longer to compile the technical dossiers required for full registration (registration deadlines then depend on tonnage and/or hazardous nature). It is then mandatory for companies to get together in groups, often referred to as consortia, to share existing animal test data on substances to minimise further testing that may be needed for registration. One company in the group then submits the registration information to the Agency. Companies have the ability to be compensated for the data that they share.

Compliance with the registration process will require companies to start planning now to avoid difficulties in the future. Companies will need to identify and evaluate the data they currently hold on substances. The consortia groups will require contractual agreements to properly set out each member's rights, liabilities and obligations. Some sectors are setting up such consortia now to share data and prepare for registration. In all dealings with competitors, companies must take care not to infringe anti-trust law (competition law). Companies will also need to carefully consider data-share compensation issues from a commercial angle as well as an anti-trust law compliance perspective.

What Technical Information Must Be Submitted?

A key part of Registration involves manufacturers, importers and users further down the supply chain preparing and submitting a "Chemical Safety Assessment," along with a "Chemical Safety Report." The "Chemical Safety Report" will document the "Chemical Safety Assessment." Essentially, it is a risk assessment in which the registrant takes account of the life-cycle risk management measures that it intends to either implement for its own uses of a chemical, or which will be proposed to users further down the supply chain for their intended uses.

Identifying, applying and recommending risk reduction measures will be a tall order for businesses. Although certain criteria are set out to enable companies to undertake the "Chemical Safety Assessment" and put together the "Chemical Safety Report" this exercise will not be straightforward. Companies will need to implement a thorough compliance strategy, especially as getting it wrong may entail liability and sanctions.

What Does Evaluation Mean?

The European Chemicals Agency will check a percentage of the dossiers submitted to make sure that they contain the right information and may request registrants provide additional data. More substantively, for certain priority substances identified by the Agency, member states will evaluate the dossiers. These substances may then need to be Authorised or Restricted (see below).

What Does Authorisation Mean?

All uses of substances with intrinsic properties of "very high concern" must be authorised before they can be placed on the market. "Very high concern" means that the effects of the hazardous properties on living organisms are usually irreversible. This could include, for example, substances that are carcinogenic, bioaccumulate or persist in the environment. The European Chemicals Agency will compile and publish a priority list of substances that must go through this process.

Authorisation will apply to particular uses of a chemical and will only be granted if the manufacturer or importer can show that risks from the uses in question can be adequately controlled, or that the socio-economic benefits of the use of the chemical outweigh the risks and there are no suitable alternatives. Companies will need to prepare a substitution plan when applying for an Authorisation. Authorisation will be valid down the supply chain, with certain regulatory obligations for such users.

General Counsel should consider whether their company's chemicals could be targeted for Evaluation and/or Authorisation. The data required for an Authorisation application is significant and will be very costly to prepare. Companies will need to consider the cost/benefit and whether early substitution is a viable alternative, considering the potential effect on product formulations. A strategic approach will be needed as such chemicals are inevitably going to be politically sensitive.

What Does Restriction Mean?

Separate to the Authorisation process, certain substances may have additional restrictions imposed or be banned outright, where the risks cannot be adequately managed and there is a need for regulation at EU level. This stage acts as a safety net. Again, General Counsel will need to consider if this might apply to their company's chemicals and develop a management strategy to deal with this accordingly.

What About Confidentiality And Data Protection?

The Agency will make a large amount of information submitted under Registration publicly available on its website. Companies can request that some of this data be kept confidential, where disclosure may harm the company's commercial interests. As for data protection, as mentioned above, companies are required to share animal test data they hold. However, there are data compensation mechanisms under REACH to avoid free-riders from using such information.

General Counsel should therefore be careful to ensure that its confidentiality rights are being protected throughout the REACH process. Mechanisms can be put in place within consortia agreements to address such issues as confidentiality, data ownership (including data-share compensation issues as mentioned above) and where possible, the protection of intellectual property rights.

What Are The Penalties For Non-compliance?

EU Member States are responsible for imposing sanctions for infringement of REACH according to their national laws. Currently, no member states have drafted any legislation setting out details of any penalties. Each member state will appoint a national agency to deal with enforcement. For example, in the United Kingdom, this is the Health and Safety Executive. As sanctions are not determined at an EU-wide level, there will be concern as to variances in approach throughout the EU, where penalties may vary in both substance and practice. Nevertheless, General Counsel are recommended to devise a compliance programme for the company in order to minimise the risk of breaching REACH.

Can Decisions Be Challenged Under REACH?

Appeals to a limited number of Agency decisions can be made before a "Board of Appeal." Including, for example, decisions concerning certain aspects of Registration and Evaluation. There is also the possibility of taking legal action in the form of judicial review before the European Court of Justice, both against decisions of the Board of Appeal and also, where no right of appeal exists against the Board of Appeal, against decisions of the Agency. General Counsel should ensure that a good paper trail is being kept by the company in case it needs to use these avenues of redress.

Conclusion

REACH therefore imposes a number of challenges for companies, both through the detailed internal management of information necessary for compliance and the wider strategic impact and costs of REACH. However, with appropriate preparation and planning, the most successful companies will be able to avoid being caught out by REACH.

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