

POPCORN WORKERS LUNG DISEASE PREVENTION ACT

JULY 18, 2007.—Committed to the Committee of the Whole House on the State of
the Union and ordered to be printed

Mr. GEORGE MILLER of California, from the Committee on
Education and Labor, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany H.R. 2693]

[Including cost estimate of the Congressional Budget Office]

The Committee on Education and Labor, to whom was referred the bill (H.R. 2693) to direct the Occupational Safety and Health Administration to issue a standard regulating worker exposure to diacetyl, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Popcorn Workers Lung Disease Prevention Act”.

SEC. 2. FINDINGS.

Congress finds the following:

(1) An emergency exists concerning worker exposure to diacetyl, a substance used in many flavorings, including artificial butter flavorings.

(2) There is compelling evidence that diacetyl presents a grave danger and significant risk of life-threatening illness to exposed employees. Workers exposed to diacetyl have developed, among other conditions, a debilitating lung disease known as bronchiolitis obliterans.

(3) From 2000–2002 NIOSH identified cases of bronchiolitis obliterans in workers employed in microwave popcorn plants, and linked these illnesses to exposure to diacetyl used in butter flavoring. In December 2003, NIOSH issued an alert “Preventing Lung Disease in Workers Who Use or Make Flavorings,” recommending that employers implement measures to minimize worker exposure to diacetyl.

(4) In August 2004 the Flavor and Extract Manufacturers Association of the United States issued a report, “Respiratory Health and Safety in the Flavor Manufacturing Workplace,” warning about potential serious respiratory illness in workers exposed to flavorings and recommending comprehensive control measures for diacetyl and other “high priority” substances used in flavoring manufacturing.

(5) From 2004–2007 additional cases of bronchiolitis obliterans were identified among workers in the flavoring manufacturing industry by the California Department of Health Services and Division of Occupational Safety and Health (Cal/OSHA), which through enforcement actions and an intervention program called for the flavoring manufacturing industry in California to reduce exposure to diacetyl.

(6) In a report issued in April 2007, NIOSH reported that flavor manufacturers and flavored-food producers are widely distributed in the United States and that bronchiolitis obliterans had been identified among microwave popcorn and flavoring-manufacturing workers in a number of States.

(7) Despite NIOSH’s findings of the hazards of diacetyl and recommendations that exposures be controlled, and a formal petition by labor organizations and leading scientists for issuance of an emergency temporary standard, the Occupational Safety and Health Administration (OSHA) has not acted to promulgate an occupational safety and health standard to protect workers from harmful exposure to diacetyl.

(8) An OSHA standard is urgently needed to protect workers exposed to diacetyl from bronchiolitis obliterans and other debilitating conditions.

SEC. 3. ISSUANCE OF STANDARD ON DIACETYL.

(a) INTERIM STANDARD.—

(1) RULEMAKING.—Notwithstanding any other provision of law, not later than 90 days after the date of enactment of this Act, the Secretary of Labor shall promulgate an interim final standard regulating worker exposure to diacetyl. The interim final standard shall apply—

(A) to all locations in the flavoring manufacturing industry that manufacture, use, handle, or process diacetyl; and

(B) to all microwave popcorn production and packaging establishments that use diacetyl-containing flavors in the manufacture of microwave popcorn.

(2) REQUIREMENTS.—The interim final standard required under subsection (a) shall provide no less protection than the recommendations contained in the NIOSH Alert “Preventing Lung Disease in Workers Who Use or Make Flavorings” (NIOSH Publication 2004–110) and include the following:

(A) Requirements for engineering, work practice controls, and respiratory protection to minimize exposure to diacetyl. Such engineering and work practice controls include closed processes, isolation, local exhaust ventilation, proper pouring techniques, and safe cleaning procedures.

(B) Requirements for a written exposure control plan that will indicate specific measures the employer will take to minimize employee exposure; and requirements for evaluation of the exposure control plan to determine the effectiveness of control measures at least on a biannual basis and whenever medical surveillance indicates abnormal pulmonary function in employees exposed to diacetyl, or whenever necessary to reflect new or modified processes.

(C) Requirements for airborne exposure assessments to determine levels of exposure and ensure adequacy of controls.

(D) Requirements for medical surveillance for workers and referral for prompt medical evaluation.

(E) Requirements for protective equipment and clothing for workers exposed to diacetyl.

(F) Requirements to provide written safety and health information and training to employees, including hazard communication information, labeling, and training.

(3) EFFECTIVE DATE OF INTERIM STANDARD.—The interim final standard shall take effect upon issuance. The interim final standard shall have the legal effect of an occupational safety and health standard, and shall apply until a final standard becomes effective under section 6 of the Occupational Safety and Health Act (29 U.S.C. 655).

(b) FINAL STANDARD.—Not later than 2 years after the date of enactment of this Act, the Secretary of Labor shall, pursuant to section 6 of the Occupational Safety and Health Act (29 U.S.C. 655), promulgate a final standard regulating worker exposure to diacetyl. The final standard shall contain, at a minimum, the worker pro-

tection provisions in the interim final standard, a short term exposure limit, and a permissible exposure limit that does not exceed the lowest feasible level, and shall apply at a minimum to all facilities where diacetyl is processed or used.

SEC. 4. STUDY AND RECOMMENDED EXPOSURE LIMITS ON OTHER FLAVORINGS.

(a) **STUDY.**—The National Institute of Occupational Safety and Health shall conduct a study on food flavorings used in the production of microwave popcorn. The study shall prioritize the chemicals that are most closely chemically associated with diacetyl to determine possible exposure hazards. NIOSH shall transmit a report of the findings of the study to the Occupational Safety and Health Administration.

(b) **RECOMMENDED EXPOSURE LIMITS.**—Upon completion of the study conducted pursuant to subsection (a), NIOSH shall establish recommended exposure limits for flavorings determined by such study to pose exposure hazards to workers involved in the production of microwave popcorn.

I. PURPOSE

The purpose of this legislation is to direct the Occupational Safety and Health Administration to issue a standard regulating worker exposure to diacetyl, an artificial chemical butter flavoring product that has been shown to cause serious lung disease called bronchiolitis obliterans, also known as “popcorn lung.” While the first cases of popcorn lung were identified in a Missouri microwave popcorn plant in 2000 and the disease was linked to diacetyl shortly thereafter, the Occupational Safety and Health Administration has not taken any significant action to prevent worker exposure to diacetyl.

**II. COMMITTEE ACTION INCLUDING LEGISLATIVE HISTORY AND VOTES
IN COMMITTEE**

Action in previous Congresses

There was no action on diacetyl in previous Congresses.

110th Congress

Hearing on “Have OSHA standards kept up with workplace hazards?”

On April 24, 2007, the Workforce Protections Subcommittee, led by chairwoman Lynn Woolsey (D-CA), conducted an oversight hearing titled “Have OSHA Standards Kept up With Workplace Hazards?” in order to address the lack of OSHA standards issued over the past six years. The witnesses discussed the obstacles to issuing OSHA standards, opportunities to speed up the process and the human cost of failing to issue needed protective standards. Witnesses included Assistant Secretary of Labor Edwin Foulke, Scott Schneider Director of Occupational Safety and Health for the Laborers’ Health and Safety Fund of North America, Frank Mirer, PhD, Professor of Environmental and Occupational Health Sciences, Hunter School of Urban Public Health, New York, Baruch Fellner an attorney at Gibson, Dunn and Crutcher, and Eric Peoples, a former employee of Glister-Mary Lee popcorn factory, victim of bronchiolitis obliterans (popcorn lung).

Introduction of H.R. 2693, the “Popcorn Workers Lung Disease Prevention Act”

On June 13, 2007, the Popcorn Workers Lung Disease Prevention Act, as H.R. 2693, was introduced in the 110th Congress by Representative Lynn Woolsey, joined by 13 original co-sponsors, including Chairman George Miller (D-CA) as a lead co-sponsor.

Full Committee markup of H.R. 2963

On June 20, 2007 the Committee on Education and Labor met to markup H.R. 2693, Popcorn Workers Lung Disease Prevention Act. The Committee adopted by voice vote an amendment in the nature of a substitute offered by Mrs. Woolsey which added a short title.

Mr. Wilson offered an amendment in the nature of a substitute that would have delayed promulgation of a final standard until “the National Institute of (sic) Occupational Safety and Health concludes there is sufficient data to support a recommended exposure limit.” Mr. Wilson withdrew the amendment pending further discussion.

A second amendment offered by Mr. Wilson was adopted by voice vote. The adopted amendment requires the National Institute for Occupational Safety and Health to conduct a study of possible substitutes for diacetyl in popcorn manufacturing, and to develop Recommended Exposure Limits for those found to be hazardous. The Committee voted to favorably report H.R. 2693 by a voice vote.

III. SUMMARY OF THE BILL

A number of individuals employed in microwave popcorn production and packaging and food flavoring manufacturers have contracted an irreversible and life threatening respiratory disease called bronchiolitis obliterans. There is compelling scientific evidence that a chemical used in artificial butter flavoring called diacetyl presents a grave danger and significant risk of bronchiolitis obliterans and other respiratory disease to exposed employees.

H.R. 2693 would require OSHA to issue an interim final standard minimizing worker exposure to diacetyl. The standard must contain provisions for engineering controls, respiratory protection, exposure monitoring, medical surveillance and worker training. It must not be less protective than guidelines issued by the National Institute for Occupational Safety and Health in 2003.

OSHA would then be required to issue a final standard within two years. This final standard would apply to all locations where there is worker exposure to diacetyl and would include a permissible exposure limit.

IV. STATEMENT AND COMMITTEE VIEWS

The Committee on Education and Labor of the 110th Congress is committed to ensuring that the federal government does everything within its power to ensure that workplaces are safe and that the health and safety of American workers is protected, consistent with the goals of the Occupational Safety and Health Act of 1970.

H.R. 2693 addresses the protection of workers from diacetyl, and food-flavoring chemical that has been shown to cause serious, irreversible obstructive lung disease, called bronchiolitis obliterans (or popcorn lung), in exposed employees working in popcorn production and packaging facilities, as well as food flavoring production facilities throughout the country.

The Committee considers this matter an emergency. Urgent action is needed by OSHA to protect exposed workers. NIOSH has reported the onset of respiratory symptoms as only months after exposure to diacetyl. Government officials have been aware of the dis-

ease since 2000 and have linked the disease to food flavoring chemicals since 2002. Mere guidelines for limiting diacetyl exposure are not sufficient. California researchers, for example, have found that despite the fact that government and industry guidance materials were issued in 2003 and 2004, many of their recommendations had not been implemented in flavor manufacturing facilities in California, according to a compliance survey conducted in 2006.¹

In the absence of government protections, hundreds of former popcorn plant workers have sued companies supplying or making diacetyl and more than \$100 million has been awarded by juries or paid in settlements.

The Food and Flavoring Manufacturing Association reported that at least 3,000 workers are employed in producing flavorings throughout the country. Thousands of others working in the microwave popcorn and other food industries are exposed in the “downstream” use of flavorings.

OSHA has failed to act to protect workers even though effective measures to protect workers from the effect of exposure to diacetyl are well recognized. For example, the National Institute for Occupational Safety and Health issued guidelines to be used by employers to protect workers in 2003, and the Flavor and Extract Manufacturers Association (FEMA) issued similar detailed guidelines in 2004.

OSHA has not proceeded aggressively to prevent worker exposure to diacetyl

The first suspicions that bronchiolitis obliterans among a group of workers was linked to their work surfaced in 2000. NIOSH first linked bronchiolitis obliterans to food flavorings in 2002 and evidence quickly accumulated pointing to an artificial butter flavoring chemical called diacetyl.

Despite evidence of substantial work-related hazards, OSHA has not taken action to minimize exposure to diacetyl. In 2002, it notified its Regional Administrators about the problem and formed a short term alliance with the Popcorn Board.² Since then, OSHA has announced its intention to issue a Safety and Health Information Bulletin, but nothing has been issued as of this time. Hours before the Subcommittee’s April 24 hearing, OSHA announced a National Emphasis Program (NEP) for the popcorn industry, where all microwave popcorn facilities that use diacetyl would be inspected before the end of 2007. Despite the announcement, the NEP has not yet been implemented, nor has any significant OSHA action been taken in addressing the problem in flavoring manufacturing.

In July 2006, two labor unions, the United Food and Commercial Workers and the International Brotherhood of Teamsters, petitioned OSHA to immediately issue an Emergency Temporary Standard for diacetyl. The petition was accompanied by a supportive letter from 42 of the nation’s leading occupational safety

¹Materna B, et. al. “Fixed Obstructive Lung Disease Among Workers in the Flavor-Manufacturing Industry—California, 2004–2007,” *Morbidity and Mortality Weekly Report*, 56(16) (Apr. 27, 2007) at 389–393.

²Have OSHA Standards Kept up With Workplace Hazards? Hearing before the Subcommittee on Workforce Protections, 110th Congress, 1st Session (2007) (written testimony of Edwin Foulke, at 3).

and health scientists and experts (see Appendix). In August of 2007, U.S. Representatives George Miller (D–CA), Major Owens (D–NY), and Hilda Solis (D–CA) sent a letter to OSHA supporting the union petition. OSHA has not responded to the petition.³

Workers are paying the price for OSHA inaction

Bronchiolitis obliterans is a severe, irreversible and often fatal lung disease that has been found to be caused by exposure to diacetyl. Dozens of workers at microwave popcorn plants and flavor manufacturing facilities have suffered severe occupational lung disease and several have died.

Eric Peoples, a former microwave popcorn plant worker in Jasper, Missouri, contracted bronchiolitis obliterans from exposure to diacetyl. In his testimony before the committee, Peoples revealed that the company that supplied the butter flavor, Bush Boake Allen, a subsidiary of International Flavors & Fragrances (IFF) had extensive notice about the hazards of butter flavor and took measures to protect its own workers including respiratory protection and enclosure of the process.⁴

He went on to describe how BASF Chemical Company, a supplier of diacetyl, sent IFF a Material Safety Data Sheet (MSDS) in 1994 which disclosed rats that had inhaled the chemical diacetyl developed severe respiratory problems including emphysema. IFF was also aware of two employees at a baking company who had been diagnosed with bronchiolitis obliterans in 1986 while mixing a butter flavoring for use on cinnamon rolls.

Peoples described how he worked with the hazardous chemical without information that could have protected him.

Despite all this information the buckets containing this product said the product was safe. The Material Safety Data Sheets said the product had “no known health hazards” and that’s what I believed.⁵

Peoples paid the price for this negligence:

Let me bring it home to you if I can. I have a 24% lung capacity. I am currently on the inactive Lung Transplant registry. One case of pneumonia could cause me to need the transplant now. The average rate of survival for someone with a lung transplant is about five years. Seventy-five percent of lung transplant patients are dead after 10 years.⁶

Linda Redman worked with Eric Peoples. Her experience was described in a story in the St. Louis Post Dispatch:

Linda Redman started working as a packer at the Jasper popcorn plant in 1995, two years after the original study. Within two years, her breathing was so bad that she had to quit.

Redman used to work 12 hours a day and then come home to garden, cook dinner, and do her family’s laundry. Now, she lives alone in Joplin, relying on home health

³Letter to the Department of Labor Secretary Elaine Chao (Aug. 2, 2006).

⁴Have OSHA Standards Kept up With Workplace Hazards? Hearing before the Subcommittee on Workforce Protections, 110th Congress, 1st Session (2007) (written testimony of Eric Peoples, at 2) [Hereinafter Peoples Testimony].

⁵Peoples Testimony at 3.

⁶*Id.*

nurses four days a week to help with basic chores around the house.

Redman, 55, doesn't have the stamina to change her bedsheets or cook herself dinner, unless it's something out of a can.

Only 15 percent of her lung capacity remains. Redman bides her time while waiting for a lung transplant by taking breathing treatments every four hours. She is constantly tethered to an oxygen tank, but she still gets exhausted walking from the bedroom to the couch.

"There's no amount of money that can ever buy back what we've lost—our health," Redman said of herself and the other sick workers. "There's a couple of us I don't think can make it much longer."⁷

Linda Redman died April 30, 2006.⁸

The Sacramento Bee reported on Irma Ortiz and Frank Herrera who also suffered irreversible lung damage due to exposure to diacetyl.

Hacking and gasping, Irma Ortiz could cart her groceries only so far before she'd catch other shoppers glaring at her.

Mortified, she'd abandon her cart on the spot and bolt for the door.

Frank Herrera could gun his dirt bike only so far before choking on the rush of air. Go. Stop. Go. Stop. Exasperated, he gave up riding.

Ortiz, 44, and Herrera, 34, are odd candidates for lung transplants, being nonsmokers and having considerable youth on their side.

How they lost 70 to 80 percent of their breathing capacity is no less astonishing. They acquired the same rare, lung-ravaging disease from breathing the same chemicals on the same type of job.

The two weren't working in a chemical or pesticide plant. Nor in a weapons plant. They didn't metal-plate, fumigate, degrease, demolish, smelt or weld.

They made, of all things, artificial food flavorings.

* * *

"They never said nothing to us about the chemicals there, the kinds of dangers or give us a warning like, you know, 'This is bad for you guys, protect yourselves better,'" Ortiz said of her former employer. "They never say nothing to us like that."⁹

Compelling scientific evidence that diacetyl is hazardous

There is compelling human and animal-based evidence that diacetyl is hazardous, presents a grave risk to exposed workers, and must be controlled.

There is evidence as far back as 1985 that flavoring chemicals, including diacetyl, were hazardous when bronchiolitis obliterans

⁷ Sarah Shipley, "Study Showed Chemical was Toxic," St. Louis Post Dispatch (Feb. 28, 2004).

⁸ "Popcorn Lung Victim Linda Redman Dies," Associated Press (May 2, 2006).

⁹ Chris Bowman, "Two Workers Need Transplants; Threat Could Be Widespread," Sacramento Bee (July 30, 2006).

was identified in flavoring manufacturing workers, although the cause was not identified at that time.¹⁰ In 1993, BASF, a manufacturer and supplier of diacetyl, conducted an inhalation study of diacetyl using rats. The study found that that “mid and high concentrations resulted in an abundance of symptoms indicative for respiratory tract injury. In the mid concentration group, these symptoms developed mainly from day one onward * * *” The study was never reported to the government or published in scientific literature.¹¹

In 2002, a NIOSH investigation found “that workers exposed to flavorings at microwave popcorn factories are at risk for developing fixed obstructive lung disease.” Workers at one plant had chronic cough and shortness of breath at a rate 2.6 times higher than what would be expected in the U.S. population. Twice as many workers as expected reported being told by their physicians that they had asthma or chronic bronchitis. Lung function testing revealed that three times as many workers as expected had obstruction to air-flow.¹²

NIOSH has conducted eight investigations at microwave popcorn facilities at facilities in a number of locations throughout the United States, finding respiratory impairment among workers at a majority of the plants and recommending actions similar to those recommended in H.R. 2693 to reduce exposure.¹³

In its most recent report at Carmi Flavor and Fragrance Company, where workers worked mostly with powdered flavorings, NIOSH found that “it is highly likely that exposures to diacetyl contributed to the occurrence of severe fixed obstructive lung disease in production workers” and recommended engineering controls, respiratory protection, improved work practices and medical monitoring.¹⁴

A NIOSH investigation of Gilster MaryLee popcorn plant found that workers “had 3.3 times the rate of obstruction on NIOSH spirometry tests compared to national rates; the prevalence of obstruction in never-smokers was 10.8 times the national rate” and that 19 of 21 affected workers had symptoms consistent with bronchiolitis obliterans.

Furthermore, “a strong exposure-response relationship was demonstrated between quartiles of estimated cumulative exposure to diacetyl (a volatile butter flavoring chemical contaminating the air in the plant) and the frequency of airways obstruction on

¹⁰ Materna B, et. al. “Fixed Obstructive Lung Disease Among Workers in the Flavor-Manufacturing Industry—California, 2004–2007,” *Morbidity and Mortality Weekly Report*, 56(16) (April 27, 2007) at 389–393.

¹¹ BASF. Report: Study on the Acute Inhalation Toxicity LC50 of Diacetyl FCC as a Vapor in Rats 4-hour Exposure. Project No. 1310247/927010 (June 8, 1993).

¹² Kreiss K, et al. “Clinical Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant.” *N Engl J. Med.* 347(5) (2002) at 330–338.

¹³ Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report*. Fixed Obstructive Lung Disease in a Microwave Popcorn Factory—Missouri, 2000–2002. 51 (Apr. 26, 2002) at 345–347. See also: HETA 2006–0303–3043, Carmi Flavor and Fragrance Company, Inc., Commerce, California (April 2007); HETA 2006–00195–3044, Yatsko’s Popcorn, Sand Coulee, Montana (April 2007); HETA 2000–0401–2991, Gilster-Mary Lee Corporation, Jasper, Missouri (Jan. 2006); HETA 2001–0474–2943, American Pop Corn Company, Sioux City, Iowa, July 2004, HETA 2003–0112–2949, ConAgra Snack Foods, Marion, Ohio (Dec. 2004); HETA 2002–0089, Nebraska Popcorn, Clearwater, Nebraska (July 2003); HETA–2002–0408–2915, Agrilink Foods Popcorn Plant, Ridgeway, Illinois (Oct. 2003); HETA 2001–0517, B.K. Heuermann Popcorn Inc., Phillips, Nebraska (final and interim letters) (May 2003); HETA 1985–171–1710, International Bakers Services, Inc., South Bend, Indiana (July 1986).

¹⁴ HETA 2006–0303–3043, Carmi Flavor and Fragrance Company, Inc., Commerce, California (April 2007).

spirometry tests.” NIOSH recommended engineering controls (such as closed systems), air sampling, respiratory protection and medical monitoring.¹⁵

Cases of bronchiolitis obliterans have also been found among diacetyl-exposed workers in flavorings plants. The California Department of Health Services has recently reported eight cases among diacetyl-exposed workers employed at factories at which the flavorings are produced.¹⁶

There is compelling scientific evidence supporting a permissible exposure limit at the lowest feasible level, since there is currently no evidence of a safe level of exposure to diacetyl. In their evaluation of six microwave popcorn plants (five of which had workers with flavoring-associated lung disease), NIOSH scientists reported sick workers were found even in areas with the lowest exposure levels measurable. On the basis of this finding, the NIOSH scientists concluded “it would seem prudent to maintain worker exposures to diacetyl below these levels.” The study also concluded that very high (peak) exposures needed to be controlled even if average levels were low.¹⁷

Some have objected to the requirements of H.R. 2693 because employers may substitute other chemicals that may be as dangerous as diacetyl. Substitution of one chemical for an equally or more dangerous chemical is always a risk. That possibility, however, could be used as a reason never to regulate any chemical. Federal law requires manufacturers and employers to evaluate the safety of chemicals to which workers are exposed. Due diligence and compliance with the law should minimize this risk with diacetyl or any other hazardous chemical.

While many of the studies of food flavoring and popcorn production workers describe exposure to a variety of food flavoring chemicals, there is compelling scientific evidence from animal and human studies showing that diacetyl is the main chemical causing respiratory symptoms and bronchiolitis obliterans.

The role of diacetyl in the development of bronchiolitis obliterans has been confirmed in studies of laboratory animals. In addition to the BASF study mentioned above, NIOSH scientists conducted a study in which rats were exposed to airborne concentrations of heated butter flavoring whose primary constituent was diacetyl. The rats were exposed for a single, six-hour period. The scientists reported significant lung damage among rats whose exposure was as low as 203 ppm, which according to the authors was “not extraordinary when compared with levels measured in the workplace.”¹⁸

NIOSH scientists then conducted a study in which rats were exposed to pure diacetyl and found similar results.¹⁹

A toxicological study of guinea pigs exposed to diacetyl found exposure to the chemical caused adverse effects to respiratory tissue

¹⁵ HETA 2000-0401-2991, Gilster-Mary Lee Corporation, Jasper, Missouri (Jan. 2006).

¹⁶ Harrison R, Gelb A, Harber P. Department of Health Services, State of California. State of California Study: “Food Flavoring Workers with Bronchiolitis Obliterans Following Exposure to Diacetyl” (May 15, 2006).

¹⁷ Kanwal R, et al. “Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants,” *J. Occup. Environ. Med.*, 48(2) (2006) at 149-157.

¹⁸ Hubbs AF, et al. “Necrosis Of Nasal And Airway Epithelium In Rats Inhaling Vapors Of Artificial Butter,” *Toxicology and Applied Pharmacology* (2002) at 185, 128-135.

¹⁹ Hubbs AF, et al. “Inhalation Toxicity Of The Flavoring Agent, Diacetyl (2,3-Butanedione), In The Upper Respiratory Tract Of Rats,” *Toxicologist*, 78 (S-1) (2004) at 438-439.

and structure.²⁰ And a study of the effects of diacetyl on the respiratory tracts of mice also showed respiratory damage.²¹

A recent Dutch study of the effects of diacetyl on workers employed in the manufacture of diacetyl found that the exposed workers had a considerably higher number of cases of bronchiolitis obliterans than the unexposed population, as well as significantly more symptoms of continuous trouble with breathing, daily cough and asthma. The authors concluded that, while they could not definitively identify diacetyl as the cause of the disease cases, the findings were “consistent with findings in the literature of bronchiolitis obliterans (BO) cases associated with butter flavoring exposure and in particular diacetyl in popcorn workers.”²²

The California Department of Health Services (DHS), which is taking an active role in addressing workplace diacetyl hazards, has strong evidence concerning the threat of diacetyl. DHS sent a letter to employers last year warning about two cases of bronchiolitis obliterans among workers at food flavoring companies in California. “This disease has been linked to exposure to diacetyl, a butter flavoring ingredient.”²³

California DHS has also issued an Alert specifically targeting diacetyl use. The Alert states that “Exposure to diacetyl used in flavoring manufacturing companies may cause a serious lung disease called bronchiolitis obliterans.* * * If you work at a flavoring company that uses diacetyl, see a doctor immediately to make sure that your health is not being affected.” The Alert recommends substitution for less hazardous flavoring ingredients, closed production processes, ventilation and respiratory protection.²⁴

While more study of diacetyl and other food flavoring chemicals can and should be done, the overwhelming weight of current evidence points to diacetyl as the culprit chemical causing respiratory disease. Evidence available today necessitates action and the passage of this bill. We know how to prevent workers from getting sick and dying. Inaction is unacceptable.

Workers can be protected against diacetyl

While more studies are needed to identify the precise mechanisms by which diacetyl causes lung disease, there are proven measures that can be implemented immediately by employers to effectively protect workers from dangerous exposure. Based on these proven measures, H.R. 2693 directs OSHA to mandate that these measures be taken—within three months in microwave popcorn and food flavoring manufacturers, and within two years for other locations where workers are exposed to diacetyl.

²⁰Fedan JS, Dowdy JA, Fedan KB, Hubbs AF. “Popcorn Worker’s Lung: In Vitro Exposure To Diacetyl, An Ingredient In Microwave Popcorn Butter Flavoring, Increases Reactivity To Methacholine.” *Toxicol Appl Pharmacol*, 215 (2006) at 17–22.

²¹Morgan DL, Flake G, Kirby PJ, et. al. “Respiratory Tract Toxicity Of Diacetyl In C57BL/6 Mice.” *Toxicol Sci*, 90 (Suppl 1) (2006) at 210.

²²Van Rooy, G.B.G.J., et. al. “Respiratory Effects In Workers Of A Diacetyl Production Plant With A Special Focus On Bronchiolitis Obliterans,” *Nederlands Kenniscentrum Arbeid en Longaandoeningen*, University of Utrecht, Institute for Risk Assessment Sciences (2005).

²³“To Cases of Bronchiolitis Obliterans (Life-Threatening Lung Disease) Among California Flavoring Manufacturing Workers,” Occupational Health Branch, CA Dept of Health Services (May 15, 2006).

²⁴“Diacetyl (Butter Flavor Chemical) Use in Flavoring Manufacturing Companies,” Hazard Evaluation System & Information Service, Occupational Health Branch, CA Dept of Health Services (Aug. 2006).

The National Institute for Occupational Safety and Health issued guidelines in 2003 after documenting bronchiolitis obliterans in several different plants where flavorings were used or where chemicals were handled in the production of flavorings. NIOSH recommended that companies limit hazardous exposures by substituting safer chemicals, enclosing operations that use flavoring chemicals, use local exhaust ventilation, employ work practices that reduce the likelihood of inhaling harmful vapors, and use appropriate respiratory protection. NIOSH also recommended air monitoring, medical surveillance, worker training and labeling of containers.²⁵

The industry association that represents food flavoring manufacturers has recognized the hazard and is recommending measures that employers should take to protect workers. In August 2004 the Flavor and Extract Manufacturers Association (FEMA) issued a report, "Respiratory Health and Safety in the Flavor Manufacturing Workplace," warning about potential serious respiratory illness in workers exposed to flavorings and recommending comprehensive control measures for diacetyl and other "high priority" substances used in flavoring manufacturing.²⁶

Despite the need for more investigation, FEMA recognizes that sound respiratory health and safety programs can be implemented without absolute certainty about the contribution of other food flavors to the observed effects. It is clear that flavors can be handled in such a manner that present a minimal health risk. The Association recommends that employers take the same measures recommended by NIOSH and includes detailed information that employers can use to prevent worker exposure.

A 2007 CDC publication recommends basic industrial hygiene precautions:

Safe occupational exposure levels for diacetyl and many other flavoring chemicals have not been established. Employers should implement measures to minimize exposure. Engineering controls, including local exhaust ventilation and closed transfer of chemicals, should be the primary control measures. Work practices such as covering containers and minimizing spills also will reduce exposures. Employers should establish a comprehensive respiratory protection program for organic vapors and particulates that adheres to the OSHA Respiratory Protection Standard. Consultation with an industrial hygienist or occupational safety and health professional might be necessary to implement appropriate engineering controls, work practices, and an appropriate respiratory protection program.²⁷

Because we know how to protect workers against diacetyl exposure, particularly in the production of microwave popcorn and food flavorings, it would be unacceptable from a public or occupational health perspective to delay these protections in microwave popcorn

²⁵"Preventing Lung Disease in Those Who Use or Make Flavorings," National Institute for Occupational Safety and Health (NIOSH) Alert (2004).

²⁶"Respiratory Health and Safety in the Flavor Manufacturing Workplace," Flavor and Extract Manufacturers Association of the United States (2004).

²⁷Materna, Barbara, Dep't of Health Services, State of California, Summary of Eight Known Cases of Confirmed or Suspected Fixed Obstructive Lung Disease in California Food Flavor Manufacturing Workers (Jan. 11, 2007).

or food flavorings facilities while OSHA receives comments on the Interim Final Standard by stakeholders, or reviews the standard under the Small Business Regulatory Enforcement Fairness Act, the Administrative Procedures Act or other requirements of OSHA rulemaking. Such procedures would still be available prior to issuance of the final OSHA standard.

Workers still are not being protected from diacetyl exposure

The urgent need for protections, as mandated under H.R. 2693, was emphasized in a CDC Morbidity and Mortality Weekly Report published in April 2007 that reported that California food flavoring workers exposed to diacetyl and butter flavorings still are not being adequately protected despite government and industry warnings and guidelines issued in 2003 and 2004.

The hazards of diacetyl and butter flavoring were documented in published literature in 2002. However, by 2006, many flavoring suppliers still had not addressed the risk for bronchiolitis obliterans in their material safety data sheets. During 2004, NIOSH and the Flavor and Extract Manufacturers Association disseminated information encouraging flavor manufacturers to implement exposure controls and medical surveillance. These measures were virtually nonexistent in California during 2006, when industry wide government intervention measures began. Before June 2006, only eight California flavor-manufacturing companies had begun medical screening.²⁸

The report also revealed that a review of material safety data sheets collected by the California Department of Health Services from 11 diacetyl manufacturers or distributors revealed that only “five mention bronchiolitis obliterans and none listed potential symptoms or recommended medical surveillance for the disease.”

California is moving ahead to regulate diacetyl

The California Division of Occupational Safety and Health is moving ahead to regulate the chemical. CalOSHA established an advisory committee in 2007 to work on developing a diacetyl standard. Cal/OSHA expects to send a proposed standard to protect flavoring industry workers from diacetyl to the Standards Board in the summer of 2007. (Unlike the federal OSHA process, the seven-member CalOSHA Standards Board is authorized to issue OSHA standards.)

Like the interim final standard mandated by H.R. 2693, the California standard will not address “downstream” use of diacetyl, in the food manufacturing industry. The current advisory committee will continue to study the issue of how to address issues in these workplaces.

The draft California standard would apply to:

- Places of employment where one or more flavorings are manufactured, packaged or blended with other flavorings.
- Any flavoring containing diacetyl at a specified concentration and weight, or sprayed or added to powdered food product or ingre-

²⁸ Materna B, et al. “Fixed Obstructive Lung Disease Among Workers in the Flavor-Manufacturing Industry—California, 2004–2007,” *Morbidity and Mortality Weekly Report*, 56(16) (Apr. 27, 2007) at 389–393.

dients. Workplaces with enclosed processes that discharge emissions outside the facility would be exempted from this provision.

- Facilities where an employee has been diagnosed with fixed obstructive lung disease and no other cause than occupational exposure to one of more flavorings is readily apparent.

The California proposal would also require employers to measure employee exposure in order to determine the effectiveness of exposure control measures. Employers also would be required to implement engineering and work practice controls, and provide respiratory protection, medical surveillance and training.

The OSHA standard-making process is not protecting workers

The Bureau of Labor Statistics reported that in the year 2005 there were over 5,700 workers, or 16 workers a day, killed in the workplace. NIOSH estimates that almost 60,000 workers die each year of occupational disease, many of which are caused by exposure to toxic chemicals.²⁹

OSHA's standard-making process is broken, particularly standard-making related to hazardous chemicals. Workers exposed to diacetyl have fallen victim to this breakdown in the system. Out of the almost 3,000 chemicals produced in large quantities (more than one million pounds annually), OSHA enforces exposure limits for fewer than 500 chemicals, standards that were adopted when OSHA was created in 1971. Most of those are based on science from the 1940's and 1950's. Since the OSHAct passed in 1970, OSHA has issued comprehensive standards for only 27 substances, most issued in the first two decades of OSHA existence.

In recent years, it appears that the standard-making process had ground to a halt. Dr. Frank Mirer, a professor of environmental and occupational health sciences, testifying at the Workforce Protections subcommittee hearing on April 24, 2007, discussed the breakdown of OSHA's standard making process:

OSHA, since 2001, has checked out of the standards business. Slow progress in earlier years has ground to a halt and may even be moving stealthily backward. OSHA has staff and other resources to set standards, but that staff has not been permitted to operate. Since 2001, this Administration set one new chemical standard, for carcinogenic chromium, under court order. That standard actually permits employers to increase exposure levels under some circumstances. Unions were forced to sue to get improvements, and that litigation still pends. Regarding employers' responsibility to pay for required protective equipment like respirators and wire mesh gloves, Labor Secretary Elaine Chao finally committed to issuing a final rule in response to a union lawsuit and a court ordered deadline. That rule was promised by November 2007. The rule-making record was completed in 1999.³⁰

²⁹"Workers' Memorial Day—April 28, 2007," *Morbidity and Mortality Weekly Report*, 56(16) (Apr. 27, 2007) at 389–393.

³⁰Have OSHA Standards Kept up With Workplace Hazards? Hearing before the Subcommittee on Workforce Protections, 110th Congress, 1st Session (2007) (written testimony of Frank Mirer, at 3) [Hereinafter Mirer testimony].

At a 2006 hearing on using non-consensus health and safety standards, Dr. David Michaels, Director of the Project on Scientific Knowledge and Public Policy and Research Professor and Associate Chairman Department of Environmental and Occupational Health at the George Washington University School of Public Health and Health Services, pointed out that American workers are left to rely on chemical standards issued by such organizations like the American Conference of Governmental Industrial Hygienists because OSHA no longer issues chemical standards:

The regulatory agencies are simply unable to keep up. In 1971, OSHA adopted en masse, about 400 ACGIH TLVs, reached using the science of the 1950's and 1960's, before we knew as nearly as much as we know today about the long-term effects of many hazardous chemicals.

Since then, OSHA has updated only a handful of them. The rest have been unchanged in more than 35 years. The OSHA standard setting process is cumbersome and easily delayed by those intent on slowing action. The political appointees who run the agency at the present time have no desire to strengthen weak standards; except when under a court order. Workers cannot rely on OSHA to issue new regulations on chemical hazards. OSHA is paralyzed and has abdicated its responsibility to issue health standards that protect workers.³¹

Scott Schneider, Director of Occupational Safety and Health for the Laborers' Health and Safety Fund of North America, testifying at the Workforce Protections subcommittee hearing on April 24, 2007, pointed out three major problems with OSHA rulemaking: lack of budget, the burden of regulatory review, and lack of political will.³²

Dr. Frank Mirer expanded on the political obstacles:

The first barrier to setting a new standard is getting the Labor Department to recognize that something needs to be done about a hazard. That's a political leadership decision. Once there's a decision to move forward, the task that causes the most delay is gathering business data to estimate costs. But, OSHA staff have figured out how to get that cost information. After that, the barriers, and sources of delay, are getting approval from the Office of Management and Budget to put a standard on the agenda, complete the small business (SBREFA) review, to release a proposed standard, and to finally promulgate the final standard. But, OMB is not a free agent. The same President who appointed the Secretary of Labor and Assistant Secretary of Labor for OSHA also appointed the heads of OMB and the Small Business Administration.³³

³¹Addressing Concerns about the U.S. Department of Labor's Use of Non-Consensus Standards in Workplace Health and Safety. Hearing before the Subcommittee on Workforce Protections, 109th Congress, 2nd Session (2006) (written testimony of David Michaels at 3) [hereinafter Michaels Testimony].

³²Have OSHA Standards Kept up With Workplace Hazards? Hearing before the Subcommittee on Workforce Protections, 110th Congress, 1st Session (2007) (written testimony of Scott Schneider, at 2) [hereinafter Schneider Testimony].

³³Mirer Testimony at 4.

OSHA standards protect workers from occupational disease and injury

One of the most important responsibilities that Congress gave OSHA under the Occupational Safety and Health Act is the issuance of safety and health standards. Congress declared in passage of the Act that its "purpose and policy" was "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions. . . by providing for the development and promulgation of occupational safety and health standards."

Mirer illustrated the importance of OSHA chemical standards:

Chronic illness arising from long term chemical exposures at work accounts for the large majority of known work-related mortality. Few of these victims are named on Workers Memorial Day, and many are not aware of the chemical cause of their illness. Reducing those known dangerous exposures is therefore the best opportunity to protect the lives and health of American workers. Recognizing the dangers of chemicals at work also would facilitate controlling those chemicals at home and in the community environment.³⁴

OSHA standards have proven to be effective in reducing exposures and protecting workers' health. According to Mirer:

The standards process, when allowed to proceed according to law, drastically reduces permissible and actual exposures. The OSHA asbestos permissible exposure limit, revised several times, was cut to 1% of what it was in 1970, and even this limit leaves behind a substantial cancer risk. We still pay for the legacy of those old, high exposures. In the accompanying table, we see that OSHA's new rules have reduced allowable exposure by up to 1000-fold.³⁵

ANNOTATED CHRONOLOGY OF OSHA PEL'S SHOWING EXTENT OF EXPOSURE LIMITATION

Substance	1910	Date	Previous	Final	Reduction
Asbestos	1001	1971	12 f/cc	5 f/cc	2.4
13 Carcinogens	1003	1974	NA	NA	
Vinyl Chloride	1017	1975	500 ppm	1 ppm	500
Asbestos	1001	1976	5 f/cc	2 f/cc	2.5
Coke Oven Emissions	1029	1977	0.2 mg/M ³	0.15 mg/M ³	1.3
Inorganic Arsenic	1018	1978	0.5 mg/M ³	0.01 mg/M ³	50
Lead	1025	1978	200 ug/M ³	50 ug/M ³	4
DBCP	1044	1978		0.001 mg/M ³	na
Acrylonitrile	1045	1978	20 ppm	2 ppm	10
Cotton Dust	1043	1978	1 mg/M ³	0.2 mg/M ³	5
Asbestos	1984	2 f/cc	0.2	f/cc	10
Ethylene Oxide	1047	1986	50 ppm	1 ppm	50
Benzene	1028	1987	10 ppm	1 ppm	10
Formaldehyde	1048	1988	3 ppm	0.75 ppm	4
Cadmium	1027	1992	0.2 mg/M ³	0.005 mg/M ³	40
Methylenedianiline	1050	1992		0.01 ppm	na
Lead In Construction	1926.62	1993	200 ug/M ³	50 ug/ M ³	4
Asbestos	1001	1994	0.2 f/cc	0.1 f/cc	*2
Asbestos in Construction	1926.1101	1994		0.1 f/cc	na
Butadiene	1051	1996	1000 ppm	1 ppm	1000
Methylene Chloride	1052	1998	500 ppm	25 ppm	20

³⁴Mirer Testimony at 5.

³⁵Mirer Testimony at 6

ANNOTATED CHRONOLOGY OF OSHA PEL'S SHOWING EXTENT OF EXPOSURE LIMITATION—
Continued

Substance	1910	Date	Previous	Final	Reduction
Chromium (VI)	1026	2006	52 µg/M ³ c	5 µg/M ³	**10.4

*The four PEL's set for asbestos eventually mandated a 120-fold reduction from pre-OSHA PEL.

**Pre-existing PEL was a ceiling limit in units of a different chemical form; actual permitted exposure under the new PEL could be higher than previous.

The need for an interim standard

The Committee has determined that exposure to diacetyl presents the sort of grave danger to workers that warrants immediate action. A large number of studies and investigations show that bronchiolitis obliterans and other respiratory disease have been identified among a significant number of microwave popcorn and flavoring-manufacturing workers in a number of states. Extensive evidence exists that exposure to diacetyl presents a grave danger and significant risk of life-threatening illness to exposed employees, and that flavoring and food producers are widely distributed in the United States. Furthermore, there are effective and feasible means to minimize exposure to diacetyl.

Despite this grave danger, OSHA has failed to develop a comprehensive standard that would protect workers. The Committee also believes that guidance being developed by OSHA is not adequate to protect workers from the health threat posed by diacetyl. H.R. 2693 therefore requires OSHA to issue an Interim Final Standard within 90 days of enactment to be followed by a final standard that would be promulgated within two years.

The interim standard must contain provisions for engineering controls, respiratory protection, exposure monitoring, medical surveillance and worker training. It must not be less protective than guidelines issued by the National Institute for Occupational Safety and Health in 2003.

The interim standard requires employers to simply implement measures that were recommended several years ago as effective and feasible by NIOSH as well as the Flavor and Extract Manufacturers Association, the association representing flavoring manufacturers. In fact, FEMA supports the bill and the OSHA regulation. According to a statement issued by FEMA:

“FEMA supports legislation that could lead to appropriate, science-based regulation to enhance the safety of workers in the flavor industry” said John Hallagan, FEMA General Counsel. “This legislation calls for regulation by OSHA that is very similar to the recommendations to protect workers that FEMA made three years ago in its report Respiratory Health and Safety in the Flavor Manufacturing Workplace.³⁶

The interim regulation is not an occupational safety and health standard as that term is defined in section 3(8) of the Occupational Safety and Health Act of 1970 and must be adopted notwithstanding any other provision of law. The Secretary of Labor has previously recognized in promulgating a standard regulating hazardous waste operations the distinction between an interim regula-

³⁶Statement by the Flavor and Extract Manufacturers Association (June 13, 2007).

tion and an occupational safety and health standard is legally significant because it means that the procedural requirements of section 6 of the OSH Act do not apply to the promulgation of the interim final regulation. Nor, as the Secretary has previously recognized in publishing an interim final regulation governing hazardous waste operations, do the notice and comment provisions of the Administrative Procedures Act apply.

The Committee relied upon these precedents when it directed the Secretary of Labor to publish an interim final regulation governing lead exposure in the construction industry. The Committee intends that the Secretary rely on similar procedures to publish an interim final regulation governing diacetyl within three months. These procedures have recently been upheld by OSHRC the Occupational Safety and Health Review Commission (OSHRC) in the Manganas Painting Co, Inc decision. OSHRC agreed with the Secretary of Labor's assessment of Congressional intent which cited

The preamble to the lead in construction standard that "Congress . . . did not impose any procedural requirements that must be followed" and that Congress intended that "the Secretary need not follow the procedural requirements of the OSH Act or the APA [Administrative Procedure Act, 5 U.S.C. 553]." 58 Fed. Reg. at 26,591.³⁷

While the Secretary is authorized to publish the interim regulation without the notice and comment procedures required by section 6 of the OSH Act, it is the Committee's expectation that OSHA will work closely with the National Institute for Occupational Safety and Health, as well as the affected industry, labor representatives and industrial hygiene experts in developing the interim final diacetyl regulation.

The final standard

H.R. 2693 requires OSHA, within two years of enactment, to issue a permanent standard regulating worker exposure to diacetyl in compliance with section 6(b) of the Occupational Safety and Health Act (OSHAct). The final standard would expand the scope of the regulation to all locations where workers are exposed to diacetyl and require OSHA to include a permissible exposure limit.

While there is compelling evidence, as indicated above, on which to base an interim standard covering the food flavoring and popcorn manufacturing industries, additional data must be collected and analyzed before extending the standard to all locations where workers are exposed to diacetyl. Workers are also exposed to diacetyl in downstream food manufacturing facilities other than microwave popcorn production, although the level of exposure and health effects suffered by workers in these establishments have not been characterized to the same extent as in microwave popcorn production, nor have feasible means of abatement been fully identified by OSHA or NIOSH.

In addition, scientists at OSHA and NIOSH have not yet determined an appropriate exposure limit for diacetyl that would prevent serious health effects.

³⁷Secretary of Labor v. Manganas Painting Company Inc, OSHRC Docket No. 94-0588 (March 23, 2007).

H.R. 2693 requires OSHA to issue a final standard covering all workplaces where diacetyl is used within two years of enactment. The Committee is confident that this standard can be issued within the timeframe allotted.

It is the Committee's hope and expectation that, in addition to public and scientific input, OSHA will work closely with NIOSH to develop the information base and analysis necessary to develop exposure, feasibility and other information needed to issue a fully protective diacetyl standard in a timely manner.

H.R. 2693 does not exempt OSHA from the requirements of section 6 of the OSHAct that Congress and the courts have established to ensure that OSHA standards reflect the best science available, or that the standards are technologically and economically feasible. In addition, regulatory oversight laws, including the Administrative Procedures Act, the Small Business Regulatory Enforcement Fairness Act (SBREFA), the Regulatory Flexibility Act, the Paperwork Reduction Act, or Executive Order 12866 are flexible enough to provide for expedited action in emergency situations like these.

Congress has afforded OSHA a great deal of leeway in identifying hazards and setting protective exposure limits to enable the agency to act before large numbers of individuals were injured as a result. Section 6(b)(5) of the law lays out the criteria for issuance of standards concerning toxic materials. Section 6(b)(7) requires standards to include requirements for labeling, protective equipment, exposure monitoring and medical monitoring as appropriate.

OSHA is mandated to attain the "highest degree of health and safety protection for the employee" and to base standards on the "best available evidence."³⁸ The courts have recognized, however, that such data is often imperfect and that "OSHA cannot let workers suffer while it awaits the Godot of scientific certainty."³⁹ Subsequent court decisions have also required OSHA to show that substance presents a "significant risk" and that the new standard will reduce that risk. OSHA must also show that the new standard is technologically and economically feasible.

Two years provides adequate time for OSHA to develop the evidence and findings necessary to issue a final standard. Extensive studies and investigations have been conducted of workers exposed to diacetyl and serious, readily observable health effects have been linked to these exposures. The courts have held that in cases where the risk of exposure "can be readily observed," OSHA would be able to establish significant risk without the theoretical modeling involved, for example, in determining exposure limits for carcinogens at very low levels.⁴⁰

OSHA can establish significant risk without the theoretical modeling required to construct a dose-response curve when risk can be directly observed or the hazard is obvious. For example, in upholding the Agency's electric power generation standard, the Eleventh Circuit approved OSHA's reliance on a videotape showing that certain work

³⁸ 29 U.S.C. 655(b)(5).

³⁹ *United Steelworkers of America, etc. v. Marshall*, 647 F.2d 1189, 1266 (U.S. App. D.C.); 8 OSH Cases 1810.

⁴⁰ Rabinowitz, Ed. *Occupational Safety & Health Law* 2d Ed. (BNA 2000) at 453-454.

clothes were flammable, finding it “powerful” evidence of harm.⁴¹ The court did not require OSHA to quantify the magnitude of the fire hazard. Similarly, in upholding the standard on logging operations, the Fourth Circuit observed that common sense and the opinion of experts were enough to establish significant risk.⁴²

In order to issue a standard under Section 6(b) of the Act, OSHA also has a number of procedural requirements that must be satisfied. Again, because of the emergency nature of this problem, OSHA will be able to meet those requirements within the two year timeframe. SBREFA⁴³, the Regulatory Flexibility Act,⁴⁴ Executive Order 12866 and the Paperwork Reduction Act contain flexible provisions for waivers, delay or acceleration of their requirements under emergency conditions or other special circumstances. The Committee expects OSHA, the Small Business Administration, the Office of Management and Budget, and other agencies involved in the regulatory process to fully utilize whatever actions are necessary and permitted within relevant laws and executive orders affecting the regulatory process to ensure that this mandated Congressional deadline is met.

Experts confirm that OSHA can issue standards much faster than the agency has acted over the past several years. Frank Mirer expresses confidence that OSHA should be capable of issuing standards much faster than it currently does, even starting from scratch.⁴⁵

Adam Finkel, Sc.D., CIH, Professor of Environmental and Occupational Health at the UMDNJ School of Public Health, and a visiting professor of public affairs at the Woodrow Wilson School at Princeton University, submitted testimony for the record following the April 24 hearing on OSHA standards, stating that despite the many requirements for OSHA to invite participation by stakeholders and respond substantively to their comments, standards can be completed “cleanly and rather quickly.” Finkel is the former Director of Health Standards for OSHA.

In one 18-month period of activity (late 1996 to early 1998)—OSHA promulgated three major final health standards—those for 1,3-butadiene, methylene chloride, and generic respiratory protection—and defended them in Congressional oversight hearings and court challenges, without a single provision being substantively weakened following any of this scrutiny.⁴⁶

History of Congressional intervention in OSHA rulemaking

Congress has a long history of mandating OSHA regulation to protect workers when the Agency fails to act on its own. H.R. 2693 continues the Congress’s tradition of ensuring that OSHA acts promptly when faced with evidence that American workers face

⁴¹ Alabama Power Co. v. OSHA, 89 F.3d 740, 745 (11th Cir. 1996); 17 OSH Cases 1675.

⁴² Homelite v. OSHA, 74 F.3d 1232 (4th Cir. 1996); 17 OSH Cases 1489.

⁴³ P.L. 104-121. Small Business Regulatory Enforcement Fairness Act of 1996.

⁴⁴ P.L. 96-354. Regulatory Flexibility Act of 1980, as amended.

⁴⁵ Mirer Testimony at 5.

⁴⁶ Have OSHA Standards Kept up With Workplace Hazards? Hearing before the Subcommittee on Workforce Protections, 110th Congress, 1st Session (2007), Letter from Dr. Adam Finkel to Rep. Lynn Woolsey (May 8, 2007).

grave dangers and delay will result in needless illness and death. In 1986, as part of the Superfund Amendments and Reauthorization Act (SARA), Congress mandated the issuance an “interim” standard for Hazardous Waste Operations and Emergency Response within 60 days and a final standard within one year of SARA’s enactment.⁴⁷ In 1990, as part of the Clean Air Act Amendments, Congress required OSHA to issue the Process Safety Management standard within one year. Congress also included directions on the content of the standard.⁴⁸ In 1991, Congress ordered OSHA to issue the final Bloodborne Pathogens Standard by a certain date, and stated that if that deadline was not met, the previously published proposed standard would take effect.⁴⁹ In 1992, Congress mandated OSHA to issue the Lead in Construction standard and required the new standard to be “as protective” as the U.S. Department of Housing and Urban Development’s worker protection guidelines for identification and abatement of lead based paint in certain housing. The standard was issued in 1993.⁵⁰ Finally, in 2000, Congress required OSHA issue an update to the Bloodborne Pathogens standard, requiring safer syringes and sharps.⁵¹ That standard was issued in 2001.

Some OSHA experts feel that Congress must take a much more active role in encouraging OSHA to issue standards that protect workers’ health and safety; Scott Schneider, who testified at the April 2007 standards hearing argued in favor of Congress setting strict time limits for OSHA to issue standards:

Congress can set time limits for OSHA to consider and then issue proposals and final rules. In the past Congress has mandated that OSHA issue rules within a six-month period and the agency has done so (e.g. lead, hazardous waste). Congress should give OSHA a limited time, say four months, to consider any petition for new standards and require the agency to publish a response in the Federal Register as to its reasons for accepting or denying the petition. The burden should be on the agency to show why a standard should not be issued. Once committed to a rule making, the agency would be given additional deadlines to meet to ensure that rules are issued in a timely manner, say no more than three years. Congress would have to provide additional funding for OSHA dedicated to standard setting in order for it to meet these deadlines.⁵²

Due to the serious health effects caused by exposure to diacetyl and the ready availability of means to prevent worker exposure, H.R. 2693 requires OSHA to take swift action to protect workers.

⁴⁷P.L. 99-499. Superfund Amendments and Reauthorization Act of 1986, Title I Sec. 126 a-f (Oct. 26, 1986).

⁴⁸P.L. 101-549. Title III, Sec. 304 (Nov. 15, 1990).

⁴⁹P.L. 102-170. Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, Sec. 100 (1992).

⁵⁰P.L. 102-550. This interim final rule was mandated by, and issued under the exclusive authority of, title X, subtitle C, sections 1031 and 1032, Worker Protection, of the Housing and Community Development Act of 1992.

⁵¹P.L. 106-430. Needlestick Safety and Prevention Act.

⁵²Schneider Testimony at 5.

V. SECTION-BY-SECTION ANALYSIS

Section 1. Short Title

Provides that the Short Title of H.R. 2693 is the “Popcorn Workers Lung Disease Prevention Act.”

Section 2. Findings

This section declares that an emergency exists concerning worker exposure to diacetyl and that a standard is urgently needed to protect workers. This section establishes that there is strong evidence documenting the link between diacetyl and serious lung disease. The findings also establish that government and industry health guidelines have existed since 2003 and 2004. Additionally, OSHA has taken no significant action to begin the development of a standard and has taken not other significant action to protect workers.

Section 3. Issuance of Standard on Diacetyl

Section 3 (a)(1). Requires the Secretary of labor to issue an interim final standard regulating worker exposure to diacetyl within not later than 90 days after enactment.

Section 3(a)(1)(A). Applies the interim standard to the flavoring manufacturers that use diacetyl.

Section 3(a)(1)(B). Applies the interim standard to all microwave popcorn production and packaging establishments that use diacetyl.

Section 3(a)(2). Requires that the interim standard provide no less protection than NIOSH guidelines issued in 2003.

Section 3(a)(2)(A). States that the interim final standard must require engineering, work practice controls, and respiratory protection

Section 3(a)(2)(B). States that the interim final standard must require employers to develop a written exposure control plan that will indicate specific measures the employer will take to minimize employee exposure. The plan must be re-evaluated at least biannually or whenever medical surveillance indicates abnormal pulmonary function in employees exposed to diacetyl,

Section 3(a)(2)(C). States that the interim final standard must require airborne exposure assessments

Section 3(a)(2)(D). States that the interim final standard must require medical surveillance for workers and referral for prompt medical evaluation

Section 3(a)(2)(E). States that the interim final standard must require protective equipment and clothing

Section 3(a)(2)(F). States that the interim final standard must require employers to provide written safety and health information and training to employees.

Section 3(a)(3). Requires interim final standard to take effect upon issuance, have the legal effect of an OSHA standard, and remain in effect until a final standard becomes effective.

Section 3(b). Mandates OSHA to issue a final standard regulating worker exposure to diacetyl not later than two years from the date of enactment. The final standard must contain the worker protection provisions of the interim final standard as well as a per-

missible exposure limit that does not exceed the lowest feasible level.

Section 4. Study and Recommended Exposure Limits on Other Flavorings

This section requires the National Institute for Occupational Safety and Health to conduct a study on the exposure hazards of possible substitutes that are closely related to diacetyl in microwave popcorn production and transmit the report to OSHA. NIOSH is then required to establish recommended exposure limits for those flavoring chemicals found to be hazardous.

VI. EXPLANATION OF AMENDMENTS

Because regulation of any chemical often encourages users to substitute for other chemicals, the amendment offered by Mr. Wilson and adopted by the Committee requires the National Institute for Occupational Safety and Health (NIOSH) to conduct a study on the exposure hazards of food flavoring chemicals closely related to diacetyl that could be used as substitutes for diacetyl in microwave popcorn production and transmit the report to OSHA. NIOSH is then required to establish recommended exposure limits (RELs) for those flavoring chemicals found to be hazardous. The RELs developed by NIOSH are to be forwarded to OSHA.

NIOSH was established under the Occupational Safety and Health Act of 1970 to, among other things, develop and establish recommended occupational safety and health standards and to conduct research necessary for the development of criteria for new and improved occupational safety and health standards.

VII. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104-1, the Congressional Accountability Act, requires a description of the application of this bill to the legislative branch. H.R. 2693 has no direct application to the legislative branch.

VIII. REGULATORY IMPACT STATEMENT

The Committee has determined that H.R. 2693 will have only a minor impact on the regulatory burden.

IX. UNFUNDED MANDATE STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act (as amended by Section 101(a)(2) of the Unfunded Mandates Reform Act, P.L. 104-4) requires a statement of whether the provisions of the reported bill include unfunded mandates.

(The attached CBO letter addresses this issue)

X. EARMARK STATEMENT

H.R. 2693 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e) or 9(f) of rule XXI.

XI. STATEMENT OF OVERSIGHT FINDINGS AND RECOMMENDATIONS OF THE COMMITTEE

In compliance with clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the rules of the House of Representatives, the Committee's oversight findings and recommendations are reflected in the body of this report.

XII. NEW BUDGET AUTHORITY AND CBO COST ESTIMATE

With respect to the requirements of clause 3(c)(2) of rule XIII of the House of Representatives and section 308(a) of the Congressional Budget Act of 1974 and with respect to requirements of 3(c)(3) of rule XIII of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following estimate for H.R. 2693 from the Director of the Congressional Budget Office:

H.R. 2693—A bill to direct the Occupational Safety and Health Administration to issue a standard regulating worker exposure to diacetyl

H.R. 2693 would require the Department of Labor to issue regulations intended to protect workers from harmful exposure to the chemical diacetyl. Interim standards would be issued no later than 90 days after this bill is enacted, and a final standard no later than two years after enactment. Diacetyl is a substance used in many food flavorings, such as artificial butter flavorings for microwave popcorn. Since 2000, several organizations, including the National Institute of Occupational Safety and Health (NIOSH), have raised concerns regarding the health affects of diacetyl on workers in manufacturing plants that use the chemical. The Occupational Safety and Health Administration (OSHA) is developing an inspection program but no regulations have been issued to date.

In addition, the bill would require NIOSH to conduct a study of food flavorings used in the production of microwave popcorn. The study would prioritize which chemicals are most closely associated with diacetyl in order to determine possible exposure hazards. Furthermore, NIOSH would establish recommended exposure limits based on the study's findings and transmit those findings to OSHA.

Estimated cost to the federal government: CBO estimates that implementing H.R. 2693 would cost approximately \$1 million in 2008, assuming appropriation of the necessary amounts. CBO assumes these funds would be used primarily to fund the NIOSH study required by the bill. Costs in 2009 would not be significant. Enacting the bill would not affect revenues or direct spending.

Impact on state, local, and tribal governments: H.R. 2693 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). States may develop and operate their own job safety and health programs if those programs are approved by OSHA; currently, 26 states operate such programs. Those states might incur costs to administer and enforce the new standards that OSHA would be required to promulgate under the bill. However, those costs would be incurred voluntarily, and half of those costs could be reimbursed through matching grants from the federal government under an existing program.

The state of California is in the process of developing standards regulating workers' exposure to diacetyl. Under H.R. 2693, California would be required to demonstrate to OSHA that the state's standards will be at least as effective as the standards promulgated by OSHA. If its standards were determined to be less effective, the federal standards would apply. Any costs incurred by California to demonstrate the effectiveness of the state standards would be incurred as a result of its voluntary participation in the federal program.

Impact on the private sector: H.R. 2693 would impose private-sector mandates as defined in UMRA on facilities that use, handle, or produce diacetyl—primarily involving food flavorings and microwave popcorn. The interim standards promulgated by OSHA would have to be consistent with the recommendations in the NIOSH Alert, "Preventing Lung Disease in Workers Who Use or Make Flavorings." Because a large segment of those two industries has implemented many of NIOSH's recommended protections for diacetyl exposure, CBO estimates that the costs associated with compliance with the interim standard would fall below the annual threshold for private-sector mandates established by UMRA (\$131 million in 2007, adjusted annually for inflation). The interim standard would remain in effect until the final standard is issued.

The final standard would contain, at a minimum, the provisions in the interim standards, as well as limits on short-term exposure and permissible exposure. The final standard would apply to all facilities where diacetyl is produced or used. The cost to the private sector of complying with mandates in the final standard is uncertain because it would depend on regulations that have not yet been established. Because there is no basis for predicting the specific equipment and procedures the final standard would require and the industries that would be affected, CBO cannot estimate the incremental costs that could result from that standard. Therefore, CBO cannot determine whether the aggregate cost of the mandates would exceed the UMRA's annual threshold for private-sector mandates.

Previous CBO estimate: This estimate supersedes the previous cost estimate for H.R. 2693, which CBO transmitted on July 13, 2007. Our July 13 estimate erroneously indicated that the bill would require the NIOSH study to be completed prior to issuance of final standards from OSHA and that OSHA had already implemented a diacetyl inspection program. This revised estimate corrects the description of those provisions but does not change the estimated cost of the bill.

The CBO staff contacts for this estimate are Sean Dunbar or Geoffrey Gerhardt (for federal costs), Lisa Ramirez-Branum (for the impact on state and local governments), and Justin Hall (for the impact on the private sector). This estimate was approved by Robert A. Sunshine, Assistant Director for Budget Analysis.

XIII. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with Clause 3(c) of House rule XIII, the goal of H.R. 2693 is to provide basic health and safety protections for workers exposed to diacetyl.

XV. CONSTITUTIONAL AUTHORITY STATEMENT

Under clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee must include a statement citing the specific powers granted to Congress in the Constitution to enact the law proposed by H.R. 2693. The Committee believes that the amendments made by this bill, which direct OSHA to issue an OSHA standard regulating worker exposure to diacetyl are within Congress' authority under Article I, Section 8, Clause 3 of the Constitution of the United States.

XV. COMMITTEE ESTIMATE

Clause 3(d)(2) of rule XIII of the Rules of the House of Representatives requires an estimate and a comparison of the costs that would be incurred in carrying out H.R. 2693. However, clause 3(d)(3)(B) of that rule provides that this requirement does not apply when the Committee has included in its report a timely submitted cost estimate of the bill prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act.

XVI. COMMITTEE CORRESPONDENCE

None.

JULY 26, 2006.

The Hon. ELAINE L. CHAO,
Secretary of Labor, U.S. Department of Labor,
Washington, DC.

DEAR SECRETARY CHAO: We are writing to express our strong support for the petition submitted by the United Food and Commercial Workers International Union and the International Brotherhood of Teamsters calling upon the Occupational Safety and Health Administration to issue an Emergency Temporary Standard (ETS) to protect workers exposed to the chemical diacetyl (2,3-butanedione, CAS # 431-03-8), and to initiate formal rulemaking for permanent regulations to protect workers exposed to diacetyl and other harmful flavoring-related chemicals.

Diacetyl is a commonly used food flavoring and is the primary constituent of artificial butter flavoring. There is compelling scientific evidence linking occupational exposure to diacetyl to bronchiolitis obliterans, a debilitating and sometimes fatal lung disease.

In the general population, bronchiolitis obliterans is rare. In the last few years, however, numerous cases have been reported to or identified by the National Institute for Occupational Safety and Health (NIOSH) among workers employed in factories where flavorings containing diacetyl are produced or used.¹ Dozens of workers employed at popcorn plants have developed occupational lung disease, and at least one has died. Several of these workers are on lung transplant lists.^{2 3 4}

The sentinel case of the recent outbreak of bronchiolitis obliterans was a Missouri microwave popcorn plant worker diagnosed with the condition in 1999. The physician who diagnosed the case notified Missouri's health department, which in turn notified the Centers for Disease Control and Prevention (CDC), NIOSH's parent agency. In August 2000, NIOSH began an investigation at

the Jasper, Missouri microwave popcorn plant where eight current or former workers had developed the disease.⁵ In this investigation, NIOSH scientists found that respiratory symptoms were linked with exposure to diacetyl and butter flavor. Workers at this plant had chronic cough and shortness of breath at a rate 2.6 times higher than what would be expected in the U.S. population. Twice as many workers than expected reported being told by their physicians that they had asthma or chronic bronchitis. Lung function testing revealed that three times as many workers as expected had obstruction to airflow. These results were reported first in the CDC's Morbidity and Mortality Weekly Report and then in the *New England Journal of Medicine*.^{6 7} In all, NIOSH has conducted six investigations at 102 microwave popcorn facilities, finding respiratory impairment among workers at a majority of the plants.^{3 8 9 10 11 12}

Since the initial reports focused on individuals employed in microwave popcorn factories, the disease is often called "popcorn workers lung."^{13 14} It has become clear, however, that the disease has struck workers in other segments of the food and flavoring industry, and is not limited to microwave popcorn facilities.¹⁵ The California Department of Health Services has recently reported two cases among diacetyl-exposed workers employed at factories at which the flavorings are produced.¹⁶

To pursue their investigations, NIOSH has developed sampling and analytical methods for measuring exposure to flavoring-related chemicals.¹⁷ At the Jasper, Missouri plant, diacetyl was measured in concentrations ranging as high as 98 parts per million parts air by volume (ppm), with a mean of 8.1 ppm.¹⁸ In their evaluation of six microwave popcorn plants (five of which had workers with flavoring-associated lung disease), NIOSH scientists reported that the "lowest mean TWA [time weighted average] diacetyl air concentrations that we measured in mixing areas (0.02 ppm personal exposure and 0.2 ppm area air concentration) were at a plant with an affected mixer." On the basis of this finding, the NIOSH scientists concluded "it would seem prudent to maintain worker exposures to diacetyl below these levels."¹⁹

The role of diacetyl in the development of bronchiolitis obliterans has been confirmed in studies of laboratory animals. In 1993, a manufacturer of diacetyl conducted a study, which was never reported to the government or published in scientific literature, in which rats were exposed to pure diacetyl. The study found that one four-hour period of exposure to diacetyl resulted in an "abundance of symptoms indicative for respiratory tract injury."²⁰ Following the recent outbreak of cases among humans, NIOSH scientists conducted a study in which rats were exposed to airborne concentrations of heated butter flavoring, of which diacetyl was the primary constituent. The rats were exposed for a single, six-hour period. The scientists reported significant lung damage among rats whose exposure was as low as 203 ppm, which according to the authors was "not extraordinary when compared with levels measured in the workplace."²¹ NIOSH scientists then conducted a study in which rats were exposed to pure diacetyl and found similar results.²² A toxicological study of guinea pigs exposed to diacetyl found exposure to the chemical caused adverse effects to respiratory tissue and structure.²³

Although the precise number of workers already suffering respiratory effects from exposure to diacetyl is unknown, the potential magnitude of the problem is sizeable. NIOSH is currently investigating 15 cases of respiratory disease, including some workers with bronchiolitis obliterans, among the employees at a single Cincinnati, Ohio flavor manufacturing plant.³

Additional research will provide useful data on the mechanism through which flavoring related chemicals cause obstructive lung disease. However, NIOSH has already generated sufficient information for OSHA to issue rules to reduce exposure to these toxic chemicals. In their recent report, NIOSH scientists wrote that “(b)ecause entirely safe levels of occupational exposure to butter-flavoring chemicals are not known, it is important to limit 3 worker exposures as much as possible.”¹⁹ It is the regulatory responsibility of OSHA to protect workers from exposure to workplace hazards. OSHA has issued permissible exposure limits (PELs) and/or NIOSH has recommended exposure limits (RELs) for only 46 of the 1,037 flavoring ingredients considered by the flavorings industry to represent potential respiratory hazards.¹ This regulatory gap² needs to be addressed; for this reason, we support the United Food and Commercial Workers (UFCW) and the International Brotherhood of Teamsters (IBT) petition to OSHA to initiate formal rule-making to establish a permanent standard to protect workers from lung disease caused by flavoring-related chemicals.

Until OSHA completes permanent rulemaking on flavoring-related chemicals, an ETS for diacetyl is essential. The data gathered by NIOSH indicate an appropriate emergency PEL would be below 0.2 ppm.¹⁹ In order to provide a sufficient margin of safety, the petition calls for an emergency temporary PEL of 0.05 ppm, averaged over an eight-hour day. Although other flavoring-related chemicals are likely to contribute to the adverse lung effects as well, controlling exposure to diacetyl, a known cause of bronchiolitis obliterans and a primary component of butter flavor, will also result in the reduction of exposure to other airborne contaminants in the workplace.

In summary, there is compelling epidemiologic and toxicological evidence linking exposure to diacetyl to severe respiratory impairment and disease. It is more than thirty months since NIOSH issued an alert calling upon employers to “minimize occupational exposures to flavorings or flavoring ingredients.”¹ It is now time for OSHA to use the scientific evidence to protect American workers from debilitating lung disease.

If you have any questions regarding this matter, please contact: David Michaels, PhD, Professor and Associate Chairman, Department of Environmental and Occupational Health, George Washington University School of Public Health, 2100 M Street NW, Suite 203, Washington, DC 20037, Phone: 202-994-2461.

Respectfully submitted,

(Affiliations listed for identification purpose only)

Nicholas A. Ashford, PhD, JD, Professor of Technology and Policy, and Director, MIT Technology and Law Program, Massachusetts Institute of Technology.

Dean Baker, MD, MPH, Professor and Chief, Occupational and Environmental Medicine and Director, Center for Occupational and Environmental Health, University of California, Irvine.

John M. Balbus, MD, MPH, Director, Health Program, Environmental Defense.

John R. Balmes, MD, Professor of Medicine, University of California San Francisco, and Professor of Environmental Health Sciences, University of California Berkeley School of Public Health.

Eula Bingham, PhD, Professor, Department of Environmental Health, University of Cincinnati College of Medicine, and Assistant Secretary of Labor for Occupational Safety and Health, 1977–1981.

David C. Christiani, MD, MPH, MS, Professor of Occupational Medicine and Epidemiology, Harvard School of Public Health, and Professor of Medicine, Harvard Medical School.

Richard Clapp, DSc, MPH, Professor, Department of Environmental Health, Boston University School of Public Health.

Mark R. Cullen, MD, Professor of Medicine and Public Health, Yale University School of Medicine.

Ellen A. Eisen, ScD, Adjunct Professor of Environmental Health, Harvard School of Public Health.

Adam M. Finkel, ScD, CIH, Professor of Environmental and Occupational Health, UMDNJ School of Public Health, and Director, Directorate of Health Standards Programs, OSHA, 1995–99, and Regional Administrator, Region VIII, OSHA, 2000–2003.

Arthur L. Frank MD, PhD, Professor of Public Health and Chair, Department of Environmental and Occupational Medicine, Drexel University School of Public Health.

Laurence Fuortes, MD, Professor of Occupational and Environmental Health, College of Public Health, University of Iowa.

Michael Gochfeld, MD, PhD, Professor and Director, Occupational & Environmental Residency Program, Environmental and Occupational Health Sciences Institute, UMDNJ-Robert Wood Johnson Medical School.

Lynn R. Goldman, MD, MPH, Professor, Bloomberg School of Public Health, Johns Hopkins University, and Assistant Administrator for Toxic Substances, Environmental Protection Agency, 1993–1998.

Philip Harber, MD MPH, Professor and Chief, Division of Occupational and Environmental Medicine, David Geffen School of Medicine at UCLA.

Peter F. Infante, DDS, DrPH, Professorial Lecturer, Department of Environmental and Occupational Health, George Washington University School of Public Health, and Director, Office of Standards Review, OSHA, 1982–2002.

Leslie M. Israel, DO, MPH, Associate Clinical Professor, Center for Occupational and Environmental Health, University of California Irvine.

Joel Kaufman, MD, MPH, Professor, Departments of Environmental & Occupational Health Sciences and Medicine, and Director of the Occupational and Environmental Medicine Program, University of Washington.

Matthew Keifer, MD, MPH, Associate Professor of Medicine and Environmental and Occupational Health, University of Washington.

Joel N. Kline, MD, Professor and Director University of Iowa Asthma Center, Division of Pulmonary, Critical Care, and Occupational Medicine.

Roy J. and Lucille A. Carver College of Medicine, University of Iowa.

David Kriebel, ScD, Professor, Department of Work Environment, University of Massachusetts Lowell.

Sheldon Krimsky, PhD, Professor of Urban & Environmental Policy & Planning, School of Arts and Sciences, Tufts University, and Adjunct Professor, Department of Public Health and Family Medicine, Tufts School of Medicine.

Stephen M. Levin, MD, Medical Director, IJ Selikoff Center for Occupational and Environmental Medicine, Mount Sinai School of Medicine.

Steven Markowitz, MD, Professor and Director, Center for the Biology of Natural Systems, Queens College, The City University of New York.

Robert McConnell, MD, Professor of Preventive Medicine, Keck School of Medicine, University of Southern California.

David Michaels, PhD, MPH, Professor and Associate Chairman, Department of Environmental and Occupational Health, George Washington University School of Public Health, and Director, Project on Scientific Knowledge and Public Policy (SKAPP), Assistant Secretary of Energy for Environment, Safety and Health, 1998–2001.

Rafael Moure-Eraso, PhD, CIH, Professor and Chair, Department of Work Environment, University of Massachusetts Lowell.

Karen B. Mulloy, DO, MSCH, Co-Director Program in Occupational & Environmental Health, University of New Mexico Health Sciences Center.

L. Christine Oliver, MD, MPH, MS, Assistant Clinical Professor of Medicine, Harvard Medical School, and Associate Physician, Massachusetts General Hospital.

David Ozonoff, MD, MPH, Professor and Chair Emeritus, Department of Environmental Health, Boston University School of Public Health.

Allen J. Parmet, MD, MPH, FACPM, Colonel, United States Air Force (Retired).

Anthony Robbins, MD, MPA, Professor, Tufts University School of Medicine, and Assistant Surgeon General and Director, National Institute for Occupational Safety and Health, 1971–1981.

Kenneth Rosenman, MD, Professor of Medicine and Chief, Division of Occupational and Environmental Medicine, Department of Medicine, College of Human Medicine, Michigan State University.

Marc Schenker, MD, MPH, Professor and Chair, Department of Public Health Sciences, University of California at Davis School of Medicine.

Brian S. Schwartz, MD, MS, Professor of Environmental Health Sciences, Epidemiology, and Medicine, Bloomberg School of Public Health, Johns Hopkins University.

Joel Schwartz, PhD, Professor, Environmental Epidemiology, Exposure, Epidemiology, and Risk Program, Harvard School of Public Health.

Michael A. Silverstein, MD, MPH, Clinical Professor, University of Washington School of Public Health and Community Medicine, and Director of Policy, OSHA, 1993–1995.

Rosemary K. Sokas, MD, MOH, Director and Professor, Environmental & Occupational Health Sciences, University of Illinois at Chicago.

Leslie Stayner, PhD, Professor and Director, Division of Epidemiology and Biostatistics, University of Illinois at Chicago School of Public Health.

Laura S. Welch, MD, Center to Protect Workers' Rights, and Professorial Lecturer, Department of Environmental and Occupational Health, George Washington University School of Public Health.

REFERENCES

¹National Institute for Occupational Safety and Health. Preventing lung disease in workers who use or make flavorings. NIOSH Publication No. 2004–110, 2004. Available at: <http://www.cdc.gov/niosh/docs/2004-110/>.

²Michaels D, Monforton C. Scientific evidence in the regulatory system: Manufacturing uncertainty and the demise of the formal regulatory system. *J Law Policy* 2005;13(1): 17–41. Available at: <http://www.defending-science.org/upload/Scientific-Evidence-in-the-Regulatory-System-Manufacturing-Uncertainty-and-the-Demise-of-the-Formal-Regulatory-System.pdf>.

³Schneider A. Disease is swift, response is slow. *Baltimore Sun*. April 23, 2006. Available at: <http://www.baltimoresun.com/news/health/bal-te.flavoring23apr23,0,2684871.story?coll=balnationworld-utility>.

⁴Akpinar-Elci M, Travis WD, Lynch DA, Kreiss K. Bronchiolitis obliterans syndrome in popcorn plant workers. *Eur Resp J* 2004;24: 298–302.

⁵NIOSH Health Hazard Evaluation Report. HETA–2000–0401–2991: Gilster-Mary Lee Corporation, Jasper, Missouri. (January 2006). Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2000-0401-2991.pdf>.

⁶Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Fixed obstructive lung disease in a microwave popcorn factory-Missouri, 2000–2002. *MMWR* 2002; 51:345–347 (Apr. 26, 2002). Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5116a2.htm>.

⁷Kreiss K, et al. Clinical bronchiolitis obliterans in workers at a microwave-popcorn plant. *N Engl J. Med.* 2002–347(5):330–338.

⁸NIOSH Health Hazard Evaluation Report. HETA 2003–0112–2949: ConAgra Snack Foods, Marion, Ohio. (December 2004) Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2003-0112-2949.pdf>.

⁹NIOSH. Letter to Frank Morrison, Nebraska Popcorn, regarding HETA 2002–0089: Nebraska, Popcorn, Clearwater, Nebraska. (July 2, 2003). Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2002-0089-letter.pdf>.

¹⁰NIOSH. Letter to Keith Heuermann, B.K. Heuermann Popcorn, regarding HETA 2001–0517, B.K. Heuermann Popcorn Inc., Phillips, Nebraska. (May 13, 2003) Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2001-0517-letter.pdf>.

¹¹NIOSH Health Hazard Evaluation Report. HETA 2001-0474-2943: American Pop Corn Company, Sioux City, Iowa. (July 2004). Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2001-0474-2943.pdf>.

¹²NIOSH Health Hazard Evaluation Report. HETA-2002-0408-2915: Agrilink Foods Popcorn Plant, Ridgeway, Illinois. (October 2003). Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2002-0408-2915.pdf>.

¹³Schachter EN. Popcorn workers lung. *N Engl J Med*. 2002;347(5):360-361.

¹⁴Parinet AJ, Von Essen S. Rapidly progressive, fixed airway obstructive disease in popcorn workers: a new occupational pulmonary illness? *J Occup Environ Med*. 2002;44:216-218.

¹⁵Lockey J.E. et al. Bronchiolitis obliterans in the food flavoring manufacturing industry. Abstract presented at the Annual Meeting of The American Thoracic Society, 20 May 2002. Available at: <http://www.abstracts2view.com/atsall/>

¹⁶Harrison R, Gelb A, Harber P. Department of Health Services, State of California. Food flavoring workers with bronchiolitis obliterans following exposure to diacetyl, California, May 15, 2006. Available at: http://www.capanet.org/pdfs/BO_cases_%20final_5_16_06.pdf.

¹⁷Pendergrass SM. Method development for the determination of diacetyl and acetoin at a microwave popcorn plant. *Environ Sci Technol*. 2004;38(3):858-861.

¹⁸Kullman G, et al. Characterization of respiratory exposures at a microwave popcorn plant with cases of bronchiolitis obliterans. *J Occup Environ Hyg*. 2005;2:169-178.

¹⁹Kanwal R, et al. Evaluation of flavorings-related lung disease risk at six microwave popcorn plants. *J Occup Environ Med*. 2006;48(2):149-157.

²⁰BASF. Report: study on the acute inhalation toxicity LC50 of diacetyl FCC as a vapor in rats 4-hour exposure. Project No. 1310247/927010, June 8, 1993. Available at: <http://www.defendingscience.org/>

²¹Hubbs AF, et al. Necrosis of nasal and airway epithelium in rats inhaling vapors of artificial butter flavoring. *Toxicol Appl Pharmacol*. 2002;185:128-135.

²²Hubbs AF, et al. Inhalation toxicity of the flavoring agent, diacetyl (2,3-butanedione), in the upper respiratory tract of rats. *Toxicologist*. 2004 ;78(S-1):438-439. Available at: <http://www.toxicology.org/AI/Pub/tox/2004Tox.pdf>.

²³Fedan JS, Dowdy JA, Fedan KB, Hubbs AF. Popcorn worker's lung: In vitro exposure to diacetyl, an ingredient in microwave popcorn butter flavoring, increases reactivity to methacholine. *Toxicol, Appl Pharmacol* (in press). Abstract: *Proc Am Thorac Soc* 2005 May; 2(Abstracts):A814.

MINORITY VIEWS

INTRODUCTION

Committee Republicans are united in their support for a safe and healthy workplace for every American worker. In 2005, the most recent year for which data is available, the American workforce saw all-time lows in occupational injury, illness, and fatality rates. The overall workplace injury/illness rate, 4.6 per 100 employees in 2005, was the lowest since the Bureau of Labor Statistics began publishing data in 1973.¹ In the last five years alone, the nationwide injury/illness rate has fallen by more than 13 percent, while the overall fatality rate has fallen by 7 percent since 2001.² These numbers underscore and highlight Committee Republicans' commitment to and success in protecting the safety and health of the nation's workforce.

Committee Republicans are equally committed to ensuring that the regulation of health and safety in the workplace is always based on science, hard data, and the best available evidence, and not on political expediency or the agenda of any single interest, party, or stakeholder, however well-intentioned. As detailed herein, it is our view that H.R. 2693, which would mandate the Secretary of Labor to establish significant new workplace health and safety standards in the absence of sufficient scientific evidence and reliable data, wholly fails to meet that standard. For this reason, we oppose enactment of the bill.

BACKGROUND: THE OSH ACT AND WORKPLACE SAFETY REGULATION

Since its enactment in 1970, the Occupational Safety and Health Act ("OSH Act" or the "Act")³ has fostered safe and healthy working environments through standards-setting, employer and worker education and training, and hazard elimination.

Section 5 of the OSH Act requires that a covered employer must provide its employees with a workplace "free from recognized hazards that are causing or are likely to cause death or serious physical harm."⁴ In furtherance of that goal, section 6 of the Act sets forth the procedures which the Secretary of Labor is required to follow when promulgating workplace health and safety standards and provides for judicial review of these standards to any person adversely affected by them.⁵ These requirements guarantee that in promulgating regulations, the Occupational Safety and Health Administration (OSHA) must determine whether there is a significant

¹See Testimony of the Honorable Edwin G. Foulke, Jr., Committee on Education and Labor Subcommittee on Workforce Protections Hearing, "Have OSHA Standards Kept up with Workplace Hazards?" (April 24, 2007) (hereinafter "Foulke Testimony"), at 2.

²See *id.*

³29 U.S.C. § 651 et seq.

⁴29 U.S.C. § 654(a).

⁵See generally *id.* § 655.

risk and, if so, fashion a feasible compliance scheme that provides both for technical feasibility and economic feasibility from the standpoint of the regulated community.

Throughout its history, the Act's standard-setting processes have been governed foremost by the Administrative Procedures Act (APA), which generally requires a federal agency to develop and draft proposed regulations; issue proposed rules and regulations via a transparent process which allows for comment and input from affected stakeholders; and review and incorporate as appropriate that input in the publication of its final rule.⁶ In addition to the requirements of the APA, OSHA must ensure that its proposed regulations adhere to, *inter alia*, guidelines specified in Executive Orders, the Paperwork Reduction Act,⁷ Regulatory Flexibility Act,⁸ the Small Business Regulatory Enforcement Fairness Act, ultimately, with the Congressional intent of the law of its underlying⁹ authorizing statute.¹⁰

While the standard-setting process and the legal framework in which it operates have been criticized by some for its deliberate pace, it has nonetheless served to ensure that any agency sets standards based on hard evidence, sound science, and robust stakeholder input. It is within this framework that the Committee addresses the question of whether and how OSHA should regulate exposure to the chemical diacetyl in the workplace.

RESEARCH AND REGULATORY ACTIVITY RELATING TO DIACETYL

Diacetyl is a chemical compound commonly used in the production of butter-flavored popcorn, but also used in a wide range of other products, such as baked goods and snacks.

In 2000, the National Institute for Occupational Safety and Health (NIOSH) was asked by the State of Missouri's Department of Health and Senior Services to provide technical assistance in conjunction with its investigation of workers at a Jasper, Missouri microwave popcorn plant who were suffering from obstructed lung function, specifically the condition bronchiolitis obliterans, potentially relating to exposure to diacetyl. Following up on its interim 2001 report, in December 2003, NIOSH published an alert entitled "Preventing Lung Disease in Workers Who Use or Make Flavorings," which recommended that employers control worker exposure to diacetyl. In 2004, the Flavor and Extract Manufacturers Association (FEMA) similarly published recommendations to control workers' exposure to diacetyl in the workplace.

In January, 2006, NIOSH released its final investigative report on the Jasper facility, in which it determined that inhalation exposure to butter flavoring chemicals presents a risk for occupational lung disease. To date, however, scientists who have been examining the occurrence of bronchiolitis obliterans and the issues sur-

⁶ 5 U.S.C. § 5 *et seq.*

⁷ See 44 U.S.C. § 3501 *et seq.*

⁸ See 5 U.S.C. § 601 *et seq.*

⁹ See 5 U.S.C. § 801 *et seq.*

¹⁰ Moreover, as a matter of practice, in recent years it has become a near-certainty that one or more stakeholders affected by a rule will pursue a legal challenge to OSHA's final regulation. These challenges may result in a rule being upheld in its entirety; modified in some form or fashion by the courts; or struck down in its entirety. Once the final disposition of any legal challenges have been reached, a final rule is either implemented or revised according to court direction and subsequently administered by the Secretary of Labor through OSHA.

rounding diacetyl exposure have not recommended an exposure standard. In February, 2006, NIOSH experts published this conclusion in the *Journal of Occupational and Environmental Medicine*:

At this time, insufficient data exist on which to base workplace exposure standards or recommended exposure limits for butter flavoring. Because the risk of occupational lung disease may be partly due to short-term peak exposures, an exposure limit based on an 8-hour TWA [Time-Weighted Average] may not be sufficient to protect workers. Moreover, because flavorings are complex mixtures of many chemicals, most of which have not been evaluated with respect to inhalation toxicology, focusing solely on diacetyl air concentrations may not be adequate to assess risk in different plants using a variety of different flavorings.¹¹

This lack of data notwithstanding, on July 26, 2006, the International Brotherhood of Teamsters (IBT) and the United Food and Commercial Workers (UFCW) petitioned OSHA to promulgate an emergency temporary standard (ETS) regulating diacetyl in the workplace. This petition is currently under consideration by OSHA.¹²

OSHA ACTIVITY RELATING TO DIACETYL

On April 24, 2007, the Committee on Education and Labor Subcommittee on Workforce Protections held a hearing entitled "Have OSHA Standards Kept up with Workplace Hazards?" While not devoted exclusively to the question of diacetyl regulation, the issue was discussed in detail by witnesses. At that hearing, Department of Labor Assistant Secretary for Occupational Safety and Health Edwin G. Foulke, Jr. testified at length as to the actions that his agency had taken with respect to diacetyl regulation. As Secretary Foulke recounted:

In 2001, OSHA took immediate action when the hazard of butter flavorings containing diacetyl was brought to the Agency's attention by NIOSH's interim report on microwave popcorn manufacturing plants. The report's findings indicated that uncontrolled exposure to butter flavorings containing diacetyl was associated with the development of a severe obstructive lung disease called *bronchiolitis obliterans*.

OSHA promptly alerted its Regional Administrators and Area Directors to NIOSH's findings and instructed its field personnel to look into the issue when encountering individuals working around butter flavoring in popcorn manufacturing. OSHA's Region VII published a brochure on this topic and arranged for its distribution in the region. In 2004, OSHA issued a memorandum to senior field man-

¹¹ See "Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants," *Journal of Occupational and Environmental Medicine*, Volume 48, Number 2, February 2006 (emphasis added).

¹² WUFCW has also petitioned California's state occupational safety and health administration ("Cal-OSHA") to set a state Permissible Exposure Limit (PEL) for diacetyl. Rather than implementing an emergency temporary standard, Cal-OSHA has referred the matter for further study. NIOSH has been working in a consulting mode with Cal-OSHA on this matter.

agers and encouraged them to contact employers in their regions who may have workers exposed to this potential hazard.

To further protect workers who may be exposed to this hazard, OSHA is finalizing a National Emphasis Program (NEP) for butter flavorings containing diacetyl in the manufacturing of microwave popcorn. The goal is to direct inspections to the facilities where workers may be at the greatest risk of exposure to this hazard. In addition, the NEP contains elements aimed at educating stakeholders about the hazard posed by butter flavorings containing diacetyl. Implementation of this NEP would allow OSHA to begin inspecting microwave popcorn manufacturing facilities by the end of May, and 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.

OSHA is also developing guidance to alert employers and workers to the potential hazards associated with food flavorings containing diacetyl. The guidance will provide recommendations on how to control these hazards and to ensure that information about those hazards is effectively communicated to workers.

The Agency is currently reviewing the petition for an Emergency Temporary Standard and is engaged in site visits to microwave popcorn and flavor manufacturing facilities in order to fairly evaluate the merits of the petitioner's request.¹³

On April 24, 2007, OSHA announced its establishment of a National Emphasis Program (NEP) to address the hazards and control measures associated with working in the microwave popcorn industry where butter flavorings containing diacetyl are used. Under the NEP, OSHA will target inspection resources to workplaces where potential exposure to diacetyl is greatest. Research by NIOSH and other occupational safety and health experts as to the effects of diacetyl, its relationship (if any) to *bronchiolitis obliterans*, and recommended exposure tolerances continues today.

H.R. 2693, THE POPCORN WORKERS LUNG DISEASE PREVENTION ACT

On June 13, 2007, Workforce Protections Subcommittee Chair Woolsey introduced H.R. 2693, which would direct OSHA to issue standards regulating worker exposure to diacetyl. Specifically, H.R. 2693 would require OSHA to set an interim final standard relating to diacetyl exposure within 90 days of passage, and promulgate a final rule (including a Permissible Exposure Limit or "PEL") for diacetyl within two years of the date of enactment. The interim final rule would apply to flavor manufacturers who manufacture, use, handle, or process diacetyl and all microwave popcorn production and packaging establishments that use diacetyl, and would be based on NIOSH's 2003 alert.

Under the bill, OSHA's interim final rule must include requirements for:

¹³Foulke Testimony at 5.

- Engineering, work practice controls, and respiratory protection to minimize worker exposure to diacetyl;
 - Written exposure control plans outlining specific measures to minimize exposure;
 - Biannual medical surveillance when abnormal pulmonary functions indicate employees have been exposed to diacetyl, with appropriate medical evaluation;
 - Airborne exposure assessments;
 - Personal protective equipment for workers exposed to diacetyl;
- and

Written safety and health plan for training employees and hazard communication.

Within two years of enactment, the bill requires OSHA to set a final standard which incorporates the elements of the interim standard set forth above and establishes a PEL for diacetyl. This exposure limit will apply to all facilities where diacetyl is processed or used, expanding application of the standard from diacetyl manufacturers and microwave popcorn facilities to all food production facilities.

COMMITTEE CONSIDERATION OF H.R. 2693

No legislative hearing on H.R. 2693 was held in the Committee on Education and Labor subcommittee of jurisdiction, the Subcommittee on Workforce Protections.

No legislative hearing on H.R. 2693 was held in the Committee on Education and Labor.

The Subcommittee on Workforce Protections did not meet to consider H.R. 2693.

On Wednesday, June 20, 2007, the Committee on Education and Labor met to consider and mark up H.R. 2693. An Amendment in the Nature of a Substitute offered by Representative Woolsey was adopted without objection. Two additional amendments were offered by Representative Joe Wilson of South Carolina. The first Wilson Amendment was withdrawn by unanimous consent. The second Wilson Amendment was adopted by the Committee. The Committee favorably reported H.R. 2693, as amended, by voice vote.

REPUBLICAN VIEWS

Over the course of its thirty-five year history, a robust body of law governing the regulatory standard-setting process utilized by OSHA has been developed under the OSH Act. Congress, courts, and the agency's own directives have created a system to which its regulatory activities must conform, and which guarantee that any regulation is measured against a standard of technical feasibility, economic feasibility, and the agency's overarching mission to protect workers from recognized hazards, while providing for the input of all stakeholders and affected parties. As one of the nation's most experienced OSHA practitioners explained at the Committee's April 24 hearing:

[T]he OSHA statute, as interpreted by decades of case law, requires the agency to make detailed findings of significant risk of material impairment of employee health

before it can pursue regulation of a workplace hazard. In addition, OSHA must gather credible evidence with respect to the technological and economic feasibility of its regulations, and it must do so industry by industry. Finally, it must perform what amounts to a cost benefit analysis. These are not simple tasks and to do them in a cursory fashion is to invite court rejection of OSHA standards.¹⁴

This well-developed system of checks, balances, and transparency counsels an abundance of caution before Congress places itself in the role of regulatory standard writer mandates a standard or outcome which fundamentally lacks an adequate scientific basis.¹⁵ Sadly, this is exactly what H.R. 2693 does.

Most telling and troubling is the principle at the core of the legislation. Scientists who have been examining the occurrence of bronchiolitis obliterans and the issues surrounding exposure have not recommended an exposure standard for diacetyl, nor, as noted above by NIOSH, does there yet exist scientific data sufficient to do so. Despite this fact, H.R. 2693 directs OSHA to set a permissible exposure limit for diacetyl when there is no clear and convincing science to indicate what a PEL should be.

To date, there is no standard by a public or private standard-setting organization for diacetyl. Further, within the scientific community, many have expressed concern that while diacetyl is a “marker” for bronchiolitis obliterans, it may not be the true or sole cause of lung obstruction. As detailed more fully under the discussion of the second Wilson Amendment below, it may well be that exposure to diacetyl, in concert with other chemical flavorings, that is harming workers.

These concerns have been repeatedly underscored. The American Society of Safety Engineers (ASSE), while supportive of the legislation, has highlighted the lack of science problem: “ASSE does recognize, however, that there are wide gaps in industry’s knowledge on this issue, as the NIOSH alert itself indicates.” Similarly, the Institute for Risk Assessment Sciences has found that “A relation between lung function abnormalities and exposure to diacetyl could not be established.”¹⁶ Without conclusive evidence, H.R. 2693 forces OSHA to undertake a regulatory action for which it has no justification.

By circumventing the regulatory process,¹⁷ it is unclear if the legislation’s intent will be achieved. Put more simply, the mandate

¹⁴Testimony of Baruch A. Fellner, Committee on Education and Labor Subcommittee on Workforce Protections Hearing, “Have OSHA Standards Kept up with Workplace Hazards?” (April 24, 2007), at 1 (citations omitted).

¹⁵The Majority may be critical of the pace of standard setting by OSHA, and plainly objects to the fact that OSHA has not set an emergency temporary standard (ETS) for diacetyl, as petitioned for by representatives of organized labor. That objection notwithstanding, it is worth noting that the ETS process itself has a mixed history of success. Of the nine emergency temporary standards issued by OSHA in its history, five of these were challenged in court. OSHA lost four of those five challenges.

¹⁶Institute for Risk Assessment Sciences, “Respiratory effects in workers of a diacetyl production plant with a special focus on bronchiolitis obliterans: An evaluation among currently working and retired workers,” Final Report (December 30, 2005).

¹⁷H.R. 2693’s circumvention of regular order and legislative process also deserves mention here. Had the bill proceeded by way of a legislative hearing, concerns expressed by the Minority

of a regulation by Congressional fiat does nothing to ensure that workers are ultimately protected in the most effective way. Indeed, H.R. 2693 in many instances sets before OSHA tasks that simply cannot be accomplished in the time provided for under the bill. As stated to the Committee by Assistant Secretary Foulke:

*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. . . . 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.*¹⁸

In addition, H.R. 2693 requires OSHA to rely on non-scientific documents as the underpinnings of an interim final standard which, while helpful, simply do not live up to that task. Again, as noted by OSHA:

*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.*¹⁹

Others have similarly expressed strong concern about the lack of data upon which to set a standard as well as the circumvention of the regulatory process embodied in H.R. 2693. The OSHA Fairness Coalition, an association of employers and trade groups which seeks to ensure fairness and balance in OSHA’s rulemaking, put it most clearly:

This bill would establish a regulation even though the science and data available are insufficient to support a reg-

in these views—and equally important, concerns raised by OSHA itself—perhaps could have been aired and addressed.

¹⁸Letter to Chairman George Miller from Edwin G. Foulke, Jr., Department of Labor Assistant Secretary for Occupational Health and Safety (June 19, 2007) (emphasis added). A full copy of this letter is attached to these Views as Appendix A.

¹⁹Id. (emphasis added).

ulation. Such a mandate would be completely at odds with all other laws, judicial decisions, executive orders and sound policy considerations under which OSHA currently operates.

This bill mandates that OSHA issue an interim final regulation within 90 days of enactment, and a final regulation which would include a Permissible Exposure Limit (PEL), within two years of enactment. Unfortunately, no data currently exist as to where such a line could be drawn. *The very NIOSH document cited in the bill for the recommendations that are to be enshrined in the OSHA regulation also states with respect to diacetyl and other flavorings: "Little is currently known about which chemicals used flavorings have the potential to cause lung disease and other health effects, and what workplace exposure concentrations are safe. . . . Most chemicals used in flavorings have not been tested for respiratory toxicity via the inhalation route, and occupational exposure limits have been established for only a relatively small number of these chemicals."*

Most importantly, this bill would completely ignore the carefully developed, balanced, and necessary requirements for rulemaking that Congress and the courts have put in place to make sure OSHA standards reflect the best science available, are responsive to a specific hazard, and are both technologically and economically feasible for the affected employers. Both Congress and the Supreme Court have made clear that OSHA can regulate only after it has satisfied specific requirements for data and analysis.²⁰

Similarly, the American Bakers Association has expressed its strong concern with this legislation to the Committee:

Mandating specific requirements that OSHA must include in a diacetyl standard sets a precedent that should be avoided. Congress's role as set forth in the OSH Act of 1970 is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." However, it is the role of the Department of Labor to use its expertise for implementing regulations).²¹

Committee Republicans, regulators, and the regulated community are unanimous in their view that regulation of diacetyl may be warranted—but equally clear that the scientific evidence that answers that question, or counsels how best to regulate, is simply not available at this time. Particularly where, as here, science does not yet suggest, let alone dictate, the best outcome, Congress should not interject itself in the process of micromanaging regulatory agencies, or substituting its view for reliable and objective analysis.

²⁰Letter to Members of Committee on Education and Labor from OSHA Fairness Coalition (June 19, 2007) (citation omitted; emphases added).

²¹Letter to Chairman Miller from American Bakers Association (June 19, 2007) (emphasis added).

CALIFORNIA IS NOT MOVING AHEAD TO REGULATE DIACETYL IN THE
ABSENCE OF APPROPRIATE SCIENCE

One final argument bears particular note. The Majority attempts to justify the intervention of federal OSHA in the absence of appropriate science by suggesting that the State of California is moving more quickly, and that the federal government should follow suit. This argument misses the mark.

Foremost, California is not moving with any more or less urgency on the regulation of diacetyl than federal OSHA. The California Assembly passed legislation to urge Cal-OSHA to make the regulation of diacetyl a high priority, but affirmatively opted not to impose a date certain for the completion of a regulation. California's regulatory body also did not set an exposure standard, and is instead working toward setting a standard that largely relies on engineering controls to control exposure—far less than that contemplated by H.R. 2693. Finally—and as noted at hearing—the simple fact is that OSHA and California's state regulatory agencies do not have the same regulatory processes and are not subject to the same constraints. In response to questioning by Chairwoman Woolsey, Assistant Secretary Foulke elucidated these differences:

Well, you know, with respect to California, I would just have to say that we have different statutory and legal burdens to support our rulemaking effort that California does not have. . . . I would submit to you that if you look at the regulatory process that we have in place under the federal system, as opposed to California, we have things that the Congress has put in—Administrative Procedures Act. We have things in the OSH Act that we have to follow, so those are just three of the things that the Congress has intended.

And all those things were put on for specific reasons, that the Congress, in its wisdom said, “You know, we have got to look at these things, because we can't rush into a standard, unless we have sound science.” And I know that is what you want to have.

Plus, on top of that, the court systems, as part of their review process on these things, have indicated that we have to do certain other things on feasibility and risk assessment.²²

As a general matter, and specifically in this instance, to assert that there should be a race to promulgate a regulation, for which the science is simply science, is bad public policy.

AMENDMENTS OFFERED IN COMMITTEE

Woolsey Amendment in the nature of a substitute

An Amendment in the Nature of a Substitute offered by Workforce Protections Subcommittee Chair Woolsey was adopted without objection. The Woolsey Amendment simply provided a short title for H.R. 2693, the “Popcorn Workers Lung Disease Prevention Act.”

²²Foulke Testimony, at ____ (not yet printed).

Wilson Amendment to require scientific data supporting a rule-making

As noted above, NIOSH has stated—and no party has seriously disputed—that the current state of scientific data concerning diacetyl offers an insufficient basis on which to set a workplace exposure standard. For this reason, and to ensure that any workplace standard set by OSHA was based on scientific evidence, during Committee consideration of the bill Representative Joe Wilson of South Carolina offered an amendment which would have: (a) required NIOSH to set a recommended exposure limit (REL) for diacetyl when the scientific evidence so warranted; and (b) provided that OSHA would have two years from that time to set a permissible exposure limit based on NIOSH’s findings.

The Wilson Amendment would have allowed the interim final rule contained in H.R. 2693 to become effective as scheduled under the bill, while ensuring that any standard set by OSHA would have been based on the best available science and still allowing for robust stakeholder input. At markup, the Majority expressed a willingness to work with Committee Republicans in fashioning a compromise that might serve these goals. Based on this representation, the Wilson Amendment was withdrawn without objection.²³

Wilson Amendment to require NIOSH to gather data as to other flavorings

As discussed above, scientific evidence is inconclusive as to diacetyl’s causal link to bronchiolitis obliterans, and in particular, whether a risk of lung damage is presented by diacetyl, any related compounds, or some combination of both.

Given this lack of information, during Committee consideration, Representative Wilson offered an amendment which directs NIOSH to study flavorings that have a chemical make up similar to diacetyl, so as to determine exposure hazards (if any) and, where appropriate, set recommended exposure limits. The amendment further directs NIOSH to inform OSHA of its findings, so that all parties have this evidence for use in future regulation. The Wilson Amendment was accepted without objection.

CONCLUSION

Committee Republicans recognize that the question of whether and how OSHA should regulate worker exposure to diacetyl in the workplace is one on which Members on both sides of the aisle can in good conscience disagree. Committee Republicans are united, however, in their view that any workplace regulation, however well intended, must be supported by objective evidence, sound science, and reliable data. To do less threatens the thirty-five years of accomplishment achieved under the OSH Act, and, far worse, does nothing to protect the health and safety of American workers.

Measured against those standards, H.R. 2693 is, foremost, fundamentally flawed policy with respect to the discrete issue of whether and how to federally regulate exposure to diacetyl. Equally important, in the larger context, it sets an unfortunate precedent

²³ At the time of the filing of these Minority Views, discussions as to a possible compromise continue on a staff level. To date, however, they have not produced a consensus position.

for the consideration of future workplace safety standards. H.R. 2693 short-circuits the rulemaking process and thereby eliminates many of the critical features of rulemaking under the OSH Act which serve to guarantee that regulation is based on sound science, stakeholder input, and the best evidence available. At bottom, the bill is based on incomplete evidence as to appropriate workplace exposure controls and standards, and, perhaps most disappointing, provides no guarantee that workers will enjoy greater protection from the risk of bronchiolitis obliterans.

For all of these reasons, we respectfully oppose this legislation.

HOWARD P. MCKEON.

PETER HOEKSTRA.

MARK SOUDER.

JUDY BIGGERT.

JOE WILSON.

JOHN KLINE.

K. MARCHANT.

THOMAS PRICE.

LUIS FORTUÑO.

C. W. BOUSTANY, Jr.

ROB BISHOP.

DAVID DAVIS.

TIM WALBERG.

RIC KELLER.

APPENDIX A

U.S. DEPARTMENT OF LABOR, ASSISTANT SECRETARY FOR
OCCUPATIONAL SAFETY AND HEALTH,
Washington, DC., June 19, 2007.

Hon. GEORGE MILLER,
*Chairman, Committee on Education and Labor,
House of Representatives, Washington, DC.*

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 zero-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 MOSH 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 NEP1 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 pro-

tection 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.

