

Defending Flavors

A decade of litigation spurs new proactive defensive measures

“**M**y whole message today is: How can you produce a safe product for its intended use and then find a way to [effectively] communicate how people should use that product,” said attorney Jacqueline Simmons, a partner at Baker & Daniels, during a contentious breakfast session of the Society of Flavor Chemists during the Institute of Flavor Technologists expo in Chicago. During the talk, Simmons presented some of her expertise and experiences working in the area of environmental compliance, including the removal of diacetyl from microwave popcorn formulations and the identification and review of the safety of flavoring substitutes. Her solution for avoiding future flavor/flavor-ingredient-related litigation? Address problems—or, more often, perceived problems—before they become litigation, and go beyond industry standards in communicating with customers about safety steps that should be taken to handle flavors safely and effectively.

The presentation came as two bronchiolitis obliterans-related court cases concluded with different outcomes, exemplifying the challenges facing the flavor industry. In one case, a former Midwestern flavor manufacturing worker who was exposed to diacetyl won a judgment of \$30 million, a record for this type of litigation. The worker had been employed at a plant for eight years and claimed a 75% reduction in lung capacity as a result of excessive diacetyl exposure. Elsewhere, a former video store worker claimed her job duties, which reportedly included popping significant amounts of microwave popcorn in-store for customers, had led to serious lung damage. This case has been dismissed as of press time.

During her presentation, Simmons focused on ways in which flavor manufacturers can effectively educate and communicate with those who use their products in order to minimize future legal wrangling. This means



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efforts that go beyond issuing material safety data sheets (MSDS), she said, “that frankly get filed in a workplace three-ring binder that gets changed out about once every eight to 10 years.” She added that there are likely many manufacturing workers who have never looked at those sheets.

Simmons, using the example of furfural (GRAS# 2489; CAS# 98-01-1)—which imparts brown, sweet, woody, bready, nutty, caramellic and burnt astringent nuances to flavor formulations—walked the audience through the key contents of an MSDS, including:

- Citation of an Occupational Safety and Health Administration (OSHA; www.osha.gov) guideline^a
- Hazardous Materials Identification System ranking, which rates health hazards on a scale of 0 to 4, with 4 being the highest risk (furfural has a risk of 3, a moderate risk)
- National Fire Protection Association (www.nfpa.org) rating, which denotes flammability/explosiveness

In reviewing the MSDS, Simmons noted that furfural has been determined to be toxic if inhaled and that the

^awww.osha.gov/SLTC/healthguidelines/furfural/recognition.html



Speaker Jackie Simmons and J.D. Vora (Robertet).



Paige Crist (P&F magazine), Serhan Rende (Carmi Flavors) and Cyndie Lipka (Sethness Greenleaf).

material is irritating to mucous membranes and the upper respiratory tract. The exposure limits cited by OSHA's website are as follows:

The current Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) for furfural is 5 ppm (20 milligrams per cubic meter (mg/m³)) as an 8-hour time-weighted average (TWA) concentration. The OSHA PEL also bears a "skin" notation, which indicates that the cutaneous route of exposure (including mucous membranes and eyes) contributes to overall exposure [29 CFR 1910.1000, Table Z-1].

The National Institute for Occupational Safety and Health has not established a recommended exposure limit for furfural.

The American Conference of Governmental Industrial Hygienists (ACGIH) has assigned furfural a threshold limit value (TLV) of 2 ppm (7.9 mg/m³) as a TWA for a normal 8-hour workday and a 40-hour workweek. The ACGIH also assigns a "skin" notation to furfural [ACGIH 1994, p. 22].

"I can tell you that a plaintiff's attorney would turn that around and say [to a manufacturer], 'See, you knew when you put that into your flavor ... that it was going to cause problems because you knew every human being has mucous membranes and that this was toxic and that the [threshold limit value] was at 2 ppm,'" said Simmons. She acknowledged that she did not agree with such an assertion and that this is obviously a frustrating issue for the industry. Despite the ready availability of technical and safety data on flavor materials, said Simmons, potential plaintiff claims are a dangerous prospect that companies



The team from FONA following the morning's presentation.

must be prepared to defend against. For these reasons, she said, companies require additional tools to amend MSDS and enhance educational outreach and depth of data for customers and workers using flavors and flavor materials.

"One way companies are now trying to defend [against] lawsuits is to issue a technical guidance document with their product that addresses the warnings issue head on," said Simmons. "It says, 'not only have we provided you with MSDS sheets, we have also provided you a summary of all the scientific literature that exists today and the best workplace practices that exist today, even if OSHA hasn't set a limit.' Technical guidance documents in my opinion go a long way toward defending [against] those lawsuits—especially for those substances for which you really do want your customers to follow certain workplace practices or where the government has not yet set a limit."

Here, Simmons raised the example of flavors containing diacetyl, for which she highly recommended companies provide a technical guidance document. The reason for this—and the issuance of any such document—rests on one fundamental question: "Who do you think in your company knows the most about your customers' workplace and whether or not they handle your products safely?" Sales staff occasionally may stop by plants, said Simmons, and even sometimes see how flavors are handled. They also may transmit additional information to customers regarding safety. However, Simmons stressed, the reality is that suppliers have no idea how any safety measures are implemented on a daily basis or even what is done with safety documents once they're sent out. And yet, she said, echoing the frustration of the flavor industry, the supplier can be held liable for misuse by customers.

To supplement MSDS and technical guidance documents, Simmons suggested suppliers use warning labels on packaging, but again, those labels are only effective if they're actually seen by the employees who are actually handling the material and then correctly implemented. Again, the breakfast attendees were left wondering: how much effort is enough to show due diligence and protect against litigation.

For the most part, said Simmons, the courts have ruled on the side of industry, “if you can show you’ve gone above and beyond the standard in the industry by providing these technical guidance documents, by offering seminars to your customers on how to handle your products in the workplace, and by providing them with warnings of this sort.

“Another thing I’ve suggested to people is some Web-based training that your customers can provide their employees for additional ways to prove the employees have some training and understanding of the hazards of what they are dealing with,” she added. “All of those things, although they can’t prevent lawsuits, can help you defend those lawsuits.”

Pointing again to diacetyl litigation, Simmons noted that MSDS were present in plants prior to the lawsuits of the last decade, but that technical guidance documents were not routinely issued, detailing such things as under what conditions to wear a respirator, the need for negative air pressure in key spaces, etc.

If these guidance documents are sent electronically, said Simmons, one should provide links to NIOSH reports, which can be another favorable way to show the supplier was proactive about providing information to customers.

She then walked the audience through a demo diacetyl technical guidance document, which encompassed “diacetyl and possible other related substances,” or DAPORs. Simmons explained that as media awareness of substances other than diacetyl has grown, it has become necessary to acknowledge them in documentation. Again, she said, this is part of a continuously expanding set of information that, for the protection of flavor suppliers,

should be provided to customers. Including DAPORs on a technical guidance document is not a declaration of them as hazards, but rather an additional layer of defense and disclosure. Currently, DAPORs encompass materials including 2,3-pentanedione, 2,3-hexanedione, 2,3-heptanedione, acetoin, acetaldehyde, furfural and acetic acid. Of course, she noted, complicating matters is the fact that diacetyl occurs naturally in popcorn kernels at a level of 80-100 ppm. OSHA levels effectively specify thresholds below those naturally occurring.

One audience member then asked, “How do you regulate that?”

Here, Simmons acknowledged that much of the litigation surrounding flavors is not about science, but that fact alone is insufficient to protect the industry.

Similar to drug makers and car manufacturers, the public relies on the flavor industry to keep it safe, said Simmons. “You may not believe that, but the average consumer believes that all of the people in this room have thought about these issues before you make your products that we use.” And, she warned, there are industries that have been severely harmed not by science but by consumer perception. And so a strong proactive approach to safety is crucial.

As another audience member put it, “Perception is reality.”

Simmons added, “It’s shocking what can be done when the consumers *perceive* something rather than what’s real.”

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