



SEP 25 2007

Mr. James Hoffa
General President
International Brotherhood of
Teamsters
25 Louisiana Avenue, NW
Washington, DC 20001

Dear Mr. Hoffa:

This is in response to your petition, dated July 26, 2006, to Secretary of Labor Elaine L. Chao on behalf of the United Food and Commercial Workers International Union (UFCW) and the International Brotherhood of Teamsters (IBT). Your petition was forwarded to the Occupational Safety and Health Administration (OSHA) for evaluation and response.

In your petition, you express concern that employees in microwave popcorn plants and other facilities that produce or use flavorings are exposed to diacetyl, a food flavoring chemical that has been associated with the respiratory disease *bronchiolitis obliterans*, and request that OSHA immediately issue an Emergency Temporary Standard (ETS) to reduce occupational exposure to diacetyl. You request that the ETS establish a diacetyl permissible exposure limit (PEL) of 0.05 ppm over an eight hour work period. You also request that employers be required to conduct air monitoring of diacetyl exposure and to provide appropriate respirators and medical surveillance to all employees exposed above 0.05 ppm, as well as asking that OSHA implement other provisions typically included in its health standards.

After a thorough review by OSHA of the evidence relevant to diacetyl exposures, I must deny your petition for the reasons discussed below. I assure you, however, that OSHA takes the concerns you expressed very seriously, is aware of the hazards associated with exposure to flavoring chemicals, and is already taking action to address them. OSHA also intends to propose a permanent standard addressing the hazards of flavorings containing diacetyl.

1. Background

Section 6(c) of the Occupational Safety and Health (OSH) Act authorizes OSHA to issue an ETS when it finds both that employees are exposed to a grave danger from exposure

to a toxic substance, and that issuance of an ETS is necessary to protect employees from that danger. As you know, an ETS becomes effective immediately upon publication in the *Federal Register* without the benefit of notice and public comment. The ETS remains in effect until superseded by a standard promulgated under the Act's regular Section 6(b) rulemaking procedures. The Act requires the Secretary to complete these proceedings and issue a permanent standard within six months of issuing the ETS. The test for issuing an ETS under Section 6(c) of the OSH Act has a high threshold to meet and courts have applied it rigorously, resulting in several successful challenges to ETSs promulgated by OSHA in the past. See, e.g., *Asbestos Information Ass'n v. OSHA*, 727 F.2d 415 (5th Cir. 1974).

The "grave danger" finding required for an ETS includes compelling evidence of a serious health impairment involving incurable, permanent or fatal consequences. See, *Fla. Peach Growers Ass'n Inc. v. United States Department of Labor*, 489 F.2d 120, 132 (5th Cir. 1974). Grave danger also involves a degree of risk that is higher than the "significant risk" that is required to support a permanent standard under Section 6(b) of the OSH Act. Compare *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 640 (1980) (permanent standard) to *Dry Color Mfgs Ass'n v. Department of Labor*, 486 F.2d 98, 104-105 (ETS). To determine that an ETS is "necessary," OSHA must be able to show that the ETS would substantially reduce the grave danger during the six months the ETS would be in effect and must also show that such reduction could not be obtained by enforcement of existing specific standards. See, e.g., *Asbestos Information Ass'n*, 727 F.2d at 422, 426.

Thus, in this case, OSHA would need compelling evidence that the health effect at issue, *bronchiolitis obliterans*, constitutes a grave danger, that diacetyl is the specific chemical agent responsible for *bronchiolitis obliterans*, and that current workplace exposure to diacetyl is causing *bronchiolitis obliterans*. There must also be adequate evidence that an ETS is necessary because no existing OSHA requirements can substantially reduce that grave danger. Additionally, OSHA must show that the ETS would be technologically and economically feasible. Although *bronchiolitis obliterans* is undoubtedly a very serious disease, currently available evidence does not establish that current exposures constitute a grave danger, or that an ETS is necessary to reduce any existing risk. Moreover, it is not clear, based on current scientific evidence, that diacetyl is the specific chemical agent responsible for *bronchiolitis obliterans*.

2. Grave danger

The principal evidence of grave danger cited in your petition was developed during investigations conducted by the National Institutes for Occupational Safety and Health (NIOSH) at least three years ago at six microwave popcorn plants. Most of those popcorn plants have either already implemented or are in the process of implementing control measures that have reduced employee exposure to flavoring vapors. OSHA

staff also evaluated current workplace exposure conditions at site visits to three other microwave popcorn plants over the past eight months. All of the facilities we visited had already installed specialized local exhaust ventilation to capture and exhaust butter flavoring vapors from the headspace of the mixing tanks and from the breathing zone of the mixer engaged in pouring operations. The mixing rooms at all three sites were separate from the production line either in a dedicated room that is under negative pressure or on a mezzanine ventilated by local exhaust ventilation. Exposure of production employees to butter flavoring chemicals in these plants had been reduced significantly by enclosing or automating the packaging production line. Employers had also implemented strict respiratory protection requirements for employees who entered the mixing room or mixing area. Air sampling during these site visits found consistently lower diacetyl exposures than those reported in the earlier investigations of microwave popcorn plants. The microwave popcorn industry is relatively small, and the control measures and work practices implemented in the recently visited plants indicate that the industry is taking effective action to significantly reduce exposures to butter flavorings, including diacetyl. Thus, OSHA does not have sufficient evidence that a grave danger currently exists in microwave popcorn manufacturing facilities to support the issuance of an ETS for diacetyl. Furthermore, four leading companies recently announced that they are now or in the near future will be eliminating diacetyl from their microwave popcorn products.

The evidence relating to possible exposure hazards related to flavorings in manufacturing facilities outside the microwave popcorn industry is much less well developed. Although several cases of *bronchiolitis obliterans* and severe airways obstruction have recently been identified among flavoring manufacturing facilities in California, there is ongoing investigation to characterize the risks among employees who regularly work in areas where butter flavoring ingredients are blended. At this time, all California flavor manufacturing establishments are undergoing medical and exposure assessments to identify potential flavoring-related respiratory disease among their employees as part of the Flavor Industry Safety and Health Evaluation Program (FISHEP), a State cooperative compliance initiative from California State OSHA (Cal/OHSA). The participating flavor manufacturers are committed under FISHEP to implement recommended measures to address respiratory disease and reduce exposures to potentially hazardous flavoring substances. Cal/OSHA is also in its normal process of developing a standard to protect workers from hazardous exposures in establishments that manufacture and use food flavorings that contain diacetyl.

Even less is known about any danger from existing workplace conditions in flavor manufacture outside of California. There is also very limited available information on the rate of small airways disease or diacetyl exposures in the many other industries known to use diacetyl-containing food flavorings. Without more current information on existing exposure conditions in these workplaces, it is not possible to make the legal findings required to support an ETS.

We also note that, although there is evidence of an association between *bronchiolitis obliterans* and diacetyl exposure, there is still a significant question as to whether diacetyl is the causative agent. The occupational sources most closely associated with this lung disease include exposures to other potential airways-reactive flavoring substances in addition to diacetyl. Many of these other compounds have not been adequately studied for their ability to cause damage to the respiratory tract. Therefore, the existing occupational surveys of microwave popcorn, flavor manufacture, and chemical production facilities are not able to establish diacetyl as the causative agent responsible for *bronchiolitis obliterans*. Preliminary animal experiments showed extensive injury to the nose and pulmonary airways of rats breathing high concentrations of butter flavoring vapors for a short period of time. Rats breathing similar amounts of pure diacetyl caused damage to tissue lining the nose and upper airways, but not to the lower airways of the lung where *bronchiolitis obliterans* is known to occur. Future inhalation toxicology and workplace study data are needed to clarify the specific agents and exposure levels contributing to flavoring-related lung disease. As described below, OSHA began a National Emphasis Program (NEP) earlier this year for microwave popcorn manufacturing and plans to implement an NEP for flavoring manufacturing plants. These programs will provide additional information on uses and hazards associated with diacetyl.

3. Necessity of an ETS

Even if the grave danger basis for a diacetyl ETS could be demonstrated, OSHA believes that the necessity basis for the ETS has not been adequately established at this time. As noted above, employers are taking steps to reduce exposures on their own, and we expect they will continue to do so. In addition, several existing OSHA standards provide some additional protection for workers exposed to diacetyl-containing flavorings. OSHA's Respiratory Protection standard, 29 CFR 1910.134, requires employers to provide and require the use of respirators when "necessary to protect the health of the employee" from exposure to harmful airborne substances. The existing evidence is adequate to meet this standard, and employers with employees exposed to diacetyl must perform the hazard assessment required by the respirator standard. Furthermore, if necessary, employers must provide employees with appropriately protective respirators and require their use. Similarly, OSHA's existing Personal Protective Equipment (PPE) standards, 29 CFR 1910.132, 133, and 138, require the provision of appropriate PPE and training in its use, and the Hazard Communication Standard, 29 CFR 1910.1200, requires employers to train employees about the hazards of diacetyl.

4. OSHA Response to Diacetyl

Even though the currently-available evidence does not meet the stringent legal requirements for an ETS, it does show that employees exposed to butter flavoring vapors containing diacetyl may be at risk of material impairment. Our review confirms that elevated risk of airways obstruction was observed in six facilities studied by NIOSH among microwave popcorn plant employees who routinely poured butter flavoring in heated, improperly sealed mixing tanks, as well as among employees who operated packaging line equipment in the vicinity of the tanks and quality control employees who regularly popped large numbers of packages of popcorn in microwave ovens without adequate ventilation. As previously mentioned, OSHA is also aware of increased rates of obstructive lung disease among production workers in facilities that manufacture butter flavoring. OSHA staff is closely tracking ongoing efforts by Cal/OSHA, NIOSH, the Flavor Extract Manufacturer's Association, and the National Jewish Medical Research Center to collect exposure and pulmonary function data from employees engaged in the production of diacetyl-containing food flavorings. OSHA staff is also in contact with researchers at NIOSH and the National Institute of Environmental Health Sciences who continue to study the health effects in experimental animals following exposure to artificial butter flavoring vapors, including diacetyl.

Because of the potential risk of health impairment to a sizable number of employees, OSHA has decided to develop a proposed rule addressing occupational exposure to flavorings containing diacetyl under Section 6(b) of the OSH Act. We are in the process of gathering the data necessary to prepare the health and economic assessments to support this regulatory action. In the meantime, OSHA has already initiated a NEP that requires inspections of all workplaces where butter flavored microwave popcorn is being produced. This will be followed by a second NEP that focuses on establishments manufacturing food flavorings containing diacetyl. OSHA has published a Safety and Health Topics Page titled Flavorings-Related Lung Disease. We are also issuing guidance to help employers address diacetyl exposures. The Hazard Communication Guidance for Diacetyl and Food Flavorings Containing Diacetyl will assist employers who manufacture, import, or use diacetyl and certain food flavorings containing diacetyl. The guidance contains new information for conducting hazard determinations, updating material safety data sheets, instituting control measures, and updating labeling information and training. A Safety and Health Information Bulletin entitled Respiratory Disease Among Employees in Microwave Popcorn Processing Plants provides recommendations on how to control exposures to butter flavoring chemicals and ensure that the hazards are effectively communicated to workers, as well as information about applicable OSHA standards.

OSHA appreciates your interest in the occupational health of employees exposed to flavorings containing diacetyl. As rulemaking progresses, OSHA looks forward to cooperating with the UFCW and the IBT. Thank you for your efforts to protect employees.

Sincerely,


Edwin G. Foulke, Jr.