

## Interagency

# Proposed regulations on diacetyl not based on science, groups argue

By Amber Healy

Someone who has been smoking half a pack of cigarettes every day for 15 years is exposed to more diacetyl, a chemical flavoring most commonly associated with microwave popcorn's buttery taste and aroma, than would be allowed under the proposed exposure limit suggested by the National Institute for Occupational Safety and Health.

That's according to Leslie Ungers and Frank Mink, the owner and a toxicologist respectively at Ungers & Associates Inc., a Cincinnati-based environmental and health hygiene consulting firm that's written a comment in response to NIOSH's proposed exposure limits for diacetyl and 2,3-pentanedione (see *FCN* Aug. 19, 2011, Page 1).

NIOSH, a division of the Centers for Disease Control and Prevention, has received more than a dozen comments to its 518-page draft proposal, released back in August. The deadline was Nov. 18. Most of the comments are from food companies and makers of chemical flavorings. They argue that NIOSH's recommendations are based on weak, outdated science and would result in overly restrictive limits on worker exposure to the chemicals.

There are currently no exposure limits set for the two chemicals, which have been linked with bronchiolitis obliterans, also known as "popcorn worker's lung" due to the number of people who have contracted it while working in microwave popcorn facilities, when inhaled, the chemicals cause decreased lung capacity.

NIOSH suggested establishing a limit of exposure to diacetyl at 5 parts per billion as a time-weighted average for workers who are exposed to the chemical over the duration of a 40-hour work week. For those workers not normally exposed to diacetyl consistently over a normal work week, the agency proposes a short-term exposure limit of 25 ppb for 15 minutes.

NIOSH proposes a slightly different exposure level for 2,3-pentanedione, the long-term effects of which are not as well

known as that of diacetyl. For this chemical, NIOSH suggests a concentration of 9.3 ppb in a time-weighted average for a 40-hour work week, with a short term exposure limit of 31 ppb for a 15 minute period.

A 15-year, half-pack-per-day smoker would be exposed to 10-times more diacetyl than someone exposed to the recommended limit, and yet there have been no cases of bronchiolitis obliterans reported among smokers, says the nine-page letter submitted to NIOSH by Ungers and Mink.

"This is remarkable evidence that diacetyl is not causative of BO in humans and explains to a large degree why no significant dose response could be established for diacetyl exposure and bronchiolitis obliterans by NIOSH," they write.

Many of the letters sent to NIOSH argue that, for the long amount of time that diacetyl has been used as a chemical flavoring agent, there are few cases of bronchiolitis obliterans reported.

## Evidence lacking to support widespread risk from exposure

Also questioning the need for further consideration of NIOSH's recommendations are letters from the Grocery Manufacturers Association, Weaver Popcorn Company, Sensient Flavors & Fragrances, Industrial Hygiene Solutions LLC, and the Flavor and Extract Manufacturers Association of the United States (FEMA).

NIOSH should acknowledge that FDA has approved both diacetyl and 2,3-pentanedione, a diacetyl substitute, as generally recognized as safe, writes John Hallagan, FEMA's general counsel, in his 15-page comments to NIOSH. Diacetyl is "commonly found in butter, dairy products, and in many other foods often as a product of fermentation," and is made naturally in small amounts in humans.

FEMA and other groups warn that if NIOSH's recommended exposure levels are turned into regulation, many foods not associated with added chemical flavorings, such as strawberries, wine, milk, butter, cheese, breads and other baked goods,

and roasted chicken, could be deemed a public health threat by consumers. Workers in bakeries, or short-order cooks, would be required to wear the same protective respirators suggested by NIOSH in the proposed exposure level recommendations, because they'd be working in violative conditions every day.

"FEMA requests that NIOSH revise the criteria document to describe the relationship between diacetyl and respiratory illness, including bronchiolitis obliterans, as an association and not as a causative relationship," because there is little research directly linking the chemical with the illness.

In its recommendation draft, NIOSH repeatedly refers to a single popcorn company and a cluster of five employees who complained of diminished breathing capacity, believed to be due to diacetyl exposure. However, only one worker was officially diagnosed as having developed bronchiolitis obliterans; it is unknown whether the other four workers also contracted the disease, which eventually requires a lung transplant, Nancy Rachman, senior director of science policy and chemical safety with GMA, says in a 15-page letter.

"The presumption that latent cases of fixed obstructive lung disease would be discovered throughout the food manufacturing has not been borne out in spite of 11 years of experience" since the first cases were found, she writes. "Furthermore, the presumption of risk in the food manufacturing industry as a whole has not been supported by data on workers' compensation claims, which our members believe provide no indication of a problem. It is also noteworthy that despite the increased awareness of diacetyl usage in food flavorings, not only in California due to their emphasis program and subsequent rulemaking, but also by the federal Occupational Safety and Health Administration (OSHA), there is still no evidence of incidence or pattern of diacetyl-associated illnesses in general

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food manufacturing, including a lack of development of new disease in microwave popcorn plants.”

Rachman also says in her letter that NIOSH collected data on exposure to diacetyl in a plant that had already incorporated an improved ventilation system, meaning the amount of the chemical workers were breathing in was likely less than the amount NIOSH deemed hazardous to employee health. As a result, the threat to employee health was likely overestimated.

Many of the letters sent to NIOSH also wanted the organization to explain why factories using diacetyl are urged to use half-face mask, instead of one covering an employee's entire face, or other protective gear that would reduce the amount of exposure during a work week.

**Don't forget meat and poultry exposure, FSIS says**

But not everyone is strongly against NIOSH's exposure limits for diacetyl.

In a brief, one-and-a-half page letter, USDA's Food Safety and Inspection Service asks NIOSH to take into consideration the exposure to diacetyl faced by meat and poultry industry workers and inspectors and to “explicitly consider diacetyl's irritant effects in setting occupational exposure limits.”

Daniel Smigal, director of the Worker's Safety and Health Division at FSIS, writes that butter flavoring used as a “starter distillate” at a poultry slaughter and processing plant was linked with “highly prevalent eye and upper airway irritation among the inspection workforce,” which ceased the day after the starter was used.

The exposure limits are protective against bronchiolitis obliterans but might not be sufficient to prevent other kinds of harm to workers, he adds.

He also warns that the kind of ventilation systems described by NIOSH in the draft exposure guidance might be cost prohibitive for some smaller facilities.

“In the absence of criteria other than ‘ever/never enter a potential exposure area,’ and arbitrarily assuming a typical exam cost of \$200 [for workers regularly exposed to the chemical], an agency of our size could expect to pay \$1.2 million annually in medical expenses alone, not including time away from work or related intangibles. The potential cost to industry could be significantly higher.”

Additionally, letters from the International Brotherhood of Teamsters and the United Food and Commercial Workers International unions encourage NIOSH to push for even more restrictive orders.

The Teamsters and UFCW note that they first approached NIOSH with concerns about worker safety in 2006,

pointing to “compelling and toxicological evidence linking exposure to diacetyl to severe respiratory impairment and disease” and asked OSHA to issue an emergency temporary standard while exposure limits could be drafted. A second request was submitted in 2008, when the Teamsters were supporting workers at a baker mix factory in Los Angeles who were concerned about exposure to the chemical.

“In both cases, NIOSH could not find ‘the results of any in-depth medical evaluations resulting from abnormal findings identified by the monitoring and surveillance program’” the organization had devised to research the link between diacetyl exposure and negative health effects, but the unions “fully embrace” the exposure limits NIOSH has recommended now.

The California Department of Industrial Relations, Division of Occupational Safety and Health (Cal/OSHA), which released its own worker protection limits for diacetyl last year (see *FCN* Dec. 10, 2010, Page 12), also generally supports the limits recommended by NIOSH. But the state agency wants a few clarifications, including the difference in exposure levels from diacetyl in powder form versus vapor form. Cal/OSHA also suggests that, in a final recommendation, NIOSH provide a list of all diacetyl substitutes.

**~~U.S. and Canada unveil action plan for regulatory cooperation~~**

*By Stephen Clapp*

~~The United States and Canada on Wednesday unveiled a Beyond the Border (BTB) Action Plan and Regulatory Cooperation Council (RCC) Action to further cooperation between the two nations, including a focus on agriculture and food. Could the USDA's new test and hold proposal be threatened?~~

~~“BTB and RCC are complementary and promote transparency, efficiency, and the free and secure flow of people and trade~~

~~across our borders while maintaining and expanding our already robust relationships that keep people, goods, and services safe and secure,” the White House says in a news release issued Wednesday.~~

~~The February Statement on Regulatory Cooperation, announced by President Obama and Prime Minister Stephen Harper on Feb. 4, established the RCC, with a two-year mandate to promote economic growth, job creation, and benefits to consumers and businesses through increased regulatory transparency and coordination.~~

The United States and Canada are each other's largest export market, with roughly 20% of all U.S. goods exports destined to Canada. U.S. exports to Canada already support 1.7 million jobs, and last year U.S. exports to Canada grew more than U.S. exports to the rest of the world. Canada is the top export destination for 36 U.S. states, the White House reports. The White House points out that the United States and Canada enjoy the largest bilateral trade and