



OSHA INSTRUCTION

U.S. DEPARTMENT OF LABOR

Occupational Safety and Health Administration

DIRECTIVE NUMBER: CPL 03-00-011

EFFECTIVE DATE: 10/30/09

SUBJECT: National Emphasis Program –Facilities that Manufacture Food Flavorings Containing Diacetyl

ABSTRACT

Purpose: This Instruction describes policies and procedures for implementing a National Emphasis Program (NEP) to identify and reduce or eliminate hazards associated with exposures to flavoring chemicals in facilities that manufacture food flavorings containing diacetyl.

Scope: This Instruction applies OSHA-wide.

- References:**
- A. OSHA Instruction CPL 02-00-148, March 26, 2009, Field Operations Manual (FOM).
 - B. OSHA Notice 09-05 (CPL 02)-Site-Specific Targeting 2009 (SST-09) Effective, July 20, 2009.
 - C. OSHA Instruction CPL 02-02-038, March 20, 1998, Inspection Procedures for the Hazard Communication Standard (HCS).
 - D. OSHA Instruction CPL 02-00-120, September 25, 1998, Inspection Procedures for the Respiratory Protection Standard.
 - E. OSHA Instruction CPL 02-00-025, January 4, 1995, Scheduling Systems for Programmed Inspections.
 - F. OSHA Memorandum for Regional Administrators, Area Directors, State Plan Designees, Consultation Program Managers, October 12, 2004, Subject: Popcorn/Flavoring Establishment Assistance.
 - G. OSHA Publication “Hazard Communication Guidance for Diacetyl and Certain Food Flavorings Containing Diacetyl.” September 24, 2007.

- H. OSHA Safety and Health Information Bulletin (SHIB), Respiratory Disease Among Employees in Microwave Popcorn Processing Plants, September 24, 2007.
- I. OSHA Directive CPL 03-00-005, July 27, 2007, National Emphasis Program -Microwave Popcorn Processing Plants.
- J. OSHA Safety and Health Information Bulletin (SHIB), Occupational Exposure to Flavoring Substances: Health Effects and Hazard Control (soon to be released).
- K. OSHA Instruction CPL02-02-072, August 22, 2007, Rules of Agency Practice and Procedures Concerning OSHA Access to Employee Medical Records.
- L. NIOSH Health Hazard Evaluation Report, HETA # 2000-0401-2991, Gilster-Mary Lee Corporation, Jasper, Missouri, January 2006.
- M. NIOSH Health Hazard Evaluation Report, HETA # 2006-0303-3043, Severe Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant, April 2007.
- N. Morbidity and Mortality Weekly Report (MMWR). Fixed Obstructive Lung Disease Among Workers in the Flavor- Manufacturing Industry--- California, 2004-2007. MMWR Weekly 56(16);389-393, 2007

Cancellations: None.

State Impact: States with establishments that fall within the scope of this NEP are encouraged to participate in this national emphasis effort. State notice of intent regarding this direction is required. (See Paragraph VI.)

Action Offices: OSHA National, Regional and Area Offices, State Plan and State On-site Consultation Offices

Originating Office: Office of Health Enforcement

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By and Under the Authority of

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Executive Summary

In January 2006, the National Institute for Occupational Safety and Health (NIOSH) released a final Health Hazard Evaluation Report on its investigation at a microwave popcorn production facility. Several employees from this facility were diagnosed with bronchiolitis obliterans, a severe obstructive lung disease. Following this investigation and the evaluation of lung function tests and air sampling results, NIOSH determined that inhalation exposure to butter-flavoring chemicals presents a risk for occupational lung disease. In April 2007, the Centers for Disease Control and Prevention (CDC) reported in its Morbidity and Mortality Weekly Report (MMWR) seven additional cases of bronchiolitis obliterans in employees working in facilities where flavorings were manufactured. This instruction establishes an NEP to identify and reduce or eliminate hazards associated with employee exposure to flavoring chemicals in facilities that manufacture food flavorings containing diacetyl. Diacetyl is one of the most common compounds found during investigations of microwave popcorn and flavoring manufacturing facilities. This NEP provides guidance on targeting, inspection procedures, engineering controls, work practice controls, and compliance assistance.

Significant Changes

None. This Instruction describes a new enforcement initiative by the Occupational Safety and Health Administration.

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- I. Purpose. This Instruction describes a Federal program change which establishes policies and procedures for implementing an NEP to identify and reduce or eliminate hazards associated with exposure to flavoring chemicals in facilities that manufacture food flavorings containing diacetyl. This NEP does not apply to diacetyl that occurs naturally, nor does it apply to facilities that use flavoring chemicals in the manufacturing of food products.

- II. Scope. This Instruction applies OSHA-wide.

- III. References.
 - A. OSHA Instruction CPL 02-00-148, March 26, 2009, Field Operations Manual (FOM).
 - B. OSHA Notice 08-07 (CPL 02) – Site-Specific Targeting 2008 (SST-08) Effective, November 5, 2008.
 - C. OSHA Instruction CPL 02-02-038, March 20, 1998, Inspection Procedures for the Hazard Communication Standard (HCS).
 - D. OSHA Instruction CPL 02-00-120, September 25, 1998, Inspection Procedures for the Respiratory Protection Standard.
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- N. Morbidity and Mortality Weekly Report (MMWR): Fixed Obstructive Lung Disease Among Workers in the Flavor-Manufacturing Industry California, 2004-2007. April 27, 2007/56(16):389-393.

IV. Cancellations. None.

V. Action Offices.

A. Responsible Office Directorate of Enforcement Programs, Office of Health Enforcement.

B. Action Offices National, Regional and Area Offices; On-site Consultation Projects.

C. Information Offices OSHA National Offices.

VI. Federal Program Change/Notice of Intent Required. This Instruction describes Federal program change which establishes an NEP to identify and reduce or eliminate hazards associated with exposures to flavoring chemicals in facilities that manufacture food flavorings containing diacetyl. States where employees are exposed to such hazards in covered manufacturing facilities are encouraged to participate in this national emphasis effort. State notice of intent regarding this directive is required.

The State's notice of intent must indicate whether the State currently has or will initiate an emphasis program and if so, whether the State's program will be identical to or different from the Federal Program. The State's implementation policies and procedures are expected to be at least as effective as those in this instruction and must be available for review. If the State's new or existing program differs from the Federal one, the State may either post its different emphasis program on its State plan Web site and provide the link to OSHA or provide a copy to OSHA with information on how the public may obtain a copy. If the State adopts an identical emphasis program, it must provide the date of adoption to OSHA. OSHA will provide summary information about the State responses to this instruction on its Web site. States should code any inspection conducted under this emphasis program as directed in section XIV.G of this Instruction.

- VII. Expiration. This Instruction will expire three (3) years from the date of issuance.
- VIII. Significant Changes. There are no significant changes. This is a new program.
- IX. Application. This Instruction applies to all establishments that manufacture natural and or artificial food flavorings (as defined by the Food and Drug Administration (FDA) in 21 CFR 101.22: <http://www.fda.gov/RegulatoryInformation>) containing diacetyl. This NEP does not apply to naturally occurring diacetyl, nor does it apply to facilities that use flavoring chemicals in the manufacture of food products.
- X. Background.

In 2000, the Missouri Department of Health and Senior Services (MDHSS) and NIOSH conducted an investigation of a microwave popcorn processing plant in Jasper, Missouri (Ref.2). Nine former employees had been diagnosed with a rare, severe lung disease called bronchiolitis obliterans characterized by the finding of fixed airways obstruction on lung function tests (see next section “Fixed Airways Obstruction and Bronchiolitis Obliterans”). The employees reported similar symptoms, including progressive shortness of breath with exertion, persistent cough, and fatigue. The NIOSH investigation of the plant found that other employees working in the plant had symptoms and lung function abnormalities (fixed airways obstruction) similar to the original nine former employees (Ref.1,2,3). Diacetyl, a butter flavoring chemical, was the predominant chemical isolated from air samples in the facility and was used by NIOSH as a marker for exposure to volatile organic compounds (VOC) during the investigation (Ref.1). The investigation of the Jasper plant concluded that there was a risk for occupational lung disease in employees with inhalation exposure to butter flavoring (Ref.2). Five of the nine original employees diagnosed with bronchiolitis obliterans were considered candidates for lung transplants (Ref.3). One of the ill employees died in 2006.

Since 2000, NIOSH has investigated a total of six microwave popcorn manufacturing facilities and has documented similar lung disease in employees (Ref.4,5). NIOSH researchers identified employees who had fixed airways obstruction in five of these plants, including employees with clinical findings consistent with bronchiolitis obliterans. The study of these six facilities concluded that employees exposed to butter flavorings were at risk of developing occupational lung disease. The study also concluded that peak exposures to butter flavoring may be hazardous, even with low average exposures in the workplace (Ref.5).

Similar cases of occupational lung disease have been identified in employees working in flavoring manufacturing facilities in California. In 2004, an employee working in a flavoring manufacturing plant was diagnosed with bronchiolitis

obliterans. The published case report stated that diacetyl was considered the cause of the employee's disease although exposure to other flavoring substances may also have contributed (Ref.6). In April 2006, another flavoring manufacturing employee in California was diagnosed with bronchiolitis obliterans, and five other employees were found to have lung disease characterized by severe fixed airways obstruction. Six of the seven employees identified in California were flavoring compounders who mixed and handled flavoring substances including diacetyl. The other employee packaged powdered flavorings, some of which included diacetyl (Ref.6,7,8). In 2008 a case report was published describing an employee in a flavoring manufacturing plant in Britain who developed pulmonary symptoms and non-reversible lung function changes. The employee intermittently worked with diacetyl and developed symptoms of chest tightness and shortness of breath four months after an episode where he was exposed for several hours to a reportedly acute, high concentration of diacetyl. Per the study, the employee's symptoms and lung function did not improve even after removal from the workplace (Ref.9).

Cases of lung disease have also been reported among employees who worked in a chemical production plant that produced diacetyl for the flavoring industry. This group of employees was exposed to diacetyl, as well as acetoin (a chemical structurally-related to diacetyl), acetic acid, acetaldehyde, chlorine and ammonia. The study identified at least 4 cases of bronchiolitis obliterans among 206 employees that were exposed during the period of diacetyl production from 1960 - 2003. The authors concluded that exposure to an agent during diacetyl production appeared to be responsible for the cases of bronchiolitis obliterans that were diagnosed in this group of employees (Ref.10).

The occurrence of severe fixed airways obstruction, including the rare lung disease bronchiolitis obliterans, demonstrates the potential risk to employees from uncontrolled airborne exposures to flavoring substances (Ref.4, 5). As of April 2007, an additional 22 flavoring manufacturing employees in California were undergoing medical evaluations due to abnormalities on lung function tests. Information from 28 flavoring manufacturing plants in California is currently being evaluated to gain a better understanding of work-related risk factors for development of occupational lung disease (Ref.6). NIOSH has also received reports of cases of bronchiolitis obliterans in flavoring manufacturing facilities in Ohio, New Jersey and in Maryland (after a dimethylphenol spill) (Ref.6,11,12).

Flavorings are complex mixtures of chemicals and the inhalational toxicities of many of these substances have not been evaluated (Ref.5). Other volatile flavoring substances, in addition to diacetyl, were found in air samples during NIOSH investigations of microwave popcorn plants and flavoring manufacturing facilities. It is possible that some of these substances may have a role in the development of the lung disease found in these facilities. Scientists from NIOSH, National Jewish Medical Center, the National Institute for Environmental Health Studies (NIEHS), and other researchers are currently investigating the role of

various flavoring substances in the development of fixed airways obstruction and bronchiolitis obliterans.

Fixed Airways Obstruction and Bronchiolitis Obliterans

The lung disease identified in the NIOSH investigations of popcorn and flavoring manufacturing plants is usually characterized by findings of fixed airways obstruction on spirometry (a common type of pulmonary function test, or PFT). Airways obstruction is diagnosed when the person tested has difficulty blowing air out of the lungs. Fixed airways obstruction means that spirometry shows little or no improvement in lung function after administration of medication (i.e., bronchodilators) (Ref.2,4). In addition to fixed airways obstruction, a few employees in both the microwave popcorn and flavoring manufacturing industries have demonstrated lung function tests consistent with restriction, which is a decreased ability to expand the lungs (Ref.2,4,8).

The symptoms seen in these employees include cough, fatigue, shortness of breath with exertion, and nasal and sinus irritation and inflammation. Symptoms generally do not improve when employees go home for the weekend or go on vacation (Ref.1,2). Symptoms usually have a gradual onset, but in some cases severe symptoms have occurred suddenly with rapid progression of lung disease (Ref.4,8). Early lung function decline can have minimal or no symptoms (Ref.4). For example, during a NIOSH investigation of a flavoring facility, one employee had a very large decline in lung function over a 4.5-month period. This employee did not report any symptoms despite his loss of lung function (Ref.8).

Bronchiolitis obliterans is a rare, potentially life-threatening lung disease characterized by cough, shortness of breath with exertion, and spirometry findings of fixed airways obstruction (Ref.13). Constrictive bronchiolitis obliterans occurs when the smallest airways of the lung become inflamed and scarred, resulting in thickening and narrowing of the airways. Established occupational risk factors for development of bronchiolitis obliterans include inhalation of toxic fumes, grain dusts, mineral dusts, and irritant gases (Ref.4,14,15). The diagnosis of bronchiolitis obliterans is usually confirmed by additional medical tests, including paired inspiratory and expiratory high-resolution computerized tomography scans (HRCT).

The initial signs and symptoms of fixed airways obstruction including bronchiolitis obliterans may be subtle. Affected employees may be misdiagnosed with other lung diseases such as asthma or chronic obstructive pulmonary disease (Ref.16). Even when diagnosed correctly, employees with fixed airways obstruction including bronchiolitis obliterans have not had improved lung function with treatment (e.g., corticosteroid medications). While a few employees have noticed gradual improvement in their cough several years after removal from exposure, their pulmonary function has never improved and they continue to have shortness of breath with exertion. As noted earlier, some of these employees have

developed such severe, disabling lung disease that they have been placed on lung transplant waiting lists (Ref.3).

Flavorings

Flavorings can be either natural or man-made substances. Some flavorings are simple and made up of only one chemical, but many others are complex mixtures of several substances. When properly compounded, these mixtures provide the fragrance and taste perception of a specific flavor, such as butter or strawberry. There are more than 2,000 substances used to manufacture flavorings (Ref.17). The Food and Drug Administration (FDA) regulates flavorings for safety when eaten, but it does not require testing by other routes of exposure, such as inhalation.

Occupational exposure to flavoring substances usually occurs via inhalation or skin contact, not the oral route of exposure evaluated by the FDA. Appendix D of this NEP entitled Guidelines for Air Sampling identifies flavoring substances, some of which have OSHA permissible exposure limits (PELs). Most of these substances also have industry applications other than for use as flavoring. Most of the substances listed in Appendix D are respiratory tract irritants, and some are also associated with potentially severe respiratory illnesses such as asthma and pulmonary edema (fluid in the lungs).

The Flavor and Extract Manufacturers Association (FEMA), a trade association for the flavorings industry, has identified a number of flavoring substances for their potential to pose respiratory hazards in flavoring manufacturing workplaces. FEMA has identified 34 "high priority" flavoring substances that may pose a respiratory hazard in the workplace and which "merit a higher degree of attention" including consideration of work practice controls, engineering controls, and personal protective equipment (PPE). FEMA also identified 48 "low priority" substances which may pose a respiratory hazard depending on the circumstances of exposure or use, such as when used in very large volumes or when heated or blended in a manner resulting in high air concentrations. In these situations, more attention is recommended regarding workplace exposure control and safety measures (Ref.17). Diacetyl, acetoin, and acetaldehyde are some examples of FEMA high priority substances found in flavorings analyzed during NIOSH investigations of microwave popcorn and flavoring manufacturing facilities.

Diacetyl

Diacetyl (Ref.2,3-butanedione), a diketone, is used to produce a butter flavor in foods and occurs naturally in some foods, such as dairy products, wine, and beer (Ref.17,18,19). NIOSH identified diacetyl as one of the most common VOCs found during investigations of microwave popcorn and flavoring manufacturing facilities. It may be found in other types of flavorings in addition to butter

flavorings. For example, diacetyl was used in the production of a vanilla flavoring powder during a NIOSH investigation of a California flavoring manufacturing facility (Ref.7). Diacetyl reacts with the amino acid arginine (Ref.20) and inhibits enzymes containing arginine that are important for protecting cells from oxidative damage (Ref.21, 22). Diacetyl does not have an OSHA PEL or a NIOSH Recommended Exposure Level (REL), although OSHA has initiated rulemaking for flavorings containing diacetyl pursuant to its authority under Section 6(b) of the Occupational Safety and Health Act.

Diacetyl has been detected and used as a marker for flavoring exposure in NIOSH investigations in microwave popcorn and flavoring manufacturing facilities where cases of fixed obstructive lung disease, including bronchiolitis obliterans, have been diagnosed (Ref.5, 7). One NIOSH investigation of a California flavoring manufacturing plant found three employees with lung disease consistent with bronchiolitis obliterans. All three employees were involved in the production of powdered flavorings. The production room had the highest time-weighted average diacetyl concentrations. All other areas of the plant had lower levels. The highest levels of diacetyl were measured during the production of powdered flavorings. The highest peak diacetyl concentrations were measured when employees poured liquid diacetyl into the ribbon blender, when a butter flavoring powder (finished product) was dispensed into boxes, and during blender cleaning operations (Ref.7).

In some facilities, flavoring manufacturers have replaced diacetyl with alternative flavoring chemicals. Some manufacturers have substituted acetyl propionyl (2,3 pentanedione) and diacetyl trimer in formulating butter and other flavorings. However, these substances have not been tested and it is unclear whether they pose health risks. There is specific concern that diacetyl may be released from diacetyl trimer under certain manufacturing conditions that involve heat and the presence of water as well as in the moist environment of the respiratory track after inhalation.

Additional Flavoring Substances Identified in NIOSH Investigations

In addition to diacetyl, over 150 VOCs were identified when emissions from 40 samples of butter flavorings from six microwave popcorn facilities were analyzed (Ref.26). Acetoin (acetyl methyl carbinol) is a ketone that has been consistently found during investigations of microwave popcorn manufacturing plants. NIOSH also identified acetoin as a predominant chemical in the production room of a California flavoring manufacturing plant (Ref.7). Acetoin was also found in a diacetyl chemical manufacturing facility where four employees developed bronchiolitis obliterans (Ref.10). Acetoin is very similar in chemical structure to diacetyl. It is anticipated that some diacetyl may be metabolized to acetoin in humans. The National Toxicology Program is planning inhalation toxicology studies on acetoin as part of a testing nomination for artificial butter flavoring and its ingredients (Ref.27). Acetoin does not have an OSHA PEL. It is irritating to

the skin, eyes, mucous membranes, and respiratory tract (Ref.2).

Furfural and acetic acid were also identified during the analysis of VOCs emitted from certain butter flavorings (Ref.26). Studies of rats exposed to furfural 6 hours/day, 5 days/week for 28 days reported changes in nasal tissue at concentrations as low as OSHA's PEL of 5 parts per million (ppm) for furfural (Ref.28). In an earlier study, rats exposed to concentrations of 38 ppm furfural for one hour/day, 5 days/week for 30 days had tissue changes in the lungs around the bronchioles and small blood vessels (Ref.29).

The OSHA PEL for acetic acid is 10 ppm. Acetic acid is irritating to the skin, eyes and the respiratory tract. It was detected in the mixing room of the Jasper microwave popcorn manufacturing plant (Ref.2). NIOSH also reported that acetic acid was a predominant airborne chemical in the production room of a California flavoring manufacturing plant (Ref.7).

Another common flavoring substance, acetaldehyde, has been identified in air samples in several microwave production facilities. The OSHA PEL for acetaldehyde is 200 ppm (Ref.1, 26). Acetaldehyde is highly irritating to the eyes, nose, and throat (Ref.2). Occupational exposure to acetaldehyde was reported in a flavor manufacturing facility where five employees developed fixed airways obstruction. One of these employees reported developing respiratory symptoms (shortness of breath and coughing) after pouring acetaldehyde into a flavoring mixture. Two months later the employee developed shortness of breath with exertion and lung function tests indicated that the employee had fixed airways obstruction (Ref.4).

In addition to VOCs, respirable dust may be produced from the handling of powdered flavoring formulations or spices. Inhalation of these respirable particles (i.e., particles less than 10 microns (μm) in diameter) may result in flavoring exposure directly to the small airways of the lung (Ref.26). Exposure to garlic dust or aniseed dust has been associated with the development of occupational asthma (Ref.30,31). Individual case reports have described other lung diseases such as bronchiolitis obliterans organizing pneumonia after exposure to spice dust in a potato chip factory, and interstitial pneumonia after exposure to curry and pepper dust in a curry sauce factory (Ref.32,33).

Currently, OSHA is in the process of developing a diacetyl standard. OSHA does not have specific PELs for many of the substances used in the flavoring industry, and NIOSH has not recommended any exposure levels. However, NIOSH has recommended that facilities that use or manufacture flavorings implement engineering and work practice control measures to minimize employee exposure during working conditions that may place employees at risk (Ref.3). Specifically NIOSH has recommended that the use of respiratory protection be mandatory for all mixers and employees entering the mixing room until such time as the production process is reengineered or enclosed to eliminate exposures to flavoring

chemicals (Ref.7).

XI. National Emphasis Program Goals.

- A. To minimize and/or eliminate employee exposure to the hazards associated with food flavoring chemicals in facilities that manufacture food flavorings containing diacetyl. Reduction and/or elimination of these exposures will help to prevent the occurrence of skin and eye injuries as well as occupational lung disease and illness, including fixed airways obstruction and bronchiolitis obliterans, restriction, and other pulmonary abnormalities.
- B. To accomplish this goal, OSHA will implement a combined effort that includes inspection targeting and outreach to employers and employees.
- C. Inspections will be directed to the facilities described in section XII below and other establishments known to manufacture food flavorings containing diacetyl.

XII. Program Procedures.

A. Site Selection.

1. Targeting Sources.

- a. Inspections conducted under this NEP will focus on facilities where employees are manufacturing food flavorings which contain diacetyl for use in foods, beverages, and other consumer products.
- b. Eighty three (83) facilities in Federal enforcement states have been identified as facilities that manufacture food flavorings containing diacetyl. A list of these facilities is posted on the Directorate of Enforcement Programs (DEP) intranet web site. An additional number of facilities in State Plan States are also posted.

NOTE: This list is for internal scheduling purposes only and shall not be released to the public.

- c. Sites not included on the DEP Intranet list, but that are known to the Area Office to be manufacturing food flavorings containing diacetyl, shall be added to the inspection targeting list for that Area Office.

2. Inspection Scheduling.

- a. All 83 facilities posted on the Intranet must be inspected. Area Offices must inspect at least three facilities per year under this NEP until they have inspected all of the facilities on the DEP list that fall within their jurisdiction, as well as any facilities they know to be manufacturing food flavorings containing diacetyl.
- b. For reporting purposes, all enforcement inspections under this NEP will be reported as “Health” inspections on the IMIS. Any establishment previously visited, but not inspected, under the Microwave Popcorn Manufacturing NEP may be revisited and inspected under this NEP.

3. Deletions.

Any facility that has received an inspection where OSHA evaluated employee exposures to food flavoring chemicals within the two (2) years prior to the effective date of this Directive shall be deleted from the list if OSHA has documentation that no hazardous exposures were identified or that the employer instituted effective engineering and work practice controls and provided respirators (where necessary) and appropriate personal protective equipment.

B. Complaints and Referrals.

Inspections at facilities that manufacture food flavorings containing diacetyl that result from complaints or referrals alleging employee exposure to safety or health hazards other than those addressed by this NEP shall be expanded to address the hazards targeted by this NEP. For further guidance, CSHOs should refer to the FOM.

C. Programmed Inspections.

Some establishments covered by this NEP may be selected for inspection under the Site-Specific Targeting (SST) plan or under one or more other OSHA initiatives (NEPs or Local Emphasis Programs (LEPs)). This NEP shall be run **concurrently** with the SST plan and any other NEPs or LEPs. This NEP has equal priority as the SST plan.

Whenever an establishment to be inspected under this NEP is also scheduled for inspection on the current cycle of the SST plan, the inspections may be scheduled at the same time. CSHOs shall use all IMIS codes applicable for the inspection. The employer’s Data Universal Numbering System (DUNS) number must also be recorded for each

inspection.

In cases where an establishment is scheduled for inspection under both the SST and this NEP, an inspection addressing the issues targeted by the NEP must be conducted even if all CSHO-calculated days away, restricted or transferred (DART) rates for the establishment are found to be below the SST inspection thresholds.

B. Expanding Scope of Inspection.

Inspections under this NEP shall normally be limited to evaluating employee exposure to the hazards described in this Instruction, but the CSHO may expand the scope of the inspection if other safety and health hazards or violations are observed or the facility is covered under another LEP or NEP, such as amputations.

XIII. Outreach.

OSHA will not begin enforcement activity until at least 60 days after the effective date of this NEP. During that time, and for the duration of this NEP, the following outreach efforts will be conducted.

- A. The OSHA Training Institute (OTI) will develop OSHA training and outreach programs to support enforcement efforts under this NEP. OTI has posted a Diacetyl webcast at: <https://learninglink.dol.gov> # 0020.
- B. The Office of Communications will draft news releases to national news organizations.
- C. The Regional Offices should consult with the States to ensure that they are addressing flavoring related problems during their consultation visits.
- D. Guidelines for Area Office outreach activities are provided in Appendix I. Suggested outreach activities include:
 - 1. Letters and news releases to local news organizations and trade magazines disseminating information about this NEP. Letters should be sent alerting employers to this NEP, the upcoming Safety and Health Information Bulletin (SHIB) on flavorings (when it is complete), and NIOSH's most recent reports:
 - The 2007 Report - NIOSH Kanwal: Report on Severe Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant. National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation Report #2006-0303-3043, April 2007

- The 2006 Report - NIOSH: Gilster-Mary Lee Corporation - Jasper, Missouri. National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation Report #2000-0401-2991, January 2006.

The SHIB, when it becomes available, will provide employers with information about the chemicals used in flavoring manufacturing, the potential health effects associated with those chemicals, and the recommended workplace exposure controls that are available. Appendix B contains a sample form letter which the Area Office can utilize to transmit information to employers.

2. If not contacted previously, local hospitals, occupational health clinics, and local occupational physicians should be alerted by mail about the potential hazards associated with occupational exposure to flavoring chemicals. Appendix B contains a form letter that can be sent to healthcare providers to alert them of the potential for lung disease amongst employees exposed to diacetyl and other flavoring chemicals during the course of their employment.
3. If a lung transplant facility exists in an Area Office's jurisdiction, they should be contacted and advised to inquire about their patients' occupational history. The facility should also be provided with information regarding this NEP.
4. Compliance Assistance Specialists (CAS) should conduct outreach activities such as seminars and informational sessions for the health care sector and employer and employee groups.
5. Temporary Employment Agencies may be contacted to alert them to this NEP so that they can provide appropriate information to their employees and clients who may be assigning employees to establishments covered by this NEP.

XIV. Inspection Procedures.

This section outlines procedures for conducting inspections and preparing citations. For further guidance, CSHOs should consult the OSHA directives, appendices, and other references provided herein.

Appendix E describes some of the hazardous conditions that may be encountered at facilities that manufacture food flavorings containing diacetyl.

A. Opening Conference.

1. During the opening conference, the CSHO shall initially confirm that the employer manufactures food flavorings containing diacetyl. Some employers may not be aware of the potential for workplace diacetyl exposures. Therefore, if the employer reports that it does not manufacture food flavorings containing diacetyl, CSHOs should ask the following additional questions:
 - Ask if the employer manufactures butter distillate, butter starter distillate or natural butter starter distillate. (These are all common terms for a diacetyl-containing substance that not everyone recognizes as containing diacetyl.)
 - Ask if the employer manufactures dairy flavorings (including butter, cheese, sour cream, and yogurt flavors), “brown” flavorings (such as coffee, caramel, chocolate and butterscotch flavors), or any of a variety of other flavors that may contain diacetyl (including rum, honey, and strawberry flavors). See Appendix A for a more complete list of flavors that may contain diacetyl.
2. CSHOs shall explain the goals of this NEP to the employer and provide copies of:
 - The Hazard Communication Guidance Document for Diacetyl and Food Flavorings
 - The 2007 NIOSH Report
 - The 2006 NIOSH Report
 - The SHIB on flavorings (when it becomes available)
 - Centers for Disease Control and Prevention. Fixed obstructive lung disease among workers in the flavoring manufacturing industry --- California, 2004 - 2007. MMWR Weekly 56(16): 389-393, 2007. (CDC MMWR)

NOTE: CSHOs may choose to provide copies of these documents to the employer for copying or inform the employer that copies can be accessed at: <http://www.osha.gov/dsg/guidance/diacetyl-guidance.html>, <http://www.cdc.gov/niosh/hhe/default.html>, <http://www.cdc.gov/niosh/topics/flavorings/hhe-eval.html> and <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5616a2.htm>

3. CSHOs shall request copies of material safety data sheets (MSDSs) for flavoring chemicals to which employees are exposed under normal operating conditions at the facility.

4. CSHOs shall also request information on any hazard analyses performed at the facility for the following:
 - a. 29 CFR §1910.132(d): Hazard assessment and equipment selection. OSHA's Personal Protective Equipment (PPE) standards require employers to assess their workplaces to determine if hazards are present, or are likely to be present, which necessitate the use of PPE (29 CFR §1910.132(d)(1)). If such hazards are present or are likely to be present (as determined in part by the information from the MSDS), employers must ensure that employees use the appropriate PPE for the hazard(s) in question (29 CFR §1910.132(d)(1)(i)). The employer is responsible for both the quality of the hazard assessment and the adequacy of the PPE selected.
 - b. 29 CFR §1910.134(d): Selection of Respirators. If employees are exposed to flavoring chemicals for which MSDSs show inhalation hazard potential, the employer **must conduct** the evaluation required by 29 CFR §1910.134(d)(1)(iii).

The hazard evaluation requirement is performance-oriented, and a variety of estimation techniques may be used to characterize employee exposures depending upon the nature of the chemical products, processes, operating environment, and other factors. The employer **must** assess the nature and magnitude of the hazard relative to the conditions of use in its workplace, considering both normal operating conditions and reasonably foreseeable emergencies.

- c. 29 CFR §1910.1200(d): Hazard determination. OSHA's Hazard Communication standard (HCS) provides that chemical manufacturers must evaluate chemicals produced in their workplaces to determine if they are hazardous. Other employers can either rely on the hazard evaluation performed by the manufacturer or conduct their own hazard evaluation (29 CFR §1910.1200(d)(1), (2) and (3)). In conducting a hazard evaluation, the employer must consider the available scientific evidence concerning that chemical.

NOTE: If the CSHO determines during the opening conference that the employer does not manufacture food flavoring containing diacetyl, he or she will exit the facility with no inspection

conducted. But if the establishment is targeted under another LEP or NEP, the CSHO shall proceed with an inspection under the other LEP or NEP.

B. Walk Around and Records Review.

1. MSDS. CSHOs must thoroughly review a representative sample of MSDSs for the flavoring chemicals to which employees are exposed at the facility to ensure that they are in compliance with the requirements of 29 CFR §1910.1200(g). If upon reviewing an MSDS there is a question regarding possible deficiencies in an upstream chemical manufacturer's hazard determination, a referral to another Area Office may be necessary pursuant to OSHA Instruction CPL 02-02-038-Inspection Procedures for the Hazard Communication Standard.

- a. Review the health effects and personal protective equipment sections of the MSDSs to determine whether hazard information adequately addresses respiratory, eye, and dermal hazards.
- b. For additional information, CSHOs should refer to OSHA's "Hazard Communication Guidance for Diacetyl and Food Flavorings Containing Diacetyl," <http://www.osha.gov/dsg/guidance/diacetyl-guidance.html> and the SHIB.

2. Injury/Illness Records.

- a. CSHOs must review the employer's injury and illness records to identify the following types of entries:
 - Log entries for respiratory issues such as: bronchiolitis obliterans, fixed airways obstruction, airways obstruction, breathing or respiratory restriction, chronic bronchitis, asthma, emphysema, pneumonia, toxic effects, fume/vapor respiratory inflammation, abnormal lung function and other similar entries that could be associated with exposure to flavoring chemicals.

NOTE: Physicians unfamiliar with bronchiolitis obliterans – a rare disease – may incorrectly diagnose an employee's illness. Accordingly, CSHOs should investigate and follow up on entries such as asthma, respiratory abnormalities, and toxic effects. If there is uncertainty about whether a recorded injury or illness may be associated with exposure

to flavoring chemicals, consult with the Directorate of Technical Support and Emergency Management's Office of Occupational Medicine (OOM) as soon as possible for guidance.

- Log entries for skin or eye injuries involving exposure to flavoring chemicals.
- b. CSHOs shall follow up on entries identified per paragraph XIV.B.2.a. by interviewing employees in accordance with paragraph XIV.B.2.c. In addition, CSHOs should determine if any medical surveillance (i.e. spirometry testing) is conducted by the employer. If so, document the frequency of testing and the type of medical evaluation performed. If spirometry is performed, contact OOM to discuss medical review of medical surveillance and spirometry records.
- c. CSHOs shall interview **all** employees whose names are recorded on the logs in entries identified in accordance with paragraph XIV.B.2.a. To identify other cases of respiratory illness which may not have been recorded, CSHOs should interview employees working in mixing, packaging, quality control, and other areas such as maintenance and warehousing. These employees are likely to be exposed to flavoring chemicals.

Appendix F contains an employee questionnaire to assist with these interviews.

- d. Through employee interviews, CSHOs should attempt to obtain contact information for some employees no longer working at the facility and attempt to interview them regarding any respiratory health effects they may have developed while working with food flavorings.
3. Medical Access Orders. Based on information obtained from illness/injury records and interviews, CSHOs may need to review additional employee medical information as per paragraph XIV.B.2.b above. When accessing employee medical information, CSHOs should follow the procedures in 29 CFR §1913.10 and obtain a written medical access order in accordance with CPL 02-02-072-Rules of Agency Practice and Procedures concerning OSHA Access to Employee Medical Records. CSHOs may also consider obtaining specific written consent from the employee pursuant to 29 CFR §1910.1020(e)(2)(ii). In such cases CSHOs

should ensure that the agency or an agency employee is listed on the consent form as the designated representative to receive the information.

4. Production Process Evaluation. CSHOs shall request and review the employer's production and processing records. Areas of particular concern for hazards covered by this NEP include:
 - Mixing areas where flavoring chemicals are mixed, poured, heated and added to heated oil.
 - Areas where flavoring chemicals are weighed, measured, or sampled.
 - Areas where employees engage in research, development and quality assurance activities.
 - Locations where flavoring chemicals are transferred into containers and blenders.
 - Places where packages, boxes and containers are filled with blended flavoring product.
 - Areas where spray drying takes place.
- a. CSHOs should document the types and quantities of food flavorings that are manufactured by the employer.
- b. CSHOs should document whether the employer heats any flavoring chemicals during processing and, if so, to what temperature. Heating is particularly likely to increase exposure to diacetyl, especially if conducted in open containers.
- c. CSHOs should evaluate and document how frequently flavoring chemicals are directly handled by employees (e.g., measuring, weighing, pouring, mixing, transferring, etc.) and the extent to which engineering controls, work practices, and protective equipment, if any, are implemented during these operations.
- d. CSHOs should evaluate employees' respirator usage, if any, and request a copy of the employer's respiratory protection program.
- e. CSHOs should evaluate and document process parameters such as:
 - Temperature controls
 - Volume of material
 - Closed or open process

- Open material transfer information
- Ventilation readings
- Distance to breathing zone
- Length of exposure on short term operations
- Other parameters as outlined in the engineering controls section of the Hazard Alert Letter attached at Appendix C and in the recommended engineering controls and workplace practices at Appendix G.

f. CSHOs should take photos of processes sampled before and after any controls are implemented.

5. Exposure Monitoring.

CSHOs should conduct full-shift personal air monitoring and short-term personal air monitoring for diacetyl and/or other flavoring chemicals to which employees are exposed. The Salt Lake Technical Center (SLTC) has developed two validated methods for the simultaneous analysis of diacetyl and acetoin. OSHA Method-1012 allows for the analysis at levels of about 50 parts-per-billion, and OSHA Method-1013 allows for the analysis of levels about 500 parts-per-billion.

NOTE: When the specified sampling and analytical procedures are followed, up to 80% relative humidity has no effect on the sample results. The samples remain stable for at least two weeks before analysis.

- a. Air monitoring should generally be conducted on employees who work in the following areas of the facility:
- Rooms where flavoring mixing and holding tanks are located;
 - Quality assurance and quality control laboratories;
 - Spray-dry flavor manufacturing processes;
 - Weighing and pouring stations;
 - Packaging area(s); and,
 - During cleaning and maintenance activities.

In addition, any employees working in any areas of the facility who exhibit symptoms that can be attributed to exposure to flavoring chemicals should be monitored. CSHOs should seek assistance from OOM for questions about whether identified health effects could be associated with exposures to the flavoring chemicals documented at

the worksite.

- b. CSHOs should be aware that sampling tubes must not be changed in areas where food and food flavoring products are processed. Any breakage of tubes in these areas can result in the recall of these food products per FDA regulations. Appendix D provides more sampling information.

C. Citation Guidance.

1. Citations for Hazardous Diacetyl Exposures Under The General Duty Clause (§5(a)(1) of the OSH Act):

- a. If the CSHO documents exposure(s) to diacetyl and/or flavoring substances containing diacetyl, and exposed employees have experienced or are experiencing documented instances of bronchiolitis obliterans, obstruction of airways, lung-function abnormalities, or other lung disease, the Area Office must notify their Regional Office who will then contact DEP and OOM for an evaluation of whether a 5(a)(1) citation is appropriate.

NOTE: A Hazard Alert Letter (HAL) may be issued when the CSHO has evidence that exposures to food flavoring chemicals (other than diacetyl) that are not listed in Table Z-1, Z-2 or Z-3 of 29 CFR § 1910.1000 are resulting in employee health effects. The HAL should recommend specific actions that would assist in the prevention and reduction of illnesses and include a notification that a follow-up inspection may be conducted. A sample HAL is included in Appendix C. Whenever a HAL is issued, a copy must be forwarded to DEP's Office of Health Enforcement (OHE). For guidance on writing citations for overexposures to chemicals listed in Table Z-1, Z-2 or Z-3 of 29 CFR § 1910.1000 see XIV.C.2 below.

- b. Sample Alleged Violation Description (AVD) for citing employee exposures to diacetyl or food flavoring chemicals containing diacetyl.

NOTE: *Sample AVD language is presented as a model to assist CSHOs in developing citations. Care should be taken to tailor citations to reflect the conditions found at particular facilities and to give notice to cited establishments of the violative conduct.*

Section 5(a)(1) of the Occupational Safety and Health Act: The employer did not furnish to each of his employees employment and a place of employment which were free from recognized hazards that were causing or likely to cause death or serious physical harm to employees, in that employees were required to perform tasks that exposed them to the hazard of severe lung disease and obstruction of lung airways from inhalation of diacetyl and/or food flavoring substances containing diacetyl.

(a) (LOCATION)(DATE)(IDENTIFY SPECIFIC OPERATION/TASK(S) AND DEPARTMENTS, DESCRIBE CONDITIONS, INCLUDING EXPOSURE LEVELS). An evaluation of this operation/task(s) indicated that employees required to perform this task were exposed to a hazard which caused, or was likely to cause, severe lung disease and obstruction of lung airways.

Abatement

Feasible and effective abatement methods for reducing hazards associated with exposure to diacetyl and/or food flavoring substances containing diacetyl include, but are not limited to, the implementation and use of engineering and work practice controls. In addition, employee illnesses may be reduced by identifying exposed employees, developing a medical surveillance program to include spirometry, using medical questionnaires to identify employees with respiratory symptoms of lung dysfunction and airway obstruction, and referring symptomatic employees to physicians who specialize in occupational or pulmonary medicine for appropriate medical treatment.

NOTE: CSHOs should consult Appendix G. Additional resources include NIOSH Health Hazard Evaluation Report: “*Report on Severe Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant, Carmi Flavor and Fragrance Co., Inc Commerce California* by R. Kanwal and G. Kullman (HETA) 2006-0303-3043, April 2007” for further information on control measures.

2. OSHA PELs

If there are documented exposures to a flavoring chemical in excess of an OSHA PEL, ceiling limit, or short-term exposure limit listed in Table Z-1, Z-2 and Z-3 of 29 CFR §1910.1000, the applicable sections of that standard shall be cited. Refer to

Appendix D for a list of potentially applicable exposure limits.

3. Respirator Standard

- a. If there are respiratory hazards present at the worksite and the employer failed to conduct an initial respiratory hazard evaluation, 29 CFR §1910.134(d)(1)(iii) shall be cited.
- b. Where the employer requires the use of respirators, but fails to comply with a requirement in the Respirator standard, the appropriate paragraph(s) of 29 CFR §1910.134 shall be cited. CSHOs should refer to CPL 02-00-120, Inspection Procedures for the Respiratory Protection Standard for detailed inspection and citation guidance.
- c. When appropriate, the respirator standard may be cited in conjunction with the General Duty Clause or 29 CFR § 1910.1000 (Air Contaminants).

4. PPE Standards

Where flavoring chemicals have irritant properties, employees' eyes and/or skin are potentially exposed, and the employer is not ensuring the use of appropriate protective equipment, the applicable paragraph(s) of OSHA's PPE standards shall be cited. (See, e.g., 29 CFR §§1910.132, .133, .138).

- a. Chemical goggles or other appropriate eye protection must be used when there is a potential for splash or vapor exposure to a substance that is likely to cause injury to the eye.
- b. Chemical-resistant gloves, sleeves, or other appropriate protection for exposed skin must be used when employees are handling flavoring chemicals that can cause dermal injury. CSHOs should consult MSDSs for the appropriate gloves.
- c. If the employer did not provide training, including information about when and how to use appropriate PPE, the appropriate paragraph(s) in 29 CFR §1910.132(f) shall be cited.

5. Hazard Communication

- a. If the employer does not provide required hazard communication training to employees who may be exposed

to hazardous flavoring chemicals, the appropriate paragraph(s) in 29 CFR §1910.1200(h)(3) shall be cited.

- b. If MSDSs are not readily accessible to employees, 29 CFR §1910.1200(g)(8) shall be cited.
- c. If all containers containing hazardous flavoring chemicals, including those used for mixing process chemicals, are not adequately labeled, the appropriate paragraph(s) in 29 CFR § 1910.1200(f) shall be cited. Although some flavoring chemicals may be exempt from the hazard communication standard's labeling requirements due to coverage under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), even those chemicals must be labeled once they are transferred into in-plant containers.

NOTE: No labeling is required for portable containers into which the flavoring chemicals are transferred from labeled containers and which are intended to be used immediately by the employee who performed the transfer.

Citation Guidance: For additional information, CSHOs should refer to OSHA's "Hazard Communication Guidance for Diacetyl and Food Flavorings containing Diacetyl."
(<http://www.osha.gov/dsg/guidance/diacetyl-guidance.html>)
Additional inspection and citation guidance, including guidance on how to address inadequate MSDSs, is contained in OSHA Instruction CPL02-02-038-Inspection Procedures for the HCS.

6. Exposure and Medical Records.

- a. CSHOs should interview employees to determine whether they understand their rights to review their medical and exposure records, as well as their rights regarding the confidentiality of such records.
- b. If a review of the employer's recordkeeping program reveals that the employer is not collecting and recording required information, the appropriate paragraph(s) in 29 CFR Part 1904 and/or 29 CFR § 1910.1020 shall be cited.
- c. CSHOs should also refer to CPL 02-02-072-Rules of Agency Practice and Procedures Concerning OSHA Access to Employee Medical Records.
- d. If the employer does not follow OSHA requirements for

ensuring the confidentiality of employee medical records, the applicable section(s) of 29 CFR Part 1904, 29 CFR § 1913.10, and/or 29 CFR § 1910.1020 shall be cited.

7. Flammable and combustible liquids.

Diacetyl is highly flammable as both liquid and vapor. Other food flavoring chemicals may also be flammable. Therefore, during the course of an investigation under this NEP, attention should be paid to the handling and storage of these chemicals. The CSHO should investigate whether flammables are kept in closed containers.

Citation Guidance: Violations of 29 CFR § 1910.106(e) should be cited where appropriate.

8. Confined Spaces.

Some facilities covered by this NEP may use large containers and tanks for storage and mixing. CSHOs should determine whether any confined spaces exist and evaluate the employer's procedures for employee entry when cleaning and maintaining this equipment.

Citation Guidance: Violations of 29 CFR § 1910.146 should be cited where appropriate. In addition, compressed air may not be used for cleaning except when reduced to less than 30 p.s.i and used with certain precautions. See 29 CFR § 1910.242(b).

D. Follow-up Inspections.

Where citations are issued under Section 5(a)(1) or 29 CFR § 1910.1000 for exposures to diacetyl or other food flavoring chemicals, follow-up site visits must be conducted to determine whether the employer has implemented appropriate abatement measures, including engineering controls or work practices, and whether respirators and other appropriate PPE are being provided where necessary.

E. Program Evaluation.

This NEP will be evaluated using data collected from case files and follow-up site visit reports. Information on the effectiveness of the employer's abatement of hazardous exposures must be noted in the case file, including the types of ventilation and flow rates utilized to reduce exposure(s), and the use of PPE and the initiation of any medical

surveillance programs. The results of this evaluation shall be transmitted to DEP within one year of the effective date of this NEP.

F. Coordination.

National Office: This NEP has been developed by OHE. All questions and comments should be directed to OHE. OHE will coordinate with OOM for assistance as needed.

- G. IMIS Coding Instructions. The instruction below is for recording inspections under this NEP. All inspections conducted under this NEP will be "Health" inspections and should be coded as such. When an inspection under this NEP is conducted in conjunction with an SST inspection, the OSHA-1 Forms must be marked as "programmed planned" in item 24, and in item 21, Inspection Category must be recorded as "H." In addition, the "NEP" value of "SSTARG08" will be recorded in Item 25d along with the NEP code "FLAVRING." If during an SST inspection (or other safety-related inspections) hazards associated with exposure to flavoring ingredients or substances are observed, the NEP code "FLAVRING" should be recorded.

This new "FLAVRING" code applies to the following enforcement forms: OSHA-1, OSHA-7, OSHA-36, OSHA-90 and OSHA-55.

Consultation request/visit forms are to be completed with the NEP code "FLAVRING" in item 25 on Form-20, in Item 28 on Form-30 and Item 15 on OSHA-55.

- XV. Consultation. When appropriate, 21(d) Consultation Projects are encouraged to develop their own outreach activities to address the hazards covered by this NEP.

APPENDIX A

Flavorings That May Contain Diacetyl

Diacetyl may be considered both a chemical (it has uses other than as a flavoring) and a flavoring in its own right. Butter distillate and natural butter distillate are simply terms for concentrated (but not 100 percent) diacetyl.

Both natural and artificial flavorings, as the terms are defined by the FDA, are relevant to this NEP. Do not cease inquiries because the employer represents that its business manufactures only “natural flavorings.” Natural flavoring may be just as hazardous as artificial flavorings; they are chemically identical.

Some foods, mainly dairy products, wine, and beer, all contain naturally-occurring diacetyl that is not added as a flavoring. This NEP does not cover the manufacturing of such food products.

The following table lists food flavorings that may contain diacetyl.

Dairy Flavors	Hybrid Dairy Flavors (contain a substantial dairy content)
Butter	Butter Pecan
Cheese	Strawberry Cream
Cream Cheese	Vanilla Cream
Cheesecake	Any other Crème flavor (or “creamy” in the name)
Ranch dressing	
Milk	Root Beer Float
Yogurt	Chai
Ice Cream	
Egg	
Sour Cream	
Buttermilk	
Mayonnaise	
Starter Distillate or Butter Starter Distillate	
“Brown” Flavors	Other Flavors
Butterscotch	Nutmeg
Coffee	Honey
Caramel	Graham Cracker
Vanilla	Vinegar
Tea	Meat flavors (such as in gravy)
Toffee	Malt
Chocolate (esp. milk chocolate)	Wine ¹
Cocoa Butter	Beer
Cocoa	Tequila
Maple	
Brown Sugar	
Marshmallow	
Hazelnut & Other nut flavors	
Peanut Butter	
Praline	

Fruit Flavors	Other Flavors
Strawberry	
Cranberry	
Raspberry	
Blackberry	
Boysenberry or other berry flavors	
Nearly any other kind of fruit flavor (e.g., banana, apple, grape, pear)	
Tomato	
Cider	

¹ Note: This NEP does not target exposures to naturally-occurring diacetyl in beer and wine.

APPENDIX B

Health Care Form Letter

Area Office Header

Date

Name of Health Care Provider

Address of Health Care Provider

Dear _____:

Subject: Occupational Lung Disease Among Employees in the Flavoring Manufacturing Industry

The Occupational Safety and Health Administration (OSHA) Region/Area office is alerting health care professionals to the occurrence of occupational lung disease among employees who are exposed to diacetyl and other food flavoring chemicals. In 2000, the National Institute for Occupational Safety and Health (NIOSH) investigated a microwave popcorn manufacturing facility in Missouri where nine employees developed bronchiolitis obliterans, a severe, potentially fatal, pulmonary disease. The investigation concluded that there was an increased risk for occupational lung disease among employees with inhalational exposure to butter flavorings. Since this initial investigation, additional cases of occupational lung disease, including bronchiolitis obliterans, have been recognized among employees at other microwave popcorn manufacturing plants and flavor manufacturing facilities. Occupational exposure to diacetyl, a butter flavoring chemical, is considered the most likely cause of the lung disease found in employees exposed to flavoring chemicals, but other flavoring chemicals may also contribute to the disease.

The April 2007 NIOSH Health Hazard Evaluation Report #2006-0303-3043: *Report on Severe Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant*, reported two diagnoses of bronchiolitis obliterans in employees who were employed at two different California flavor manufacturing facilities. Neither employee was employed in the microwave-popcorn industry, but both employees handled pure diacetyl and other flavoring chemicals.

Occupational History:

Occupational history inquires should include questions about current and past jobs, as well as information about workplace exposures to diacetyl and other food flavoring chemicals. It is important to ask if any other employees are experiencing respiratory

symptoms or are known to have developed lung disease. Additional information about workplace exposures to diacetyl and other food flavoring chemicals can be found in Material Safety Data Sheets (MSDS) or by contacting flavoring manufacturers. Diacetyl is listed by the CAS number 431-03-8.

Symptoms:

Symptoms experienced by employees include cough (usually non-productive) and dyspnea, particularly with exertion. These symptoms may not improve when employees are away from work (e.g., nights, weekends, vacations). Additional signs and symptoms related to exposure may include eye, nose, throat and skin irritation, fever, night sweats and weight loss. Symptoms are usually gradual in onset but severe symptoms may occur suddenly. Bronchiolitis obliterans is a rare disease and employees may be misdiagnosed as having asthma, chronic bronchitis, emphysema, or other lung diseases.

Medical Evaluation:

The occupational lung disease identified in the NIOSH investigations was characterized by fixed airways obstruction on spirometry after challenge with bronchodilators. Spirometry findings may also include evidence of restriction. Spirometry should follow criteria established by the American Thoracic Society (ATS) guidelines for standardization of spirometry, which can be obtained through the ATS website: <http://www.thoracic.org/sections/publications/statements/index.html>.

Additional studies such as diffusing capacity are usually normal, but lung volumes may show hyperinflation. Chest radiographs are also usually normal. Findings on paired inspiratory and expiratory high resolution computerized tomography scans (HCRT scans) and lung biopsy are also used to establish the diagnosis of bronchiolitis obliterans. If there is evidence of fixed airways obstruction and bronchiolitis obliterans is suspected, referral to pulmonary and radiographic specialty care is optimal to ensure correct diagnosis and follow-up of this rare and severe lung disease.

More information about occupational lung disease related to exposure to food flavoring chemicals is available at:

<http://www.osha.gov/SLTC/flavoringlung/index.html>
<http://www.cdc.gov/niosh/topics/flavorings/>

Healthcare providers, who suspect flavorings-related lung disease, including bronchiolitis obliterans, can contact NIOSH at the following link:

www.cdc.gov/niosh/topics/flavorings/contact.html.

Providers can use this above link to inquire about or provide information regarding lung disease that may be related to exposures to flavoring chemicals. Cases should also be reported to local and state public health departments.

OSHA is dedicated to saving lives, preventing injuries and illnesses, and protecting America's working men and women. Safety and health add value to business, the workplace and life. For more information about OSHA programs, visit our website at www.osha.gov.

Sincerely,

Area Director

Enclosure(s)

Employer Sample Letter

Area Office Header

Date

Name of Employer
Address of Employer

Dear _____

You may be aware of reports of severe cases of an irreversible lung disease identified as bronchiolitis obliterans in employees working with diacetyl and other food flavoring chemicals. Bronchiolitis obliterans is characterized by fixed airways obstruction on lung function tests. The main respiratory symptoms experienced by workers include cough and shortness of breath on exertion. These symptoms typically do not improve when the worker goes home at the end of the workday or on weekends or vacations. Additional symptoms may include eye, nose, throat and skin irritation, fever, night sweats and weight loss. Bronchiolitis obliterans has many known causes, such as inhalation of certain chemicals, certain bacterial and viral infections, organ transplantation, and reactions to certain medications. Known causes of bronchiolitis obliterans due to occupational or other environmental exposures include gases such as nitrogen oxides, sulfur dioxide, chlorine, ammonia, phosgene and other irritant gases. Recent investigations by the National Institute for Occupational Safety and Health (NIOSH) concluded that diacetyl and other flavoring chemicals pose a risk for bronchiolitis obliterans in the flavoring manufacturing workplace. See, e.g., Kanwal's Report on Severe Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant. National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation Report #2006-0303-3043, April 2007. Bronchiolitis obliterans is often misdiagnosed as asthma or chronic bronchitis by the local physician.

Case clusters of fixed obstructive lung disease have been documented among workers at several different plants where chemicals are handled in the production of flavorings. Enclosed are recommended preventative and control measures which, if implemented, should reduce the risk of obstructive lung disease among workers. These are best practice recommendations, but should not be considered all-inclusive worker protective measures. Your unique knowledge of your workplace may indicate the need for alternative or additional protective measures. References for additional information and assistance are also included.

If you need assistance identifying hazards, you may wish to consider hiring an outside safety and health consultant, talking with your insurance company, or contacting your state's worker's compensation agency for advice. An excellent way for employers to address safety and health in their workplace is to ask for assistance from OSHA's onsite consultation program. This program is administered by a state agency and operated separately from OSHA's enforcement program. The service is free and confidential, and there are no monetary fines if problems are found.

B-4

Designed primarily for small employers, the onsite consultation program can help you identify hazards in your workplace and find effective and economical solutions for eliminating or controlling them. In addition, the OSHA state consultant can assist you in developing and implementing a safety and health management system for your workplace.

In your state, the OSHA onsite consultation program may be contacted at:
Give address and phone number

OSHA is dedicated to saving lives, preventing injuries and illnesses and protecting America's workers. Safety and health add value to business, the workplace and life. For more information about OSHA programs, visit our website at www.osha.gov.

Sincerely,

Area Director

Enclosure(s)

Recommended Preventative and Control Measures

1. Engineering and Work Practice Controls

Engineering controls are the first line of defense in employee protection. Therefore, employers should provide appropriate engineering controls and should train their employees in the use of those controls and in appropriate work practices to ensure that employee exposures are eliminated or minimized. The following engineering controls are recommended for exposures to flavoring chemicals:

- Use local exhaust ventilation when weighing and transferring flavoring chemicals.
- Use local ventilation for ribbon blenders.
- Isolate or enclose the production room from the rest of the plant using walls, doors, or other appropriate barriers.
- Doors between production areas and other connecting areas should be kept closed when not in use.
- Equip the production room with a separate ventilation system or ensure that negative air pressure (relative to the rest of the plant) is maintained in the production room to avoid the outward migration of food flavoring chemicals to adjacent areas of the plant.
- Direct all exhaust ventilation outside the plant, but in accordance with state and local regulations, and sufficiently away from other building air intakes.
- Reduce the operating temperature of the holding and mixing tanks to as low as the process will allow.
- Automate the cleaning and mixing processes.
- Use local exhaust ventilation in the liquid compounding room to capture evaporating chemicals from the mixing tanks.
- During mixing, maintain the tanks/vessels under a slight negative pressure at all times.
- Use hinged tank covers equipped with a ventilation takeoff and keeps them closed during mixing.
- Move tanks into a ventilated enclosure while mixing or use a ventilated booth with flexible strip curtains to allow for movement of tanks in and out of the ventilated enclosure.
- Use lids with smaller openings for adding ingredients and use funnels for pouring ingredients into the tanks.
- When using 55-gallon drums, an annular exhaust can provide a semi-circular ventilation ring around the edge of the drum.
- When adding chemicals to tanks whose diameter is larger than about 2 feet, limit the open area by using lids and small openings for pouring. The use of a back-draft slotted hood is not recommended.
- During bag dumping into blenders, enclose the face of the blender using local exhaust ventilation and maintain a face velocity of approximately 150 feet per

minute. For large blenders the use of slots would help distribute the exhaust flow more evenly across the hood.

- Use a bag disposal chute or compactor and spray the inside of the bags with water before compacting to reduce airborne dust.
- Prevent spillage from overfilling tanks, leaks in seals and fittings, and manual transfer of materials, all of which have been identified as sources of emissions.
- Establish standard operating procedures for cleaning mixing and holding tanks, containers, and spills.
- Reduce dust exposure during bag dumping by installing commercially available bag dumping stations equipped with local exhaust ventilation (three-sided canopy hood) and bag disposal.
- Put lids on transfer buckets to avoid residual vapor release and/or place buckets in a ventilated area following transfer; or use pumps to avoid manual transfer altogether.
- Add food flavoring chemicals at room temperature.
- If food flavoring chemicals must be heated prior to adding them to the flavoring tank or mixing tank, transfer them to the tank via a pumping system rather than manual transfer.
- Provide additional general dilution ventilation by increasing the air changes in the room.
- Keep the storage room under negative pressure with respect to the rest of the plant.
- Isolate cleaning areas and ensure that vessels used for powdered food flavoring chemicals are not cleaned with compressed air. When vessel entry is necessary, ensure compliance with the confined spaces entry requirements.
- Maintain good housekeeping in any areas where food flavorings or their ingredients are handled.

2. Personal Protective Clothing and Equipment

a. Skin and Eye Protection

Ensure that appropriate protective clothing is worn when necessary to protect employees from skin or eye hazards associated with food flavoring chemicals, particularly where such chemicals are being mixed or processed. Protective clothing includes garments worn over the employee's skin. To be effective, personal protective equipment must be appropriate to the hazard it is meant to protect against, individually selected, properly fitted and periodically refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. See 29 CFR §1910.132. In addition, employers must:

- Perform a workplace hazard assessment in accordance with 29 CFR §1910.132(d) to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE);
- Provide and ensure the use of chemical-resistant gloves or sleeves or other appropriate protection when there is potential for dermal injury, and provide and

ensure the use of chemical goggles or appropriate eye protection when a potential eye hazard exists; and

- Train employees on the limitations and use of PPE required during the handling of food flavoring chemicals.

b. Respiratory Protection

- Employers requiring the use of respiratory protection must establish, implement, and maintain a written respiratory protection program in accordance with 29 CFR §1910.134(c).
- Employees must be trained annually and medically evaluated prior to using respiratory protection.
- Employees must be fit tested prior to being required to use respirators.
- Employers must provide employees with clean respirators and ensure that respirators are being stored in a manner to protect them from damage or contamination.
- A NIOSH-certified half-facepiece negative-pressure respirator with organic vapor cartridges and particulate filters is the minimum level of respiratory protection recommended for entry into production areas. Employers should have a documented cartridge change out program.
- Powered air-purifying respirators or supplied-air respirators are also appropriate and will provide a higher level of protection.

3. Training and Information

Employers must ensure that employees exposed to hazardous food flavoring chemicals are provided hazard communication training and information in accordance with 29 CFR §1910.1200. Employees should have access to, or be provided with, the following information:

- The specific nature of the operations in their workplace where exposure to food flavoring chemicals may occur.
- MSDSs for food flavoring chemicals.
- The signs and symptoms of hazardous exposures to food flavoring chemicals.
- The importance of avoiding skin contact when working with chemicals that pose a skin hazard.
- The engineering controls the employer is using to reduce employee exposures.
- Specific work practices that should be used to reduce exposures.
- The use of appropriate protective equipment, including respirators (where required) and skin protection.
- Methods that may be used to detect the presence of hazardous food flavoring chemicals in the workplace, such as workplace monitoring.
- The results of any industrial hygiene sampling the employer or others have conducted.

4. Medical Surveillance

A medical screening program can help employers identify employees experiencing adverse health effects from exposure to hazardous food flavoring chemicals. Spirometry, or pulmonary function testing (PFT), measures the breathing capacity of the lungs and is the best available test for early detection of decreasing or abnormal lung function among exposed employees. It is recommended that employers:

- Perform a baseline spirometry test for all newly-hired employees and ask each employee to complete a health questionnaire before starting work in areas where there is exposure.
- Perform a medical evaluation (i.e. health questionnaire) and spirometry every six months for all employees exposed. A qualified physician with expertise in occupational lung disease can make additional recommendations regarding the nature and frequency of medical examinations and spirometry based on employee exposures specific to operations in your facility.

[Please refer to the OSHA SHIB for more information on medical screening.]

Appendix C Sample Hazard Alert Letter

Note: This letter must be adapted to the specific circumstances noted in each inspection. The letter below is an example of the type of letter that may be appropriate in some circumstances. If the employer has implemented, or is in the process of implementing, efforts to address hazardous conditions, those efforts should be recognized and encouraged, if appropriate.

Italicized comments are for OSHA compliance use only and should not be included in the letter.

Dear Employer:

An inspection of your workplace and evaluation of your OSHA recordkeeping logs at (location) on (date) disclosed the following workplace condition(s) which may be associated with the development of occupational lung disease in your employees.

[Include a general description of working conditions for each task/job associated with respiratory disease or fixed airways obstruction, such as lack of ventilation, lack of PPE, inappropriate PPE, etc.]

The results of sampling showed exposure(s) above the detection limit(s) for [insert appropriate chemical(s)] and exposed employees have experienced or are experiencing documented instances of [insert appropriate illness (es) bronchiolitis obliterans, obstruction of airways, lung-function abnormalities, or other lung disease.] In the interest of workplace safety and health, I recommend that you voluntarily take the necessary steps to materially reduce or eliminate your employees' exposure to the conditions listed above.

Based on the results of its own studies at a flavoring manufacturing facility, NIOSH found that the following recommended engineering and work practice controls can help reduce employee exposures to flavoring chemicals. (See Kanwal NIOSH: Report on Severe Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant. National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation Report #2006-0303-3043, April 2007.)

1. Engineering Controls

Engineering controls are the first line of defense in employee protection. Therefore, employers should provide appropriate engineering controls and should train their employees in the use of those controls and in appropriate work practices to ensure that employee exposures are eliminated or minimized. The following engineering controls are recommended:

- Use local exhaust ventilation when weighing and transferring flavoring chemicals.
- Use local ventilation for ribbon blenders.
- Isolate or enclose the production room from the rest of the plant using walls, doors, or other appropriate barriers.

- Doors between production areas and other connecting areas should be kept closed when not in use.
- Equip the production room with a separate ventilation system or ensure that negative air pressure (relative to the rest of the plant) is maintained in the production room to avoid the outward migration of food flavoring chemicals to adjacent areas of the plant.
- Direct all exhaust ventilation outside the plant.
- Reduce the operating temperature of the holding and mixing tanks to as low as the process will allow.
- Automate the cleaning and mixing processes.
- Use local exhaust ventilation in the liquid compounding room to capture evaporating chemicals from the mixing tanks.
- During mixing, maintain the tanks/vessels under a slight negative pressure at all times.
- Use hinged tank covers equipped with a ventilation takeoff and keep them closed during mixing.
- Move tanks into a ventilated enclosure while mixing or use a ventilated booth with flexible strip curtains to allow for movement of tanks in and out of the ventilated enclosure.
- Use lids with smaller openings for adding ingredients and use funnels for pouring ingredients into the tanks.
- When using 55-gallon drums, an annular exhaust can provide a semi-circular ventilation ring around the edge of the drum.
- When using tanks whose diameter is larger than about 2ft., limit the open area by using lids and small openings for pouring. The use of a back draft slotted hood is not recommended.
- During bag dumping into blenders, enclose the face of the blender as much as possible and maintain a velocity of approximately 150 feet per minute. For large blenders the use of slots would help distribute the exhaust flow more evenly across the hood.
- Use a bag disposal chute or compactor and spray the inside of the bags with water before compacting reduces dust generations.
- Prevent spillage from overfilling tanks, leaks in seals and fittings, and manual transfer of materials, all of which have been identified as sources of emissions.
- Establish standard operating procedures for cleaning mixing and holding tanks, containers, and spills.
- Reduce dust exposure during bag dumping by installing commercially available bag dumping stations equipped with local exhaust ventilation (three-sided canopy hood) and bag disposal.
- Put lids on transfer buckets to avoid residual vapor release and/or place buckets in a ventilated area following transfer; or use pumps to avoid manual transfer altogether.
- Add food flavoring chemicals at room temperature.
- If food flavoring chemicals must be heated prior to adding them to the flavoring

tank or mixing tank, transfer them to the tank via a pumping system rather than manual transfer.

- Provide additional general dilution ventilation by increasing the air changes in the room.
- Keep the storage room under negative pressure with respect to the rest of the plant.
- Isolate cleaning areas, and ensure that vessels used for powdered food flavoring chemicals are not cleaned with compressed air. When vessel entry is necessary, ensure compliance with the confined spaces entry requirements.
- Maintain good housekeeping in any areas where food flavorings substances or their ingredients are handled.

2. Personal Protective Clothing and Equipment

a. Skin and Eye Protection

Ensure that appropriate protective clothing is worn when necessary to protect employees from skin or eye hazards associated with food flavoring chemicals, particularly where such chemicals are being mixed or processed. Protective clothing includes garments worn over the employee's skin. To be effective, personal protective equipment must be appropriate to the hazard it is meant to protect against, individually selected, properly fitted and periodically refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. See 29 CFR §1910.132. In addition, employers must:

- Perform a workplace hazard assessment in accordance with 29 CFR §1910.132(d) to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE);
- Provide and ensure the use of chemical-resistant gloves or sleeves or other appropriate protection when there is potential for dermal injury, and provide and ensure the use of chemical goggles or appropriate eye protection when a potential eye hazard exists; and
- Train employees on the limitations and use of PPE required during the handling of food flavoring chemicals.

b. Respiratory Protection

- Employers requiring the use of respiratory protection must establish, implement, and maintain a written respiratory protection program in accordance with 29 CFR §1910.134(c).
- Employees must be trained annually and medically evaluated prior to using respiratory protection.
- Employees must be fit tested prior to being required to use respirators.
- Employers must provide employees with clean respirators and ensure that respirators are being stored in a manner to protect them from damage or contamination.

- A NIOSH-certified half-facepiece negative-pressure respirator with organic vapor cartridges and particulate filters is the minimum level of respiratory protection recommended for entry into production areas. Employers should have a documented cartridge change out program.
- Powered air-purifying respirators or supplied-air respirators are also appropriate and will provide a higher level of protection.

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Employers must ensure that employees exposed to hazardous food flavoring chemicals are trained in accordance with 29 CFR §1910.1200. Employees should have access to, or be provided with, the following information:

- The specific nature of the operations in their workplace where exposure to food flavoring chemicals may occur.
- MSDSs for food flavoring chemicals.
- The signs and symptoms of hazardous exposures to food flavoring chemicals.
- The importance of avoiding skin contact when working with chemicals that poses a skin hazard.
- The engineering controls the employer is using to reduce employee exposures.
- Specific work practices that should be used to reduce exposures.
- The use of appropriate protective equipment, including respirators and skin protection.
- Methods that may be used to detect the presence of hazardous food flavoring chemicals in the workplace, such as workplace monitoring.
- The results of any industrial hygiene sampling the employer or others have conducted.

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- Perform a baseline spirometry test for all newly-hired employees and ask each employee to complete a health questionnaire before starting work in areas where there is exposure.
- Perform a medical evaluation (i.e. health questionnaire) and spirometry every six months for all employees exposed. A qualified physician with expertise in occupational lung disease can make additional recommendations regarding the nature and periodicity of medical examinations and spirometry based on employee exposures specific to operations in your facility.

[Please refer to the OSHA SHIB, when it becomes available, for more information on medical screening.]

Using the above components, together with information gathered during the inspection, describe the specific conditions or weaknesses and suggest methods of abatement.

You may voluntarily provide this Area Office with progress reports on your efforts to address these conditions. OSHA may return to your worksite to further examine the conditions noted above.

Enclosed is a list of available resources that may be of assistance to you in preventing work-related injuries and illnesses in your workplace. *(provide a copy of OSHA booklet)*

If you have any questions, please feel free to call [name and phone number] at [address].

Sincerely,
Area Director

Enclosure

APPENDIX D Guidelines for Air Sampling

This appendix summarizes the procedures for obtaining air samples for diacetyl, acetoin, and other food flavoring chemicals. Air concentrations tend to be highest in flavor blending processes and during packaging of final flavoring products. Most often the facilities have an open process with large tanks of flavorings which can be supplied as powders, liquids or pastes. The food flavorings are often weighed, measured, poured, and blended.

CSHOs should ensure that both full-shift personal monitoring and short-term personal monitoring (especially during pouring and blending) are conducted in the production room where flavoring tanks are located, as well as in the production line, quality control/assurance laboratories and packaging areas. CSHOs should be aware that some employers may use powdered flavorings, which may become airborne. Therefore, CSHOs should be prepared to conduct both total and respirable dust sampling when deemed necessary. PNOR sampling may not be useful to determine exposures for short-term operations. Whether or not to take PNOR samples is left to CSHO judgment.

1. DIACETYL and ACETOIN

Diacetyl (IMIS: D740) and acetoin (IMIS: A624) are sampled at the same time using the sampling media specified below. This sampler will be cited in the new OSHA analytical methods and it is currently available from SKC. OSHA personnel can obtain these sampling tubes from SLTC.

Sampling Media: Two silica gel tubes in series each containing 600 mg sections of specially washed and dried silica gel, 20/40 mesh, with a glass-fiber filter plug (SKC 226-183 or equivalent).

NOTE: Wrap samples with aluminum foil (or other opaque material) during sampling to prevent sample loss caused by exposure to light. Use a tube holder to entirely enclose the sampler to protect the employee from the sharp glass and to prevent contamination of any food products with glass shards. Separate and cap the two tubes after sampling. Also wrap tubes with foil after separation.

TWA Sampling

Maximum volume: 9 liters
Maximum flow rate: 0.05 L/min
Maximum time: 180 mins

Short-Term Sampling

Maximum volume: 3 liters
Maximum flow rate: 0.2L/min
Maximum time: 15 mins

2. POWDERED FLAVORINGS:

CSHOs should obtain bulk samples when possible. CSHOs should request analysis for diacetyl bulk samples. Submit bulk samples in tightly sealed 20-mL glass scintillation vial. Vials should be approximately $\frac{3}{4}$ full and covered with aluminum foil.

Be certain to state that these samples may contain diacetyl and/or acetoin in the “Interferences and IH Comments to Lab” block on the form OSHA-91A.

(a) PNOR, Respirable Dust OSHA Method #2
OSHA IMIS Code Number: 9130

Sampling Media: Tared 37-mm diameter low-ash polyvinyl chloride filter preceded by a 10 mm Nylon cyclone
Maximum volume: 816 Liters
Maximum flow rate: 1.7 L/min

(b) PNOR, Total Dust OSHA Method #2
OSHA IMIS Code Number: 9135

Sampling Media: Tared 37-mm diameter low-ash polyvinyl chloride filter-DO NOT USE A CYCLONE
Maximum volume: 960 Liters
Maximum flow rate: 2.0 L/min

Below is a table showing other flavoring chemicals, PELs, and analytical methods.

**APPENDIX D
 FLAVORING SUBSTANCES**

FEMA No. and Priority ¹	CAS No. and OSHA IMIS ² No.	Substance	Synonyms	PEL	IDLH ³	Respiratory Acute ^{3,4}	Analytical Method ²	Sampling Medium ²	Air Volume and Sampling Rate ²
1231 Low	78-92-2 0461	sec-Butyl alcohol	2-Butanol; Butylene hydrate; 2-Hydroxybutane; Methyl ethyl carbinol ³	TWA 150 ppm (450 mg/m ³)	2000 ppm	Irritating to respiratory tract	NIOSH 1401	Charcoal tube (100/50 mg)	10 L 0.2 L/min
2003 High	75-07-0 0010	Acetaldehyde	Acetic aldehyde; ethanal; ethyl aldehyde ³	TWA 200 ppm (360 mg/m ³)	2000 ppm	Mildly irritating to respiratory tract	OSHA 68	HMP-coated XAD-2 tube (450/225 mg)	3 L 0.05 L/min
2006 High	64-19-7 0020	Acetic acid	Acetic acid (aqueous); glacial acetic acid (pure compound); ethanoic acid; methane-carboxylic acid ³	TWA 10 ppm (25 mg/m ³)	50 ppm	Pulmonary edema	OSHA PV2119	Charcoal tube (400/200 mg)	48 L 0.2 L/min
2008 High	513-86-0 A624	Acetoin	Acetyl methyl carbinol; 1-hydroxyethyl methyl ketone; gamma-hydroxy-beta oxybutane; 3-hydroxy-2,3-butanone; 2,3-butanolone; dimethylketol ²	None	No Data in NPG		NIOSH 2558	Anasorb CMS tube(150/75 mg)	10 L 0.2 L/min
2008 High	513-86-0 A624	Acetoin	Acetyl methyl carbinol; 1-hydroxyethyl methyl ketone; gamma-hydroxy-beta oxybutane; 3-hydroxy-2,3-butanone; 2,3-butanolone; dimethylketol	None	No Data in NPG		OSHA 1012 ⁷ OSHA ⁸ 1013 ⁸	Two silica gel tubes in-series (600 mg with GFF)	TWA 9L 0.05L/min Short Term 3L 0.2 L/min
2035 High	870-23-5	Allyl mercaptan	2-Propene-1-thiol ⁵	None	No Data in NPG				
2053 High	12124-99-1	Ammonium sulfide	Ammonium sulfide; ammonium sulphide; ammonium hydrogen sulfide; ammonium hydrosulfide; ammonium mercaptan; ammonium sulfhydrate; monoammonium sulfide ⁶	None	No Data in NPG	Strong irritant to skin and mucous membranes ⁵			
2055 Low	123-92-2 1530	Isoamyl acetate	Banana oil; isopentyl acetate; 3-methyl-1-butanol acetate; 3-methylbutyl ester of acetic acid; 3-methyl-butyl ethanoate ³	TWA 100 ppm (525 mg/m ³)	1000 ppm	Irritating to respiratory tract	OSHA PV2142	Charcoal tube (100/50 mg)	10 L 0.2 L/min

**APPENDIX D
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FEMA No. and Priority ¹	CAS No. and OSHA IMIS ² No.	Substance	Synonyms	PEL	IDLH ³	Respiratory Acute ^{3,4}	Analytical Method ²	Sampling Medium ²	Air Volume and Sampling Rate ²
2057	123-51-3 1532	Isoamyl alcohol	Primary isoamyl alcohol; fermentation amyl alcohol; fusel oil; isobutyl carbinol; isopentyl alcohol; 3-methyl-1-butanol ³	TWA 100 ppm (360 mg/m ³)	500 ppm	Irritating to respiratory tract	NIOSH 1402	Charcoal tube (100/50 mg)	10 L 0.2 L/min
2127 High	100-52-7 B105	Benzaldehyde	Benzoic aldehyde; benzenecarbonyl; benzene carbaldehyde ³	None	No Data in NPG				
2147 Low	100-53-8	Benzyl mercaptan	α-Toluenethiol; benzylthiol ⁵	None	No Data in NPG	Toxic by inhalation and ingestion; irritant to tissue ⁵			
2170 Low	78-93-3 0430	2-Butanone	Ethyl methyl ketone; MEK; methyl acetone; methyl ethyl ketone ³	TWA 200 ppm (590 mg/m ³)	3000 ppm	Irritating to respiratory tract	OSHA 1004	Anasorb CMS (150/75 mg) SKC 575-002 Passive Sampler 3M 3520 Organic Vapor Monitor	12 L 0.05 L/min 5 to 240 min 5 to 240 min
2174 Low	123-86-4 0440	Butyl acetate	n-Butyl acetate; n-butyl ester of acetic acid; butyl ethanoate ³	TWA 150 ppm (710 mg/m ³)	1700 ppm [10%LEL]	Irritating to respiratory tract	OSHA 1009	Charcoal tube (100/50 mg)	10 L 0.2 L/min
2175 Low	110-19-0 1534	Isobutyl acetate	Isobutyl ester of acetic acid; 2-methylpropyl acetate; 2-methylpropyl ester of acetic acid; b-methylpropyl ethanoate ³	TWA 150 ppm (700 mg/m ³)	1300 ppm [10%LEL]	Irritating to respiratory tract	OSHA 1009	Charcoal tube (100/50 mg)	10 L 0.2 L/min
2178 Low	71-36-3 0460	Butyl alcohol	n-Butyl alcohol; 1-butanol; n-butanol; 1-hydroxy-butane; n-propyl carbinol ³	TWA 100 ppm (300 mg/m ³)	1400 ppm [10%LEL]	Irritating to respiratory tract	NIOSH 1401	Charcoal tube (100/50 mg)	10 L 0.2 L/min
2179 Low	78-83-1 1536	Isobutyl alcohol	IBA; isobutanol; isopropylcarbinol; 2-methyl-1-propanol ³	TWA 100 ppm (300 mg/m ³)	1600 ppm	Irritating to respiratory tract	NIOSH 1401	Charcoal tube (100/50 mg)	10 L 0.2 L/min

**APPENDIX D
 FLAVORING SUBSTANCES**

FEMA No. and Priority ¹	CAS No. and OSHA IMIS ² No.	Substance	Synonyms	PEL	IDLH ³	Respiratory Acute ^{3,4}	Analytical Method ²	Sampling Medium ²	Air Volume and Sampling Rate ²
2219 Low	123-72-8	Butyraldehyde	Butaldehyde; <i>n</i> -butanal; <i>n</i> -butylaldehyde; butyric aldehyde ⁵	None	No Data in NPG				
2220 High	78-84-2 R237	Isobutyraldehyde	2-Methylpropanal; isobutyric aldehyde; isopropylformaldehyde; isobutnal; methyl propanal; valine aldehyde; isobutaldehyde; 2-methylpropionaldehyde ³	None	No Data in NPG		NIOSH 2539 (OSHA modified)	HMP-coated XAD-2 tube (150/75 mg)	5 L 0.05 L/min
2221 High	107-92-6 B709	Butyric acid	Butanoic acid; ethylacetic acid; propylformic acid ³	None	No Data in NPG		SLTC in-house literature file	Silica Gel tube (520/260 mg)	18 L 0.1 L/min
2222 High	79-31-2	Isobutyric acid	2-Methylpropanoic acid ³	None	No Data in NPG				
2230 Low	76-22-2 0522	Camphor	2-Camphonone; Synthetic camphor; Gum camphor; Laurel camphor ³	2 mg/m ³	200 mg/m ³	Irritating to respiratory tract, skin, and eyes	NIOSH 1301	Charcoal tube (100/50 mg)	24 L 0.2 L/min
2286 Low	104-55-2	Cinnamaldehyde	3-Phenylpropenal; cinnamyl aldehyde; cinnamic aldehyde ⁵	None	No Data in NPG				
2370 High	431-03-8 D740	Diacetyl	Biacetyl; 2,3-butanedione; 2,3-diketobutane; dimethyldiketone; dimethylglyoxal; glyoxal, dimethyl ²	No PEL	No Data in NPG		OSHA 1012 ⁷ OSHA 1013 ⁸	Two silica gel tubes in-series (600 mg each with GFF)	TWA 9 L 0.05 L/min Short Term 3L 0.2L/min
2370 High	431-03-8 D740	Diacety	Biacetyl; 2,3-butanedione; 2,3-diketobutane; dimethyldiketone; dimethylglyoxal; glyoxal, dimethyl ²	No PEL	No Data in NPG		OSHA PV2118 ⁹	Two silica gel tubes in-series (150/75 mg each)	3L 0.05L/min
2414 Low	141-78-6 1040	Ethyl acetate	Acetic ester; acetic ether; ethyl ester of acetic acid; ethyl ethanoate ³	TWA 400 ppm (1400 mg/m ³)	2000 ppm [10%LEL]	Irritating to respiratory tract	NIOSH 1457	Charcoal tube (100/50 mg); ship cold to lab	6 L 0.2 L/min
2418 High	140-88-5 1050	Ethyl acrylate	Ethyl acrylate (inhibited); ethyl ester of acrylic acid; ethyl propenoate ³	TWA 25 ppm (100 mg/m ³) [skin]	Ca [300 ppm]	Irritating to respiratory tract	OSHA 92	TBC coated Charcoal tube (110/55 mg)	12 L 0.05 L/min

**APPENDIX D
 FLAVORING SUBSTANCES**

FEMA No. and Priority ¹	CAS No. and OSHA IMIS ² No.	Substance	Synonyms	PEL	IDLH ³	Respiratory Acute ^{3,4}	Analytical Method ²	Sampling Medium ²	Air Volume and Sampling Rate ²
2419 Low	64-17-5 1060	Ethyl alcohol	Alcohol; ethanol; EtOH; grain alcohol; cologne spirit ³	TWA 1000 ppm (1900 mg/m ³)	3300 ppm [10%LEL]	Irritating to respiratory tract	OSHA 100	Two Anasorb 747 tubes in-series (400/200 mg); separate tubes after sampling	12L 0.05 L/min
2434 Low	109-94-4 1155	Ethyl formate	Ethyl ester of formic acid; ethyl methanoate ³	TWA 100 ppm (300 mg/m ³)	1500 ppm	Irritating to respiratory tract	NIOSH 1452	Charcoal tube (100/50 mg)	10 L 0.2 L/min
2487 High	64-18-6 1310	Formic acid	Formic acid (85%–95% in aqueous solution); hydrogen carboxylic acid; methanoic acid ³	TWA 5 ppm (9 mg/m ³)	30 ppm	Corrosive, Pulmonary edema	OSHA 186SG	Charcoal tube (400/200 mg) ship cold to lab	48 L 0.2 L/min
2489 High	98-01-1 1325	Furfural	Fural; 2-furancarboxaldehyde; furfuraldehyde; 2-furfuraldehyde ³	TWA 5 ppm (20 mg/m ³) [skin]	100 ppm	Irritating to respiratory tract	OSHA 72	Petroleum-base Charcoal tube (100/50)	180 L 1.0 L/min
2491 Low	98-00-0 1330	Furfuryl alcohol	2-Furylmethanol; 2-hydroxymethylfuran ³	TWA 50 ppm (200 mg/m ³)	75 ppm	Irritating to respiratory tract	NIOSH 2505	Porapak Q tube (150/75 mg)	25 L 0.05 L/min
2525	56-81-5 1363	Glycerol	Glycerin (anhydrous); glyceryl alcohol; 1,2,3-propanetriol; trihydroxypropane ³	TWA 15 mg/m ³ (total) TWA 5 mg/m ³ (resp)	No Data in NPG	Irritating to respiratory tract	OSHA PV2121	Tared 37-mm low-ash PCV filter	960 L 2.0 L/min (Total Dust) 10-mm Nylon Cyclone; 816 L 1.7 L/min (Respirable Fraction)
2544	110-43-0 1675	2-Heptanone	Amyl methyl ketone; n-amyl methyl ketone; methyl (n-amyl) ketone ³	TWA 100 ppm (465 mg/m ³)	800 ppm	Irritating to respiratory tract	NIOSH 1301	Charcoal tube (100/50 mg)	25 L 0.2 L/min
2676 Low	79-20-9 1650	Methyl acetate	Methyl ester of acetic acid; methyl ethanoate ³	TWA 200 ppm (610 mg/m ³)	3100 ppm [10%LEL]	Irritating to respiratory tract	NIOSH 1458	Charcoal tube (100/50 mg)	7 L 0.2 L/min
	96-17-3		2-Methylbutanal ⁵	None	No Data				

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 FLAVORING SUBSTANCES**

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2691 Low		2-Methylbutr-aldehyde			in NPG				
2692 Low	590-86-3 1201	3-Methylbutyr-aldehyde	Isovaleral; isovaleral; isovaleric aldehyde; 3-methylbutyraldehyde ⁵	None	No Data in NPG		SLTC in-house literature file	Three DNP-coated filters; two stacked, one separated by a cassette ring; store collected samples in dark	3 L 0.05 L/min
2716 High	74-93-1 1643	Methyl mercaptan	Mercaptomethane; methanethiol; methyl sulfhydrate ³	C 10 ppm (20 mg/m ³)	150 ppm	Irritating to respiratory tract	OSHA 26	Mercuric acetate-coated 37-mm glass fiber filter	20 L 0.2 L/min
2731 Low	108-10-1 1385	4-Methyl-2-pentanone	Isobutyl methyl ketone; methyl isobutyl ketone; MIBK; hexone ³	TWA 100 ppm (410 mg/m ³)	500 ppm	Irritating to respiratory tract	OSHA 1004	Anasorb CMS (150/75 mg) SKC 575-002 Passive Sampler 3M 3520 Organic Vapor Monitor	12 L 0.05 L/min 5 to 240 min 5 to 240 min
2742 Low	554-12-1	Methyl propionate	Propionic acid, methyl ester; methyl propanoate; methyl propylate; propanoic acid, methyl ester ⁶	None	No Data in NPG				
2746 High	75-18-3 D650	Methyl sulfide	Dimethyl sulfide; dimethyl sulphide; thiobismethane; DMS; methylthiomethane; 2-thiopropene; 2-thiapropene ³	None	No Data in NPG		SLTC in-house literature file	Charcoal tube (100/50 mg)	5 L 0.1 L/min
2842 Low	107-87-9 2010	2-Pentanone	Ethyl acetone; methyl propyl ketone; MPK ³	TWA 200 ppm (700 mg/m ³)	1500 ppm	Irritating to respiratory tract	NIOSH 1300	Charcoal tube (100/50 mg)	10 L 0.2 L/min

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 FLAVORING SUBSTANCES**

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2908 High	110-89-4 R269	Piperidine	Cyclopentimine; azacyclohexane; cypentil; hexahydropyridine; hexazane; pentamethyleneimine; pentaethyleneimine; pyridine, hexahydro ³	None	No Data in NPG				
2923 High	123-38-6 P129	Propionaldehyde	Propanal; propyl aldehyde; propionic aldehyde ⁵	None	No Data in NPG	suffocating odor ⁵			
2925 Low	109-60-4 2180	Propyl acetate	n-Propyl acetate; n-propyl ester of acetic acid ³	TWA 200 ppm (840 mg/m ³)	1700 ppm	Irritating to respiratory tract	NIOSH 1450	Charcoal tube (100/50 mg)	10 L 0.2 L/min
2926 Low	108-21-4 1540	Isopropyl acetate	Isopropyl ester of acetic acid; 1-methylethyl ester of acetic acid; 2-propyl acetate ³	TWA 250 ppm (950 mg/m ³)	1800 ppm	Irritating to respiratory tract	NIOSH 1454	Charcoal tube (100/50 mg)	9 L 0.2 L/min
2928 Low	71-23-8 2170	Propyl alcohol	n-Propyl alcohol; ethyl carbinol; 1-propanol; n-propanol ³	TWA 200 ppm (500 mg/m ³)	800 ppm	Irritating to respiratory tract	NIOSH 1401	Charcoal tube (100/50 mg)	10 L 0.2 L/min
2929 Low	67-63-0 1560	Isopropyl alcohol	Dimethyl carbinol; IPA; isopropanol; 2-propanol; sec-propyl alcohol; rubbing alcohol ³	TWA 400 ppm (980 mg/m ³)	2000 ppm [10%LEL]	Irritating to respiratory tract	OSHA 109	Two Anasorb 747 tubes in-series (400/200 mg); separate tubes after sampling; ship cold to lab	18 L 0.2 L/min
2943 Low	110-74-7	Propyl formate	Pormic acid, propyl ester; propyl methanoate; propylformate ⁶	None	No Data in NPG				
2944 Low	625-55-8	Isopropyl formate	Formic acid, isopropyl ester; isopropyl formate; isopropyl methanoate; isopropylformate ⁶	None	No Data in NPG				

**APPENDIX D
 FLAVORING SUBSTANCES**

FEMA No. and Priority ¹	CAS No. and OSHA IMIS ² No.	Substance	Synonyms	PEL	IDLH ³	Respiratory Acute ^{3,4}	Analytical Method ²	Sampling Medium ²	Air Volume and Sampling Rate ²
2966 High	110-86-1 2220	Pyridine	Azabenzene; azine ³	TWA 5 ppm (15 mg/m ³)	1000 ppm	Irritating to respiratory tract	SLTC in-house file	Two XAD-7 tubes in-series (100/50 mg); separate tubes after sampling	10 L 0.1 L/min
3039 High	7446-09-5 2290	Sulfur dioxide	Sulfurous acid anhydride; sulfurous oxide; sulfur oxide ³	TWA 5 ppm (13 mg/m ³)	100 ppm	Irritating to respiratory tract	NIOSH 6004	MCEF filter followed by Na ₂ CO ₃ -coated cellulose filter	200 L 1.5 L/min
3173 Low	5077-67-8	1-Hydroxy-2-butanone		None	No Data in NPG				
3217 High	764-40-9	2,4 Pentadienal		None	No Data in NPG				
3218 High	764-39-6	2-Pentenal		None	No Data in NPG				
3219 High	107-85-7	Isopentylamine	1-Amino-3-methylbutane ⁶	None	No Data in NPG				
3223 High	108-95-2 2040	Phenol	Carbolic acid; hydroxybenzene; monohydroxy-benzene; phenyl alcohol; phenyl hydroxide ³	TWA 5 ppm (19 mg/m ³) [skin]	250 ppm	Corrosive, Pulmonary edema	OSHA 32	XAD-7 tube (100/50 mg)	24 L 0.1 L/min
3233 Low	100-42-5 2280	Styrene	Ethenyl benzene; phenylethylene; styrene monomer; styrol; vinyl benzene ³	TWA 100 ppm C 200 ppm 600 ppm (5-minute maximum peak in any 3 hours)	700 ppm	Irritating to respiratory tract	OSHA 89	TBC-coated Charcoal tube (100/50 mg)	12 L 0.05 L/min

**APPENDIX D
 FLAVORING SUBSTANCES**

FEMA No. and Priority ¹	CAS No. and OSHA IMIS ² No.	Substance	Synonyms	PEL	IDLH ³	Respiratory Acute ^{3,4}	Analytical Method ²	Sampling Medium ²	Air Volume and Sampling Rate ²
3326 Low	67-64-1 0040	Acetone	Dimethyl ketone; ketone propane; 2-propanone ³	TWA 1000 ppm (2400 mg/m ³)	2500 ppm [10%LEL]	Irritating to respiratory tract	OSHA 69	Carbosieve S-III tube (130/65 mg)	3 L/0.05 L/min
3368 Low	141-79-7 1635	4-Methyl-3-penten-2-one	Isobutenyl methyl ketone; isopropylideneacetone; methyl isobutenyl ketone; mesityl oxide ³	TWA 25 ppm (100 mg/m ³)	1400 ppm [10%LEL]	Irritating to respiratory tract	NIOSH 1301	Charcoal tube (100/50 mg)	10 L 0.2 L/min
3382 Low	1629-58-9	1-Penten-3-one	Ethyl vinyl ketone ⁶	None	No Data in NPG				
3407 Low	497-70-0	2-Methyl-2-butenal		None	No Data in NPG				
3417 Low	625-33-2	3-Penten-2-one	Ethylidene acetone; methyl propenyl keto ⁶	None	No Data in NPG				
3478 Low	109-79-5 0480	1-Butanethiol	Butanethiol; n-butanethiol; 1-mercaptobutane; n-butyl mercaptan ³	TWA 10 ppm (35 mg/m ³)	500 ppm	Irritating to respiratory tract	SLTC in-house literature file	Mercuric acetate-coated 37-mm glass fiber filter	20 L 0.2 L/min
3521 High	107-03-9	Propanethiol	3-Mercapto-propane; propane-1-thio; propyl mercaptan; n-propyl mercaptan ³	None	No Data in NPG				
3523 High	123-75-1	Pyrrolidine	Azacyclopentane, prolamine, pyrrole, tetrahydro-; tetrahydropyrrole, tetramethyleneimi ⁶	None	No Data in NPG				
3536 Low	624-92-0	Dimethyl disulfide	Methyl disulfide; dimethyl disulfide; dimethylsulphide, dimethyldisulfide, disulphide, dimethyl; disulfide, dimethyl; 2, 3-dithiabutane; DMDS Evolution ⁶	None	No Data in NPG		SLTC in-house literature file	Charcoal tube (100/50 mg)	10 L 0.1 L/min
3537	108-83-8 0924	2,6-Dimethyl-4-heptanone	Diisobutyl ketone; DIBK; sym-diisopropyl acetone; isovalerone; valerone ³	TWA 50 ppm (290 mg/m ³)	500 ppm	Irritating to respiratory tract	NIOSH 1300	Charcoal tube (100/50 mg)	25 L 0.2 L/min

**APPENDIX D
 FLAVORING SUBSTANCES**

FEMA No. and Priority ¹	CAS No. and OSHA IMIS ² No.	Substance	Synonyms	PEL	IDLH ³	Respiratory Acute ^{3,4}	Analytical Method ²	Sampling Medium ²	Air Volume and Sampling Rate ²
3553 Low	78-59-1 1538	Isophorone	Isoacetophorone; 3,5,5-trimethyl-2-cyclohexenone; 3,5,5-trimethyl-2-cyclohexen-1-one ³	TWA 25 ppm (140 mg/m ³)	200 ppm	Irritating to respiratory tract	NIOSH 2508	Petroleum-based Charcoal tube (100/50 mg)	12 L 0.2 L/min
3584 Low	616-25-1	1-Penten-3-ol	Ethyl vinyl carbinol; 1-pentenol-3 ⁶	None	No Data in NPG				
3646 Low	107-86-8	3-Methyl-2-butenal	3-Methyl-2-butenal; 3, 3-dimethylacrylaldehyde; 3, 3-dimethylacrolein; 3-methylcrotonaldehyde; senecioaldehyde ⁶	None	No Data in NPG				
3647 Low	556-82-1	3-Methyl-2-buten-1-ol	2-Buten-1-ol, 3-methyl-; dimethylallyl alcohol; gamma, gamma-dimethylallyl alcohol; 3, 3-dimethylallyl alcohol; prenil; prenyl alcohol ⁶	None	No Data in NPG				
3667 Low	101-84-8 2047	Diphenyl ether	Diphenyl oxide; phenoxy benzene; phenyl oxide; phenyl ether ³	TWA 1 ppm (7 mg/m ³)	100 ppm	Irritating to respiratory tract	SLTC in-house file	XAD-7 tube (100/50 mg)	20 L 0.2 L/min
3779 High	7783-06-4 1480	Hydrogen sulfide	Hydrosulfuric acid; sewer gas; sulfuretted hydrogen ³	C 20 ppm 50 ppm [10-minute maximum peak]	100 ppm	Irritating to respiratory tract, Pulmonary edema	OSHA 1008	Special sampling tube containing uncoated GFF followed by Na ₂ CO ₃ -coated GFF followed by two AgNO ₃ -coated silica gel beds (200/200 mg)	7.5 L 0.5 L/min ceiling 5 L 0.5 L/min Peak
3860 Low	624-89-5	Methyl ethyl sulfide		None	No Data in NPG				
3897 High	75-33-2 S248	2-Propanethiol	Isopropanethiol; 2-propanethion; 2-mercaptopropane ³	None	No Data in NPG				

**APPENDIX D
 FLAVORING SUBSTANCES**

FEMA No. and Priority ¹	CAS No. and OSHA IMIS ² No.	Substance	Synonyms	PEL	IDLH ³	Respiratory Acute ^{3,4}	Analytical Method ²	Sampling Medium ²	Air Volume and Sampling Rate ²
3898 High	5724-81-2	1-Pyrrolidine		None	No Data in NPG				
3909 Low	108-94-1 0830	Cyclohexanone	Anone; cyclohexyl ketone; pimelic ketone ³	TWA 50 ppm (200 mg/m ³)	700 ppm	Irritating to respiratory tract	OSHA 1	Chromosorb 106 tube (100/50 mg)	10 L 0.2 L/min
3946 Low	583-60-8 1765	2-Methylcyclohexanone	o-Methylcyclohexanone ³	TWA 100 ppm (460 mg/m ³) [skin]	600 ppm	Irritating to respiratory tract	NIOSH 2521	Porapak Q tube (150/75 mg)	6 L 0.05 L/min
3965 Low	78-96-6 A606	1-Amino-2-Propanol	Isopropanolamine; 1-aminopropan-2-ol; aminopropyl alcohol; 2-hydroxypropylamine ³	None	No Data in NPG		OSHA PV2122	NTIC-coated XAD-2 tube (80/40 mg)	20 L 0.1 L/min
	Not applicable 9135	Particulates not otherwise regulated (Total Dust)	PNOR (Total Dust)	15 mg/m ³			OSHA PV2121	Tared 37-mm low-ash PCV filter	960 L 2.0 L/min
	Not applicable 9130	Particulates not otherwise regulated (Respirable Fraction)	PNOR (Respirable Fraction)	5 mg/m ³			OSHA PV2121	Tared 37-mm low-ash PCV filter	10-mm Nylon Cyclone; 816 L 1.7 L/min

† OSHA Method PV2118 is suitable for diacetyl, but it would be more convenient to use either OSHA Method 1012 or Method 1013.

Notes / References:

- ¹ The High/Low Priority notations were assigned by the Flavor And Extract Manufacturers Association (FEMA). The priority levels were assigned based on inhalation exposure data, chemical structure, and volatility. FEMA stated that the higher priority chemicals pose a greater risk of respiratory injury, whereas, the lower priority chemicals pose a hazard only in more extreme circumstances of exposure. {Ref:17}
- ² OSHA Chemical Sampling Information http://osha.gov/dts/chemicalsampling/toc/toc_chemsamp.html
- ³ NIOSH Pocket Guide to Chemical Hazards. <http://www.cdc.gov/niosh/npg/>
- ⁴ International Chemical Safety Cards. <http://www.cdc.gov/niosh/ipcs/ipccard.html>
- ⁵ Lewis, R.J. *Hawley's Condensed Chemical Dictionary*, 14th Edition [CD-ROM] Wiley Interscience: New York, 2002.
- ⁶ ChemWatch Material Safety Data Sheet. <http://osha.chemwatch.us/> (accessed May 22, 2007 by paid subscription).

7, 8 Air samples for both diacetyl and acetoin are collected on two single-section sampling tubes connected in series with flexible tubing. The two sampling tubes must be protected from light because light will decompose diacetyl and acetoin. If the protective tube cover is opaque it may be sufficient to protect the sampling tubes from light, otherwise wrap the sampler with aluminum foil. The two tubes must be separated, capped, and protected from light with aluminum foil or other opaque material after sampling. Two methods were fully validated at different levels for the analysis of samples; both diacetyl and acetoin are determined simultaneously. OSHA Method 1012 has been optimized for levels of about 50 parts-per-billion and uses post sampling chemical derivatization and analysis by gas chromatography with electron capture detection. The other method, OSHA Method 1013, has been streamlined for levels of about 500 parts-per-billion; and uses solvent extraction and analysis by gas chromatography with flame ionization detection. Samples are stable for at least two weeks before analysis; and up to 80% relative humidity in the sampled air has no effect on sample results when the specified sampling and analytical procedures are followed.

9 Persons wishing to sample for diacetyl may find it more convenient to use either OSHA Method 1012 or Method 1013 than OSHA Method PV2118. Methods 1012 and 1013 allow both diacetyl and acetoin to be determined from the same sample and permits a longer sampling time.

NPG = NIOSH Pocket Guide to Chemical Hazards (referenced above)

Appendix E

Hazards at Flavoring Manufacturing Workplaces

Introduction:

The Flavor and Extract Manufacturers Association (FEMA) has identified the following conditions under which significant exposures to diacetyl or other food flavoring chemicals may occur. However, CSHOs should examine **all** potential exposures, especially in the production room.

Production Room:

In the production room, liquid and/or powdered flavors are formulated by manually (scooping, pouring) combining several different chemical ingredients and/or mixing flavor compounds with food ingredients. Most often, open containers are used to pour and measure these ingredients which are then transferred to open tanks for liquid flavorings, or blenders for powdered flavorings. In some instances, the flavoring is heated repeatedly, mixed, and then re-heated again.

The following work practices can greatly reduce opportunities for employee exposure to diacetyl and other food flavoring chemicals:

- Mixing should be conducted in fully or partially closed containers with local ventilation.
- Liquid flavoring substances should be piped, not poured, into mixing containers.
- Any pouring should be done slowly and carefully to prevent spilling.
- In some instances liquids can be transferred into mixing containers below the surface of solutions in the container to minimize splashing.
- Pouring powdered flavors slowly, and close to the mixing container, minimizes airborne particulates.
- Cold storage should be provided for flavoring chemicals, as this would reduce evaporative emissions arising from pouring.
- When feasible, use a closed transfer process.
- Using lids on mixing and holding tanks while not in use.
- Adding the powdered ingredients last to the liquid mixture also minimizes airborne particles.

Laboratory:

Research and Development (RD) and Quality Assurance and Control laboratories all provide opportunities for exposure to flavoring chemicals. NIOSH recommends using laboratory exhaust hoods whenever employees are required to handle open containers of flavoring chemicals.

Spray-Dry Manufacturing Process:

The Spray-drying manufacturing process is a process in which a flavor is attached to a carbohydrate substrate. This process includes flavors such as fruit, dairy and savory flavors. In their finished form, the spray dried flavors are powders, and this process provides opportunities for inhalation exposure. Other sources of exposure during this process include the blending in, and collection of powder product from, the ribbon blender.

NIOSH has recommended the following:

- Securing the top of the product bag to the outlet of the blender when unloading.
- Using a continuous liner to provide a continuous pull-down bag to contain any dust generated during collection.
- Using a local exhaust ventilation hood around the outlet to contain potential dust emissions.

Cleaning Operations:

Tanks or other vessels that contain liquid flavors or mixtures are cleaned with steam or heated water. Tanks or vessels that contain powdered flavoring most often are cleaned with compressed air. These cleaning methods can result in increased exposures to employees. The cleaning areas should be isolated and contained to prevent the dissemination of airborne food flavoring chemicals. FEMA recommends an automated cleaning process, while NIOSH recommends that during cleaning, an initial wash down of the tank or vessel be done with cold water, followed by a rinse with warm water.

Appendix F CSHO Guidance for Employee Interviews

*This appendix contains some questions that may assist CSHOs during employee interviews. This is not a specific questionnaire, but these questions may help to assess possible health issues in employees in the flavoring manufacturing industry. The questions do not need to be asked verbatim, but the topics can guide the interview. **It is very important to ask employees questions about a history of cough or breathing problems, and specifically ask if employees have ever been diagnosed with airways obstruction or bronchiolitis obliterans.** Please be aware that the answers to some of these questions may contain privileged medical information, which must be maintained in such a manner as to ensure employee confidentiality. The CSHO should also inform the employee that he/she is not a medical professional and cannot provide medical advice, diagnosis, or treatment to the employee. The CSHO can provide the letter in Appendix B for the employee to take to his/her physician.*

A. Smoking history:

1. Do you currently smoke or have you smoked in the past? (If yes, ask how many packs/day and how long has the employee smoked, and when did the employee quit.)

B. Eye and Skin Irritation

Ask the employee about eye and skin irritation, and ask if the employee associates any symptoms with workplace exposure. For example:

1. Since working at the plant, have you had any symptoms of eye irritation, such as watery eyes, red eyes, burning or itching eyes?
2. Is there any exposure at work that you associate with eye irritation?
3. Have you seen a doctor for eye irritation? (If yes, ask if employee was given a specific diagnosis).
4. Since working at this plant have you developed any skin problems, such as itching, rash, eczema, blisters, or burns?
5. Is there any exposure at work that you associate with skin problems?
6. Have you seen a doctor for skin problems? (If yes, ask if employee was given a specific diagnosis).

C. Respiratory Symptoms and History

*Ask the employee about respiratory symptoms and ask if the employee associates any symptoms with workplace exposures. **Be sure to specifically ask employees about breathing difficulty and coughing.***

1. **Do you usually have a cough?** If yes, when did the cough start?
2. Have you seen a doctor for your cough? (If yes, ask if employee was given a specific diagnosis).
3. Have you ever had any symptoms of wheezing when you breathe? If yes, when did the wheezing start?
4. Have you seen a doctor for your wheezing? (If yes, ask if employee was given a specific diagnosis).
5. **Have you developed any trouble with your breathing, or do you ever feel short of breath?** If yes, when did this start?
6. How often do you have trouble with your breathing?
7. Does it ever get completely better?
8. Do you have breathing trouble when walking up a slight hill, or going up a flight of stairs, or hurrying on level ground? (If yes, please have employee describe when they have breathing difficulty).
9. Have you seen a doctor for your breathing problems? (If yes, ask if employee was given a specific diagnosis).
10. **Is there any exposure at work that you associate with any of your respiratory symptoms?**

*Ask employee if they have a history of any lung disease. **Be sure to specifically ask about any diagnosis of airways obstruction and bronchiolitis obliterans.***

1. Have you ever been diagnosed by a doctor with any lung or respiratory disease? For example: bronchitis, chronic bronchitis, pneumonia, emphysema, asthma, reactive airways disease.
2. If yes, what is your diagnosis and when were you diagnosed?
3. If yes, are you currently seeing a physician for this condition?
4. Have you ever been told by a doctor that you had airways obstruction or bronchiolitis obliterans?
5. Have you ever been told you had a lung disease or lung condition related to workplace exposures, including exposure to food flavorings containing diacetyl?

Ask employee about former co-workers who developed respiratory illnesses.

Appendix G Recommended Engineering and Work Practice Controls

1. Engineering and work practice controls are the primary methods for controlling exposures to hazardous flavoring chemicals in the workplace and include local exhaust and general dilution ventilation, isolation of process or source, and restricted access to areas where the chemicals are used or stored.
 - NOTE: NIOSH has recommended that the use of respiratory protection be **mandatory** for all mixers and employees entering the mixing room until such time as the production process is reengineered or enclosed to eliminate exposures to flavoring chemicals.
2. CSHOs should investigate the employer's process to determine whether any of the following recommended engineering and work practice controls, which have been shown to help reduce employee exposures to flavoring chemicals, are being utilized where applicable. CSHOs should also investigate whether other control measures not listed below have been implemented. Recommended controls include:
 - a. Isolating flavoring production areas from the rest of the plant using walls, doors, or other appropriate barriers.
 - b. Equipping the production room and other areas where flavorings are handled with a separate ventilation system and ensuring that negative air pressure (0.04 w.g. \pm 0.02 w.g. relative to the rest of the plant) is maintained in those areas. This will control the outward migration of contaminated air to adjacent areas of the plant.
 - c. Installing movable exhaust hoods (flexible exhaust ducts) and ensuring the movable LEV can be utilized where powder or liquid flavorings are manually blended, weighed, mixed, poured, transferred, packed, or handled (i.e., tank or blender filling operations, powder dumping operations, drum pouring operations, quality control operations, and compounding operations). The LEV should at a minimum achieve a capture velocity of 100 feet per minute (fpm) between the emission source and hood opening. Direct ventilation exhaust outside of the plant in a manner compliant with environmental regulations.
 - d. Reducing the operating temperature of the holding and mixing tanks to that necessary to prevent solidification of the flavoring mixture (normally $<120^{\circ}$ F). This aids in reducing the volatilization of components not limited to the butter or food flavorings containing diacetyl and their release into the workroom air.

- e. Equipping the head space of flavoring blenders and tanks where flavorings are compounded or held in pure form with local exhaust ventilation or using a closed process to transfer flavorings. Ensuring the tank opening is achieving a minimum of 100 fpm across the opening of the tank (face).
- f. Automation of the mixing process.
- g. Covering the flavoring and finished oil tanks, and ventilating the headspace to reduce emissions into the room.
- h. Eliminating spillage from overfilling tanks, leaks in seals and fittings, and the manual transfer of materials, all of which have been identified as sources of emissions.
- i. Reducing dust exposure during bag dumping by installing commercially available bag dumping stations equipped with local exhaust ventilation (three-sided canopy hood) and bag disposal.
- j. Controlling exposure to flavoring powders during collection or dispensing of final product. Collection bags secured to the outlet and continuous liners used with local exhaust ventilation are options to control exposures to flavoring dust and VOCs.
- k. Using laboratory hoods in quality control and quality assurance areas where products are compounded or handled and exposure to VOCs or respirable dust may occur and achieving a minimum face velocity of 100 fpm across the opening of the hood.
- l. Putting lids on transfer buckets to avoid residual vapor release and/or placing buckets in a ventilated area following transfer; or pumping flavoring from smaller to larger tanks to avoid manual transfer altogether.
- m. Adding flavorings at room temperature.
- n. If a flavoring must be heated prior to adding it to the flavoring tank or mixing tank, transferring the flavoring to the tank via a pumping system rather than by manual transfer.
- o. Providing additional general dilution ventilation using axial flow wall fans.
 - o Note: During the cold months, adequate tempered make-up air is required.
- p. Storing volatile flavoring substances in cooled storage areas, with their own air handler that has minimum circulation.
- q. Establishing and instituting standard procedures for cleaning workplace tanks, containers, and spills. Isolating cleaning areas, and ensuring that vessels used for powdered flavoring chemicals are not cleaned with compressed air.
- r. When vessel entry is necessary, ensuring compliance with confined spaces entry requirements.
- s. Using a closed system cleaning process, Clean-In-Place (CIP), for tanks, and blenders
- t. Maintaining good housekeeping in any areas where flavoring chemicals are handled.

Appendix H

Safety & Health Precautions for Compliance Staff

General

The CSHO will review the employer's hazard assessment during the opening conference. Special attention shall be given to the types of personal protective equipment required by the employer for his employees. This will assist the CSHO in determining his or her own PPE needs prior to entering the facility. A CSHO must be vigilant about wearing PPE that is appropriate for the operations being performed at the establishment.

1. CSHOs should avoid all exposure to diacetyl and other food flavoring chemicals to the extent possible.
2. If a CSHO's exposure is unavoidable during inspection or sampling activities, the CSHO should wear full-face or half-face with organic vapor cartridges and particulate filter and goggles. In addition, he/she should wear protective clothing, such as disposable coveralls, and protective gloves. If there is any potential for contact with skin from splashes, or particulates, and the CSHO has only a half-face Air-purifying respirator (APR), he or she should also wear chemical splash goggles and/or a face shield to protect the eyes.
3. CSHOs must change their cartridges each day they enter a facility, even if they assume exposure to diacetyl and other food flavoring chemicals is limited. For example if the inspection takes more than one day to complete, then the CSHO must have one set of cartridges for each day.

Appendix I Guidelines for Outreach Activities

This Appendix summarizes the procedures for conducting outreach activities. Outreach offers employers an opportunity to address potential health hazards before they result in employee illness. Studies have shown that lung dysfunction, restrictive airways obstruction and bronchiolitis obliterans are associated with exposure to flavoring chemicals.

NIOSH Health Hazard Evaluation and Petition for an Emergency Temporary Standard

NIOSH released its final Health Hazard Evaluation Report titled Gilster-Mary Lee Corporation, Jasper, Missouri, in January 2006. This report concluded that workers with inhalation exposure to butter flavoring ingredients, including diacetyl, were at risk for occupational lung disease. Since the publication of this final report, major news organizations published several articles on employees' exposure to diacetyl. As a result, on July 26, 2006, the United Food and Commercial Workers International Union (UFCW) and the International Brotherhood of Teamsters (IBT) petitioned the Department of Labor to issue an Emergency Temporary Standard (ETS) for diacetyl (2,3-butanedione, CAS #431-0308). This petition received strong support from several former OSHA and EPA officials, as well as several members of academia and occupational safety and health experts.

OSHA's Response

Currently, the Directorate of Standards and Guidance (DSG) is developing a proposed standard covering food flavorings containing diacetyl. Meanwhile the Directorate of Enforcement Programs (DEP) issued a Direction entitled "*National Emphasis Program-Microwave Popcorn Processing Plants*," the Directorate of Science, Technology and Medicine (DSTM) issued its Safety and Health Information Bulletin (SHIB) entitled "*Respiratory Disease Among Workers in Microwave Popcorn Processing Plants*," and that office is also developing a SHIB specifically addressing flavoring chemicals. DSG also issued a guidance document entitled "*Hazard Communication Guidance for Diacetyl and Certain Food Flavorings containing Diacetyl*."

OSHA Outreach Activity

In an October 12, 2004 Memo, the regions were asked to contact employers within their regions who may have employees exposed to popcorn flavoring chemicals and alert them of NIOSH's 2002 preliminary findings that workers in the microwave popcorn industry were identified with the disease bronchiolitis obliterans. Now that NIOSH's 2006 (Gilster-Mary Lee Corporation - Jasper, Missouri. National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation Report #2000-0401-2991, January 2006) and 2007 (Kanwal NIOSH's Report on Severe Fixed Obstructive Lung Disease in Workers at a Flavoring Manufacturing Plant. National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation Report #2006-0303-3043, April 2007) reports are out, OSHA will institute the following:

Directorate of Training and Education

- Outreach materials will be developed by DTE and should be used as applicable by the OSHA field staff for their outreach activities.
- DTE and NIOSH developed a Diacetyl webcast which is now available at:
<https://learninglink.dol.gov> # 0020

Regional Offices

- Regional Offices should consult with the States to ensure that they are addressing flavoring related problems during their consultation visits.

Area Offices

- OSHA will not begin enforcement activity until at least 60 days after the effective date of this NEP.
- Each Area Office is also encouraged to mail letters to employers covered by this NEP. Letters with information about this NEP should also be sent to local hospitals, local unions, local occupational health clinics, local occupational physicians and professional organizations.
- News releases through local and national news organizations will increase the awareness of affected employees and health care organizations.
- Area Offices are also encouraged to contact temporary employment agencies to alert them about this NEP, and request that they provide information about the NEP to any of their clients who are involved with manufacturing flavors containing diacetyl.
- Compliance Assistance Specialists are encouraged to conduct speeches and or other outreach activities aimed at the health care sector and employer and employee groups.
- During outreach activities, **employers** that manufacture flavorings containing diacetyl should be encouraged to implement the following:
 - Provide respiratory protection for all workers entering the mixing room.
 - Provide eye and skin protection for all workers entering the mixing room.
 - Provide spirometry testing for all affected workers.
 - Educate workers on the hazards of exposure to flavoring chemicals.
- During outreach activities **employees** should be encouraged to do the following:
 - Minimize their exposure to flavoring chemicals while working by using the recommendations outlined in this NEP, and becoming familiar with MSDSs for chemicals they work with.
 - Use their respirators at all times, especially when mixing.
 - Participate in all employer training and medical testing programs.
 - Report to their doctors any symptoms they develop, such as persistent cough or difficulty breathing, and provide the doctor with a copy of NIOSH's findings.

- During these outreach activities, the Compliance Assistant Specialists (CASs) are encouraged to compile a list of frequently asked questions, along with their responses, and utilize these as a reference for future questions.
- Regional and Area Offices are encouraged to work with their State OSHA Consultation Office to communicate the goals of this NEP. Consultation Offices are encouraged to conduct outreach activities to support this NEP. Any request for consultative visits from employers as a result of this NEP should be given priority over other consultation requests.

Appendix J References:

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