

Written Statement
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at
OSHA's "Informal Stakeholder Meeting on Occupational Exposure
to Diacetyl and Food Flavorings Containing Diacetyl."

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In May 2000, the Missouri Department of Health officially notified OSHA of a cluster of cases of bronchiolitis obliterans and other lung disease among current and former workers at a single microwave popcorn plant.¹ Since that time, we have learned quite a bit more about the adverse, and in many cases severe, respiratory effects of exposure to flavoring agents containing diacetyl. The results of NIOSH investigations have consistently found impaired lung health among exposed workers, and the results have been published in top-tier journals, including the *New England Journal of Medicine*, *American Journal of Respiratory and Critical Care Medicine*, and the *Morbidity and Mortality Weekly Report*. In all, NIOSH has conducted nine investigations of workers exposed to diacetyl-containing flavoring agents, and found respiratory impairment among workers at a majority of the plants.²

We now know enough to be confident that exposure to airborne diacetyl is harming workers' lungs, and that this exposure must be controlled without delay in order to prevent more workers from losing their lung function. More research would be useful, but its absence should not be used as an excuse for delaying the standard setting process. The research that would provide regulators with irrefutable proof of the diacetyl-lung disease dose response relationship simply cannot be undertaken - researchers cannot set up experiments in which human volunteers are exposed to different levels of diacetyl and other flavor chemicals. Useful information can be obtained from animal studies, and NIOSH has done two important ones that show that both artificial butter flavor vapors and pure diacetyl cause lung disease in lab animals.

Beyond animal studies, the primary information we have comes from humans, and the evidence is powerful - diacetyl has been present in every workplace where workers developed BO and where flavoring chemicals were manufactured or used. And in some cases, the average exposure to workers who developed BO was quite low - under 1 ppm (1 ppm is the equivalent of making a martini of one drop of vermouth in a bathtub of gin - an extremely low level of exposure). This is consistent with measurements taken in the kitchen of Wayne Watson, the Colorado man who was diagnosed with bronchiolitis obliterans after years of heavy microwave popcorn consumption. He was exposed to peak levels of .5-3 ppm twice a day for approximately ten years. Some of the workers who have developed the disease, though, were exposed for less than a year before suffering severe and irreversible decline in lung function. Many of the sick workers are young, otherwise healthy nonsmokers.

In short, we know that exposures to airborne diacetyl can cause severe damage to workers' lungs, even when the exposure levels are relatively low and the time frame short.

It is OSHA's statutory duty to issue health and safety standards to protect workers from occupationally-related injuries and illnesses. The OSH Act gives the agency the authority to regulate toxic materials based on "the best available evidence," and not wait endlessly for more evidence to accumulate. There is strong evidence that diacetyl exposure causes occupationally related illness in food and flavoring workers; there is sound evidence in the medical literature on which OSHA can base a standard.

Opponents of OSHA regulation have said that more research is needed to set a PEL. Given the known cases that have occurred following what appear to be extremely low exposure levels, any PEL that OSHA develops will be driven by technological and economic feasibility, rather than by a risk assessment that shows cases at different exposure levels.

It is also likely that additional research on human cases will provide relatively little information useful to setting a PEL. The research process to date is that environmental measurements are done after workers are discovered to be sick. Fortunately, many employers who use these flavorings are now reducing exposure levels. The places where new cases of BO are likely to occurring are probably ones that are not now conducting ongoing exposure monitoring, so any exposure measures will be done, if at all, after the disease has already occurred and been diagnosed. As a result, further investigations into disease outbreaks are unlikely to yield much more information than we have at the moment. It is possible that other diacetyl users, especially the large food manufacturers, are in possession of additional useful data, but an expanded human research program to better understand the dose response curve, or identify what may be a safe level, is not feasible. This should not be seen as a barrier to setting a standard, however.

In fact, we don't need a PEL, and the excuse that more research is needed to develop a PEL is just that – an excuse. If OSHA adopted the Flavor and Extract Manufacturers Association's voluntary Respiratory Health and Safety Program³ today, it would prevent many cases of lung disease among workers exposed to flavor chemicals

Finally, OSHA needs to demonstrate that it is committed to promulgating a rule quickly. There are already indications that OSHA is backtracking on its commitment to a rule on flavor chemicals. According to OSHA spokesperson George Chartier, quoted in the Orange (CT) Bulletin, this stakeholder meeting is "part of the steps to determine if a rule is necessary."

It appears that OSHA is unable to issue new standards to protect workers from toxic substances unless the agency is required to do so by a federal judge or Congress. We've been waiting for silica and beryllium rules for many years. In 1999, the US Department of Labor issued a beryllium disease prevention standard that included an action level ten

times more stringent than that of OSHA.⁴ OSHA issued an RFI for beryllium in 2002.⁵ Since then, the beryllium industry has come around to the position that the current standard is inadequate,⁶ but there is no indication that OSHA will issue a new beryllium standard in the foreseeable future.

OSHA needs to move quickly and forcefully to save the lungs and the lives of food industry workers exposed to diacetyl and other dangerous flavor chemicals.

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For additional information on failure of the US public health protection system to address this problem, see “A Case of Regulatory Failure - Popcorn Workers Lung” at http://defendingscience.org/case_studies/A-Case-of-Regulatory-Failure-Popcorn-Workers-Lung.cfm

For additional documents and studies on diacetyl and bronchitis obliterans in food industry workers, see: http://defendingscience.org/case_studies/Documents-for-Popcorn-Workers-Lung.cfm

Additionally, this subject has been covered extensively at the public health blog: <http://thepumphandle.wordpress.com/>

References

¹ View letter at: http://defendingscience.org/case_studies/upload/Roberts-Letter.pdf

² NIOSH. HETA 2003-0112-2949: ConAgra Snack Foods, Marion, Ohio, December 2004; NIOSH. HETA-2000-0401-2991: Gilster-Mary Lee Corporation, Jasper, Missouri, January 2006; NIOSH. HETA 2006-0303-3043: Carmi Flavor and Fragrance Company, Inc., Commerce, California. (April 2007); NIOSH. HETA 2002-0089: Nebraska Popcorn, Clearwater, Nebraska, July 2, 2003; NIOSH. HETA 2001-0517: B.K. Heuermann Popcorn Inc., Phillips, Nebraska, May 13, 2003; NIOSH. HETA 2001-0474-2943: American Pop Corn Company, July 2004; NIOSH. HETA-2002-0408-2915: Agrilink Foods Popcorn Plant, Ridgeway, Illinois, October 2003; NIOSH. HETA-206-0195-3044: Yatsko's Popcorn, Sand Coulee, Montana, April 2007; NIOSH. HETA-2007-0033: Gold Coast Ingredients, Inc., Commerce, California, March 2007; NIOSH. Interim Report 2. HETA-2007-0033: Gold Coast Ingredients, Inc., Commerce, California, August 2007.

³ http://www.femaflavor.org/html/public/respiratory_safety.html

⁴ DOE, 1999. 'Chronic Beryllium Disease Prevention Program, Final Rule'. *Fed. Regist.* Vol. 64, pp. 68854.

⁵ OSHA, 2002. 'Occupational exposure to beryllium: Request for Information'. *Fed. Regist.* Vol. 67 No 228, pp.70707-12.

⁶ Borak J. 2006. The beryllium occupational exposure limit: historical origin and current regulatory inadequacy. *J. Occup. Environ. Med.* Vol. 48 No. 2, pp. 109-116.