

REACH - An Enforcement Update

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In the months leading up to the REACH first registration date on 1 December 2010, the focus of the European Chemicals Agency (ECHA) was understandably on the 25,000 registration dossiers submitted. It is understood that it is still considering some of these, but it would still be safe to say that the ECHA's attention is now on matters of compliance.

What is important to remember in connection with REACH is that it has a continuing and evolving effect on your business. For example:

There are three further deadlines for manufacturers and importers:

- 1 June 2013 - registration for substances over 100 mts per year
- 1 June 2015 - the EU Regulation on Classification, Labelling and Packaging of Chemical Substances 1272/2008 will apply to mixtures
- 1 June 2018 - registration for substances over 1 mt per year.

While these dates may seem like a long time away, there is an aspect of REACH that could have a sudden and dramatic impact: an inspection from the local State competent authority.

Article 126 requires that each Member State has to lay down provisions for the enforcement of REACH. These provisions "must be effective, proportionate and dissuasive."

Article 121 states:

"Member States shall appoint the competent authority ... responsible for performing the tasks allotted to competent authorities under this Regulation and for cooperating with the Commission and the Agency in the implementation of this Regulation."

The competent authority is therefore the State organ that is tasked with ensuring that any company affected by REACH, complies with its dozens of legal obligations. The ECHA clearly

regards the obligations to enforce REACH compliance as proactive as well as reactive. In case competent authorities were in doubt, the Regulation specifies that Member States have to report to ECHA every five years (Article 117):

1. Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127.

The first report was due by 1 June 2010, which was a little early from the point of view of enforcement. However, statistics are now becoming available on enforcement activity among Member States. Although it may be early days in respect of enforcement, there are already some important points to note and some action that needs to be taken now.

Current trends in enforcement, and the future:

- Every Member State was required to notify their penalty regimes to the ECHA by 1 December 2008. These regimes vary significantly from State to State:
 - a. Most have catch-all provisions which penalize any breach of the Regulation, but some do not, which may mean that there are gaps in the national laws which fail to address certain breaches;
 - b. Some States adopt administrative penalties only;
 - c. Some States adopt criminal penalties only;
 - d. Some States have a regime incorporating both;
 - e. Within each regime the penalties can be very different. For example, in the UK offenders face unlimited fines and up to two years in prison, whereas in Italy the maximum fine is €150,000 or up to three months in prison.
 - f. Although some regimes may not include criminal sanctions, their administrative sanctions can represent a more significant commercial penalty. For example, a company may be required to cease operations in the jurisdiction for a significant period.
- You may have wondered how one might get caught in breach of one of the many REACH obligations. The answer is that the likelihood and method of being found in breach currently varies from State to State. Officially, competent authorities should adopt both a proactive and a reactive approach to enforcement. On the reactive side, the competent

authorities should make it easy for those who are concerned that they are in breach to gain advice on how to comply and also for those concerned about the compliance of others, to have an accessible structure within which to lodge a complaint about perceived breaches.

- On the proactive side, all States were meant to participate in REACH-EN-FORCE-1, which is the first of a number of EU-wide REACH enforcement projects. It commenced across Europe in May 2009 and will continue to the end of April 2011. The project was designed to enforce the core principle of REACH: "no data, no market". Inspectors in the participating countries were charged with checking (through inspections) whether companies have a valid pre-registration or registration and, where appropriate, that adequate safety data sheets are compiled and provided.
- Between May and December 2009, almost 1,600 companies were inspected. You might have expected a majority of these companies to have been manufacturers, but a high percentage were downstream users of substances.
- It is understood that, for the most part, the inspections are approached in a constructive manner in recognition of the learning curve that companies have had to go through. For example, the current approach to enforcement by the Health and Safety Executive (HSE) (the UK competent authority) is as follows:

"Enforcement can involve prosecution, but more usually it involves less forceful approaches. These include issuing enforcement notices to change behaviour, as well as approaches to help companies understand what their legal duties are and how they can be met."

- There have been very few sanctions imposed, and those that have been imposed have mainly been administrative in nature. However, inspectors have found that, having made recommendations for improvement/compliance, some companies have failed to take any action at all. Clearly this kind of behaviour carries with it the danger of turning what might have been seen as negligence at the first inspection, into a culpable breach at the second, and is therefore likely to result in penalties being imposed.

- There has been a big difference in the number of inspections made in each Member State, but it is safe to predict that ECHA will be looking hard at those with a poor record in this area and be expecting them to bring their figures into line with the other more proactive States.
- REACH-EN-FORCE-2 is to commence from April 2011. The project will target formulators of mixtures, as a natural continuation of the REACH-EN-FORCE-1.
- However, the future is likely to see:
 - a. inspections being more widespread and frequent; and
 - b. the inspectors being less indulgent of any issues arising.

Recommendations:

- One of the least impressive reactions to the arrival of the inspectors is to demonstrate a complete absence of preparation for an inspection. In contrast, you can impress the inspectors by:
 - a. Introducing the designated REACH Team;
 - b. Providing the inspectors with a REACH Inspection dossier, which should include:
 - i. The REACH Team chain of command;
 - ii. The company's REACH compliance protocols/policies, which should cover how amendments and developments of the REACH Regulations are tracked and incorporated where necessary;
 - iii. A REACH documentation log - i.e. what REACH documents you have and where they are kept.
- Inspections can also be a much less stressful event if you already have developed a relationship with the local competent authority. In this way you will have up to date information on new developments and will also know what worries them most. In the process of creating a dialogue, there will be queries arising on both sides - discuss them

and take advantage of the conclusions reached. The UK contact details are:

REACHCompliance@hse.gsi.gov.uk

- If your competent authority is unable to help, go to ECHA if necessary (echa.europa.eu). They will be very keen to help.

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