Responses to Public Comments Received on the Proposition 65 Draft Interpretive Guideline: Guideline for Hand-to-Mouth Transfer of Lead Exposure from Fishing Tackle Products

Office of Environmental Health Hazard Assessment
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The Office of Environmental Health Hazard Assessment (OEHHA) released for public comment the draft Interpretive Guideline "Guideline for Hand-to-Mouth Transfer of Lead Exposure from Fishing Tackle Products" in May 2007, and held a Public Workshop on the Guideline on August 1, 2007. The table below gives the names of those commenting verbally or in writing on the draft interpretive guideline. Following the table responses to comments received are given.

Table 1. List of Commenters

Commenter No.	Commenter / Affiliation	Form of comments:
C1	W. Verick & B. Lee / Klamath Environmental Law Center representing Mateel Environmental Justice Foundation	Written and oral
C2	D. Brown, B. Callahan & A. Boissevain / Health Risk Consultants, Inc.	Written
C3	K. DiBiasio / DTSC	Written and oral
C4	A. Lawyer / Technology Sciences Group	Oral
C5	J. Vorhees of Berkeley, CA / not stated	Oral

C1

Comment #1

$L_{loading}$ should be measured as parts of the hand that are in contact with the mouth. Add clear definition of three fingertips. The contact surface area for indirect hand-to-mouth activities should be extended from three fingers to five fingers.

Response

We agree that the lead concentrations should be measured at the specific parts of the hand that are in contact with the mouth, thus the definition has clearly been stated in the document (pages 3-4 of $L_{hand\text{-}D}$ and $L_{hand\text{-}I}$). The clarification of three fingertips ("i.e. the thumbtip and two other fingertips") is added in the text. For indirect hand-to-mouth

contact surface area, we present two cases corresponding to two different exposure scenarios, one with three fingertips and the other with 90% of the palmar surface of the hand. These two cases are meant to represent the most common hand-to-mouth exposure scenarios likely to occur during recreational fishing. Therefore, no changes were made to the indirect hand-to-mouth contact surface area in the Interpretive Guideline.

Comment #2
The guideline should state that it does not address exposure in retail marketplaces to workers or consumers, or the use of fishing tackle products in artwork, jewelry or other forms of ornamentation.

Response
OEHHA has added text addressing this comment in the first paragraph of page 1 of the Interpretive Guideline.

Comment #3
The guideline should add and address scenarios that estimate the hand-to-mouth transfer for children.

Response
Lead exposure for children is important; however, this guideline is developed in the context of Proposition 65. The Proposition 65 Maximum Allowable Dose Level (MADL) is lower than the No Significant Risk Level (NSRL) for lead (i.e., 0.5 µg/day versus 15 µg/day), and the most sensitive endpoint covered by the MADL is developmental toxicity. Given that postnatal exposures of infants and children are not considered under Proposition 65 for purposes of determining whether a warning for developmental toxicity is required, this guideline focuses on exposures to women of child-bearing age, and presents scenarios that estimate the hand-to-mouth transfer of lead for women and men. The guideline does not present scenarios that estimate the hand-to-mouth transfer of lead for children, as exposures expressed in terms of µg lead/day will be smallest for children, due to the smaller surface area of a child's hand compared to an adult's).

Comment #4
Change symbols used in the formula (such as "f" for frequency not transfer factor)

Response
Each symbol has been clearly defined in the document, and OEHHA finds no compelling reasons to change the symbols used.

Comment #5
Add explanation to the formulae: $f_{indirect} = f_{direct} * (1-f_{loss})$

1. *Pb on the hands that is removed by direct hand-to-mouth activities is no longer available for indirect hand-to-mouth activities.*
2. *Pb removed from the hands is replenished by subsequent contact with leaded fishing tackle.*

3. *The total Pb exposure is a summation of direct and indirect exposure.*

Response
The statement of Point 1 is not correct. The guideline assumes that lead will be reloaded onto the hand with repetitive handling of fishing tackle after each direct or indirect hand-to-mouth activity (see text after Eq. 1b on page 5). Additional clarification on Point 1 has been added to the text.

f_{loss}, the fraction of lead mass loading lost during the intermediate steps, is intended to capture the overall mass loss between the hand and the mouth for indirect hand-to-mouth activities. f_{loss} is not used in the intake estimate for direct hand-to-mouth contact (i.e., no lead mass is lost between the hand and the mouth for direct contact).

Point 2 has been added to the text.

Point 3 was already stated in the guideline (see last formula on page 5); no changes were made as a result of this comment.

Comment #6
The 50% hand-to-mouth transfer factor used by CPSC and EPA continues to be accepted when no situation-specific data is available. It is agreed that 50% is consistent with data from studies mentioned by OEHHA. Data on pesticides may not be appropriate for lead exposure from fishing tackle products. Due to pesticide formulation adherence and pesticide skin permeation, 50% may be expected to underestimate the hand-to-mouth transfer and should be considered as the minimum amount that would be transferred from the hand to the mouth with regard to fishing tackle.

Response
It is acknowledged in the guideline that pesticides may behave differently from lead. Due to lack of lead-specific data, we have to rely on the best available data, and these currently consist of data from laboratory studies of pesticides. 50% might underestimate lead transfer, but we do not have any solid data to adjust the selected value. It is noted that the exposure time to the three pesticides in Camann's study was limited to only 10 to 20 seconds, thus the impact of pesticide permeation on the data of Camann et al. may be minimal. (Quoted from page 3 of Camann's report: "Saliva-moistened wipes of each test hand were performed and these hand wipes commenced between 10 seconds and 20 seconds after the press transfer of pesticide residue from the foil to the hand had been completed.")

Comment #7
The adult contact frequency of 9/hr would be reasonable for direct hand-to-mouth activities.

Response
Comment acknowledged.

Comment #8
The calculation of surface area is confusing. For direct hand-to-mouth surface area contacted, it should be four fingers (thumb + 3 fingers = 50 cm^2). For indirect contact surface area (Scenario 2), please eliminate 10% reduction for hypothetically non-exposed sides of the fingers and hand.

Response
We have clarified what is meant by "three fingertips" in the text of the guideline: "three fingertips (i.e., the thumbtip and two other fingertips)." The direct hand-to-mouth contact surface area in the Interpretive Guideline is based on the assumption that three fingertips will come in direct contact with the mouth. This assumption is used to represent the average direct hand-to-mouth contact situation. Each fingertip is assumed to be 30% of the surface area of the finger, not two-thirds of the finger, as stated in the submitted comments. For the indirect contact surface area, we assume that only 90% of the palmar surface area is in contact with the intermediate object based on the scenario of holding a large food item such as an apple or a sandwich. Using 100% of the palmar surface as the contact surface area would represent an extreme case, whereas 90% of the palmar surface is more representative of the most likely situation.

Comment #9
The assumption of 4 hr of fishing per day would be reasonable for adults. Fishing duration for children may be 2 hours. However, the duration for an accompanying adult should be extended 1 hour due to assisting in the setup, adjustment and takedown of the child's tackle.

Response
OEHHA is not proposing a default value for fishing duration. The four hours per fishing trip cited by the commenter was only included in the guideline as part of a hypothetical example to explain how to calculate the total lead intake in a hypothetical fishing trip. Additional clarifying language has been added to the guideline stating this.

Comment #10
The formula and the factors are the right ones to consider. The empirical work this draft guideline bases its hand-to-mouth transfer factor on is thin. It is suggested that there is not adequate empirical information available to issue this interpretive guidelines if the same scientific maxim for safe harbor number development has been applied (the 22 Cal. Code Regs. Section 12701(a), "the determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purpose of Health and Safety Code Section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as know to the state to cause cancer.")

Response
OEHHA does not agree with the general statement that there is not adequate empirical information available to issue the Interpretive Guideline, but does agree that there is limited empirical data on which to base some of the parameters covered in the guideline.

This does not include all parameters, as the surface area of hands is known, nor does it include the formula which all commenters have stated are reasonable models for intake estimate. It is important to note that this guideline applies to the exposure assessment, not chemical listing for Proposition 65 nor the establishment of safe harbor values. The quoted regulation applies to safe harbor development. This Interpretive Guideline provides guidance for reasonable parameter values to select because there is so much uncertainty. This approach is consistent with the 1994 National Academy of Science report "Science and Judgment in Risk Assessment." This commenter indicated at the workshop that the factors and formula "are generally the right ones to consider" and that the draft Interpretive Guideline represents "a fairly good approach." The commenter raised specific issues regarding certain parameters and these are addressed in responses above.

C2

Comment #1

We agree with the HTM scenario selected and would like to see its application to other hand-to-mouth exposures.

Response

The basic concept and formula structure for exposure assessment provided in this Interpretive Guideline may be applied, with appropriate modifications, to other hand-to-mouth exposures, but it would be inappropriate to apply the specific values selected for the several parameters listed on page 14 of the guideline to other hand-to-mouth exposures. Thus, the use of this Interpretive Guideline should be restricted to the hand-to-mouth transfer of lead exposure from fishing tackle products, as used in recreational fishing. Additional text has been added to the guideline on this issue.

Comment #2

The summary list of selected values of defaults on page 14 needs to be reconsidered. It is not public health-protective to only consider the average exposures. Standard deviation should be added to the average as an upper bound estimate to capture the variability.

Response

We agree that the average is not sufficient to represent the overall distribution of exposures. However, this Interpretive Guideline is developed under the context of Proposition 65, where exposures to consumer products are calculated using the average rate of intake or exposure for average users of the consumer product (Title 22, Cal. Code of Regs., sections 12721(d)(4) and 12821 (c)(2)). No changes were made to the guideline.

Comment #3

The values from pesticide studies may not be representative of the exposures for lead. It is suggested that the mean value plus the standard deviation be used in those cases where there is sufficient sample size to stabilize the variance estimate.

Response
See responses to C1's comment #6 and C2's comment #2 above. No changes were made to the guideline.

Comment #4
Some scoping tests are needed to collect data to estimate the indirect pathway (such as the example given in Figure 1; wiping hands on the pants and then wiping an apple on the pants and subsequently eating the apple).

Response
Comments acknowledged. We agree that more research needs to be done to collect empirical data to better characterize hand-to-mouth exposure. Default values will be modified when new relevant data become available.

Comment #5
A systematic effort is needed to identify the variability of lead in the various (and specific) areas of contact. The different components of fishing tackle potentially contain different levels of lead. The use of a frequency scenario that includes areas that would be more commonly and more frequently touched or handled by fishers would be sounder than the application of the aggregated average of fishing tackle. It is suggested that a sensitivity analysis should be conducted to identify the areas of greatest contribution to the variability of the estimation of human lead exposures.

Response
Development of this guideline, which aggregates hand-to-mouth lead exposure from fishing tackle using various scenarios (i.e., direct and indirect hand-to-mouth contacts; scenarios 1 & 2) was challenging, given the very limited nature and extent of the relevant data available. Conducting the suggested sensitivity analysis would require even more specific and detailed data, which are not currently available.

C3
Comment #1
Use 4/hr for direct hand-to-mouth contact frequency based on data of 6-11 year olds in the U.S. EPA external review draft of Child-Specific Exposure Factors Handbook (2006). The contact frequency of 9/hr used in the Interpretive Guideline is high, and it is not appropriate to assume a small child and an adult have the same kind of indirect hand-to-mouth activity.

Response
Note that 9/hr is selected in this Interpretive Guideline as the direct hand-to-mouth contact frequency, not the indirect hand-to-mouth contact frequency. The value of 9/hr is selected based on the following considerations: the available hand-to-mouth contact frequency data, which are presently limited to studies conducted in children, the assumptions used by Cherrie et al. (2006) for adults in two occupational settings, and the more relaxed atmosphere associated with recreational fishing and the types of activities

(e.g., eating, drinking) likely to occur during recreational fishing. Seven of the eight studies in Table 2 have average hand-to-mouth contacts per hour higher than the value assumed here for adults; thus, the value for λ_D should not be construed as the adoption of a child specific value for adult use. The value suggested by the commenter of 4/hr for direct hand-to-mouth contact frequency is based on a study of nine children, aged 6-11 years (Freeman et al., 2001) in residential setting. It would not be appropriate to select this value of 4/hr, based on this single study of nine children in Minnesota, to represent the direct hand-to-mouth contact frequency for recreational fishers. No changes were made to the guideline's selection of 9/hr as the direct hand-to-mouth contact frequency.

Comment #2
Recommend to use 34 cm^2, instead of 17 cm^2, for the hand surface area for direct hand-to-mouth contact because if someone is going to lick their fingers or bite their nails, it's not just the front surface but both surfaces.

Response
The selected value of 17 cm^2 is the surface area of three fingertips on the palmar surface of the hand. No changes were made to this selection, for the following reasons. First, the palmar side of the hand has much higher potential to be exposed to lead from fishing tackle than the other side of the hand. Second, the other side of the hand is not likely to have significant lead loading from handling tackle. Third, it is not likely that fishers will contact more than the palmar surface of three fingertips in direct hand-to-mouth contacts, except under the situation of nail-biting. For nail-biting, while much of the fingertip, including the nail surface (i.e., the non-palmar surface) could be in contact with the mouth, the total contact area could be less than 30% (e.g., 10% or less) of the palmar finger surface area during each direct hand-to-mouth contact event.

Comments #3
The contact surface area for direct hand-to-mouth activities, i.e., 17 cm^2, is less than the U.S. EPA (2001) recommended surface area of children's hands involved in hand-to-mouth contact, 20 cm^2. The appropriate comparator between children and adults would be percentage or proportionality of contact surface area with respect to total hand surface area.

Response
We do not agree that both children and adults have the same percentage of body surface area for hand-to-mouth contacts. Behavior patterns are different for children and adults. Children, especially toddlers, may put their partial or even whole hand into their mouth, but adults are less likely to do so. The selected value is based on the scenario of touching/licking three fingertips for recreational fishers, a reasonable assumption for adults. No changes were made to the guideline.

Comments #4
Verify the U.S. EPA (2001) citation: Science Advisory Council for Exposure. Policy Number 12 on Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments.

Response
The citation is correct. The electronic version of the reference has been sent via email to the commenter.

C4

Comment #1
Do we assume fairly periodic contact with the tackle using the formula presented in the document?

Response
Yes, we assume that lead loading on the hand would reoccur every time a fisher touches the tackle because fishing involves repetitive handling of the tackle product. This assumption applies to both direct and indirect hand-to-mouth activities, as explained on page 5 of the guideline document.

Comment #2
Add language saying why the Interpretive Guideline is limited to fishing tackle only, either because of legal ramification or scientific reasons.

Response
The Interpretive Guideline is limited to the hand-to-mouth transfer of lead from the use of fishing tackle in recreational fishing because it was developed specifically for this exposure scenario. Hand-to-mouth transfer of lead from an object will vary, depending upon the use patterns and exposure scenario. Additional language addressing this has been added on page 16 of the revised document.

Comment #3
The Interpretive Guideline is an elegant paper presented in a nice orderly way of taking the concept of hand to mouth into some elegant mathematical treatments. This is helpful for people working with Proposition 65.

Response
Comments acknowledged.

Comment #4
In the workshop, Commenter 4 (C4) asked several questions, including how U.S. EPA addresses the hand-to-mouth exposure. These questions and comments that are not directed to changes in the Interpretive Guideline are not addressed in this response to public comments.

C5

Comment #1

Agrees that the method quite possibly can be applied to different products, but variables which are inserted into the equations are clearly limited to fishing tackle.

Response

Comments acknowledged. See response to C2's Comment #1 above.

Comment #2

There should be some consideration for use of a standard deviation for the variables, rather than just using the averages, to protect perhaps a smaller portion of the population, but one that clearly exists.

Response

This guideline is developed under the context of Proposition 65, and thus is focused on estimating the exposure of the average user/consumer. No changes were made to the guideline text.