Client Alert

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Outlook for 2012: New REACH Challenges Ahead

This coming year will bring new challenges for chemical manufacturers, importers, distributors and users. After the busy 2010 REACH registration year, the European Chemicals Agency (ECHA) started in 2011 with the evaluation of testing proposals and dossiers, and industry geared up for getting 2013 registration dossiers done.

This year will be different: as far as REACH is concerned, 2012 will be a pivotal year for both industry and the authorities. This alert discusses, first, important ongoing REACH procedures and processes, and, second, the key issues companies should follow.

I. Ongoing REACH Procedures and Processes

1. Evaluation of 2010 registrations

The 2010 registrations were generally deemed to be successful, but ECHA has concerns about some of the submissions. ECHA believes that some dossiers, including intermediate dossiers, do not meet the applicable requirements and offer no adequate justifications for deviations and exceptions. On review of testing proposals there have been questions on substance identity and read across, which may result in calls for further information/additional testing. These issues may get resolved, and the "standards" for registration, adaptation of registration requirements and exemptions may be further defined. Or they may result in disputes or protracted litigation, which would result in uncertainty for some time to come.

2. Next, 2013 registrations

The next registration deadline is May 2013. In practice, dossiers will have to be prepared by lead registrants earlier, to allow all registrants to get their registrations in by the deadline. Because the 2013 registrations need nearly as much work as those submitted in 2010, they will still require considerable effort and resources to complete. Based on the 2010 experience, the timeline is now very tight, and progress in 2012 will be critical for successful registrations in 2013.

Also, by May 2012 downstream users must have reported their uses to their suppliers. May 2012 is also the deadline for late preregistrations.

3. REACH Candidate List

The Commission has committed to having 136 substances on the Candidate List by 2012. As of the end of 2011, however, there were only 73 on the list. Bridging this gap will require a significant amount of work for the authorities and may potentially raise issues that could lead to more disputes. Please click here for a list of REACH-related court cases: http://www.reachpsforum.eu/status_legal_proceedings/.

4. Applications for authorization

Although the earliest application deadline for authorization is February 2013, companies may start submitting their first applications this year. There are still many open questions, however: How will the

authorities respond? What exactly will they require in terms of showing risk controls and socio-economic analyses?

II. Key Issues

In addition, in 2012, several important policy issues will continue to be discussed. The debate about nanomaterials, for instance, will likely focus on the nonbinding definition that has recently been adopted by the Commission and in ongoing studies. Further, the release of the recent RIP-oN reports on REACH information requirements, exposure assessment and hazard/risk characterization will undoubtedly prompt reactions from the authorities. The first endocrine disruptor has recently been added to the Candidate List, and chemicals considered as such will continue to be a focus of regulatory attention. Concerns raised by stakeholders about mixtures of chemicals and possible synergistic effects may well result in further proposals, etc. The final list of substances that will be subjected to evaluation should also be adopted this year. The authorities might finally agree on the information requirements for substances in articles, and how to apply the 0.1 percent threshold.

Challenges for industry will therefore continue to be considerable. They include getting prepared for the 2013 registrations, getting authorities to agree on a single interpretation for the application of the 0.1 percent threshold for substances of very high concern (SVHCs) in articles, preparing and submitting authorization applications, and remaining on top of all the ongoing processes and issues that affect them through a sound compliance and product stewardship program.

To facilitate the planning of companies' REACH activities for this year, a calendar of meetings of the relevant bodies involved with REACH is provided here. A calendar covering important dates related to all REACH processes and ongoing hot issues can be accessed here.

How We Can Help

The firm's lawyers have been involved with the REACH regulation since its inception and advise non-EU and EU companies, including chemical manufacturers, importers and distributors, and producers of other goods that use chemicals in their processes, as well as consortia and special purpose vehicles established for purposes of complying with various parts of the REACH Regulation. Hunton & Williams is recognized by *Chambers* 2011 and *Legal 500* 2011 as one of the leading European law firms in the chemical law and regulatory areas. If you have any questions about the future of the REACH regulation, please contact us.

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