



July 29, 2011

ACGIH®

Attn: The Science Group
c/o Dr. Terry Gordon
1330 Kember Meadow Dr.
Cincinnati, OH 45240

Re: Comments on the American Conference of Governmental Industrial Hygienists Notice of Intended Change for Diacetyl- Publication #7NIC-185

Dear Sir/Madam:

Based in Washington, D.C., the Grocery Manufacturers Association 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 an active lifestyle.

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 ACGIH concerning the Notice of Intended Change for Diacetyl. Our comments represent the collective view of GMA and five additional associations representing the food manufacturing industry: the American Baker's Association, the American Beverage Association, the National Coffee Association, the National Confectioners Association and the Snack Foods Association.

Summary of Comments

Our collective members recognize the importance of worker safety health and support and encourage the work done by ACGIH to help industrial hygienists understand and address emerging workplace safety issues. Relevant to this recognition of ACGIH, we commented in our submission during the California rule-making on diacetyl (August 20, 2010) that compliance with an OEL, such as that prepared by ACGIH, would satisfy the requirements of the regulation. However, we are compelled to note publicly during the comment period

GROCERY MANUFACTURERS ASSOCIATION

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that the proposed OEL put forward by ACGIH either inappropriately or inadvertently omitted the latest risk assessment approach relevant to diacetyl that is available in a respected peer reviewed journal. We conclude that the ACGIH evaluation is not complete and potentially inaccurate without including this most recent risk assessment. Our rationale around these comments is addressed here in a manner consistent with the format requested as described on ACGIH website.

Executive Summary: It is our understanding that the draft documentation published and available on the ACGIH website is intended to be a critical evaluation of the scientific literature relevant to recommending a TLV. We also recognize that it has been noted by ACGIH that this TLV scientific literature summary is not an exhaustive or broad based critical review. However, in reviewing the draft TLV documentation for diacetyl (Publication #7NIC-185), we noted a key peer-reviewed publication is missing and should be taken into consideration as part of the TLV setting process. The article in reference is entitled “Evaluation of concentration-response options for diacetyl in support of occupational risk assessment” by Maier et al, 2010 (attached in Appendix A). Based upon the importance of this reference in context of the TLV setting process for diacetyl, we believe it is necessary for Chemical Substances Committee to revoke the current Draft NIC for diacetyl until this paper can be reviewed and considered in the decision making process. Once this reference is reviewed, we are confident that ACGIH will conclude that the authors of the paper are recognized for their expertise in occupational risk assessment and that they utilize modern risk assessment tools to deliver a quantitative risk analysis of the available data. The Maier et al. publication will be seen as a valuable tool in the determination of an occupational exposure level for diacetyl that will provide a health based TLV. We are further confident that ACGIH will conclude that a health based TLV is preferred over the precautionary approach put forth in the current draft that defaults to the limits of detection of the analytical methods for diacetyl.

We are confident that a reconsideration of the above mentioned reference will result in significant changes to the conclusions drawn by ACGIH. However, should ACGIH not agree a new OEL should be put forth, we recommend that the committee consider the precedent set by California State OSHA in Standard 5197 of using a trigger level of 1% diacetyl by weight in the final flavor formulation. This request is based on the evidence that all available information indicates that bronchiolitis obliterans and bronchiolitis obliterans syndrome have not been associated with processes using less than a 1% concentration of diacetyl-containing flavors even when occupational exposures have been well above the reliable limit of quantitation in air.

List of Recommendations/Actions

We recommend that the Threshold Limit Values for Chemical Substances Committee revoke the current Draft NIC for Diacetyl until the reference article (attached- Appendix A) Maier et al. 2010 entitled “Evaluation of concentration-response options for diacetyl in support of occupational risk assessment” can be given full consideration in the setting of the TLV.

As part of a reevaluation, we ask that the committee consider the potential consequences of using the limits of detection of the analytical method for a naturally occurring compound as the 8-hr TLV.

If the committee feels that either no-revaluation is necessary or, in review of the paper disagrees with the conclusion, then we would suggest that the committee consider a trigger level such as that used by state OSHA programs (ref California as described in Standard 5197 , see appendix B

Rationale –

1. We believe that as part of the literature review process used by the Chemical Substances committee, an important publication entitled “Evaluation of concentration-response options for diacetyl in support of occupational risk assessment” should have been included. This article was publicly available as of June, 2010 in the journal *Regulatory Toxicology and Pharmacology*. Of relevance also is that the authors (Maier et al.)

are well recognized across both government and industry groups for their work in modern risk assessment methods.

Some of the key points which are addressed in the above mentioned paper and that we believe are relevant to any discussion around diacetyl occupational exposure levels are as follows:

- The goals, as stated by the authors of the above mentioned paper, are clearly in line with the intent of the Chemical Substances committee's goal: "evaluate whether the database for diacetyl-related research is adequate to develop an OEL that will increase the effectiveness of risk management and if so, to provide a systematic evaluation of the data to highlight key issues for OEL development".
 - The authors further state, "We provide an issues-based discussion with the aim of informing the development of OELs by organizations and agencies charged with developing occupational risk assessments and thus contributing to improved worker safety and health."
 - The review process used in the above mentioned paper led to the conclusion that "the current data allow for the derivation of an OEL for diacetyl vapor".
 - The authors highlight areas of uncertainty and explain their thinking as they evaluated the diacetyl database. Their review leads them to the conclusion based on the currently available data at the time of an OEL recommendation of 0.2 ppm vapor as an 8-h TWA.
 - Thus, the use of a modern risk assessment process (benchmark dose methodology) indicates it is possible to develop a quantitative health based actual value as opposed to setting a precautionary default of the limit of detection which appears to be the method used by the Chemical Substances Committee.
 - This publication also supports that there is insufficient data to establish a STEL and this finding should be taken into consideration by the committee.
2. Based on our review of the draft documentation, it appears that the proposed 8hr TLV of 0.01 ppm is essentially the limit of detection of the current analytical method. This approach of controlling to the "zero tolerance" level is inappropriately conservative based upon available data and is essentially a "ban" on the use of a naturally occurring chemical in the workplace. Such an approach should only be considered with the most toxic of chemicals, yet millions of workers in the food manufacturing industry have safely handled low levels of this particular chemical for years. An approach of forcing exposure levels to the limits of detection of the analytical method will require workplaces to create complicated engineering controls to achieve these levels in environments where no risk of harm was ever shown to exist. This approach also creates uncertainty from a risk communication point of view and could also lead to unsubstantiated litigation.
 3. If the committee fails to agree with any of the above points for consideration in changing the proposed 8hr TLV then we request that the committee should at a minimum consider a 1% trigger level in line with the approach adopted by OSHA in the state of California (Standard 5197).
 - In developing its standard for diacetyl, Cal-OSHA determined that it would exclude flavors containing less than 1% diacetyl.
 - This approach is consistent with the OSHA Hazard Communications Standard, which does not require the disclosure of diacetyl levels below 1% unless the chemical manufacturer has evidence that diacetyl could be released at concentrations that could pose a risk to employees.
 4. Particulate Matter Containing Diacetyl. We would also like to raise your awareness that a number of complex flavors are in particulate form and used in a variety of products. The current proposed TLV documentation is silent as to how the Industrial Hygienist should deal with powdered flavors placing a

segment of the end users of this material at a disadvantage if the diacetyl encapsulated in these flavoring mixtures is not expected to be volatile under normal use conditions.

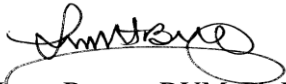
Citable Material

Appendix A – peer reviewed scientific reference: Maier A, Korhman-Vincent M, Parker A, Haber LT (2010) “Evaluation of concentration-response options for diacetyl in support of occupational risk assessment” *Regulatory Toxicology and Pharmacology* 58: 285-296.

Appendix B – Calif DA standard 5197

Thank you for your consideration of our comments on the notice of intended change.

Sincerely,



Leon Bruner, DVM, Ph.D.
Senior Vice President
for Scientific and Regulatory Affairs
and Chief Science Officer

Cosigned by:

American Bakers Association
American Beverage Association
National Coffee Association
National Confectioners Association
Snack Food Association

Appendix A-double click on icon (also attached separately)



Maier et al 2010.pdf

Appendix B – Cal OSHA standard on diacetyl (also attached separately)



Title 8, Section
5197_ Occupational E