Responses to Major Comments on Technical Support Document

Public Health Goal
For
N-Nitrosodimethylamine
In Drinking Water

Prepared by

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INTRODUCTION

The following are the combined responses to major comments received by the Office of Environmental Health Hazard Assessment (OEHHA) on the proposed public health goal (PHG) technical support document for N-nitrosodimethylamine (NDMA), based on the pre-release review draft. Changes have already been made in response to these comments, and have been incorporated into the final PHG document posted on the OEHHA website. For the sake of brevity, we have selected the more important or representative comments for responses. Comments appear in quotation marks where they are directly quoted from the submission; paraphrased comments are in italics.

These comments and responses are provided in the spirit of the open dialogue among scientists that is part of the process under Health and Safety Code Section 57003. For further information about the PHG process or to obtain copies of PHG documents, visit the OEHHA Web site at www.oehha.ca.gov. OEHHA may also be contacted at:

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RESPONSES TO MAJOR COMMENTS RECEIVED

Comments from Marvin A. Friedman, SNF Floerger

Comment 1. *Dr. Friedman presented a PowerPoint slideshow at the public workshop. A major portion of his presentation was originally presented by investigators from the U.S. EPA at the 2005 Meeting of the Society of Risk Analysis (Fristachi and Rice, 2005). An abstract of this research is available but details of the investigation are only in a paper that is currently "in press" (not yet published). The EPA investigators evaluated various sources of exposure to NDMA, and concluded that drinking water represents a very small fraction of the average overall exposure to NDMA.*

Response 1. The exposure section of the draft document was expanded to discuss the contribution of drinking water to overall exposure to NDMA. The analysis in IPSC (2002) and information in the abstract of Fristachi and Rice (2005) that was the subject of their presentation was added to the exposure section. Because details of the exposure analysis were not provided and are not yet published, the exposure discussion is still quite brief.

Comment 2. *Dr Friedman recommended:* "Although the mathematics appears correct to calculate the risk, care should be taken to insure the application of this standard is restricted to levels at the tap water and not to all surface water…" and "Application of this PHG to applications such as ground water recharge and the outflow from [waste treatment plants] is wholly inappropriate and not cost effective."

Response 2: The PHG was developed to address exposure to chemicals in drinking water, and is based solely on considerations of public health. As a public health guidance criterion, it can be considered by other agencies as they deem appropriate or useful. The actual regulatory level for drinking water, the Maximum Contaminant Level, or MCL, is set by the Department of Health Services Division of Drinking Water and Environmental Management (DHS DDWEM). Cost and technical feasibility are considered by DHS in setting the standard, in addition to the health goal. No changes to the PHG document were made in response to this comment.

Comment 3. "Changing the current action level to the PHG is not warranted at this time."Response 3. DHS requested OEHHA to develop a PHG for NDMA, for their use in developing a California MCL. The action level (now known as a notification level) is an interim criterion, which will be superseded by the MCL. Public comments on the draft regulation will be invited by DHS during that rule-making process. No changes to the PHG document were made in response to this comment.

Comments from Bruce Bingham, Ciba Geigy

Comment 1. *Mr. Bingham indicated that he was at the public workshop because Ciba Geigy manufactures polymers used in water treatment plants, which have been considered by some authors to be a source of NDMA or contribute to NDMA formation. He was therefore interested in the process for development of the NDMA standards applicable to drinking water.*

Response 1. No changes to the PHG document were made in response to these comments.

Comments from Dick Wilson, Environmental Services Manager, Anaheim Public Utilities Department

Comment 1. "I question the value of the proposed PHG for NDMA. Various reports indicate that NDMA levels in milk and cured meat are orders of magnitude higher than the proposed PHG for NDMA in drinking water. Isn't a PHG irrelevant when a person's typical exposure to a substance exceeds the exposure from drinking water at the PHG level?"

Response 1: The risk assessment of a chemical for development of a PHG is based exclusively on health considerations from exposure to the chemical. Acceptable levels for non-carcinogens include a consideration of all sources, resulting in a "relative source contribution" calculation for drinking water. For carcinogens, including NDMA, all sources are assumed to provide additive cancer risks, so a relative source contribution is not used. That is, the risk from exposure to NDMA in drinking water is independent of, but can be added to, risks of exposure to NDMA from other sources. Management of the resulting risk, including considerations of economic and technical feasibility of meeting a public health goal for total exposure, is under the regulatory control of the Department of Health Services Division of Drinking Water and Environmental Management. No change was made to the PHG document in response to this comment.

REFERENCES

Fristachi A, Rice G (2005) Estimation of the total daily oral intake of n-nitrosodimethylamine (NDMA) attributable to drinking water. Abstract W-17.1 Annual meeting of the Society of Risk Analysis, Orlando, Fl.

IPSC (2002). N-Nitrosodimethylamine. International Programme on Chemical Safety. Accessed at: http://www.inchem.org/documents/cicads/cicads/cicad38.htm [Aug 7, 2003].