

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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**NOTICE OF PROPOSED MODIFICATION TO
CALIFORNIA CODE OF REGULATIONS**

TITLE 8: Division 1, Chapter 4, Subchapter 7, Group 16, Article 109, Section 5197
of the General Industry Safety Orders

Occupational Exposure to Food Flavorings Containing Diacetyl

Pursuant to Government Code Section 11346.8(c), the Occupational Safety and Health Standards Board (Standards Board) gives notice of the opportunity to submit written comments on the above-named regulation in which modifications are being considered as a result of public comments and/or Standards Board staff consideration.

On November 19, 2009, the Standards Board held a Public Hearing to consider revisions to Title 8, Section 5197 of the General Industry Safety Orders, California Code of Regulations. The Standards Board received written and oral comments on the proposed revisions. Further modifications are now proposed for all subsections and appendices.

This notice of proposed modification contains numerous nonsubstantive, editorial, reformatting, and grammatical revisions. These nonsubstantive revisions are not all discussed. However, these proposed revisions are clearly indicated in the regulatory text. In addition to these nonsubstantive revisions, the following actions are proposed:

Subsection (a), scope and application, has been restructured to clearly differentiate between the two aspects. It is proposed to re-title the subsection as "General Requirements" and clearly demarcate scope and application in different parts of the subsection. The restructuring of the scope and application requirements as well as other changes in wording are in response to comments requesting greater clarity. Also proposed for addition to subsection (a) is exposure to other artificial butter flavoring. The purpose and necessity for adding this concept is to address the fact, raised by numerous public comments, that diacetyl is increasingly being replaced in the work environment by substitute butter flavoring compounds which early research indicates in some cases may be as toxic as diacetyl. One "NOTE" in the originally noticed subsection (a) has also been relocated for clarity, and another "NOTE" is proposed for deletion because it is no longer needed in the restructured and easier to follow subsection. An additional "NOTE" is proposed to clarify that none of the provisions of the proposed regulation supplant or otherwise contradict workers compensation regulations. This additional note is necessary to avoid any possibility of confusion about the relationship of this proposed regulation to the workers compensation system by assuring the regulated public that this proposed regulation is merely supplemental, additional or complementary to workers compensation regulations.

For subsection (b) [definitions], numerous alterations and additions are proposed for purposes of clarity, consistency or technical accuracy. In most cases the new terms are not defined elsewhere in Title 8. The following are the proposed new definitions: “Authorized person,” “Certified industrial hygienist (CIH),” “Equivalent method,” “Limit of detection,” “Medical guidelines,” “NIOSH,” “OSHA Method,” “OSHA reliable quantitation limit (OSHA RQL),” “Other artificial butter flavoring,” and “Reliable quantitation limit (RQL).”

Modifications are proposed for subsection (c) [exposure assessment]. One proposed change clarifies that sampling and analytical methods equivalent in accuracy to the OSHA method are permitted. Another modification specifies the date following the adoption of this regulation by which initial monitoring must be completed. Also an “Exception” is proposed to clarify that it may not be necessary to repeat air monitoring done prior to the adoption of this regulation if the proper sampling and analytical methods were utilized. It is also proposed here and elsewhere in the regulation that the concept of detection of diacetyl be clarified from the ambiguous “detectable diacetyl” to a more specific reference to the OSHA RQL.

Restructuring of the temporary regulated area provisions of subsection (d) are proposed for the purpose of achieving greater clarity. In subsection (d)(4)(A) a reference to a recordkeeping requirement contained in subsection (k)(1) is changed for purposes of clarity and consistency, to directly reference Section 3204 of Title 8.

For subsection (e) [engineering controls and work practices], additional examples of methods to control diacetyl exposures are proposed for the purpose of providing increased information in and clarity to this subsection. In response to comments, a requirement that the employer document reasons for any delay in implementation of work practice and engineering controls is proposed for addition.

A proposed change to subsection (f) [respiratory protection] would require that appropriate respiratory protection be selected from a new Respiratory Protection Selection Table. This change is necessary for clarity because the regulation as originally proposed could have lead to incorrect selection of respirators based upon inappropriate reliance on parts of Section 5144 of these Orders that do not at this time give appropriate guidance for respirator selection decisions for exposure to diacetyl. Addition of three new “Notes” is also proposed for this subsection to ensure there is sufficient guidance for respiratory selection within the proposed regulation.

For clarity, a restructuring of part of subsection (g), medical surveillance, is proposed. Also, in response to comments, a change is proposed for the timing of the provision of initial medical surveillance. The suggested change is necessary for consistency with the latest scientific and medical evidence regarding the duration of exposure to diacetyl that might cause permanent injury, and is therefore necessary for protection of employees.

Minor rewording is proposed for part of subsection (h) [PLHCP Written Opinion] addressing circumstances when an employee wishes the employer to pay for a second medical opinion. The rewording is necessary to clarify the originally noticed description of this requirement. Also, a reference to Section 5144(e)(6) of these Orders is proposed for deletion as it is duplicative and not necessary in subsection (h).

For subsection (i) [medical removal], only minor alterations are proposed for the purpose of clarity and consistency.

Changes are proposed for subsection (j) [information, training and labeling] to add information about other artificial butter flavoring to the training and labeling provisions of the regulation. These changes are necessary because of increased usage of diacetyl alternatives whose toxicity, while not yet thoroughly tested, looks from preliminary data to be similar to that of diacetyl. The inclusion of requirements for training and labeling for these substitutes is consistent with the requirements of the Hazard Communications standard, Section 5194 of these Orders. It is necessary to include this requirement in the information, training and labeling subsection of Section 5197 so that all training requirements are clear and located succinctly in one regulation. An additional change proposed is a requirement that employers include information from CDPH Health Hazard Alerts in their training of employees. This change is necessary because the information from the CDPH, while still an essential training element, was contained in the originally proposed mandatory Appendix C. However, Appendix C is now proposed for deletion.

In subsection (k) [record keeping and reporting], as a result of limited Division capability to maintain database security, deletion is proposed for the requirement for submittal of the questionnaire contained in Appendix D. This factor and other resource concerns make impractical Division utilization of that questionnaire. In place of the deleted questionnaire, addition of a one-time reporting requirement is proposed for all employers covered by the standard. The new proposed reporting requirement is responsive to comments that questioned the exclusion of certain users from reporting, and the proposed requirement will still fulfill some of the same purposes as the Appendix D questionnaire without presenting the same database security issues.

Deletion of subsection (l) [MSDS preparation] is proposed because of potential conflict with Federal OSHA requirements and because Section 5194 provides coverage.

Substantial deletions are proposed for Appendix A [sampling and analytical protocol] because the OSHA Method, incorporated by reference, includes the material proposed for removal, so the deletions are for the purpose of avoiding duplication. Other proposed changes are for the purpose of clarity and for consistency with the terminology now proposed in the definitions in subsection (b).

Appendix C, a Health Hazard Alert of the CDPH, was mandatory in the regulation as originally proposed. Deletion of Appendix C is proposed to make the proposed regulation shorter and more user-friendly. Access to the material is still provided by additional training requirements proposed for subsection (j), which includes the CDPH Health Hazard Alert as an element of training.

Appendix D, a questionnaire, is proposed for deletion because of data base security concerns discussed above. A one-time report of use requirement proposed for subsection (k) would still provide some of the information that would have been accessible from the questionnaire.

A copy of the revised text with these modifications clearly indicated is attached for your information.

Any written comments on these modifications must be received by 5:00 p.m. on August 20, 2010, at the Occupational Safety and Health Standards Board's Office, 2520 Venture Oaks Way, Suite 350, Sacramento, California 95833 or submitted by fax to (916) 274-5743 or e-mailed to oshsb@dir.ca.gov. This proposal will be scheduled for adoption at a future Business Meeting of the Occupational Safety and Health Standards Board.

The Occupational Safety and Health Standards Board's rulemaking file on the proposed action is open to public inspection Monday through Friday, from 8:00 a.m. to 4:30 p.m. at the Standards Board's Office, 2520 Venture Oaks Way, Suite 350, Sacramento, California.

Inquiries concerning the proposed changes may be directed to the Executive Officer, Marley Hart at (916) 274-5721.

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Original signed by

Marley Hart, Executive Officer

Date: August 5, 2010

PROPOSED MODIFICATIONS
(Modifications are indicated in bold
underline wording for new language
and bold strikeout for deleted language.)

STANDARDS PRESENTATION
TO
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PROPOSED STATE STANDARD, 5197
TITLE 8, DIVISION 1, CHAPTER 4

Add Section 5197 as follows:

§ 5197. ~~Repair of Magnesium Dust Collecting Units.~~ Occupational Exposure to Food Flavorings Containing Diacetyl.

(a) ~~Scope and Application~~ General Requirements.

(1) Scope.

(A) This section applies to all places of employment where food products or flavorings are manufactured, processed or used and one or more processes in the establishment utilize diacetyl or food products or flavorings that contain diacetyl at a concentration of 1% or more by weight, that meet both of the following conditions:

~~(A) Food products or flavorings are manufactured in the establishment, and~~

~~(B) One or more processes in the establishment utilize diacetyl or food products or flavorings that contain diacetyl at a concentration of 1% or more by weight.~~

(2B) This section also applies in part, as set forth in subsection (a)(2), to any place of employment utilizing food products or flavorings that contain diacetyl or other artificial butter flavoring at any concentration, and non-manufacturing place of employment at which all of the following conditions are met:

~~(A) Food products or flavorings containing diacetyl at a concentration of 1% or more by weight are processed or used, or diacetyl is used, and,~~

~~(B) An employee has been diagnosed by a physician or other licensed health care professional [PLHCP] as having fixed obstructive lung disease and,~~

~~(C) The PLHCP has determined that no cause other than occupational exposure to diacetyl is readily apparent.~~

~~(3) Places of employment other than those identified in subsections (a)(1) and (a)(2).~~

~~(A) The provisions listed in subsection (a)(3)(B) apply to any place of employment that meets both of the following conditions:~~

~~1. an employee has been diagnosed by the PLHCP as having a work-related fixed obstructive lung disease, and~~

~~2. the PLHCP has determined that no cause other than occupational exposure to diacetyl at any concentration is readily apparent.~~

(2) Application.

(A) All employers meeting conditions identified in subsection (a)(1)(A) shall comply with all requirements of this Section.

~~(B) Each employer meeting the conditions identified in subsection (a)(3)(B) shall do all of the following in regard to the diagnosed employee:~~

~~1. treat the diagnosed employee as s~~Subject the employee to medical surveillance pursuant to subsection (g) of this standard,

~~2. Obtain~~ Obtain a written opinion from the PLHCP pursuant to subsection (h),

~~3. provide Comply with medical removal pursuant to the provisions of~~ Comply with medical removal pursuant to the provisions of subsection (i), and

~~4. Report~~ Report the diagnosis to the Division pursuant to subsection (k)(2).

~~(E3) Pursuant to Section 332.3, the Division may require an employer identified in subsection~~

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(a)(~~13~~)(~~BA~~) to take additional actions to protect employees against exposure to diacetyl **or other artificial butter flavor**.

(4) The employer shall provide all safeguards required by this section, including provision of personal protective equipment, respirators, training, and medical surveillance and management in accordance with subsections (g) through (i), at no cost to the employee, at a reasonable time and place for the employee, and during the employee's working hours.

~~NOTES: 1. Obstructive lung disease for which there is an apparent non-occupational cause, such as chronic obstructive lung disease due to smoking, does not trigger application of this standard under subsections (a)(2) and (a)(3).~~

2. NOTES to Section 5197:

1. This section does not preclude the application of other sections of Title 8 including, but not limited to, Sections 3203, 3204, 5141, 5143, 5144, 5155, and 5194.

2. None of the requirements in Section 5197, in particular those described in subsections (g), (h), or (i), supplant or otherwise contradict the rights, privileges, and obligations set forth in Division 4 of the Labor Code (commencing with section 3200), regarding workers' compensation. The requirements in subsections (g), (h), and (i), for medical surveillance, physician opinions regarding an employee's physical condition and work limitations, and medical removal, are supplemental, additional, or complementary to any medical evaluation or indemnity payment procedure required or specified in Division 4 of the Labor Code. The fact that a medical opinion is provided or an employer action is taken pursuant to Section 5197 shall have no bearing on whether the opinion or action is determinative of rights or benefits provided under Division 4 of the Labor Code.

(b) Definitions.

(1) "American Thoracic Society Guidelines" means "ATS/ERS Task Force: Standardisation of Lung Function Testing," a five part series published jointly in 2005 by the American Thoracic Society [ATS] and the European Respiratory Society in five consecutive issues of the European Respiratory Journal **and which is hereby incorporated by reference.**

(2) "**Authorized person**" means **any person specifically authorized by the employer and required by work duties to be present in regulated areas, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures, or the Chief.**

(~~3~~) "CDPH Guidelines" means "Medical Surveillance for Flavorings-Related Lung Disease Among Flavor Manufacturing Workers in California," published in August 2007 by the California Department of Public Health (**CDPH**), **which is hereby incorporated by reference.**

(4) "**Certified industrial hygienist (CIH)**" means **an industrial hygienist who is certified by the American Board of Industrial Hygiene.**

(~~5~~) "Chief" means the Chief of the Division of Occupational Safety and Health, or designee.

(~~4~~) "**Detectable level of diacetyl**" means **an airborne concentration of diacetyl that is above the reliable quantitation limit (RQL) of the sampling and analytical method referenced in Appendix A of this standard.**

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(65) “Diacetyl” means the substance that is also known as 2,3-Butanedione and has CAS (Chemical Abstract Service) #~~4321~~321-03-8. **“Diacetyl” also means a proprietary formulation containing diacetyl, e.g., diacetyl starter distillate [Chemical Abstract Service (CAS) #977019-27-4] unless the manufacturer indicates through the accompanying material safety data sheet (MSDS) or through other written means that the material contains less than one percent diacetyl by weight.**

(76) “Diacetyl-containing” means containing diacetyl at a concentration of 1% or more by weight.

(87) “Enclosed process” means a process that is completely enclosed and from which all emissions are conveyed to a suitable point of safe disposal as verified by an exposure assessment conducted in accordance with subsection (c) and certified in accordance with subsection (e)(5)(F). A process is not enclosed if there are any visible emissions.

(9) **“Equivalent method” means a sampling and analytical method for diacetyl that has been fully validated by the United States Department of Labor’s Occupational Safety and Health Administration (OSHA) or NIOSH as being at least as accurate, specific and sensitive as the OSHA Method and has an RQL less than or equal to the OSHA RQL.**

(108) “Fixed ~~O~~obstructive ~~L~~ung ~~D~~isease” means a medical condition diagnosed by a PLHCP in an individual for whom spirometry has shown fixed airways obstruction. Airways obstruction is defined by a ratio of forced expiratory volume in one second (FEV1) to forced vital capacity (FVC) and an FEV1 value which are both below the lower limit of normal (LLN) as determined by the 95% confidence limits of the values published in “Spirometric Reference Values.” Airways obstruction is considered fixed when, **after the passage of 10 to 20 minutes following administration of 4 puffs of albuterol using a spacer or volume chamber, FEV1 does not increase by at least 12% and 200 milliliters. it persists 10-20 minutes after administration of 4 puffs of albuterol using a spacer or volume chamber.**

(119) “Flavoring” means any substance which is intended primarily to impart flavor to food products.

(1210) “Flavor Worker Initial Questionnaire” means the full-length questionnaire contained in Appendix B1 of this section.

(1311) “Flavor Worker Follow-Up Questionnaire” means the shorter questionnaire contained in Appendix B2 of this section.

(1412) “Food product” means any substance, other than a substance used primarily for the purpose of imparting flavor, intended to be consumed by humans or animals.

(15) **“Limit of detection (LOD)” means the lowest air concentration level of a substance that can, with 99% confidence, be determined to be statistically different from a sample blank.**

(16) **“Medical guidelines” means the following documents which are hereby incorporated by reference:**

(A) CDPH Guidelines

(B) American Thoracic Society Guidelines

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(C) Spirometric Reference Values

(17) NIOSH means the National Institute for Occupational Safety and Health, United States Centers for Disease Control and Prevention.

~~(1813)~~ “Open process” means any process that does not meet the definition of “enclosed process.”

(19) “OSHA method” means OSHA Sampling and Analytical Method #1013 for diacetyl and acetoin, published September, 2008, which is hereby incorporated by reference.

(20) “OSHA reliable quantitation limit or (OSHA RQL)” means the airborne concentration published as the reliable quantitation limit of the OSHA Method. This is 0.012 ppm (0.041 mg/m³) as a 180-minute Time-Weighted Average (TWA) or 0.035 ppm (0.12 mg/m³) as a 15-minute short term average.

(21) “Other artificial butter flavoring” means any flavoring containing diacetyl trimer [CAS #18114-49-3], acetoin [CAS #513-86-0], 2,3 pentanedione [CAS #600-14-6], 2,3 hexanedione [CAS #3848-24-6], or 2,3 heptanedione [CAS #96-04-8].

~~(2214)~~ “PLHCP” means physician or other licensed health care professional who is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the health care services required by this section.

~~(2315)~~ “Process” means an activity or combination of activities that at any stage cools, heats, sprays, mixes, blends, transfers, or otherwise utilizes diacetyl or diacetyl-containing flavorings or food products in the preparation or manufacture of flavorings or food products. For purposes of this standard any interconnected group of vessels that utilizes diacetyl or diacetyl-containing flavorings or food products at any stage shall be considered a single process. Cleaning or sanitizing is considered a distinct process, and spill cleanup is also considered a distinct process.

~~(2416)~~ “Program reviewer” means a certified industrial hygienist or licensed professional engineer who is knowledgeable in both industrial ventilation design and the control of hazardous exposures, and who is responsible for certifying the effectiveness of the employer’s diacetyl control program in accordance with subsection (e)(6).

~~(2517)~~ “Regulated area” means an area demarcated by the employer in which ~~there is potential employees are potentially exposed exposure to detectable~~ levels of diacetyl above the OSHA RQL or an area in which one or more open processes are located.

(26) “Reliable quantitation limit (RQL)” means the smallest concentration of analyte which can be quantitated precisely, providing that the recovery is 100 ± 25% of the theoretical value.

~~(2718)~~ “Signs or symptoms of diacetyl related disease” means persistent irritation of the eyes, nose, throat, or upper or lower respiratory tract, or persistent chest tightness, shortness of breath, cough or wheezing.

~~(2819)~~ “Spirometric Reference Values” means the values set forth in the article titled “*Spirometric Reference Values from a Sample of the General U.S. Population*” by Hankinson, JL, Odencrantz, JR, and Fedan, KB published in 1999 in the ~~journal~~ American Journal of

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Respiratory and Critical Care Medicine, Volume 159, pages 179-187, ~~which is hereby incorporated by reference.~~

~~(2920)~~ “Supervising physician” means the occupational or pulmonary medicine physician **identified described** in subsection (g)(1)(A) who is: **a)** knowledgeable about spirometry, obstructive pulmonary disease, surveillance for occupational disease, the diagnosis and management of occupational disease, and the requirements of this standard; and **b) who is** responsible for ensuring that **compliance with all components of** the medical program **requirements** described in subsection (g), **(h), and (i)** of this standard, **as well as all applicable meet the requirements of this standard and comply with the referenced** medical guidelines.

~~(3021)~~ “Temporary regulated area” means, a) an area that contains an enclosed process but in which exposure to airborne diacetyl or diacetyl-containing flavorings or food products may occur because part or all of the process is temporarily opened, or b) an area in which **employee** exposures to **detectable** levels of diacetyl **above the OSHA RQL** may reasonably be expected to occur due to a spill, leak, or process upset.

(c) Exposure assessment.

(1) General.

(A) A determination of the concentration of airborne diacetyl to which each employee is exposed as an 8-hour time weighted average (TWA) and as a short term exposure, as described in subsections (c)(1)(B) and (c)(1)(C), shall be made from air samples that are representative of the employee's exposure without regard to the employee's use of respiratory protective equipment.

The employer shall follow the **instructions in Appendix A and shall utilize the OSHA Method or an equivalent method. sampling and analytical protocol in Appendix A.**

Cleaning and sanitizing shall be monitored separately from production processes. The employer shall ensure that personal samples include samples that are taken during operations and periods of operations when there is reason to believe exposures are high, such as when tanks or containers are opened, filled, unloaded or cleaned; when process equipment is opened; and when diacetyl or diacetyl-containing flavorings or food products are heated or sprayed.

(B) To determine an 8-hour TWA, the employer shall collect full shift (for at least 7 hours during that shift) personal samples for at least one employee per shift for each job classification and for each process in each work area. If the total duration in which processes involving diacetyl or diacetyl-containing flavorings or food products is less than seven hours, then a representative assessment is the full duration of the employee's exposure on that day.

(C) The employer shall collect personal short term exposure samples to represent the highest likely 15-minute exposure(s) to airborne diacetyl for each process. One or more short term exposure sample shall be collected for at least one employee per shift for each job classification and for each process in each work area.

(2) Initial Monitoring.

(A) **Each Within 60 days following the effective date of this standard, each** employer who has a place of employment or work operation covered by this standard shall monitor each

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process to accurately determine the 8-hour TWA and the short term exposure levels of airborne diacetyl to which employees may be exposed, in accordance with subsection (c)(1).

Exception to subsection (c)(2)(A): Employers need not conduct initial monitoring of a process for which monitoring was performed within six months prior to the effective date of this standard provided that the monitoring was conducted in accordance with subsection (c)(1).

(B) Monitoring To Verify That A Process Is Enclosed. When the program reviewer determines that a process is enclosed (based on its design and construction), the employer shall monitor that process to verify that no **detectable** levels of diacetyl **above the OSHA RQL** are present in the work area. The employer shall conduct an inspection to determine if there are any visible emissions and, in accordance with Appendix A **and the OSHA Method or equivalent method**, shall arrange to conduct a combination of area and personal sampling. If the program reviewer determines that **the design and construction of the process is enclosed**, there are no visible emissions, and that monitoring has not found **detectable** levels of diacetyl **above the OSHA RQL**, then the employer may consider that process to be enclosed for the purposes of this standard.

(C) Monitoring For Regulated Areas. When a regulated area is established due to the presence of an open process, the employer shall conduct, in accordance with Appendix A **and the OSHA Method or equivalent method**, a combination of area and personal sampling to determine whether there are **detectable** levels of diacetyl **above the OSHA RQL** in the regulated area and in areas adjacent to regulated areas.

(3) **Periodic Monitoring Frequency**. Exposure monitoring required by subsection (c)(2) shall be repeated at least annually.

(4) Additional Monitoring. Additional representative monitoring which complies with subsections (c)(1) and (c)(2) shall be conducted within 30 days to evaluate the exposure of all potentially affected employees whenever:

(A) A new process is initiated;

(B) There is any change in process, or production, or in a control measure that may result in new or increased exposures to airborne diacetyl.

(5) Employee Notification.

(A) Within five working days of the employer's receipt of monitoring results, and no later than 30 days after the monitoring was conducted, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(B) Whenever the monitoring results representative of an employee's exposure indicate that the employee's exposure was in excess of the **OSHA RQL detection limit**, the written notice shall include a statement that the **OSHA RQL detection limit** was exceeded and shall also include a description of any corrective actions taken to reduce the employee's exposure to or below the **OSHA RQL detection limit** if such measures are different from those already in place.

(d) Regulated areas.

(1) Establishment.

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(A) The employer shall establish a regulated area for each process using diacetyl or diacetyl-containing flavorings or food products unless the process is ~~an enclosed process. If an enclosed process is opened, or there is a spill, leak, or process upset that would reasonably be expected to release diacetyl, a temporary regulated area, complying with the requirements of this subsection, shall be established for the entire time during which the process is open or until the spill, leak, or process upset has been repaired and all spilled or leaked diacetyl-containing materials have been removed.~~

(B) A temporary regulated area complying with the requirements of this subsection shall be established during any period in which:

1. An enclosed process is opened, or

2. There is a spill, leak, or process upset that could reasonably be expected to result in airborne concentrations of diacetyl above the OSHA RQL or could reasonably be expected to result in exposures to diacetyl-containing powders. The temporary regulated area shall be maintained until the spill, leak, or process upset has been repaired and all spilled or leaked diacetyl-containing materials have been cleaned up and removed.

(2) The regulated area shall be clearly demarcated from the rest of the workplace by signs or other effective means.

(3) Access. Access to regulated areas shall be limited to authorized persons ~~or to persons authorized by the Chief~~. Regulated areas shall be designed or configured so as to minimize the number of employees required to enter or pass through the area.

(4) Supervision. The regulated area shall be supervised by a person designated by the employer, who is knowledgeable about the employer's procedures for controlling exposures to diacetyl, and who has the authority necessary to take prompt measures to correct diacetyl related hazards. The supervisor shall ensure that:

(A) The name and employee identifier of each person who enters the regulated area is recorded on a daily log. These logs shall be maintained as employee exposure records in accordance with ~~subsection (k)(1) of this standard~~ **Section 3204**.

(B) Each person who enters the regulated area has been trained in accordance with this section.

(C) Each person who enters the regulated area utilizes the personal protective equipment and respirators that are required for that area.

(D) The employer's control measures to minimize employee exposure to airborne diacetyl are followed.

(e) Engineering Controls and Work Practices.

(1) The employer shall implement engineering controls and work practices to reduce employee exposure to airborne diacetyl to the lowest levels feasible.

(2) The employer shall utilize measures to minimize vapor, mist and dust exposure to diacetyl including:

(A) Capturing vapors, mists, **powders**, and dusts ~~as effectively as possible~~ by utilizing local exhaust ventilation or by enclosing ~~operations~~ **the process**; and,

(B) Minimizing where practicable the application of heat to processes where heat can contribute

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to exposure to airborne diacetyl; **and,**

(C) Use of other control methods such as isolation of the processing area from the rest of the workplace using walls, doors or other barriers, or use of cold storage of bulk materials, as applicable.

(3) The employer shall prohibit the following practices:

(A) The use of compressed air to remove pastes, powders or liquids that contain diacetyl from surfaces, clothing or equipment.

(B) The opening of pressurized vessels containing diacetyl until the vessels have been depressurized.

(C) Dry sweeping of materials that contain diacetyl.

(4) The employer shall implement procedures to protect employees in the event of an uncontrolled release of diacetyl or diacetyl-containing flavorings or food products.

(5) The employer shall establish and implement a written diacetyl control program describing how the engineering controls and work practices limit exposures to airborne diacetyl to the lowest feasible level. This written program shall include at least the following:

(A) A description of each process in which diacetyl or diacetyl-containing flavorings or food products are used, including equipment, material processed, control measures, crew size, operating procedures and maintenance practices;

(B) Any engineering plans or studies used to determine methods selected for controlling exposure to airborne diacetyl;

(C) An evaluation of the technology alternatives considered in achieving the lowest feasible exposures;

(D) All diacetyl measurements and monitoring data, including **information about or measurements of the concentration of diacetyl in the** bulk material;

(E) A detailed schedule for implementation of any engineering controls, **and** work practices **and any other control measures** that cannot be implemented immediately **and for the adaptation and implementation of any additional control measures. The reasons for any delays in implementation of the schedule or for any changes to the schedule shall be documented in writing.**

(6) Program evaluation. A program evaluation shall be performed by the employer and then validated by a program reviewer. The program reviewer shall certify in writing **that each of the following:**

(A) The program's control methods are adequate to reduce employee exposure under worst-case conditions of use to below the **OSHA RQL detection limit** or, if that is not achievable, to as low a level as feasible. **This determination shall be without regard to employee use of respiratory protective equipment.**

(B) The program's control methods will prevent airborne diacetyl contamination outside the regulated areas, as measured by monitoring meeting the requirements of subsection (c) of this section.

(C) Processes considered enclosed for the purposes of this standard are in fact enclosed by

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design and construction, there are no visible emissions, and monitoring meeting the requirements of subsection (c) has ~~verified detected~~ that there are no ~~detectable~~ emissions of diacetyl from the process ~~in into other areas of~~ the workplace ~~that result in airborne concentrations above the OSHA RQL~~.

(D) When respirator use is not to be required in a regulated area, the design and construction of control measures are sufficient to prevent employee exposures to ~~detectable~~ levels of airborne diacetyl ~~above the OSHA RQL~~, as verified by exposure monitoring conducted in accordance with subsection (c) and that there are no diacetyl-containing powders in the area.

(E) All required respirator use is fully compliant with subsections (f)(2) and (f)(3).

(f) Respiratory Protection.

(1) The employer shall provide, and ensure that employees use, respirators in accordance with Section 5144 whenever:

(A) An employee enters or works in a regulated area or a temporary regulated area.

EXCEPTION to subsection (f)(1)(A). Respirator use is not required in regulated areas in which:

1. There are no diacetyl-containing powders; and,
2. There has been an assessment conducted pursuant to subsection (c) that found no ~~detectable~~ levels of airborne diacetyl ~~above the OSHA RQL~~ in the area; and
3. The program reviewer has certified, in accordance with subsection (e)(6), that the design and construction of the process and control measures are sufficient to prevent employee exposures to ~~detectable~~ levels of airborne diacetyl ~~above the OSHA RQL~~.

(B) Employees are exposed to airborne diacetyl or diacetyl-containing ~~materials flavorings~~ in operations for which monitoring has not been conducted or for which ~~detectable~~ levels of airborne diacetyl ~~above the OSHA RQL~~ have been found, or are engaged in spill clean-up of diacetyl or diacetyl-containing materials.

(C) The employee is working in or adjacent to a regulated area or an area in which there is an enclosed process and has requested to use a respirator. This use shall be considered as required use for purposes of complying with Section 5144.

(2) Where a respirator is required by this section, the employer shall establish, implement and maintain a respiratory protection program in accordance with Section 5144 ~~and the table in subsection (f)(3) below~~. The employer shall at a minimum select, and provide to employees, a respirator that provides both high efficiency particulate air filtration and also provides protection against organic vapors (as applicable, HEPA/OV cartridge, P100/OV cartridge, or atmosphere supplying respirators). Additional protection may be required where other contaminants are present, in accordance with Section 5144.

(3) Where the exposure assessment determines that exposures to diacetyl may exceed 0.2 ppm the OSHA RQL, either as a short term exposure or as an 8-hour TWA, or where diacetyl-containing powders are used, the employer shall provide respirators in accordance with the following table: a full-facepiece, or powered-air purifying or supplied air respirator.

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RESPIRATORY PROTECTION SELECTION TABLE

<u>Maximum Diacetyl Concentration</u>	<u>Type of Respirator^{1,3}</u>
<u>Less than or equal to 0.2 ppm, no exposure to diacetyl-containing powders</u>	<u>Half mask respirator</u>
<u>Less than or equal to 0.5 ppm</u>	<u>Any powered air purifying respirator (PAPR) or supplied air respirator (SAR), or full facepiece air purifying (APR)</u>
<u>Less than or equal to 1.0 ppm, diacetyl</u>	<u>Full facepiece APR or any tight-fitting PAPR or SAR</u>
<u>Less than or equal to 20 ppm</u>	<u>Tight fitting full facepiece PAPR or SAR in continuous flow or pressure demand mode, or PAPR or SAR with helmet or hood in continuous flow mode² which have been found to provide a protection factor of 1000</u>
<u>Above 20 ppm</u>	<u>Self-contained breathing apparatus (SCBA) in pressure demand mode</u>

Notes to Respiratory Protection Selection Table:

- 1. Employers may select respirators assigned for use in higher workplace concentrations for use at a lower concentration.**
- 2. The employer must have evidence provided by the respirator manufacturer that testing of helmet/hood respirators demonstrates performance at a level of protection of 1000 or greater to permit use against concentrations of diacetyl greater than 0.5 ppm. Absent such testing, all other PAPRs and SARs with helmets/hoods may only be used for concentrations that do not exceed 0.5 ppm.**
- 3. The respiratory protection program administrator or diacetyl program reviewer must decide the appropriate respirator from the table to provide employees protection from diacetyl-containing powders, taking into account powder concentrations and concentrations of any co-contaminants. The minimum level of respiratory protection for diacetyl-containing powders shall be any powered air-purifying respirator or supplied air respirator or full facepiece air purifying respirator.**

(g) Medical Surveillance.

(1) General.

(A) The employer shall establish, implement and maintain a medical surveillance program for all employees identified in subsection (g)(2). The program shall be under the supervision of an occupational or pulmonary medicine physician who is knowledgeable about spirometry, obstructive pulmonary disease, surveillance for occupational disease, the diagnosis and management of occupational disease, and the requirements of this standard. The supervising

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physician shall be responsible for ensuring all components of the program meet the requirements of this standard and comply with the ~~referenced~~ medical guidelines.

(B) All components of the program shall be administered confidentially by a PLHCP and provided during the employee's normal working hours or at a time and place convenient to the employee and shall be administered in a manner that ensures that the employee understands its content. All required components of the PLHCP evaluation shall be made available in a language the employee can read, or the subject matter shall be covered in an interview with the PLHCP. If the PLHCP is not fluent in the employee's language, the employer shall request that the PLHCP provide an interpreter. For the purposes of this standard "interpreter" means a person fluent in English and in the necessary second language, who can accurately speak, read, and readily interpret the necessary second language, or a person who can accurately sign and read the employee's sign language. Interpreters shall have the ability to translate the names of body parts and to describe competently symptoms and injuries in both languages. Interpreters may include, but are not limited to, members of the PLHCP's medical or professional staff.

(C) The employer shall provide the employee with an opportunity to discuss all components of the medical surveillance program and evaluation results with the PLHCP.

(D) The program shall include an initial medical evaluation, follow-up and termination or reassignment medical evaluations, and reports from the PLHCP. All medical evaluations, including all tests, shall be provided and assessed in accordance with the medical guidelines. ~~current CDPH Guidelines.~~

(2) The medical surveillance program shall include ~~each every~~ employee who:

(A) ~~Enters, for any portion of 30 or more days within any 12 month period, a regulated area (including a temporary regulated area), or an area containing an open process or detectable levels of diacetyl, or,~~

~~(B) Develops Reports~~ signs or symptoms of diacetyl related disease, or,

~~(C) Has been in an area in which an uncontrolled release of diacetyl or diacetyl-containing materials has occurred., or~~

(C) Enters, for any portion of a day on 14 or more different days (as a cumulative total) within any 12 month period, any of the following areas:

1. A regulated area (including a temporary regulated area).

2. An area containing an open process.

3. An area containing levels of diacetyl above the OSHA RQL.

(3) Initial medical evaluation. Each employee identified under subsection (g)(2)(~~AC~~) shall be provided with an initial medical evaluation that focuses on detecting and preventing respiratory disease. Prior to the provision of the initial medical evaluation, employees shall be trained pursuant to subsection (j). ~~The~~ When feasible, the initial medical evaluation shall be provided no later than the thirtieth day the employee works in prior to the employee's assignment to an area requiring in which medical surveillance is required, in accordance with subsection (g)(1)(A). A medical evaluation for respirator use, in accordance with Section 5144(e)(6) of these Orders, shall be provided prior to an employee being fit tested for respirator use and

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prior to the employee using a respirator. In no case shall the initial medical evaluation occur later than 14 calendar days after the employee has met the criteria in subsection (g)(2)(C). Any employee not previously provided an initial medical evaluation who develops signs or symptoms of diacetyl related disease or who has been in an area in which an uncontrolled release of diacetyl or diacetyl-containing materials has occurred, shall be provided with an initial medical evaluation as soon as practicable, and in no case later than 10 working days following **report development** of the **signs or** symptoms or after the exposure to the uncontrolled release.

The initial evaluation shall include:

(A) Employee completion and PLHCP evaluation of a detailed occupational history that includes past and current work exposure to flavorings and other substances known or suspected to be respiratory hazards.

(B) Employee completion and PLHCP evaluation of a respiratory health questionnaire that is at least as comprehensive as the Flavor Worker Initial Questionnaire in Appendix B1.

(C) Spirometry conducted and evaluated in accordance with the American Thoracic Society Guidelines or equivalent and administered by technicians who:

1. have successfully completed a NIOSH-certified initial course in spirometry,
2. maintain a valid NIOSH-approved spirometry course training certificate, and
3. have demonstrated to the supervising **PLHCP physician** knowledge of proper techniques for coaching test subjects.

(D) Appropriate additional tests as necessary, in the opinion of the evaluating PLHCP.

(4) Follow-up evaluations.

(A) No less frequently than every six months and whenever recommended by the PLHCP, the employer shall provide a follow-up medical evaluation that includes each of the elements listed below:

1. Spirometry meeting the requirements of subsection (g)(3)(C);
2. Employee completion and PLHCP evaluation of a questionnaire at least as comprehensive as the Flavor Worker Follow-Up Questionnaire in Appendix B2;
3. Appropriate additional tests as necessary in the opinion of the evaluating PLHCP.

(B) Whenever an employee **develops reports to the employer** signs or symptoms of diacetyl related disease, or has been in an area in which an uncontrolled release of diacetyl or diacetyl-containing materials has occurred, the employer shall provide the employee with a follow-up medical evaluation meeting the requirements of subsection (g)(4)(A) as soon as practicable, and in no case later than 10 working days following **development report** of the signs and symptoms or 10 working days after the exposure to the uncontrolled release.

(C) An employee who is in the medical surveillance program as a result of a spill, leak, or process upset shall have a follow-up evaluation within six months, meeting the requirements of subsection (g)(4)(A) and shall receive further follow-up evaluations as recommended by the PLHCP. The employee shall remain in the medical surveillance program for not less than 12 months.

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(5) Termination of Employment or Reassignment. Whenever an employee who has been a participant in this medical surveillance program terminates employment with the employer or is reassigned to a job that does not require medical surveillance in accordance with subsection (g)(2), the employer shall provide a follow-up medical evaluation meeting the requirements of subsection (g)(4)(A), unless the employee has had a follow-up evaluation within the previous 30 calendar days. Reassigned employees shall be provided with follow-up medical evaluations as required by subsection (g)(4) for a minimum of 12 months following reassignment.

(6) Information Provided to the PLHCP. The employer shall provide the following information to the evaluating PLHCP:

(A) A copy of this standard and its appendices.

(B) A copy of the ~~CDPH-G~~ **medical** guidelines.

(C) A description of the employee's duties as they relate to the employee's exposure to diacetyl, diacetyl-containing flavorings or food products, and other flavorings.

(D) The employee's actual or representative breathing zone exposure levels.

(E) A description of any personal protective equipment used or to be used.

(F) For employees who will use respirators, the information required by Section 5144(e)(5) of these Orders.

(G) The written opinion from any previous medical evaluations.

(H) A listing of any spills, leaks or process upsets to which the employee had been exposed. The employer shall additionally provide a description of such events including any measurements or indications of exposure resulting from the event.

(7) Change of Supervising Physician. If the employer changes supervising physician, the employer shall take all reasonable steps to ensure that all records of medical surveillance, including spirometry results, are transferred to the new supervising physician.

(h) PLHCP Written Opinion.

(1) For each initial, follow-up, termination of employment or reassignment evaluation required under this standard, the employer shall obtain a written opinion from the PLHCP within 15 days of the evaluation. This written opinion shall include only the following information:

(A) A list of any limitations on respirator use related to the medical condition of the employee, or relating to the workplace conditions in which the respirator will be used, including whether or not the employee is medically able to use the respirator, ~~pursuant to Section 5144(e)(6) of these Orders.~~

(B) A list of any recommended limitations on the employee's exposures to diacetyl or other flavoring substances or ingredients, on the employee's use of personal protective equipment, or on the employee's performance of specific tasks.

(C) A conclusion concerning whether medical conditions may have resulted from exposure to diacetyl or other potentially hazardous flavoring constituents or from exposure in an emergency, and whether there is a need for further evaluation.

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(D) The PLHCP's recommendation, in accordance with subsection (i), regarding whether the employee should be removed from particular job assignments and/or any necessary modification of jobs to which the employee is assigned.

(E) A statement that the employee has been informed of any medical conditions which would be aggravated by exposure to diacetyl or other flavoring constituents.

(2) The employer shall provide a copy of the PLHCP's written opinion to the employee within 5 calendar days of its receipt. This opinion shall also include a notice of the right of the employee to seek a second medical opinion in accordance with the provisions of subsection (i)(4), including the requirement for the employee to inform the employer in writing ~~of any intent to seek~~ **if the employee is requesting that the employer pay for** a second medical opinion.

(i) Medical Removal.

(1) When the PLHCP recommends an employee's removal from a job assignment or recommends modification of an employee's job to reduce exposure, the employer shall:

(A) Modify the employee's job or transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to six months). The employer shall maintain the employee's current earnings, seniority, and other benefits. If there is no work available that would not involve the employee being exposed to diacetyl or other potentially hazardous flavoring constituents, the employer shall maintain the employee's current earnings, seniority and other benefits **until any of the following occurs:**

1. ~~Until such~~ **Such** work becomes available. ~~, or,~~
2. ~~Until the~~ **The** employee is determined by the PLHCP, or is determined in accordance with subsection (i)(4), to be able to return to his or her original job status. ~~, or,~~
3. ~~Until the~~ **The** employee is determined by the PLHCP, or is determined in accordance with subsection (i)(4), to be permanently unable to return to work involving exposure to diacetyl or other potentially hazardous flavoring constituents. ~~, or,~~
4. ~~For a~~ **Six months, whichever comes first have elapsed since the beginning of the current medical removal period.**

(B) Provide competent medical counseling on the increased risk of significant health impairment for employees with medical conditions that may be directly or indirectly aggravated by exposure to diacetyl or other potentially hazardous flavoring constituents.

(2) Worker's Compensation Claims. If a removed employee files a claim for worker's compensation for a diacetyl-related disability, then for up to a maximum of six months pending final disposition of the claim, the employer shall continue to provide medical removal protection benefits. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal payment obligation shall be reduced by such amount. The employer shall receive no credit for worker's compensation payments received by the employee or a health care provider for treatment related expenses.

(3) Other Credits. The employer's obligation to provide medical removal protection payments to a removed employee may be reduced by the amount that the employee receives in compensation for:

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(A) ~~e~~Earnings lost during the period of removal from a publicly or employer-funded compensation program, or

(B) ~~i~~Income received from employment with another employer made possible by virtue of the employee's removal.

(4) Multiple Physician Review.

(A) After any medical evaluation or consultation conducted pursuant to subsection (g), the employee may designate an independent physician to review any findings, determinations or recommendations and to conduct such examinations, consultations, and laboratory tests as this second physician deems necessary and appropriate to facilitate this review.

(B) The employer may condition its ~~participation in, and~~ payment for, **the employee designated physician in** the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the notification of the right to seek a second medical opinion, or receipt of the initial PLHCP's written opinion, whichever is later:

1. The employee informs the employer in writing of the intention to seek a second medical opinion, and

2. The employee initiates steps to make an appointment with a second physician.

(C) If the findings, determinations or recommendations of the second physician differ from those of the initial PLHCP, then the employer and the employee shall assure that efforts are made for the initial PLHCP and the second physician to resolve the disagreement. If they are unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician who shall be a specialist in the field at issue:

1. To review the findings, determinations or recommendations of the initial PLHCP and the second physician; and

2. To conduct such examinations, consultations, laboratory tests and discussions with the prior PLHCP and physician as the third physician deems necessary to resolve the disagreement.

(D) In the alternative, the employer and the employee or authorized employee representative may jointly designate such third physician.

(E) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(j) Information, Training and Labeling.

All information, training material and labeling shall be appropriate in content and vocabulary to the educational level, literacy, and language of employees.

(1) Information and Training. The employer shall ensure that all employees in workplaces covered by this standard participate in a training program which must be provided during working hours.

(A) Awareness Training. All employees in workplaces covered by this standard must receive awareness training, including employees (such as office workers) not likely to be directly exposed to flavorings. Awareness training shall include information on the health effects of exposure to diacetyl and diacetyl-containing flavorings or food products, the location and

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description of processes in which diacetyl or diacetyl-containing flavorings or food products **or other artificial butter flavorings** are used, the location of any regulated areas and the fact that employees are prohibited from entering those areas unless they are protected as required.

(B) Additional Training.

Training for employees at the time of initial assignment to areas in which exposure to diacetyl or diacetyl-containing flavorings or food products **or other artificial butter flavoring** are present shall be provided pursuant to subsections 1 and 2 below:

1. Frequency of training shall be as follows:

a. At the time of initial assignment to tasks where exposure to diacetyl or diacetyl-containing flavorings or food products **or other artificial butter flavoring** may take place. Training for employees must take place prior to their entry into regulated areas.

b. Annual training shall be provided within one year of the employee's previous training.

c. Employers shall provide additional training when changes, such as introduction of new engineering, administrative or work practice controls, modification of tasks or procedures or institution of new tasks or procedures may affect the employee's exposure. The additional training may be limited to addressing the new exposures created and the use of new or modified equipment and control measures.

2. The training program shall contain at a minimum the following elements:

a. **An explanation of the specific nature** of the operations that result in or are reasonably likely to result in exposure to airborne diacetyl, and diacetyl-containing flavorings or food products **or other artificial butter flavoring**;

b. The results of exposure monitoring or other exposure assessments and the right of employees to obtain copies of this information in accordance with this Section and Section 3204 of these Orders;

c. The limitations of current exposure monitoring methods for detection of diacetyl-containing powders and mists.

d. A description of the employer's medical surveillance program. This **description** shall include the adverse health effects and signs or symptoms of diacetyl related disease and the need for employees to **recognize and** report these **health effects and signs or** symptoms promptly to the employer if they experience any of them. **This information shall also describe the mechanism by which employees are to report the occurrence of the signs or symptoms to the employer. This description and information shall also include any Health Hazard Alerts pertaining to the health effects of diacetyl or food flavorings that are produced by the CDPH Occupational Health Branch, including by its Hazard Evaluation System and Information Service (HESIS: <http://www.cdph.ca.gov/programs/hesis/Pages/default.aspx>).** ~~This information shall also include the information contained in Appendix C.~~ Employees shall be encouraged to report any of these **signs or** symptoms to their employer.

e. The engineering controls, work practices, labeling, and personal protective equipment associated with the employee's job assignment and how they should be used to reduce exposure to diacetyl and diacetyl containing materials. This shall include the means of demarcating

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regulated areas, and requirements for entry into those areas.

f. For employees who use respirators or who enter regulated areas, training shall also be provided in accordance with Section 5144 of these Orders.

(2) Labeling **Containers in the Workplace.**

(A) In addition to any labeling required by the Food and Drug Administration, Section 5194 of these Orders and other standards, the employer shall ensure that any container of diacetyl or diacetyl-containing flavoring or food product **to be used within the workplace** is labeled with the following warning which shall also be translated into any language necessary to be understood by each employee in the workplace:

WARNING: This product contains diacetyl which can be a severe respiratory hazard.

Breathing dust, **powder**, mist or vapor from this product could result in irritation of the eyes and respiratory tract and in permanent lung damage.

(B) In lieu of affixing the above warning label to individual stationary process containers, the employer may use color coding, signs, placards, process sheets, batch tickets, operating procedures, or other such written materials as long as the alternative method identifies the containers to which it is applicable and effectively conveys the warning information to employees.

(C) Containers of other artificial butter flavoring to be used in the workplace shall be labeled with the following warning which shall also be translated into any language necessary to be understood by each employee in the workplace:

WARNING: This product contains an artificial butter flavoring other than diacetyl. The health effects of these materials selected as substitutes for diacetyl are currently being studied for potential respiratory hazards. Avoid eye contact or breathing dust, powder, mist or vapor from this product as irritation of the eyes or respiratory tract may result.

(k) Recordkeeping and Reporting.

(1) The employer shall maintain and provide access to all exposure and medical records in accordance with Section 3204. Entry logs for regulated areas shall be maintained as employee exposure records in accordance with Section 3204. Records of training shall be maintained for at least three years. Records of assessments of ventilation systems shall be created and maintained in accordance with Section 5143 of these Orders.

(2) Within 24 hours of becoming aware of any flavor-related diagnosis of fixed obstructive lung disease, the employer shall report the diagnosis to the Chief at the following address:

Report of Fixed Obstructive Lung Disease
c/o Research and Standards Health Unit
Division of Occupational Safety and Health
Post Office Box 420603
San Francisco, California 94142

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(3) All employers covered by this standard shall report any use of diacetyl in writing to the Chief within 60 calendar days of the effective date of this standard. New users shall report such new use to the Chief within 15 calendar days of the new use. complete the questionnaire in Appendix D for all processes utilizing diacetyl-containing flavorings. The questionnaire shall be submitted electronically unless other arrangements are made with the Division.

~~EXCEPTION: Employers who have participated in the Division's Flavoring Industry Safety and Health Evaluation Program (FISHEP) are not required to complete the questionnaire in Appendix D.~~

(A) Reports of Use shall be sent to:

Research and Standards Health Unit
Division of Occupational Safety and Health
Post Office Box 420603
San Francisco, California 94142

(B) The Report of Use shall include:

1. The name of the employer and address of each workplace where a diacetyl or diacetyl-containing materials are in use;
2. A description that identifies where the use of diacetyl or diacetyl-containing materials is located in the workplace;
3. A brief description of each process or operation which creates employee exposure to the diacetyl, as well as the estimated number of employees engaged in each process or operation; and
4. The names and addresses of any collective bargaining units or other representatives of the affected employees.

(C) Posting. A copy of the written report of use shall be posted where the diacetyl or diacetyl-containing material is in use or other appropriate location where the posting is conspicuous to affected employees. The report shall be posted until the use no longer takes place at the worksite.

~~(1) Material Safety Data Sheet Preparation.~~

~~(1) Manufacturers and importers, as defined by Section 5194 of these Orders, shall ensure that an MSDS, meeting all of the requirements of Section 5194, accompanies all flavorings and food products that contain diacetyl at a concentration of 0.1% or higher by weight, unless the flavoring or food product meets the criteria for an exception to the MSDS requirements of Section 5194 of these Orders.~~

~~(2) When an MSDS for a flavoring or food product is required because of its diacetyl content and such a flavoring or food product is not subject to an exception to the MSDS requirements of Section 5194, the MSDS shall include all of the following:~~

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~~(A) A statement that the product contains diacetyl at a concentration of 0.1% or higher by weight. This information shall be placed in the section of the MSDS containing the list of ingredients. It shall also state the actual concentration of diacetyl in the flavoring or food product, or shall state the appropriate range of concentrations from this list:~~

~~1. 0.1 to 1%~~

~~2. 1 to 5%~~

~~3. 5 to 10%~~

~~4. 10 to 20%~~

~~5. More than 20%~~

~~(B) All appropriate hazard warnings and information about the health effects and toxicology of diacetyl as required by Section 5194 of these Orders.~~

NOTE: Authority cited: Section 142.3, Labor Code. Reference: Section 142.3, Labor Code.

~~[See Appendix A on following page]~~

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Appendix A: Diacetyl Sampling and Analytical Protocol (Mandatory)

This appendix establishes requirements for sampling protocols and the procedure for taking and analyzing air samples for diacetyl including quality control procedures that must be implemented by the person conducting the sampling and by the laboratories performing the analysis. All employers who are required to conduct air monitoring under subsection (c) of this section are required to utilize analytical laboratories that use this procedure, or an equivalent method, for collecting and analyzing samples.

(a) Sampling Protocols.

(1) Personal Samples

(A) 8-hour time-weighted average. Due to the limited sampling time for the **OSHA Method specified sampling and analytical method**, eight-hour time-weighted average (TWA) exposure estimates must be constructed for each employee. Collect sequential samples as recommended by **the OSHA mMethod 1013 (which is hereby incorporated by reference) or an equivalent method** for periods no longer than 180 minutes per sample to cover the full work-shift of the employee. **Typically For an eight-hour work shift**, this will include the collection of a minimum of three dual-tube samples for each employee unless the full duration of the employee's exposure to diacetyl or diacetyl-containing flavorings or food products is less than the full work shift. Cleaning and sanitizing activities must be sampled separately from production processes.

(B) Short-term exposure. Collect short term exposure samples as recommended by **the OSHA mMethod 1013 or an equivalent method**, to represent the highest likely potential 15 minute exposure(s) for each process. Examples of activities that should be monitored for short term exposures include periods of a process in which tanks or containers are opened, filled, unloaded or cleaned; where process equipment is opened; and where diacetyl or diacetyl-containing flavorings or food products are heated or sprayed.

(C) Each sampling tube shall be analyzed separately, and the results recorded. For each sampling tube, the employer shall ensure that the record includes the date, time, location and identity of the process being sampled, the name and employee identifier of the employee being sampled, the employee's job classification, the specific job duties of the employee, **and the mass collected from the tube. The records for each dual-tube sample shall include** the measured air concentration from the dual-tube samples, the **method RQL limit of detection of the method for the sample**, and evidence of its accuracy, including ambient temperature and humidity. The record for short term exposure samples shall also identify the specific activity being sampled.

(2) Monitoring for verification of enclosed processes or to determine whether respirators need not be required in a regulated area.

(A) Eight-hour TWA and short term exposure personal samples, in accordance with section (a)(1), shall be collected for each shift and each job classification for employees in the area where process vessels or operations are located.

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(B) Area samples shall also be collected by the placement of samplers in the areas the program reviewer determines ~~are~~ likely to have the highest levels of airborne diacetyl. A minimum of four locations shall be sampled for each process. The employer shall record the nature of and location of the process being sampled, the location of the sampler, the time and date of the sampling, the measured air concentration from the dual-tube samples, the ~~limit of detection method RQL for the sample of the method~~, and evidence of its accuracy, including the ambient temperature and humidity.

(C) If any individual ~~sample sampling tube~~ collected in the course of testing to verify that a system is enclosed is determined to contain diacetyl above the ~~OSHA RQL limit of detection~~, then the process shall not be deemed enclosed. If any individual ~~sample sampling tube~~ collected in the course of testing to determine if respirator use must be required in a regulated area is determined to contain diacetyl above the ~~OSHA RQL limit of detection~~, then respirator use shall be required in the regulated area.

(3) This sampling protocol cannot be used ~~as the sole basis to determine for~~ respirator ~~use requirements selection~~ in a regulated area if diacetyl-containing powders are used in the regulated area.

(b) Sampling Procedure.

(1) ~~Equipment specifications.~~

~~(A) For personal sampling, the sampling equipment shall be attached to the worker in such a manner that it will not interfere with work performance or safety.~~

~~(B) Samples shall be collected using a personal sampling pump calibrated prior to and after each day of sampling, with a representative sampling train attached between the pump and the calibration device, to within $\pm 5\%$ of the recommended flow rate specified in the ~~analytical method in subsection (c)(2) of this appendix~~. OSHA Method or in the equivalent method selected.~~

~~(C) Silica gel tubes of the type specified in the analytical method in subsection (c)(2) of this appendix shall be used.~~

~~(2) Technique. The following steps must be followed.~~

~~(A) (2) Review and follow the sampling procedures in the OSHA Method or in the equivalent method selected. The sampling procedure shall also include the following: Immediately before sampling, break off the ends of the flame-sealed tube to provide an opening approximately half the internal diameter of the tube. Wear eye protection when breaking ends. Use tube holders to minimize the hazard of broken glass. All tubes shall be from the same lot. Use aluminum foil, opaque tape, or a tube cover to protect samples from light.~~

~~(B) Connect two tubes in series to the sampling pump with flexible tubing. The smaller sections of the silica gel tubes should be positioned nearer the sampling pump. The tube closer to the pump is used as a backup. A minimum amount of tubing is used to connect the two sampling tubes together. Position the sampling pump, tube holder and tubing so they do not impede work performance or safety.~~

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~~(C) Draw the air to be sampled directly into the inlet of the tube holder. The air being sampled is not to be passed through any hose or tubing before entering the front sampling tube.~~

~~(D) After sampling for the appropriate time, remove the adsorbent tube and seal it with plastic end caps. Separately wrap each tube in aluminum foil to protect it from light and seal each sample end-to-end as soon as possible.~~

~~(A/E) Record sample air volumes (liters), sampling time (minutes) and sampling rate (mL/min) for each sample, along with any potential interference(s) on a sample summary form.~~

~~(F) Submit the samples to the laboratory for analysis as soon as possible after sampling. If delay is unavoidable, store the samples at refrigerator temperature. Ship any bulk samples separate from the air samples.~~

~~(G) Calibrate each personal sampling pump before and after use with a representative sampling train installed between the pump and the calibration devices.~~

~~(BH) Personal samples small shall be taken in the "breathing zone" of the employee (i.e., attached near the collar or lapel near the worker's face). The sampler inlet shall be located outside of the respirator, and outside of any personal protective equipment or clothing, and there shall be no impediment to airflow into the sampler.~~

~~(I) For each person being sampled, an eight hour TWA shall be constructed from the collection of a sequential series of samples collected at the sampling rate and for the duration recommended by OSHA Method 1013. Each sample tube shall be analyzed and reported separately, and the total exposure calculated by constructing an 8-hour time-weighted average from the sequential series of samples.~~

~~(CJ) Each set of samples taken will include 10% field blanks or a minimum of one field blank, whichever is greater. These blanks must come from the same lot as the tubes used for sample collection. Handle the blank sample in the same manner as the other samples except draw no air through it. A set consists of any sample or group of samples for which an evaluation for this standard must be made. Any samples represented by a field blank having an excess of the ~~detection~~ limit of detection (LOD) of the method being used shall be rejected, and additional sampling conducted to represent that exposure.~~

~~(c) Analytical Procedures.~~

~~(1) All samples shall be analyzed by a laboratory accredited in accordance with the program of the American Association for Laboratory Accreditation.~~

~~(2) The laboratory shall analyze all samples using the OSHA Method **1013** or an equivalent method, that is at least as accurate. The reliable quantitation limit for the analytical method shall be no greater than 0.041 milligrams of diacetyl per cubic meter (0.012 ppm diacetyl) for 8 hour TWA sampling and 0.13 milligrams of diacetyl per cubic meter (0.36 ppm diacetyl) for 15 minute short term exposure sampling. The reliable quantitation limit (RQL) is the smallest concentration of analyte which can be quantitated within the requirements of 75% recovery and 95% confidence limits, when the sample is collected in accordance with the referenced sampling method OSHA 1013.~~

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(3) All laboratories as part of their accreditation shall participate in an appropriate national sample testing scheme such as the Proficiency Analytical Testing Program (PAT) for organics that is sponsored by the American Industrial Hygiene Association (AIHA).

NOTE: Authority cited: Section 142.3, Labor Code. Reference: Section 142.3, Labor Code.

~~[See Appendix B1 and B2 next page]~~

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Appendices B1 and B2: Respiratory Health Questionnaires (Mandatory)

Adapted from forms prepared for the CDPH Guidelines by the
Hazard Evaluation System and Information Service (HESIS),
Occupational Health Branch, California Department of Public Health,
with assistance from the Division of Respiratory Disease Studies,
National Institute for Occupational Safety and Health

NOTE: The following additional respiratory health questionnaires contained in the CDPH Guidelines may be utilized as appropriate:

1. Initial Questionnaire in Spanish
2. Follow-Up Questionnaire in Spanish

APPENDIX B1 FLAVOR WORKER INITIAL QUESTIONNAIRE

PLEASE READ BEFORE BEGINNING!

- Please try to answer every question.
- Please read the whole question before answering.
- Most questions should be answered by checking a box for “Yes” or “No”. If you are not sure how to answer this type of question, please answer, “No” to the question. Some questions are answered by writing a number or a few words on a line.
- Sometimes we ask you to skip one or more questions. An arrow “→” or directions “(Go to Question 10)” will tell you what question to answer next. In the example below, if you answer “Yes”, you would go next to Question 9a, but if you answer “No” you would go to the next question which is Question 10.

9. Do you have brown eyes?
 Yes No (Go to Question 10)



9a. If Yes, please answer: do your parents have brown eyes?

10. Do you have brown hair?

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4. Have you ever had asthma?

Yes No (*IF NO, please answer Question 5 next*)



IF YES to Question 4:

4a) How old were you when the asthma began? _____ Years old

4b) Has a doctor ever told you that you had asthma? Yes No

4b) Do you still have asthma? Yes No

5. Since you began working at this plant, have you had attacks of bronchitis? Yes No

6. Has a doctor ever told you that you had chronic bronchitis?

Yes No (*IF NO, please answer Question 7 next*)



IF YES to Question 6:

6a) How old were you when you were diagnosed with chronic bronchitis? _____ Years old

7. During the past 12 months have you had any episodes of watery, itchy eyes? Yes No

8. Since you began working at this plant, have you had any of the following eye symptoms: red or burning eyes, eye pain, eye swelling, or blurred vision? Yes No

9. Have you ever had to change your job, job duties, or work area at this plant because of cough, shortness of breath, or wheezing?

Yes No (*IF NO, please answer Question 10 next*)



IF YES to Question 9:

9a) Describe your job, job duties and work activities before the change:

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Work Information

10. Your current employer: -

11. Month and year you were hired by this company: ___ / ___ / ___
(Month) (Year)

12. Your current job title:

13. Do you ever enter the work areas where diacetyl or diacetyl-containing flavorings are used as part of your current job? Yes No

14. Check ALL work activities that you currently perform:

- 14a) Pour, mix, measure, or fill containers with liquid ingredients or flavorings
- 14b) Make, use, or work with flavoring powders
- 14c) Test product quality or develop new diacetyl-containing products
- 14d) Repair or clean machinery that contained diacetyl or diacetyl-containing flavorings
- 14e) Work in warehouse with diacetyl-containing products
- 14f) Ship or receive diacetyl-containing products
- 14g) Other activities (*Please describe*) _____

15. At this plant, do you currently work as or have you ever worked with a:

- 15a) Powder flavoring or diacetyl-containing product? Yes No
- 15b) Liquid flavoring or diacetyl-containing product? Yes No

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16. Please estimate the total number of years and months you have performed the following work activities at this plant.

	<u>Total Years</u>	<u>Total Months</u>
16a) Pour, mix, measure, or fill containers with liquid ingredients or flavorings	_____ years	_____ months
16b) Make, use or work with flavoring powders	_____ years	_____ months
16c) Test product quality or develop new diacetyl-containing products	_____ years	_____ months
16d) Repair or clean machinery that contained diacetyl or diacetyl-containing flavorings	_____ years	_____ months
16e) Work in warehouse with diacetyl-containing products	_____ years	_____ months
16f) Ship or receive diacetyl-containing products	_____ years	_____ months
16g) Other (<i>Please describe</i>) _____	_____ years	_____ months

17. Have you had cough or shortness of breath when you were around diacetyl-containing flavorings, ingredients or products used in this plant?

- Yes No (*IF NO, please answer Question 18 next*)



IF YES to Question 17:

17a) Please list those flavorings, ingredients and/or products:

18. Have you ever been exposed to a spill or chemical release at work in this plant?

- Yes No (*IF NO, please answer Question 19 next*)



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IF YES to Question 18, please fill in the following table. List each spill or release on a separate line.

Chemical spilled or released	Date of spill or release	Did you have any symptoms following the spill or release?	If YES, what were your symptoms?
	____ / ____ (Month) (Year)	<input type="checkbox"/> No <input type="checkbox"/> Yes →	
	____ / ____ (Month) (Year)	<input type="checkbox"/> No <input type="checkbox"/> Yes →	
	____ / ____ (Month) (Year)	<input type="checkbox"/> No <input type="checkbox"/> Yes →	

19. Have you ever worked at any other plants that make, use or work with flavorings?

Yes No (*IF NO, please answer Question 20 next*)



IF YES to Question 19:

19a) Total number of years and months worked at these other plants? (*Example: if 2½ years, write as 2 years 6 months*) ____ Years ____ Months

19b) Did you pour, mix, use or work with liquid flavorings? Yes No

19c) Did you make use or work with powder flavorings? Yes No

20. Do you now (or have you ever) worked with the following chemicals in liquid flavoring, powdered flavoring, or other production operations at this plant or any other plant:

20a) Diacetyl? Yes No Don't Know

20b) Acetoin? Yes No Don't Know

20c) Acetaldehyde? Yes No Don't Know

20d) Benzaldehyde? Yes No Don't Know

20e) Acetic acid? Yes No Don't Know

Cigarette Smoking History

21. Have you ever smoked cigarettes? (*Answer NO if you have smoked fewer than 20 packs of cigarettes in your lifetime*)

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- Yes No (*IF NO, you have finished the survey*)
↓

IF YES to Question 21:

21a) How old were you when you first started smoking regularly? _____ Years old

21b) Over the entire time that you have smoked, what is the average number of cigarettes that you smoked per day? _____ Cigarettes per day

21c) Do you still smoke cigarettes?

- Yes No



IF NO to Question 21c:

21d) How old were you when you stopped smoking regularly? _____ Years old

NOTE: Authority cited: Section 142.3, Labor Code. Reference: Section 142.3, Labor Code.

~~[See Appendix B2 on following page]~~

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**APPENDIX B2
FLAVOR WORKER FOLLOW-UP QUESTIONNAIRE**

If you have not filled out a similar questionnaire in the past, please let the staff know that you need the “Initial Questionnaire” instead of this one.

About this Questionnaire:

The purpose of this questionnaire is to help health care providers monitor the health of workers in companies that manufacture food flavorings. It should be given to workers by health care providers who can follow up on the results. For more information, see www.dhs.ca.gov/ohb/flavorings.htm.

PLEASE READ BEFORE BEGINNING!

- Please try to answer every question.
- Please read the whole question before answering.
- Most questions should be answered by checking a box for “Yes” or “No.” If you are not sure how to answer this type of question, please answer, “No” to the question. You may occasionally need to answer questions by writing a number or a few words on a line.
- Sometimes we ask you to skip one or more questions. An arrow “→” or directions “Go to Question 2” will tell you what question to answer next.
- In the example below, if you answer “Yes,” you would go next to Question 9a, but if you answer “No,” you would go on to the next question which is Question 10.

9. Do you have brown eyes?

Yes No (Go to Question 10)



9a. If Yes, please answer: Do your parents have brown eyes?

10. Do you have brown hair?

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- Although we would like everyone to answer the questions as completely as possible, you may skip any questions that you do not want to answer.

Note to Health Care Provider: This questionnaire is for health care providers to use to monitor the health of workers in companies that manufacture food flavorings. For more information, please see the guidance document, *Medical Surveillance for Flavorings-Related Lung Disease Among Flavor Manufacturing Workers in California*, which can be found at www.dhs.ca.gov/ohb/food-flavor-guidelines.pdf.

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General Information

Today's Date: ___ / ___ / _____
(Month) (Day) (Year)

First Name: _____ Middle Initial: ___ Last Name: _____

Address: _____
(Number, Street, and/or Rural Route)

City: _____ State: _____ Zip: _____

Home Telephone Number: () _____ - _____

Cell Phone Number: () _____ - _____

Date of Birth: ___ / ___ / _____
(Month) (Day) (Year)

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Health Information

1. Since the time of the last questionnaire, have you been troubled by shortness of breath when hurrying on level ground or walking up a slight hill?

Yes No (*IF NO, please answer Question 2 next*)



IF YES to Question 1:

1a) Do you get short of breath while walking with people of your own age on level ground? Yes No

1b) Do you ever have to stop for breath when walking at your own pace on level ground? Yes No

1c) Do you ever have to stop for breath either after walking about 100 yards or after a few minutes on level ground? Yes No

2. Do you usually have a cough?

Yes No (*IF NO, please answer Question 3 next*)



IF YES to Question 2:

2a) Did this usual cough start after the date of the last questionnaire? Yes No

2b) Do you have a cough on most days for 3 or more consecutive months during the year? Yes No

3. Apart from when you have a cold, does your chest ever sound wheezy or whistling?

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Yes No (*IF NO, please answer Question 4 next*)



IF YES to Question 3:

3a) In what year did you first experience wheezing or whistling
in your chest when you did not have a cold? _____
(Year)

4. Have you ever had asthma?

Yes No (*IF NO, please answer Question 5 next*)



IF YES to Question 4:

4a) Has a doctor ever told you that you had asthma? Yes No

4b) Do you still have asthma? Yes No

4c) Do you use any medication for your asthma? Yes No

5. Since the last questionnaire, have you had attacks of bronchitis? Yes No

6. Has a doctor ever told you that you had chronic bronchitis?

Yes No (*IF NO, please answer Question 7 next*)



IF YES to Question 6:

6a) How old were you when you were diagnosed
with chronic bronchitis? _____ Years old

7. Since the date of the last questionnaire, have you had any episodes of
watery, itchy eyes? Yes No

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8. Since the date of the last questionnaire, have you had any of the following eye symptoms: red or burning eyes, eye pain, eye swelling, or blurred vision? Yes No

9. Since the date of the last questionnaire, have you had to change your job, job duties, or work area at this plant because of cough, shortness of breath, or wheezing?

Yes No (*IF NO, please answer Question 10 next*)



IF YES to Question 9:

9a) Describe your job, job duties and work activities before the change:

Work Information

10. Your current employer:

11. Your current job title:

12. Do you ever enter the liquid or powder production areas as part of your current job?

Yes No (*IF NO, please answer Question 13 next*)



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IF YES to Question 12:

12a) On average, how often do you enter a liquid or powder production area in a week?

- One time or less per week
- 2 to 5 times per week
- 6 to 10 times per week
- More than 10 times per week

13. Check ALL work activities that you currently perform:

- 13a) Pour, mix, measure, or fill containers with either small or large amounts of liquid ingredients or flavorings
- 13b) Make small or large amounts of flavoring powders
- 13c) Package small or large amounts of flavoring powders
- 13d) Make small or large amounts of spray dry powders
- 13e) Make small or large amounts of colors
- 13f) Test product quality or develop new products
- 13g) Repair or clean machinery
- 13h) Work in warehouse
- 13i) Ship or receive products
- 13j) Drive a truck
- 13k) Work in office
- 13l) Other activities (*Please describe*) _____

14. At this plant, do you currently work as or have you ever worked as:

- 14a) a powder flavoring production worker? Yes No
- 14b) a liquid flavoring production worker? Yes No
- 14c) a spray drying production worker? Yes No

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15. Since the date of the last questionnaire, have you been exposed to a spill or chemical release at work in this plant?

Yes No (*IF NO, please answer Question 16 next*)



IF YES to Question 15, please fill in the following table. List each spill or release on a separate line.

Chemical spilled or released	Date of spill or release	Did you have any symptoms following the spill or release?	If YES, what were your symptoms?
	____ / ____ (Month) (Year)	<input type="checkbox"/> No <input type="checkbox"/> Yes →	

16. Do you now (or have you ever) worked with the following chemicals in liquid flavoring, powdered flavoring, or spray drying operations at this plant or any other flavoring plant:

- | | | | |
|--------------------|------------------------------|-----------------------------|-------------------------------------|
| 16a) Diacetyl? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Don't Know |
| 16b) Acetoin? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Don't Know |
| 16c) Acetaldehyde? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Don't Know |
| 16d) Benzaldehyde? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Don't Know |
| 16e) Acetic acid? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Don't Know |

Cigarette Smoking History

17. Do you currently smoke cigarettes?

Yes No

Thank you for your time!

NOTE: Authority cited: Section 142.3, Labor Code. Reference: Section 142.3, Labor Code.

~~[See Appendix C next page]~~

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~~Appendix C (Mandatory): Health Hazard Alert: Diacetyl (Butter Flavor Chemical) Use in Flavoring Manufacturing Companies (in English and Spanish)~~

~~**Diacetyl (Butter Flavor Chemical) Use
In Flavoring Manufacturing Companies
Health Hazard Alert**~~

~~Exposure to diacetyl used in flavoring manufacturing companies may cause a serious lung disease called bronchiolitis obliterans. Workers from California flavoring companies that use diacetyl have been diagnosed with this disease. Damage to the lungs can be permanent, can require a lung transplant, and can lead to death. The main symptoms are a persistent cough and shortness of breath when using extra energy (such as walking fast or up a slight hill) and wheezing when you do not have a cold. The symptoms do not go away in the evenings, on weekends, and on vacations. They can start gradually and get worse over time, or they can suddenly be very severe. Doctors sometimes think the symptoms are due to asthma, chronic bronchitis, emphysema, pneumonia, or smoking. If you work at a flavoring company that uses diacetyl, see a doctor immediately to make sure that your health is not being affected. Take this information sheet with you. Your company should follow the recommendations on page 2 to reduce exposure to diacetyl and other flavoring chemicals.~~

~~**How to know if you are working with diacetyl**~~

~~Diacetyl is a yellowish liquid that is usually mixed with other ingredients to produce butter flavor or other flavors in a variety of food products. If you think diacetyl is used in your workplace, read labels on containers and ask to see a Material Safety Data Sheet (MSDS). The MSDS must list diacetyl in Section 2 by the Chemical Abstract Service (CAS) number 431-03-8. Cal/OSHA's Hazard Communication Standard (Title 8, Section 5194), requires your employer to tell you if you are using diacetyl, and to train you on the health hazards and how to use it safely.~~

~~**How you are exposed to diacetyl**~~

~~Diacetyl enters your body when you breathe vapors, droplets of spray, or dust containing diacetyl in the air. Your risk of health effects depends on how much diacetyl enters your body. The amount of diacetyl in the air and how long you are exposed, determines how much enters your body.~~

~~**How diacetyl can affect your health**~~

~~**Lungs.** Diacetyl can damage your lungs. Symptoms include a dry cough, shortness of breath when using extra energy, and wheezing. The symptoms can start gradually, or severe symptoms can occur suddenly. The symptoms continue when you are not at work. Asthma medicines are not effective. Some workers do not have symptoms. See Medical Tests (page 2). Diacetyl damages the respiratory system of test animals.~~

~~**Eyes, nose, and throat.** Diacetyl vapors can sting or burn your eyes. They can cause your nose and throat to burn and feel sore. Eye contact with vapors can also cause chemical burns which require medical treatment to heal.~~

~~**Skin.** Diacetyl can irritate the skin. It can cause a rash with dryness, redness, flaking, and cracking of the skin.~~

~~**Cancer and reproductive effects.** Diacetyl has not been tested for these effects. Reducing exposure (page 2) to prevent lung disease will help to protect you.~~

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HEALTH HAZARD ALERT HESIS

HAZARD EVALUATION SYSTEM & INFORMATION SERVICE

Occupational Health Branch, California Department of Public Health

850 Marina Bay Parkway, Building P, Third Floor, Richmond, CA 94804

866-282-5516 • www.cdph.ca.gov/programs/ohb

August 2006

California Department of Public Health • California Department of Industrial Relations

Medical tests for health Effects

Breathing tests (spirometry) that measure how well your lungs are working, and a respiratory symptom questionnaire, are the best ways to detect bronchiolitis obliterans and other serious lung disease. Early detection is critical. You should have a lung function test before you begin working in a company that uses diacetyl and on a regular basis while you are working.

How to reduce exposure to diacetyl

Substitution. Less hazardous flavoring ingredients should be used whenever possible. Make sure that substitutes are safe.

Closed production processes. Handling open containers of diacetyl and other flavoring ingredients should be avoided.

Ventilation. Maintain air levels of diacetyl as low as possible using local exhaust ventilation. A safe exposure level has not been identified.

Respiratory protection. Respirators should be used until ventilation and other controls are determined to be effective. Use NIOSH-approved air-purifying respirators with organic vapor cartridges and particulate filters, or supplied-air respirators. Employers must comply with the Cal/OSHA Respiratory Protection Standard (Title 8, Section 5144). See www.dir.ca.gov/title8/5144.html

Skin and eye protection. Employers must provide protective gloves, goggles, and other protective equipment.

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WHERE TO GET HELP

➤ **HESIS** can answer questions about diacetyl, other workplace hazards, and information in this fact sheet. Call (866) 282-5516.

➤ **California Division of Occupational Safety and Health (Cal/OSHA)** investigates workers' complaints and makes enforcement inspections. Complainants' identities are kept confidential. Call the nearest office to your workplace, or see www.dir.ca.gov/DOSH/districtoffices.htm

➤ **Cal/OSHA Consultation Service** helps employers who want free, non-enforcement help to evaluate the workplace and improve health and safety conditions. Flavoring companies can call (562) 944-9366.

➤ **National Institute for Occupational Safety and Health (NIOSH)**. See www.cdc.gov/niosh/topics/flavorings

➤ **Occupational health services can be found at:**

- **University of California (UC)**
San Francisco: (415) 885-7580
- **UC Davis:** (530) 754-7635
- **UC Irvine:** (949) 824-8644
- **UC San Diego:** (619) 471-9210
- **UCLA:** (310) 794-8144

➤ **Flavor and Extract Manufacturers Association of the United States (FEMA)**. See www.femaflavor.org/html/public/RespiratorRpt.pdf

REGULATIONS THAT HELP TO PROTECT WORKERS

➤ **Injury and Illness Prevention Program**. See www.dir.ca.gov/title8/3203.html

➤ **Hazard Communication**. See www.dir.ca.gov/title8/5194.html

➤ **Control of Harmful Exposures to Employees**. See www.dir.ca.gov/title8/5141.html

➤ **Access to Employee Exposure and Medical Records**. See www.dir.ca.gov/title8/3204.html

- **Arnold Schwarzenegger, Governor, State of California**
- **Kimberly Belshé, Secretary**
California Health and Human Services Agency
- **Victoria L. Bradshaw, Secretary**
Labor and Workforce Development Agency
- **Dr. Mark Horton, Director**
California Department of Public Health
- **John Duncan, Director, Department of Industrial Relations**

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~~Uso de diacetil (aromatizante químico con sabor
amantequilla) en compañías que fabrican
aromatizantes~~
ALERTA DE PELIGRO DE SALUD

~~La exposición al diacetil utilizado por las compañías que fabrican aromatizantes puede causar una enfermedad seria en los pulmones llamada bronquiolitis obliterante. Trabajadores de fabricantes de aromatizantes en California que usan diacetil fueron diagnosticados con esta enfermedad. Los pulmones pueden quedar dañados en forma permanente, y la enfermedad puede requerir un trasplante de pulmón o ser fatal. Los síntomas principales son una tos persistente y falta de aire cuando se hace un esfuerzo (como caminar rápido o subir una pendiente suave), y sibilancias sin tener un resfriado. Los síntomas no desaparecen por la noche, en los fines de semana o cuando está de vacaciones. Pueden comenzar en forma gradual y empeorar con el tiempo, o se pueden hacer muy severos de golpe. Los médicos creen a veces que los síntomas son causados por el asma, bronquitis crónica, enfisema, pulmonía, o el fumar. Si trabaja en una empresa que fabrica aromatizantes y que usa diacetil, vea a un médico inmediatamente para comprobar que no le haya afectado la salud. Lleve esta hoja informativa a la consulta. Su empresa debe seguir las recomendaciones de la página 2 para reducir su exposición al diacetil y otros aromatizantes químicos.~~

Cómo saber si está trabajando con diacetil

El diacetil es un líquido amarillento que generalmente se mezcla con otros ingredientes para producir un aromatizante con sabor a mantequilla u otros sabores. Estos se usan en una variedad de productos alimenticios. Si cree que se está usando diacetil en su lugar de trabajo, lea las etiquetas de los recipientes y pida ver una Hoja Informativa de Seguridad de Material (MSDS, por sus siglas en inglés). La MSDS deberá incluir el diacetil en la sección 2 con el número 431-03-8 del Servicio de Resumen Químico (CAS, por sus siglas en inglés). La Norma de Comunicación de Sustancias Peligrosas de Cal/OSHA (Título 8, Sección 5194) exige que su empleador le informe si usted está usando diacetil, y que lo capacite sobre los peligros para la salud y cómo usarlo de manera segura.

Cómo se expone al diacetil

El diacetil entra en el cuerpo cuando respira vapores, gotas de rocío o polvo que contiene diacetil del aire. El riesgo para la salud depende de cuánto diacetil entra en el cuerpo. La cantidad de diacetil que entra en el cuerpo depende de la cantidad que haya en el aire, y del tiempo de exposición.

Cómo puede afectar su salud el diacetil

Pulmones. El diacetil puede dañar los pulmones. Los síntomas incluyen tos seca, falta de aire cuando hace un esfuerzo, y sibilancias. Los síntomas pueden comenzar gradualmente o pueden aparecer de golpe en forma de síntomas graves. Los síntomas continuarán aunque no esté trabajando. Los medicamentos contra el asma no son efectivos. Algunos trabajadores no tienen síntomas. Vea la sección sobre pruebas médicas (página 2). El diacetil daña el sistema respiratorio en animales de laboratorio.

Ojos, nariz y garganta. Los vapores de diacetil pueden causar escozor o ardor en los ojos. Pueden causar dolor y ardor en la nariz y la garganta. El contacto de estos vapores con los ojos también puede causar quemaduras químicas que sólo se pueden curar con tratamiento médico.

Piel. El diacetil puede irritar la piel. Puede causar un sarpullido con sequedad, enrojecimiento, escamas y grietas en la piel.

Cáncer y efectos reproductivos. No se han estudiado estos efectos en el diacetil. Si reduce su exposición para prevenir enfermedades de los pulmones (página 2) se protegerá también contra estos efectos.

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HEALTH HAZARD ALERT HESIS

HAZARD EVALUATION SYSTEM & INFORMATION SERVICE

Occupational Health Branch, California Department of Public Health
850 Marina Bay Parkway, Building P, Third Floor, Richmond, CA 94804
866-282-5516 • www.cdph.ca.gov/programs/ohb

August 2006

California Department of Public Health • California Department of Industrial Relations

Pruebas médicas para ver si hay efectos sobre la salud

Las mejores maneras de detectar la bronquiolitis obliterante y otras enfermedades serias de los pulmones son pruebas de respiración (espirometría) para medir cómo funcionan los pulmones, y un cuestionario sobre sus síntomas respiratorios. La detección temprana es crítica. Debería hacerse una prueba de funcionamiento del pulmón antes de comenzar a trabajar en una empresa que usa diacetil, y en forma periódica mientras siga trabajando allí.

Cómo reducir la exposición al diacetil

Sustitución. Use ingredientes aromatizantes menos peligrosos en la medida de lo posible. Compruebe que

Procesos de producción cerrada. Evite el manejo de recipientes abiertos de diacetil y otros ingredientes aromatizantes.

Ventilación. Use un sistema de extracción de contaminantes para mantener más bajo posible el nivel de diacetil en el aire. No se ha identificado cuál es un nivel de exposición segura.

Protección respiratoria. Se deben usar respiradores hasta que se haya comprobado la efectividad de la ventilación y otros controles. Use respiradores purificadores de aire aprobados por NIOSH, con cartuchos de vapor orgánico y filtros de partículas, o respiradores con suministro de aire propio. Los empleadores deben cumplir con la Norma de Protección Respiratoria de Cal/OSHA (Título 8, Sección 5144).
Visite: www.dir.ca.gov/title8/5144.html

Protección de la piel y los ojos. Los empleadores deben proporcionar guantes, lentes protectores, y otros equipos de protección.

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DÓNDE OBTENER AYUDA

→ **HESIS** puede responder a preguntas sobre el diacetil, otras sustancias peligrosas en el lugar de trabajo, y esta hoja informativa. Llame al (866) 282-5516.

→ La División de Seguridad y Salud Ocupacional de California (Cal/OSHA) investiga las quejas de los trabajadores y efectúa inspecciones para verificar el cumplimiento de las normas. No se divulgará la identidad de las personas que presentan quejas. Llame a la oficina más cercana a su lugar de trabajo o visite: www.dir.ca.gov/DOSH/districtoffces.htm

→ El Servicio de Consultoría de Cal/OSHA ayuda a los empleadores que quieren obtener información gratis y sin ser multados para evaluar su lugar de trabajo y mejorar las condiciones de salud y seguridad. Compañías que fabrican aromatizantes pueden llamar al: (562) 944-9366.

→ Instituto Nacional para la Salud y Seguridad Ocupacional (NIOSH): www.cdc.gov/niosh/topics/flavorings

→ Se pueden encontrar servicios de salud ocupacional en:

- University of California (UC)
San Francisco: (415) 885-7580
- UC Davis: (530) 754-7635
- UC Irvine: (949) 824-8641
- UC San Diego: (619) 471-9210
- UCLA: (310) 794-8144

→ Asociación de Fabricantes de Aromatizantes y Extractos de EE UU. (FEMA). Visite:

www.femaflavor.org.html/public/RespiratorRpt.pdf

REGLAMENTOS QUE AYUDAN A PROTEGER A LOS TRABAJADORES

→ Programa de prevención de lesiones y enfermedad.

Visite: www.dir.ca.gov/title8/3203.html

→ Comunicación de sustancias peligrosas.

Visite: www.dir.ca.gov/title8/5194.html

→ Control de exposiciones peligrosas a los empleados.

Visite: www.dir.ca.gov/title8/5141.html

→ Acceso a los registros médicos y de exposición de los empleados.

Visite: www.dir.ca.gov/title8/3204.html

• Arnold Schwarzenegger, Governor, State of California

• Kimberly Belshé, Secretary
California Health and Human Services Agency

• Victoria L. Bradshaw, Secretary
Labor and Workforce Development Agency

• Dr. Mark Horton, Director
California Department of Public Health

• John Duncan, Director, Department of Industrial

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Appendix D: Diacetyl Use Questionnaire (Mandatory)

THIS QUESTIONNAIRE APPLIES TO USE OF PURE DIACETYL OR FOOD FLAVORINGS CONTAINING at least 1% DIACETYL in places of employment covered by Section 5197.

NOTE: This questionnaire expands based on the Company's number of CA facilities specified in Question #2: ~~1~~, product/processes in Question #6: ~~1~~, and diacetyl-containing ingredients in question #8: ~~1~~

If you need to make corrections, please make changes in the boxes below before submittal.

However, remember that once submitted you cannot re-submit the same specific questionnaire to substitute for any previous submissions. Questions/corrections can be directed to Cal/OSHA Research and Standards at 510-286-7000

Top of Form

1. Name of Company:

2. Number of CA facilities:

3. Address of California Facility:

City: CA, ZIP:

4. Number of people employed at facility:

5. Contact :

Title:

Email:

Phone:

6. At this facility how many processes use pure diacetyl or diacetyl-containing flavorings?

7. Name of the Process (note this question sequence will be repeated for each process):

8. Number of ingredients that contain diacetyl in this process:

9. Name of diacetyl or diacetyl-containing flavoring ingredient

(Use names you commonly apply to the diacetyl-containing products such as the name on the label or MSDS.)

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10. Form or physical state of the ingredient used in the process:

- Liquid
- Powder
- Paste
- Encapsulated
- Other:

11. Quantity of the ingredient used in the process (lbs): lbs.

12. The % diacetyl in the ingredient (if known): % (if no change is made, that means "UNKNOWN".)

13. Frequency process is used/performed on average:

times

14. How many employees directly handle diacetyl or diacetyl-containing flavorings in this process?

- 1-5
- 6-10
- 11-20
- More than 20

15. Does this process include? (check all that apply)

- Mixing
- Spraying
- Sprinkling
- Heating

16. During the process, are the ingredients:

- Totally covered & contained throughout the process
- Partially covered
- Uncovered

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~~17. If conducted uncovered or partially uncovered, how long is the process uncovered?~~

- ~~Less than ½ hr~~
- ~~1-2 hr~~
- ~~2-4 hr~~
- ~~4-8 hr~~

~~18. What kind of ventilation is in the process area?~~

- ~~Local exhaust ventilation~~
- ~~General mechanical~~
- ~~Doors and windows~~

~~19. Are there any other engineering controls?~~

- ~~Yes, describe type:~~
- ~~No~~

~~20. Do employees use respirators for this process?~~

- ~~Yes, ½ or full face cartridge type~~
- ~~Yes, dust mask-type~~
- ~~Yes, describe type:~~
- ~~No~~

~~21. Do you have any results of air monitoring for diacetyl for employees in this process?~~

- ~~Yes~~
- ~~No~~

CLEANING AND SANITIZING (This group should not repeat)

~~22. How many additional employees not already doing the processes listed above are involved in cleaning or sanitizing operations?~~

- ~~1-5~~

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6-10

More than 10

23. Do these operations include (check all that apply):

Hot water

Steam

24. How often are cleaning/sanitizing activities performed on average?

times

25. How long does the cleaning/sanitizing take on average per day?

Less than ½ hr

1-2 hr

2-4 hr

4-8 hr

26. What kind of ventilation is used during cleaning/sanitizing?

Local exhaust ventilation

General mechanical

Doors and windows

27. Are there any other engineering controls used during cleaning/sanitizing?

Yes, describe type:

No

28. Do employees use respirators for cleaning/sanitizing?

Yes, ½ or full face cartridge type

Yes, dust mask type

Yes, other type:

No

29. Do you have any results of air monitoring for diacetyl for employees who perform cleaning/sanitizing operations?

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- Yes
- No

~~SPILL CLEAN UP AND MAINTENANCE~~ (This group should not repeat)

~~30. How many additional employees are involved in support activities such as maintenance or spill clean up?~~

- 1-5
- 6-10
- More than 10

~~31. Do employees use respirators for these support activities?~~

- Yes, ½ or full face cartridge type
- Yes, dust mask type
- Yes, other type:
- No

~~32. Do you have a designated spill response team?~~

- Yes
- No

~~33. What is the largest size spill of diacetyl containing materials (in pounds) that you have had in the past 24 months?~~

- Less than 1 pound
- 1 to 10 pounds
- 10 to 100 pounds
- More than 100 pounds

~~34. Do you have any results of air monitoring for diacetyl for spill clean up or maintenance employees?~~

- Yes
- No

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- ~~All submissions are final. You may need to print a copy of this form first for your own record.~~

- ~~To finalize your entries for this current questionnaire, please click to transmit it to DOSH.
(If applicable, your next tentative questionnaire will be generated and ready for another facility and/or product pre-populated with similar answers in this form for easy edit.)~~

- ~~To clear all entries click to restart with a blank form.~~

~~Bottom of Form~~