Chemical Reaction: Two Views of Fragrance Safety

As DfE fragrance criteria come to light, tensions between industry and NGOs come to the fore

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Two months after Sustainable Fragrances 2010 was held in Alexandria, Virginia, the US Environmental Protection Agency (EPA) approved the Design for the Environment (DfE) criteria for fragrances (http://epa.gov/dfe/pubs/projects/gfcp/index.htm), *effective Dec. 31, 2011. Leading up to the end of 2011, manufacturers seeking to receive the DfE label will have to meet its human health criteria.*[a] *The fragrance criteria will be used to guide manufacturers and fragrance houses toward DfE compliance by the 2011 deadline. A fragrance industry consortium formed by the International Fragrance Association (IFRA;* www.ifraorg.org) *is reviewing fragrance materials against the criteria. According to the organization, all fragrance houses are eligible to participate; only those who join the consortium will have access to the list of DfE approved fragrance ingredients.*

–Jeb Gleason-Allured, Editor

Sustainable Fragrances 2010 drew 102 attendees, reflecting growing industry interest in this topic—but what exactly is sustainability and how do we get it in fragrances? In the broadest sense it can embrace renewable resources, reduced carbon footprint, natural or organic sourcing, and social responsibility, all with a presumption of human and environmental safety and regulatory compliance.

Opposing approaches to safety are exemplified by the activities of DfE and the Environmental Working Group (EWG; *www.ewg.org*), illustrated by a preconference seminar on the DfE criteria for fragrances, which at the time had just been released to stakeholders in draft form. The human health component, as noted in the introduction, is available on the DfE website. The final seminar speaker was Jane Houlihan, senior vice president for research at EWG, an organization that—in cooperation with the Campaign for Safe Cosmetics (*www.safecosmetics.org*), Commonweal (*www.commonweal.org*), the Breast Cancer Fund (*www.breastcancerfund.org*) and Women's Voices for the Earth (*www.womenandenvironment.org*)—had just released a scathing critique of the fragrance industry, titled "Not So Sexy: The Health Risks of Secret Chemicals in Fragrance" (*www.ewg.org/notsosexy*).[b]

The standard bearer for fragrance safety has long been RIFM, the science of which is reviewed by an external, independent Expert Panel that selects its own rotating membership of dermatologists, pathologists, toxicologists and environmental scientists, which is in turn supplemented by adjunct experts on genetic toxicity, respiratory science, reproductive effects, environmental fate and epidemiology. This Panel, according to RIFM, "provides strategic guidance, determines scientific study design and interprets test results for relevance to human health and environmental protection." These interpretations form the basis of Standards issued by IFRA regarding the safety of use of fragrance ingredients which, when necessary, may include restrictions.

RIFM has a risk-based approach, with safe use based on product categories and specifics. There are no dark secrets in the RIFM science, Expert Panel assessments or IFRA Standards. RIFM has current initiatives in environmental and respiratory safety, and quantitative risk assessment (QRA) for skin sensitization. The guiding principles are laid out in key papers and the results are published in peer-reviewed journals.[c] Despite RIFM's best efforts, some

[a] *http://epa.gov/dfe/pubs/projects/gfcp/dfe_screen_for_fragrances_human_health_criteria_version_1.pdf*

[b] At the time of the report's release, the Fragrance Materials Association (FMA, soon to be IFRA North America; *www.fmafragrance.org*) crafted a response in concert with the Research Institute for Fragrance Materials (RIFM; *www.rifm.org*) and IFRA, which stated in part: "The fragrance industry has repeatedly offered to engage interest groups in a dialogue about the industry's safety program. In fact, industry representatives have even sat cordially across the table with several of the groups which contributed to this report. We are, therefore, shocked to see the continuation of inaccuracies perpetuated in this document concerning our safety program and its effectiveness. Scare mongering through the use of 'suggested' or 'potential' associations between fragrance materials and various toxicities is deplorable, particularly when present in a document that purports to be scientific. Facts are not 'secret,' and good science is very objective; an objective review of the facts confirms that an industry safety program that has been in place for more than four decades provides assurance of safe use of the fragrances contained in consumer products." The response of the Personal Care Products Council (PCPC) can be found at *www.personalcarecouncil.org/newsroom/20100512*.

[c] RA Ford, B Domeyer, O Easterday, K Maier and J Middleton, Criteria for development of a database for safety evaluation of fragrance ingredients. *Regulatory Toxicology and Pharmacology*, **31** (2000) 166-181; DT Salvito, RJ Senna and TW Federle, A framework for prioritizing materials for aquatic risk assessment. *Environmental Toxicology and Chemistry*, **23**(3) (2001) 1301-1308; DR Bickers, P Calow, HA Greim, JM Hanifin, AE Rogers, JH Saurat, IG Sipes, RL Smith and T Tagami, The safety assessment of fragrance materials. *Regulatory Toxicology and Pharmacology*, **37** (2003) 218-273; PA Cadby, WR Troy and MGH Vey, Consumer Exposure to Fragrance Ingredient: Providing Estimates for Safety Evaluation. *Regulatory Toxicology and Pharmacology*, **36** (2002) 246-252.

critics distrust it because it is funded by industry, the science is risk-based and perfume formulas are confidential.

The DfE and EWG have tackled the fragrance safety issue from a hazard rather than risk perspective. The DfE began a fragrance project as an extension of its prior work certifying surfactants and solvents for its seal. RIFM actively participated in the process with the DfE, but was not consulted in project of the EWG and its partners, which resulted in the publication of "Not So Sexy: The Health Risks of Secret Chemicals in Fragrance" (see footnote [b]). A very scientific document emerged from the DfE, and, in my opinion, a controversial one from the EWG and its partners. (As noted in footnote [b] FMA, IFRA and RIFM released a response to the report's charges following its publication.) By my reading, media announcements heralding the EWG/Campaign for Safe Cosmetics report had a distinctly tabloid feel: "Secret chemicals revealed in celebrity perfumes, teen body sprays," not to mention the title of the report itself.[d] In the body of the complete report, the following is typical: "The average fragrance product tested contained 14 secret chemicals not listed on the label." Secret chemicals!

By self-publishing and skirting the discipline of a peer-reviewed process that a scientific journal report would require, the nongovernmental organizations (NGOs) were able to make what could be considered scientifically questionable claims. For example, the assertion that fragrances are endocrine disruptors is based on results from animal testing that may not carry over to humans, or from exposure levels thousands of times what a consumer would experience in a real-world scenario. The weight of evidence of the best current science does not support the NGO position.

Why are these chemicals "secret?" Well, the European Union for years has required labeling of 26 fragrance allergens.[e] No other fragrance materials are labeled. In the United States, no individual fragrance ingredients must be labeled—just the word "fragrance." So, if some materials are on the label and others are not, it is because regulations are being followed, not because there is a secret conspiracy. The papers' authors know this, as is quite evident in reading their text; yet they describe fragrance as "a complex mix of clandestine compounds."

The report's Table 1 and Table 2 list "secret chemicals" that are, in fact, very standard ingredients. The authors rely heavily on PubMed (*www.ncbi.nlm.nih.gov/pubmed/*)

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[d] *www.mnn.com/lifestyle/natural-beauty-fashion/blogs/secret-chemicals-in-popular-perfumes*

[e] Amyl cinnamal (CAS# 122-40-7); benzyl alcohol (CAS# 100-51-6); cinnamyl alcohol (CAS# 104-54-1); citral (CAS# 5392-40-5); eugenol (CAS# 97-53-0); hydroxycitronellal (CAS# 107-75-5); isoeugenol (CAS# 97-54-1); amylcinnamyl alcohol (CAS# 101-85-9); benzyl salicylate (CAS# 118-58-1); cinnamal (CAS# 104-55-2); coumarin (CAS# 91-64-5); geraniol (CAS# 106-24-1); hydroxy-methylpentylcyclohexenecarboxaldehyde (CAS# 31906-04-4); anisyl alcohol (CAS# 105-13-5); benzyl cinnamate (CAS# 103-41-3); farnesol (CAS# 4602-84-0); 2-(4-tert-butylbenzyl) propionaldehyde (CAS# 80-54-6); linalool (CAS# 78-70-6); benzyl benzoate (CAS# 120-51-4); citronellol (CAS# 106-22-9); hexyl cinnamaldehyde (CAS# 101-86-0); d-limonene (CAS# 5989-27-5); methyl heptin carbonate (CAS# 111-12-6); 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one; (CAS# 127-51-5); oak moss and treemoss extract (CAS# 90028-68-55); treemoss extract (CAS# 90028-67-4).

as its source for published data. In addition to publishing in the peer-reviewed literature, which would be found in a correct PubMed search, RIFM has the world's greatest fragrance safety database, available through subscription. The report's authors have not availed themselves of this unrivaled resource. Materials like hedione or dihydro-α-terpineol, for which the authors claim a dearth of published data, actually have RIFM monographs. RIFM peer-reviewed publications reference all data—RIFM-sponsored, company-sponsored and open literature. Referenced in the database, any study practicing due diligence should have considered them.

On the other hand, the DfE criteria were the result of years of work, with the participation of a wide range of stakeholders including government, NGOs, fragrance and consumer goods companies, and consultants. Anyone with an interest in the process was free to join. Discussion on controversial points was lively, and the nature of the criteria took dramatic turns as difficult points were addressed. The results are a model of precision, replacing the rather fuzzy guidelines that preceded them.

DfE Environmental Toxicity & Fate (ET&F) involves conformance on acute aquatic toxicity, persistence (biodegradation), and bioaccumulation determined by data (preferred) or models such as EPI (Estimation Program Interface) Suite.[f] Complete formula disclosure is required, but only to a third party certifier. Details are given on test protocols with acceptable values for a variety of human health concerns. The draft document is 36 pages: this is but a hint of its thoroughness.

If there is one valid criticism of the DfE criteria it is that it is hard for an ordinary mortal to understand. Finding materials that conform requires a highly skilled regulatory expert, and indeed a consortium has been formed to use such a person to wade through the details. And this snag can easily lead to a fundamental question: how would ingredient disclosure help a consumer—or even a doctor—assess the safety of a product? If one knew a product was category 2 and had 0.012% 3,7-dimethyl1,3,7-octatriene, what would you do?

Where is the high ground in sustainable fragrances? There are some goals that everyone embraces: careful stewardship of resources, reduction of carbon footprint, social responsibility, and safety for both humans and the environment. Most of the Sustainable Fragrances speakers considered those issues and more, including natural ingredients, green sourcing, meeting standards and regulatory conformance.

In the question of safety, a few conclusions are reasonable based on a detailed knowledge of the industry:

1. Disclosure of fragrance formulas isn't going to help anyone.
2. The work of RIFM and the IFRA Standards guarantee a high degree of safety and are being constantly improved.
3. The DfE criteria are very restrictive, making perfume creation difficult, but offer a clear path to earning an EPA-endorsed, voluntary seal for cleaning products.
4. The "Not So Sexy" authors use what looks like real science, but is in fact seriously flawed and biased propaganda.

The report was immediately repudiated by the industry through the PCPC, FMA, IFRA and RIFM, as mentioned. Unfortunately, the hardest part of convincing the public that fragrances are safe, or that any chemical is safe, is the low level of scientific literacy in our society. John Bailey, PCPC's chief scientist, said it well at the end of the organization's statement: "Cosmetic and personal care product manufacturers take their safety responsibilities very seriously. Cosmetic ingredients are carefully selected for safety and suitability for their specific applications, and consumers can be confident in the safety of their products." Amen.

[f] *www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Toxicity*
www.epa.gov/opptintr/exposure/pubs/episuite.htm

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