

INTRODUCTION TO REACH

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A new European Union chemicals regulation will be passed by the European Parliament in early 2007. Although this is a chemicals regulation, the cosmetics industry has not been exempted and will be impacted. REACH stands for **Registration, Evaluation and Authorization of Chemicals**. All cosmetics ingredients manufactured and sold within the European Union or those imported into the European Union after REACH takes effect will require a registration number. Finished goods that are imported into the European Union will require documentation that all individual ingredients are similarly registered.

What is REACH and why was it drafted? According to the drafters of this new chemicals regulation, the previous collection of regulations was flawed because only 200 of the approximately 100,000 "existing" chemicals have been identified for risk assessment. Only 27 risk assessments have been completed. These shortcomings are thought to have potentially put human health and the environment at risk. The REACH regulation shifts the burden for data generation and risk assessment from the regulators to the manufacturers and importers. No existing chemicals are grandfathered. A key principle is **NO DATA, NO MARKET**. Very few categories of chemicals are exempted, namely, natural substances and polymers. However, the definition of these two classes of ingredients is very narrow—much narrower than cosmetic or even non-regulatory chemical definitions. The REACH data requirements are extensive and there is no indication that the requirements will be flexible since REACH is based on the precautionary principle. In other words, a menu of tests will need to be submitted regardless of risk.

Further, the requirements of REACH differ depending upon whether a company is a downstream user, a manufacturer or an importer. Of course, these categories of receivers of ingredients have specific REACH definitions as well. A cosmetic manufacturer may be all three categories of receivers depending upon the circumstances relevant to an ingredient. If a cosmetic company uses an ingredient or mixture of ingredients (referred to as a preparation in the REACH regulations) from an European Union supplier, then the cosmetic company is a **DOWNSTREAM USER** and need only register the ingredients and make sure the European Union supplier includes cosmetic use in their safety assessment and registration. However, if a cosmetic company imports finished goods or receives ingredients from a non-European Union supplier, even though the cosmetics finished product is made in the European Union, then the cosmetics company is an **IMPORTER**. If the cosmetic company alters the ingredients, it is a **MANUFACTURER**. The importers and manufacturers are required to register the ingredients even though they are used for cosmetics. Certain chemicals, such as, CMR's, those that are persistent in the environment (vPvB) and any substance having scientific evidence of probable serious effects to humans or to the environment, will require evaluation and authorization.

This introduction to the REACH regulations will give key definitions of REACH terms and several points to stimulate discussion. The REACH regulation is anticipated to pass in April, 2007 and registration of new chemicals and pre-registration of phase-in chemicals (that have EINECS numbers) will likely begin in April, 2008 and close October, 2008. Consortia of suppliers will begin forming in November, 2008 as the REACH principle of "one substance, one registration" will mandate sharing of data and testing costs among suppliers (manufacturers and importers) and perhaps downstream users. Some of the data submission deadlines are in conflict with the Seventh Amendment to the Cosmetics Directives marketing ban on animal testing of cosmetic ingredients. All of the safety and environmental information will be available to the public through the Internet.

The legislation is still under debate in the European Parliament and may change but this presentation will provide an update on the status at this point in time. This presentation will lay the foundation for other presenters to discuss in more detail what the requirements are by category and how their companies are preparing for the new legislation. Come to the session and share what your company is doing or the outstanding questions you have on this impact legislation.

Helpful websites: <http://ecb.jcr.it/REACH/>
<http://ecb.jrc.it/REACH-IT-INFORMATICS> (for RIP reports)