Regulatory Watch: Trans Fat, GRAS, Fragrance Guidelines and More

Recently, a range of regulatory activities affecting the flavor and fragrance industry have been announced, impacting everything from trans fat to product-specific fragrance disclosure.

Trans Fat & GRAS Under Attack

In June, the U.S. Food and Drug Administration (FDA) officially concluded that partially hydrogenated oils (PHOs), the primary dietary source of artificial trans fat in processed foods, are not generally recognized as safe or GRAS for use in human food. As a result, food manufacturers will have three years to remove PHOs from products, or petition the FDA regarding their safety. In food formulations, trans fats can enhance flavor, texture and shelf life. Many companies had already reformulated products to avoid the use of PHOs.

That same month, the Flavor and Extract Manufacturers Association (FEMA; www.femaflavor.org) issued a response to an article, "Meet the Secret Group That Decides Which Flavors Are 'Natural,'" published by the Center for Public Integrity (CPI) at *www.time.com*, which questioned the legitimacy of the FEMA generally recognized as safe (GRAS) process for flavor ingredient assessments. FEMA noted in a statement that it was "disappointed that CPI failed to report on the information that fully describes our process, rationale and safeguards to assure flavor safety, which was provided to the organization in extensive documentation." The organization had provided more than 250 citations of accessible flavor safety publications on flavor safety and the FEMA GRAS program.

Virtually simultaneously, the Natural Resources Defense Council (NRDC), in conjunction with CSPI and other activist groups, filed a petition to the FDA claiming that eight FEMA GRAS flavoring materials were known carcinogens that "should be banned by the FDA." The ingredients in question were: benzophenone (syn: diphenylketone), ethyl acrylate, eugenyl methyl ether (syn: 4-allylveratrole; syn: methyl eugenol), myrcene (syn: 7-methyl-3-methylene-1,6-octadiene), pulegone (syn: p-menth-4(8)-en-3-one), pyridine, styrene and *trans*,*trans*-2,4-hexadienal. The petition seeks to have the GRAS statuses of the ingredients revoked, as well as a ban enacted to prevent their future use in flavors and foods.

Ingredient Disclosure & New Code of Practice

Meanwhile, SC Johnson continued its aggressive transparency push. Last year, it disclosed a list of fragrance materials it would

no longer use in its North American fragrance palette. (Reckitt Benckiser and Clorox announced similar fragrance ingredient disclosure moves in recent years.) Then, this June, the company announced that it would disclose product-specific fragrance ingredient lists to consumers for its Glade air care products. The information, which will be made available at *whatsinside-scjohnson.com*, will comprise fragrance ingredients present at the highest concentrations down to 0.09 percent of the product formula, or the top 10 ingredients when there are at least 20 ingredients, whichever provides the most information.

Finally, the International Fragrance Association (IFRA; *www.ifraorg.org*) released its 48th Amendment to the IFRA Code of Practice. The publication includes new standards based on the dermal sensitization quantitative risk assessment (QRA) for 6,7-dihydro-1,1,2,3,3-pentamethyl-4(5H)-indanone, 3-(m-tert-butylphenyl)-2-methylpropionaldehyde, and acetic acid, anhydride, reaction products with 1,5,10-trimethyl-1,5,9-cyclododecatriene; a revised standard based on the dermal sensitization QRA, with a corrected maximum for pragmatic use level of p-tert-butyl-alpha-methylhydrocinnamic aldehyde; new standards prohibiting use due to insufficient data for safety assessment for 2,4-dodecadien-1-ol, (2E,4E), and 2,4-hexadienon-1-ol; a revised policy on combined use of four phototoxic ingredients and clarification on the application scope of all phototoxicity standards; a revised standard on methyl eugenol on the restriction level for non-skin products; and revised standards (for clarification) for acetylated vetiver oil, cyclamen aldehyde and furfuryl alcohol; and standards revised to reflect the addition of new CAS# for anisyl alcohol, massoia lactone, and methyl ionone, mixed isomers. For more information on the standards, visit IFRA; see the September 2015 edition of *P&F* for more details on the standards and their implications for the industry.[a]

[a]*www.perfumerflavorist.com/magazine/*