

HR 2693 Submitted by Mr. McKem

U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210



JUN 19 2007

The Honorable George Miller
Chairman
Committee on Education and Labor
U. S. House of Representatives
Washington, D.C. 20515

Dear Chairman Miller:

I am writing to express my strong concerns with legislation (H.R. 2693) that would require the promulgation of an interim final standard (IFR) regulating employee exposure to diacetyl in the popcorn and flavor manufacturing industries and mandate that the Occupational Safety and Health Administration (OSHA) issue a final rule covering all workplaces that use diacetyl.

I share your goal of protecting workers from the risk of obstructive lung disease. As outlined below, OSHA is in the process of taking important steps to strengthen worker protections in this area. However, after careful review of this legislation, we have concluded that the regulatory approach mandated by H.R. 2693 will not afford the best level of protection for workers. Equally important, the process the bill would require may result in missed opportunities to provide needed worker safety. Instead, I urge you to allow OSHA to thoroughly evaluate all available science concerning the effects of exposures to food flavorings, feasible abatements, and related issues.

Several considerations lead us to the conclusion that the approach mandated by H.R. 2693 would not best protect workers:

1. *The expanded scope of the final rule and the lack of knowledge about the industries that use diacetyl will lead to superficial analysis that may fail to provide needed worker protection.*

H.R. 2693 would require OSHA to expand the scope of the final rule to include all establishments where there is potential for exposure to diacetyl. Unfortunately, little is known about industries – other than the microwave popcorn manufacturing and food flavoring manufacturing industries – that use diacetyl and diacetyl-containing flavorings. OSHA would need to identify those companies that use diacetyl, then conduct site visits to gather needed data to (1) identify processes where exposures occur, (2) develop control strategies for each process, and (3) identify employers who have implemented control strategies to determine if those control strategies are effective. Although OSHA has been obtaining this information for microwave

popcorn and food flavoring manufacturing establishments, to date little information is available on the many other industry sectors that would potentially be covered by the final rule required by the bill. OSHA believes that two years is too short a period of time to develop the information base and analysis necessary to adequately support the proposed and final rule, and to afford the public adequate time to comment on OSHA's proposal. The Agency believes that robust public input is essential to achieving a final rule that provides protection for employees while addressing potential impacts on all affected industries.

2. *Focusing solely on a Permissible Exposure Limit (PEL) for diacetyl may ignore other components that are playing an important role in the development of disease.*

H.R. 2693 requires OSHA to develop a PEL for diacetyl that would apply to all facilities where diacetyl is processed or used. Research is ongoing by groups such as the National Institute for Occupational Safety and Health (NIOSH), the National Jewish Medical Center, the National Institute for Environmental Health Studies and California Department of Industrial Relations, Division of Occupational Safety and Health (Cal OSHA) to better determine the role that exposures to diacetyl and other chemicals may play in the development of bronchiolitis obliterans.

By focusing solely on diacetyl, H.R. 2693 raises two major concerns:

- a. Focusing on diacetyl ignores the possibility that other flavoring components – many of which are irritants and airway-reactive substances – are playing a role in the development of disease. Given the wide variety of ways and forms (e.g., liquids or powders) in which diacetyl and other flavoring components are used in the food manufacturing industry, a narrow focus on diacetyl would likely result in the selection of risk management strategies that may not adequately protect employees. These might include substitution of diacetyl with other chemicals that may be as dangerous under similar circumstances as diacetyl.
 - b. NIOSH has stated that “*at this time, insufficient data exist on which to base workplace exposure standards or recommended exposure limits for butter flavorings.*” Given the state of the data currently available, OSHA would only be able to develop an imprecise PEL for diacetyl which would have a considerable amount of uncertainty associated with respect to the degree of protection afforded.
3. *As drafted, the bill would require the interim final rule to impose engineering requirements based on NIOSH recommendations that lack the clarity and specificity necessary to form the basis of a new health standard.*

H.R. 2693 would direct OSHA to issue an interim rule at least as stringent as the 2004 NIOSH Hazard Alert. The NIOSH recommendations serve as good general recommendations, but do not provide specific performance criteria that would be necessary to develop an unambiguous and enforceable interim rule. The NIOSH Alert refers to the 2001 ACGIH Ventilation Manual, which provides some general objective design criteria, but mixing and blending processes in flavoring establishments vary greatly. For example, they can range from a 10-gallon batch operation up to several hundred pounds of batch mixing. Each of these operations may use similar control strategies but would require different engineering design parameters to achieve the same level of effectiveness. Therefore, the NIOSH Hazard Alert is not helpful to specify required minimum operating parameters for engineering controls because these minimum parameters will not provide equal protection to all employees in affected establishments. Furthermore, there is simply not enough information available at this point on flavoring processes and current exposure control practices to develop a specification-oriented standard.

OSHA traditionally has used PELs instead of specification-oriented standards to protect workers in this type of situation, because a PEL will set a precise, measurable standard to protect workers. However, as previously mentioned, currently available data do not support setting a PEL for diacetyl. Thus, OSHA would be forced by H.R. 2693 to issue a PEL based on imprecise information and an IFR based on a NIOSH Hazard Alert that does not provide specific performance criteria.

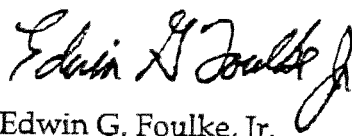
Additionally, the Department of Labor is very concerned that the IFR that is mandated by this legislation will not be open for comment by stakeholders, or reviewed in accordance with the requirements of the Small Business Regulatory Enforcement Fairness Act (SBREFA), the Administrative Procedures Act, and the rulemaking requirements of the Occupational Safety and Health Act. These statutes ensure thorough consideration and transparency in rulemaking. We do not believe these regulatory requirements should be waived except in the most exceptional situations. Thorough vetting is particularly critical when the medical and scientific studies do not provide unequivocal conclusions.

The Department of Labor is committed to protecting employees from obstructive lung diseases. The Department recently announced that OSHA will focus on health hazards of microwave popcorn butter flavorings containing diacetyl through a new National Emphasis Program (NEP). The NEP will direct inspections to the facilities where workers may be at the greatest risk of exposure to this hazard. Implementation of this NEP would allow OSHA to inspect every such facility under Federal jurisdiction by the end of this year. This will be followed by a second NEP that focuses on establishments manufacturing food flavorings containing diacetyl.

In addition to the NEP, OSHA is also preparing a Safety and Health Information Bulletin (SHIB) to better inform and instruct employers on how to protect employees from obstructive lung disease caused or exacerbated by food flavorings used in the microwave popcorn manufacturing industry. The SHIB will provide guidance to alert employers and workers to the potential hazards associated with butter flavorings containing diacetyl and will provide recommendations on how to control these hazards. OSHA is also developing a hazard communication guidance document to ensure that material safety data sheets and labels properly convey hazard information on diacetyl and diacetyl-containing food flavorings. Given that NIOSH has stated that insufficient data exist on which to base workplace exposure standards or recommended exposure limits for butter flavorings, the approach we are taking is the quickest and most effective means of providing protection to workers in the popcorn and flavor manufacturing industries.

Because of the concerns I have outlined, the Department of Labor is opposed to H.R. 2693. We have concluded that the approach proposed by H.R. 2693 will not afford the best level of protection for workers. By not providing sufficient time to do a proper rulemaking, OSHA may unintentionally overlook opportunities to provide needed worker safety and, at the same time, require expensive process isolation, and ventilation and other control strategies that may be ineffective. Instead, I urge you to allow OSHA to thoroughly evaluate all available science concerning the effects of exposures to food flavorings, feasible abatements, and related issues.

Sincerely,



Edwin G. Foulke, Jr.