ARE YOU READY FOR REACH?

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REACH stands for Registration, Evaluation and Authorization of CHemicals. REACH is going to touch everyone in the personal care industry that manufactures or sells raw materials or finished goods that are imported into Europe. European Union members agreed to institute these new regulations on December 13, 2005. According to the EU, the major objective of the REACH program is to cut occupational diseases and environmental issues through better monitoring of chemical products. This will require a new level of safety and ecological data.

REACH will create a single system for both "existing" and "new" chemicals. It applies to all substances used in all products, including cosmetics, both synthetic and natural. There will be no grandfathering of substances. The anticipated date for REACH to become law is April, 2007. There will be a six month window (from April, 2008 through October, 2008) for pre-registration of phase-in substances. Phase-in substances are defined as substances listed in EINECS or have ELINCS numbers as well as materials manufactured in the European Community at least once in the last 15 years but not placed on the EU market. New substances, those that do not have EINECS/ELINCS numbers, and are not exempt, and manufactured in amounts over one ton, require full registration. Full registration will also begin in April, 2008. In November, 2008, a list of pre-registered substances will be published and registration for phase-in substances will be open. Dates by which registration, including safety and ecological data, for phase-in substances are due will depend on the volume of the substance being manufactured or imported: April, 2010 for substances over 1,000 tons; April, 2013 for substances from 100 to 1,000 tons; April, 2018 for substances from 1 to 100 tons.

The basic elements of REACH are:

1 – **Registration** requires manufacturers and importers of chemicals, in quantities of one ton or more, to submit a registration dossier to the authorities for each substance and to obtain relevant information (human and environmental safety data) on their substances and to use that data to manage them safely. A registration dossier is to be submitted by each company registering a substance, thus, if there is more than one company manufacturing or importing a substance, there will be more than one registration dossier. There are increased requirements on the dossiers based on the imported tonnage for each chemical with thresholds of 1, 10, 100 and 1,000 tons. The requirements are also modified by the expected classification and use pattern. The time by which registration submission is required to be submitted also depends on the quantity and the classification of the substance. Registration under REACH is of substances only, not preparations (mixtures of substances or finished formulas). However, every chemical in a preparation that is being imported into the EU needs to be registered. Substances manufactured or imported in volumes less than one ton do not need to be registered.

2 – To reduce testing on vertebrate animals, **data sharing** is required for studies on such animals. A system is being established to help registrants find other registrants of the same substance with whom they can share data (a consortia). Pre-registrants of the same phase-in substance are then required to share animal test data and agree on the generation of new animal test data in a substance information exchange forum (SIEF).

3 – To provide better **information** on hazards and risks and how to manage them will be passed down and up the supply chain.

4 – To bring downstream users (any industrial user of chemicals) in to the system.

5 – The aim of **Evaluation** is to prevent unnecessary testing, by having authorities evaluate the proposals for testing made by industry and to check compliance with the registration requirements, and if not, ask industry for further information. Evaluation also enables authorities to investigate chemicals with potential risks by asking industry for further information. This information may be used later to prepare proposals under Restrictions or Authorization.

6 – Substances with properties of very high concern will be made subject to **Authorization**: Applicants will have to demonstrate that risks associated with the uses of these substances are adequately controlled. In this case the Commission will grant an authorization. The substances required to be authorized are substances which are: carcinogenic, mutagenic or reproductive toxins (CMRs) category 1 and 2; persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); identified as causing serious and irreversible effects on humans or the environment equivalent to those above on a case-by-case basis, such as endocrine disrupters.

7 – The **Restrictions** provide a procedure that will regulate the manufacture; the placing on the market; or the use of certain dangerous substances. Such substances shall be either subject to conditions of use or prohibited from sale. This is meant to act as a safety net to adequately control health and ecological risks.

More information can be found through the following websites:
http://europa.eu/index_en.htm or http://ecb.jrc.it/