Responses to Major Comments on Technical Support Document

Public Health Goal For Ethylene Dibromide In Drinking Water

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TABLE OF CONTENTS

INTRODUCTION

The following are 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 ethylene dibromide as discussed at the PHG workshop held on July 22, 2002, or as revised following the workshop. 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 U.C. Davis reviewer 1

Comment 1: *There is concern that the risk assessment is based on a study (NCI, 1978) in which the compound was delivered by gavage and tumors were found in the forestomach at the site of delivery…,use of a cancer potency factor that would have resulted in a proposed PHG that was entirely consistent with the current federal and California MCLs of 5 ppb might have been preferable in this case. The significance of finding tumors at this site, at doses higher than normally expected in drinking water, is questionable.*

Response 1: The commenter raises an issue that has been a subject of discussion in the scientific community relation to the use of rodent forestomach tumor data. We recognized that there is an inherent weakness on the data, and mentioned such in the risk characterization portion of the document. EDB is, however, a multi-organ carcinogen via both the inhalation and oral routes of administration, and OEHHA considers the rat oral data to represent a prudent, health-protective choice for this risk assessment. As discussed in the PHG technical document, the U.S. EPA (and California) MCL is 0.05 ppb based on carcinogenic hazard, limited by analytical feasibility, and it corresponds to 1.25 times the 1 x 10^{-4}risk level based on a q_1* value of 85 $(mg/kg\text{-}day)^{-1}$ derived from the NCI study (1978). The PHG is health protective at the 1 x 10-6 risk level, based on a q_1* of 3.6$(mg/kg\text{-}day)^{-1}$ from the 1978 NCI study. Consequently, the OEHHA evaluation assumes that EDB is less potent than the U.S. EPA evaluation.

Comment 2: *Was the assumed value of 152 grams appropriate for the Rowe and Spencer (1952) study?*

Response 2: As mentioned in the document, the authors did not mention the strain of rat used. OEHHA considers the assumed value for a "generic" rat in this type of study to be as appropriate as possible.

Comment 3: *Why is a LOAEL rather than a NOAEL used for the non-cancer value?*

Response 3: After further deliberations, we have changed the calculation of the health protective concentration based on non-cancer endpoint by using the slightly lower NOAEL from the study of Nitschke (1981), which resulted in a more health protective concentration of 50 ppb (changed from 150 ppb).

Comments from U.C. Davis reviewer 2

None of the comments required further explanation or revision of the PHG document. One of the full citations given as a reference was neither mentioned in the provided comments nor in our PHG technical document. The citation was for a paper by Fanini *et al.*, 1984. We have reviewed this work, in which authors studied the effects of paternal exposure to ethylene dibromide exposure on F1 generation behavior in the rat. The

usefulness of the paper is limited by the route of exposure (i.p.) as well as the lack of complete dose/response data associated with some of the behavioral assessments (e.g. swimming head angle and swimming limb movement). Thus the paper will not be used in our document.

Fanini D, Legator M, Adams P. Effects of paternal ethylene dibromide exposure on F1 generation behavior in the rat. Mutation Research, 1984, 139(3), 133-8.

Comments from the Health and Ecological Criteria Division of the Office of Science and Technology, Office of Water, U.S. EPA

None of the comments required explanation or revision of the PHG document.