ORs vital for fair global regulatory compliance

A REACH only representative (OR) has the right to act on behalf of a non-EU manufacturer to fulfil several obligations of REACH. In doing this, the OR prevents a distortion of competition between EU and non-EU firms.

This facility is important in order to protect non-EU firms from discrimination – and the EU from infringing its obligations under World Trade Organization rules. It also enables EU enforcement authorities to have a means of ensuring compliance by non-EU firms. But despite these crucial functions, the term OR appears only four times in REACH – in Article 8 and in Annex II concerning safety data sheets – and the rights and responsibilities of ORs have been ill-defined. In fact, the term OR is not defined at all and references to their duties are scarce and imprecise in REACH guidance.

Due to this lack of definition and clarity, a lot of controversial discussions and interpretations have occurred involving all REACH actors on what an OR is and what their roles and duties are. Different interpretations by enforcement authorities have resulted in varying compliance obligations. In addition, due to shortfalls in the legal text, the OR has been asked to assume responsibilities that were initially not foreseen.

For non-EU manufacturers, choosing the right OR is an important decision as this will be a long-term contractual relationship. The OR role does not stop with the registration of a substance but continues, involving, for example, the tracking of annual volumes and importers or safety data sheets (SDSs). Hence, mutual trust is a prerequisite because the OR acts as trustee for his principal, safeguarding access to the EU market for its client's products.

To address the lack of recognition, in 2009 some leading ORs founded the Only Representative Organisation (ORO), whih is located in Brussels. One of its main purposes is to maintain a dialogue with ECHA, the European Commission, competent authorities and other stakeholders in the REACH implementation process in order to facilitate REACH compliance by ORs and non-EU companies. Another objective is to promote professional conduct and competence – to provide reliable information on OR duties and tools to help non-EU firms select the right OR. Given that no satisfactory information regarding the skills and qualifications of ORs exists, ORO has established quality standards for its members, alongside disciplinary procedures. The organisation is now an accredited ECHA stakeholder.

Through our second survey of member activity in Q4 of 2011, we established that ORO-accredited ORs have so far registered around 800 substances, which when compared with ECHA's statistics, suggests that they account for some 20% of OR registrations or 3.5% of total registrations. An analysis of the 12,000 pre-registrations made by our members shows that 10% of these were for substances to be registered in 2010, 20% for 2013 registrations and 70% for 2018 registrations. We represent many tens of thousands of EU importers and more than three quarters of our clients are in the Far East. This significant market share has enabled us to identify and contribute to the clarification of some key implementation issues for ORs under REACH so far. These include:

* tracking of substances in complex non-EU supply chains;
* tracking of re-imported substances;
* responsibilities for creation and content of SDSs;
* SME verification;
* clarifying who has importer status;
* the role of ORs under the EU classification, labelling and packaging (CLP) Regulation; and
* the role of ORs in submitting authorisations for our clients.

In January 2012 the Commission confirmed that it will allow ORs to apply for, and obtain, REACH authorisations. Another step forward is that the policy of the Commission and ECHA on whether an OR is entitled to submit a classification and labelling (C&L) notification recently changed to allow this (**CW 5 April 2012**). This new direction significantly reduces the administrative burden for importers and provides a solution for confidential compositions of mixtures.

However, one of the most pressing questions – who is responsible for the content of SDSs – remains unresolved, in particular for mixtures comprising substances that have been registered by several different ORs. ORO is currently preparing a best practice guide on only representatives. Hopefully, this document will further understanding of their roles and responsibilities.

Meanwhile, the OR-facility seems to be an attractive option within chemical control legislation in some non-EU countries that are implementing similar schemes. Turkey adopted an equivalent OR concept in its implementation of REACH-like legislation. South Korea too is maneuvering towards a REACH-like law with its own version of an OR role. But unfortunately, from a first assessment it looks as though the same mistakes regarding imprecise definitions of the roles and responsibilities of the OR-function are being made as in the EU.

ORO is prepared to contribute its expertise and cooperate with ECHA, the Commission, member states and other stakeholders to help find appropriate solutions. We are also ready to assist in setting up national OR associations in other countries that are moving forward with OR schemes in their national chemical management legislation.

The views expressed in our contributor columns are those of the authors and not necessarily shared by Chemical Watch.

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