COVINGTON

COVINGTON & BURLING LLP

E-ALERT | REACH

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COUNTDOWN TO EU REACH REGISTRATION AND CLP NOTIFICATION

Within less than two weeks – on **November 30, 2010** – companies manufacturing and marketing substances and products containing them in the European Union and European Economic Area ("EU/EEA") will face the first phase-in registration deadline under the EU's REACH Regulation on chemicals. Less than five weeks later – by **January 3, 2011** – many companies will also be required to submit a notification on the classification and labeling of substances used in their products to the European Chemicals Agency ("ECHA"), in accordance with the EU CLP Regulation on the Classification, Labeling and Packaging of Substances and Mixtures.

With these deadlines in mind, this note provides some brief recommendations for companies to help them meet the upcoming registration and notification requirements:

I. REACH REGISTRATION

1. The November 30, 2010 phase-in registration deadline applies to all EU/EEA manufacturers and importers of pre-registered substances in annual volumes of: (i) 1000 tons or more; (ii) 100 tons or more if the substances are classified as very toxic to aquatic organisms that may cause long-term adverse effects in the aquatic environment (R50/53); or (iii) one ton or more if the substances are classified as Cat. 1 or 2 carcinogens, mutagens, or toxic to reproduction substances ("CMRs"). Foreign manufacturers may ensure the registration of the substances they export to the EU/EEA through an "Only Representative."
2. Substances that are subject to this registration deadline may not be manufactured, imported or marketed in the EU/EEA as of December 1, 2010 if they have not been registered. This prohibition also applies to imports of finished products, such as cosmetics, medical devices, consumer goods and other product categories containing substances that are subject to registration.
3. EU/EEA manufacturers of products should not procure or import substances that are subject to the November 30 registration deadline after this date unless their suppliers can show that a registration dossier has been submitted. EU/EEA manufacturers of products should request their suppliers to provide them with registration numbers or to include them in their safety data sheets. Where registration numbers are not yet available, suppliers may be requested to provide the submission numbers allocated by the ECHA.
4. European authorities are likely to take the position that EU/EEA manufacturers of products that procured pre-registered substances from EU/EEA suppliers before the November 30 registration deadline may continue to market products containing those substances after that date even if their suppliers failed to registered them. This flexible interpretation is not likely to apply to importers of products, but they could try to claim the exemption if their foreign suppliers appointed an Only Representative who pre-registered the substances.
5. Where a registration dossier is not ready, registrants should consider submitting an incomplete (but not inaccurate) dossier rather than missing the registration deadline. Manufacturers and importers that submit a registration dossier within the deadline will be able to continue manufacturing and marketing their substances at least until the ECHA indicates that the dossier is incomplete. Furthermore, if the ECHA indicates that a dossier is incomplete, it must allow registrants reasonable time to provide additional information.

Registrants should also consider challenging ECHA's decisions on the incompleteness of their registration dossiers before ECHA's Board of Appeal. Among other things, an appeal should suspend ECHA's decision, and therefore, allow the registrant to continue manufacturing and marketing the substance until the Board of Appeal decides.

6. Foreign suppliers ensuring registration through an Only Representative should make sure that their contractual arrangements require their Only Representatives to provide them with all the registration data and facilitate an update of the registration dossier if they decide to change Only Representative. From ECHA's perspective, the registration is the responsibility of the Only Representative, and therefore, a new Only Representative must submit a new registration dossier unless an agreement between the foreign supplier and the old Only Representative allows for that change.

7. All registrants, including those who must register at later dates (*i.e.*, May 30, 2013, May 30, 2018), should carefully review all the data that will be included in the registration dossiers of their substances submitted by November 30, 2010. In most cases, registration dossiers submitted by this date will include the joint registration dossiers, which will also be the basis of later registrations. Furthermore, authorities may use the data included in the registration dossiers to propose additional measures, including harmonized classification, evaluation dossiers, listing in the Candidate List of Substances of Very High Concern, and marketing and use restrictions.

   Manufacturers of finished products should also carefully consider the impact that the data included in their chemical suppliers' registration dossiers may have under EU specific product legislation regulating the use of certain substances.

II. CLP NOTIFICATION

8. The January 3, 2011 classification and labeling notification deadline applies to companies that, by December 1, 2010, placed on the European market: (i) substances that are subject to registration under REACH (*i.a.*, in quantities of one ton or more); or (ii) substances that are classified as hazardous if they are marketed on their own or in mixtures in concentrations above limits that render the mixture as hazardous, independently of their volume. Where the substance is marketed after December 1, 2010, it should be notified within one month from the date it is placed on the market.

   Manufacturers and importers who already submitted a registration dossier for the substance that included its classification and labeling do not have to submit a new notification. However, where the classification included in the registration dossier was not in accordance with the CLP Regulation, the manufacturer or importer must update the notification.

9. The notification requirement applies to EU/EEA manufacturers of substances and to importers of substances or mixtures in bulk or in finished products. Certain specific products, including medicinal products, foodstuffs and medical devices used in direct physical contact with the human body, are exempted from the notification requirement only if they are in finished state and intended for the final user. Thus, imported hazardous substances intended to be used in medicinal products or foods may be subject to notification.

   Similarly, substances notified as used in product and process oriented research and development, including in clinical trials, and therefore exempted from registration under REACH, may still be subject to the classification and labeling notification of the CLP Regulation.

   Substances contained in imported articles are not subject to notification unless they are intended to be released during the normal or reasonably foreseeable conditions of use of the article and are subject to registration under REACH.

10. Foreign suppliers cannot ensure the classification and labeling notification of their substances through an Only Representative unless the latter also becomes an importer. However, foreign suppliers may request one of their EU/EEA importers to submit a group

notification listing all other importers that have agreed to the notified classification and labeling. In that case, the agreement on the proposed classification and labeling should be reflected in a contract, and only the importer notifier should receive the confidential information required for notification.

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