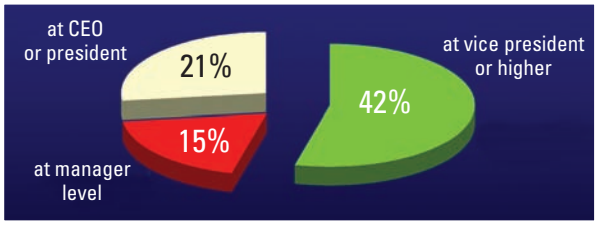
Disclosure Issues in F&F

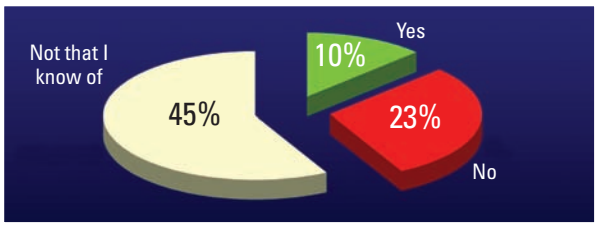
Protecting formulas, sources and other forms of intellectual property in a thriving regulatory environment

*During the joint FMA/FEMA Webinar, attendees responded to a number of informal polls. The compelling results are as follows:**

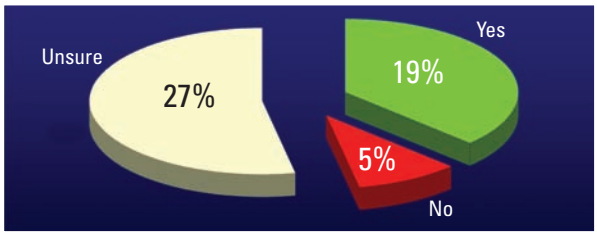
At what level in your company must a complete formula disclosure be authorized?



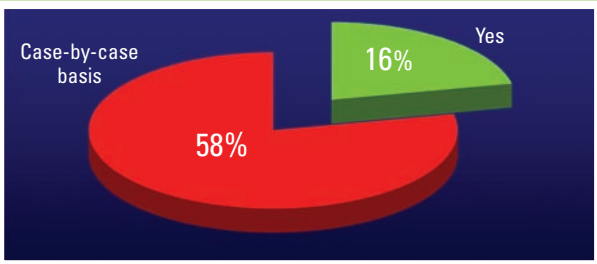
Has your company lost a sale due to a refusal to disclose a formula to a regulator or customer?



Regarding the EU cosmetics directive, have you found that customers prefer to list fragrance ingredients on their labels?



Does your company have a uniform policy for formula disclosure?



*Not every attendee voted on each question.

The Fragrance Materials Association (FMA; *fmafragrance.org*) and Flavor and Extract Manufacturers Association (FEMA; *femaflavor.org*) recently co-hosted an in-depth webinar on key intellectual property (IP) issues, particularly the protection of formulas when faced with disclosure requests from customers, physicians, the public and other sources.

The Flavor Houses' View

Kathleen Crossman of Givaudan discussed the delicate give and take in which flavor houses find themselves—the balance between the pressure to disclose and the pressure to defend IP. The solution, as Crossman put it, lies in identifying needs versus wants. And when disclosures are made, the presenter stressed that companies must mark anything they consider confidential as such. Doing so establishes an expectation of privacy. Companies that do not mark sensitive documents as confidential will have a hard time later arguing such information was privileged. Crossman also voiced some misgivings about e-mailing such information, as confidentiality is more difficult to establish. She suggested alternate means of delivering documents.

Identifying requesters: One of the basic issues Crossman addressed involved finding the appropriate person in a requesting organization with whom to discuss and/or disclose IP. "Sometimes you'll get a request in from people and you don't know who they are in the requesting organization," she said. Crossman suggested working with one's sales force to identify and assess requesters. "Generally," she noted, "if we don't have the regulatory contacts at our fingertips, we'll ask them, 'Can we speak with your regulatory group?' Encouraging that regulatory to regulatory contact does an awful lot to help speed the process along and minimize the hand-off along the way."

Disclosing carrier system information: Crossman explained that, because carriers are considered non-flavor ingredients, they should probably be disclosed. "When you get into certain encapsulation systems and things like that it might become more proprietary," she said. "I think when you start getting into what the dextrose equivalent is of the source of maltodextrin and how it's processed and what country the grain is grown in, at some point you get diminishing returns. But just to say it's maltodextrin sourced from corn is probably not going to raise a lot of concern for a flavor company."

IP disclosure hot spots: At one point in the presentation, Crossman fielded a question from the audience

regarding options for responding to requests for FEMA numbers for compounded flavors in Japan, Turkey and Indonesia. "These countries are increasingly pushing for information," said Crossman. "I do know that many companies have complied—many companies that wish they hadn't done it." Some companies resist such requests and still manage to get the goods through customs, she explained, noting that the solution usually lies in getting customs and governmental officials an explanation they're comfortable with, short of extensive disclosure. "Generally you can stop at the generic chemical class part of it where they're happy."

Medical enquiries: Crossman said that ideally it is the customer that approaches her company with medical inquiries. A physician phoning directly may well not even know what flavor is involved in the medical emergency to begin with. Once the flavor product involved is identified, regulatory teams can make a quick call back to the customer or physician (depending upon the scenario). "We'll discuss what we can with the physician over the phone to understand his concerns and needs and provide him with anything we believe could be of use," said Crossman, who pointed out that this step is generally sufficient to satisfy all parties. Though there are outside organizations that companies can work with to facilitate discussions and provide a third-party presence. "The physician will tend to believe an outside agency just a little bit more," said Crossman.

The Fragrance House's Outlook

Cheryl Kissel, director of corporate safety and regulatory affairs at Takasago USA, reinforced a number of Crossman's points. Kissel said that her company is seeing a number of disclosure requests from marketing sources seeking to back up claims such as "natural" and "green." Retailer inquests have also trickled down to the fragrance house level. Meanwhile, Kissel has fielded disclosure requests that seek to ensure that a product is not infringing on a patent. Other customers may request information to confirm that materials added to a formula to replace problematic materials are indeed safe. And new demands are coming to the fore. Even though customers are not yet reporting under the California Safe Cosmetics Act, they are already beginning to ask for the relevant information.

In all scenarios, Kissel stressed that companies must read confidentiality agreements very carefully. She explained that she generally felt a confidentiality agreement becomes necessary, "if I'm disclosing fragrance information that I wouldn't necessarily be required to disclose." Kissel used the example of an EU fragrance allergen in describing the types of legitimate disclosure a customer would need for proper labeling. Yet, even with this type of information, she reiterated that "we would certainly mark the information as confidential."

De minimis *disclosure levels:* Kissel noted that *de minimis* disclosure levels are typically set on a case-by-case basis. "Sometimes it is 1.0% or 0.1%. When you disclose to government agencies and discuss it up front, they'll usually say 0.1% is sufficient. And other times we might set a limit of 1 ppm—it's a very common threshold. Design for the Environment was looking at 0.01%."

The Customer's View

Neil Snyder, director of regulatory, safety and environmental services for household products at Reckitt Benckiser provided insights from the other side of the supplier-customer equation. There are numerous negative (and often inaccurate) media stories, emerging biomonitoring programs and anti-fragrance activists. "Various nongovernmental organizations and activist groups are not in favor of some of the ingredients and fragrances used in consumer products," Synder noted. "We're also seeing more and more data being put out by these same groups on chemical analysis of our products. If you were to have asked me several years ago whether someone would take one of our products off the shelf and analyze it, I would have said it certainly could be done, but it's unlikely. Now we're seeing this as a rather regular occurrence."

The result is a growing demand for formula disclosure from all quarters. Snyder identified this shift as a growing adherence to the precautionary principle, which puts the burden of proof on industry and which views virtually any hazard or risk as unacceptable. In other words: "Any exposure to ingredients of concern or selected ingredients would be harmful and there really are no safe exposure levels for these materials. There are calls that the everyday exposures, which were previously pretty much taken for granted, may in fact be harmful; the safety of these has been called into question." In short, those in the precautionary principle camp believe products should be risk/hazard-free in essentially any context of use.

Fragrances are widely seen as part of the "problem." Snyder highlighted vague fears of a "toxic world" in which most of the ~80,000 chemicals in commerce are "untested" over time. Fragrance opponents often cite indoor air quality as a key threat and charge that fragrances have no functionality—thus, no risk is worth it. Complicating this climate is the REACH program. "Inherent in REACH is risk mitigation information up and down the supply chain," said Snyder. "Much more than it currently is. That's going to put a lot of stress on ingredient disclosure for things like fragrances."

Despite these complications, it has been proven time and again that the consumer wants fragrance. Scents reinforce efficacy and product claims, act as branding markers and fragrance signatures for spaces such as homes, and mask off-notes. They are not going away.

Changing project briefs: Snyder explained that his company does include ingredient restrictions on the briefings presented to fragrance houses. He gave the example of geranyl nitrile, a fragrance material that appeared in the EU Cosmetic Directive as a class three reproductive toxin. The class three designation allows for use under specific conditions. Yet questions were raised about the material's safety; the International Fragrance Association (IFRA; *ifraorg.org*) reclassified the material ahead of any formal regulatory action, designating the material unfit for fragrance applications. Snyder noted that when consumer goods companies monitor the regulatory situation and

stay in close contact with suppliers, it becomes easier to stay familiar with potentially problematic materials and take action ahead of time to reposition out of harm's way. "That's something where you may come in with an injunction against using [a material] in fragrances, which would show up in a brief."

Just how big is the consumer inquiry issue? "There is a steady stream of people who have primarily allergic concerns," Snyder said. "If they have a problem with a product, they may suspect the fragrance. They're not necessarily going to know whether it's something in the fragrance or in the product or whatever. They're really just looking for information." Snyder added that his company—as with all the large companies—maintains a large consumer relations group.

Disclosure of ingredient sources: "As an industry, we're really driven by consumers and what they're asking for in products," said Snyder. "Sustainability is an issue which is very much to the fore. People are looking for natural products." The speaker pointed out that even internal marketing staff often seeks to back up various claims they wish to make. "The marketing people may come back and say 'I want to make a natural claim,' or 'I want to say that this uses natural ingredients.' There are green and sustainable products which are now on the market from a number of manufacturers. If we follow that through a lifecycle assessment or evaluation of these products, the source of these ingredients and whether they are in fact coming from natural sources or sustainable sources or whether they're coming from petrochemical stock is becoming more of a question which will be asked." Snyder believes these questions will only increase over time. "We will have a need for this kind of information and have begun to ask for it in certain circumstances," he continued.

Defining fragrance-free: Snyder explained that currently his company looks at fragrance-free claims on a case-by-case basis. "I am not aware of a specific regulation that says 'this is going to be fragrance-free,'" he said. "If we look at products on the market that are advertised as fragrance-free, I think that would fall under the casework and regulations that would govern how you defend your claims—if those claims are challenged. And it would be handled in the way that all claims are if challenged." Snyder expressed some uncertainty over whether products containing masking agents are indeed fragrance-free. "You'd have to look at that on a case-by-case basis to understand how those odors were masked and what that meant."

Worker safety: "In many cases," said Snyder, "MSDSs from fragrance houses are a compendium of hazards that you may see that have been alleged from various parts of the fragrance or ingredients in the fragrance. And it can be difficult to try and understand what you're being told exactly or if you have a particular ingredient of concern, whether that's going to be a concern in your product or not." Fragrances are a tiny fraction of most consumer products—typically 0.2% or 0.3%—excepting air fresheners. Yet, said Snyder, workers deal with bulk raw materials, meaning that potential exposures are much higher. Some ingredients may be rather small constituents or lower-concentration constituents in a fragrance oil and may deplete to de minimis levels in the final product, but on the plant floor the exposure potential is greater. Because this may not be listed on the MSDS, more information may be requested from the fragrance house. This of course is not the fault of suppliers or customers but of poor hazard reporting standards.

Further readings on intellectual property issues: Protecting Formulas, Perfumer & Flavorist *magazine, October 2007, pp 14–15;* perfumerflavorist.com/articles/9958561.html.

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