"Exploding" Formulas, GHS and Other Compliance Issues for Flavor Suppliers

Regulatory has to become a core competency of every flavor company today, said Michael Bloom (Flavor & Fragrance Specialties), during a panel session at the annual convention of the National Association of Flavors & Food-ingredient Systems (NAFFS).^a Safety and efficacy are not the focus here, he added; instead, this competency is wholly centered around meeting a legal or regulatory test.

The panel agreed that retailers such as Whole Foods have taken strong positions on genetically modified organisms (GMO), which can impact the use of natural ethyl alcohols created from GMO corn sugars, for instance. As a result, a synthetic version may ironically be preferable. Also impacting formulators is the inclusion of vanillin—presumably non-vanilla-bean-derived vanillin—on Whole Foods' "Unacceptable Ingredients for Food" list.

This push for ingredient exclusion and disclosure has continued to ramp up. Recently, the fragrance industry learned that SC Johnson would expand its What's Inside program to disclose product-specific lists of fragrance ingredients beginning in the spring of 2015.

Some of this trend, the panel noted, may stem from the fact that many consumer goods houses are run as marketing groups, rather than goods manufacturers. As a result, fewer customer companies are staffed with those who understand flavors and flavor chemistry and how disclosure or ingredient restrictions could impact innovation. Education on the part of flavor suppliers might help counteract this.

Meanwhile, in the absence of Toxic Substances Control Act (TSCA) reform, some U.S. states are stepping in to regulate chemicals locally, potentially creating an unwieldy patchwork of regulations. In all matters regulatory, Bloom encouraged NAFFS attendees and the flavor industry in general to meet with their local and national legislators and inform them about the safety work undertaken by the industry, as well as the scope of its employment and impact on the economy. (In New Jersey alone, it is estimated that about 26,000 jobs are attached to the flavor industry.)

The compliance issue is crucial for the flavor industry, particularly as it cannot pass on these costs to customers or consumers. If anything, customers are looking for cost reductions.

How can compliance be managed? In part, by implementing the right mix of human expertise and flexible and accurate software systems.

^aLook for full coverage in the January 2015 issue of P&F.

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As the June 1, 2015, deadline for compliance with the globally harmonized system of classification and labeling of chemicals (GHS) looms, and in light of pressure from NGOs, consumers, regulators and retailers, flavor companies' customers are seeking increasing amounts of disclosure, said Bill Brugger (Global Directions). In addition, these customers are seeking to exact more control over suppliers' development processes.

Brugger explained that to meet various stakeholder demands and meet regulatory requirements, flavor suppliers must keep track of end-use limitations for individual and groups of ingredients (ex: gluten), ideally using software that provides inventory-style lists that index such limitations on a country by country basis. A good software system should allow flavorists to assess component levels at ingredient and end-use levels, which will allow them to make necessary adjustments middevelopment, rather than discovering compliance issues at the end of the process.

Software used by flavor companies should also allow for calculations that take GHS into account, Brugger noted. To undertake a thorough assessment, flavor suppliers should be able to "explode" their formulas as needed, to take them apart and examine them by individual materials or groups of materials, or by individual chemical components of materials. This should include solutions, proprietary corporate bases, sub formulas, oils and other natural products, and generic items.

Flavor suppliers' software should allow them to assess formulas against various regulations, Brugger noted, with live updates of new restrictions, which might be added by retailers or other regulator stakeholders. Results data from assessments must be formatted and stored for use by other systems, for instance issuing specific reports for customers. These report writers should be in-house.

Bloom added that there is no single panacea for regulatory compliance. Stephen Somers, Sr. (Vigon International), added that the best system might provide about 90% accuracy. Companies will require multiple systems to cover regulatory compliance, all of which should be compatible with existing systems. Quality assurance staff will have to make up the knowledge gap left over. Brugger concurred that no one vendor does everything well and that there are limitations in every area. This is particularly true, said Somers, as there are different safety data sheets (SDS) for different regions within the GHS framework, rendering it anything but harmonized. Whatever system is chosen, added Joe Piazza (Comax Flavors), there must be a technical bridge to ensure any implementation of new systems minimizes downtime.

Membership in key industry organizations such as NAFFS and the Flavor and Extract Manufacturers Association is another critical compliance tool, concluded Cynthia Astrack (Astral Extracts).