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# The Long Arm of REACH

If you export beauty products into the European Union, by now you should have assessed whether the ingredients in your products must have either been registered or preregistered to comply with REACH regulations. Candido Garcia Molyneux, a REACH specialist and of counsel at the Brussels office of Covington & Burling LLP, answers some questions about deadlines that cosmetic marketers should be paying attention to.

## What happens if companies do not register their substances?

The REACH registration requirement applies to virtually all substances that are imported in volumes of 1 ton or more per importer per year. This requirement also applies to substances that are present across cosmetic products imported into the EU during a single year.

Manufacturers and importers that did not register their substances by June 1, 2008, or did not preregister their phase-in substances by December 1, 2008, cannot continue to market their substances, and products containing them, in the EU/European Economic Area (EEA) until they register the substances in full. In the case of foreign (e.g., U.S.) cosmetic manufacturers, it is forbidden to import into the EU/EEA any product containing substances that have not already been preregistered or registered.

## How will REACH affect U.S. beauty brands selling products in the EU?

REACH poses an enormous organizational challenge for U.S. cosmetic manufacturers marketing their prod-

ucts in the EU/EEA. While, in theory, non-EU/EEA manufacturers of cosmetic products, including U.S. manufacturers, have no legal obligations under REACH, in practice they are among the industry groups for which the REACH regulation poses the biggest challenge. This challenge is mainly organizational and will only be overcome if the manufacturer can ensure appropriate communication with, and cooperation from, its suppliers and EU/EEA importers/customers.

Even if, in theory, the REACH requirements apply only to EU/EEA importers of cosmetic products, as they are the entities present in the EU/EEA, in practice, U.S. cosmetic manufacturers will have to ensure the REACH compliance of their products to facilitate their import into the EU/EEA. As a result, U.S. cosmetic manufacturers will in many cases be forced to ensure the following three qualifiers:

- Preregistration and registration of most of the substances they use in their products in quantities above 1 ton per year (across all products they ship to the EU/EEA).
- Compliance with the requirements of restrictions if they use substances that are identified as "substances of very high concern" or that are considered to pose unacceptable risks to the environment.
- The provision of REACH information to their customers.

In most cases, U.S. cosmetic manufacturers will only be part of a global chain of supply of ingredients and cosmetic products. U.S. cosmetic

## Dow's ORT Program Helps REACH Companies Lower Costs

In December, The Dow Chemical Co. launched its new Dow Only Representative Trustee (ORT) program, designed to help companies along its supply chain save money when complying with REACH.

Under the ORT program, Dow has preregistered—and plans to register—all of the substances that it imports or manufactures in the EU. Companies along the Dow supply chain that use those chemicals can be covered by Dow's preregistration and registration status, saving them the costs of registering or preregistering the chemicals. "Thanks to this program, companies don't have to reregister their ingredients, which will help them minimize costs," says Hans-Norbert Adams, leader of Dow's program management office for REACH implementation.

On its Web site, [www.reach.dow.com](http://www.reach.dow.com), Dow lists the preregistration and registration status of its chemicals.

Not all companies will be eligible to use Dow's registrations. Only those companies within the same supply chain are eligible.

To protect the privacy of brands' product formulations, Dow has employed PricewaterhouseCoopers as a third party to handle brands' chemical information, not telling Dow which brands purchase which chemicals, and in what quantities. "PricewaterhouseCoopers is handling all of the information, not telling us who, at the other end, are the companies importing our chemicals," says Adams. If Dow were in possession of such information, the company says it would then have knowledge about downstream customer markets and be able to draw conclusions about proprietary brand formulations.

manufacturers will typically purchase ingredients from chemical manufacturers, and they will sell their products to importers in the EU/EEA. This means that, in most cases, they will not have much information on the substances they use. At the same time, their chemical suppliers may not feel compelled to comply with REACH because they may believe that they do not market their substances in the EU/EEA.

### How does REACH affect the entire supply chain?

If both chemical supplier and cosmetic manufacturer are in the EU/EEA, most of the REACH obligations will fall on the chemical supplier. By contrast, if both chemical supplier and cosmetic manufacturer are outside the EU/EEA (e.g., the United States), then the REACH liability will fall on the importer of the cosmetic product. But in practice, the foreign cosmetic manufacturer will have to ensure its REACH compliance.

### What should companies be doing now to prepare for REACH?

Cosmetic manufacturers that at this point have not ensured the registration or preregistration of the substances of their cosmetic products should immediately seek the advice of legal counsel before continuing to market their products in the EU/EEA.

Cosmetic manufacturers that have preregistered should start participating in the Substance Information Exchange Fora of their substances in order to prepare for registration.

All cosmetic manufacturers should follow closely the REACH procedures for the authorization of substances of very high concern and for the restrictions of substances posing unacceptable risks. They should be ready to make use of the opportunities granted by the REACH regulation to defend their key ingredients unless they are ready to switch to alternatives.

In general, compliance with REACH will require cosmetic manufacturers to

enhance the communication and cooperation with their chemical suppliers and EU/EEA customers.

### Is it true that certain natural substances that are not classified as dangerous may be exempt from registration?

Yes. The regulation exempts from registration substances that meet all of the following three conditions: 1) they are natural; 2) they are not chemically modified; and 3), under European Community chemicals law, they are not classified as "dangerous" or as PBTs (persistent, bioaccumulative, and toxic substances), vPvBs (very persistent and very bioaccumulative substances), or as substances raising an equivalent level of concern.

### What are some important future deadlines to look out for?

- **June 2009**—the European Chemicals Agency is likely to present its final recommendation of the first list of substances of very high concern that are subject to a prior authorization requirement.

- **June 2009**—the REACH restrictions procedure will enter into force. Under this procedure, the European Chemicals Agency and the European Commission may ban the use of substances in cosmetic products if such use poses an unacceptable risk to the environment.

- **Second half of 2009**—the European Commission is expected to adopt the first list of substances subject to authorization. The list will specify a deadline for the submission of applications for authorization. That deadline will be a sunset date after which the substances cannot be used, including in cosmetic products, unless an authorization has been granted (or an application has been submitted but not yet decided upon); and any exempted uses. The first sunset date is expected to be around the second half of 2011.

- **December 1, 2010**—the first registration deadline of phase-in substances that have been preregistered. It applies to those substances manufactured or imported in quantities of

1000 tons or more per manufacturer or importer per year; to all category 1 and 2 carcinogens, mutagens, and toxic-to-reproduction substances; and to substances classified as R50-53 substances if they are imported in quantities of 100 tons or more per manufacturer or importer per year. Later registration deadlines (for small quantities) are June 1, 2013, and June 1, 2018.

• **December 1, 2010**—entities marketing substances in the EU/EEA, including cosmetic manufacturers, must have reported the chemical classification of their substances to the European Chemicals Agency.

*Do you anticipate seeing a lot of companies being forced to reformulate their products to comply with REACH? Will REACH severely limit the number of ingredients they can work with?*

Cosmetic manufacturers are likely to have to reformulate their product or incur substantive costs if they use

unique ingredients that are not commonly used by their competitors or in other industry sectors. This is because REACH will force chemical suppliers to specialize their portfolios and to drop the supply of those substances for which they do not have large markets.

In the long run, cosmetic manufacturers will have to drop the use of substances that meet the criteria of PBTs, vPvBs, or substances raising equivalent level of concern. The REACH authorization procedure is, in effect, intended to put pressure on manufacturers to drop the use of such substances.

In practice, whether REACH will severely limit the number of ingredients will largely depend on two factors: the political will of the EU institutions when interpreting and enforcing the REACH requirements, and the extent of cosmetic manufacturers' active participation in the REACH procedures. Manufacturers can help by increasing communication with their customers and suppliers and defend-

ing the use of their substances before the EU institutions.

*Do you have any other warnings to offer readers?*

It is important to point out that the REACH regulation is technical, and many of its provisions are open to different interpretations. It is important to monitor how the rules are being implemented in more detailed provisions and guidelines. None of the information provided here is intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned in this column.

*Information on REACH and on Covington's REACH practice can be found at [www.cov.com/practice/environmental\\_carbon\\_markets\\_and\\_clean\\_technology/reach](http://www.cov.com/practice/environmental_carbon_markets_and_clean_technology/reach).*

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