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Chemical Reaction

By Steven Vaughan

At the start of June, the European Chemicals Agency (ECHA) began the task of substantively administering what has been described by EU Commission officials as the EU's most complex and complicated piece of legislation to date. REACH, the Regulation on the Registration, Evaluation and Authorisation of Chemicals, came into force a year ago and will require the scrutiny of some 30,000 of the more than 100,000 chemical substances currently on the EU market.

Replacing around 40 pieces of existing legislation, REACH requires producers and other users of chemicals to register, and potentially test, substances manufactured in or imported into the EU in quantities greater than one tonne per annum. Registration with ECHA is also required for chemical substances in certain 'articles', where the chemical substances in those articles are intended to be released during normal conditions of use. There are, however, some substances that are exempt from REACH, such as those that are naturally occurring and which are thought to have low hazard properties (such as water) and those which have existing targeted EU regulatory controls (such as waste). As part of the general 'no data, no market' rule, failure to register substances subject to REACH with ECHA will result in their continued manufacture or import becoming unlawful.

To make the new policy administratively workable (for regulated and regulator alike), there are phased deadlines for registration of substances with ECHA, staggered between 2010 and 2018 depending on the tonnage band in which the chemical substance is manufactured or imported and the relative toxicity of the substance. In order to take advantage of these deadlines, manufacturers and importers must pre-register their so-called 'phase-in substances' between 1 June 2008 and 30 November 2008. The EU Commission has estimated that somewhere in the region of 200,000 pre-registration dossiers will be submitted over the course of the next six months (with ECHA disclosing at its inauguration ceremony on 3 June that some 2,000 pre-registrations had been filed in the first two days of the system going live).

On a practical level, pre-registration comprises the electronic transmission of certain information via the REACH-IT portal on the ECHA website by each individual legal entity within a business. Companies can either:

- encode all necessary information directly online with REACH-IT (which would be exceptionally labour-intensive for any large manufacturer); or
- use a pre-registration software plug-in called IUCLID 5 (which

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allows the company to use existing information in a local database offline and in advance, before then submitting that information to ECHA via REACH-IT).

Glitches have been identified with ECHA's online pre-registration system and with IUCLID 5 on a number of occasions, through pilots of both systems by various EU companies and through internal checks by ECHA. In early May, the general consensus was that the IT infrastructure designed to handle pre-registration (and due to go live four weeks later) was not fit for use. One week before pre-registration went live, a further trial run of the system by a number of industry associations, including Cefic, showed that matters had improved somewhat since the start of May, but that glitches remained. One of the key questions concerns the ability of the system to handle the bulk submission of data, where a company that has hundreds or even thousands of chemicals to pre-register tries to upload the necessary data on them all at the same time.

Following pre-registration, ECHA will identify those pre-registrants looking to register the same chemical substance. Under REACH, and as part of a 'one substance, one registration' rule, pre-registrants of the same substance (as well as potentially other stakeholders, such as non-governmental organisations) will come together in a substance information exchange forum (SIEF) to share data and decide on the ambit and cost apportionment of additional substance testing. The general principle is that for any given substance, a single set of information on its intrinsic

properties is produced that is shared by the members of the SIEF, although business-specific and business-sensitive information will be submitted separately by each company. While REACH does not prescribe what legal form these SIEFs are to take (or how SIEFs are to be managed or run), a number of consortia have already been organised under the umbrella of industry associations.

Looking forward, in the near term, the following six months will present a series of challenges for ECHA, and for those companies subject to REACH, as pre-registration progresses and wrinkles in the associated infrastructure systems are ironed out. In the longer term, REACH stakeholders will also be faced with wider, and perhaps less immediately obvious, concerns, including the regulation and risk assessment of nanotechnologies under REACH and the possible knock-on effects of the EU's new chemicals policy in the context of US disclosure and liability laws. We are also likely to see the future landscape of the EU chemicals sector alter, as a number of substances are removed from the market as their continued production or import is no longer economically viable and as certain companies find that compliance costs make their businesses unsustainable. At the moment, it is very much a case of 'wait and see' for those stakeholders interested in the progress of REACH. However, for those companies subject to the Regulation's provisions, doing nothing is not an option.

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