Legal Insight

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Intermediates Compliance Warning

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ECHA raised serious concerns recently about the quality and compliance of 574 companies' registration dossiers, all of which relate to intermediate substances. The companies have been notified via REACH-IT and given 3 months to either rectify their dossiers or face regulatory sanctions.

REACH Article 3(15) defines intermediates as chemicals that are "manufactured for and consumed in or used for chemical processing in order to be transformed into another substance." If the on-site or transported isolated intermediate is "manufactured and used under strictly controlled conditions," REACH allows registrants to submit a dossier with no chemical safety report and reduced information on substance properties. This saves time, fees, and simplifies the registration procedure.

To be able to submit a reduced dossier, substances must both meet the definition of an intermediate and be appropriately contained during their life cycle. ECHA's criticism has centred on registrants failing to meet these criteria, as described in REACH legislation and ECHA's Guidance on Intermediates. Of the 5,500 registrants of intermediates, ECHA found 2,388 dossiers that failed in this regard, representing 760 substances. Several common reasons emerged for this:

- Substances did not fully transform in accordance with the REACH criteria during the manufacturing process.
- Substances were used by industrial or professional workers in any of the 23 process categories considered incompatible with intermediates.
- Substances were used with dispersal wider than that prescribed by the intermediate status.
- Dossiers depicted any of the 20 non-suitable environmental release categories contravening the intermediate identity.
- Substances depicted technical functions incompatible with the technical function of an intermediate, such as agents absorbing gases or liquids, binding agents, colouring agents, pigments, pH-regulating agents, and so on.
- Dossiers described consumer contact with the substance, which by definition is in contravention of the intermediate identity.

All registrants of intermediates should carefully consider whether their manufacturing process meets the criteria for reduced registration requirements or whether a full registration dossier should be submitted. Changing from an intermediate to a full registration requires a new, full registration fee to be paid as ECHA has to fully re-process the dossier and carry out the appropriate follow-up work. ECHA has indicated to us that this holds true, notwithstanding the advice in 1.2.2 of ECHA's Guidance on Intermediates, which states that such a change merely requires the dossier be "updated," a process that should involve a lower fee. In addition, the status of intermediate registrations should be monitored by registrants who have referred to data contained in dossiers of such intermediates, as there may be implications for their own registrations.

With the 31st May 2013 REACH deadline for manufacturers of 100 to 1,000 tonnes fast approaching, time is ever more of the essence.

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Deadline approaching for updating dossiers in light of 2nd Adaptation to Technical and Scientific Progress (ATP)

In addition to reviewing compliance of registration dossiers for intermediates, companies should note that they must update their dossiers and notifications to the Classification and Labeling Inventory by 1 December 2012, according to the provisions of the 2nd ATP.

The ATP features amendments concerning new subcategories in hazard classes of respiratory and skin sensitisation, along with a revision of the classification criteria for aquatic chronic toxicity, and a new hazard class for classification: "hazardous to the ozone layer."

REACH registration dossiers for all substances must be updated and notifications made to the C&L Inventory by 1 December 2012, whilst compliant classification, labeling and packaging standards must also be applied. The following transitional provisions may apply:

- Substances placed on the market before 1 December 2012 and classified, labeled and packaged according to the CLP Regulation do not require relabeling and repackaging until 1 December 2014.
- Mixtures do not need to be relabeled and repackaged until 1 June 2015. Note that mixtures placed on the market before 1 June 2015 and classified, labeled and packaged in accordance with the CLP Regulation or the Dangerous Preparations Directive require ATP compliant relabeling and repackaging only by 1 June 2017.

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