

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****29 CFR Part 1910**

[Docket No. OSHA-2008-0046]

RIN 1218-AC33

Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: OSHA is requesting data, information, and comment on issues related to occupational exposure to diacetyl and food flavorings containing diacetyl, including current employee exposures to diacetyl; the relationship between exposure to diacetyl and the development of adverse health effects; exposure assessment and monitoring methods; exposure control methods; employee training; medical surveillance for adverse health effects related to diacetyl exposure; and other pertinent subjects. In this notice, OSHA intends the term “diacetyl and food flavorings containing diacetyl” to encompass other constituents of food flavorings containing diacetyl. In addition to information on diacetyl, OSHA seeks information on acetoin, acetaldehyde, acetic acid, furfural, and other compounds present in food flavorings that may cause or contribute to flavoring-related lung disease. The Agency is also interested in and seeks information about diacetyl present in substances other than food flavorings (e.g., naturally occurring diacetyl or diacetyl in fragrances) as well as substitutes used in place of diacetyl (e.g., diacetyl trimer). The information received in response to this document will assist the Agency in developing a proposed standard addressing occupational exposure to diacetyl and food flavorings containing diacetyl.

DATES: Comments must be submitted (postmarked, sent, or received) by April 21, 2009.

ADDRESSES: You may submit comments, identified by Docket No. OSHA-2008-0046, by any of the following methods:

Electronically: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Fax: If your comments, including attachments, do not exceed 10 pages, you may fax them to the OSHA Docket Office at 202-693-1648.

Mail, hand delivery, express mail, messenger or courier service: You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2008-0046, Room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone 202-693-2350 (TTY number 877-889-5627). Deliveries (hand, express mail, messenger or courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (Docket No. OSHA-2008-0046). Because of security-related procedures, submissions by regular mail may result in significant delay in their receipt. Please contact the OSHA Docket Office at the above address for information about security procedures for submitting comments by hand delivery, express delivery, and messenger or courier service.

All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at <http://www.regulations.gov>. Therefore, OSHA cautions you about submitting certain personal information, such as social security numbers and birthdates. For further information on submitting comments, see the “Public Participation” heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To read or download comments submitted in response to this **Federal Register** notice or other materials in the docket, go to Docket No. OSHA-2008-0046 at <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket are listed in the <http://www.regulations.gov> index, however, some information (for example, copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This notice, as well as news releases and other relevant information, also are available at OSHA's Web site at <http://www.osha.gov>.

FOR FURTHER INFORMATION CONTACT:

Press Inquiries: Jennifer Ashley, OSHA Office of Communications, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: 202-693-1999.

General and Technical Information: David O'Connor, OSHA Directorate of Standards and Guidance, Office of Chemical Hazards—Non-Metals, Room N-3718, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone 202-693-2090.

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In this document, OSHA references a number of supporting materials, and includes a list of these materials (see Section IV—References). These materials are posted in Docket No. OSHA-2008-0046. See **ADDRESSES** section above and Section III (Public Participation) for further information about accessing exhibits referenced in this **Federal Register** notice.

I. Background*A. Events Leading to This Action*

On July 26, 2006, the United Food and Commercial Workers International Union and the International Brotherhood of Teamsters petitioned OSHA for an Emergency Temporary Standard (ETS) covering all employees exposed to diacetyl. The petition cited evidence from NIOSH Health Hazard Evaluations to show that some employees exposed to butter flavorings developed bronchiolitis obliterans, a serious and sometimes fatal lung disease. OSHA denied the ETS petition on September 25, 2007, indicating that the evidence available at that time did not support the stringent legal findings required for an ETS. However, the

Agency acknowledged that the available evidence showed that employees exposed to butter flavoring vapors containing diacetyl may be at risk of material impairment, and initiated rulemaking under Section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651, 655).

The information available to date indicates that regulating occupational exposures to diacetyl and food flavorings containing diacetyl presents a number of complex and difficult issues. Flavorings, including butter flavoring, are complex mixtures and may contain a number of potential airway reactive substances (e.g., diacetyl, acetoin, acetaldehyde, acetic acid, furfural). Diacetyl has been used as an indicator of exposure to butter flavoring vapors in a variety of occupational studies in microwave popcorn plants. While there is evidence that diacetyl is a factor in flavoring-related airway injury, other compounds may contribute to the development of obstructive airway disease and bronchiolitis obliterans. Gaps also exist in the available data on current usage of and exposure to diacetyl and food flavorings containing diacetyl.

As part of the information-gathering process, OSHA hosted a stakeholder meeting on October 17, 2007. The meeting provided OSHA representatives and stakeholders an opportunity for informal discussion, open conversation, and the exchange of data, ideas, and points of view regarding occupational exposure to diacetyl and food flavorings containing diacetyl. The meeting addressed not only specific OSHA information requests, but also identified stakeholder concerns associated with developing a standard addressing occupational exposure to diacetyl and food flavorings containing diacetyl. A summary report of this stakeholder meeting is available in the docket and on OSHA's Web page (OSHA, 2007a).

OSHA has initiated a number of enforcement and compliance assistance activities. On July 27, 2007, the Agency announced a National Emphasis Program requiring inspections of all workplaces where butter flavored microwave popcorn is produced (OSHA, 2007b). OSHA has published a Safety and Health Information Bulletin that addresses respiratory disease among employees in microwave popcorn processing plants (OSHA, 2007c). The Agency has also published a guidance document that addresses responsibilities of flavoring manufacturers and employers who must comply with OSHA's Hazard Communication Standard with regard to

diacetyl and food flavorings that contain diacetyl (OSHA, 2007d).

In this notice, OSHA is seeking information to help the Agency resolve some of the issues discussed above. OSHA believes that its decisionmaking process will benefit from gathering public input on relevant studies and scientific information; data regarding the frequency, intensity, duration, and other parameters of employee exposure in the affected industries, occupations, and activities; key default factors and assumptions; and other relevant information related to the development of a health standard regulating occupational exposure to diacetyl and food flavorings containing diacetyl.

B. Properties and Uses

Flavorings containing diacetyl are in a variety of foods. Of particular note is the use of butter flavorings that contain diacetyl in microwave popcorn. Butter flavoring is mixed with oils and other ingredients and added to the bag during microwave popcorn production. Both natural and artificial butter-flavored popcorn may contain diacetyl. Diacetyl (C₄H₆O₂, other names: butanedione or 2,3-butanedione, CAS number 431-03-8) is an organic chemical that occurs naturally in dairy products, and is a natural byproduct of fermentation and brewing. It also is widely used in flavorings, particularly flavorings designed to provide a dairy, buttery, or ripe taste. In addition, diacetyl is used in some fragrances.

Diacetyl can be produced several ways, including by extraction from dairy products, fermentation processes or chemical synthesis. Under Food and Drug Administration classifications, diacetyl produced by extraction from natural products is classified as a natural flavoring while diacetyl produced by other means is classified as an artificial flavoring. There is no difference in the chemistry of "natural" and "artificial" diacetyl.

The Flavor and Extract Manufacturers Association (FEMA) estimates that each year the U.S. flavorings industry consumes approximately 228,000 pounds of diacetyl, most of which is imported (FEMA, 2005). Flavoring manufacturers are largely firms that mix natural and artificial substances to create flavorings. OSHA has identified 139 establishments, employing an estimated 8,972 employees, that produce flavorings containing diacetyl (ERG, 2007).

The principal types of flavorings that use diacetyl are dairy flavors such as butter, cheese, sour cream, egg, or yogurt flavors; and the so-called "brown flavors" such as caramel, butterscotch,

brown sugar, maple or coffee flavors. Some fruit flavors (e.g., strawberry and banana) may also contain diacetyl. There are also a variety of special uses of diacetyl such as in vanilla, tea, and other flavorings that are difficult to categorize broadly.

Food flavorings containing diacetyl are used in a wide variety of products throughout the food processing sector. In addition to microwave popcorn, flavorings containing diacetyl are commonly used in the production of margarine and butter-flavored oils and cooking sprays, in retail and commercial bakeries, the production of some snack foods (particularly those with cheese flavoring), and in many confectionaries. Dairy, butter, and cheese flavors are sometimes used in frozen foods, canned foods, salad dressings, cheese and dairy substitutes, flavored wines and liquors, pet food, and specialty preparations. Fruit flavorings containing diacetyl are used in some yogurt and ice cream products.

When food preparation facilities and restaurants heat food and other products containing butter-flavored margarines, oils, cooking sprays, and butter, food preparation employees may be exposed to diacetyl. Diacetyl is reported to be used in fragrances for some fruit scents and for some floral scents, such as geranium and magnolia. Diacetyl may in turn appear in some fragrance-using products such as scented candles (Lone Star, 2003). Diacetyl also has antibacterial properties and may be used as a preservative (Bibek, 2004).

Flavorings, including butter flavoring, are complex mixtures and may contain volatile compounds, including other potential airway reactive substances. Apart from diacetyl, one of those substances is acetoin (C₄H₈O₂, other names: 3-hydroxybutanone or acetyl methyl carbonol, CAS number 513-86-0). Acetoin is known to be used in butter flavorings and may be used in other flavorings, including flavorings in which diacetyl is used. Acetoin is structurally similar to diacetyl and shares common metabolic pathways with diacetyl. It has been found in the same workplace environments at concentrations approaching those of diacetyl. Like diacetyl, acetoin also occurs naturally in dairy products and has uses similar to diacetyl. Other volatile organic compounds found in some food flavorings include acetaldehyde, acetic acid, and furfural.

Motivated by public concerns about possible health effects of diacetyl, some flavoring and food product manufacturers have begun or are planning to substitute other chemicals for diacetyl, since most flavorings can

be made without diacetyl. For example, many microwave popcorn producers have substituted or are seeking to substitute alternatives to diacetyl in butter flavoring (ConAgra, 2007; Pop Weaver, 2008). OSHA has noted three substances promoted as diacetyl substitutes—acetoin, diacetyl trimer (OSHA, 2007a), and a sulfite adduct of diacetyl (Turin, 2007). Both diacetyl trimer and the sulfite adduct of diacetyl have a low vapor pressure in their basic form, and are thus less likely to evaporate and result in employee inhalation exposures during the production process. However, both are converted to diacetyl during consumer food preparation, so that the foods when consumed will contain diacetyl. For example, if placed on popcorn, both convert to diacetyl when the popcorn is popped.

C. Health Effects Studies of Exposure to Butter Flavorings and Diacetyl

A number of studies, including several occupational investigations and case reports, have documented obstructive airway disease among employees exposed to airborne butter flavoring chemicals (Kanwal *et al.*, 2008). While cases of obstructive lung disease had been described among employees at flavoring manufacturing sites in a few earlier reports, the scientific community did not become aware of flavoring-related obstructive airway disease until 2000 after a case cluster was identified at a microwave popcorn production plant. Subsequent investigations at microwave popcorn production plants demonstrated higher rates of respiratory symptoms such as chronic cough, shortness of breath, and wheezing among employees engaged in certain job activities when compared to the rates expected among the U.S. population adjusted for age and smoking status. In some cases, these effects may be symptomatic of a potentially disabling obstructive lung disease known as constrictive bronchiolitis obliterans. Higher-than-expected rates of physician-diagnosed asthma and chronic bronchitis have also been reported. Some employees exposed to butter flavoring have also experienced eye, skin, nose, and throat irritation.

Spirometry surveys in the investigations of microwave popcorn production plants revealed higher prevalences of airway obstruction, defined as a reduction in FEV₁ and FEV₁/FVC ratio,¹ than expected based

¹ The most common pulmonary function tests, including FEV₁ and FVC, are often measured using *spirometry*, which measures the flow of air in and

on the adjusted rates among the U.S. population. Airway obstruction is described as *fixed* when abnormal pulmonary function test results do not improve with bronchodilator treatment. The onset of symptoms associated with fixed airway obstruction has been reported to occur after a few months to several years of exposure to butter flavorings that contained diacetyl in a microwave popcorn production facility (Akpinar-Elci *et al.*, 2004).

Fixed airway obstruction is characteristic of bronchiolitis obliterans. This lung disease results from inflammation and scarring of the tissue lining the small airways of the lung. In response to the damage, the airways become thickened, narrowed, and sometimes completely obstructed, limiting movement of air into and out of the lung. Because it is an uncommon condition, bronchiolitis obliterans may be misdiagnosed as the more frequently encountered obstructive lung diseases of chronic bronchitis, emphysema, or asthma. A high resolution computerized tomography (CT) scan or, sometimes, a specialized lung biopsy is needed to confirm a diagnosis of bronchiolitis obliterans. As airways become more severely damaged, employees with bronchiolitis obliterans suffer persistent symptoms and permanent loss of pulmonary function. Several employees with severe disease are on waiting lists to receive lung transplants. At least three employee deaths have been attributed to flavoring-related bronchiolitis obliterans (Egilmann *et al.*, 2007).

Investigations of Microwave Popcorn Plants

The respiratory hazards associated with butter flavoring came under scrutiny with the diagnosis of bronchiolitis obliterans in eight former employees who had worked in mixing and packaging operations at a Missouri microwave popcorn plant (Parmet *et al.*, 2002). The National Institute of Occupational Safety and Health (NIOSH) evaluated the medical condition of current employees at the plant (Kreiss *et al.*, 2002). The prevalence of airway obstruction was 3.3 times higher than expected for all employees and 10.8 times higher than expected for employees who had never

out of the lungs. Forced expiratory volume—one second (FEV₁) is the volume of air that a person can exhale through a mouthpiece in one second. Forced vital capacity (FVC) is the amount of air that can be exhaled following full inspiration. For accurate measurement of FVC, a person must inhale as deeply as possible and then exhale as forcefully as possible through a mouthpiece, for as long as possible.

smoked based on national statistics. The frequency and extent of the airway obstruction was greatest among mixing room and packaging area employees with the highest exposures to the butter flavoring vapors. Medical symptoms that were elevated among production workers included chronic cough, shortness of breath upon exertion, wheezing, physician diagnosed asthma and chronic bronchitis, unusual fatigue, and skin and mucous membrane irritation. Rates of physician-diagnosed asthma and chronic bronchitis were also higher than expected based on national statistics. NIOSH noted that five of six current employees who worked in the quality control room popping nearly 100 bags of product in microwave ovens per shift suffered airway obstruction despite relatively low full shift exposure to butter flavoring vapors.

NIOSH then investigated five additional microwave popcorn plants which confirmed and extended its initial findings (Kanwal *et al.*, 2006). The prevalence of airways obstruction and respiratory symptoms was highest among flavorings mixers with longer work histories and packaging operators who worked in close proximity to mixing tanks of oil and flavorings. Six employees currently engaged in these job operations at four microwave popcorn plants were found to have clinical evidence consistent with bronchiolitis obliterans. Production and non-production employees with the least exposure to butter flavoring chemicals had the lowest rates of airway disease and respiratory symptoms.

As an indicator of exposure to butter flavoring vapors, NIOSH measured full shift area and personal time-weighted average (TWA) air concentrations of diacetyl in several job locations of the six investigated plants (Kanwal *et al.*, 2006). The average full shift air levels of diacetyl in the mixing areas and production locations in close proximity to mixing tanks ranged from 0.2 to 38 ppm.² By contrast, average diacetyl concentrations were 0.03 ppm or less in the packaging areas that were isolated from the mixing tanks. Several task-based measurements at one plant showed that diacetyl concentrations averaged 5 to 10 ppm for 30 to 60 minutes following the open transfer of

² NIOSH subsequently determined that the diacetyl sampling method used in its investigations of microwave popcorn and flavor manufacturing facilities can be affected by relative humidity and that high humidity levels may result in an underestimation of true airborne diacetyl concentrations (NIOSH, 2003b). NIOSH is working to develop a set of correction factors and to validate a new method for the measurement of diacetyl in the workplace.

butter flavoring to heated mixing tanks (NIOSH, 2003a).

Investigations of Plants That Manufacture Food Flavors That Contain Diacetyl

Cases of airway obstruction have also been reported and investigated in food flavor manufacturing facilities. NIOSH described severe fixed airway obstruction compatible with bronchiolitis obliterans in two former employees of a company that blended large batches of flavoring ingredients with corn starch and flour to make "cinnabutter" and other flavors for use in the baking industry (NIOSH, 1986). Researchers at the University of Cincinnati College of Medicine reported severe respiratory disease with clinical findings consistent with bronchiolitis obliterans in five employees at a large flavor manufacturing facility (Lockey *et al.*, 2002). The State of California began an active investigation of obstructive airway disease at flavoring manufacturing establishments in the State after learning of two employees with confirmed bronchiolitis obliterans at separate Southern California plants (CDC, 2007). By January 2007, the State identified six additional employees with suspected fixed obstructive lung disease at three additional flavor manufacturing establishments (Materna, 2007). The eight individuals were flavoring compounders and their jobs involved mixing chemicals, including diacetyl, to make food flavorings.

Recently, NIOSH conducted health hazard evaluations at two Southern California flavor manufacturing plants (NIOSH, 2007a; 2007b) where four current or former employees who worked in powder production and handled diacetyl or diacetyl-containing flavors had severe fixed airway obstruction. Personal air sampling completed at one plant found mean full-shift TWA diacetyl air levels of 0.22 ppm (range: 0.002 ppm to 1.1 ppm) and mean process-associated diacetyl air levels of 7.7 to 21 ppm over one to two hour productions of diacetyl-containing butter-flavored and vanilla-flavored powders.²

A study by the National Jewish Medical and Research Center (NJMRC) found that production employees from eleven flavoring manufacturing sites reported higher than expected rates of respiratory symptoms and asthma (Rose, 2007). The study also found that employees with the highest cumulative exposures to diacetyl were more likely to experience process-related breathing problems and eye, nose, and throat irritation than employees with the lowest cumulative exposures. The

highest diacetyl air levels were measured during the production of powder and liquid formulations using the NIOSH sampling method² (Martyn *et al.*, 2008).

Workplace air levels of diacetyl in powder production areas of monitored plants as well as the type of respiratory problems experienced by the employees were similar to those found in the mixing areas of microwave popcorn plants. However, one important distinction is that employees who work in mixing operations at microwave popcorn plants are typically exposed to butter flavorings on a daily basis while flavoring compounders are usually exposed less frequently at some flavor manufacturing facilities. Thus, based on currently available information, it is not clear whether the risk of airway obstruction among blenders working at food flavoring manufacturing would be similar to mixers in microwave popcorn production.

Investigation at a Diacetyl Production Plant

Four cases of obstructive airway disease compatible with bronchiolitis obliterans were found among diacetyl process operators who worked at a Dutch chemical plant that produced diacetyl (Van Rooy *et al.*, 2007). These workers were regularly exposed to diacetyl and a limited number of other agents, as opposed to the much larger number of compounds present during flavor manufacture or use of butter flavoring in microwave popcorn production. In addition to diacetyl, acetoin was manufactured as a co-product during the diacetyl production process. Acetaldehyde and acetic acid were also formed as side products during the process. The employees in the study reported a greater prevalence of certain respiratory symptoms, such as trouble breathing, chronic cough, and physician-diagnosed asthma than the general Dutch population when adjusted for age and smoking habits (Van Rooy *et al.*, 2008).

Inhalation Studies in Experimental Animals

NIOSH examined the effects of liquid butter flavoring vapors (BFV) and pure diacetyl on the respiratory tract of Sprague Dawley rats exposed to a one-time six hour inhalation study (Hubbs *et al.*, 2002; 2008). Rats exposed to diacetyl above 200 ppm either as pure vapor or as a mixture with other butter flavoring compounds suffered dose-dependent inflammation and necrosis of the epithelium extending from the nose into the bronchii. The epithelial injury in rats exposed to pure diacetyl covered

a less extensive area of the respiratory tract than BFV-exposed animals receiving similar diacetyl concentrations. This suggests that other butter flavoring components in addition to diacetyl may contribute to the flavoring-induced airway damage. There also was no difference in respiratory damage whether the total diacetyl dose was administered continuously over six hours or in four 15 minute pulses. There were no significant pathological changes in bronchiolar epithelium or alveoli at any diacetyl concentration.

A National Institute of Environmental Health Sciences (NIEHS) study found respiratory effects in mice exposed to pure diacetyl. NIEHS evaluated the respiratory tract toxicity in C57BL/6 mice exposed to repeated inhalations of pure diacetyl for up to twelve weeks (Morgan *et al.*, 2008). Mice exposed to 50 ppm and 100 ppm dose levels were found to have dose-dependant mild to moderate nasal tissue necrosis. A lymphocytic bronchitis extending into the lower airways was found in the mice exposed to 100 ppm. In an effort to bypass the extensive removal of water-soluble diacetyl vapors that occurs in the nasal passages of mice, liquid diacetyl was forced deep into the lung by oropharyngeal aspiration. This caused fibrotic foci in the terminal bronchioles and alveolar ducts. Although these lesions were not identical to bronchiolitis obliterans, there was sufficient similarity to suspect that they may progress to bronchiolitis with continued exposure. The National Toxicology Program has approved the nomination of BFV, diacetyl, and acetoin for longer term inhalation testing.

II. Request for Data, Information, and Comment

OSHA is seeking data, information, and comment on a variety of topics relevant to the Agency's development of a proposed rule addressing occupational exposure to diacetyl and food flavorings containing diacetyl. The questions below highlight specific areas of concern to OSHA. When answering specific numbered questions below, please key your responses to the number of the question, explain the reasons supporting your views, and identify and provide relevant information on which you rely, including any studies or articles that support your comments. In addition to the questions presented below, respondents are encouraged to address any aspect of occupational exposure to diacetyl and food flavorings containing diacetyl that they feel is pertinent.

When requesting information, OSHA refers to "diacetyl and food flavorings containing diacetyl." In addition to food flavorings, OSHA intends the term to encompass diacetyl present in substances other than food flavorings (e.g., naturally occurring diacetyl or diacetyl in fragrances), as well as other constituents of food flavorings containing diacetyl. "Starter distillate," also referred to as "butter starter distillate," should be considered a form of diacetyl.

As discussed previously, butter flavorings are complex and variable mixtures, containing a number of respiratory irritants and potential airway reactive substances. In addition to information on diacetyl, OSHA seeks information on acetoin, acetaldehyde, acetic acid, furfural, and other compounds present in food flavorings that may cause or contribute to flavoring-related lung disease. The Agency is also interested in information on substitutes used in place of diacetyl (e.g., diacetyl trimer).

A. Production and Uses

Diacetyl and food flavorings containing diacetyl are used in a wide variety of industries and processes, and employee exposure to these substances occurs in many different occupational settings. Exposures have been recorded in various operations in the microwave popcorn and the flavor manufacturing industries. Exposures are also likely in a wide range of food processing and food service industries where diacetyl and food flavorings containing diacetyl are used and in other industries where diacetyl is volatilized (e.g., fragrance-related exposures). OSHA would appreciate detailed responses to these questions concerning the production and use of diacetyl and food flavorings containing diacetyl.

1. What is your primary line of business? Please indicate the types of products or services your firm produces or provides, the number of establishments you have, and how many full-time and part-time employees work at each establishment.

2. Does your firm or any other U.S. firm produce diacetyl? If so, indicate the form of diacetyl (e.g., powder, liquid, encapsulated) and the quantity produced, how frequently it is produced, and the circumstances in which it is produced.

3. Does your firm use diacetyl? If so, indicate the form of diacetyl (e.g., powder, liquid, encapsulated) and quantity used, the purpose(s) it is used for, how frequently it is used, and the circumstances in which it is used. OSHA is particularly interested in the

extent of diacetyl use as a preservative. Does your firm use diacetyl for that purpose? If so, please describe the nature of the use, the total volume of diacetyl used and potential employee exposure.

4. Does your firm use any natural or artificial flavorings that might contain diacetyl, such as dairy (e.g., butter, cheese, sour cream, yogurt), "brown" (e.g., caramel, butterscotch, brown sugar, maple, coffee flavors), fruit, marshmallow, or egg flavorings? If so, please indicate which flavorings you use, the quantity you use, and the purpose(s) for their use. If any of these flavorings are known to contain diacetyl, please indicate which flavorings contain diacetyl and the percentage of diacetyl, by weight, they contain.

5. Does your firm heat margarine or use butter-flavored cooking oils or cooking sprays? If so, please indicate the quantity of these substances you use and the purpose(s) for their use. If any of these substances are known to contain diacetyl, please indicate which substances contain diacetyl and the percentage of diacetyl, by weight, they contain.

6. Does your firm use, add, or handle flavorings or food products that contain naturally occurring diacetyl, such as dairy products, wine or beer? Please describe the circumstances in which you use, add, or handle naturally occurring diacetyl.

7. Does your firm manufacture or use fragrances? If so, do any of these fragrances contain diacetyl? Please indicate which fragrances contain diacetyl, how much diacetyl they contain, how the fragrances are used, and the quantities produced or used.

B. Employee Exposure

8. What are the job categories and operations in which employees are potentially exposed to diacetyl or food flavorings containing diacetyl in your company or industry? For each job category or operation, please provide a description of how the exposure takes place. OSHA is particularly interested in any operations that involve manual tasks; operations that involve products being sprayed, sprinkled, or coated with flavorings or ingredients containing diacetyl; operations that involve heating of ingredients; and tasks in laboratories for product testing or research and development that involve handling of diacetyl or food flavorings containing diacetyl.

9. How many employees are exposed to diacetyl or food flavorings containing diacetyl, or have the potential for

exposure, in each job category or operation in your company or industry?

10. What are the frequency, duration, and levels of employee exposures to diacetyl in each job category in your company or industry? Please indicate the engineering or other controls in place when exposures were measured, as well as the analytical method and type of samples used for determining exposure levels. If possible, OSHA requests that you provide personal exposure sampling data with clear descriptions of the length of time the samples were collected. If personal sampling data are not available, OSHA requests any exposure data you provide indicate the form and length of the exposure. If sampling was performed using NIOSH Method 2557, please indicate the flow rate used and the temperature and relative humidity at the time sampling was performed, if possible.

11. How many years do employees potentially exposed to diacetyl or food flavorings containing diacetyl remain in their jobs? Do employees who leave such positions typically move to new jobs that do not involve exposure, or are they likely to transfer to jobs that involve potential exposure to diacetyl or food flavorings containing diacetyl?

C. Health Effects

The Background section discusses several studies that report an increased occurrence of airway obstruction, bronchiolitis obliterans, and other respiratory disorders among employees in jobs involving exposure to diacetyl and food flavorings containing diacetyl. Diacetyl and other potential airway reactive compounds (e.g., acetoin, acetaldehyde, acetic acid, furfural) present in food flavorings may contribute to the observed respiratory effects. The Agency is seeking additional studies, articles, data, and information that OSHA can use to evaluate health effects related to occupational exposure to these substances. The Agency specifically requests the following:

12. Describe and provide any additional case reports, epidemiological and animal studies, and data not mentioned in this notice that OSHA should consider in evaluating the potential health risks associated with exposure to diacetyl and food flavorings containing diacetyl. If available, please include associated short-term, task-oriented, and full-shift time weighted average exposure data and indicate the method of sampling and analysis used. If sampling was performed using NIOSH Method 2557, please indicate the flow rate used and the temperature and

relative humidity at the time sampling was performed. Describe and provide any studies and data that report changes in the occurrence of flavoring-related health risks from implementing exposure controls and work practices.

13. Describe and provide any available reports and data, not mentioned in this notice, on employees experiencing respiratory symptoms, pulmonary function abnormalities, clinical evidence of respiratory disease, or other adverse health outcomes associated with exposure to diacetyl or food flavorings containing diacetyl at your establishment or other establishments where these substances are manufactured or used. Please include information on the nature of the use, processes, job tasks, and exposures.

14. Describe any ongoing efforts to collect information and data that would assist in the identification of adverse health effects associated with diacetyl and food flavorings containing diacetyl. Please provide any currently available reporting information, anticipated date of completion and when the completed research report and/or data collection could be made available to OSHA for the development of a proposed rule.

15. Occupational investigations have reported respiratory symptoms and spirometry abnormalities, particularly reduced FEV₁ and FEV₁/FVC, among employees in jobs involving exposure to diacetyl and food flavorings containing diacetyl. What respiratory symptomatology and declines in these spirometry test values should OSHA consider to be indicative of flavoring-related respiratory disease? Please identify the prevalence of symptoms and other clinical findings associated with various levels of reduction in FEV₁ and FEV₁/FVC. Please cite your sources.

16. Where longitudinal information is available, please describe any progression of symptoms, pulmonary function test results, and other clinical findings or abnormalities that may have preceded cases of bronchiolitis obliterans.

17. Is there any evidence that other potential airway-reactive flavoring compounds, such as those mentioned in the lead paragraph of this section, contribute to flavoring-related respiratory disease? Are there structure activity data that may be useful for predicting compounds likely to cause airway damage? Please explain and provide supporting data.

18. Describe and provide any studies and data related to respiratory tract absorption, clearance, and metabolism of diacetyl or other flavoring agents that may be likely to contribute to flavoring-related respiratory disease. Describe and

provide studies and data pertinent to understanding the mechanism of action by which these compounds may cause adverse respiratory system effects.

19. Research studies report that diacetyl preferentially damages the lining of the nose and upper respiratory tract when inhaled by rats and mice. Should OSHA consider the upper airway damage in experimental animals exposed to diacetyl or butter flavoring vapors as clinically relevant to the respiratory disease that occurs in the lower airways of employees exposed to food flavorings containing diacetyl? Please explain. Are there other examples of toxic agents that damage the nose and upper airways when inhaled by rodents but cause primarily lower airway disease in humans? Please support your response with specific examples and studies.

D. Risk Assessment

OSHA is interested in data that will assist the Agency in developing quantitative estimates of any occupational risk of airway obstruction, fixed airways obstruction, bronchiolitis obliterans, and any other relevant biological endpoints from exposures to diacetyl and food flavorings containing diacetyl.

20. What biological endpoints should OSHA consider to estimate the occupational risk to employees exposed to diacetyl or food flavorings containing diacetyl? Are there endpoints other than airway obstruction, fixed airway obstruction, and bronchiolitis obliterans that OSHA should consider? Please explain.

21. What studies or data should be used to derive a quantitative estimate of the risk resulting from exposure to diacetyl or food flavorings containing diacetyl? OSHA seeks studies, scientific information, and data regarding frequency, intensity, duration, and other parameters of worker exposure in the affected industries, occupations, and activities; key default factors and assumptions; and other relevant information related to the potential development of a health standard regulating diacetyl and food flavorings containing diacetyl.

22. In its risk assessment, how should the Agency treat cross-sectional data describing the prevalence of airway obstruction? Please describe the relationship that might be expected, in an occupational setting, between the prevalence and incidence of airway obstruction.

23. In studies investigating employees exposed to diacetyl or food flavorings containing diacetyl, what proportion, if any, of employees who experienced

airway obstruction in those studies might be expected to develop bronchiolitis obliterans? Please explain your reasoning.

24. When developing dose-response assessments from animal studies, what adjustments and/or scaling factors should OSHA consider to account for species differences between animals and humans in the dose delivered to the lower respiratory tract? Are there toxicokinetic models that can assist in these interspecies extrapolations? Please explain.

25. Some of the job categories associated with higher-than-expected prevalences of airway obstruction involved tasks that generated very high short-term peak exposures to food flavorings containing diacetyl. What role may short-term and cumulative exposures to diacetyl or food flavorings containing diacetyl play in causing health effects and how should OSHA account for this in the risk assessment?

26. What exposure metric(s) (e.g., cumulative exposure, duration of exposure, and short-term task-based exposure) should OSHA consider in assessing the risk associated with exposure to diacetyl or food flavorings containing diacetyl? Are means, geometric means, or medians preferable as measures of central tendency of group exposure data?

27. What statistical methods, models, and data should OSHA consider for estimating the risk from exposure to diacetyl and food flavorings containing diacetyl?

28. What job classifications, tasks, or operations involving diacetyl or food flavorings containing diacetyl may be associated with an elevated occurrence of adverse health effects? For example, some studies have reported higher-than-expected prevalences of airway obstruction in employees performing mixing and quality control tasks.

29. Please describe and provide any studies or data you believe the Agency should consider regarding dose-response behavior and mode of action of diacetyl including physiochemical, metabolic, cellular, mechanistic, and dosimetric considerations. For instance, are adverse health effects dependent on the dose rate and intensity over the exposure period rather than the total cumulative dose received? Please explain. Do the data and mode of action suggest a threshold effect? Please explain.

30. Does the form of diacetyl (e.g., liquid vs. powdered) affect dose-response behavior? For example, does the form of diacetyl affect its respiratory deposition? If so, please explain.

31. Are there any existing risk assessments addressing diacetyl or food flavorings containing diacetyl that OSHA should consider? Please identify and provide.

E. Exposure Assessment and Monitoring Methods

32. Do you conduct exposure monitoring for diacetyl or other chemicals (e.g., acetoin, acetaldehyde, acetic acid, furfural) found in food flavorings? If so, please indicate the chemical(s) sampled for; the method(s) of sampling and analysis used; the type of samples collected (i.e., personal or area samples); the job categories, tasks, operations, or areas where sampling is performed; the duration of sampling (e.g., 8-hour time-weighted average, 15 minute peak); and the frequency of sampling.

33. What type of sampling methods are available for measuring diacetyl in the workplace when it is encapsulated within a powder matrix or adsorbed onto a powder surface? Please provide information on any sampling and analytical methods applicable for determining exposure to diacetyl-containing powders based on total, respirable, thoracic, or inhalable size fractions. Are there any methods under development or any laboratory methods used by food flavorists or food chemists that could potentially be applied? Please provide any information available on the precision and accuracy of the sampling method, the range and limits of detection, and the method of validation of sampling and analysis. Please also provide methods for analysis of diacetyl in bulk process materials.

34. If sampling is conducted by in-house staff to evaluate employee exposure to diacetyl and food flavorings containing diacetyl, please indicate the number of hours required to collect the samples and costs for laboratory analysis. If you engage an outside party to perform sampling and analysis, please indicate the costs incurred.

F. Control Measures

35. To what extent have you or other users reduced or eliminated use of diacetyl or food flavorings containing diacetyl? Please explain how you have achieved those reductions. What substitutes are used for diacetyl? What types of flavorings have been most affected by reduction or elimination of diacetyl use? What types of flavorings are most suitable for change and what types are most difficult to produce without diacetyl? What factors have been responsible for changes in diacetyl use (e.g., employee health concerns, consumer demand)? If you have not

reduced or eliminated the use of diacetyl, what were your reasons for not substituting at this time? OSHA requests that commenters indicate why substitutes for diacetyl have or have not been used, and describe any technological, economic or other barriers or hindrances to substitution. OSHA also requests measurements of employee exposure to substances used as substitutes for diacetyl, and any measurements of employee exposure to diacetyl after substitution, particularly for substitutes which may convert to diacetyl.

36. Have you installed engineering controls or adopted work practices to reduce exposures to diacetyl and food flavorings containing diacetyl? If so, please indicate the types of controls implemented and the operations, tasks, or processes where they have been applied. Please describe whether and to what extent these controls have reduced employee exposure. Please indicate any operations or processes in your facility for which engineering controls are not available or have not been applied. Please explain what difficulties you have encountered in applying engineering controls in those operations.

37. Does your firm limit access to areas where diacetyl or food flavorings containing diacetyl are present in order to control employee exposures to these substances? Please describe the basis for establishing these areas (e.g., operations, exposure levels), methods used to demarcate and control access to the areas, and any obstacles to implementation.

38. Do you provide respirators or other types of personal protective equipment (e.g., gloves) to employees exposed to diacetyl or food flavorings containing diacetyl? If so, describe your program and identify the type of equipment provided, the basis for selection, and any difficulties encountered in implementing your program.

39. Describe the conditions in which respirators and other personal protective equipment are used, including any criteria (e.g., regulated area, exposure level, type of operation, duration of exposure) you use for triggering their use. Are there any processes or areas where it is not possible to use respirators or other protective equipment? Please explain.

G. Employee Training

40. What information and training do you provide to your employees about occupational exposure to diacetyl and food flavorings containing diacetyl? Please describe your training program,

including job categories included in the program, criteria for determining which employees receive information and training, program content, methods of providing information and training, length of training, frequency, and any procedures used to address language or literacy barriers.

41. How do you determine the effectiveness of training? Describe methods used and any factors taken into account in examining the effectiveness of training programs.

H. Medical Surveillance Programs

OSHA is interested in medical surveillance programs that employers use or recommend to identify and monitor employees who exhibit signs, symptoms, or other clinical findings associated with occupational exposure to diacetyl and food flavorings containing diacetyl.

42. Do you have a medical surveillance program to identify or prevent health effects associated with exposure to diacetyl and food flavorings containing diacetyl (this could include a general medical surveillance program that would cover exposure to other chemicals)? Please describe your program. What tests, procedures, examinations, and questions does your program include and at what frequency? Please provide any protocols and standards of care. What are the qualifications and credentials of the health professionals supervising and administering the surveillance program?

43. What criteria (e.g., job categories, duties, exposure levels) do you use or recommend to determine when to provide medical screening or surveillance?

44. What signs, symptoms, test results, or illnesses have been detected or reported that you believe may be related to exposure to diacetyl or food flavorings containing diacetyl? What jobs, tasks, and operations did affected employees perform? What levels of diacetyl were affected employees exposed to (including 8-hour time-weighted averages during an 8-hour work shift and during specific tasks, 15 minute peaks, cumulative exposure, and the duration of exposure, if available)?

45. Have any of your employees been diagnosed with bronchiolitis obliterans? If so, please describe any pulmonary function abnormalities or other clinical signs or symptoms that preceded the diagnosis.

46. If your medical surveillance program includes pulmonary function testing, please describe any cross-sectional findings or longitudinal trends that you have observed. Specifically, what correlations, if any, have you

observed between pulmonary function test results and exposure to diacetyl or food flavorings containing diacetyl (including associations with peak exposures, cumulative exposure, duration of exposure, or particular job classifications, tasks, or operations)? Please describe whether and how findings or trends have varied depending on the form of diacetyl to which employees have been exposed (e.g., powdered vs. liquid formulation).

47. Have you ever removed employees from a job because of adverse health effects attributed to exposure to diacetyl or food flavorings containing diacetyl? If so, please describe the circumstances of the removal, what jobs they were moved into, and potential return. For how long were these employees generally removed? Have any employees ever been permanently removed from a job because of such adverse health effects?

48. Have medical screening and surveillance had any effect on the number and severity of adverse health effects detected or reported?

49. Please describe the costs of medical surveillance for employees exposed to diacetyl and food flavorings containing diacetyl. Where possible, please indicate the number of hours per year the average employee spends on activities related to medical surveillance or screening and how many of those hours are spent traveling to see health care providers. If you employ a health care provider to administer medical surveillance programs, please indicate the number of hours the health care provider spends each year on screening, surveillance and management of employees exposed to diacetyl or food flavorings containing diacetyl. If you do not employ a health care provider to administer medical programs, please indicate the costs per employee for surveillance or screening for adverse health effects associated with diacetyl or food flavorings containing diacetyl. Also, please describe the cost of any equipment or supplies that you have purchased for use in medical programs associated with exposure to diacetyl or food flavorings containing diacetyl.

I. Environmental Impacts

The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, *et seq.*), the Council on Environmental Quality (CEQ) regulations (40 CFR part 1500), and the Department of Labor (DOL) NEPA Compliance Regulations (29 CFR part 11), require that OSHA give appropriate consideration to environmental issues and the impacts of proposed actions that significantly affect the quality of the human environment. OSHA is currently collecting written

information and data on possible environmental impacts that could occur outside of the workplace (e.g., exposure to the community through contaminated air/water, contaminated waste sites) if the Agency were to promulgate a standard for occupational exposure to diacetyl and food flavorings containing diacetyl. Such information should include both negative and positive environmental effects that could be expected to result from a revised standard on occupational exposure to diacetyl or food flavorings containing diacetyl. Specifically, OSHA requests comments and information on the following:

50. What is the potential direct or indirect environmental impact (for example, the effect on air and water quality, energy usage, solid waste disposal, and land use) that might result from a reduction in employee exposure to diacetyl or food flavorings containing diacetyl or the use of substitutes for diacetyl or food flavorings containing diacetyl?

51. Are there any situations in which reducing exposures of diacetyl or food flavorings containing diacetyl to employees would be inconsistent with meeting environmental regulations? (Note: In estimates of control costs, OSHA will account for any costs of meeting air quality requirements associated with increased ventilation controls. The issue here is whether there are situations in which ventilation and other controls would be incompatible with air pollution controls.)

J. Economic Impacts

52. What do you estimate would be the expected costs of a standard to control occupational exposure to diacetyl and food flavorings containing diacetyl? What do you estimate would be the costs for enhanced ventilation controls in your establishments? What do you estimate would be the costs of providing exposure assessments, medical surveillance and training? Please explain how you derived your cost estimates.

53. What are the potential economic impacts associated with a standard to control occupational exposure to diacetyl and food flavorings containing diacetyl? Will the expected costs have a severe impact on your firm or your industry? Please explain. Please indicate what industry segment you represent. Do you anticipate any difficulties in providing exposure assessments, medical surveillance, or training? Please explain.

54. Are there foreign sources of food flavorings containing diacetyl? What are those sources?

55. In response to a standard on occupational exposure to diacetyl or food flavorings containing diacetyl, will firms stop manufacturing or using food flavorings containing diacetyl, or will they implement controls to reduce potential exposures? Can you estimate the share of flavoring manufacturers that will eliminate food flavorings containing diacetyl and the share that will continue to manufacture them? What substances are available now, or might be available in the future, as substitutes for diacetyl or food flavorings containing diacetyl? What would be the costs and economic impacts associated with substituting other flavoring ingredients for diacetyl?

K. Impacts on Small Entities

The Regulatory Flexibility Act requires that OSHA assess the impact of proposed and final rules on small entities (5 U.S.C. 601 *et seq.*). OSHA requests that members of the small business community and others familiar with small business concerns address any special circumstances small entities might face in controlling occupational exposure to diacetyl and food flavorings containing diacetyl. OSHA has already determined that this regulatory action will require a preliminary regulatory flexibility analysis, and thus a Small Business Regulatory Enforcement Fairness Act panel (5 U.S.C. 609(b)).

56. How many and what kinds of small entities perform operations using diacetyl or food flavorings containing diacetyl? What percentage of the affected industries do they comprise?

57. How and to what extent would small entities in your industry be affected by the promulgation of a standard that addresses occupational exposure to diacetyl and food flavorings containing diacetyl? Are there special circumstances that make the control of occupational exposure to diacetyl and food flavorings containing diacetyl more difficult or more costly in small entities? Describe those circumstances.

58. The most important goal of the regulatory flexibility analysis is to find and consider alternatives that may serve to meet the goals of OSHA while alleviating burden on affected small entities. Please suggest and discuss any alternatives that might serve to minimize these impacts.

L. Duplication/Overlapping/Conflicting Rules

59. Are there any Federal rules that might duplicate, overlap, or conflict with any standard that OSHA may promulgate on diacetyl or food flavorings containing diacetyl? If so, please identify which ones and explain

how they would duplicate, overlap, or conflict.

60. Are there any Federal programs in areas such as defense or energy that might be impacted by any standard that OSHA may promulgate on diacetyl or food flavorings containing diacetyl? If so, please identify which ones and explain how they would be impacted.

M. Approaches to Regulation

Most OSHA health standards apply when there is occupational exposure to the substance being regulated. Although OSHA is aware of possible occupational exposures to diacetyl that do not involve food flavorings, the known cases of occupational lung disease are associated with employees exposed to food flavorings containing diacetyl. Employee exposures to diacetyl may occur during processing of foods in which diacetyl occurs naturally, such as dairy products, wine, and beer; when using flavored oils or butter for cooking purposes; when making fragrances; and when adding fragrances to products. Should OSHA cover all occupational exposures to diacetyl under a proposed standard, or should the standard focus on certain industries, processes, or applications? Which sectors should OSHA consider covering under a proposed rule?

61. Acetoin is a plausible contributor to flavoring-related lung disease, given its volatility, structural similarity to diacetyl, and presence in all of the work environments in which elevated prevalence of respiratory disease has been noted. In addition to diacetyl, should OSHA cover occupational exposures to acetoin under a proposed standard? Please indicate the basis for your position and include any supporting evidence.

62. Should OSHA exclude chemical mixtures containing diacetyl at concentrations below a certain threshold from coverage under a proposed standard? If so, what threshold (*i.e.*, percent content) should OSHA consider? Please indicate the basis for your position and include any supporting evidence.

63. Should OSHA propose a permissible exposure limit (PEL) for diacetyl or, instead, should the Agency propose process-specific requirements for engineering controls, exposure monitoring, exposure control planning, and respiratory protection (*i.e.*, a non-PEL approach)? Although a PEL approach would be consistent with the majority of the Agency's previous standards that regulate chemical hazards, OSHA typically relies on specified engineering and work practice controls in regulating safety hazards, so

such an approach would not be novel. OSHA welcomes comments on the merits of the two approaches as well as any other approaches to addressing occupational exposure to diacetyl and food flavorings containing diacetyl.

64. What provisions should OSHA include in a proposed standard addressing occupational exposure to diacetyl and food flavorings containing diacetyl? OSHA substance-specific health standards typically include provisions for exposure monitoring, regulated areas, methods of compliance, respiratory protection, protective clothing and equipment, medical surveillance, and training, as well as other requirements. Please indicate what provisions would or would not be appropriate for protecting employees from exposure to diacetyl and food flavorings containing diacetyl, and explain the reasons for your position.

65. The California Division of Occupational Safety and Health (Cal/OSHA) has initiated rulemaking proceedings on diacetyl and other food flavorings. In March 2007, Cal/OSHA released a draft regulatory text titled "Occupational Exposure to Food Flavorings" (Cal/OSHA, 2007). The draft regulatory text includes requirements for exposure assessment, engineering and work practice controls, respiratory protection, medical surveillance, training and labeling, and recordkeeping, but does not establish a PEL. Are there any provisions in the draft that OSHA should include in a proposed rule on occupational exposure to diacetyl or food flavorings containing diacetyl? Are there any aspects of the draft that you consider inappropriate? Please explain.

66. NIOSH has issued an alert entitled "Preventing Lung Disease in Workers Who Use or Make Flavorings" as well as recommendations for minimizing employee exposures to flavorings and flavoring ingredients (NIOSH, 2003). Are there any provisions or recommendations in those documents that OSHA should include in a proposed rule on occupational exposure to diacetyl or food flavorings containing diacetyl? Do you consider any of the provisions or recommendations inappropriate? Please explain.

III. Public Participation

You may submit comments in response to this document (1) Electronically at <http://www.regulations.gov>, (2) by hard copy, or (3) by facsimile (FAX). All comments, attachments, and other materials must identify the Agency name and the docket number for this document (Docket No. OSHA-2008-0046). You

may supplement electronic submissions by uploading document files electronically. If, instead, you wish to mail additional materials in reference to an electronic or FAX submission, you must submit three copies to the OSHA Docket Office (see **ADDRESSES** section). The additional materials must clearly identify your electronic or FAX comments by name, date, and docket number so OSHA can attach them to your comments.

Because of security-related problems there may be a significant delay in the receipt of comments by regular mail. For information about security procedures concerning the delivery of materials by express delivery, hand delivery, and messenger or courier service, please contact the OSHA Docket Office at 202-693-2350 (TTY 877-889-5627).

All comments and submissions in response to this **Federal Register**, including personal information, are placed in the public docket without change. Therefore, OSHA cautions against submitting certain personal information such as social security numbers and birthdates. All comments and submissions are listed in the <http://www.regulations.gov> index; however, some information (for example, copyrighted material) is not publicly available to read or download through the Web site. All comments, submissions, and supporting materials are available for inspection and copying at the OSHA Docket Office (see the **ADDRESSES** section of this notice). Information on using <http://www.regulations.gov> to submit comments and access dockets is available at that Web site. Contact the OSHA Docket Office (see **ADDRESSES** section) for information about materials not available through the OSHA Web site and for assistance in using the Web site to locate and download docket submissions.

Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This document, as well as news releases and other relevant documents, are also available at OSHA's Web site at <http://www.osha.gov>.

IV. References

- Akpinar-Elci M, Travis WD, Lynch DA, Kreiss K. 2004. Bronchiolitis Obliterans Syndrome in Popcorn Production Plant Workers, *Eur Respir J*. 2004; 24:298-302.
- Bibek R. 2004. *Fundamental Food Microbiology*, CRC Press, pp. 228 and 608.
- Cal/OSHA. 2007. Occupational Exposure to Food Flavorings (Draft Regulatory Text). California Department of Industrial Relations, Division of Occupational Safety and Health.

- CDC. 2007. Fixed Obstructive Lung Disease Among Workers in the Flavor-Manufacturing Industry—California, 2004–2007, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report. 56(16):389–393.
- ConAgra Foods. 2007. News Release: ConAgra Foods Introduces Orville Redenbacher's® and Act II® Microwave Popcorn with a New Great Tasting Butter Flavoring with No Added Diacetyl. ConAgra Foods, Inc.
- ERG. 2007. Support for the Development of Economic Profile Data of Diacetyl-Using Industries (Microwave Popcorn and Flavoring). Eastern Research Group, Inc. Interim Final Report: Task Order No. 12, Contract No. GS–10F–0125P.
- Egilman D, Mailloux C, Valentin C. 2007. Popcorn-worker Lung Caused by Corporate and Regulatory Negligence: An Avoidable Tragedy. Intern. J. Occupational Environ. Health 13:85–98.
- FEMA. 2005. Flavor and Extract Manufacturers Association. Poundage and Technical Effects Update Survey, p. 61.
- Hubbs AF, Battelli LA, Goldsmith WT, Porter DW, Frazer D, Friend S, Schwegler-Berry D, Mercer RR, Reynolds JS, Grote A, Castranova V, Kullman G, Fedan JS, Dowdy J, Jones WG. 2002. Necrosis of nasal and airway epithelium in rats inhaling vapors of artificial butter flavoring. Toxicol Appl Pharmacol 185(2):128–35.
- Hubbs AF, Goldsmith W, Kashon M, Frazer D. 2008. Respiratory Toxicologic Pathology of Inhaled Diacetyl in Sprague-Dawley Rats, Toxicol. Pathol. 36(2):330–344.
- Kanwal R. 2008. Bronchiolitis Obliterans in Workers Exposed to Flavoring Chemicals, Curr. Opin. In Pulmon. 14:141–146.
- Kanwal R, Kullman G, Piacitelli C, Boylstein R, Sahakian N, Martin S, Fedan K, Kreiss K. 2006. Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants, JOEM 48(2):149–157.
- Kreiss K, Gomaa A, Kullman G, Fedan K, Simoes EJ, Enright PL. 2002. Clinical Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant, New England J. of Med. 347(5):330–338.
- Lockey J, McKay R, Barth E, Dahlsten J, Baughman R. 2002. Bronchiolitis Obliterans In The Food Flavoring Manufacturing Industry. Meeting of the American Thoracic Society.
- Lone Star Candle Supply. 2003. Material Safety Data Sheet for Marshmallow Madness Fragrance Oil.
- Martyny JW, Van Dyke M, Arbuckle S, Towle M, Rose CS. 2008. Diacetyl Exposure in the Flavoring Industry. Journal of Occupational and Environmental Hygiene 5:679–688.
- Materna B. 2007. Summary of eight known cases of confirmed or obstructive lung disease in California food flavor manufacturing workers. January 11, 2007.
- Morgan D, Flake GP, Kirby PJ, Palmer SM. 2008. Respiratory Toxicity of Diacetyl in C57BL/6 Mice, Toxicol. Sci. 105(2):429–32.
- NIOSH. 1986. Health Hazard Evaluation Report. HETA–85–171–1710: International Bakers Services, Inc., South Bend, Indiana.
- NIOSH Alert. 2003a. Preventing Lung Disease in Workers Who Use or Make Flavoring. DHHS Publication Number 2004–110.
- NIOSH 2003b. NIOSH Manual of Analytical Methods. Diacetyl: Method 2557 Issue 1:15 March.
- NIOSH. 2007a. Health Hazard Evaluation Report. HETA–2007–0033: Gold Coast Ingredients, Inc., Commerce, California. Interim Report.
- NIOSH. 2007b. Health Hazard Evaluation Report. HETA 2006–0303–3043: Report on Severe Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant. Carmi Flavor and Fragrance Company, Inc., Commerce, CA.
- OSHA. 2007a. Diacetyl and Food Flavorings Containing Diacetyl Stakeholder Meeting Notes Stakeholder Meeting, Arlington, Virginia (October 17, 2007), Meeting Summary Report. Available at: <http://www.osha.gov/dsg/guidance/101707-diacetyl-meeting-notes.html>.
- OSHA. 2007b. National Emphasis Program—Microwave Popcorn Processing Plants. Directive No. CPL 03–00–005. Available at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=3649.
- OSHA. 2007c. Respiratory Disease Among Employees in Microwave Popcorn Processing Plants. Safety and Health Information Bulletin SHIB 09–24–07 Available at: <http://www.osha.gov/dts/shib/shib092107.html>.
- OSHA. 2007d. Hazard Communication Guidance for Diacetyl and Food Flavoring Containing Diacetyl. Available at: <http://www.osha.gov/dsg/guidance/diacetyl-guidance.html>.
- Parmet AJ, Von Essen S. 2003. Rapidly Progressive, Fixed Airway Obstructive Disease in Popcorn Workers: A New Occupational Pulmonary Illness? JOEM 44(3):216–218.
- Pop Weaver®. 2007. Pop Weaver Introduces the First Microwave Popcorn with Flavoring Containing No Diacetyl. Available at: <http://www.popweaver.com/PopWeaverNoDiacetyl.pdf>.
- Rose C, VanDyke M, Ellison M, Towle M, Martyny J. 2007. Respiratory Symptoms and Airflow Limitation in Flavoring Manufacturing Workers. Am J Respir Crit Care Med 175:A17.
- Turin L. 2007. Diacetyl Derivatives. World Intellectual Property Organization. Available at: <http://www.wipo.int/pctdb/en/wo.jsp?LA=US2006026827&DISPLAY=STATUS>.
- Van Rooy, FGBJ, Rooyackers, JM, Prokop M, Houba R, Smit LAM, Heederik DJJ. 2007. Bronchiolitis Obliterans Syndrome in Chemical Workers Producing Diacetyl for Food Flavorings. Am J Respir Care Med 176:498–504.
- Van Rooy FGBJ, Smit L, Houba R, Zaat VAC, Rooyackers J, Heederik DJJ. 2008. A Cross Sectional Study on Lung Function and Respiratory Symptoms Among Chemical Workers Producing Diacetyl for Food Flavoring. Occup Environ Med. Sept. 19, 2008.

V. Authority and Signature

This document was prepared under the direction of Thomas M. Stohler, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor. It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911, and Secretary's Order 5–2007 (72 FR 31160).

Signed at Washington, DC, this 14th day of January 2009.

Thomas M. Stohler,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. E9–1125 Filed 1–16–09; 8:45 am]

BILLING CODE 4510–26–P