Defending Fragrance Ingredients on Both Sides of the Atlantic

What the Rest of the World should know about the EU's REACH Program

Why is REACH registration so critical to the fragrance industry? Because if ingredient suppliers do not properly register perfumery's "crown jewels," the aromatic character of legendary fragrances such as *Chanel No.* 5 could be at risk.

This was the takeaway presented by Jens-Achim Protzen (EFEO; Paul Kaders GmbH) and Eric Angelini (EFEO; MANE) during a joint meeting of the European Federation of Essential Oils (EFEO; *efeo-org.org*), Women in Flavor & Fragrance Commerce, Research Institute of Fragrance Materials (RIFM) and International Fragrance Industry North America (IFRA NA) in New Jersey, which focused on the impact of E.U. regulations on the global industry.

He added that, under the constraints of REACH regulations, if there is no data, there is no market for aromatic ingredients. If products are not properly registered, they cannot be sold in the European Union. Given this state of affairs, the ingredient industry has mobilized to register materials—particularly essential oils, which fall under the category of "natural complex substances" (NCS).

Producers and suppliers have pursued three phases of material registration, beginning with the largest-volume and critical ingredients, including citrus, mint and vetiver.

During this first phase, Protzen and Angelini said, the industry learned a number of lessons. First, the earlier one starts, the earlier problems can be detected and addressed. It can take a long time to locate partners and fellow suppliers to assist in the ingredient registration process, as can administrative steps such as securing VAT trustees.

Phase two of REACH registration has already wrapped up, Protzen said, and now the industry is gearing up for 2018 registrations. His message: Now is the time to start.

To register an NCS to achieve a single dossier, classification and safety data sheet (SDS), ingredient suppliers must develop a single identification based on a shared characterization, and toxicity and ecotoxicity tests.

Maximizing consistency is crucial to proper registration and minimization of costs. Costs related to registration and substance information exchange fora (SIEF) management can be significant, Protzen and Angelini warned, and so cooperation is critical.

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From left: Jens-Achim Protzen (EFEO), David Wilcox (RIFM), Megan Ekstrom (IFRA NA), Jennifer Abril (IFRA NA) and Eric Angelini (EFEO); photo courtesy of Daniel D'Errico Photographs.

The Shifting Goal Line of Science

How the fragrance industry collected, analyzed and presented ingredient information 10 years ago "doesn't cut it today," said David Wilcox, president of RIFM. And how the industry does these things today will not be sufficient in the future. In short, the fragrance industry will have to continuously evolve to keep up with changing safety and disclosure standards.

In 2012, RIFM's experts developed a threshold of toxicological concern, which estimates aggregate exposure to fragrance materials and takes into account toxicological endpoints. The industry has at its disposal in silica modeling to review safety. RIFM was able to review, characterize and standardize NCS. The group was also able to gather information on components and genotoxicity data. The thresholds for some of these touchpoints are very low, Wilcox noted.

Simultaneously, RIFM has partnered with Elsevier to post RIFM's peer-reviewed publications online (*www.rifm.org/publications.php*), boosting information access within the industry and for external stakeholders.

Growing Scrutiny

The advent of genotoxicity testing, REACH registrations and other regulatory pressures are the result of increased scrutiny of the fragrance industry, noted Jennifer Abril, president of IFRA NA (*ifrana.org*). Consumer groups are influencing the media, which in turn influences legislators. As a result, concerns rapidly turn into news stories and regulatory action.

In the digital information age, speed is more important than accuracy, Abril noted. Consumers don't know what to do with the information and allegations they receive from mainstream and emerging media sources. And, when consumers doubt, they default to an attitude of concern.

Elsewhere, said Abril, there are growing efforts for chemical regulation reform under Toxic Substances Control Act, cosmetics safety bills under consideration and emerging pressures from retailers, who dictate changes all through the value chain.