

The Future of Fragrance CBI: A Formula for Transparency?

As NGO and regulatory pressure grows for ingredient disclosure and other challenges to intellectual property, North American stakeholders gather to assess opportunities and threats



On matters such as accessibility of fragrance ingredient safety data, Bill Troy (Firmenich) noted that the industry "must be responsive to pressures, while at the same time defending the principles of confidential business information (CBI) upon which the trade secret status of fragrance formulas is based." Troy spoke at the start of the inaugural fall workshop and luncheon of the International Fragrance Association North America (IFRA NA; www.ifrana.org), which focused on nongovernmental organization (NGO) and regulatory pressures surrounding fragrance ingredient disclosure and other challenges to CBI in the United States and Canada. Troy continued, "Our industry has a long record of providing discreet ingredient information when there is a medical need. Opening formulas simply for the sake of publishing a long list of ingredients, however, destroys the value of the products we create. Clearly we have a big challenge ahead of us in dealing with those who demand full disclosure."



Charles Auer (Charles Auer & Associates).



Speakers Darren Praznik (Candian Cosmetic, Toiletry and Fragrance Association), John Hurson (Personal Care Products Council), Charles Auer (Charles Auer & Associates) and Laurie Nelson (Randlett Nelson Madden).



Bill Troy (Firmenich) introduced the day's speakers.



John Hurson (Personal Care Products Council).



Richard Pisano, Sr. (Citrus & Allied) and Kishor Fozdar.



Stephen Manheimer (Kerry) and Stephen Somers (Vigon).



Scott Hagedorn, Karen Manheimer and Dave Carroll (all Kerry).

IFRA NA Analysis of Proposed “Safer Consumer Products” Regulation

IFRA NA recently published an analysis of the California Department of Toxic Substances Control’s (CDTSC) proposed “Safer Consumer Products” regulation under the Green Chemistry Initiative. It reads as follows:

This regulation contains a number of proposals that are of significant concern to the fragrance industry and that would be precedent setting for both ingredient disclosure and fragrance safety proposals that currently exist on the state and federal levels.

Prioritization Process

In the Chemical Prioritization Process section, the prioritization factors that DTSC may use to place chemicals on the Priority Chemicals list are outlined. Among the 26+ factors, listed on pages 31-35 of the proposed regulations, are adverse public health impacts that may result from single, intermittent or frequent use or contact with a chemical, including dermal, oral and inhalation exposures, and a number of listed hazard traits, as well as any others that California determines may adversely impact public health. While the proposed regulation allows an exclusion for any chemicals regulated by other California or federal agencies for the same potential threat, the same chemical cannot be excluded if the Department determines that there are any data gaps related to cumulative exposure. The proposed regulation also allows DTSC the discretion to determine whether a de minimus exemption is applicable to a particular priority chemical.

Products that contain one or more priority chemicals and can be reasonably expected to be placed into the stream of commerce in California would be contained on the Priority Product list (pg 37). Products on this list must provide various data points (pg 43) to DTSC, including all persons involved in the supply chain. In addition, any person can petition DTSC to include a chemical or a product in the prioritization process. As proposed, neither the Priority Chemical nor Priority Product list has a limit to the number of items that they can contain.

Alternatives Assessment

Once a chemical is determined to be a priority for DTSC, the chemicals’ manufacturer would be required to undergo an Alternatives Assessment, a process which is outlined in the proposed regulations. The regulation includes requirements for qualified in-house assessment entities (pg 80) to consist of a manufacturer, consortium of manufacturers, trade association, or public-private partnership. A potential assessment entity must apply to be a qualified in-house assessor. Once an entity is approved as an assessor, the entity must apply for renewal of its status every 5 years.

Confidential Business Information

Lastly, the proposed regulations contain a section on Confidentiality of Information (pg. 86). While the proposal allows for claims of trade secret status, a manufacturer must provide upfront substantiation, as well as a non-redacted copy of the information. If DTSC determines that a claim is unsubstantiated, it would immediately make the information public.

“We no longer live in a siloed world of different jurisdictions,” warned Darren Praznik, president and CEO of the Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA; www.cctfa.ca). While Canada is a sovereign marketplace of 34 million people, featuring personal care sales of some 7.5 billion CAD per year, regulatory pressures don’t respect national boundaries. Praznik explained, “What happens now in one country can [move] very quickly into another.” Thus, it is very easy for initiatives developed in Canada to quickly move into a place such as California, setting off a pan-continental regulatory issue. The threat is so real, Praznik said, that the CCTFA’s membership now numbers 165 companies, representing brand owners, distributors, manufacturers (including fragrance), and retailers, allowing for coherent messaging across stakeholder categories. It is crucial for industry to work cooperatively, Praznik continued, particularly as

anti-fragrance campaigns ramp up calls for cautionary labeling and fragrance ingredient disclosure, the latter of which, in his words, “has legs.”

When discussing cosmetic regulations, the biggest single issue for legislators and NGOs is fragrance ingredient disclosure, said John Hurson, executive vice president for government affairs for the Personal Care Products Council: “It is the poster child of the NGO community in terms of what they want to achieve in legislation.” In one telling anecdote, Hurson recalled being told by one NGO staffer that even if every fragrance ingredient in a product is 100% safe, it should still be included on the product label for the simple reason that, by the NGOs’ estimation, consumers have a basic right to know when it comes to the ingredients in products. Hurson noted that in the Internet age of free-flowing information, calls for disclosure continue to grow.



Stephen Manheimer paid tribute to longtime friend and colleague, Richard Pisano, Sr. (Citrus & Allied), recipient of IFRA North America's lifetime achievement award.



Bill Troy (Firmenich) presented Richard Pisano, Sr. with the official plaque.



Jennifer Abril, executive director of the officially renamed and reorganized International Fragrance Association North America.



Laurie Nelson (Randlett Nelson Madden).



Richard Pisano, Sr. was credited by Stephen Manheimer for his "invaluable" industry knowledge, thoughtful comments that have steered FMA's board over the years, and for his status as a "true pillar of the industry."



Colin McIntosh and Glenn Sabat (both Firmenich).

While Hurson explained that legislative calendars and expected changes to the composition of the US Congress in this election cycle will likely keep reform of the US Toxic Substances Control Act (TSCA) stagnant for some time, Charles Auer (Charles Auer & Associates) noted that any version of TSCA reform would seek to shift burdens to industry. Recent iterations of proposed reforms have highlighted green chemistry, expanded the fee authority and reporting "universe" of regulators to encompass processors, and called for the launch of a public ingredient database. Whatever the eventual reforms and timeline, significant burdens and costs threaten the industry and could fundamentally harm CBI and negatively impact competitiveness. As a result, Auer encouraged the fragrance industry to "consider what it can be 'for' and use that to advance a supportive public posture."

Hurson noted that CBI challenges have been sharpened further as a result of the introduction of "The Safe Cosmetics Act of 2010" to the US House of Representatives by Representative Jan Shakowsky (D-IL). The Act was pushed by groups such as the Breast Cancer Fund and Environmental Working Group. In response, despite its objections to many elements of the bill, PCPC's members, in cooperation with IFRA NA, are looking into options for industry-friendly fragrance ingredient disclosure. The two biggest hurdles, he explained, are that 1) the Research Institute for Fragrance Materials (RIFM)

is not considered sufficiently independent in its evaluation of ingredients by those outside the industry, and 2) there is a general pervasive belief in consumers' "right to know" when it comes to ingredients in products. Possible fragrance ingredient disclosure strategies cited by Hurson included the labeling of allergens, the labeling of fragrance ingredients that are CMRs (carcinogenic, mutagenic or toxic to reproduction), company website listings of entire fragrance ingredient palettes (not broken down by brand), submission of fragrance manufacturing dossiers to the US Food and Drug Administration (FDA; upside: confidential, allows for focus on what the ingredients are composed of and what's safe; downside: will not fulfill calls for transparency), a public list of fragrance ingredients used in cosmetics, or even FDA determination for fragrance ingredient safety use levels (again, this doesn't address calls for transparency and disclosure).

Whatever strategy—if any—stakeholders eventually settle on, Hurson noted, "This issue is not going away. Fragrance ingredient disclosure is something that is going



Jill Costa (Bell Flavors & Fragrances) and Fred Kiefer (Firmenich).



Paige Crist (Perfumer & Flavorist magazine), Heather Sims (Arylessence) and Daniela Knoop (Symrise).

to continue to be ... characterized by the activists as the huge loophole in labeling requirements in personal care products. It's not going away, due to the nature of our society."

More immediate is the threat of proposed "Safer Consumer Products" regulations in California's "Green Chemistry Initiative." In that state, Laurie Nelson (Randlett Nelson Madden) warned, environmental concerns trump the economy. And among these concerns, ingredient disclosure leads the way, and the industry faces ever-expanding interest groups with which to contend. As mentioned by Hurson, among activists there is a sense of "right to know" when it comes to fragrance formulas. Overall, she added, there is a lack of respect for CBI in California, particularly for products such as cleaners.

The practical impact?^a The green chemistry legislation represents a broadened statute that would provide the California Department of Toxic Substances Control (CDTSC) wide-ranging authority to demand information from manufacturers. In addition, said Nelson, it discourages innovation by asking for data on product modifications. The true danger, she added, is if this becomes the national model.

^aRead IFRA NA's recently published analysis of the CDTSC's proposed "Safer Consumer Products" legislation in the sidebar on **Page 30**.

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