Dragon, Karen E. (CDC/NIOSH/EID)

From: Gold, Deborah@DIR <DGold@dir.ca.gov>
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To: NIOSH Docket Office (CDC)
Cc: Horowitz, Mike@DIR; Widess, Ellen@DIR; Materna, Barbara (CDC cdph.ca.gov); Howard, Kelly@DIR; Murphy, Gene@DIR; Smith, Steve C.@DIR; Riley, Peter@DIR
Subject: Docket number NIOSH -- 245
Attachments: Cal OSHA Comments on NIOSH criteria document docket 245.pdf

On behalf of Cal/OSHA, I am submitting the attached comments regarding the draft NIOSH Criteria Document on Diacetyl and 2,3-Pentanedione, Docket number NIOSH – 245.

Thank you for your consideration. If you have any questions, please call me at 510-286-7013, or email me at this address.

Deborah Gold

Deborah Gold, MPH, CIH
Deputy Chief for Health and Engineering Services
Cal/OSHA
1515 Clay St. Room 1901
Oakland CA 94612
(510)286-7013

STATE OF CALIFORNIA EDMUND G BROWN, JR. *Governor*

DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF OCCUPATIONAL SAFETY AND HEALTH
1515 CLAY STREET, SUITE 1901
OAKLAND, CA 94612
(510) 286-7000 FAX: (510) 286-7037

ADDRESS REPLY TO:
PO BOX 420603
SAN FRANCIXSCO 94142-0603

Technical Comments on Draft NIOSH Criteria Document on Diacetyl and 2, 3-Pentanedione
Docket Number 245

Prepared jointly by Cal/OSHA and the California Department of Public Health
Submitted November 18, 2011

The California Department of Industrial Relations, Division of Occupational Safety and Health (Cal/OSHA), and the California Department of Public Health (CDPH), Occupational Health Branch, have prepared these technical comments based on our joint work over the past several years regarding flavoring-related illness.

General Comments

The draft Criteria Document on Diacetyl and 2, 3-Pentanedione is a very comprehensive, detailed compilation of available information on these flavoring chemicals. It is a valuable resource for employers and workers and for Federal OSHA standard setting as well.

We have two general concerns. The first is that throughout the document there should be greater emphasis on the hazard stemming from the powder forms of diacetyl and other butter flavoring ingredients. This greater emphasis on the powder forms is most necessary during discussion of engineering, administrative (particularly with regard to considerations of temperature effects), and personal protective equipment (PPE) controls. The document should also make it clear that the proposed Recommended Exposure Limits (RELs) for diacetyl and 2,3-pentanedione apply only to vapor exposures and may not be protective for mixed-phase exposures (i.e., where exposures to both vapors and particulates exist). The second concern is that the Criteria Document should include a comprehensive list of all the known substitutes for diacetyl, including the trimer form (which is not listed in the draft). At the same time, the document should make clear that other proprietary substitutes not on the list may also be in use.

We also have the following comments on the individual sections.

Executive Summary

The Executive Summary should include more key information about the conclusions and "take-home messages." This would make the findings and recommendations more accessible to a wider range of people who may not have the technical background necessary to follow the detailed information on toxicological risk assessment or industrial hygiene analytical issues, but who need to understand the hazards of working with diacetyl and related substances. Given

the length and technical nature of this document, many people will not read the entire document, making a statement of the key public health messages in the summary more critical.

Chapter 2 – Assessing Exposure

This section includes an excellent and very detailed discussion about the pros and cons of a long list of sampling and analytical methods. However, it takes a close reading to determine which of these methods have been validated. We suggest more clearly indicating the validation status of each method, such as by indicating the status in parentheses when each method is first introduced in the text. Also, although this section mentions that there are currently no validated sampling and analytical methods to adequately assess powder or mixed powder/vapor exposures, it is important that this section clearly address the limitations this lack of methodology places on assessing and controlling exposures to workers.

Chapter 3 – Effects of Exposure

This section needs emphasis on the fact that the health risks associated with combined powder and vapor exposure as opposed to vapor exposure alone are not known.

Chapter 4 – Toxicology

We would like the Criteria Document to address these questions, or to at least make clear in this section that these remain questions for further research:

1. Apart from the added amount of diacetyl that may be present on surfaces or encapsulated in powdered flavors (and presumably is not captured in vapor monitoring), does the deposition of particles directly into sensitive regions of the lung impart added toxicity?
2. What is the relative toxicity of diacetyl inhaled as a powder as compared to the same quantity of diacetyl inhaled as a vapor?

Chapter 5 – Quantitative Risk Assessment Based on Worker Data

In Section 5.3, NIOSH makes a conjecture about a susceptible portion of the exposed population leaving the studied workforce. Further explanation of this factor would be beneficial, including an explanation of any epidemiological or toxicological evidence for this effect, beyond the fit of the mathematical model.

Chapter 7 – Basis of Recommended Standards

The Criteria Document states that the REL for 2,3-pentanedione should be equivalent to the REL for diacetyl, but that a higher REL was selected due to limitations of the sampling and analytical method. The use of technological feasibility to establish a REL that exceeds the health-based recommendation is inconsistent with previous practice. Is it NIOSH's intention to change the REL if more sensitive methods are developed? It would be more appropriate to propose a health-based REL, and acknowledge that airborne vapor concentrations cannot be measured at that level. This would encourage method development. Also, the REL is used to develop maximum use concentrations for respirators, and there is no difficulty in measuring 2,3 pentanedione at those concentrations. We believe this section must emphasize that the 2,3-

pentanedione REL should be changed to a more appropriate health-based number when more sensitive methods become available.

Cal/OSHA and CDPH also recommend the following issues be given consideration in this section:

1. Provide a reference for NIOSH's selection of a short-term exposure limit (STEL) that is 5 times the TWA value. Is there a reason why a multiplier of 5 was selected?
2. Provide a clear acknowledgment that the RELs are based on risk assessments derived from measurements of flavoring chemicals in the vapor phase only, which may inadequately represent the risk in workplaces where both dust and vapor exposures are present. Give guidance on the implications of this problem.
3. The Criteria Document states that engineering controls are available to control worker exposures down to the RELs, but also acknowledges (in a different section) that there may be situations where extended respirator use may be necessary. Should these apparently contradictory statements be reconciled or given fuller explanation?
4. Since the REL is based on full-shift, 40-hr/week exposure, provide guidance on how employers should adjust the REL to account for alternative work schedules (e.g., 10-hr shifts, 6-day work weeks).
5. Section 7.5.1 on the proposed Action Level should include an explanation of the basis for the AL being proposed.
6. In Section 7.7 concerning controlling vapor exposures, the statement that engineering controls can reduce exposures to less than the limit of detection (LOD) appears to be based on only one study involving popcorn flavor manufacturing. That there is but a single example backing this statement may cause some to question the plausibility of the assertion.
7. Section 7.8 on the hazards of diacetyl substitutes should include a complete listing of substitutes NIOSH knows of and is concerned about (or refer to another section or table where they are listed). The list should include diacetyl trimer.

Chapter 8 – Hazard Prevention / Exposure Control

1. Consider recommending additional protections (e.g., higher level of respiratory protection) where both dust and vapor exposures are present and/or stating that in these situations process-based controls are especially important. Since there is no current method to quantify additional exposure coming from the particulate phase, basing protections on vapor measurements alone will not address the true level of risk.
2. Consider recommending additional protections for workers exposed to 2,3-pentanedione levels in the 5 ppb – 9.3 ppb range, which has been identified as a range with potential health risk but cannot be measured with current analytical methods.
3. In the Hazard Communication section, since flavor manufacturers will be preparing Material Safety Data Sheets (MSDSs) for their downstream customers, NIOSH should encourage them to list the presence of diacetyl and its substitutes at any level as well as listing the known health effects and necessary protective measures. Non-informative MSDSs for flavoring mixtures seriously limit employers' efforts to

protect workers in food production. NIOSH could also state that inadequate MSDSs may result in OSHA action against the preparing company.

4. In regard to the respirator selection table, explain what is meant by Maximum Use Concentrations. Are these 8-hr TWAs? Are there any circumstances where half-mask respirators may be appropriate (if not, that should be stated)? Since NIOSH believes the risk assessment supports the same REL for both diacetyl and 2,3-pentanedione, and they are only different because of the analytical constraints, would it be appropriate for the Maximum Use Concentrations in this table to be the same?
5. NIOSH should recommend that employers adopt policies on the duration of use for hand protection, i.e., policies on when it is necessary to dispose of gloves so as to prevent exposure via breakthrough.
6. In Section 8.2 on Engineering Controls, the statement that PPE is more expensive than engineering controls may not be true for all circumstances. There are stakeholders that may contest this statement given typical costs of $150,000 to $300,000 for installation of local exhaust systems in some flavoring manufacturing facilities with additional costs for ongoing operating of the controls. In addition, respiratory protection is often still warranted in addition to engineering controls.
7. With regard to Section 8.2.1:
   a. Emphasize the need to prevent paper, gloves, etc., from being pulled into local exhaust systems, something that has been demonstrated to substantially impact exhaust efficiencies. Screens or other barriers have proven effective for this purpose.
   b. Consider recommending continuous negative room pressure indicators for isolation rooms.
   c. Address the advisability and limitations on the use of contact/proximity switches that activate local exhaust systems on an as-needed basis, something employers will consider for energy conservation purposes.
   d. In this section, NIOSH proposes that manufacturers "install hood static pressure gauges (manometers) near hoods to provide a way to verify proper hood performance." By listing manometers in parentheses, NIOSH leaves the impression that these are the only acceptable device. In fact, there are other types of qualitative airflow monitors that are commonly utilized and, increasingly, quantitative airflow monitors with digital readouts are being used for exactly this purpose.
8. In section 8.2.2, add quality control, research and development, and maintenance to the listing of job categories that may incur significant exposures to flavoring chemicals.
9. In Section 8.3.2, point out that some closed transfer processes can also produce significant exposure for personnel required to dismantle and clean/sanitize the equipment after a production run. These activities can be required frequently for certain flavoring manufacturing processes.
10. In Section 8.4, Table 8.2, also list the half-face air-purifying respirator (APR) as a minimal option for short, transitory exposures – e.g., supervisors or QC personnel that are only momentarily in an isolation room where powder forms of diacetyl are not being processed. Powder forms of diacetyl and 2,3-pentanedione also need to be included in the respirator decision logic, although their selection cannot be based on measured concentrations at this time.

Chapter 9 – Medical Monitoring and Surveillance

1. The Criteria Document should provide clearer guidance on what should trigger inclusion of specific workers in the medical monitoring program. The current guidance seems more applicable to flavor manufacturing jobs; how should food production facilities determine who to include? What does "regular" exposure mean? Since disease develops quickly, please provide any guidance on how frequency of exposure should be considered (e.g., some standards such as the lead standards specify a more specific trigger for including workers without daily exposure). Should the percentage of diacetyl in the flavorings used be a factor to consider in deciding which workers should be included in medical monitoring, and if so, how?
2. A medical monitoring program director (or supervising physician) may work with a team of providers such as spirometry technicians. Section 9.1 suggests that the physician him- or herself will be in face-to-face contact with workers. Is NIOSH recommending that each employee have a baseline physical exam performed by this lead physician? Or would this contact happen only if screening identifies an abnormality or symptoms requiring follow-up? This ambiguity should be clarified. If no baseline physical exam is recommended, language could be added to emphasize that the person(s) administering spirometry and questionnaires should be trained to ascertain worker knowledge of risks, assess PPE use, explain findings in an understandable way to workers, etc.
3. Section 9.5 provides guidance intended to ensure that surveillance results get transferred when a company makes a change in medical surveillance provider. In our experience, this is an important issue and one that was not handled optimally by many flavor manufacturing companies we worked with in California. We recommend the following as a preferred method of addressing this situation: on the next surveillance visit for spirometry/questionnaire following a change in provider, the new provider should have employees sign a release allowing the new provider to request previous surveillance records from the previous provider. This approach allows providers to avoid any potential liability related to privacy laws and still obtain previous results that are critical to detecting any decrements in respiratory health over the course of employment.

Cal/OSHA and CDPH are very appreciative of the opportunity to submit technical comments on this complex and thoroughly researched draft Criteria Document. We are sure that this document will provide invaluable guidance to manufacturers, employers, workers, physicians and regulators in making safer workplaces with exposures to diacetyl and its substitutes. We look forward to its publication in final form in the near future. Any questions related to these comments may be directed to Deborah Gold, MPH, CIH, Cal/OSHA Deputy Chief for Health and Engineering Services, at dgold@dir.ca.gov or 510-286-7013, or Barbara Materna, PhD, CIH, CDPH Occupational Health Branch Chief, at barbara.materna@cdph.ca.gov or 510-620-5730.

Sincerely,

D. Gold

Deborah Gold
Cal/OSHA Deputy Chief for Health and Engineering Services