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FINAL STATEMENT OF REASONS

CALIFORNIA CODE OF REGULATIONS

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

Occupational Exposure to Food Flavorings Containing Diacetyl

MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE 45-DAY PUBLIC COMMENT PERIOD

There are no modifications of the information contained in the Initial Statement of Reasons (ISOR) except for the following substantive and/or sufficiently related modifications that are the result of public comments and/or Board staff evaluation.

Subsection (a), scope and application, has been restructured to differentiate clearly 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 incorporation into subsection (a) is workplace 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) is 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 led to incorrect selection of respirators based upon inappropriate reliance on parts of Section 5144 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) 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) [Material Safety Data Sheet (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.

<u>Summary and Response to Oral and Written Comments:</u>

I. Written Comments

Paul A. Schulte, Ph.D., Director, Education and Information Division, National Institute for Occupational Safety and Health (NIOSH) in written comments received on December 9, 2009.

Comment #NIOSH1: Regarding the ISOR,

1. Use "*for*" in place of "*of*" in "*National Institute for Occupational Safety and Health."*

2. Page 1, paragraph 4, line 6. "*NIOSH identified a cluster of nine workers with bronchiolitis obliterans*…" NIOSH identified a cluster of **eight** workers…

3. Regarding the parenthetical on page 2, paragraph 1 regarding *tentative* identification of diacetyl as causative agent of the observed lung changes:

The information in the parenthesis was pertinent only to the interim health hazard reports for the sentinel popcorn plant because animal toxicological studies were not available at the time results were first disseminated. When animal experiments for *pure* diacetyl became available, NIOSH ceased describing diacetyl as only a *marker* of flavoring exposure since the animal experiments supported the biologic plausibility of diacetyl being a sufficient causal agent.

4. Regarding page 3, paragraph 4 sentences about NIOSH statements concerning the limitations of findings that exposure of animals to flavoring mixtures containing diacetyl caused irritation and that these findings being of too limited explanatory power to label diacetyl as the cause of bronchiolitis obliterans seen among popcorn and flavor workers:

These statements are no longer correct. Diacetyl in the presence of butyric acid *is* more toxic because it prevents diacetyl from binding in the upper airway, thereby allowing deeper diacetyl penetration. But diacetyl is a sufficient [though not necessarily the only] cause of fixed airways obstruction, as the criteria for causal association have been met: a) consistency of findings in many plants, three industries and by many investigators; b) degree of association; c) exposure-response relations; d) temporality, in that exposure preceded the health response and cessation of exposure resulted in stabilization in FEV1; e) biologic plausibility.

5. Page 5, paragraph 1 regarding the subsection's specification that covered employers conduct representative assessments using sampling and analytical methods of Appendix A:

It may be more efficient to cite the reported reliable quantitation limit (RQL) of OSHA method 1013 instead of directly referencing the method. Citing the RQL will not discourage future use of improved sampling methods and will provide an exact target point for engineering controls.

6. Page 8, paragraph 3, line 5 regarding findings that development of obstructive lung disease is possible in as few as 6 months:

The interval is less than 6 months, NIOSH discovered two instances of symptom onset in 5 months and one worker at California flavor manufacturer Gold Coast developed symptoms in 4.5 months.

7. Regarding page 12, paragraph 3's statement "Information developed by NIOSH, FEMA and NJMRC between 2000 and the present provide a powerful indication that diacetyl may cause serious lung harm at concentrations below 1%:

Limiting application of the standard to food or flavoring products with diacetyl content 1% or greater by weight may not be protective of all workers. NIOSH has documented exposures to diacetyl where employees worked with formulations less than 1% by weight. Factors other than diacetyl content, for example work practices and process considerations such as heating, can greatly affect exposures and potential disease. NIOSH does not presently possess a quantitative risk assessment to prescribe a threshold, but a possible alternative threshold might apply to the proposed standard when the diacetyl content of food or flavorings is 0.1% or greater by weight. Although not exposure risk-based, this alternative would be consistent with the proposed MSDS reporting requirement of greater than 0.1%, and also consistent with the current federal Hazard Communications Standard requirement for hazardous mixtures containing a carcinogen. Although diacetyl is not a carcinogen, the rapid progression and severity of health effects that it causes provide a rationale for treating it in a similar fashion. Whatever threshold is chosen, accurate labeling of food and flavoring products is critical; in recent Health Hazard Evaluation, NIOSH has encountered products that contain diacetyl but are not labeled.

Response #1: The Board acknowledges and agrees to the corrections noted in points 1, 2, 3, 4 and 6. In regard to point 5, the Board agrees with NIOSH's and others' comments that employers should not be restricted to utilizing only the analytical and sampling method specified by Appendix A. Amendments have been proposed to allow utilization of equivalent methods that are at least as accurate, specific and sensitive as OSHA Method 1013. The Board additionally notes that only those parts of Appendix A that contain important clarifications to OSHA Method 1013 have been retained in the modified proposed regulation. In regard to point 7, the Board appreciates NIOSH support of the requirements in subsection (l) to list on MSDS any concentration of 0.1% or greater of diacetyl. However, because the Hazard Communication Standard already contains provisions requiring the listing of health effects that can occur regardless of the percentage of an ingredient, subsection (l) is removed in the modified proposal.

Comment #NIOSH2: Subsection (a), Scope and Application. Limiting application of the standard to food or flavoring products with diacetyl content 1% or greater by weight may not be protective of all workers.

Response #2: While agreeing in principle with this statement, the Board notes that there are inadequate findings about the health effects from diacetyl exposures arising from work with food or flavoring products containing less than 1% diacetyl. The regulation therefore addresses the potential existence of such health effects through "Scope" subsection (a)(1)(B), through its medical surveillance and removal provisions and through a requirement to report the occurrence of such health effects to the Division.

Comment #NIOSH3: Subsection (b), Definitions. NIOSH has the following comments on these definitions, as currently numbered in the proposed rule:

"California Department of Public Health (CDPH) Guidelines" -- Update the CDPH guidelines referenced (August 2007). The 2007 guidelines include an abnormality criterion (FEVl/FVC ratio less than 90% predicted) that is not consistent with American Thoracic Society (ATS) guidelines *[ATS/ERS 2005]*.

"Detectable level of diacetyl" -- The terms "detectable level of diacetyl," "reliable quantitation limit," and "lowest feasible level" are all used interchangeably. Use standard terminology and one definition.

"Diacetyl" Chemical Abstract Service (CAS) number-- The CAS number is incorrect and should be 431-03-8.

"Enclosed Processes" definition states a process is not enclosed if there are visible emissions -- since diacetyl and other flavor vapors are not visible to the eye, the term "detectable emissions" is more appropriate.

"Fixed obstructive lung disease" -- Include the following ATS criteria [AT*S/ERS* 2005]: FEV1 does not increase by at least 12% and 200 ml 10 to 20 minutes after administration of 4 puffs of albuterol using a spacer or volume chamber.

"Regulated Area" definition mentions "potential employee exposure to detectable levels of diacetyl" -- For clarity, "*employee potential exposure to detectable levels of diacetyl*" could be used.

Response #3: In the modified proposal, corrections are made to definitions addressing most of the above concerns except that the term "visible emissions" has been retained as part of the description of "enclosed process," and the 2007 CDPH Guidelines remain the most up-to-date version available, leaving any potential future change to this reference to follow-up rulemaking. This "visible emissions" phrasing addresses circumstances in which diacetyl-containing material is released in powder or aerosol forms. Current sampling and analytical methods for diacetyl-containing powders and aerosols do not accurately quantify exposures to diacetyl. Current methods are adequate to measure diacetyl only as a vapor. "Visible emissions" also covers circumstances when the release

of a substance other than invisible diacetyl vapor may serve as a marker or indicator of the escape of diacetyl from a vessel or other containment system.

The definition of "detectable level of diacetyl" has been deleted from the modified proposal, while a clarifying definition of "reliable quantification level (RQL)" has been added. "Lowest feasible level" is found only in subsection (e)(5). This phrase is maintained because its meaning is clear from both the context of the general use of the term and its use within this regulation as the level of diacetyl that can be achieved through engineering and work practice controls. The concept of reducing employee exposures to the lowest level possible is utilized in substance specific regulations with PELs such as Methylene Chloride and Hexavalent Chromium. These regulations state that when the PEL cannot be attained, engineering and work practice controls shall be utilized to bring exposures down to the lowest level achievable.

Comment #NIOSH4: Subsection (c), Exposure assessment (1) General (B):

The time-weighted averaging required by this subsection is subject to bias during the batch operations typical of flavoring manufacture. Instead of full shift time-weighted averaging, short-term exposure sampling for batch operations or short-term exposures may be of more utility in assessing the need for medical surveillance and controls and, in the long term, for identifying the short-term exposures that are associated with flavoring-related lung disease.

Response #4: The Board agrees that short-term exposures may be more significant as causes of health effects than lower average full shift exposures. The regulation addresses assessment of short-term exposures in the very next subsection.

Comment #NIOSH5: Subsection (d), Regulated Areas:

In (d)(3), a definition for "authorized persons" is needed. Additional detail about the type of training provided to employees who enter regulated areas is necessary in subsection (d)(4)(B).

Response #5: A definition of "authorized persons" has been added. Training requirements are comprehensively covered in subsection (j).

Comment #NIOSH6: Subsection (e), Engineering Controls and Work Practices (2) and (6):

For subsection (e)(2)(A), give examples, such as, use of cold storage; isolation of the mixing room from the rest of the plant using walls, doors, or other barriers; and positioning the collection hood as close as possible to the source of the flavoring ingredients. The program evaluation requirement of subsection (e)(6) should include a provision for periodic testing and assessment of ventilation systems to ensure that they are operating properly and maintained at the specified flow rates for capture of diacetyl.

Response #6: Additional examples have been added to subsection (e)(2). The commenter's suggestions regarding subsection (e)(6) are unnecessary because of existing requirements elsewhere in Title 8 for periodic testing and assessment of ventilation systems.

Comment #NIOSH7: Subsection (f)(2), Respiratory Protection:

The draft standard would allow respirators with a wide variation in assigned protection factors from 25-1000 to be used for protection against concentrations of diacetyl greater than 0.2 ppm. The basis of 0.2 ppm is not provided (it differs from the detectible level of diacetyl and reliable quantitation limit mentioned above). It is unclear if 0.2 ppm should be used to calculate the maximum use concentration (MUC) for respirator use. If a respirator with a lower assigned protection factor is used, potential overexposures could result from concentrations observed during previous investigations [Martyny et al. 2008; Kullman et al. 2005]. Therefore, paragraph (f)(2) should be reworded to state: "*Maximum use concentrations will be calculated based on the mathematical product of the assigned protection factor (APF) times 0.2 ppm.*"

Response #7: The basis for utilizing 0.2 ppm is in fact the possibility mentioned by the commenter: use of a respirator with a lower assigned protection factor at this concentration could lead to exposures harmful to health, as indicated by several independent investigations. A Respiratory Protection Selection Table has been added to provide appropriate guidance for the proper selection of respiratory protection.

Comment #NIOSH8: Subsection (g), Medical Surveillance:

At the end of subsection (g)(1)(A), add: "The PLHCP should attend a NIOSH - approved spirometry course every five years."

The initial medical evaluation described by subsection (g)(3) should require an initial (baseline) medical evaluation before workers are allowed to work in any area where they may be exposed to diacetyl.

Response #8: The Board agrees that the supervising physician *should* attend an appropriate spirometry review course at least every five years, but such attendance need not be mandatory as this subsection makes this physician responsible for ensuring all components of the program comply with the referenced medical guidelines. This means that the supervising physician must ensure that persons performing the spirometry are current in their review training.

A change has been made in subsection (g)(3) to require the initial medical evaluation prior to initial exposure to diacetyl when feasible, but in no case later than 14 days after an employee begins work in an area requiring medical surveillance.

Comment #NIOSH9: Subsection (h)(2), PLHCP Written Opinion:

Clarify that the employee is required to inform the employer in writing if the employee is requesting that the employer pay for a second medical opinion.

Response #9: A clarifying change has been made.

Comment #NIOSH10: Subsection (i)(1)(A)(4), Medical Removal:

The medical removal section indicates that the employer has a maximum of 6 months responsibility given three criteria, which ever comes first. The wording should be changed to "*For six months, whichever comes last*." This change would allow PLHCPs to operate in a health protective way and not facilitate a situation in which the employer can terminate the employee immediately if no other work is available.

Response #10: A clarifying change has been made to subsection (i)(1)(A).

Comment #NIOSH11: Subsection (j), Information, Training, and Labeling:

In subsection (j)(1)(B), include additional training for changes in flavors introduced in production which may contain diacetyl substitutes of unknown toxicity.

In subsection (j)(2)(A), should also include labeling for diacetyl substitutes.

Response #11: Changes as suggested have been made to subsection (j) and in other subsections to address the issue of diacetyl substitutes.

Comment #NIOSH12: Subsection (k)(3), Recordkeeping and Reporting:

There are differences between the questionnaires required by the Flavoring Industry Safety and Health Emphasis Program (FISHEP) and non-FISHEP participants. It is recommended that all companies submit an annual report with updated information required by Appendix D.

Response #12: Due to Division limited capabilities for maintaining database security and other resource issues, Appendix D has been removed from the proposed regulation.

Comment #NIOSH13: Appendix A, Sampling and Analytical Protocol:

1. Subsections (a)(l)(C) and (a)(2)(C) limit of detection, see previous comment regarding page 12, paragraph 3 of the ISOR. Note: On 3/29/10, upon Division query, NIOSH corrected this comment to state: "*See previous comments on Page 5, paragraph 1 in the Standards Board's Initial Statement of Reasons (ISOR) and on (b) Definitions (4) Detectable level of diacetyl in the draft standard."*

Specifically NIOSH comments state:
It may be more efficient to cite the reported quantification limit (RQL) of OSHA Method 1013, instead of directly referencing the method. Citing the RQL will not discourage future use of improved sampling methods and will provide an exact target point for engineering controls.

The terms "detectable levels of diacetyl," "reliable quantification limit" and "lowest feasible level" are all used interchangeably throughout the standard. NIOSH recommends using standard terminology and one definition.

2. Subsection (b)(l)(C): Change "Silica gel tubes" to "Silica gel adsorbent tubes."

3. Subsection (b)(2)(D): For clarity, revise text to "*After sampling for the appropriate time, immediately remove the adsorbent tubes, separate them by removing the connecting tubing, seal each with plastic end caps and individually wrap each tube with aluminum foil to protect it from light*."

4. Subsection (b)(2)(I): Guidance should be given for handling samples below detectable or quantifiable limits in terms of calculating 8-hour time weighted averages (TWA) considering the sequential nature of the sampling methods for diacetyl.

5. Subsection (c)(2)

Regarding the statement, "*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.*" The reference to 95% confidence limits does not seem meaningful in this sentence; OSHA requires recovery to be 75-125%. More meaningful phrasing would be: "*The reliable quantitation limit (RQL) is the smallest concentration of analyte which can be quantitated precisely, providing that the recovery is 100 ± 25% of the theoretical value."*

Response #13: For the first paragraph of point 1, see the response to Comment #NIOSH 1, point 5. For the second paragraph of point 1, see the response to Comment #NIOSH 3, point 4. In regard to points 2 and 3, these sections have been deleted, as they are covered in the OSHA method which is incorporated by reference. As to point 5, the definition of RQL has been appropriately changed and moved to subsection (b). In regard to point 4, the Board notes that instructions for the handling of sequential sampling are addressed in an appendix to existing Section 5155.

Comment #NIOSH14: Appendices Bl and B2

These questionnaires should be modified based on the utility of information obtained by CDPH with FISHEP. In addition, question 20 should include diacetyl substitutes, such as pentanedione, diacetyl trimer, and starter distillate. The follow-up questionnaire is not

practical, since practitioners do not keep track of initial versus follow-up visits, nor do employees remember at six month intervals when they were last tested (Kim et al., forthcoming).

Response #14: Appendices B1 and B2 are in fact identical to the questionnaires developed by the CDPH in conjunction with FISHEP.

Comment #NIOSH15: Appendix C

The respiratory toxicity of butter flavorings other than diacetyl remains understudied. Safe substitutes are not currently available. NIOSH recommends the Substitution subsection be placed after skin and eye protection and state the following: "*The respiratory toxicity of flavorings other than diacetyl remains understudied. Make sure substitutes are safe."*

Response #15: While acknowledging the truth of the statements NIOSH proposes adding to the diacetyl hazard alert for workers, Appendix C, which was a CDPH Health Hazard Alert on diacetyl, is deleted from the modified proposal. However a provision has been added to subsection (j) of the modified proposal requiring training to include information from any CDPH Health Hazard Alerts pertaining to diacetyl or food flavorings. In any case, the hazard communication regulation requires the employer to communicate this type of information about chemical substitutions to employees.

Elizabeth A. Treanor, Director, Phylmar Regulatory Roundtable, in written comments received November 9, 2009.

Comment #PRR1: We support adoption of a rule for exposure to food flavorings containing diacetyl.

However, that rule must be based on a permissible exposure limit (PEL) rather than the lowest feasible level achieved through engineering controls and work practices. Most of the companies affected by the proposed regulation have been following NIOSH guidance--essentially a restatement of the performance-based principles of industrial hygiene. These principles are inherently vague and require the application of professional judgment in their implementation. The proposal, on the other hand, would eliminate professional judgment by imposing an effective PEL of zero by requiring engineering controls to reduce exposure to the lowest feasible level. This approach is inappropriate public policy.

Further, for remaining exposure after engineering controls are introduced, respiratory protection is required to reduce exposures below the RQL—again an effective PEL of zero. Requiring respirators when they are not needed is inadvisable because such use exposes employees to the inherent hazards of wearing a respirator such as additional cardiovascular burden and reduced ability to see and hear. To prevent these inherent respiratory hazards, the lowest proposed PEL of 1 $\mu g/m^3$ for hexavalent chromium was

not adopted. This diacetyl proposal is clearly inconsistent with this well-established principle of limiting inherent risk by not requiring respirator use when it is not necessary.

Response #1: The Board appreciates the commenter's overall support for adoption of a rule. The Board does not agree that sufficient scientific data exists presently to establish a PEL. Until a safe level of exposure is scientifically established, it would not be protective of the exposed workforce to allow exposures to levels of diacetyl that may be harmful. This does not mean there is an effective PEL of zero as the commenter alleged, but the commenter is correct in stating that the proposal establishes performance-based practices to limit exposures to the greatest practical extent—an approach common to many existing substance specific standards. So the Board also does not agree that the proposal eliminates professional judgment; rather, the proposal provides some guidelines so that judgment can be more effectively made. Nor does the Board agree the proposal requires respirator use when it is not necessary. Implementation of performance-based practices such as engineering controls will limit the need for respiratory protection in the first place. In the second place, the example of hexavalent chromium is inapposite, as the risk addressed in that instance is lung cancer developed over a lifetime of exposure to a substance for which a total accumulated dose is part of the mechanism of causation. In contrast, in the case of diacetyl, short term peak exposures may lead to total loss of lung function in as little time as a few months.

Comment #PRR2: This proposal is a departure from established regulatory approaches in other ways:

1. The Reliable Quantitation Limit (RQL) is not well understood within the regulated community. At a minimum, a definition should be provided in the regulation—and not, as at present, a mere reference to Appendix A. As we understand it, the RQL is essentially the limit of detection and effectively becomes the exposure limit. While we understand the proposal was developed when there may have been insufficient data to establish a PEL, we ask the Board not to adopt a rule that, in effect, establishes a PEL of zero.

2. Subsection (b)(7). The last sentence of the definition of "*enclosed process*" needs more clarity. The definition does not consider the possibility that the lack of visible emissions does not automatically mean a process is fully enclosed. There could be non-visible emissions that could potentially expose employees.

3. Subsection (e). The *lowest feasible levels* concept is not an objective standard and does not create a level playing field. This concept exposes employers to subjective determinations by Cal/OSHA Enforcement and will result in unnecessary litigation about the meaning of this term. How can an employer demonstrate "*lowest feasible*" to the Division? The criteria upon which feasibility arguments will be judged are unclear. If the Board continues with this approach, we recommend criteria for evaluating feasibility be identified and included in the regulations.

4. Subsection (g). The medical surveillance requirement for supervision by occupational or pulmonary medicine physicians with specific knowledge is infeasible. Many manufacturing sites are located where such expertise is not available. Secondly, for liability reasons, it seems unlikely that anyone other than an in-house physician would be willing to "supervise" a company's medical surveillance program.

Response #2: The Board does not agree that the proposal departs from regulatory approaches utilized elsewhere. Specifically:

1. In all cases there will be a limit to what an analytical technique can detect (sensitivity) and what can with statistical confidence be quantified (accuracy). As is well understood by industrial hygiene analytical chemists and laboratories, these common concepts are respectively referred to as the Limit of Detection (LOD) and the Limit of Quantification (LOQ). Typically, as a consequence of universally accepted statistical necessity, the LOQ is three times the LOD. So in contrast to the commenter's understanding, the RQL is in fact significantly higher than the limit of detection. However, the Board does agree that a definition of RQL should be added to the regulation.

2. The Board does not agree that the full definition of "*enclosed process*" allows a lack of visible emissions to mean a process is enclosed.

3. The *lowest feasible levels* concept is, from its context, clearly a performance-based requirement. Performance-based requirements are common in many Cal/OSHA regulations, and the determinations of Cal/OSHA Enforcement are always rebuttable with facts. Such is the case for the *lowest feasible levels* concept. In the revised proposed regulation, this terminology appears only in the engineering controls and work practices subsection wherein the employer's program reviewer is specifically required to make a performance based assessment of the adequacy of the chosen engineering controls and work practices. See also the response to Comment #NIOSH3, point 4.

4. Special medical knowledge of pulmonary conditions and spirometry are necessary for an effective medical surveillance program that will recognize respiratory health effects possibly attributable to flavoring exposures and will be able to distinguish them from respiratory effects due to other causes. However, the Board believes the commenter has to some degree misunderstood this provision. There is nothing in the proposal that requires the supervising physician to be on-site. This individual needs to merely exercise suitable supervision of other medical professionals. The Board does not agree that locating appropriate medical expertise to supervise the medical surveillance would be problematic.

Judith Freyman, Vice President of Western Occupational Safety and Health Operations, ORC Worldwide in written comments received November 9, 2009.

Comment #ORC1: ORC supports the proposed rule in general but has several concerns, including the lack of a PEL. ORC notes the impressive level of collaboration amongst and between governmental organizations and the employer community during the three years it has taken to submit this proposal to the Board.

Response #1: The Board is appreciative of ORC's general support of the proposal.

Comment #ORC2: Section (a), Scope and Application. Despite fewer opportunities during the advisory process for DOSH to visit food processing facilities using diacetyl, representations of trade associations, companies, and other stakeholders as well as NIOSH research in the popcorn manufacturing industry have made the case for including food processing workplaces in the regulation along with the flavor manufacturing industry.

Response #2: The Board is appreciative of ORC's general support for including food processing workplaces in the regulation. Food processing workplaces are covered by the proposed regulation if either of two conditions exists in the workplace: the utilization of a food product or flavoring containing diacetyl at a concentration of 1% or more by weight or the diagnosis of work-related fixed obstructive lung disease in an employee. In order for these two facets of the proposed regulation's scope to be made clear, this subsection has been reorganized from its originally proposed form.

Comment #ORC3: Lack of a Permissible Exposure Level and Subsection 5197(e). Except for the ISOR statement about insufficient data available to determine a safe exposure level, there is no explanation for the proposed regulation's approach of exposure monitoring and establishment of regulated areas. The monitoring method referenced in Appendix A has a detection limit of 0.012 ppm, in effect establishing a default PEL without any data establishing a risk at the 0.012 ppm level. Requiring engineering controls and work practices [Subsection 5197(e)] to reduce employee exposures to the lowest feasible level is problematic without explanation of how to achieve and demonstrate compliance with those low levels. ORC understands to some degree that the lack of a recommended PEL for diacetyl from any authoritative body and the limited resources available for DOSH for generating precedent-setting PELs may have made DOSH feel compelled to take this approach. We believe this approach is supportable as an interim action given that the health consequences of exposure to diacetyl exposure can be so serious. However, when sufficient data to establish a PEL becomes available, we urge DOSH to take steps to adopt a PEL and revise this rule at that time.

Response #3: NIOSH unequivocally stated that presently there is not a quantitative risk assessment to prescribe a threshold. See Comment #NIOSH1. The Board agrees with the commenter that a PEL should be adopted when sufficient data become available. The

Board does not agree that referencing the analytical method's RQL creates a defacto PEL. See also responses to Comment #PRR1 and Comment #PRR2.

Comment #ORC4: Labeling, subsection (j)(2)(A). ORC finds no supporting data for labeling de minimis containers of diacetyl or diacetyl-containing flavoring or food product with a warning. The scope and application sections of the proposed rule establish a 1% by weight trigger while the MSDS requirements call out a threshold level of 0.1%. We question therefore the lack of an exemption for de minimis amounts of diacetyl from the labeling requirement.

Response #4: See Comment #NIOSH1 for discussion of the 0.1% labeling requirement. The Board believes and Federal OSHA interpretations have stated that the hazard communication standard requires MSDS listing of health effects of mixture ingredients regardless of percentage if that percentage is capable of causing harm. NIOSH, FISHEP and other research has revealed there is reason to be concerned about the magnitude of employee exposures to airborne concentrations of diacetyl that may be generated from mixtures containing less than 1% diacetyl. Therefore the Board does not agree that it is necessary or correct for this proposed regulation's labeling requirement to be based on 1% diacetyl by weight. A percentage of diacetyl in a mixture that does not pose a health risk would not require labeling under this proposed regulation or under the hazard communication regulation. Whether or not a particular percentage by weight of diacetyl or other artificial butter flavoring is or is not a de minimis percentage is a factual matter that an employer may demonstrate as a performance aspect of both the existing hazard communication regulation and this proposed regulation.

Clay Detlefsen, Vice President & Counsel, International Dairy Foods Association, in written comments received on November 13, 2009.

Comment #IDFA1: IDFA represents 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States, a $110-billion a year industry.

There is no record of unusual occurrence of respiratory illnesses related to diacetyl in our industry. Where flavors containing diacetyl are used within our industry, they typically contain less than 1% diacetyl. We are concerned that the proposed rule will unnecessarily cover many operations where diacetyl use is minimal and not a problem. In the scope of the proposed rule, Cal/OSHA should consider situations like the dairy industry in which diacetyl use is infrequent, added to cold, wet foods in low concentrations in partially enclosed or enclosed systems in areas with good ventilation.

Response #1: Only a few dairy operations in which starter distillate of high diacetyl concentration is utilized will be covered by the proposed regulation. The use of refrigerated solutions, good ventilation, and enclosed systems are precisely the measures required by the proposed regulation, so the small sector of the dairy industry that may be

effected should experience little difficulty or additional expense in complying with these provisions of the regulation.

Comment #IDFA2: One of our concerns with the proposed rule is that a single container containing diacetyl at 1% will bring an entire facility into the scope of the rule, requiring labels for all containers of diacetyl-containing food in the facility. By extrapolation, a facility using a 1% diacetyl-containing flavoring once a month would have to put warning labels on all food products containing *any* amount of diacetyl, including naturally occurring diacetyl found in strawberries. It would also appear that if these containers were final consumer packages, the conveyance of information would then extend to consumer labels.

We do not believe that Cal/OSHA intended to regulate in such a manner. We urge Cal/OSHA to reconsider its approach in favor of that offered by the Grocery Manufacturers Association (GMA) in its comments. The PEL approach that GMA discusses will enhance and optimize worker safety.

Response #2: The commenter is incorrect in interpreting the scope of the regulation. Only the part of the plant exceeding the trigger percentage of diacetyl would be covered by its provisions. Also, labeling requirements under the proposed regulation do not exceed the requirements of the hazard communication regulation, which only apply to containers in use in the workplace and to containers of substances that will be used as chemical ingredients in other industrial facilities. Therefore, this proposal's labeling requirements do not apply to consumer labels.

Caroline Silveira, Director, State Affairs, of the Grocery Manufacturers Association, [cosigned by the following trade associations: American Bakers Association, California League of Food Processors, California Manufacturers and Technology Association, Dairy Institute of California, and International Dairy Foods Association] in written comments received on November 17, 2009, December 3, 2009, and December 16, 2009.

November 17, 2009, GMA Comments

Comment #GMA1: The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The GMA believes the scope and approach of the proposed rule are overly broad. GMA questions whether the current draft proposed regulation can meet the "no reasonable alternative" test. The scope of application for this proposed rule should be ***food flavorings***, not foods. In 2000, the occurrence of the cluster of lung obstruction cases among workers in microwave popcorn plants led to a demand for action ahead of the science. The presumption that latent cases of fixed obstructive lung disease would be discovered throughout food manufacturing has not been borne out. Aside from microwave popcorn production, there is little opportunity for significant exposure to diacetyl elsewhere in food manufacturing. There is little evidence of risk in California or nationally from workers compensation claim data from the food manufacturing industry, despite increased awareness of diacetyl

usage in food flavorings. This lack of evidence includes no development of new disease in microwave popcorn plants.

It is important to understand that the high potential for cumulative exposure to diacetyl that exists in flavoring manufacturing [and existed pre-engineering controls in microwave popcorn facilities] is not representative of food manufacturing generally. At the time the microwave popcorn cluster of obstructive lung disease was discovered, popcorn manufacturers were using flavorings containing uniquely high concentrations of diacetyl [15 to 30%] never used in general food manufacture. The high concentration diacetyl-containing flavorings were added to hot oil and mixed with popcorn under open conditions which promoted volatilization of diacetyl. These popcorn plants operated on a continuous basis, producing a single product. By contrast among GMA member companies the majority of food flavorings used contain less than 1% diacetyl by weight and are added in small amounts. Final food products typically have exceedingly low diacetyl concentrations, on the order of hundredths of a percent or less. Most food processing operations operate on a batch (intermittent) basis, and do not produce the same product continuously; not every product's formulation will have diacetyl-containing flavorings. Finally, since pursuant to federal Good Manufacturing Practice regulations food is manufactured to the extent feasible under closed conditions in order to minimize contamination, the potential for diacetyl to volatilize into the workplace air is limited.

During the years of the proposed rule's development, usage of diacetyl-containing flavorings in food manufacturing has changed considerably in ways not adequately reflected in the current draft. Growing awareness of the diacetyl risk has prompted modifications in food flavoring and food product formulations to significantly reduce or eliminate diacetyl content.

Response #1: Although it is true that most food manufacturing companies are not using diacetyl in the high percentages formerly utilized by microwave popcorn facilities, NIOSH has documented a range of decrements in respiratory function less severe than frank bronchiolitis obliterans that are associated with airborne exposures consistent with much lower diacetyl percentages in the bulk material. However, to the extent that the commenter's description of the prevailing conditions in the industry is the case (i.e., manufacture under closed conditions, reduced or eliminated diacetyl content), food manufacturers will find they have few obligations under the proposed regulation.

Comment #GMA2: To the extent a California regulatory standard is justified, GMA believes a PEL based rule would provide the highest degree of assurance that workers are being adequately protected. We agree with the inclusion of processes using 1% or greater concentrations of diacetyl in the proposed rule. However, we believe understanding of diacetyl dose-response has advanced sufficiently to allow safe exposure levels to be derived at least for the establishment of an interim occupational exposure guidance limit (OEL) for diacetyl.

Available science supports an Occupational Exposure Limit for diacetyl. Cal/OSHA should adopt an OEL using the Morgan et al and Lockey et al studies and results of the National Toxicology Program (NTP) studies. The relationship between diacetyl exposure level and adverse effects is emerging from studies on animals and epidemiological studies and exposure assessments in flavoring and food manufacturing. Corrections of uncertainties in original NIOSH exposure assessments, the publication in 2009 of an epidemiological study [Lockey et al] of microwave popcorn workers and initial animal studies completed by the NTP are examples of this emerging knowledge. These studies and this emerging knowledge should be considered as part of the body of best available evidence the California Administrative Procedure Act requires regulatory agencies to consider.

GMA believes that a PEL for diacetyl should be developed using the Benchmark Dose Methodology (BMD), as suggested by Toxicology Excellence for Risk Assessment (TERA) in an assessment submitted to this Board. The TERA assessment is in process of being submitted to a peer-reviewed journal for publication. TERA determined that the most important measure of adverse effect of diacetyl was inflammation of the tracheobronchial region and that a dose-response curve for this effect could be developed based upon Morgan et al's 2008 study in mice and the aforementioned 2009 Lockey cohort study. Using BMD, TERA derived a suggested OEL of an 8-hour TWA of 0.2 ppm. TERA cites these and other studies as evidence that an 8-hour TWA was supported by available data, but not a Short Term Exposure Limit (STEL). TERA states another rodent study [Hubbs, et al, 2008] demonstrated that cumulative exposure is better than peak concentration as a predictor of the tracheobronchial inflammation effect while Lockey's supporting data found that duration of employment in the popcorn worker cohort was not associated with pulmonary function changes. GMA acknowledges that this body of data is far less robust than the body of human and animal data traditionally assembled and relied upon in setting a PEL and that this fact raises a question for how Cal/OSHA should proceed where the current data seem to support the OEL suggested by TERA.

Response #2: See responses to Comment #NIOSH1 and Comment #ORC3. NIOSH does not concur that there is sufficient information to support an OEL at present, and the Board defers to the judgment of that organization. When sufficient information does become available to support a PEL, the Division will convene and prioritize an advisory committee that includes GMA along with other key stakeholders to develop a proposed change to Section 5197 and the Board will initiate follow up rulemaking to add a PEL.

Comment #GMA3: If it is not feasible to wait for the results of the NTP studies and establish an OEL, an interim rule should be adopted applicable to the only two industrial sectors for which current data appear to establish a significant risk of harm from exposure to diacetyl or diacetyl-containing flavorings: concentrated flavor compounding and the manufacture of microwave popcorn containing high concentrations of diacetyl as triggered by a flavoring content of 1% or more by weight. Any such interim rule should specify that the once a PEL is established by federal OSHA, or an OEL is published by a

recognized expert entity such as the ACGIH etc., then compliance with the PEL or OEL will satisfy the requirements of the CA regulation.

Response #3: As stated in response to Comment #GMA1, the Board believes it is reasonable to include food manufacturing within the scope of the standard in the limited manner of the proposed regulation. As stated in the response to #GMA2, the Board remains open to revisiting the matter of a PEL in a future rulemaking.

Comment #GMA4: GMA believes a regulation as comprehensive and detailed as the proposed rule is not necessary while a PEL or OEL is being derived. However, if the Board finds such a rule is advisable, GMA believes food manufacturing operations should be limited to those plants where characteristics of diacetyl containing flavoring usage suggest significant cumulative exposures may be possible. A mandatory questionnaire such as that in the attachment to this written comment would provide Cal/OSHA the necessary information to make such determinations. Given the enormous diversity of food manufacturing, a targeted approach is needed in order for regulation to be effective and efficient in protecting workers. Some systematic prioritization of food manufacturing operations for evaluation and regulation is imperative. There is sufficient knowledge about the major factors that influence the nature and magnitude of cumulative exposure of food manufacturing workers to diacetyl. GMA members developed a detailed questionnaire for purposes of evaluating and prioritizing food manufacturing operations for inclusion in the rule. This questionnaire was provided to Cal/OSHA during the advisory process and is included as an attachment to this comment.

Response #4: The Board's mandate to protect the workforce of California coupled with the rapid onset of harm that has been demonstrated to be a potential consequence of exposure to diacetyl informs the Board's decision to not wait for derivation of a PEL to establish this proposed regulation. The Board believes that the selective triggers included in the scope of the regulation already limit the regulation only to appropriate workplaces. The Board acknowledges with thanks the assistance provided by the GMA in the development of the proposed questionnaire. However, due to Division limited capabilities for maintaining database security and other resource issues, Appendix D has been removed from the proposed regulation.

December 3, 2009, GMA Comments

Comment #GMA5: In the current proposed regulation, GMA firmly endorses the use of the 1% trigger, the scope of the regulation being limited to diacetyl and the focus on fixed obstructive lung disease. However, in the current form the regulation lacks needed clarity, is unnecessarily prescriptive and includes provisions that overlap or attempt to supersede other areas of law.

Response #5: The Board does not agree the proposed regulation lacks clarity, is unnecessarily prescriptive, or includes provisions superseding other laws. Nonetheless, numerous changes have been made to the proposal to improve clarity.

Comment #GMA6: A number of statements at the November 19, 2009, Standards Board Hearing made reference to a recent NIOSH Health Hazard Evaluation (HHE). Comments utilizing the findings of this HHE as a reason to include food manufacturers as covered entities in the proposed regulation were not accurate. NIOSH did not find any problems at this plant and the HHE bears this out. Moreover, the commenters would like to point out that:

- The 15 -20% diacetyl flavor mentioned was only used in one product made once every 4 – 6 weeks for 1 - 2 shifts.
- Almost all of the airborne exposures to any of the flavor components were non-detectable or extremely low.
- No obstructive lung disease was found.
- Symptoms such as shortness of breath were only found by questionnaire – only a few participants reported symptoms consistent with a possible work related pattern.
- The food manufacturer in question already limits exposure through a combination of engineering controls, work practices and respiratory protection.

Response #6: The Board has carefully considered the entire published body of NIOSH and other investigations. No one study has been dispositive in crafting the proposed regulation.

December 16, 2009, GMA Comments

Comment #GMA7: The proposal put forth by the Division of Occupational Safety and Health (DOSH) appears to be locked into the same invalid approach that was rejected by the U.S. Supreme Court in its Benzene decision of 1980. The commenters hope to assist DOSH and the Standards Board in adopting a practical and reasonable PEL-based approach that will adequately protect workers against any significant workplace risks posed by exposure to food flavorings containing diacetyl.

GMA believes the proposed rule is inconsistent with applicable law. It seems DOSH concluded available scientific information is inadequate to determine what levels of exposure/doses to diacetyl are hazardous, and therefore, that exposures must be reduced to the lowest feasible level via engineering and administrative controls, and then to zero through the use of respirators. This is the same rationale that Federal OSHA attempted to rely on, and that the U.S. Supreme Court squarely rejected in Benzene [*Industrial Union Dept., AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 100 S.Ct. 2844 (1980)]*. While the delegation of rulemaking authority to Federal OSHA and the California Standards Board are not identical, we believe they are substantially the same on the critical threshold issue of “significant risk” – a health hazard may be regulated only to the extent necessary to eliminate or control a “significant risk” and no further.

In Benzene, industry groups challenged a final OSHA rule which would have reduced the OSHA PEL for benzene from 10 ppm to 1 ppm. Adoption of the proposed Cal-OSHA rule on food flavorings containing diacetyl would effectively impose an 8-hour TWA PEL of 12 ppb (almost zero). In Benzene the Supreme Court found that even though OSHA had failed to demonstrate exposures to benzene below 10 ppm had ever caused leukemia, the agency still concluded that, in the absence of definitive proof of a safe level, it must be assumed that any level above zero presents some increased risk of cancer. This violated the OSHA Act, the Supreme Court ruled, because OSHA is limited to setting exposure levels to the higher of the demonstrated safe level, if known, or the lowest feasible level, if the safe level is unknown. In its proposed diacetyl rule, DOSH is violating the same principle. Also, the proposed rule appears to be inconsistent with longstanding law as to what is considered feasible. The courts have ruled that "a standard is technologically infeasible if it cannot be achieved in a typical facility without reliance on respiratory protection in more than a few, isolated operations" even if the Agency has determined that employees remain exposed to a significant risk of harm. This policy is based on a finding that harm resulting from widespread use of respiratory protection outweighs the harm posed by exposure to the chemical at issue. That policy was relied upon by Federal-OSHA in setting the PEL for hexavalent chromium at 5 ug/m3 rather than a lower level that could be achieved by greatly expanded use of respirators. In mandating the use of respirators whenever detectable levels of diacetyl are present, the proposed diacetyl rule would appear to violate that well-established legal principle.

From the industrial sector perspective, the potential existence of a significant risk of harm has been established only for the manufacture of concentrated flavorings containing diacetyl and the manufacture of microwave popcorn with flavorings containing relatively high concentrations of diacetyl. OSHA has not established that exposure to diacetyl poses a significant risk of harm for any other sectors of the food industry, much less the entire industry. Federal OSHA's Technical and Economic Feasibility Analysis, which is far more comprehensive than any analysis prepared by or for Cal-OSHA, indicates that the final product of the flavoring manufacturer, which generally has a diacetyl concentration below 1%, in the incoming raw material (flavoring) for the receiving food manufacturer. OSHA's contractor, ERG, found that the incoming flavor is quickly diluted by a factor of 100 to 1000 at the beginning of the typical food manufacturing process, which strongly suggests that the small concentration of diacetyl that is generally present further downstream would be insignificant from the standpoint of worker health and safety. The scope of a standard should only include those sectors in which a significant risk of harm has been established.

For the reasons stated above, we believe adoption of the proposed rule without a PEL would be legally invalid. Cal-OSHA would impermissibly force compliance with requirements where no significant risk of harm was ever shown to exist and in situations where any significant risk that may have existed has already been eliminated. We believe Cal-OSHA should establish a PEL using the databases underlying the Morgan et al. 2008 and Lockey et al. 2009 studies and the results of the NTP studies, as detailed in GMA's

earlier comments to the OSHSB and the submission of Dr. Andrew Maier, Toxicology Excellence for Risk Assessment (TERA).

Response #7: Neither the Benzene decision nor Federal OSHA's hexavalent chromium ratiocination is directly applicable to this rulemaking because this rulemaking takes place pursuant to California, not Federal law. In addition, the regulation at issue in Benzene set a PEL, which is not the case with the present rulemaking. California Labor Code Section 144.6 provides the mandate for the Board to adopt regulations as broad as necessary to protect the workforce, including "attainment of the highest degree of health and safety protection for employees." This broad mandate is further elaborated in Labor Code section 142.3(a)(4)(B) which authorizes state standards that are *more* effective than federal counterparts. The proposal before the Board was developed over several years with considerable input from the scientific and regulated communities. It can be truthfully said that the proposed regulation is based upon the latest available scientific data in the field. No one disputes that for the most part food manufacturers utilize products that are diluted to diacetyl percentages lower than those utilized by flavor manufacturers compounding initial flavors, although use of high diacetyl content has been reported. The proposed regulation is performance based and has been structured so that food manufacturers whose use of diacetyl flavorings is minimal will have minimal obligations.

Andrew Maier, Ph.D., CIH, DABT, Director, Toxicology Excellence for Risk Assessment (TERA) in written comments received on November 12, 2009.

Comment #TERA1: TERA submitted a review and analysis of the published research on diacetyl and its resulting conclusions and recommendations in a 33 page report with an additional 6 pages of data tables. As indicated in the GMA comments, TERA concluded that the tracheobronchial effects are the primary end points of relevance for occupational risk assessment. Utilizing the benchmark dose method and adjusting for additional safety factors, TERA concluded that 0.2 ppm as an eight-hour TWA was supported as an OEL by the current occupational epidemiology literature, and recommended this level could be adopted as a PEL with moderate to high confidence. [See the GMA comments for a broader understanding of some of the toxicological considerations evaluated in the TERA report.]

Response #1: The Board thanks TERA for its input. However, the Board believes the suggested OEL may be too high. See Comment #NIOSH1 and Comment #ORC3.

Rasma Zvaners, Policy Director, American Bakers Association (ABA), in written comments received on November 17, 2009.

Comment #ABA1: The ABA is the Washington D.C. - based voice of the wholesale baking industry, advocating on behalf of over 200 companies - both baking companies and their suppliers. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious, baked products for America's families.

The baking industry generates more than $70 billion in economic activity annually and employs close to half a million highly skilled people. ABA has been coordinating with the GMA on this issue for the past several years. ABA supports the comments submitted by GMA to the OSHSB on this issue, except that the ABA does not support GMA's recognition of the American Conference of Governmental Industry Hygienists (ACGIH) as an "expert entity." [See Comments #GMA2, #GMA3, and #GMA4 for the specific GMA comments with which ABA agrees.]

Response #1: See the previous responses to the GMA. The Board acknowledges the ABA position on the ACGIH.

Comment #ABA2: While California has the authority to implement standards protecting its workforce as it sees fit, ABA urges the Board to consider the value in creating regulatory consistency for those companies that have facilities nationwide. As representatives of commercial bakeries, ABA notes that there has not been a formal data collection effort to accurately determine and review the use of diacetyl in the baking industry. That said it is our understanding that several trends have been taking place in recent years. First, many bakers are phasing out of their use of flavorings containing diacetyl or already have moved to different flavorings that do not contain diacetyl. Second, while some bakers continue to use flavorings, the amount of diacetyl in the flavorings utilized is generally less than 1% diacetyl by weight. Further the baking industry, as others in food production, must adhere to Good Manufacturing Process regulations by federal law. Our operations tend to be batch and seasonal depending on consumer demand for specific baked goods.

Response #2: As stated in response to the GMA, the Board is aware of the trends in diacetyl usage in the baking industry and other food manufacturers. The proposed regulation's performance based orientation operates to minimize the impact of the regulation on food manufacturers whose use of diacetyl is minimal or non-existent.

Barbara Materna, Ph.D., CIH, Chief, Occupational Health Branch, California Department of Public Health (CDPH), in written comments received on November 19, 2009, and oral comments at the Board Hearing.

Comment #CDPH1: After discussing its experience with evaluations of the health of workers in California's flavor manufacturing industry, CDPH expressed support for the proposal, stating that all of the proposed regulation's measures are warranted given the serious hazard posed by diacetyl exposure and the current lack of information on which to base a PEL for this chemical. CDPH noted that NIOSH has performed an epidemiological analysis on the data collected by the CDPH, and these findings corroborate the need for regulating diacetyl.

Response #1: The Board thanks the CDPH for its role in helping to develop the proposed regulation and for its support.

Comment #CDPH2: Diacetyl substitutes - We are concerned about the growing use of diacetyl substitutes (e.g., 2, 3-pentanedione, diacetyl trimer, starter distillate) similar in chemical structure to diacetyl and posing unknown but potentially similar health risks. As proposed, companies replacing diacetyl with such substances will not be required to implement any of the control measures necessary for diacetyl, including medical surveillance. We are particularly concerned about worker exposure to diacetyl substitutes in flavor manufacturing, where workers would be handling these chemicals in their pure form and potentially receiving the highest exposures. It is very important, therefore, that the flavor manufacturing industry continue to be covered. If a company were to phase out their diacetyl use, currently they would not be required to do anything by the proposed standard, including medical surveillance. Thus, there would be no way to build knowledge about the affected workers that may be handling these substitutes. While we support moving forward with adoption of a diacetyl standard, we encourage Cal/OSHA to pursue possible ways of addressing the potential risks of diacetyl substitutes, such as by requiring employers to: a) inform their employees that diacetyl substitutes of unknown toxicity may pose a similar hazard to respiratory health; b) label diacetyl substitutes and identify their presence on MSDSs; c) utilize similar worker protection measures as for diacetyl. Also, the proposed Appendices B1 and B2, and Appendix D could be expanded to collect information about use of diacetyl substitutes.

Response #2: In the Notice of Proposed Modification, revisions of the proposal have been made to include consideration of potential toxicity of diacetyl substitutes in subsection (a)(1)(B) and (a)(2). Substitutes such as diacetyl trimer that may generate diacetyl vapors during use are proposed to be incorporated within a new definition of "other artificial butter flavoring." Diacetyl starter distillate is proposed to be specifically included in the definition of diacetyl as a diacetyl-containing formulation. Should an instance of fixed obstructive lung disease caused by artificial butter flavors other than diacetyl or diacetyl generating compounds be discovered, medical surveillance, medical removal and possibly other provisions of the regulation are triggered in the revised proposal. As more definite knowledge of the toxicity of diacetyl substitutes such as 2, 3-pentanedione becomes available, the scope and application sections of the standard could, if warranted, be revised or amended by future Board actions.

Comment #CDPH3: Case-based triggers – Reliance in the proposed standard on physician diagnosis of a worker with *fixed* (i.e., irreversible) obstructive lung disease with no apparent cause other than occupational diacetyl exposure fails to incorporate more recent findings of reversible airways obstruction in workers exposed to diacetyl. The current requirement for a diagnosis of fixed obstruction in order for the standard to be triggered for exposures to below 1% diacetyl could result in workers with reversible lung disease caused by diacetyl to be overlooked. There is now some indication that reversible obstruction has been seen in some workers exposed to flavorings, and it is unknown whether this is a precursor to fixed obstruction or if it is an additional condition. CDPH recommends that if Cal/OSHA retains a diagnosed case as a trigger, that this be modified to "obstructive lung disease that is likely caused by diacetyl or other

flavorings." In addition, cases meeting this definition of obstruction should be reported to both Cal/OSHA and CDPH.

Response #3: The Board does not agree that reversible airway obstruction needs to be addressed in the triggering mechanism of the scope because such non-fixed lung conditions will be picked up by the medical surveillance program and addressed appropriately by the PLHCP. Medical surveillance is required whenever there is detectable exposure to diacetyl, so appropriate medical handling of exposed workers will occur whether fixed or non-fixed lung conditions are observed. The Board therefore does not agree with the substitute case definition suggested, although alternative wording similar to that suggested by the commenter to address disease caused by flavorings other than diacetyl is now proposed for (a)(1)(B). Finally, while at this time the Board declines to require employers to make reports to agencies other than Cal/OSHA, it has no doubt that Cal/OSHA Enforcement would share with the CDPH any notification of a diagnosed case that it receives.

Comment #CDPH4: Revise the CDPH Medical Surveillance Guidelines. The 2007 CDPH Guidelines, *Medical Surveillance for Flavorings-related Lung Disease Among Flavor Manufacturing Workers in California,* are currently referenced in the proposed standard. Instead, reference an updated version of the Guidelines that will incorporate some revisions recommended by NIOSH based on CDPH experience with surveillance since 2007.

Response #4: A future updated version of the CDPH Guidelines, when it becomes available, will be considered for follow-up rulemaking.

Comment #CDPH5: A requirement should be added to the effect that physicians or licensed health care professionals (PLHCP) overseeing the medical surveillance program attend a NIOSH-approved spirometry training course every five years. Spirometry technicians should: a) have successfully completed a NIOSH-approved spirometry training course within the last five years or be certified by the National Board for Respiratory Care as a Certified Pulmonary Function Technologist (CPFT); b) maintain a valid NIOSH-approved spirometry course training certificate; and 3) have ongoing PLHCP review of their spirometry tests for quality and correction of performance resulting in poor-quality tests.

Response #5: The spirometry concerns of the commenter are addressed by subsection (g)(3)(C). This subsection requires spirometry to be 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 physician knowledge of proper techniques for coaching test subjects.

Comment #CDPH6: Initial medical evaluations should occur *before* assignment to work in a regulated area or immediately upon exposure to an uncontrolled release or spill of diacetyl, rather than within 30 days as proposed. There is no evidence that a month of exposure is safe, and it is important to have a true baseline for workers prior to any potential exposure to diacetyl. Also, each worker assigned to work in a regulated area needs to be medically cleared for respirator use prior to beginning such work--since respiratory protection is required in regulated areas.

Response #6: The Board agrees and the timing of the initial medical evaluation has been changed to before assignment to work in a regulated area when feasible, or in no cases later than 14 days. The Board believes this time frame is adequate to establish an accurate employee medical baseline.

Comment #CDPH7: In the proposal as written, there is an exception for the FISHEP companies not to have to complete the diacetyl use questionnaire, and the CDPH feels that the information from those companies is outdated and that exception should be removed.

Response #7: Due to limited Division capabilities for maintaining database security and other resource issues, Appendix D [the diacetyl use questionnaire] has been removed from the proposed regulation, and in its partial stead, a one time reporting requirement has been instituted without any exception for the FISHEP companies.

Jeremy Smith, Legislative Advocate for the California Labor Federation (CLF), and other cosigners from entities representing organized labor and workers in general: United Food and Commercial Workers International Union (UFCW), Jackie Nowell; International Brotherhood of Teamsters (IBT), LaMont Byrd; Bakery, Confectionary, Tobacco Workers, and Grain Millers International Union (BCTGM), Ray Scannell; Fran Schreiberg Pro Bono Attorney (Kazan, McClain, Lyons, Greenwood & Harley, LLC); Worksafe, Gail Bateson in written comments received on November 16, 2009.

Comment #CLF1: In 2006, three of the cosigners of this written comment had petitioned the Board for an Emergency Temporary Standard (ETS) for diacetyl. At that time severe lung disease had been found across the nation in workers in the microwave popcorn industry and the flavoring industry since the 1980s. Cases of disease in California flavoring plant workers had been identified at least since 2004, so we believed an ETS was necessary during the time it would take to establish a permanent standard. Three years have passed, and while we appreciate the collaborative efforts of CDH, NIOSH and the Cal/OSHA FISHEP program, we do not believe that these efforts have been sufficient to protect workers from the dangers of lung disease due to diacetyl exposure. So we are now pleased that rulemaking for a permanent standard is underway. We agree with parts of the proposed rule, but believe others are either lacking in detail or are incorrect.

We *applaud* the specific sections of the proposed regulation pertaining to medical removal, medical surveillance, control measures, sampling, training, material safety data sheet preparation and regulated areas.

Response #1: The Board acknowledges the California Labor Federation's participation in the advisory process and support for much of the proposal.

Comment #CLF2: The 1% by weight trigger has no data or other sound scientific justification presented either in the Initial Statement of Reasons for this rulemaking nor in any scientific reports or studies that support this seemingly arbitrary number. In fact, at one of the advisory meetings, employer stakeholders offered 1% as an estimate of the concentration by weight of diacetyl in their workplaces. We do not believe it can be proven that exposures to diacetyl of less than 1% is not harmful, and we hope Cal/OSHA did not use the regulated community's insistence on this number as the basis for its inclusion in the final regulation. NIOSH has not completed its risk assessment for diacetyl and has not determined a safe level of exposure. Concentrations of less than 1% diacetyl by weight can still be detected in workplace air, so the potential for toxic effects may be present. At best, this number is arbitrary, and at worst, it derives from the community to be regulated without any supporting evidence. Finally, this trigger may eliminate a significant number of food production facilities, so-called "*downstream user,"* from coverage by the regulation. Such facilities include manufacturers of frozen and snack foods (potato/corn chips), confectionary, baked goods and mixes, dairy products such as processed cheese, sour and cottage cheese, sauces, dressings and marinades. Some of these have replaced diacetyl with chemicals of similar toxicity so that while the concentration of diacetyl in a product may now be less than 1%, the inhalation hazard to workers may be the same. The 1% trigger encourages such substitution without addressing the continuing hazards of flavoring to workers in downstream user facilities.

Response #2: The notification and medical surveillance provisions of the proposed regulation are designed to identify health effects caused by exposures to airborne diacetyl arising from flavorings with less than the triggering concentration by weight. Once health effects are identified, other requirements of the regulation become operative.

Comment #CLF3: Scope and Application, subsection (a), requires a worker to have been diagnosed with a ***fixed*** obstructive lung disease. This requirement is contrary to the best scientific evidence, which indicates some workers with diacetyl-induced lung disease have intermittent evidence of reversibility or only manifest reversible disease. The spectrum of diacetyl-associated lung disease is still being defined; some cases can manifest as restrictive, not obstructive disease. Therefore the regulation should simply reference obstructive and restrictive lung disease. As currently written, the standard poses the unacceptable risk that workers may develop permanent, severe and irreversible lung disease, when, instead, if the standard were triggered by earlier developing reversible lung conditions, such an outcome could be prevented via the medical surveillance and removal requirements of the regulation.

Response #3: See the response to Comment #CDPH3.

Comment #CLF4: Regarding the required sampling and analytical protocol in Appendix A [OSHA Method 1013], we believe the Board should allow for any fully validated method at least as accurate and reliable. The proposed rule should state in no uncertain terms that existing or new equivalent methods could be used as long as the Reliable Quantitation Limit is at least as low as that in OSHA Method 1013.

Response #4: Changes have been made to clarify that equivalent analytical methods may be utilized.

Comment #CLF5: Given the toxic substitutes for diacetyl that have been introduced, we suggest that the standard include workers exposed to diacetyl at any percentage in the ingredients or products, and also to all flavoring-exposed workers.

Response #5: See the response to Comment #CDPH2.

Ken Nishiyama Atha, Regional Administrator, Occupational Safety and Health Administration (OSHA), U.S. Department of Labor, by letter received November 23, 2009.

Comment #OSHA1: The proposal adds a new standard to California's General Industry Safety Orders on Occupational Exposure to Food Flavorings Containing Diacetyl. This is an independent State standard for which there is no comparable Federal standard. Because OSHA is currently engaged in rulemaking on a standard for diacetyl, OSHA cannot provide a formal advisory opinion on the proposed standard at this time.

Response #1: The Board thanks the commenter and looks forward to a formal advisory opinion in the future.

II. Oral Comments

Oral comments received at the November 19, 2009, Public Hearing in Costa Mesa, California.

1. Connie Leyva, President of United Food and Commercial Workers (UFCW) Local 1428 and President of the California Labor Federation

Comment #UFCW1:

The UFCW urges the Board to adopt the standard so all workers exposed to this chemical will be protected; there is much good in the proposed standard.

Response #1: The Board acknowledges the UFCW's participation in the advisory process and support for much of the proposal.

Comment #UFCW2: One concern is the one-percent concentration of diacetyl. There are simply no data that supports that one percent is anything but an arbitrary number. Conversely, the food and flavoring industries can present no data that less than one percent exposure to diacetyl will not be harmful. The UFCW is especially concerned about the thousands of workers who make our food every day and are exposed to even very small amounts of diacetyl.

Response #2: See the response to Comment #CDPH2 and Comment #CLF2.

Comment #UFCW3: The second condition that triggers the standard is worker illness. We believe the standard should simply reference obstructive and restrictive lung disease rather than fixed obstructive lung disease. UFCW's medical colleagues do not believe that there is such a diagnosis as fixed obstructive lung disease. Research has found workers exposed to diacetyl have reversible disease. The spectrum of diacetyl associated lung disease is still being defined, and the UFCW is concerned that by limiting the scope of lung disease to fixed obstructive lung disease, workers will not receive the proper follow-up care that they need to prevent further exposure to the permanent disease.

Response #3: See the response to Comment #CDPH3.

Comment #UFCW4: A third concern regards sampling and analytical protocol, referenced in Appendix A. As with diacetyl associated disease, methods for sampling and analyzing diacetyl will emerge as the standard goes into effect and as Federal OSHA works toward a national standard on flavorings. The rule should state that existing or new equivalent methods are permitted as long as the RQL is at least as low as that in the OSHA Method.

Response 4: See the response to Comment #NIOSH1.

2. Jeremy Smith, Legislative Advocate of the California Labor Federation

Comment #JS1: One good substitute for diacetyl would be real butter. The CLF appreciates the work done by the Division, Board staff, the CDPH, NIOSH, the regulated community, and the worker community. The FISHEP program was a good first step in protecting workers and getting an idea of how deeply diacetyl permeates this industry. The Federation is pleased with the proposal's medical removal, medical surveillance, full measure sampling, training, and regulated areas provisions. The Federation has three concerns with the proposed language.

Response #1: See the response to #CDPH2 regarding diacetyl substitutes.

Comment #JS2: One concern is the one percent concentration by weight requirement that needs to be met before the regulation will go into effect. This is a de facto permissible exposure limit (PEL), and one of the facts that came out of all the meetings between the regulated community, the worker community, and the Division is that the amount of diacetyl that makes a person sick is unknown, and that is really scary. This is not a chemical for which a PEL can be established, because the level of diacetyl necessary to make a person sick is unknown. The one-percent concentration was proposed by the regulated community at an advisory committee meeting, but there was no back-up data presented to support that concentration.

Response #2: See the response to Comment #CLF2.

Comment #JS3: The second concern is the issue of diacetyl substitutes. Mr. Welsh has stated from the beginning of this process that the manufacturers are going to use other chemicals that may or may not be safe, and those chemicals will not be covered by this standard. As the Division started the process of developing a rulemaking proposal, and as people started getting sick from inhaling diacetyl, the microwave popcorn industry began labeling their bags as diacetyl free. The Federation and the UFCW pushed them to make that change and they did change because there are other chemicals that can be used to deliver the buttery taste. The Federation hopes that those chemicals are not as insidious as diacetyl, and that NIOSH and the people at the Federal OSHA level are performing studies to determine that.

Response #3: See the response to #CDPH2 regarding diacetyl substitutes.

Comment #JS4: The third concern is the fixed obstructive lung disease language that is in the proposal. Doctors and scientists do not know if "fixed obstructive lung disease" actually exists in the medical literature. Workers exposed to diacetyl could have full or partially reversible obstructive lung disorders, which mean that a person could be exposed to diacetyl, begin showing abnormalities or obstructions in their lungs, and this regulation would not monitor that person or medically remove that person from their job at that point. When a person gets to the fixed obstructive lung disease stage, the next step is a lung transplant, which is too late. The regulation must go into effect before the worker reaches that point.

Response #4: See the response to Comment #CDPH3.

3. Gail Bateson, Executive Director of WorkSafe

Comment #WS1: WorkSafe has talked to many different experts around the country, including many physicians who are board certified in occupational medicine, and they have indicated that the language "fixed obstructive lung disease" does not reflect the best scientific evidence. The standard should simply reference obstructive or restrictive lung disease. Fixed obstructive lung disease is the end stage of the disease process and ignores what happens early on, when it is more likely that the disease is reversible obstructive

lung disease like asthma, and as the disease progresses, it changes to a fixed disease and eventually bronchiolitis obliterans. Early on, when it is perhaps reversible, it can still be treated with medications. To the best of my understanding, it is not completely reversible, but like asthma, there are controller medications. The standard should be triggered before the worker develops permanent lung damage.

For example, Irma Ortiz worked in a Los Angeles area plant where she was exposed to diacetyl, and she experienced coughing and signs of obstructive lung disease early on with various symptoms. She continued to be exposed to diacetyl at work over a couple of months and eventually did develop bronchiolitis obliterans. At that point she had lost over 70% of her lung function and is now permanently disabled and waits on the list for a lung transplant.

Response #1: See the response to Comment #CDPH3.

Comment #WS2: As to subsection (g)(3), there is a fatal flaw in the medical surveillance section dealing with conditional medical evaluation, which currently requires that the initial medical evaluation be provided "no later than the 30th day the employee works in the area." Ms. Ortiz complained of constant eye irritation in less than a month on the job. She went to the company doctor, who dismissed this, telling her that she was sensitive to light. She then developed a persistent cough, and she ended up going to a number of doctors until she reached the fourth doctor, who actually asked her about the chemicals with which she worked and was able to refer her to a specialist. Thus, if somebody in Ms. Ortiz's situation was covered by this 30-day period, she would have already showed the symptoms of diacetyl exposure and there would have been no true baseline to test what her health status was prior to being diagnosed with fixed obstructive lung disease.

Response #2: Modifications have been proposed to subsection (g)(3) to reduce the maximum time before the initial medical evaluation is provided to 14 days.

4. Azita Mashayekhi of the International Brotherhood of Teamsters (Teamsters)

Comment #IBT1: Stakeholders and the Board are morally obligated to err on the side of caution, because bronchiolitis obliterans is irreversible with no cure, it can occur very quickly, and it can be due to prolonged exposure or low exposure over a period of time or peak exposures depending upon the process and the form of diacetyl used. There are a lot of factors at work, so it is necessary to set the lowest possible limits and concentrations to counter the existing variations.

Since we do not know what level of diacetyl exposure is safe, and we do not know what a 1% air concentration of diacetyl might produce, it is hard to support an arbitrary percentage concentration of 1%. NIOSH issued a Health Hazard Evaluation report on their visit to the Hansen Berry flavoring company in 2009, which stated that because diacetyl-related lung disease can occur after several months of exposure and can rapidly

progress to severe, irreversible disease, uncontrolled exposure should be minimized to the greatest extent feasible.

Response #1: See the response to Comment #CLF2.

Comment #IBT2: The Teamsters are very concerned that keeping the trigger at 1% or below is going to keep 90% of the food manufacturers in California out of the proposed standard. With an accelerating switch to structurally and toxicologically similar diacetyl substitutes, the number of food manufacturers excluded from the standard is only growing. Thus, the inclusion of diacetyl substitutes should be added to the monitoring provisions in the proposed standards.

Response #2: See the response to #CDPH2 regarding diacetyl substitutes.

Comment #IBT3: In addition, fixed obstructive lung disease is not an acceptable trigger, because it is irreversible. The proposed standard should be modified to include restrictive and obstructive lung disease. NIOSH has received reports of restrictive lung disease in people who work with flavorings. At General Mills, the prevalence of a restrictive pattern of spirometry was significantly higher than the prevalence rate for the adult population of the United States. While a restrictive pattern has been seen with a number of conditions, it may indicate the presence of lung disease. Further evaluation by a physician would be necessary to determine if patients with a restrictive pattern of spirometry have lung disease. A more inclusive trigger would allow employers to capture cases of lung disease before it has progressed to a point where it is irreversible.

In a study of a flavor manufacturing plant in Indianapolis, of 88 current and former workers who underwent spirometry testing, 33% had obstructive, restrictive, or missed patterns of abnormal spirometry while 32% of those evaluated over time had an extensive decline in (inaudible). In all, 47% of 88 workers had abnormal recent spirometry. Permanent, irreversible, fixed obstructive lung disease should be an ending point for medical surveillance, not a starting point.

Response #3: See the response to Comment #CDPH3.

Comment #IBT4: There are risks from diacetyl use other than lung disease; there are also cases of skin and eye irritation associated with it, as documented in the General Mills HHE. NIOSH has documented that many flavoring chemicals are highly irritating to the eyes and skin. Prevention of these symptoms should be included in the engineering controls through the use of gloves and goggles.

Response #4: Existing Title 8 regulations on personal protective equipment are adequate to address the eye and skin hazards mentioned.

5. Fran Schreiberg, speaking on behalf of a labor coalition consisting of WorkSafe, California Labor Federation, and others

Comment #FS1: We support the approach taken in the proposed regulation. One of the significant things about the proposed regulation is its move toward what can be called a task-based approach, particularly if there is the ability to eliminate the 1% trigger. That trigger is inappropriate because there is no scientific basis for it. A task-based approach would be similar to the regulations for lead, silica, and a number of other chemicals for which that approach works quite well.

The kind of problem presented by this particular chemical requires the specific, restrictive direction in the proposed regulation. The Division and the CDPH have done a really good job of pulling together the most necessary things; the proposal contains prescriptive provisions where they are needed, and other things have been left open, including specific work practices such as goggles, coveralls, and gloves.

In addition, when a PEL is determined that triggers Section 5155, it is one of the weakest regulations in Title 8 in terms of provision of specifics for when monitoring is required and when the Division can cite an employer for violation. Setting a PEL is a very ineffective way of approaching this type of regulation.

Response #1: The Board acknowledges the commenter's support of the proposed regulation.

Comment #FS2: Utilizing fixed obstructive lung disease as the trigger event for the regulation means an irreversible condition must exist before the regulation is triggered; therefore, at the very least, that provision should be modified to include obstructive or restrictive lung disease so that there is a possible way of addressing those illnesses before they become irreversible. In addition, the requirement that there must be no other cause than occupational exposure to diacetyl is unrealistic because no doctor is going to report that there is no other cause. The language should be modified to the effect that it is more likely than not caused by occupational exposure to diacetyl.

Although the diagnosis of obstructive lung disease triggers certain parts of the regulation, it does not trigger any of the medical surveillance requirements of the proposed regulation. If a person has been diagnosed with obstructive lung disease, that person should be covered by the medical surveillance provisions. Also, definitions that are based on scientific documents should not contain a specific edition but rather should refer to the most recent edition of the document.

Response #2: For a response to the first paragraph of the comment, see the response to Comment #CDPH3. The commenter is incorrect in stating that diagnosis does not trigger medical surveillance—see subsection (a)(1)(B). California rulemaking procedures require incorporated references to be identified as specific editions.

Comment #FS3: If the regulation is modified to include diacetyl substitutes, it should also include diacetyl substitutes that might be introduced in the future and that the information

regarding diacetyl substitutes should be added to the subsections regarding additional training.

Response #3: The proposed regulation has been modified to address additional training for diacetyl substitutes. The Board would address diacetyl substitutes other than those now listed in the proposed regulation with subsequent rulemaking should a specific need be demonstrated to regulate such currently unknown chemicals. For those diacetyl substitutes now listed in the proposed regulation, there exists sufficient evidence from animal data or chemical analysis that indicates a strong potential for harmful effects on humans.

Comment #FS4: The baseline should be established after an employee has been hired, but before he or she begins work rather than before being hired. Medical evaluations should be repeated at three-month intervals instead of six-month intervals.

Response #4: Regarding timing of the baseline medical exam, see the response to Comment #WS2. The Board believes that decisions about requiring medical evaluations at more frequent intervals than every six months should be left to the PLHCP as is currently the case in the proposed regulation.

Comment #FS5: The labor coalition is concerned about discrimination on a pre-employment basis. Should a worker decide to get a second opinion, it must be reported to the employer; this could expose that employee to discrimination.

Response #5: Subsection (h)(2) has been modified to clarify that an employee need notify the employer only if the employee is requesting that the employer pay for the second opinion.

Comment #FS6: The labor coalition recommends eliminating the exemption from the record-keeping requirement for employers that have been part of the FISHEP program.

Response #6: The exemption has been removed.

Dr. Barbara Materna of the Occupational Health Branch of the CDPH: her oral comments reflected the written comments submitted by CDPH, see comments and responses #CDPH1 through 6.

Dr. Leslie Israel, Associate Professor of Specialty Certification in Occupational Medicine and a lead physician at the University of California Irvine for Occupational and Environmental Health

Comment #Dr. Israel1: UC Irvine's occupational and environmental practice has provided oversight, medical surveillance, and outreach to companies who make flavorings, and has worked very closely with the Division, NIOSH, and CDPH. After NIOSH medical surveillance for a company in Southern California found an employee

with an abnormally low spirometry reading, the person was referred to me for evaluation. The employee had bronchiolitis obliterans, which fortunately, was mild and asymptomatic.

Dr. Frisch asked whether Dr. Israel believes there would be a large number of cases that would be falsely identified as diacetyl-related if the standard were relaxed to include reversible lung disease. Dr. Israel responded that the physician is responsible for delving into the patient's history, and to the best of her knowledge, the cases that have been identified are not false positive cases.

Response #1: The Board thanks Dr. Israel for her input into an understanding of the role of the supervising physician in a medical surveillance program. In regard to the possibility of false identification of a medical condition as diacetyl-related, note that subsection (a)(1)(B) is reworded so that a work-related specification is inserted into the requirement for diagnosis of disease. Since the term "work-related" is intended to be interpreted consistently with the use of this term in Section 14300.5, the possibility of unrelated prior medical conditions being misidentified is greatly reduced.

John Hallagan with the Flavor and Extract Manufacturers Association (FEMA)

Comment #FEMA1: FEMA would like to see the proposed standard adopted as soon as possible.

Response #1: The Board thanks FEMA for its support of the proposed standard.

Julianne Broyles, representing the Grocery Manufacturers Association (GMA), the American Bakers Association (ABA), the California Chamber of Commerce (Cal Chamber), the California League of Food Processors (CLFP), the California Manufacturers and Technology Association (CMTA), the Dairy Institute of California (the Institute), and the International Dairy Foods Association (IDFA)

Comment #JB1: GMA has been a very strong proponent of the proposed standard.

Response #1: The Board thanks GMA for its general support of the proposal.

Comment #JB2: The scope and application should be limited to the food flavoring industry. As confirmed by Dr. Materna in her comments, the cases of pulmonary obstructive lung disease are found in the food flavoring industry; no cases [in California] have been found in the food products industry.

Given the very big diversity of diacetyl use in the food products industry, diacetyl-related disease has been identified only in the Midwest popcorn manufacturing facilities where exceedingly high levels of diacetyl were used in a continuous production process, an open process in which the diacetyl was added to hot oil, which vaporized the diacetyl into the air surrounding the worker. Generally food manufacturing is a very different process,

in which mostly enclosed processes are used in best practices according to national standards. There is no open addition in the food manufacturing process. In fact, diacetyl use in the food manufacturing plants is not on a continuous basis like in popcorn plants. Processes are intermittent, and not every product produced contains diacetyl. If diacetyl is included, it is in very small amounts in relationship to the overall volume, usually much less than 1%. There are distinct differences between the food flavorings industry and the food producing industries in California. Food manufacturers are not using diacetyl at high rates, they are not using open processes where workers are exposed to diacetyl, and there has been no indication that workers in the food manufacturing industries are being afflicted with bronchiolitis obliterans.

Response #2: See the response to Comment #GMA1.

Comment #JB3: A lot of information has been gathered over the last three-and-a-half to four years. Just recently, two major studies were published: the Lockey and Hilbert report on airway obstruction related to diacetyl exposure at microwave popcorn plants and the Morgan and Flake paper on respiratory toxicity of diacetyl in mice. Information from those reports was then used by TERA in its assessment of diacetyl studies. The effect of diacetyl on the lung and the relationship between the exposure level and the adverse affects are something that needs to be questioned. Using the benchmark test method, TERA determined from the most recent reports that a diacetyl PEL for diacetyl addressing tracheal bronchial inflammation is possible: an eight hour TWA of 0.2 ppm.

Response #3: See the response to Comment #GMA 2.

Comment #JB4: Ms. Broyles stated that in 25 years of working on occupational safety and health regulations, she has never seen such a prescriptive standard. Anytime there is a step-by-step prescriptive process, reasonable and useful health and safety control measures that can be used are limited, and there is a greater danger that members of the regulated community might inadvertently violate a provision of the regulation. When there is a proactive standard that sets out the limits of the box in which the employer may operate and provides flexibility to address issues that a particular group of companies or a workplace culture might require, the result is better responses and better health and safety control.

Response #4: The Board believes the proposed regulation is more of a performance and task-based standard than a prescriptive regulation, and its provisions are typical for modern substance-specific regulations.

The commenter also summarized recommendations included in the GMA written comments. See the comments and responses for #GMA2, 3 and 4.

Board member questions for Ms. Broyles:

Mr. Kastorff asked Ms. Broyles if it was true that in food manufacturing the concentrations of diacetyl used are far less and hence the occupational exposure would be far less, below any recommended PEL. Ms. Broyles responded that the regulation would capture food manufacturers with the requirement to control the exposure to the lowest detectable level feasible, a level far below that attainable with engineering controls. Also there is a requirement to report usage of 1% or greater to DOSH, while the MSDS preparation requirement necessitates listing a concentration of 0.1% of diacetyl; the latter requirement would capture many more businesses.

Ms. Broyles said that while there are very few food processors that use a higher level than that specified in the proposal, and at this time there is no manufacturer in California that is using high percentages of added diacetyl there is naturally occurring diacetyl that occurs in products such as cream or butter that is above the 1%. Those manufacturers would be pulled into the requirements of the regulation even though it is naturally occurring diacetyl, which is not exempted in the proposed standard.

Response: NIOSH and FISHEP experience has shown that engineering controls can successfully reduce exposures.

Questions from Board members Dr Frisch, Mr. Prescott, Mr. Jackson, Mr. Washington, Mr. Kastorff, and Chairman MacLeod

Comment #Dr. Frisch1: Dr. Frisch stated that there is a lot of detail in the proposed regulation that will require implementation by an industrial hygienist, and thus asked that staff look for opportunities either to use existing standards in industry or to not be quite as prescriptive, particularly when a protocol is almost identical to one described elsewhere. Mr. Welsh stated that the Division had used other standards as models. Dr. Frisch cited the detailed procedures that need to be followed by an industrial hygienist when performing the monitoring. If they are following standard practices as is normally expected, he feels it may be unnecessary to describe the procedures so exhaustively.

Dr. Materna stated that as an industrial hygienist, she would not feel hamstrung by any of the provisions in the proposed standard. As far as how to do proper sampling, there is an amazing prevalence of poor industrial hygiene reports. In this case, sampling is being used in an attempt to understand if there is something detectable, and it is even possible to design a sampling protocol to ensure that nothing detectable will be found. In addition, there have been a lot of differences in the methods, so it is really crucial that the testing be done consistently across companies.

Dr. Frisch cited the spirometry as an example, and given Dr. Materna's comment earlier related to the nature of the spirometry and how it is performed, he echoed her concern. He stated that the issue actually goes beyond this proposed regulation and it speaks to the larger issue because spirometry is not just done with respect to the proposed diacetyl standard, it is throughout the Title 8 standards. If in fact there is a need to be more

specific, that may call for a different rulemaking that is more generic and applies to spirometry across the board.

Response #1: Many of the proposed regulations are directly modeled on existing substance specific regulations and other existing regulations. Comprehensively addressing spirometry is beyond the scope of this rulemaking, but it is a subject the Board may wish to revisit in the future.

Comment #Dr. Frisch2: Dr. Frisch observed that the scope subsection might be reordered to be more helpful to someone who is trying to implement it. Also the scope section makes reference to triggering circumstances in which it comes to an employer's attention that a former employee has been diagnosed by a physician, then that employee should perhaps come within the scope of the regulation. Dr. Frisch asked that item (a)(2)(C) be modified to clearly indicate that there must be an occupational exposure to diacetyl.

As to subsection (a)(3)(B), Dr. Frisch asked whether actions were being inserted into a definition, stating that "shall do all of the following" should not be included in the scope and application portion of the regulation.

Response #2: Subsection (a), the Scope and Application section, has been reorganized and reworded for purposes of clarity, addressing all of these points.

Comment #Dr. Frisch3: If diacetyl is not in the workplace, but a worker is diagnosed with fixed obstructive lung disease attributed to diacetyl, are certain actions on the part of the employer required?

Response #3: The standard would not be triggered if there is no diacetyl and no other artificial butter flavoring in the workplace.

Comment #Dr. Frisch4: Dr. Frisch asked whether the "diacetyl-related disease" referenced in subsection (b)(18) (proposed (b)(27)) is a recognized condition. If the intent is to try to recognize it through regulation, then it needs to be defined, as the signs and symptoms described could be asthma.

Response #4: The purpose of all the details in the medical surveillance section, the qualifications needed to be a supervising physician, and the medical guidelines, are all provided in the proposed regulations so that an informed medical decision is made that will be able to distinguish diacetyl–related disease from other conditions.

Comment #Dr. Frisch5: Dr. Frisch asked whether the sampling procedures referenced in subsection (c)(1) vary from practices that are typically required for other substances and whether this provision is one to which industrial hygienists need to pay particular attention or whether it is normal practices that they have been doing anyway.

Response #5: Industrial hygienists will often pick the average case or the most prevalent operation to sample. In this case, due to the likely mechanisms by which diacetyl causes lung damage, it is necessary to find the worst case via full shift and short-term exposure measurements.

Comment #Dr. Frisch6: Does subsection (c)(3) include closed processes?

Response #6: Yes.

Comment #Dr. Frisch7: Does the "change in process, production, or control measure that may result in new or increased exposure" referenced in subsection(c)(4)(B) apply to routine maintenance that would involve opening the closed process?

Response #7: The intent was not to capture routine maintenance, but rather a major, significant modification.

Comment #Dr. Frisch8: In subsection (d)(3), an "authorized person" is not defined, though that term is used in other areas of the regulations to refer to a person with certain training and expertise. The term may need to be further defined for purposes of this regulation, or perhaps another phrase could be used instead.

Response #8: A definition of "authorized person" has been added.

Comment #Dr. Frisch9: Subsection (d)(4) refers to subsection (k)(1), which in turn, refers to Section 3204. Why not simply direct the employer to Section 3204?

Response #9: Subsection (d)(4)(A) has been modified to refer directly to Section 3204.

Comment #Dr. Frisch10: The phrases "as effectively as possible" and "where practicable" in subsections (e)(2)(A) and (B) and other places are ambiguous.

Response #10: The purpose of these phrases in this subsection is to convey that employers are to make a reasonable effort to establish effective engineering controls and work practices to reduce employee exposure to airborne diacetyl, recognizing that perfect accomplishment is not always attainable. Other regulations also utilize these terms, and the limitations of these phrases are well understood in context as performance-based requirements. However, the phrase "as effectively as possible" has been deleted from subsection (e)(2)(A) for purposes of clarity; the phrase "where practicable" remains in subsection (e)(2)(B).

Comment #Dr. Frisch11: Does the "lowest feasible level" referenced in subsection (e)(5) needs to be documented by the employer?

Response #11: Yes. Subsection (e)(5)(D) states that all measurements and monitoring data shall be documented.

Comment #Dr. Frisch12: Subsection (e)(5)(C) requires that an evaluation of the technology alternatives be considered in achieving the lowest feasible level, but if an employer elects not to use technology that would achieve a lower exposure, there is no requirement for documentation of the decision-making process.

Response #12: To the contrary, the employer is required to go as low as they feasibly can, and there must be documentation that there has been some fair consideration of the methods that are available.

Comment #Dr. Frisch13: Language needs to be incorporated into subsection (e)(5)(E) that holds the employer accountable for actually implementing the schedule, requiring documentation of the reason for changes in the schedule.

Response #13: This subsection has been modified pursuant to the suggestion.

Comment #Dr. Frisch14: In regard to subsection (f)(1)(C), why must respirator use in adjacent areas be necessary on request? There must be some point where the exposure area ends. If an exposure area has been established, and employees outside that area are so concerned about exposure that they request a respirator, then shouldn't the restricted area be expanded to include that area?

Response #14: If workers are concerned that the regulated area might not be as exposure-tight as it is believed to be, it does not hurt to allow someone to have a respirator as a precaution, and that respirator should be fully in accordance with respirator usage principles. There are limitations to the industrial hygienist's ability to assess exposures; there is no way to measure powders except to determine whether there are visible emissions. This provision was meant to say that if an employee has a significant enough reason to want to use a respirator, that employee should be fit-tested as well. If the employee feels that he needs to use a respirator, it should be a fit-tested respirator.

Diacetyl has a very high vapor pressure so when it is being poured, it vaporizes extremely fast, and it flashes. Sometimes the person pouring the diacetyl has lower exposures than people 10 to 15 feet away, depending on air currents in the room. Because it is very difficult to assess exposures and it is not always clear that the restricted area should be expanded, the voluntary respirator use provision was added as an additional precaution.

Comment #Prescott1: Is the medical evaluation going to be a substitute for the respirator evaluation or are those who are wearing respirators going to go through both of the evaluations?

Response #1: All the requirements of the proposed regulation as well as the requirements of existing regulations must be carried out. But if the medical requirements of Section 5144 of these Orders and the medical requirements of this proposed regulation can be accomplished in one evaluation, that is acceptable. Right now, as the standard is

structured, the full medical evaluation is not required until after the person has been working in the area for 14 days, but the respirator medical evaluation has to be provided before the person makes the first entry using a respirator.

Comment #Dr. Frisch15: Subsection (g)(1)(B) concerning provision of interpretation services to employees is not seen elsewhere in the regulations. At present, an interpreter being a family member or other acquaintance would be precluded, so it would require the medical provider to provide the interpreter. Is this provision necessary in the regulation or consistent with other Cal-OSHA regulations related to providing interpretation? It could be made a lot simpler by incorporating language that indicates provision for the medical exam to be conducted with the patient where someone is there to provide interpretation services. I would not like to preclude someone bringing a family member (or other alternatives) to act as a translator.

Response #15: These provisions on interpretation have been included due to changes that have been made in California about medical translation in which people are not allowed to use children, for example, and other provisions that have been made over the course of the last several years.

Comment #Dr. Frisch16: Subsection (g)(1)(D) needs to be modified to indicate a specific version of the CDPH guidelines to ensure consistency; (g)(1)(D) refers to the most recent version of the CDPH guidelines whereas subsection (b)(2) refers to the August 2007 version specifically.

Response #16: The reference to "current" CDPH guidelines has been changed as suggested to refer only to the definition of CDPH guidelines, now renumbered as (b)(3).

Comment #Prescott2: I am concerned about using the phrase "current guidelines," particularly when it is something that is not a consensus standard. It takes any and all public opinion out of the equation and automatically updates the standard.

Response #2: See the response to #Dr. Frisch16.

Comment #Dr. Frisch17: I consulted with two attorneys on subsection (g)(2)(A), and they could not figure out the intent of that provision; it needs to be clarified.

Response #17: This subsection has been changed for clarity.

Comment #Dr. Frisch18: Subsection (g)(3) is also confusing: employees that are identified in (g)(2)(B) and (g)(2)(C) are excluded from an initial exam, and then there is a statement in (g)(3) as to employees not previously provided an initial medical evaluation, which seems to be a reference back to (g)(2)(B).

And why does subsection (g)(3)(B) permit alternative questionnaires instead of simply adhering to provisions (b)(1) and (b)(2)?

Response #18: Employees identified in subsections (g)(2)(B) and (g)(2)(C) are not "excluded" from an initial exam; it is not reasonable to predict that employees who are believed not to be exposed to diacetyl will develop signs and symptoms of diacetyl-related disease, and it is possible that some employees will unexpectedly be exposed to diacetyl spills. Subsection (g)(3) ensures that employees for whom exposure was not predicted will receive the required initial medical exam when the original expectation turns out to be untrue.

Subsection (g)(3)(B) permits alternative questionnaires in order to not hamstring the employer, should the employer have an acceptable questionnaire already in place.

Comment #Dr. Frisch19: Do those alternative questionnaires have to have the same specific content as the questionnaire included in the proposed standard?

Response #19: Yes.

Comment #Dr. Frisch20: Where in the standard is there is a mechanism for an employee to decline any of the exams? In some of the other regulations, there are ways for employees to decline a physical and sign a waiver so that the employer has a record of it.

Response #20: Yes, even if it is not stated specifically, an employee can always decline the physical examination.

Comment #Dr. Frisch21: In subsection (h), the PLHCP written opinion is mixed up with the respirator qualifications part in Section 5144. Are these additional requirements or are they the same? It gets very confusing to determine what is the respirator questionnaire, what is the respirator qualification, and what is special for diacetyl.

Response #21: A clarifying change has been made, removing reference to Section 5144(e)(6)(A).

Comment #Dr. Frisch22: In subsection (j)(1)(A), why is it necessary to train employees such as office workers, who may never set foot in the production area of the plant, the same way that employees that are in the plant are trained?

Response #22: Awareness level training is required (as in the asbestos standards, for example) so that workers whose job duties do not normally expose them to a hazardous chemical are aware of the proximity of that chemical and its risks. This is precautionary training so that unexposed workers know why a regulated area exists and why they need to stay outside of that area.

Comment #Dr. Frisch23: Is the translation requirement in subsection (j)(2)(A) similar to the medical translation requirements of subsection (g)(1)(B)?

Response #23: The provisions of (j)(2)(A) are similar in purpose to the provisions of (g)(1)(B): to ensure that employees whose primary or only language is other than English are able to understand important health information and warnings.

Comment #Dr. Frisch24: Why isn't telephonic reporting or email reporting permitted in subsection (k)(2)?

Response #24: Physical addresses and phone numbers may change; phones and emails may go unattended, but the mail is reliable.

Comment #Dr. Frisch25: There is no explanation in subsection (k)(3) as to where the questionnaire actually is or how to comply with it. Employers are required to fill out the online questionnaire, but there is no indication where it is. The Division should consider alternatives for people who choose not to do it on the internet. Why restrict this to a one-time questionnaire? Why not require employers to periodically recomplete the questionnaire in order to avoid having stale data?

Response #25: Due to limited Division capabilities for maintaining database security and other resource issues, Appendix D, the online questionnaire, has been removed from the proposed regulation.

Comment #Dr. Frisch26: Modifying MSDS requirements, as in subsection (l), may deviate from the federal standard on MSDS's. Has the Division done so in other regulations? Would this subsection require the employer to rewrite the MSDS because the manufacturer-provided document is inadequate in California?

Response #26: Subsection (l) has been deleted.

Comment #Jackson1: Labeling comes from the HazCom standard, and if an employer is purchasing the product from an out-of-state manufacturer, the provision appears to require employers to relabel the product outside of the HazCom standard, thus requiring employers to go to the manufacturer to get the appropriate label. If the MSDS or label provided by the original manufacturer is inadequate, what is the employer's obligation to reinvent them?

Response #1: Subsection (l) is now proposed for deletion partly because of concern about potential conflict with the Federal Hazard Communication rule. Also, a change is now proposed for subsection (j)(2) to clarify that the labeling and warning requirements apply *within* the workplace, i.e., in California by definition. The wording of the additional California warning is specified within the subsection, so there is no need to contact manufacturers or suppliers outside of California for this information.

Comment #Dr. Frisch27: In Appendix A, subsection (b)(2)(H), there is a typo: the word should be "shall," not "small."

Response #27: This typo has been corrected.

Comment #Dr. Frisch28: Appendices B1 and B2 need to be more accurate about what the employee needs to do in terms of completing the form, instead of using the term "we would like." Is there a medical purpose in collecting information on race and ethnicity in the questionnaire? That reason should be included in the FSOR.

Response #28: Directions for completing the Appendix B1 and B2 forms are from the CDPH Guidelines, so it would be inappropriate to substitute alternative wording. One medical reason for collecting ethnicity data, for example, is that spirometry results sometimes vary among racial and ethnic groups.

Comment #Dr. Frisch29: Appendix C language is locked into the regulation and presumes that HESIS does not intend to update or change the fact sheets. It would require a regulatory change by the Standards Board in order to change the fact sheets. What is the intent of including these fact sheets in the regulation? There is information in those fact sheets about seeing a physician immediately; is this language appropriate for a fact sheet with an intended audience of employees? There is also a section regarding respirator use that is inconsistent with the regulatory language.

Comment #Kastorff1: Appendix C should also address the fact that diacetyl is a food flavoring, and we eat it. The direction to make sure that substitutes are safe is appropriate for the employer, not for the employee.

Comment #Washington1: Diacetyl has not been tested for cancer or reproductive effects; that section should be removed from Appendix C.

Response to #Dr. Frish29, #Kastorff1 and #Washington1:

Appendix C has been removed as a mandatory appendix from the proposed regulation. Instead, the training requirement has been changed to include all informational materials pertaining to health effects of diacetyl that are produced by the CDPH Occupational Health Branch (OHB) and its HESIS program and that are maintained on its website. This change addresses the questioners' point by narrowing the information necessary to supply to employees to only that information pertinent to health effects that might affect the employees. It is in the purview of the OHB to decide what relevant health information needs to be dispersed to the public. The regulation's requirement as reworded requires the employer to include in its training program that information about health effects considered pertinent by the OHB.

Comment #Dr. Frisch30: Appendix D references use of an online form. What protects that online form from being changed absent a change in the regulation, because including it in the regulation specifically embeds it into the regulation, and any modification of the online form would have to be approved through a regulatory change? What mechanisms

have been put into place within the database management system and the internet management system to prevent changes being made to the online form?

Response #30: The questionnaire represented by Appendix D has now been withdrawn from the regulation.

Comment #Washington2: It appears that the regulation is nullifying Workers' Compensation. When it comes to an injury or an illness that precludes an employee from working, under the law it now becomes subject to the Workers' Compensation code. This regulation seems to be not only redundant but also an overlay of an additional potential cost to the employer because some of the restrictions take away the employer's ability to manage their workforce in terms of cost between workers compensation and health and safety costs. In requiring medical care for that employee, it removes the employer's ability to manage that. Would diacetyl related illness be covered under a workers' compensation claim?

Regarding subsection (i)(2), which states that an employer must continue to provide medical removal protection benefits if a workers' compensation claim is filed--filing a worker's compensation claim is not an option for the employer. As soon as that employer becomes aware that there is an injury or an illness, that employer is obligated to give the employee a worker's compensation claim form. I do not understand why this provision is included in the regulation when the proper procedure would be, once that employee has been injured or falls ill, the employer sends him to a doctor and starts the worker's compensation process.

Response #2: One problem with relying solely on the worker's compensation system is that the medical evaluation provided through the worker's compensation system is going to be for compensation, to determine whether the employee's condition is caused by a workplace exposure and how much of that is compensable.

This medical evaluation is focused on something different: it is trying to figure out how the employee's condition is related to work, whether the employee can still work there or has to be removed in order to keep from getting worse, and it is more a method of managing the employee medically while they continue to work.

The biggest problem in implementing the FISHEP program throughout the last three years has been tracking the 40 to 50 employees who have gotten some kind of pulmonary change that may be related to diacetyl and following them with periodic pulmonary function testing and making sure they keep going back to the doctor. The Division has to keep going back to the workplace and see if those employees are being properly protected from exposure.

There is an aspect of medical management for which there is no system; the Division has had to develop the system at considerable resource consumption. This provision is an attempt to make it the employer's obligation under this regulation to manage that

employee medically, remove him if necessary, put him back to work under whatever restrictions are necessary, and if in that process the employee loses pay because his job duties change or because they lose work, make sure that they are made whole and compensated. See also the response to #Washington3, below.

Comment #Washington3: Workers Comp will treat and take care of identification of all the ills that are work related and that an employee incurs, so to have a program in the proposed regulation that will circumvent that and insert another obligation on top of what the employer is already required to do is redundant and unnecessary.

Response #3: The provision in the proposal is more similar to medical removal under the lead standard or the cadmium standard, in which the employer is trying to encourage the employee to participate in medical surveillance. In the medical surveillance, the employer is going to detect changes in their pulmonary function that may or may not indicate disease and may or may not indicate diacetyl-related disease. Thus, the employers are going to perform spirometry on these employees and they are going to complete these questionnaires, and they are going to find people who are not sick. The question is what to do when something is detected through that medical surveillance—and they want to find the effect as early as possible—they want the employees to participate in the medical surveillance so we can find these effects before they have to stop working and before they have an irreversible disease. There is a provision that comes from the lead standard and similar standards with medical surveillance requirements that indicate how the medical surveillance program will interface with worker's compensation if, in fact, the employee ends up with a compensable disease. However, many of the people who are going to be medically removed are not going to have a compensable disease. They are not going to be in the worker's compensation system. They are being removed while the health care professional is trying to determine whether the employee's lung function changed from six months ago to the present because he has a cold or some other reason or whether it changed because of exposure to diacetyl. This is medical removal related to medical surveillance rather than compensation for a work-related illness. Sometimes that line will be crossed, which is why language was taken from existing standards with medical surveillance provisions.

Comment #Washington4: Both the PLHCP written opinion provision (subsection (h)) and the medical removal provision (subsection (i)) need to be carefully considered. Many of these companies are not large employers, and the cost of this program to those employers could be prohibitive. The Division should discuss these provisions with the Worker's Compensation agency and get its comments on the proposal.

Response #4: Division of Workers Compensation attorneys have reviewed the proposed regulation and determined there is no conflict with the workers compensation system. To make this perfectly clear within the regulation, a note has been added to the proposal regarding the interplay with the workers' compensation system.

Comment #Prescott3: What is the rationale or justification of the 1% concentration trigger point?

Response #3: The starting point is below 1%, because that is where the reporting requirement arises under the MSDS requirement. If the food manufacturing industry is being regulated, and we want them to know what concentration is in their food products, they can find out if it is 1% or more for their MSDS requirements; they have a way to find out. It is a bit of a different issue for food manufacturers versus flavor manufacturers. Flavor manufacturers will know what they are working with because they order chemicals based on the concentration because they actually do the formulations of the flavors. It is true, as has been stated during the November Board Hearing, that there is no proof that working with substances with lower concentrations than 1% is safe; however, there is an abundance of proof that virtually all of the cases of bronchiolitis obliterans and fixed obstructive lung disease that have been identified have occurred in environments where employees were working with substances that were significantly greater than 1% concentration.

Comment #Prescott4: Is the access provision subsection (d)(3), meant to refer to Division personnel, not the employer's?

Response #4: Yes.

Comment #Prescott5: All of the appendices are mandatory, and regarding employee training, federal standards quite often contain a provision that compliance with the appendices is voluntary, and if an employer has a procedure that provides equivalent or greater safety, it is acceptable. Such an equivalency provision in the proposed standard would serve to alleviate some of the concern regarding Appendices B1 and B2. Ordinarily in the respirator protection standards, there is a clause that states that the questionnaire goes directly to the medical provider, not to the employer. That language isn't in the proposed standard, which is a potential violation of Health Insurance Portability and Accountability Act (HIPAA) regulations regarding confidentiality.

Response #5: Subsection (g) expressly allows equivalent questionnaires, and makes it clear the questionnaire is to be evaluated by the medical provider. The reference in subsection (h) to 5144(e)(6)(A) has been removed. See also the response to Comment #Frisch20. All of the medical provisions in the proposed regulation are under the supervision of licensed medical personnel, so including language concerning HIPAA in this regulation would be duplicative and unnecessary.

Comment #Washington5: Is the records retention requirement for businesses that close consistent with other regulations dealing with carcinogens and other harmful chemicals?

Response #5: Yes.

Comment #MacLeod1: Have there been any chemicals in the past that the Board had attempted to regulate without a PEL?

Response #1: Yes, a number of carcinogens have been regulated this way, and these were the model for this proposal.

Comment #MacLeod2: Has a concentration trigger been attempted before?

Response #2: There is a concentration trigger in the asbestos standard for certain requirements.

MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE 15-DAY NOTICE OF PROPOSED MODIFICATIONS

As a result of comments to the proposed modifications contained in the 15-Day Notice of Proposed Modifications mailed on August 5, 2010, the following substantive modifications have been made to the Informative Digest published in the California Regulatory Notice Register dated October 2, 2009.

In subsection (b)(9) it is proposed to add the phrase "or a sampling and analytical method for diacetyl that has been determined to be acceptable by the Chief" to the end of the definition of "equivalent method." The purpose and necessity of this change is to provide greater flexibility in identifying alternative sampling and analytical methods to the OSHA Method while still maintaining assurance that any such method is at least as accurate, specific and sensitive as the OSHA Method.

Modifications are proposed for subsection (c) [exposure assessment]. A change to subsection (c)(1)(A) is proposed to clarify that following air monitoring, it might be necessary to evaluate for the possibility that sample overloading had occurred. Evaluation would be necessary if the backup tube evinces a diacetyl quantity more than 20% of the quantity found on the front tube. It is necessary to add this caveat because in very rare cases such a finding might invalidate the sample. A proposed modification of subsection (c)(2)(B) reformats the subsection without altering the meaning; the change is necessary to provide greater clarity. Also added to this subsection is the term "immediate or other" to clarify that when evaluating diacetyl processes, it may be necessary to evaluate potential exposure in work areas beyond the immediate zone of diacetyl release. This is a necessary clarification because in some instances diacetyl may travel via air movement to other work areas nearby to the initial release point of the diacetyl.

Several editorial and grammatical revisions are proposed for subsection (e)(6) [engineering controls and work practices] for the purpose of providing increased clarity to this subsection.

A reformatting change to subsection (f) [respiratory protection] is proposed that would relocate a respirator selection requirement concerning HEPA cartridges for Air Purifying

Respirators from subsection (f)(2) to a new footnote in the Respiratory Protection Selection Table. This change is necessary for clarity; its effect is to place all respiratory selection requirements in the Respiratory Protection Selection Table.

A revision and restructuring of subsection (j)(2) regarding labeling of containers in the workplace is proposed. These changes are necessary so that the provision pertaining to diacetyl that permits alternative effective labeling methods also applies to labeling for other artificial butter flavors.

A relocation of subsection (a)(1)(C) of Appendix A [sampling and analytical protocol] to subsection (c)(3) is proposed for clarity. Subsection (c) relates to analytical procedures. The content of the relocated subsection includes information that is necessary to include with the analysis request. Also in proposed new subsection (c)(3), an item is added to the information about the analysis that must be retained as part of the record. This addition is necessary because any assessment by the analytical laboratory pertaining to the accuracy of the sample may be critical to a proper evaluation of the sample's validity.

Another proposed change to Appendix A is the restoration of a requirement that sampling tubes be protected from the light during sampling, storage and transport. This requirement was included in Appendix A in the originally noticed proposed Section 5197. The requirement was proposed for removal in the first Notice of Proposed Modification because the provision is still included within the OSHA Method, which is incorporated by reference. Although removal of the statement about protecting samples from light helped shorten Appendix A, this protection is actually very critical to maintaining the accuracy and validity of the samples, as diacetyl is a chemical that reacts with light. Therefore, in order to ensure that this requirement is clear, and not obscure within the published OSHA Method, it is now proposed to return the light protection requirement to Appendix A.

Summary and Response to Written Comments:

Rasma Zvaners, Policy Director, American Bakers Association (ABA), in written comments received on August 20, 2010.

Comment #ABA3: There has been no formal data collection effort to determine diacetyl usage in the baking industry, and thus far, no incidence or pattern of diacetyl-associated illness in general food manufacturing has been noted. ABA supports 1% by weight diacetyl as an appropriate trigger for regulation that is consistent with studies by NIOSH, FEMA, and FISHEP. Federal OSHA has found that the incoming raw flavoring received by food manufacturers is often below 1% diacetyl by weight and is quickly diluted.

Response #3: The Board thanks ABA for its support of the 1% diacetyl by weight scope and application requirement of the proposed regulation. As modified, the regulation has a one-time reporting requirement. The Board acknowledges that no diacetyl-associated illnesses have been reported in general food manufacturing in California, but notes that

there have been claims elsewhere in the nation of diacetyl-related illness in some food manufacturing other than microwave popcorn production, such as candy manufacture.

Comment #ABA4: The regulation should state that once a PEL is established by federal OSHA, or an OEL is published by a recognized expert entity (but explicitly not ACGIH), then compliance with the PEL or OEL would satisfy the requirements of the California regulation.

Response #4: See the responses to #GMA3 and #ABA1.

Mitch Seaman, Legislative Advocate for the California Labor Federation (CLF); LaMont Byrd, Director, Safety and Health Department of the International Brotherhood of Teamsters (IBT); Fran Schreiberg Pro Bono Attorney (Kazan, McClain, Lyons, Greenwood & Harley, LLC); and Gail Bateson, Executive Director of Worksafe in written comments received on August 20, 2010.

Comment #CLF6: While remaining concerned with several elements of the proposed standard, the commenters recognize the time constraints involved and urge a "yes" vote on the proposed revisions. The modifications and the overall standard together represent a critical first step towards an adequate diacetyl and food flavoring standard. The commenters urge adoption at the September 16th meeting.

Response #6: The Board thanks the commenters for their comments.

John Halligan of the Flavor and Extract Manufacturers Association (FEMA) in written comments received August 20, 2010.

Comment #FEMA3: FEMA continues to support the scope provisions of the proposed regulation. The 1% cut-off is supported by available data. It is important to note that there are no reports of human illness associated with the substances listed as "other artificial butter flavoring" in the proposed modification. These five substances do share some common chemical structural features with diacetyl, and several recent animal studies suggest acetoin and 2,3-penatanedioane may have toxic potential in animals similar to diacetyl.

Response #3: The Board thanks FEMA for its support of the 1% cut-off and for the information about illness reporting and toxicity potential for the substances listed in the proposed modification as "other artificial butter flavoring."

Comment #FEMA4: Regarding the change proposed for definition (b)(10) for "fixed obstructive lung disease," FEMA recommends a modification to account for individual variability so that it reads "…FEV1 does not increase by ~~at least~~ **either** 12% ~~and~~ **or** 200 milliliters." A 12% increase will vary among individuals so the requirement should allow for this fact.

Response #4: The phrasing "…at least 12% and 200 milliliters" comes from Spirometric Reference Values and is accepted nationally by the American Thoracic Society and pulmonary medical specialists as the appropriate criterion. See also Comment #NIOSH3.

Comment #FEMA5: In subsections (g)(1)(A) and (i)(4) references to physicians should by modified by "Board Certified" and "Board Certified pulmonologist" respectively so that the best specialists at properly diagnosing this illness are specified.

Response #5: The suggested change does not concern any matter put forward by either 15-Day Notice of Proposed Modifications. The Board believes that sufficient expertise for physicians is already specified in proposed Section 5197.

Comment #FEMA6: The prescriptive warning statements in subsection (j) should be more flexible. The required warnings should allow for the use of similar language as suggested by Federal OSHA's hazard communications guidance for diacetyl and food flavorings. This minor change will allow flavor manufacturers to standardize their warning labels on a national basis.

Response #6: Modifications to subsection (j) now allow for the use of effective alternatives to the specified warning labels.

Comment #FEMA7: Appendix B2, Flavor Worker Follow-up Questionnaire needs an additional question on past smoking history; this is critical information.

Response #7: While information on past smoking history is currently requested in the Flavor Worker Initial Questionnaire (Appendix B1), modifications of the questionnaires may be considered in future follow-up rulemaking.

Caroline Silveira, Director, State Affairs of the Grocery Manufacturers Association, in written comments received on August 20, 2010

Comment #GMA8: GMA notes that in the three years from the first reported diacetyl-related illness in the California flavor manufacturing industry, there is no evidence of such illness in general food manufacturing in California or anywhere else, and no new diacetyl-related disease has been found in microwave popcorn plants. Therefore, GMA continues to believe that the appropriate scope for this proposed rule is the manufacture of food flavorings, not foods. However, should the Board include food manufacturing in the proposed rule, GMA agrees that the 1% by weight concentration is an appropriate trigger.

Response #8: See the response to Comment #ABA3.

Comment #GMA9: The regulation should state that once a PEL is established by federal OSHA, or an OEL is published by a recognized expert entity (but explicitly not ACGIH),

then compliance with the PEL or OEL would satisfy the requirements of the California regulation.

Response #9: See the response to Comment #ABA4.

Comment #GMA10: GMA believes the proposed standard should be limited to diacetyl and should not include the five flavoring substances defined as "other artificial butter flavoring." There are no reports of human illness to any of these substances and 2,3 hexanedione and 2,3 heptanedione are not only less related to diacetyl, but GMA understands that their properties make them unsuitable as diacetyl substitutes. As for acetoin and 2,3 pentanedione, GMA believes the information reporting toxicity in animals is preliminary. California's warning requirements for diacetyl and the latter two substances should be consistent with federal OSHA, including allowing the option to use similar warning language to meet the intent of the standard.

Response #10: In response to several other public comments including the most recent Comment #FEMA3, the Board finds it necessary to expand the scope to include 'other artificial butter flavors.' Therefore, the Board declines to limit the standard to diacetyl and refers to the FEMA comment and supporting references that illustrate sufficient evidence exists to include these diacetyl substitutes. See FEMA comment #6 regarding allowing alternative warning language.

MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE SECOND 15-DAY NOTICE OF PROPOSED MODIFICATIONS

No further modifications to the information contained in the Initial Statement of Reasons are proposed as a result of the second 15-day Notice of Proposed Modifications mailed on August 23, 2010.

Summary and Response to Written Comments:

Rick Kreutzer, MD, Chief, Division of Environmental and Occupational Disease Control, California Department of Public Health (CDPH), in written comments received on August 26, 2010.

Comment #CDPH7: CDPH recognizes development of this standard has been challenging and has required innovative approaches. CDPH supports the proposed regulation and its required health and safety practices which are necessary to protect workers from this significant chemical hazard. CDPH supports adoption of Section 5197, which would make California the first state in the nation to enact a regulation that protects workers from exposure to diacetyl.

Response #7: The Board thanks the CDPH for its comments.

Judith Freyman, Principal, Western Occupational Safety and Health Group, Mercer/ORC Networks, in written comments received September 3, 2010.

Comment #Mercer/ORC1: Mercer/ORC Networks is concerned about the extension of the scope of the proposed modification of Title 8, Section 5197 to include other artificial butter flavoring at any concentration level. Evaluation of workplace exposures to these substances is still in the early stages. Limited evidence of toxicity to animals in studies to date covers only two, acetoin and 2,3-pentanedione, and there are no reported cases of human illness resulting from exposures to other artificial butter flavoring. Because of the limited research, DOSH is struggling to elevate "may be as toxic" to the level of necessity. The Board Members should resist this characterization of precautionary concerns as an acceptable basis for expanded rulemaking.

Response #1: Although this comment does not address changes within the scope of the second Notice of Proposed Modifications, the Board notes that Ms. Freyman should refer to the response to similar comment #GMA10 in the first Notice of Proposed Modifications.

George Landers, Executive Director, Western States Council, United Food and Commercial Workers International Union (UFCW), in written comments received on September 2, 2010.

Comment #UFCW5: This standard will go a long ways in providing protections from the disabling effects of exposure to food flavorings containing diacetyl and its substitutes. UFCW urges the Board to pass this regulation.

Response #5: The Board thanks the UFCW for its comments.

Ken Nishiyama Atha, Regional Administrator, Occupational Safety and Health Administration (OSHA), U.S. Department of Labor, by letter received September 7, 2010.

Comment #OSHA2: The modifications noticed for the proposed Occupational Exposure to Food Flavorings Containing Diacetyl standard is an independent State rulemaking with no current comparable Federal Standard. Since OSHA is currently engaged in rulemaking on a standard for diacetyl, OSHA cannot provide a formal advisory opinion on the proposed modification at this time.

Response #2: The Board thanks the commenter and looks forward to a formal advisory opinion in the future.

ADDITIONAL DOCUMENTS RELIED UPON

None.

DOCUMENTS INCORPORATED BY REFERENCE

California Department of Public Health. Medical Surveillance for Flavorings-Related Lung Disease Among Flavor Manufacturing Workers in California, August 2007.

Hankinson, JL, Odencrantz, JR, Fedan, KB (1999). Spirometric Reference Values from a Sample of the General U.S. Population, *Am J Respir Crit Care Med* 159,179-187

"ATS/ERS Task Force: Standardisation of Lung Function Testing," a five part series, Eur Respir J 2005; 26: 153–161, 319-338, 511-522, 720-735, 948-968.

Sampling and Analytical Methods for Acetoin and Diacetyl, Methods ID 1012 and ID 1013, Federal OSHA Methods Development Team, OSHA Salt Lake Technical Center, Sandy, Utah, 2008.

These documents are too cumbersome or impractical to publish in Title 8. Therefore, it is proposed to incorporate the documents by reference. Copies of these documents are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the Standards Board Office located at 2520 Venture Oaks Way, Suite 350, Sacramento, California.

DETERMINATION OF MANDATE

This regulation does not impose a mandate on local agencies or school districts as indicated in the Initial Statement of Reasons.

ALTERNATIVES CONSIDERED

The Board invited interested persons to present statements or arguments with respect to alternatives to the proposed regulation. No alternative considered by the Board would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the adopted action.