REACHing First Results

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The first 2010 Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH) registration deadline passed on December 1 of last year. The deadline involved the highest volumes and most hazardous chemicals that were manufactured in or imported into Europe.

At deadline, the European Chemicals Agency (ECHA) received 24,675 registration dossiers for about 3,400 phase-in substances from all member states. Germany topped the list of most submitted dossiers with 23 percent, followed by the United Kingdom with 12 percent.

On November 30, Thomas Jakl, chair of the ECHA Management Board, said, “Today’s deadline is an important milestone within the reshaping of the European Union’s (EU) chemicals policy.”

ECHA received registrations for approximately 400 substances listed as Category 1 or 2 Carcinogenic, Mutagenic or Reprotoxic (CMRs1) and more than 150 substances listed as R50-532 (very toxic to aquatic organisms); 27 of these substances are included in the Candidate List of Substances of Very High Concern (SVHC).

ECHA Executive Director Geert Dancet said, “This is a momentous day—something that many people inside and outside Europe have been working towards since the REACH regulation was published at the end of 2006.”

The key to REACH compliance is to collect granular data on all chemical substances in all ingredients in each product, then screen measured quantities against chemical classifications and regulatory threshold limits. The right software

automates this complex process. ECHA has set up an online software system called the International Uniform Chemical Information Database (IUCLID), a tool that the chemical industry can use to fulfill data submission obligations.

“REACH and REACH-like initiatives across the globe are taking product stewardship in manufacturing to a new level,” said Russell McCann, CEO of Actio, a software company making software as a service database tools that collect supplier product data for REACH and other chemical regulatory compliance. “These regulations change the way manufacturers measure, track and report on supplied product components, raw materials and manufacturing processes.”

The Stats

The most dossier submissions came from the largest companies. One-fifth or 19 percent of all accepted dossiers were submitted by “only representatives”—legal entities representing non-EU manufacturers—proving that non-EU companies may successfully participate in REACH.

Most registrations occurred in September 2010, and the ECHA Helpdesk resolved 5,500 issues—27 percent were minor technical issues and 22 percent involved submission activities (i.e., data sharing, invoicing and business rules). Over 10,000 people participated in training sessions and webinars, and ECHA reached out to more than 500 companies to help with submission problems.

“The system can sustain all traffic. We have a backup system, but we never used it,” according to Dancet.

All registrants of phase-in substances are legally obligated to join a Substance Information Exchange Forum (SIEF) of phase-in substances that are pre-registered or registered before the deadline. The SIEF facilitates the sharing of information, helps avoid the duplication of new studies and unnecessary animal testing, and ensures agreement on classification and labeling.

Companies must also submit a testing proposal before performing tests that fulfill the information requirement in Annex IX and X of the REACH regulation. Animal testing will be subject to public consultation during the coming months.

What’s Next?

The final number of substances registered by the first REACH deadline will be available after all dossiers have been processed within the next several weeks. Moreover, ECHA will evaluate 5 percent of dossiers in each tonnage band and all dossiers that include testing proposals relevant to Annexes IX and X.

By January 3, 2011, manufacturers and importers must have notified the classification and labeling of their substances to ECHA, including hazardous substances of any volume and non-hazardous substances subject to registration after 2010.

The next REACH deadlines, for 2013 and 2018, are slated as:

- May 31, 2013—Phase-in substances manufactured or imported in quantities of 100 tons or more per year per manufacturer in the community, or per importer at least once after June 1, 2007.
- May 31, 2018—Phase-in substances manufactured in the community or imported in quantities of 1 ton or more per year per manufacturer, or per importer at least once after June 1, 2007.

“We are very thankful for the support that has been given over the past few years, and for the faith they have put in REACH and in our agency, and we have lived up to that and can now aspire to a better future,” Dancet concluded.

Laura Chidester manages regulatory content daily at Actio Corp. For more information, please visit www.actio.net [1].

Links:
[1] http://www.actio.net/