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Sent: Friday, November 18, 2011 12:03 PM
To: NIOSH Docket Office (CDC)
Cc: Carrasco, Lorena - FSIS; Derfler, Phil - FSIS
Subject: 245 - Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione

The U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) requests that NIOSH:

- recognize poultry and meat industry workers and inspectors as potentially exposed to diacetyl or related compounds;
- explicitly consider diacetyl's irritant effects in setting occupational exposure limits; and,
- consider the economic impact/feasibility of implementing the recommended medical monitoring program across a large, geographically diverse organization or company.

FSIS recently identified the use of butter flavored starter distillate in a poultry slaughter and processing establishment. In this instance, waste marinade containing starter distillate was discharged into open trenches that ran beneath the poultry inspection stands. No odors consistent with butter flavorings were reported at any time, but highly prevalent eye and upper airway irritation among the inspection workforce ceased the day after the use of starter distillate was discontinued. Previously, there was no documented evidence of diacetyl's inclusion in poultry or meat marinades. Based on available information about the consumer of this specific poultry product, we estimate that the number of birds marinated in starter distillate for this retail outlet alone approached one million annually, with product distributed to about 1,000 retail stores for rotisserie roasting. Anecdotal information from poultry industry managers suggests that the use of diacetyl is much more widespread than was observed in this single case. We believe it is plausible to expect diacetyl or diacetyl substitutes are used in a variety of meat and poultry product lines. This could entail exposure potential for several thousand federal meat and poultry inspectors, and tens of thousands of industry workers. We believe these populations should be identified as potential exposure groups in the Criteria Document and any subsequent flavorings research.

FSIS is concerned that the proposed diacetyl and 2,3-pentanedione RELs and STELs do not explicitly consider the dermal and irritant effects of these compounds. Our experience with diacetyl exposure in a poultry slaughter establishment suggested that dermatitis and intolerable eye and sinus irritation were noted in the absence of any lower respiratory symptoms. NIOSH believes that setting OELs that are protective against precursors to bronchiolitis obliterans (BO) will inherently protect against dermal and irritant effects, but no objective evidence is presented to support this assumption. The potential for differences in personal protective equipment (PPE) use in various exposure settings makes it inappropriate to draw firm inferences about irritant effects based purely on observations in popcorn and flavorings manufacturing. For example, the visual demands of poultry inspection tasks preclude the use of chemical protective eyewear in most instances, although the use of eye protection was documented in at least some of NIOSH's diacetyl-related HHEs. Additionally, the use of protective eyewear or full-faced respirators was not fully described in all HHE reports, making the assumption that the proposed REL and STEL protect against irritation tenuous at best. Explicit consideration should be given to dermal and irritant effects in the development of OELs, to ensure that an appropriate level of protection is achieved.

FSIS is also concerned about the potential economic impact and narrow benefit of the proposed medical management program. While the specific testing protocols seem reasonable as screening for precursors to BO, we feel the inclusion criteria are unrealistic and potentially cost prohibitive. In the absence of criteria other than "ever/never enter a potential exposure area", and arbitrarily assuming a typical exam cost of $200, an agency of our size could expect to pay $1.2 million annually in medical expenses alone, not including time away from work or related intangibles. The potential cost to industry could be significantly higher. While these costs may turn out to be necessary and appropriate, there is not sufficient justification in the proposed Criteria Document to support the recommended inclusion

criteria. Additionally, as with the setting of OELs, we do not see consideration given to exposure symptoms that are not precursors to BO aside from the suggestion that "additional questions (on the questionnaire) might inquire about work-related nasal, ocular and dermal symptoms." The proposed medical management program could potentially cost in excess of a million dollars annually, without having any direct relevance to the most predictable adverse effects of diacetyl exposure. Considerably more attention should be paid to justifying the proposed threshold for inclusion in a medical monitoring program, and considering the relevance of exposure effects which are not directly related to the incidence of BO.

FSIS thanks NIOSH for your attention to these issues. The potential for adverse health effects and reduction in productivity and the quality of work life due to diacetyl exposure exist outside of the popcorn and flavorings industries. Diacetyl's strong irritant and dermal effects, while not as devastating as BO or chronic lung disease, can have a very real and significant impact on workers and organizations. Due consideration is needed to ensure that they are addressed in the current body of research on diacetyl and related butter flavorings.

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