COMMENTS
TO THE
CALIFORNIA OCCUPATIONAL SAFETY AND HEALTH STANDARDS BOARD
REGARDING
GENERAL INDUSTRY SAFETY ORDERS: DIVISION 1, CHAPTER 4, SUBCHAPTER 7, ARTICLE 109, SECTION 5197 - OCCUPATIONAL EXPOSURES TO FOOD FLAVORINGS CONTAINING DIACETYL

SUBMITTED BY THE
GROCERY MANUFACTURERS ASSOCIATION

November 17, 2009

This package is being submitted on behalf of the Grocery Manufacturers Association. Other trade associations and companies who comprise the GMA membership reserve the right to submit comments to the Board on their own behalf to raise additional points and to provide information concerning their respective industries. These trade associations are signatory to these comments:

American Bakers Association
California League of Food Processors
California Manufacturers and Technology Association
Dairy Institute of California
International Dairy Foods Association

GMA
The Association of Food, Beverage and Consumer Products Companies

November 17, 2009

Ms. Marley Hart
Executive Officer
CA Occupational Safety and Health Standards Board
2520 Venture Oaks Way
Suite 350
Sacramento, CA 95833

Re: Proposed Rule, Occupational Exposures to Food Flavorings Containing Diacetyl (GENERAL INDUSTRY SAFETY ORDERS, Division 1, Chapter 4, Subchapter 7, Article 109, Section 5197)

Dear Ms. Hart:

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The $2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers and contributes over $1 trillion in added value to the nation's economy.

GMA has been constructively engaged with the California Occupational Safety and Health Administration (CalOSHA) and stakeholders in the development of the proposed draft for more than 2 years. We sincerely appreciate the opportunity to submit comments to the California Occupational Safety and Health Standards Board (OSHSB) concerning this proposed regulation.

General Comments: Scope and Approach of the Proposed Rule Are Overly Broad

The OSHSB must determine that no reasonable alternative considered by the Board or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action. We question whether the current draft proposed regulation can meet this test.

GMA believes that the appropriate scope of application for this proposed rule is the manufacture of food flavorings, not foods. The occurrence of the cluster of lung obstruction cases among

workers at microwave popcorn plants identified in the year 2000, and the initial absence of a timely regulatory response, led to a situation in which political demand for action on this issue was ahead of the science needed to responsibly develop an appropriate standard. The presumption that latent cases of fixed obstructive lung disease would be discovered throughout food manufacturing has not been borne out in spite of several years of experience. This is because those predicting widespread disease did not take into account the fact that exposure to flavorings in food manufacturing, aside from microwave popcorn, presents very limited opportunities for important levels of exposures. Furthermore, the presumption of risk in food manufacturing is not supported by data on workers' compensation claims, which our members believe provide no indications of a potential problem. In addition, it is noteworthy that despite the increased awareness of diacetyl usage in food flavorings, not only in California but also by federal OSHA, there is still no evidence of incidence or pattern of diacetyl-associated illness in general food manufacturing, including a lack of development of new disease in microwave popcorn plants.

It is important to understand that the potential for cumulative exposure in the manufacture of flavorings, and in the original microwave popcorn plants where fixed obstructive lung disease was reported prior to improved engineering controls, are not representative of food manufacturing generally, where diacetyl exposures have generally been demonstrated to be minimal or negligible. For example, at the time the problem was discovered in microwave popcorn plants, the affected microwave popcorn plants were using flavorings containing uniquely high concentrations of diacetyl (greater than 15-30% in some flavoring formulations) that are not ever used in the manufacture of other foods (and are no longer used even in the manufacture of microwave popcorn). The diacetyl-containing flavorings were added to hot oil that was then mixed into the popcorn, often under open conditions, conditions which promoted volatilization of diacetyl into the workplace air. Furthermore, these plants operated on a continuous basis, and microwave popcorn was the only product they produced. By contrast, according to GMA member companies, the majority of food flavorings in use today generally contain less than 1% diacetyl by weight. Only small amounts of such flavorings are added to food products, with the concentration of diacetyl in a food product formula typically being exceedingly low, 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. A plant will produce different products at different times, and not every product formulation will involve a diacetyl-containing flavoring, and none of these flavors will contain more than a low percentage of diacetyl. Lastly, the potential for diacetyl in a food flavoring to volatilize into workplace air is limited by the fact that food is manufactured under closed conditions to the maximum extent feasible in order to prevent or minimize the introduction of physical, chemical and microbial contamination, in accordance with the federal Good Manufacturing Practice regulations.

During the 2+ years that the proposed rule has been under development at CalOSHA, the usage of diacetyl-containing flavorings and the knowledge base concerning diacetyl respiratory hazard have changed significantly in ways that GMA believes are not adequately reflected in the current proposed draft. First, growing awareness of diacetyl risk has prompted ongoing modifications in the formulation of food flavorings (including microwave popcorn flavorings) and food products to significantly reduce diacetyl concentration or to eliminate it altogether.

Second, to the extent that a California regulatory standard is justified, GMA believes that a comprehensive health standard based on a Permissible Exposure Limit (PEL) 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. This is consistent with National Institute for Occupational Safety and Health (NIOSH) studies in the popcorn and flavoring industries, monitoring results of the Flavor Industry Safety and Health Evaluation Program (FISHEP) program at California's flavoring plants and the Flavor and Extract Manufacturer Association's (FEMA) studies regarding risk. All of this information indicates that processes using 1% or greater concentration of diacetyl-containing flavors with detectable and greater employee exposures to diacetyl constitute the only possible risk. However, as discussed in additional detail below, the scientific understanding of diacetyl dose-response and hazard in the workplace has now sufficiently advanced to allow safe exposure levels to be derived. Recent animal and epidemiology studies provide a sufficient data set for establishing at least an interim occupational exposure guidance limit (OEL) for diacetyl

GMA does not believe that a comprehensive and detailed interim standard such as the draft proposed here is necessary while a PEL or OEL is being derived. If, however, the OSHSB finds that such a detailed interim standard is advisable, GMA believes the inclusion of specific food manufacturing operations should be limited to those plants where characteristics of the usage of diacetyl-containing flavorings suggest that significant cumulative exposures may be possible. A mandatory questionnaire would provide CalOSHA the necessary information to make such determinations.

We elaborate some of these points further below.

Principles Governing the Overall Approach to the Regulation of Diacetyl

1. Basic Legal Criteria

The policy of the Standards Board is that all standards must be enforceable, reasonable, understandable, and contribute directly to the safety and health of California employees. Moreover, the standards adoption process is governed by the Administrative Procedure Act in the Government Code. The Office of Administrative Law (OAL) reviews regulations to determine whether they meet the standards of necessity (the need for a regulation is

demonstrated by substantial evidence), authority, clarity, consistency, reference, and nonduplication. (See Government Code Section 11340 et seq.)

The California Office of Administrative Law is charged with reviewing all regulations adopted pursuant to the procedure specified in Government Code Article 5 (commencing with Section 11346) and submitted to it for publication in the California Regulatory Code Supplement and for transmittal to the Secretary of State and make determinations using all of the following standards:

(1) Necessity.

(2) Authority.

(3) Clarity.

(4) Consistency.

(5) Reference.

(6) Nonduplication.

In reviewing regulations pursuant to this section, the office shall restrict its review to the regulation and the record of the rulemaking proceeding. The office shall approve the regulation or order repeal, if it complies with the standards set forth in this section and with this chapter.

In reviewing proposed regulations for the criteria in subdivision (a), the office may consider the clarity of the proposed regulation in the context of related regulations already in existence.

2. Available Science Supports an Occupational Exposure Limit for Diacetyl

a) New Data Have Advanced Understanding of Diacetyl Health Hazards

During the past 2 years the scientific understanding necessary to estimate a safe exposure level to diacetyl has advanced considerably. The effects of diacetyl on the lung and relationship between exposure level and adverse effects ("dose-response") is emerging from studies in animals and epidemiology studies and exposure assessments in flavoring and food manufacturing. And major scientific uncertainties associated with the NIOSH measurements of diacetyl concentrations in air and estimates of exposures (the analytical method was subject to interference at certain levels of humidity) have been explicated, so that the original NIOSH exposure assessments and health hazard evaluations are now in the process of being corrected. A critically important report on an epidemiological study of the association between exposure to diacetyl and lung function in workers at four microwave popcorn plants has now been published (Lockey et al 2009)[1] Even

[1] Lockey, J. E., T. J. Hilbert, et al. (2009). "Airway obstruction related to diacetyl exposure at microwave popcorn production facilities." Eur Respir J **34**: 63-71.

more significant to this rulemaking is the wealth of information in the data base of airborne exposure monitoring and medical monitoring gathered in connection with that study. Our understanding is that these medical surveillance data are in the files of the University of Cincinnati and have been have been reviewed and summarized in the publication by Lockey et al 2009. In addition, we understand that the National Toxicology Program (NTP) has completed two 90-day animal studies on exposure to airborne diacetyl; the analyses and additional testing are underway (A Maier, TERA, personal communication).

The California Administrative Procedures Act requires all regulatory agencies to consider all relevant matters presented during the rulemaking process. The issues raised by commenters must be addressed in the Initial Statement of Reason accompanying a proposed regulation, as well as in amended Statement of Reasons (SOR) issued with modifications to a proposed regulation.

The data currently available are inadequate to justify/support the adoption of a comprehensive standard of the type contemplated by the draft proposal. Without attempting to establish the bounds of the best available evidence for purposes of this rulemaking, we believe it is clear that the best available evidence would include the soon-to-be-released report and the underlying database from the Lockey et al. 2009 study and the two recently completed NTP 90-day animal studies and any other NTP studies, which are under the control of a Federal Government agency cooperative in which NIOSH is a core member and OSHA serves on the NTP Executive Committee.

b) A PEL for Diacetyl, a Non-cancer Respiratory Risk, Should Be Developed Using the Benchmark Dose Methodology

Toxicology Excellence for Risk Assessment (TERA) performed an independent assessment of the current health effects data for diacetyl and its assessment.[2] TERA is submitting its assessment to the OSHSB. The TERA assessment is in the process of being submitted to a peer-reviewed journal for publication. Based on their assessment, TERA determined that the most appropriate measure of the adverse effects of workplace exposure to diacetyl was the inflammation of the tracheobronchial region. Most importantly, TERA determined that a dose-response analysis tied to tracheobronchial inflammation could be developed -- based on a recent subchronic study in mice (Morgan et al., 2008[3]) and supported by a recent cohort study

---

[2] Maier A., M. Kohrman, et al. (2009). "Evaluation of Concentration-Response Options for Diacetyl in Support of Occupational Risk Assessment." Toxicology Excellence for Risk Assessment, Cincinnati, OH.

[3] Morgan, D. L., G. P. Flake, et al. (2008). "Respiratory toxicity of diacetyl in C57BI/6 Mice." Toxicol Sci **103**(1): 169-180.

(Lockey et al. 2009[1]) -- and relied upon to develop an OEL for airborne exposure to diacetyl vapors.

According to TERA, "the data from these studies identify the same critical effect -- tracheobronchial inflammation -- and converge on a likely OEL range making confidence in establishing an OEL from the database medium to high." TERA derived its suggested OEL – an 8-hour time-weighted average (TWA) of 0.2 ppm -- through the well recognized Benchmark Dose Methodology (BMD), which relies on an extrapolation of the health effects from the toxicology data, and addresses the uncertainties of relying on that extrapolation through the application of uncertainty factors.

TERA concluded that the data are sufficient to derive an OEL for diacetyl, and that an OEL "developed from the existing database [including the complete data base from the Lockey et al. 2009 study] can be refined as new studies are completed." The question then becomes how CalOSHA should proceed where the current data seem to support this suggested OEL, but the body of available data is far less robust than the body of human and animal data traditionally assembled and relied on in setting a PEL.

TERA also concluded that workplace exposures to airborne diacetyl are most appropriately regulated by an 8-hour TWA, and should not be subject to a short-term exposure limit (STEL). According to TERA, a study that evaluated and compared the effects of cumulative airborne exposures to peak airborne exposures in rodents, over the course of a day, demonstrated that cumulative exposure is better than peak concentration as a predictor of tracheobronchial inflammation effects (Hubbs et. al. 2008[4]). TERA also concluded that the tracheobronchial region effects do not appear to progress significantly from subacute to subchronic durations of exposure (Morgan et. al. 2008[3]) and that this finding is supported by the absence of duration of employment effect on pulmonary function testing (PFT) changes reported in the microwave popcorn workers (Lockey et al., 2009[1]). Based on these findings, TERA concluded that an OEL based on an 8-hour TWA approach was appropriate and that there was insufficient data to establish a STEL.

3. Characteristics of Usage of Diacetyl-containing Flavorings Associated with Potential for Cumulative Exposure

Given the enormous diversity of food manufacturing, a targeted approach is needed in order for regulation to be effective and efficient in protecting workers. GMA believes that some systematic prioritization of food manufacturing operations for evaluation and regulation is imperative. There is sufficient knowledge about major factors that influence the nature and magnitude of cumulative exposure potential of food manufacturing workers to diacetyl in

[4] Hubbs, A. F., W. T. Goldsmith, et al. (2008). "Respiratory toxicologic pathology of inhaled diacetyl in Sprague-Dawley rats." Toxicol Pathol **36**(2): 330-344.

food flavorings. These factors generally include (but are not limited to) characteristics of the flavoring, characteristics of the processing operation(s) in which the flavoring is used, and existing workplace engineering and exposure controls.

GMA members developed a detailed questionnaire for purposes of evaluating and prioritizing cumulative exposure potential in food manufacturing operations for inclusion in the rule. This questionnaire, included here as Attachment A to this letter, was provided to CalOSHA during the Advisory Committee process in order to assist the Agency in formulating an effective regulatory approach to the highly diverse food manufacturing sector.

Summary and Recommendations

In summary, GMA recommends the following to the OSHSB concerning the draft proposed rule:

1. CalOSHA should establish an OEL using the databases underlying the Morgan et al. 2008 and Lockey et al. 2009 studies and the results of the NTP studies.

2. If it is not feasible to wait for the results of the NTP studies and establish an OEL, an interim rule should be adopted that is applicable only to the two industrial sectors for which the current data appear to establish a significant risk of harm from exposure to diacetyl and flavorings containing diacetyl. These sectors are concentrated flavor compounding and the manufacture of microwave popcorn with flavoring containing high concentrations of diacetyl. The concentration of diacetyl in flavoring that triggers regulation should be 1% or more by weight.

3. If it is not feasible to limit the sectors covered by such an interim rule to concentrated flavor manufacturing and microwave popcorn with flavoring containing high concentrations of diacetyl, applicability of the rule to specific food manufacturing operations should be determined based on whether those operations' usage of diacetyl-containing flavorings has characteristics known to be associated with potential for significant cumulative diacetyl exposures. A mandatory questionnaire such as that in Attachment A would provide CalOSHA the necessary information to make such determinations.

4. Any such interim rule should specify that the once a PEL is established by federal OSHA[5], or an OEL is published by a recognized expert entity (e.g., the American

[5] 74 Fed Reg 11329, 17 March 2009
(**http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=21538**)

Council of Government Industrial Hygienists, ACGIH[6]; or the American Industrial Hygiene Association Workplace Environmental Exposure Committee, AIHA WEEL), compliance with the PEL or OEL will satisfy the requirements of the CA regulation.

Thank you for your consideration of GMA's comments on the draft proposed rule.

Sincerely,

Caroline Silveira

Caroline Silveira
Director, State Affairs

Co-signatories:

American Bakers Association
California League of Food Processors
California Manufacturers and Technology Association
Dairy Institute of California
International Dairy Foods Association

[6] ACGIH recently added diacetyl to its Tier 1 "Under Study" list (as a chemical which may move forward as Notice of Intended Establishment of a TLV in the coming year) (**http://www.acgih.org/TLV/CSTLVStdy.htm**)

ATTACHMENT A

(GMA Questionnaire previously submitted to CalOSHA follows this page.
Note Table I is formatted for legal size paper)

Diacetyl-Containing Flavoring Use Questionnaire

Background and Purpose:

This draft questionnaire was proposed to Cal/OSHA by GMA as a means by which Cal/OSHA could gather information relevant to identifying and prioritizing CA food manufacturing operations for evaluation of occupational exposures and potential hazards, and for determining the need for regulation. The factors covered in this questionnaire are known to critically affect the nature and extent of diacetyl exposure that could occur in any particular food manufacturing plant.

Name of Company: _____
Address of Facility: _____
Number of people employed at facility: _____

Question 1:

At this facility, in how many products/product types/processes[7] are pure diacetyl or food flavorings containing diacetyl[8] added? _____

If the answer to Question 1 is not zero:

- **Complete Table I, Questions 2-8, for *each* product/product type/process in which diacetyl or food flavoring containing diacetyl is added.**
- **Complete Table II, maintenance and cleanup of spills, Questions 9-14.**
- **Answer Question 15.**

[7] Flexibility allows a facility to answer in the way that makes the most sense for its particular operations.

[8] Cal/OSHA terminology consistent with that used by OSHA: "diacetyl or food flavorings containing diacetyl".

Table I. Complete the following table for each product/product type/process in which pure diacetyl or a diacetyl-containing flavoring is added (note – similar processes using the same diacetyl-containing flavoring may be reported as one process).

Product/Product type/Process 1:

Name of diacetyl or diacetyl-containing flavoring (Use whatever names you commonly apply to the diacetyl containing products. Insert number of diacetyl products used in box)	**Form (Liquid, Powder, Paste, Chips [encapsulated])**	**Quantity used/day that process is active (lbs)**	**Frequency**	**% diacetyl (if known)**	**Lbs diacetyl/day (will be calculated field)**	**2. How many employees directly handle diacetyl or food flavoring containing diacetyl [3] in this process?**	**3 Does this process include ? (check all that apply)**	**4. During the process, are the ingredients:**	**5. If conducted uncovered or partially uncovered, how long is the process uncovered?**	**6. What kind of ventilation is in the process area?**	**7. Are there any other engineering controls? (DESCRIBE)**	**8. Do employees use respirators for this process?**
						☐ 1-5 ☐6-10 ☐11-20 ☐More than 20	☐ Mixing ☐Spraying ☐Sprinkling ☐ Heating	☐Totally covered & contained ☐Partially covered ☐Uncovered	☐Less than ½ hr ☐1-2 hr ☐2-4 hr ☐4-8 hr	☐Local exhaust ventila ☐General mechanical ☐Doors and windows		☐Yes, ½ or full face piece ☐Yes, dust mask-ty ☐Yes, other type ☐No
						☐ 1-5 ☐6-10 ☐11-20 ☐More than 20	☐ Mixing ☐Spraying ☐Sprinkling ☐ Heating	☐Totally covered & contained ☐Partially covered ☐Uncovered	☐Less than ½ hr ☐1-2 hr ☐2-4 hr ☐4-8 hr	☐Local exhaust ventila ☐General mechanical ☐Doors and windows		☐Yes, ½ or full face piece ☐Yes, dust mask-ty ☐Yes, other type ☐No

II. How are employees protected during maintenance operations or when cleaning up spills?:

9. How many employees are involved in maintenance or cleaning up spills?	10. Does this process include (check all that apply):	11. How often performed and how long does it take?	12. What kind of ventilation is in the process area?	13. Are there any other engineering controls? (DESCRIBE)	14. Do employees use respirators for maintenance and spill cleanup?
Maintenance: ☐ 1-5 ☐6-10 ☐More than 10	☐Hot water ☐Steam		☐Local exhaust ventilation ☐General mechanical ☐Doors and windows		☐Yes, ½ or full face piece ☐Yes, dust mask-type ☐Yes, other type ☐No
Spill cleanup: ☐ 1-5 ☐6-10 ☐More than 10	☐Hot water ☐Steam		☐Local exhaust ventilation ☐General mechanical ☐Doors and windows		☐Yes, ½ or full face piece ☐Yes, dust mask-type ☐Yes, other type ☐No

15. Do you have any results of air monitoring for diacetyl for employees in this process?
_____ Yes _____ No