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As REACH Preregistration Ends, Questions Remain

By **Sara Stefanini**

Law360, New York (December 01, 2008) -- The preregistration phase in the European Union's REACH program closed Monday after millions of submissions poured in to the new European Chemicals Agency, and while the regulator has been praised for its handling so far, questions as to what happens next persist.

The ECHA, a six-month-old regulator based in Helsinki, Finland, received more than 2.2 million preregistrations since June 1 — far more than expected, according to attorneys.

As companies all over the world rushed to preregister all the substances they may potentially ship to or produce in Europe, the agency received more than 80,000 applications on Nov. 30, almost 97,000 on Nov. 28 and more than 109,000 on Nov. 27.

Although many had worried that the regulator would be unable to cope with the deluge of questions and concerns about complying with the EU's Registration, Evaluation, Authorization and Restriction of Chemical Substances legislation, the agency has been congratulated for successfully carrying out the preregistration phase, despite several all-nighters and information technology overloads.

“The question is, what do we do now?” said Kenneth Rivlin, head of the U.S. environmental and regulatory law group at Allen & Overy LLP. “ECHA has been working incredibly hard, and overall, we find them to be very pragmatic and proactive, and they really have focused on making sure it works. They have accomplished the impossible. But the real issue now is going to be supply chain disruption for companies that didn't preregister or preregistered incorrectly, and there will be confusion or uncertainty among national regulators.”

Preregistration was the first step in the REACH program, a law unveiled in June 2007 that has shifted the duty to test and register any substances produced in or sent to the European Union onto companies and created a path for phasing out chemicals considered to be the most environmentally harmful.

REACH is aimed at better protecting human health and the environment by identifying and keeping track of the dangers that substances present. The legislation calls for the registration of about 30,000 chemical substances currently in use over a period of 11 years.

The rules are intended to fill the holes in previous regulations that did not keep track of existing chemicals and their hazards and to slowly ween out the use of the most high-risk chemicals in exchange for new, more environmentally friendly substances.

If companies missed the preregistration deadline, their products will not be allowed into the EU until they complete the lengthier registration process that awaits a wide span of industries.

For those that did preregister, they will be allowed to continue importing their substances into Europe as they begin to register, a procedure companies will have to complete within either the next three and a half, six or 11 years, depending on how much of the product touches the EU every year and how dangerous the substance is deemed to be.

To register their substances and products, firms have to provide the EU with technical dossiers describing the properties and uses for each item and a guide for using the items safely, among other details.

Following preregistration, REACH allows companies to organize themselves into Substances Information Exchange Forums, groups of hundreds of members that preregistered the same substances and can share the job of collecting and analyzing data and making joint submissions to the ECHA.

However, the regulator has not issued rules or regulations on how companies should create SIEFs and cooperate and is not expected to do so, leaving many concerns and questions as to how to go about it, attorneys said.

“It’s a very rudimentary regulatory structure, there’s nothing on voting rules or procedures for organizing the SIEFs,” said Lucas Bergkamp, head of the regulatory practice in the Brussels office of Hunton & Williams LLP.

Instead, companies have so far formed smaller consortiums, more formal, voluntary groups of members that could come from more than one SIEF. Members of a consortium must agree to certain terms and rules on sharing data and jointly submitting their information.

“It will be interesting to see how these two structures interact and work together,” Bergkamp said. “There are many issues relating to intellectual property rights and data sharing between consortia and SIEFs, the conditions for joining a consortium, and all those sorts of things. It’s going to be very interesting after Jan. 1.”

Since REACH was introduced, companies also have expressed concerns about sharing data and details on the hazards of their substances with rivals that use the same ones. This cooperation could force firms to divulge trade secrets about their products, although the EU has said it is aware of the risks and will work to protect confidential information.

Despite the European Union's acknowledgment, however, companies will continue to struggle to figure out exactly how to comply with REACH's broad and extensive requirements, attorneys said.

“REACH is extraordinary complex, and it's a huge challenge for companies to understand what the obligations are,” Rivlin said. “There's not a lot of legal guidance yet that people can rely on. This is an evolving process.”