As California "Right to Know" Bill Stalls, Industry Looks Toward 2011

Defending the fundamentals of the fragrance industry's business model: safety and intellectual property protections for formulas

"It's been a brutal year so far and we're expecting a repeat next year," says Jennifer Abril, executive director of the Fragrance Materials Association of the United States/IFRA North America. In a recent conversation, Abril discussed recent challenges to intellectual property and safety programs by non-governmental organizations (NGO), legislation and the media, and outlined both the difficulties ahead and key strategies for defending the fundamentals of the industry's business model.

The conversation took place following the stalling of the California "Consumer Right to Know Act" (Senate Bill [SB] 928), introduced by State Senator Joe Simitian (D-Palo Alto) of California's 11th Senate District, which encompasses Silicon Valley.[a] The legislation, which pushed for ingredient disclosure in consumer products such as air care, automotive, cleaning, and polish and floor maintenance products, included a provision for non-disclosure for intellectual property—an assurance that the FMA/IFRA North America, the Personal Care Products Council (PCPC), Consumer Specialty Products Association (CSPA) and others felt did not adequately defend legitimate industry interests. (Key terms are defined in the **sidebar**.) In addition, the bill left open the possibility that the scope of products falling under its rules could expand further.

"Around the state capitol in Sacramento, it's colloquially known as the 'what's in it' bill," says Abril, underscoring the legislators' apparent end-game.

The bill, introduced in February of this year and amended in March, June and August before it stalled in committee, rationalized its stipulations based on a handful of points, including:

- "Current federal and state laws do not require manufacturers to disclose to consumers the ingredients contained in all cleaning products."
- "According to the United States Environmental Protection Agency, nearly 20 percent of all chemicals in commerce in the United States are kept secret by manufacturers."
- "There is a growing awareness and concern among consumers about the exposure to chemicals in their homes and workplaces and the lack of transparency about chemical content in the consumer products they purchase and use and the potential adverse health and environmental impacts caused by those products."

The bill's authors thus concluded, "It is, therefore, the intent of the Legislature in enacting the Consumer Right to Know Act to provide greater transparency to consumers about the ingredients of air care, automotive, cleaning, and polish and floor maintenance products in order to empower consumers to make informed decisions about the products they purchase and use."

The latest reading of SB 928 states: "This bill would prohibit the manufacture, sale, or distribution of a designated consumer product, as defined, unless the manufacturer discloses each ingredient, as defined, contained in the product, identified in a prescribed manner, by posting that information on the manufacturer's Internet Web site, and provides the Web site and page address on the product label, along with a prescribed statement. The bill would, under specified circumstances, allow nondisclosure of ingredients defined as trade secrets.

"Commencing July 1, 2011, no designated consumer product may be manufactured, sold, or otherwise distributed in this state unless the manufacturer discloses each ingredient contained in the product by posting the product ingredient information on the manufacturer's Internet Web site and provides the Web site and page address on the label of the designated product along with a statement directing the consumer to the Internet Web site for information concerning ingredients contained in the product."

There have been various incarnations of ingredient disclosure bills in California, Abril explains. "It's a recurring

[a]Bills are indexed here: *www.legislature.ca.gov/bill_index.html*.

Definition of Key Terms Contained in California "Consumer Right to Know Act"*

- "'Chemically formulated consumer product' means a consumer product that is manufactured from chemicals or chemical compounds to be used by household, institutional, commercial, and industrial consumers without further processing for specific purposes. For the purposes of this subdivision, dilution by the consumer is not considered further processing."
- "'Air care product' means a chemically formulated consumer product designed, or labeled to indicate that the purpose of the product is, for masking odors, or for freshening, cleaning, scenting, or deodorizing the air."
- "'Automotive product' means a chemically formulated consumer product designed, or labeled to indicate that the purpose of the product is, to maintain the appearance of a motor vehicle, *as defined in Section 670 of the Vehicle Code*, including products for washing, waxing, polishing, cleaning, or treating the exterior or interior surfaces of motor vehicles. 'Automotive product' does not include automotive paint or paint repair products."
- "'Cleaning product" means a soap, detergent, or other chemically formulated consumer product designed, or labeled to indicate that the purpose of the product is, to clean ~~or disinfect~~ surfaces, including, but not limited to, floors, furniture, countertops, showers and baths, or other hard surfaces, such as stovetops, microwaves, and other appliances, fabric care, or dish or other ware washing."
- "'Polish or floor maintenance product' means a chemically formulated consumer product, such as polish, wax, or a restorer, designed, or labeled to indicate that the purpose of the product is, to polish, protect, buff, condition, temporarily seal, or maintain furniture, floors, metal, leather, or other surfaces."
- "'Hazardous substance' means a chemical, or chemical compound, including breakdown products, identified by a state or federal agency or other governmental body or the World Health Organization as potentially having properties of eye and skin irritation, sensitization, acute or chronic toxicity, carcinogenicity, cytotoxicity, neurotoxicity, developmental or reproductive toxicity, or both, endocrine disruption, or ecotoxicity."

*Note: Strikethrough text represents text removed in the most recent version of the bill, while italicized elements indicate newly added text.

theme because there is an ingredient disclosure plank within California's green chemistry program.[b] We will likely continue to see some version of it moving forward."

Abril adds that the FMA and other stakeholders were initially optimistic at the beginning of this year as a result of positive communications with Simitian regarding the bill and the industry's needs. "I think it's important to understand his background," she says. "He comes from Silicon Valley and appreciates the value of intellectual property and research and development. He is fairly reasonable in that regard and understands the need for companies to have protection."

And so, she says, "We were hopeful at the beginning of the year that we would be able to have a common bill and by that I mean one that not only the Senator himself feels comfortable with and reaches his needs but also one that met the needs of industry and the NGO community. FMA had spent time reaching out this year and last year to several NGOs who are very active in this particular initiative."

For any version of the bill to pass, Simitian needed to get the legislation through both houses, which necessitated reaching out to entities such as unions. "When they brought in the unions, that created a new dynamic," says Abril. With the new set of players in the negotiations, she says, "the unions brought up questions that had already been addressed through earlier negotiations … and there

[b] *www.dtsc.ca.gov/pollutionprevention/greenchemistryinitiative/index.cfm*

was a desire to expand the scope of the bill to include industrial and institutional products. It brought us backward by a few steps."

In the end, she says, "There were some rewrites of the bill … that we just couldn't support."

Protecting Formulas: Intellectual Property Concerns

In announcing that SB 928 was being held in committee and was effectively dead for the year, CSPA president Chris Cathcart said, "We are pleased to see that we will be able to continue our discussions with Senator Simitian and the other stakeholders on this important issue and hope to reach agreement in 2011. Our association could not support this bill because it did not strike the appropriate balance between transparency about the ingredients in our products and the need to protect our intellectual property.

"What our industry put on the table through our work with Senator Simitian and the NGOs would have been the most far-reaching right-to-know mandate required of any industry in the world," Cathcart continued. "We need to work together so that we do not miss another opportunity in 2011."

The FMA released a more pointed statement, noting that the latest revised text "effectively calls for the fragrance industry to surrender its intellectual property and disclose individual fragrance formulas … It provides no exemptions for fragrances, levels of ingredient concentrations, or intellectual property protections. This bill undermines the fundamentals of our industry's business model and threatens irreparable economic harm to FMA member companies."

The language of the most recent version of the stalled bill states, "Any ingredient or incidental ingredient that is a hazardous substance shall not be considered a trade secret. Any designated consumer product or ingredient or incidental ingredient of a designated consumer product that ~~can be reverse engineered~~ *is readily discoverable by analysis* shall not be considered a trade secret."[c]

"We were very concerned about the reverse engineering clause that was inserted into the bill this summer," says Abril.

The bill continues:

> For purposes of this article, a manufacturer shall not be required to disclose ingredients falling within the definition of trade secret, unless that information is otherwise required to be publicly disclosed under another law of this state, has been publicly disclosed by the manufacturer, or has been lawfully disclosed by a governmental entity. A manufacturer shall indicate the existence of trade secret information in the disclosure required under Section 25219.6 by individually identifying trade secret protected chemicals and chemical compounding using a functional class descriptor name and stating that that ingredient is a trade secret.
>
> Notwithstanding Section 6254.7 of the Government Code, if a manufacturer believes that disclosure of information pursuant to this section involves the release of a trade secret, the manufacturer shall make written disclosure to the department and substantiate in writing the basis of the trade secret. In its written notice, the manufacturer shall specify the information it is keeping confidential and provide to the department at the time of submission full justification and documentation in writing supporting the trade secrecy claim, including specific explanation and documentation of all of the following:
>
> (1) How the information derives independent economic value, actual or potential, from not being known to the general public.
>
> (2) The ease or difficulty by which information could be properly acquired or duplicated if disclosure is made.
>
> (3) How revealing the chemical identity would expressly reveal the process by which the chemical is made or the portion of a mixture the chemical comprises or the proprietary nature of the chemical itself.
>
> (4) What efforts are taken by the manufacturer to maintain its secrecy.
>
> (5) The barriers to reverse engineering of the relevant consumer product.
>
> (6) The basis of the manufacturer's determination that the ingredient is not a hazardous substance.
>
> (b) Subject to this section, the department shall protect from disclosure a trade secret designated as a trade secret by the manufacturer for a period of six years, if that trade secret is not a public record. After that period expires, the manufacturer may resubstantiate the need for trade secrecy protection.

"When we go in and talk to [California legislators] about safety, they push back on us saying this isn't about a scientific or safety argument, it's about knowing what's in the product," says Abril, acknowledging the challenges for formula and other intellectual property concerns reflected in the stalled bill's language.

So why did the bill fail to leave committee? "There were probably a dozen stop points along the way between the bill's introduction and where it ended up," says Abril. "It was held in an appropriations committee, which was concerned about the financial impact [of the bill] on the state." In fact, California has reportedly, at times this year, teetered on the edge of bankruptcy due in part to the poor economy.

In addition, says Abril, "We mounted a two-pronged campaign—both a grassroots campaign where our members wrote letters … and a large and broad industry

[c]Strikethrough text indicates recently deleted language. Italicized text represents newly added wording.

coalition which opposed the bill very publically. We made sure that fragrance had a distinct voice in the process."

Key to this initiative was the question of intellectual property protections. "We made an argument that fragrance formula disclosure was a case study for why the bill overreached and why it threatened intellectual property protections," says Abril. "We started targeting our messaging, depending on the audience. So, at the point at which it was in front of an environment committee we focused on the industry having a responsible and successful safety program, and then with the appropriations committee we focused on the fiscal effects of the bill for California EPA and the fact that it had a disproportionate burden on the fragrance industry.

"There was a provision [in the bill] … about protection of confidential business information (CBI), and there was not a requirement to substantiate the CBI claim upfront." However, she adds, "Although we didn't have to substantiate it up front, [the bill] left room for public challenges to CBI claims. So we would have had to defend each and every confidential mixture that we claimed CBI under this proposed law; we would have had major financial obligations and likely legal battles. We were very concerned about the reverse engineering clause that was inserted into the bill this summer." (See bill text earlier in this section for specifics.)

Despite that the bill has stalled for the year, Abril warns, "It's certainly part of a broader agenda. There's a very well coordinated group of NGOs who are active on this particular issue and are gaining traction, particularly on the fragrance issue. And so we see it as a sort of three-pronged attack. There is pressure from the legislative point of view, from media stories and articles questioning fragrance and the need for fragrances to be protected as a [chemical] class, and from reports attacking fragrance that are authored by NGOs and sent out through the media as if they're scientific papers."

Pushing back against the broader cultural pressures for full formula disclosure, the FMA is working with other stakeholders to achieve reasonable balance. "We've been pointing toward the transparency list that has been out since January 1 of this year," says Abril of the list of fragrance materials used by IFRA members and posted to its website.[d]

"We offered to Simitian that there may be ways we can utilize that list to meet his needs, but what we've been very clear about is that the fundamentals of our business model are built on the intellectual property protection of fragrance formulas. That's what we continue to fight for. It's legal and it's fundamentally what our business is built on."

Addressing the Wider Anti-fragrance Agenda

"We're expecting to see another version of this bill [SB 928] next year," says Abril, "because it's very obvious to us that some of the NGO efforts will be going toward the green chemistry program as it continues to roll out. They'll be looking for points in that program where they can come back and try to secure what they didn't secure during this year's legislative term. We are going to be extremely vigilant within the California Green Chemistry Initiative in assuring that any potential weak points will be hardened, if you will.[e] We will be visiting the regulators who are in charge of writing and implementing the regulations."

Abril continues, "In terms of broad landscape, overall there are numerous challenges to fragrance safety and intellectual property protections. Those are the fundamental challenges that we see. The public interest groups continue to use the term 'transparency' and 'right to know,' so we're expecting to see a variety of initiatives that attempt to address what is perceived to be a public need."

Already this year those examples have been legion.

In June, FMA/IFRA North America posted a statement in response to "What's That Smell?" a report from Women's Voices for the Earth (WVE).[f] The FMA statement criticized the WVE publication as unnecessarily alarmist and lacking in any new science, in addition to repeating existing false anti-fragrance arguments.

"The ingredients used to formulate scents in cleaning products are well-known and their safety evaluations are conducted globally on an on-going basis," the statement noted in part. "Credible science is available to address specific concerns raised by the report. However, the authors ignored facts and, instead, based their conclusions on flawed studies, unsubstantiated reports, and subjective opinions.

"Safety of fragrance materials is of critical importance to the fragrance industry," the statement continued. "That is why the fragrance industry has a long-standing and effective safety program. The international scientific authority on the safety of fragrance materials, The Research Institute for Fragrance Materials (RIFM), conducts studies on fragrance materials and publishes its findings in scientific journals. RIFM's study protocols and results are also reviewed by an independent expert panel. The RIFM database is the world's largest, most comprehensive resource for information on exposure to and safe use of fragrance materials. All members of FMA abide by the International Fragrance Association's (IFRA) Code of Practice which sets the highest safety Standards for use and manufacture of fragrance materials … A comprehensive list of all ingredients used in making a fragrance is publicly available at *www.ifraorg.org*. Consumers need to know that they can continue to enjoy fragranced products without concern."

Meanwhile, the FMA responded to a May *60 Minutes* story on phthalates. The statement reiterated clarifications about the differing chemical profiles of materials in the class and concluded, "The scientific validity of some frequently cited research remains dubious and it has been seriously questioned through the process of scientific peer review."

In response to "Not So Sexy—The Health Risks of Secret Chemicals in Fragrance," a report commissioned by the Campaign for Safe Cosmetics and co-created with

[d] *www.ifraorg.org*

[e] *www.dtsc.ca.gov/pollutionprevention/greenchemistryinitiative/index.cfm*

[f] *www.womenandenvironment.org/campaignsandprograms/SafeCleaning/whatsthatsmell*

cooperation from other NGOs, the FMA and RIFM declared: "Fragrance Safety is No Secret."[g] Notably, the statement explained, "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."

"We talk to our customers, their associations and their members on a regular basis," says Abril of the stakeholder coordination necessary to communicate fragrance ingredient safety and defend intellectual property protections for fragrance and fragranced products. "We're coalitioning with them and looking at this through the angle of its impact on both [customer and supplier] because we make fragrances on their behalf. We need to be aligned in the way that we view the fragrance aspects of these kinds of challenges."

No matter the outcome of challenges to the fragrance industry's intellectual property, says Abril, "It's not going away. It's a way of life. There are challenges to the intellectual property of fragrances because it's an attractive target and part of everyone's daily life. We are going to be first and foremost used as the example. And so our companies should know this and should be vigilant about aiding their associations by coming to their defense on fragrance safety and intellectual property protections, regardless of the form that it takes.

"We're expecting not only another bill out of California next year," Abril continues, "but we're also expecting multiple [challenges] on the federal level with new bills already introduced which have wide-ranging impacts."

"The Safe Cosmetics Act of 2010" (HR 5786; *http://thomas.coc.gov/*) has been sponsored in the US House of Representatives by Representative Jan Schakowsky (D-IL). The bill was introduced only days after the PCPC petitioned Congress for greater oversight from the US Food and Drug Association (FDA) on cosmetics regulation, making this month truly the month of cosmetics regulation in the United States.

Although HR 5786 is not related to the regulatory oversight proposed by the PCPC, the two have some similarities in that both call for more FDA oversight on cosmetics regulation. However, it seems that HR 5786 calls for much more oversight. In addition, the bill reportedly is based on findings by the Campaign for Safe Cosmetics, which supports the bill based on its controversial "Not So Sexy" publication. The group's site points out the following:

"[The bill] also requires suppliers of cosmetic ingredients to make available to manufacturers information regarding the toxicological properties and the safety—including any safety tests they've conducted—of those ingredients, including the chemicals in fragrance and preservatives."

HR 5786 seeks to amend Chapter VI of the Food, Drug and Cosmetic Act (*www.fda.gov/regulatoryinformation/legislation*), which concerns adulterated and misbranded cosmetics, by adding a subchapter on the regulation of cosmetics. Highlights of this subchapter include the FDA requiring: the registration of all manufacturers, distributors and packaging houses of cosmetics; the declaration of nano-sized raw materials; a list of alternative testing methods that do not involve animals; an ingredient declaration on all product labels; and the submission of all safety information on ingredients. In addition, to fund the FDA's oversight and enforcement, the bill requires the FDA to impose fees on companies that gross more than $1 million.

Annual registration of domestic and foreign establishments that manufacture, package or distribute cosmetics in the United States would be required under HR 5786. These companies would have to provide contact information, a description of their activities, gross receipts, the number of employees and the name and address of any company that supplies a cosmetic manufacturing establishment with ingredients for its products. This list then would be made publicly available by the FDA.

Within one year of enactment, manufacturers and distributors of cosmetics and ingredients must submit all reasonably available information in the possession or control of the manufacturer or distributor that has not previously been submitted to [the FDA] regarding the physical, chemical, and toxicological properties of single or multiple chemicals listed on the cosmetic labels," including function and uses, tests of cosmetics, and exposure and fate information. Within that year, HR 5786 also requires cosmetic labels to include a declaration of the name of each ingredient in such cosmetic in descending order of predominance.

In a statement released at the time of the legislation's unveiling, PCPC president and CEO Lezlee Westine said, "Our industry has lobbied for the last several years to obtain additional funding for the FDA's Office of Cosmetics and Colors. We also just last week proposed a number of new measures, including FDA ingredient reviews, that we believe would enhance FDA oversight and give the agency the information and flexibility it needs to continue to ensure consumer safety and safeguard public health.

"We are concerned that the Safe Cosmetics Act of 2010 as written is not based on credible and established scientific principles, would put an enormous if not impossible burden on the FDA, and would create a mammoth new regulatory structure for cosmetics, parts of which would far exceed that of any other FDA-regulated product category, including food or drugs. The measures the bill would mandate are likely unachievable even with the addition of hundreds of additional FDA scientists and millions more in funding and would not make a meaningful contribution to product safety.

"We urge Congress to carefully consider our recently announced proposals to strengthen FDA cosmetics oversight, including FDA ingredient reviews, and encourage the passage of the FDA Globalization Act of 2009, sponsored by Rep. John Dingell, which also includes

[g] *http://safecosmetics.org/article.php?id=644*

enhanced FDA regulations of cosmetics manufacturers. Our proposals and Rep. Dingell's legislation constitute the strongest, most efficient, and viable approach to modernizing the FDA regulation of cosmetics, increasing transparency, and enhancing existing consumer safeguards as science and technology evolve."

The five elements of the FDA Globalization Act highlighted by Westine are:

- Enhanced FDA registration, including manufacturing facilities, disclosure of all ingredients in FDA filings, and reporting of any adverse affects in consumers by industry to the FDA.
- FDA-established safe levels for trace constituents in cosmetic ingredients and products.
- Establishment of a new FDA ingredient review process.
- FDA oversight of findings by the Cosmetic Ingredient Review Expert Panel (*www.cir-safety.org*).
- FDA-issued Good Manufacturing Practices requirements.

In addition to the Safe Cosmetics Act of 2010, Abril notes that the fragrance industry will be impacted by proposed reforms of the Toxic Substances Control Act (TSCA).[h] This legislation (HR 5820) will present new challenges under chemicals management, she adds, and includes provisions "that our industry is not going to like at all."

Historically, Abril notes, TSCA reform hasn't been problematic for the fragrance industry. "It's actually been working for us." But the provisions included in this new ToSC legislation will fundamentally go further than Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

The 2010 TSCA reform seeks to shift chemical safety determinations under the auspices of the US EPA and require that manufacturers and importers provide minimum sets of data on each individual compound, including chemical identity, hazard, exposure and use. Furthermore, ingredients used throughout the supply chain would have to be disclosed. Finally, similar to challenges presented by the California legislation, the bill would push for lesser intellectual property protections, requiring a greater sharing of information by companies with EPA—including the sharing of data with state regulators and workers.

Of the legislation, Beth Bosley of Boron Specialties, quoted in an official release from the Society of Chemical Manufacturers & Affiliates (SOCMA), said HR 820 presents serious issues for chemical manufacturers.

"It is more important than ever that we maintain our competitive edge as innovators," said Bosley in a statement before Congress. "The US chemical industry's competitiveness has continued to decrease substantially in recent years due to competition from countries like China and India with lower resource costs, lower wage standards, and a less burdensome regulatory environment."

The key concerns, noted by SOCMA, include:

- "Inappropriate safety standard—the standards used to regulate drugs and food additives should not be used as the model for regulating industrial chemicals. The bill presents major roadblocks to market entry even for low risk chemicals."
- "New chemicals and new use requirement—the bill requires an unnecessary increase in testing and reporting, discouraging research and development and introduction of new chemicals or new applications in existing chemicals into the market."
- "Inclusion of mixtures—this expansion would overwhelm the Environmental Protection Agency and disadvantage the industry. It would require a massive increase in paperwork for submittal to the EPA for mixtures containing chemical substances that do not have an identified risk."
- "Lack of confidential business information protection—by disclosing chemical identity and components of a mixture in health and safety studies, we will promote foreign undercutting of the industry."
- "No state preemption—the potential for disruption of interstate commerce will remain without some kind of preemption in place."

Of the challenges, Abril says, "You've got CBI on the one side and then fragrance safety on the other side, and in many instances [legislators] blur those lines. In some other bills they are separate and distinct from each other. So, the number of bills that we're facing is actually growing.

"These are new concepts and experiences for the industry, and I think we are trying to figure out how to aggressively promote what is a very responsible industry; it's like no other in the chemical value chain. The fact that we have RIFM and the IFRA code of practice and standards is a very strong argument in our favor, and I think it's important that we continue to promote that. At the same time, the attractiveness of going after the fragrance industry as a case study of why disclosure is needed is something that's putting us in a different position than we're used to.

"One of the strongest arguments we've used in the past is that we're present in such low volumes," says Abril of growing challenges on aggregate and cumulative exposures to fragrance materials. "However, the NGO community is raising questions about the cumulative effects of very low presence materials in products. That's another place where we used to maybe have an 'out,' but now we're hooked in. we're trying to find further avenues where we can make our case. The landscape is changing and the messaging has to change along with it."

For now, says Abril, "We have a short respite. That helps us and gives us a little bit of time to get our thoughts together and regroup for next year."

[h] *www.govtrack.us/congress/bill.xpd?bill=h111-5820*