

Regulatory Happenings on the Horizon

One of the biggest challenges facing perfumers and flavorists today is the constant change in regulations. In fact, in order to keep track of and address the barrage of new regulations, most companies have set up their own regulatory departments. Among the most important regulatory issues in the past couple of years has been REACH (Registration, Evaluation, and Authorization of CHemicals). Here, **William Troy** (FEMA regulatory affairs committee chair and FMA treasurer) explains the impact of REACH, the California Safe Cosmetics Act, and the future of regulations for the flavor and fragrance industry.

P&F: What are some of the key regulatory issues that will be at the forefront in 2007? What role will REACH play?

Troy: There is no question that the new REACH legislation in Europe is the number one regulatory topic for 2007. REACH will focus largely—but not exclusively—on fragrance materials; there are approximately 700 substances, in volumes greater than one metric ton, that are subject to REACH. It is anticipated that the legislation will become effective April 2007, which is when the 18-month preregistration phase begins. Then the registration phase starts, which could last up to 11 years. In addition to a quicker registration process, preregistered substances can continue to be marketed before completing the full registration process. All eligible substances with volumes greater than one metric ton per year (manufactured in, or imported into, the European Union) should be preregistered. This requires submission of the substance's name, the name of a contact person for the submitter, and the deadline that is envisioned for registration of the substance in the appropriate tonnage band. While flavor materials used in food are exempt from



William Troy

REACH, so-called “dual use materials”—materials that may be used in both flavors and fragrances—will have to be included due to their use in fragrance. This impacts a large number of essential oils. Finally, no company whose business is focused in the United States should assume that it will be untouched by REACH. Sales of fragrance mixtures that result in export to Europe will require the importer of record to show proof that the substances contained in the fragrance have been duly subjected to the various requirements of REACH.

P&F: How will the California Safe Cosmetics Act (going into effect this month) affect the flavor and fragrance industry?

Troy: At this point, most of the information exchange between fragrance suppliers and their customers, regarding the presence of reportable materials in fragrances, already should have occurred. This legislation requires the cosmetic product manufacturer to notify the State of California of the presence, in the finished products, of any ingredients that may be listed, in any one of five different reference sources identified in the legislation, as causing cancer or reproductive toxicity. Subsequent to the adoption of this legislation, budget funds were allocated for purposes of administering this Act, but it is unclear whether any subsequent legislative steps will be taken beyond the simple collection of ingredient information. Allegedly, California authorities would review the ingredient data to determine whether health risks may be involved.

The only significant effect on fragrance/flavor suppliers has been the one-time reporting of ingredients, to finished product manufactures, which are present in the flavor/fragrance contained in a cosmetic product and may be reportable under the Act.

P&F: Where do you see the industry's regulations heading in the next five to 10 years?

Troy: It has become clear to all that the adoption pace of regulations worldwide, which affect the flavor and fragrance businesses, has increased dramatically in the past five years. It is also certain that this will continue in the future. Europe, which has embraced the precautionary principle, is leading the way in creating legislation that is hazard-based rather than risk-based. The precautionary principle states that if an action or policy might cause severe or irreversible harm to the public, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate taking the action. The result of this type of legislation will be enormous expenditures by consumer products' manufacturers and their ingredient suppliers in testing in order to demonstrate "absolute safety" rather than "safety in use." Fueling this are non-governmental organizations (NGOs) and others who have created an

atmosphere of chemophobia such that the consumers begin to believe that they are in real danger as a result of using consumer products. This has spread well beyond Europe, as we have seen in the example of California that has been aggressively proposing and adopting various pieces of legislation dealing with consumer exposure to chemicals. Furthermore, a number of countries around the world are patterning their legislation after that of Europe. The next big thing in legislation is predicted to be biomonitoring, which will tell us how many chemicals have entered our body from the environment, and what they are doing to us. California already has adopted such a bill, and biomonitoring studies have been carried out several times in Europe. Unless reason is brought to bear, to explain that we are one with the materials from our environment that we eat, breathe and put on our skin, the consumer products industry—and its suppliers—are in for an increasingly bumpy ride.

To get a copy of this article or others, visit the P&F magazine Article Archives at www.PerfumerFlavorist.com/articles.

