

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

From: Brown, Tonnetta <TBrown@gmaonline.org>
Sent: Thursday, November 17, 2011 4:22 PM
To: NIOSH Docket Office (CDC)
Subject: 245
Attachments: FINAL NIOSH 111711.pdf

Please find attached comments ---Re: Comments on the Criteria for Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione. Docket #245.

Please feel free to contact me if you have any questions.

Thanks,

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November 17, 2011

NIOSH
Attn: NIOSH Docket Office
Docket #245
NIOSH, Robert A Taft Lab
4676 Columbia Parkway
Cincinnati, OH 45226
nioshdocket@cdc.gov?subject=245

Re: Comments on the Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione. Docket #245

Dear Sir/Madam:

Based in Washington, D.C., the Grocery Manufacturers Association (GMA) is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.

In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and active lifestyle.

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The food, beverage and consumer packaged goods industry in the United States generates sales of \$2.1 trillion annually, employs 14 million workers and contributes \$1 trillion in added value to the economy every year.

GMA sincerely appreciates the opportunity to submit comments to the National Institute of Occupational Safety and Health (NIOSH) Docket #245 concerning the draft Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione (draft criteria document). Our comments represent the collective view of GMA and six additional associations representing the food manufacturing industry: the National Coffee Association, American Bakers Association, American Beverage Association, The International Dairy Foods Association, the National Confectioners Association and the Snack Food Association.

Summary of Comments:

Our collective members recognize the importance of worker health and safety. We support and encourage the work done by NIOSH to help employers, industrial hygienists and employees understand and manage risks in the workplace. Furthermore, we support a science based regulatory process that incorporates the best available science. We appreciate the effort that the NIOSH staff has exerted to pull together the extensive draft criteria document and we want to commend NIOSH for publishing the transcript and presentations from the recent public stakeholder meeting as part of this docket. The nature and availability of these types of documents has been valuable in our review process.

NIOSH stated during the public stakeholder meeting (8/26/11) that their goal was to develop a document that is scientifically sound, has relevance and utility and is developed according to a rigorous, consistent, and transparent process. After reviewing the draft criteria document, we feel compelled to raise multiple concerns that call into question the rigor, consistency, transparency and validity of NIOSH's analysis. We are particularly concerned with the exposure estimates developed for the quantitative risk assessment based on worker data, which forms the basis for NIOSH's proposed criteria. As a result of these concerns, we believe that the proposed recommended exposure limits (RELs) and short-term exposure limits (STELs) put forward by NIOSH are overly conservative and inappropriate when applied to any worker handling food or flavors. Further, we request that NIOSH take into consideration these concerns (presented in detail below) before finalizing the criteria document. Attention to addressing these concerns is critical because the criteria document is a recommendation to OSHA that a standard be issued and, prior to any subsequent rulemaking, the finalized criteria document could be considered guidance.

The key concerns we have are as follows:

- 1. Historical epidemiological data suggest that cases of bronchiolitis obliterans have been observed in workers handling flavors at flavor manufacturing sites and/or in**

food production only where microwave popcorn was manufactured when appropriate PPE or environmental controls were not in place.

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 the food manufacturing industry has not been borne out in spite of 11 years of experience. If one considers that the first cases of bronchiolitis obliterans in the flavoring manufacturing industry were reported in 1985 (NIOSH, 1985), then the timeframe for discovery of cases is actually 26 years.

Furthermore, the presumption of risk in the food manufacturing industry as a whole has not been supported by data on workers' compensation claims, which our members believe provide no indication of a problem. It is also noteworthy that despite the increased awareness of diacetyl usage in food flavorings, not only in California due to their emphasis program and subsequent rulemaking, but also by the federal Occupational Safety and Health Administration (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 (Kanwal, 2011).

2. The lack of predicted cases in the food processing industry is likely attributable to the significant difference in exposure scenarios. In addition, NIOSH relies on the wrong set of exposure data for microwave popcorn facilities.

The lack of cases in food manufacturing (aside from microwave popcorn production facilities without appropriate engineering controls) is likely due to the fact that use of flavorings in food production presents very limited opportunities for biologically relevant levels of exposure. We believe the prediction of widespread disease did not take into account this important difference in exposure between the industries that did seem to be affected and the industries that were anticipated to show effects. In spite of the lack of widespread disease in food manufacturing facilities, NIOSH continues to focus, including in this criteria document, on a single microwave popcorn manufacturing facility in which several cases of bronchiolitis obliterans were identified. A considerable body of data has been developed and published from several other microwave popcorn and food manufacturing plants but is virtually ignored in this criteria document. These data have demonstrated a considerable difference between the original microwave popcorn plant where disease was first identified, other microwave popcorn plants and an even greater difference between microwave popcorn plants and other areas of the food industry.

For perspective on the difference between microwave popcorn facilities and other areas of the food industry, consider that at the time the problem was discovered in the first microwave popcorn plant, microwave popcorn manufacturing plants were using flavorings containing uniquely high concentration of diacetyl (greater than 15-30% in

some flavoring formulations). Levels of this magnitude are not typical of use in the manufacture of other foods (and are no longer used even in the manufacture of microwave popcorn). Additionally, 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. Thus the potential for cumulative and relatively high exposure was great. 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 contain <0.1% diacetyl by weight. Even considering that substitutes such as 2,3-pentanedione could also be present in formulations, it is common practice in the food industry that only small amounts of such flavoring are added to food products. Additionally, 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 buttery flavoring component. More specifically, none of these flavors will contain more than a low percentage of diacetyl. Lastly, the potential for diacetyl (or any of the volatile buttery flavoring components) in a food flavoring to volatilize into the 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.

Finally, the majority of subjects (57%) evaluated in the original microwave popcorn plant reported having exposures outside the popcorn plant to other possible causes of occupational lung disease (Kreiss et al, 2002). This publication describes farming, grain dust, irritant gases and nitrogen oxide exposures but this fact is dismissed (or ignored) in subsequent publications by NIOSH and these authors. A further source of uncertainty in the data from the original microwave popcorn plant is that many of the sentinel cases from this plant had symptom onset between 1993 and 1998 (Ackpinar, 2004). That is, the symptoms developed at a time when NIOSH acknowledges it has no accurate exposure data and, in fact, could have significantly underestimated exposure. Trying to correlate data from this one plant with disease and compare these findings with any aspect of food production in other plants is, simply, not a scientifically defensible approach.

Based upon these considerations, the focus of exposure estimates in this criteria document on a single microwave popcorn facility where disease was originally identified is not scientifically justified especially in light of the large amount of credible data available for many other plants.

3. The low-level exposure scenarios in the food industry are not readily apparent to the reader due to the way the table that discusses this topic is constructed (Table 2 page 57 of the draft Criteria Document).

There is evidence for the low-level exposure in the food production industry in the reports cited in the criteria document, but it is not clearly considered. Table 2 (page 57 of the Draft criteria document) conveys ranges of diacetyl measured in workplaces that used or produced diacetyl. However, with the table in the current format, the actual measurements and, thus exposures, are not clear to the reader. To this end, we ask NIOSH to consider clarifying Table 2. We also believe that clarifying Table 2 will be beneficial to NIOSH in their interpretation of these data.

A good example of how clarifying and adding more detail to the existing table brings value and impacts interpretation of the data can be seen in the Eastern Research Group (ERG) report on baked snack food production (ERG 2008d). To the reader of the draft document as it exists, Table 2 conveys that workers in the baked snack industry have time-weighted average (TWA) exposures ranging from below the detection limit to 164 parts per billion (ppb). In actuality, the ERG report indicates that the sample representing the upper end of this range (164 ppb) was collected over 57 minutes; however, when the entire shift of 7.7 hrs was accounted for, the calculated full-shift TWA was 30 ppb. Further, diacetyl was not detected in samples collected on the two other workers sampled and, in fact, diacetyl was detected in only 3 of 16 samples. This is an important clarification because the casual reader might assume that the typical 8-hr exposure in this type of industry could lead to much higher exposures than what the data actually demonstrate. Without these clarifications, the casual reader is led to a conclusion that is not supported by the available data.

Because the modification makes the table quite lengthy we have attached the suggested option for reconstruction as Attachment I to our letter. We feel this modified Table 2 will more accurately convey the data values in an easy to understand format.

4. Following the current best approach and validated methodology, the most commonly reported limit of quantification values (LOQ)'s exceed the proposed REL for diacetyl as well as the proposed action limit.

Before providing the details related to our concern listed above, it is important to mention that the terminology used by NIOSH in Table 2 (page 58) is confusing. NIOSH defines "ND" as "no limit of detection was reported". A review of the OSHA-ERG reports used to populate this table indicates that "ND" is actually defined by the authors of those reports as "not detectable" which was used when "there was no indication of the analyte in the sample". Since these are very different meanings, we would appreciate NIOSH clarifying this definition for consistency purposes.

Relative to our concern listed here, using the modified Table 2 in Attachment I, one can better see that many of the air monitoring values for the food production industry fall into the "ND" and <LOQ categories. Since the "not detectable" designation would indicate

no presence of analyte, the fact that quite a few of the TWA values resulted in "ND" designation demonstrates again, the lack of exposure in many job categories in the food industry. Further, we believe that the modified table allows one to better see that in many cases, the LOQ exceeds 5 ppb (the proposed REL). Discussions with certified industrial hygienists at our member companies have highlighted the concern that if one is to follow the strict interpretation of the currently available validated method (OSHA 1012) for sample time and flow rate, the LOQ will often exceed the newly proposed REL.

The problems with achieving an LOQ that is below the action limit need to be more openly discussed with validated examples/labs that are capable of delivering relevant and accurate results using methods reasonably anticipated to be available in work areas. Another more practical option would be to consider using a performance based approach that requires employers to utilize good administrative practices and to apply existing guidance such as that available from FEMA (2004), NIOSH and OSHA under special emphasis programs. Following such guidance would also help provide direction to employers when handling butter flavor substitutes.

5. The <LOQ range, which currently may exceed the REL, is likely associated with diacetyl that is known to occur naturally in many foods. Regulating to such a low level would cause consumer confusion and concern, as naturally occurring butter flavor components could very likely exceed the proposed REL's. This is not justified by the available data since there is no credible evidence of a risk to consumers.

As stated in the criteria document (page 56), of three cafeterias surveyed, "neither diacetyl nor acetoin was found at or above the minimum detectable concentration (0.02ppm)." Since 0.02ppm/20ppb would be above the newly proposed REL, this begs the question as to what the customer exposure in those cafeterias might be and might they exceed the level NIOSH is proposing as safe. This has the potential to cause consumer confusion when, in fact, there is no evidence that low levels of diacetyl represent a consumer hazard. Furthermore, there remains no peer reviewed published literature reports that demonstrate any risk to consumers. In fact, in response to a question about consumer risk, NIOSH posted on its "Science Blog" in 2008 the following statement: "Unlike workers, so far there have not been peer-reviewed scientific studies showing that consumers using products such as microwave popcorn that contain butter flavoring chemicals are at increased risk for lung disease. Nor is there any evidence that cooking with butter is associated with increased risk for lung disease."

Further, we know from the comments submitted in the previous Federal rulemaking Small Business Regulatory Enforcement Fairness Act (SBREFA) process and in the California rulemaking that all of the following food categories either contain diacetyl naturally or it is formed naturally as part of the manufacturing process: butter, cheese, milk, yogurt, tomatoes, citrus fruits, juices, vinegar, black tea, coffee, beer, wine, whiskey, cognac, guava to name a few. Many of these industries have been operating for multiple decades, if not approaching a century, without apparent evidence of concerning lung decrement, including the unusual condition of bronchiolitis obliterans. This also

would indicate that there are a lot of food sources that potentially offer low-level exposure to the consumer, yet in that realm, as noted above, there are no credible data to support a concern.

Based upon this information, it is a disservice to public health in general to recommend an excessively conservative REL that is not supported by the available data and could have impact on millions of consumers and workers for which, by NIOSH own statements, there is no data to support a risk.

6. The risk assessment utilizes exposure data that are limited in scope and based on data values that have many underlying uncertainties. The risk assessment cannot be considered scientifically sound if the data critical to the exposure metric (cumulative in this case) is highly uncertain.

As stated in the public transcript "the trick in risk assessment is to come up with the appropriate exposure metric and then do statistical models that relate the metric to the outcome". Unfortunately, we believe that the determination of the exposure metric is flawed due to the major uncertainty associated with historical exposure reconstruction.

The draft REL relies on the metric of cumulative exposure. In order to reconstruct cumulative exposure for workers affected, NIOSH chose to use data based primarily on exposure information from one facility: the Gilster-Mary Lee Corporation in Jasper, Missouri ("index plant"). Although NIOSH conducted nine surveys at this facility between November 2000 and July 2003 and nearly 400 personal and area samples were collected during these surveys, there are serious questions as to the adequacy of these data for use in risk assessment.

NIOSH acknowledges on page 116 of the draft that, "The characterization of historical exposures was limited by the absence of air sampling prior to the NIOSH HHEs." Thus, for purposes reconstructing exposures, NIOSH assumed that:

- Diacetyl was used at the index plant beginning July 1, 1986 (p. 118) or more than 14 years prior to the initial survey in November 2000.
- It was appropriate to apply the exposure estimates gathered at the first survey to the entire 14-year prior time period. To this point, NIOSH stated, "For work history prior to the first industrial hygiene survey, exposure estimates from the first time period were used." (p. 117).
- No engineering controls or process changes were made at the index plant between the years 1986 and 2000. NIOSH notes that "... it was assumed that there were no significant exposure control changes prior to the first survey." (p. 117).

These assumptions are fraught with uncertainty as well as a lack of consistency and transparency, the most important of which are highlighted below.

- In contrast to the draft criteria document, NIOSH notes in the August 22, 2001 interim report that, “In the summer of 1999, a local exhaust ventilation system was added to the microwave mixing room to control salt dumping operations. Roof air intake systems were also added to the microwave area in the summer of 1999.” (p. 62 of HHE Report No. 2000-0401-2291). NIOSH acknowledges that, “In the late October-November survey, 17/79 (22%) of the workers currently in microwave packaging and mixing operations reported that the addition of ventilation in the summer of 1999 had improved the work environment; an additional 33% reported that the environment had stayed the same; and the remainder (46%) didn’t know.” (p. 69 of HHE Report 2000-0401-2991). Although NIOSH concludes that “volatile organic compounds, such as diacetyl, may not have been affected by past ventilation interventions,” they provide no basis for that conclusion and, at a minimum, their choice of wording implies that NIOSH recognized that diacetyl concentrations could have been affected. Given that the highest exposures were measured in the mixing room, if these engineering measures did reduce diacetyl concentrations in this area of the plant, then the historical exposures for workers of the plant could have been greatly underestimated.
- NIOSH relied on area samples to estimate personal exposure. NIOSH acknowledges that, “... for the first industrial hygiene survey (November 2000), only area samples were collected, and thus personal sample-equivalent exposures were estimated (Appendix 4). (p. 117, l. 15-16). This is a critical point because it means that the vast majority of the estimated cumulative exposure over a period of up to 17 years (1986 to 2003) is based on a single survey in which no personal samples were collected!
- NIOSH employed a variety of methods for converting the area samples to personal samples, without providing any explanation or justification as to how these methods were applied and to what data (see Appendix 4, p 4-5). For example, the mean of the area samples collected in the warehouse were used as personal samples, whereas in the Microwave Packaging Area, personal samples were estimated based on a model of area and personal samples for two of the other surveys whereas for the Microwave Mixing area, a model of area and personal samples for all surveys was used.
- Air samples collected during the nine surveys were analyzed by NIOSH Method 2557, which is now known to be affected (underestimated) by humidity and time to extraction (p. 115). Accordingly, the sampling results from these were adjusted based on an adjustment procedure published by NIOSH staff (Cox-Ganser et al. 2011). As noted in the publication, the upper end of the range to which the adjustment is applicable is approximately 25 ppm, and it is unknown if the adjustment is appropriate for concentrations greater than 25 ppm, which were found during the first survey of mixers (p. 69 of HHE Report 2000-0401-2991). This is another example where historical exposures to mixers may have been underestimated.

Despite these fundamental uncertainties, the draft criteria document barely addresses the uncertainty and/or sensitivity of the assumptions used.

- Section 5.5 of the draft criteria document is entitled “Sensitivity Analyses and Alternate Hypotheses.” This section is less than two pages and most of it addresses “alternate hypotheses” for the apparent variability in susceptibility in a subset of the index plant workers. Regarding their sensitivity analysis, NIOSH simply states:

“NIOSH evaluated many different statistical models and procedures using continuous and discrete 20 outcomes based on different definitions of impairment, different exposure metrics, and data from 21 different plants. For Company G [index plant], the risk estimates are surprisingly similar for the different 22 modeling approaches and the diacetyl levels estimated for a given level of life-time prevalence or 23 risk are generally pretty close, within an order of magnitude.” (p. 133)

No further explanation or discussion is provided to allow the reader to understand what was done and/or which assumptions were most sensitive.

- NIOSH provides no discussion as to why the exposure estimates were based solely on its own data, even though NIOSH acknowledges and discusses other worker exposure data (e.g., Lockey et al. 2009) in an earlier chapter of the draft criteria document.
- Based upon NIOSH’s own data, engineering controls added to the mixing room also impacted other areas of the plant clearly indicating that diacetyl exposures across this entire plant were influenced by activities in the mixing room. These observations further support the difference between the index plant and other microwave popcorn plants and, especially, other food manufacturing facilities.

7. The risk assessment does not seem relevant to the food industry. The lack of cases of significant lung decrement and/or bronchiolitis obliterans versus what would be predicted by NIOSH’s risk modeling supports the risk assessment is faulty.

As noted in Comment #2 above, cases of significant lung decrement and/or bronchiolitis obliterans have not been observed in the food industry as a whole despite widespread and long-term exposure to low, naturally-occurring levels of diacetyl for decades or even centuries. This apparent disconnect may be explained by one or more of the following:

- NIOSH’s estimates of cumulative exposure used in the risk assessment are significantly underestimated, especially for the higher-exposed workers, such that the risk is significantly overestimated.

- By its own admission, the health effects data upon which the draft REL is based may be unreliable. NIOSH asserts in the draft criteria document that, “Spirometry testing was performed following ATS [American Thoracic Society] guidelines” (p. 118); however, in the actual HHE report, NIOSH acknowledges that, “Most tests could not be assessed with regard to quality because a sufficient number of force expiratory maneuvers were not recorded during the test. A minimum of three satisfactory maneuvers are necessary to comply with ATS criteria for standardization of spirometry ... Without high quality data, interpretation of lung function changes over time may not be valid (i.e., changes in test values may be due to test performance and not actual changes in lung function)” (p. 11 of HHE Report 2000-0401-2991).
- NIOSH’s proposed REL is intended to equate to less than one-in-one thousand risk of lung function decrement; however, this level is far outside of the observable range and is dependent on low-dose extrapolation that ignores the possibility of a threshold suggested and supported by other publically available data. For example, Lockey et al. (2009) did not observe lung function decrements below a cumulative exposure of 0.8 ppm-years.

As noted in Chapter 6 of the draft criteria document (Quantitative Risk Assessment Based on Animal Data), Toxicology Excellence in Risk Assessment (TERA) conducted a quantitative risk assessment based on animal data as the basis of a recommended occupational exposure limit (OEL) of 0.2 ppm. This analysis has since been published by Maier et al. 2010. NIOSH conducted a similar analysis, relying on the same study (Morgan et al. 2008) and making identical or similar assumptions. The primary difference between the two analyses is the target risk level. NIOSH again targeted a theoretical risk level of less than one in one thousand, which required extrapolating far outside the observable range. Conversely, Maier et al (2010) followed established EPA methods for benchmark dose modeling (utilizing EPA’s Benchmark Dose Modeling software), identifying a concentration predicted to result in effects in 10 percent of the population, and then applying an uncertainty factor. The rationale for the conservative approach taken by NIOSH requiring considerable extrapolation of potentially unreliable data is not clear and is not justified based upon other peer reviewed investigations of this issue (Maier et al., 2010 and Lockey et al., 2009).

8. We are concerned that NIOSH has not and will not use appropriate caution when addressing the investigation of flavor exposure and the potential for development of restrictive lung disease.

NIOSH points out in Section 3.1 that “the most significant health consideration for flavoring-exposed workers is the development of lung airways obstruction. Airways obstruction is characterized by a decreased FEV1 and a decreased FEV1 to FVC ratio on spirometry testing.” It is further mentioned that the magnitude of decline in FEV1 determines the severity of the disorder. To this end, in our opinion, the peer-reviewed, publicly available science to date has been focused on trying to understand the association between diacetyl and irreversible obstructive disease (i.e., BO). It is therefore concerning to us that NIOSH appears to be emphasizing in

the Draft Criteria Document their concerns regarding decrement in lung function associated with diacetyl exposure based solely on a decrease in FEV1 < LLON as opposed to using the definition of FEV1 < LLON and FEV1/FVC < LLON. Using this less specific definition (FEV1 < LLON) allows for an inappropriately broader "pull of cases" into consideration which includes restrictive disorders. We recognize that NIOSH wants to ensure a broader spectrum of potential health effects is included, but are concerned that the Draft Criteria Document could be misinterpreted if other confounding factors in the workplace that could lead to a false association of flavors with restrictive disorders are not considered when assessing risk. Further concerning to us is that NIOSH incorrectly cites (p 114) the work of Lockett et al., 2009, in support of a statement that "diacetyl may cause restrictive ventilatory impairment". We have reviewed this paper and, although there is a borderline loss in FVC (Table 4), the authors note in the manuscript that this is not statistically significant. Thus, despite NIOSH noting that 1) poor quality spirometry can lead to the finding of a restrictive abnormality because the test subject did not exhale long enough during the maneuver (p 280), and 2) a future research need is to determine whether "... the spectrum of diacetyl-related lung disease include restrictive lung disease" (page 306), NIOSH proposes that restrictive abnormalities be further investigated in medical surveillance programs. This is inappropriate because the chance of false positives for this endpoint is likely high and NIOSH itself by identifying the research need is not convinced an increase in risk of developing restrictive disease is associated with exposure to flavors. Thus, NIOSH must proceed with extreme caution when alleging that diacetyl and flavor exposures may lead to restrictive disorders to avoid the appearance of a biased perspective. Further we suggest that: 1) NIOSH publicly address the management of potential confounding factors related to making an association between flavor exposure and the risk of developing a restrictive lung disorder and 2) be clear that clinical signs of apparent lung restrictive disorders in workers are not to be attributed to flavor exposure based upon currently available science and other factors must be taken into consideration. For NIOSH to remain relevant, it is imperative that the organization remain objective on the science and not lead society to draw inappropriate conclusions based upon limited data.

9. We believe the above-identified concerns (low level exposure, lack of observed cases in the food production industry to date) and uncertainty in the risk assessment exposure reconstruction collectively indicates that the proposed REL is not scientifically sound or justified. These points also clearly indicate that the food industry does not fit the overall criteria that NIOSH uses to justify the need for the standard.

NIOSH begins to outline the criteria "which are often used to determine if the results of multiple studies indicate that an exposure is the likely cause of a specific health effect" on p. 82. Although these criteria—simplified in the table below—appear to meet the flavoring and microwave popcorn industries, they do not apply more broadly to the food production industry:

NIOSH Criteria	Applies to flavor industry?	Applies to microwave popcorn industry?	Applies to broader food production industry?
Exposure precedes disease development	Yes	Yes	No ^{1,2}
Disease should decline in population with cessation of exposure	Yes	Yes	No
Strength of Association	Yes	Yes	No – how can this be evaluated without a clear association?
Replication of findings	Yes	Yes	No
Dose-Response	Yes ³	Yes ³	No ² Industry falls into low end of exposure – if response is considered irritation and decline in lung function, confounders need to be considered
Consideration of alternate explanations	NIOSH concludes in the report “Analyses of data from workplace medical and environmental surveys revealed a strong, consistent association of the disease with diacetyl manufacture, use of diacetyl in flavoring production and use of diacetyl containing butter flavoring in microwave popcorn production.”		Note that <u>the food industry is not mentioned</u> in the concluding statement regarding consideration for alternate explanations.

- 1 Further support for this can be found in Table 3 in the NIOSH draft criteria document where the literature pertinent to health effects is summarized. The examples related to food production (discounting microwave popcorn) concluded no evidence of disease (work related obstruction) associated with exposure.
- 2 If one considers lung function decrement as the disease development endpoint specific to diacetyl exposure, then one must consider the great likelihood for confounding factors. There are clearly other food additives that workers in the food industry would likely handle that, if handled under unsafe conditions, could compromise lung function (e.g., enzymes, allergens, nuisance dusts). Thus, shortness of breath, work-related asthma and mucous membrane

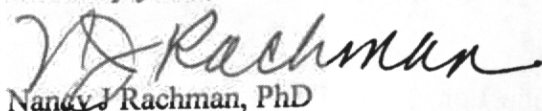
- irritation as endpoints of concern specific to diacetyl are easily confounded by these substances that occur commonly in the food production workplace that must be taken into consideration.
- 3 See concerns with uncertainty raised in point #6 above

In conclusion, we are confident, based on an independent review of the available data, that the proposed REL is not scientifically sound and does not stand up to peer review scrutiny. We agree there is a need for a base set of management principles. Available data indicate that low levels of diacetyl can be handled safely in food manufacturing and thus that diacetyl may be a better alternative to using high levels of potential substitutes. Given the current uncertainties we have identified in the exposure assessment combined with the other concerns identified above a more sensible approach would be to either:

- 1) Adopt, as a guidance level for the food industry, the peer-reviewed, publicly available OEL approach of Maier et al, 2010, which suggests a 0.2 ppm occupational exposure limit (OEL) as an 8-hr TWA with no STEL required. Or**
- 2) Implement a performance criteria approach instead of a REL. This may include a questionnaire to help employers identify workers at higher risk. To that end, many of our members have found the FEMA, NIOSH and OSHA guidance documents to be helpful in applying administrative controls to lower workplace exposure.**

We thank you for consideration of our comments.

Sincerely yours,



Nancy J Rachman, PhD

Senior Director of Science Policy, Chemical Safety

REFERENCES

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ATTACHMENT I

**Proposed modifications to Table 2
in the Draft Criteria Document**

Report	Food Type	Controls	Job Title	Sample Range (ppb)	TWA for Shift (ppb (hrs))	Range of LOQ (ppb)	Additional Comments
OSHA A (ERG 2008a)	Coffee	Dilution ventilation	Flavoring Worker #1	11-54	24 (6.8)	3-23	
			Flavoring Worker #2	14-28	28 (3.7)	3-10	
			Flavoring Worker #3	1	1 (1.9)	6	<LOQ
			Packaging Worker	ND-32	32 (4.2)	3-9	
			Sanitation/Housekeeping Worker	ND-1	ND (4.2)	3-9	<LOQ
			Maintenance Worker	ND-3	3 (5.7)	3-49	<LOQ
			Area - Flavor Storage	ND-35	Area sample	4-11	
			Area - Flavor Room	ND-11	Area sample	4-16	
			STEL (31 min) - Flavoring Worker #1	8	NA		
			OSHA B (ERG 2008b)	Commercial bakery	Dilution ventilation, LEV, process containment	<i>Unbaked Dough Product Line</i>	
Package (Container) Sealing Operator	106-425	266 (4.1)				3	
Production Relief Worker	ND-366	183 (2.7)				5-14	
Line Attendant	225-274	250 (3.5)				3-14	
Packing Operator	251-308	280 (4.2)				4-14	
Mixer Operator	183-609	396 (4.4)				4-9	
Area - liquid mixing cart	444-483	Area sample				7-20	
STEL (16-38 min) - Mixer Operator	309-334	23-148					
<i>Solid Food Product Line</i>							
Fill Station Operator	359-854	599 (8.9)				2-10	
Packaging Operator (box marker)	219-636	425 (7.9)				3-12	
Blender/Line Operator	887-1751	1282 (9.2)				3-10	
Sanitation Worker	59-60	59 (1.8)				9-25	
Area - Near Fill Station	ND-797	Area sample				3-12	
Area - Near Glycol Drum	979-1012	Area sample				3-6	
Area - Outside Solid Food Product Line Door	25-28	Area sample				4-21	
Area - Back Wall	55-58	Area sample				10-31	
STEL (28 min) - Blender/Line Operator	2702	36-70					

Report	Food Type	Controls	Job Title	Sample Range (ppb)	TWA for Shift (ppb (hrs))	Range of LOQ (ppb)	Additional Comments
OSHA C (ERG 2008c)	Seasonal snack product	No limit of detection was reported	Production Worker A	ND	ND (1.9)	29	
			Production Worker B	ND	ND (4)	15-38	
			Area - Packaging Room	ND	Area sample	15	
			STEL (15 min) - Production Worker A	ND		124	<LOQ
OSHA D (ERG 2008d)	Baked snack food	Secondary heat ventilation for heating & dumping	Production Operator A	6-164	30 (7.7)	16-59	
			Production Operator B	ND	ND (7.7)	18-34	<LOQ
			Bystander	ND	ND (6.7)	18-1017	<LOQ
			Area - Oven	ND	Area sample	18	<LOQ
			Area - Packaging	ND	Area sample	13	<LOQ
			Area - Flavor Room	111	Area sample	18	
			Area - Q/A Laboratory	ND	Area sample	18	<LOQ
			Area - Control Station	11	Area sample	19	
			STEL (15-25 min) - Production Operator A	ND-139		76-124	
			STEL (30 min) - Production Operator B	ND		56	<LOQ
OSHA E (ERG 2009a)	Sauce production	Engineering controls for other purposes, heat removal, etc.	Sauce 1: Blender Operator 1	ND-2.2	1.6 (7.3)	1.6-3.1	
			Sauce 1: Blender Operator 2	ND-5	1.8 (7.5)	1.5-3	
			Sauce 1: Production Operator (Heated Process)	ND	ND (7.1)	1.3-5.1	<LOQ
			Sauce 1: QA Lab Technician 1	ND	ND (2.9)	1.5	<LOQ
			Sauce 1: Area - Packaging	ND	Area sample	2.7	<LOQ
			Sauce 1: Area - Blender	2.2-2.4	Area sample	1.2-1.4	
			Sauce 2: Mixer Operator 1	2-5.3	3.7 (7.3)	1.3-4.6	
			Sauce 2: Mixer Operator 2	2.4-2.8	2.6 (6.3)	1.4-1.5	
			Sauce 2: Packaging Operator	ND	ND (7.1)	1.3-5.2	<LOQ
			Sauce 2: QA Lab Technician 2	ND	ND (7)	1.2-5.9	<LOQ
			Sauce 2: Sanitation Worker 1	ND	ND (5.5)	1.5-5.1	<LOQ
			Sauce 2: Sanitation Worker 2	ND	ND (6.4)	1.2-1.6	<LOQ
			Sauce 2: Area - Packaging	ND	Area sample	1.5	<LOQ
			STEL (15 min) - Sauce 2: Mixer Operator 1	9.4-11		8.9-9.4	
			STEL (15 min) - Sauce 1: Blender Operator 1	ND		9.2	<LOQ
			STEL (17-18 min) - Sauce 1: QA Lab Technician 1	ND		7.9-8.6	<LOQ

Report	Food Type	Controls	Job Title	Sample Range (ppb)	TWA for Shift (hrs)	Range of LOQ (ppb)	Additional Comments
OSHA F (ERG 2009b)	Low-calorie cracker	Canopy hood in heated production process #1, dilution ventilation	Mixer/Blender Operator 1	54-196	122 (8.1)	1.4-2.7	
			Mixer/Blender Operator 2	123-146	136 (6.2)	1.2-1.8	
			Observer	30-32	31 (6)	1.7	
			Production Operator (Heated Process #1)	4.4-10	7 (8.3)	1.5-2	
			Packaging Operator	ND-6	0.01 (8.4)	1.4-1.6	
			Area - Heated Process #1	13	Area sample	1.4	
			Area - Heated Process #2	ND	Area sample	1.3	<LOQ
			Area - Surface Coating	4.5	Area sample	1.3	
			STEL (15 min) - Mixer/Blender Operator 1	201-222		6.8-7.5	
			STEL (15 min) - Mixer/Blender Operator 3	701		4.7	
OSHA G (ERG 2009c)	Buttered popcorn production	Before: Heat extraction hoods, dilution ventilation	Production Supervisor	51-71	59 (8.4)	1.5-1.9	
			Production Worker 1	44-57	48 (7.9)	1.4-1.9	
			Production Worker 2	25-61	37 (7.9)	1.6-2.8	
			Production Worker 3	42-47	45 (8.1)	1.5-2.1	
			Area - Butter Kettles	102	Area sample	1.3	
			Area - Tumbler Mouth	8660	Area sample	1.4	
			Area - 50 ft from Butter Kettles	46	Area sample	1.5	
			Area - QA Laboratory	9.1-93	Area sample	1.5-3.3	
			Area - Packaging	3.5	Area sample	1.5	
			Area - QA Office	2.1	Area sample	1.3	
			Area - Employee break room	ND	Area sample	1.3	<LOQ
			Area - Maintenance Shop	ND	Area sample	1.4	<LOQ
			STEL (15 min) - QA Laboratory Technician	2299		6.7	
			STEL (15 min) - Product Supervisor	467-519		7.3-7.7	

Report	Food Type	Controls	Job Title	Sample Range (ppb)	TWA for Shift (ppb (hrs))	Range of LOQ (ppb)	Additional Comments
OSHA G (ERG 2009c)	Buttered popcorn production	After: Dilution ventilation in production areas, slot hood over tumbler, QC after work practice change	Production Supervisor	ND	ND (8.3)	2.7-3.5	<LOQ
			Production Worker 1	ND	ND (5.4)	3.2-3.4	<LOQ
			Production Worker 2	ND	ND (7.2)	3.1-4.1	<LOQ
			Production Worker 3	ND	ND (6.5)	3.1-9.8	<LOQ
			Area - Butter Kettles	ND-5.4	Area sample	2.3-2.7	
			Area - Tumbler Mouth	ND-2.7	Area sample	2.3-2.9	
			Area - 50 ft from Butter Kettles	ND	Area sample	3	<LOQ
			Area - QA Laboratory	ND	Area sample	3.1	<LOQ
			Area - QA Office	ND	Area sample	2.5	<LOQ
			STEL (15 min) – QA Laboratory Technician	13-99		11	
STEL (15 min) – Product Supervisor	ND-12		10-11				
OSHA H (ERG 2009d)	Sour cream production	Exhaust ventilation for dust	Mixer Operator - Day 1	ND-32	ND (7.6)	1-1.4	
			Mixer Operator - Day 2	ND-28	11 (7.5)	1-1.3	
			Area - Fill Room	4.6	Area sample	1.1	
			Area - Near Additive Tote	ND	Area sample	1	<LOQ
			Area - Control Room	2	Area sample	0.9	
			Area - Employee Break Room 1	ND	Area sample	1.4	<LOQ
			Area - Employee Break Room 2	ND	Area sample	1.3	<LOQ
			STEL (15 min) – Mixer Operator – Day 1	8.9-118		3.3-4.6	
			STEL (15 min) – Mixer Operator – Day 2	33-139		4.4-4.7	
			STEL (15 min) – QA Laboratory Technician	ND		4.5	<LOQ
OSHA I (ERG 2009e)	Ice cream	Controls for other mechanisms, submerging water bath, dilution ventilation	Batch Mixer	ND-1.6	0.63 (7.6)	1.1-1.9	<LOQ
			Area - Ice Cream Filling	ND	Area sample	1	
			STEL (15 min) – Batch Mixer	ND		3.9	<LOQ

Report	Food Type	Controls	Job Title	Sample Range (ppb)	TWA for Shift (ppb (hrs))	Range of LOQ (ppb)	Additional Comments
OSHA J (ERG 2010a)	Cottage cheese	Dilution ventilation	Blender Operator A - Flavor Management	29-55	44 (6.6)	1.2-1.7	
			Blender Operator B - Flavor Management	NA	15 (3.4)	1.4	
			Filler Operator A - Small Pack Line	ND-4.7	3.2 (7)	1-2.1	
			Filler Operator B - Bulk Pack Line	ND-1.4	0.9 (7.1)	1-1.9	
			Bander Operator A - Small Pack Line	ND-1.7	1.2 (6.9)	1-2	<LOQ
			Bander Operator B - Bulk Pack Line	ND	1.2 (6.9)	1.1-2	
			Area - Blender	19-32	Area sample	0.9-1.3	
			Area - Small Pack Line	1.3	Area sample	1	
			STEL (15-17 min) - Blender Operator A - Flavor Management	32-317		5.7-7.1	
			OSHA K (ERG 2010b)	Food flavor production	Dilution ventilation	Batch Mixer	464-2990
Production Assistant A	185	185 (3.4)				17	
Production Assistant B	43-403	159 (9.1)				1.5-20	
Operations Manager	82-212	120 (9.2)				1.4-1.7	
QA/R&D Staff	89-163	120 (9)				1.5-20	
H&S Observer A	76-179	136 (10.3)				1.5-13	
H&S Observer B	ND-140	97 (9.7)				1.7-26	
Area - Production Room	201-382	Area sample				69-78	
Area - Warehouse I	29	Area sample				1.6	
Area - Warehouse II	35	Area sample				2.9	
Area - Sample/Lab Room	98	Area sample				1.9	
Area - Conference Room	100	Area sample				1.9	
Area - Front Reception Desk	88	Area sample				1.5	
Area - Break Room	40	Area sample				2.1	
STEL (14-15 min) - Batch Mixer	ND-12373					5.4-83	
STEL (15 min) - Production Assistant A	37-530					6-65	
STEL (15-17 min) - QA/R&D Staff	245-1004					69-98	

Report	Food Type	Controls	Job Title	Sample Range (ppb)	TWA for Shift (ppb (hrs))	Range of LOQ (ppb)	Additional Comments
OSHA L (ERG 2010c)	Retail bakery	Dilution with oven ventilation	Batch Mixer	ND-50	41 (3.8)	1.4-6.4	
			Icer	ND-4.9	2.5 (5.5)	1.7-1.8	
			Cake Decorator	ND	ND (6.1)	1.4-1.7	<LOQ
			Oven Operator	1.7-42	19 (5.4)	1.5-2	
			Area - Flavor Storage	31	Area sample	1.5	
			Area - Oven	2.2-6.6	Area sample	1.5-2.1	
			Area - Office	ND	Area sample	1.9	<LOQ
			Area - Storage Room	ND	Area sample	1.5	<LOQ
			Area - Retail Shop	ND	Area sample	2.1	<LOQ
			STEL (15 min) - Batch Mixer	ND-119		6-6.8	
			STEL (15 min) - Bench Man	45		5.9	

ND = no detectable analyte
LOQ = limit of quantitation