Miller, Diane M. (CDC/NIOSH/EID)

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Friday, November 18, 2011 7:39 PM

To: NIOSH Docket Office (CDC)

Cc: McKernan, Lauralynn Taylor (CDC/NIOSH/EID); Diana, Sherri A. (CDC/NIOSH/EID) (CTR)

Subject: NIOSH Docket Number 245: Draft Criteria Document- Diacetyl and 2,3-Pentanedione

Attachments: NIOSH Criteria Document- Comments.pdf

To whom it may concern,

Please find attached my comments to NIOSH Docket Number 245: Draft Criteria Document- Diacetyl and 2,3-Pentanedione. I hope this information is helpful to NIOSH as you move forward toward final publication of the proposed NIOSH Criteria Document- Diacetyl and 2, 3-Pentanedione.

Best, Jason

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November 17, 2011

Laura Lynn McKernan, ScD, CIH NIOSH 4676 Columbia Parkway, MS-C32 Cincinnati, OH 45226

Re: NIOSH Docket Number 245: Draft Criteria Document-Diacetyl and 2,3-Pentanedione

Dear Laura Lynn,

Prior to leaving OSHA in November of 2009, it was always a great pleasure working with you and the other passionate occupational safety and health staff in NIOSH's Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS), Division of Applied Research and Technology (DART), and Division of Respiratory Disease Studies (DRDS).

I would like to commend NIOSH on their efforts in continuing to work on this very important occupational safety and health issue and publishing a draft proposed criteria document for diacetyl and 2,3 pentanedione. My review of the NIOSH criteria document pertains to the following sections:

- 1. Chapter 2: Assessing Occupational Exposure in Workers
- 2. Chapter 7: Basis of the Recommended Standards for Diacetyl and 2,3 Pentanedione
- 3. Chapter 8: Hazard Prevention and Control of Exposures to Diacetyl and 2,3 Pentanedione
- 4. Appendix 6: Typical Protocol for Collecting air samples for Diacetyl and 2,3 Pentanedione

Please consider, where applicable, explaining, addressing and/or clarifying the following issues in the document as NIOSH moves forward toward final publication.

1. Chapter 2: Assessing Occupational Exposure in Workers

- Consider researching nationwide AIHA accredited laboratories and their ability to measure to the reliable quantitation limit (RQL) for OSHA methods 1012, 1013, and 1016 before publishing a recommended exposure limit (REL).
 - It is known that the OSHA Salt Lake Technical Center (SLTC) can meet this need mainly for OSHA compliance reasons. However, since there is not a regulation on these substances and you are recommending a limit for employers to meet, it is only fair to say in the criteria document that the reliability to measure to this REL lacks confidence and cannot be achieved by most laboratories across the U.S at the current time.

- NIOSH's approach to publishing a REL without assuring laboratories can
 measure to the RQL is prudent, in that it is technology forcing; however, I
 believe it would be better received by the flavor manufacturing and food
 manufacturing industries if the REL can be measured to confidently by
 "most" laboratories prior to publication of the final criteria document.
- Because the proposed REL for 2,3 pentanedione is set at the RQL of OSHA method 1016 brings into question whether or not NIOSH fulfilled their charge in conducting a proper quantitative risk assessment (QRA) on 2,3 pentanedione.
 - I say this because if the toxicological effects 2, 3 pentanedione have a strong correlation to the toxicological effects of diacetyl as NIOSH states in the criteria document, then why stop at the RQL of OSHA method 1016 (?).
 - It appears that the proposed REL for 2, 3 pentanedione needs more research and validation.
 - If the research is not there to conduct a proper QRA, then remove
 it from the criteria document.
 - NIOSH's main charge for setting a REL is to determine a "safe" level for
 exposure to workers. The way it is currently written, it appears that
 NIOSH is going outside the scope of the criteria document and proposing a
 REL for 2,3 pentanedione based "mostly" on analytical feasibility.
- Continue efforts on developing a traditional industrial hygiene personal sampling method for quantifying powdered diacetyl, and 2, 3 pentanedione (e.g. powdered butter flavorings) because it can be assumed that occupational exposure inhalation risks are underestimated since encapsulated butter flavorings are most likely liberated once they come into contact with moisture when entering the body via inhalation routes (mouth, nose, tracheal, pulmonary lining, etc.)

2. Chapter 7: Basis of the Recommended Standards for Diacetyl and 2,3 Pentanedione

- Re-evaluate the QRA and propose a REL to a "safe" level that does not impact consumers.
- Propose a REL that does not creep into ambient naturally occurring diacetyl levels commonly found
 in industries that use strawberries, beer, wine, dairy products, tomatoes, coffee, baked goods, roast
 chicken, and margarine.
 - This is only fair because, at the current time, there is no evidence of disease in these industries.

- Consider explaining in-depth to the public what NIOSH means by "engineering control achievability".
 - As a past OSHA official, I interpret this as "capable of being done once".
 - Please clarify and consider explaining to the public the difference between technological feasibility as it relates engineering and work practice controls and engineering control achievability in the criteria document.
 - Clarifying this difference will help employers understand what NIOSH means with regard to trying or implementing "feasible" options in their workplaces.
 - This will also assist OSHA as they move forward in promulgating a health standard on food flavorings containing diacetyl and diacetyl substitutes.
- Consider making it clearer in the criteria document that most of the logic behind engineering control technology comes from two primary industries: flavor manufacturing and microwave popcorn manufacturing.
 - This is only fair to other food manufacturing industries that have not been thoroughly investigated.
 - It is important because other sectors of the food manufacturing industry must not choose to be silent on sharing effective engineering control technologies.
 - Consider stating in the criteria document the need for such information and how it assists NIOSH in the development of a REL in addition to how it assists OSHA as they move forward in promulgating a health standard (i.e. Occupational Exposure to Food Flavorings Containing Diacetyl and Diacetyl Substitutes).
 - Obtaining the aforementioned information assists OSHA in there statutory requirement to set a standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."

3. Chapter 8: Hazard Prevention and Control of Exposures to Diacetyl and 2,3 Pentanedione

- Table 8.2 on page 242, recommends the use of a full-face air purifying respirator (FFAPR) for workers exposed at or above the proposed REL (8-hr TWA).
 - O It is understood that this logic comes from the NIOSH Respirator Selection Logic; however, consider also allowing the use of a half-face air purifying respirator (HFAPR) with goggles (and, if applicable, the use of a face shield).

- A feasible alternative to a FFAPR is a HFAPR with goggles, as determined by Annex I of ANSI Z87.1-2003.
 - Goggles are effective at protecting workers eyes from exposure to butter flavoring vapors, liquids, and particulates.

4. Appendix 6: Typical Protocol for Collecting air samples for Diacetyl and 2,3 Pentanedione

• On page 4 of Appendix 6, line 18 under "Focused Sampling" replace the word "fibers" with "vapors".

I fully support your mission to protect worker safety and health. And, I hope this information is helpful to NIOSH as you move forward toward final publication of the proposed NIOSH Criteria Document- Diacetyl and 2, 3-Pentanedione.

Sincerely,

Jason T. Capriotti, CIH, CSP

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