Proposition 65

Interpretive Guideline No. 2011-001

Guideline for Hand-to-Mouth Transfer of Lead through Exposure to Consumer Products

May 2011

**Reproductive and Cancer Hazard Assessment Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency**

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Executive Summary

This interpretive guideline provides general scientific guidance on how to estimate lead intake arising from the handling of consumer products in the context of Proposition 65[1]. It builds upon the approach developed previously by the Office of Environmental Health Hazard Assessment (OEHHA) for calculating the intake of lead from the handling of fishing tackle products during recreational fishing[2,3].

This interpretive guideline consists of a general framework for estimating the hand-to-mouth transfer of lead, in the form of equations and guidance on the selection of representative values for the parameters used in these equations.

Specifically, total lead intake for hand-to-mouth activity ($Intake_{HM}$) is given by:

$Intake_{HM} = Intake_{HM\ direct} + Intake_{HM\ indirect}$

where

- $Intake_{HM\ direct}$ is the lead intake from directly handling the product containing lead and then touching the mouth. This can be calculated from the following equation:

$$Intake_{HM\ direct} = L_{hand-D} \times SA_D \times f_{direct} \times \lambda_D \times t \qquad \text{(Equation 1)}$$

   where

   - L_{hand-D} represents the lead loading on the part of the hand touching the mouth.
   - SA_D represents the surface area of the part of the hand in direct contact with the mouth.
   - f_{direct} represents the direct hand-to-mouth transfer factor. A default value for this parameter is 0.5.
   - λ_D represents the hourly rate of direct hand-to-mouth contact.
   - t represents the average number of hours during the day that a given consumer product is used.

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[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified as Health and Safety Code section 25249.5 *et seq.*
[2] Proposition 65 Interpretive Guideline No. 2008-001. Guideline for hand-to-mouth transfer of lead through exposure to fishing tackle products.
[3] OEHHA acknowledges and remembers the late Dr. James Embree, and his contributions to the field of exposure assessment. He worked on the issue of lead exposure resulting from the use of fishing tackle products.

- *Intake$_{HM\ indirect}$* is the lead intake from handling the lead-containing product and then handling and depositing lead on an intermediate item (*e.g.*, food) and then eating or touching the mouth with that item. This can be calculated from the following equation:

$$Intake_{HM\ indirect} = L_{hand-I} \times SA_I \times f_{indirect} \times \lambda_I \times t \qquad \text{(Equation 2)}$$

where

- L_{hand-I} represents the lead loading on the part of the hand touching the intermediate object(s).
- SA_I represents the surface area of the hand in contact with the part of the intermediate object(s) reaching the mouth.
- $f_{indirect}$ represents the indirect hand-to-mouth transfer factor. A default value for this parameter is 0.25.
- λ_I represents the hourly rate of indirect hand-to-mouthed object contact.
- t represents the average number of hours during the day that a given consumer product is used.

Specific default values are provided for two parameters in the above equations (f_{direct} and $f_{indirect}$), and not for others. This is because there are a wide variety of lead-containing consumer products, involving many different use scenarios. This guideline recommends parameter values be assigned considering characteristics of the product, such as leachability of lead from the product over time. Use scenarios should also be considered, including the population coming in contact with the product (*e.g.*, children, infants) and the microenvironment of use (*e.g.*, schools, hobby in home).

Scope of Interpretive Guideline

This interpretive guideline is intended for use only in the context of calculating lead exposure by the hand-to-mouth pathway, for purposes of compliance with Proposition 65. It applies only to the transfer of lead from the hand(s) to the mouth, as a result of the handling or touching of a consumer product.

This interpretive guideline does not address other possible pathways of lead exposure from consumer products, which must also be considered for purposes of compliance with Proposition 65, such as direct-mouthing of the product, direct ingestion of the product, ingestion of food or beverages stored or served in the product, and inhalation and dermal absorption of lead originating from the product.

Lead and Proposition 65

Lead has been listed under Proposition 65 as a chemical known to cause reproductive toxicity for developmental and both male and female reproductive toxicity endpoints since February 27, 1987. The substance "lead and lead compounds" has been listed as known to cause cancer since October 1, 1992. For reproductive effects, the Maximum Allowable Dose Level (MADL) for lead is 0.5 µg/day (Title 27, Cal. Code of Regs., section 25805[4]); for carcinogenic effects the No Significant Risk Level (NSRL) for lead is 15 µg/day (Section 25705(b)).

Lead is a heavy metal that occurs naturally in the earth's crust and usually occurs as a compound in combination with two or more elements. Metallic lead is resistant to corrosion. Lead can be combined with other metals to form alloys, such as brass. Lead and lead alloys have many applications, including uses in pipes, storage batteries, weights, shot and ammunition, faucets, decorative fixtures, keys, and cable covers. Some lead compounds such as lead acetate are or have been used as pigments in paints, dyes, and ceramic glazes and in caulk. Lead is sometimes added to polyvinyl chloride (PVC) as a stabilizer (*e.g.*, artificial Christmas trees, pipes, lunch boxes). The amount of lead used in many of these products has been reduced over the years, voluntarily and by legal restrictions, to minimize adverse health effects (ATSDR, 2007).

Lead is one of the most frequently named chemicals in Proposition 65 enforcement actions and settlements. Proposition 65 actions have been prompted by findings of lead in a variety of products, including calcium supplements, china, lead glazes, leaded crystal, PVC mini-blinds, cosmetics, hair dyes, garden hoses, and hand tools. Sixty-day notices for lead and lead compounds have been issued since 2006 for a number of different types of consumer products, including glassware, ceramic products, toys, plastic baby

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[4] All further regulatory references are to sections from Title 27 of the California Code of Regulations.

bibs, jewelry, children's vinyl bags and plastic clothing, backpacks, battery cables, computer motherboards, and light fixtures[5].

Thus, a wide variety of products have been the subject of Proposition 65 actions based on lead. Some of these consumer products are designed for food contact, such as glassware and ceramic bowls and dishware, whereas others, such as light fixtures, are not. They can be used in different microenvironments and by different target consumers. For example, toys are mostly handled by babies and children whereas battery cables are handled primarily by adults. Garden hoses are typically used outdoors, whereas vinyl bean bag chairs are used indoors. An appropriate exposure assessment of the hand-to-mouth transfer of lead for any given consumer product would need to address the product's unique features, use patterns, and conditions of use by each specific type of consumer.

Lead Exposure from Consumer Products via the Hand-to-Mouth Pathway
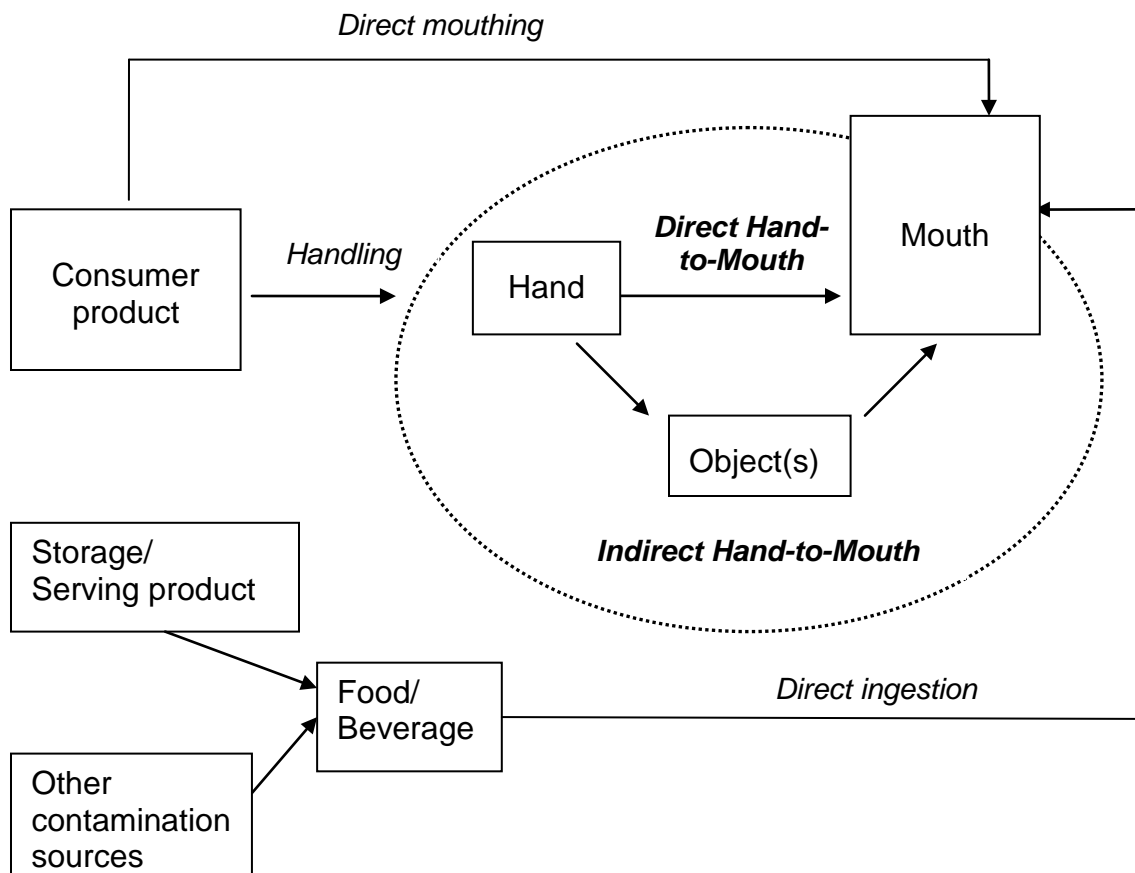
Transfer of lead from consumer products to the user by incidental ingestion may occur through three exposure pathways:

- Direct mouthing of the product
- Transfer of lead from a beverage- or food-contact product, and subsequent ingestion of the food or beverage
- Handling or touching of the product and subsequent transfer of lead via the hand-to-mouth pathway.

As noted above, the scope of this interpretive guideline is only for the hand-to-mouth pathway, as shown in the dashed oval in Figure 1. Direct-mouthing of the product is not covered in this guideline, although this exposure pathway is often very important for young children, and may also be important for other users. This guideline also does not cover ingestion of lead as a result of lead leaching into food or beverages from food- or beverage-contact products, such as tableware and food storage containers.

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[5] See the California Attorney General's Office website at
http://proposition65.doj.ca.gov/default.asp

Figure 1. Transfer pathways for incidental ingestion of lead

Direct mouthing

Consumer product → *Handling* → **Direct Hand-to-Mouth** → Hand → Mouth

Hand → Object(s) → Mouth

Indirect Hand-to-Mouth

Storage/ Serving product → Food/ Beverage

Other contamination sources → Food/ Beverage

Food/ Beverage → *Direct ingestion* → Mouth

Lead exposure from consumer products via the hand-to-mouth pathway starts with the handling of the product, during which dislodgeable lead is loaded onto the hand. Transfer of lead from the hand to the mouth may occur directly by handling the consumer product and then touching the mouth with the hand or through nail biting, finger sucking, or other direct hand-to-mouth contact. It may also occur indirectly by handling the product and then handling other materials that ultimately contact or otherwise make their way into the mouth, such as by eating food, smoking cigarettes, drinking from a straw, or chewing on a pencil. Indirect transfer may involve one or more intermediate steps or objects.

For infants and children, direct hand-to-mouth contact is an important exposure pathway. This is supported by studies of lead exposure from leaded-paint and of arsenic exposure from chromated copper arsenate (CCA)-treated wood play structures (Freeman *et al.*, 2001; Hemond and Solo-Gabriele, 2004). The hand-to-mouth exposure pathway may be especially important for toddlers, as a consequence of their increased mobility compared with infants and their more frequent hand-to-mouth activities compared with older children (Freeman *et al.*, 2001).

Lead Intake from Direct Hand-to-Mouth Contact

The intake (*i.e.*, ingestion) of lead from a single (i^{th} event) direct hand-to-mouth contact via the use of a given consumer product is a function of:

$L_{hand\text{-}D\,i}$ the lead loading on the part of the hand touching the mouth (not the loading of the whole hand), in units of weight per surface area (*e.g.*, mass of lead per surface area of the fingertip, $\mu g/cm^2$);

$SA_{D\,i}$ the surface area of the part of the hand in direct contact with the mouth (cm^2);

$f_{direct\,i}$ the direct hand-to-mouth transfer factor, presented as a fraction or percentage.

The intake of a single hand-to-mouth contact, during the ith event, can be calculated from the following equation:

$$Intake_{HM\ direct\ i} = L_{hand\text{-}D\,i} \times SA_{D\,i} \times f_{direct\,i}$$

The indicator *i* is used to denote that this is for the ith event.

There can be multiple hand-to-mouth contacts during the use of a given consumer product. Thus the total direct lead intake via the use of a given consumer product will be the sum of intake from each contact *i* during product use:

$$Intake_{HM\ direct} = \sum_{i=1}^{n} Intake_{HM\ direct\ i}$$

$$= \sum_{i=1}^{n} L_{hand\text{-}D\,i} \times SA_{D\,i} \times f_{direct\,i}$$

This expression can be simplified, using representative values for each of the parameters in the above equation, and taking into account the period over which the exposure is occurring and the number of times during that period that hand-to-mouth contact occurs. For an exposure period of one day, intake during that day can be calculated from Equation 1:

$$Intake_{HM\ direct} = L_{hand\text{-}D} \times SA_D \times f_{direct} \times \lambda_D \times t \qquad \text{(Equation 1)}$$

where

λ_D is the rate of direct hand-to-mouth contact, *e.g.*, the average number of contacts per hour during the day; and

> t is the average number of hours during the day that a given consumer product is used,

and L_{hand-D}, SA_D, and f_{direct} are as defined above.

L_{hand-D}, SA_D, and f_{direct} can take on different values each time a person contacts the product or the mouth. This reflects intra-individual variability. In addition, there are person-to-person differences, *i.e.*, inter-individual variability, for each of these parameters. In choosing representative values for these parameters, the range of values (*i.e.*, the variability) that is expected for each parameter should be taken into account.

This interpretive guideline provides Equation 1 for use in calculating lead intake from direct hand-to-mouth contact. This interpretive guideline provides a suggested value for f_{direct} of 50% as the default value. Its selection is explained later in this document. For the other parameters in Equation 1, product- and use-specific values representative of the expected values, taking into account variability, should be employed.

Lead Intake from Indirect Hand-to-Mouth Contact

The intake of lead from indirect hand-to-mouth transfer for any given consumer product is a function of t as defined above, as well as

> L_{hand-I} the lead loading on the part of the hand touching the intermediate object, in units of weight per surface area ($\mu g/cm^2$);
> SA_I the surface area of the hand in contact with material reaching the mouth;
> λ_I the rate of indirect hand-to-mouthed object contact, *e.g.*, the number of contacts per hour;
> $f_{indirect}$ the indirect hand-to-mouth transfer factor.

Analogous to direct hand-to-mouth exposure, these parameters can vary for each contact. Characteristics of the intermediate object affect the amount of lead transferred, and hence the lead intake. For example, the object's configuration, size, and condition (*e.g.*, new or aged/weathered due to sunlight or extreme heat; pH; moisture and oil content) can affect transfer of lead from the hand to an object. The condition of the individual's hands (*e.g.*, dry or sweaty) and the amount of pressure applied by the hand to the object during contact will also affect the transfer. For example, the amount of lead reaching the mouth through indirect hand-to-mouth activities may differ between eating an orange, which has a pH ≈ 4, and eating a sandwich with a large and moist surface. In the case of the orange, the lower pH may favor the transfer of lead from the hands. In the case of the sandwich, moisture may favor the transfer of lead from the hand, and the large surface may favor a larger hand to object contact surface area. A still different amount of lead may reach the mouth through indirect hand-to-mouth

activities associated with eating oily foods such as chips, where the oily surface may affect the transfer of lead from the hand and may favor a reduction in the hand to object contact surface area (*e.g.*, use of fingertips only).

The intake of lead during use of a given product from indirect hand-to-mouth contact will be the sum of intake from each indirect contact *i* during use of a given product, as given by:

$$Intake_{HM\ indirect} = \sum_{i=1}^{n} L_{hand\text{-}I\ i} \times SA_{I\ i} \times f_{indirect\ i}$$

Individuals may be exposed through their own handling of an object, as well as others handling the object that is mouthed (*e.g.*, transfer of lead from one person's hands to a food item that is then shared and eaten by another).

As for direct hand-to-mouth exposures, the above expression can be simplified using representative values for each of the parameters in the equation, and taking into account the period over which the exposure is occurring and the number of times during that period that indirect hand-to-mouth contact occurs. For an exposure period of one day, intake of lead from indirect hand-to-mouth exposure for a given consumer product can be calculated from:

$$Intake_{HM\ indirect} = L_{hand\text{-}I} \times SA_{I} \times f_{indirect} \times \lambda_{I} \times t \qquad \text{(Equation 2)}$$

The indirect transfer involves the transfer of lead from the hand to an intermediate object, and then the introduction of lead into the mouth from the intermediate object through eating or some other contact (*e.g.*, smoking a cigarette). Along the way, some lead may be lost from the intermediate object before contact with the mouth. For simplicity $f_{indirect}$ is expressed here in terms of f_{direct} and f_{loss}, the fraction of lead mass loading lost during the intermediate steps:

$$f_{indirect} = f_{direct} \times (1 - f_{loss})$$

Thus,

$$Intake_{HM\ indirect} = L_{hand\text{-}I} \times SA_{I} \times [f_{direct} \times (1 - f_{loss})] \times \lambda_{I} \times t$$

For applications of Equation 2, this interpretive guideline provides a default value of 25% for $f_{indirect}$. The selection of this value is explained on page 11. In the absence of scientifically robust data that account for the possible range of values of $f_{indirect}$, this value can be used. For the other parameters in Equation 2, product- and use- specific values representative of the mean (expected) value (that take into account variability) should be employed.

Total Lead Intake from Hand-to-Mouth Activity

Total intake of lead from hand-to-mouth activity is the sum of intake from direct (Equation 1) and indirect (Equation 2) hand-to-mouth intake:

$$Intake_{HM} = Intake_{HM\ direct} + Intake_{HM\ indirect}$$

In applying Equations 1 and 2, repetitive handling of a given consumer product is assumed, and it is further assumed that after each hand-to-mouth contact, the product is handled and lead "reloading" onto the hand occurs. That is, lead loading on the hand removed by each direct or indirect hand-to-mouth contact is replenished by subsequent handling of the product. Lead loadings on the hands for direct and indirect hand-to-mouth contacts – L_{hand-I} and L_{hand-D} – are not necessarily the same. No loss of lead loaded on the hand (L_{hand-D}) is assumed for direct hand-to-mouth contact, unless hand-washing takes place after handling of the product. As stated above, f_{loss}, the loss factor incorporated into Equation 2, is intended to capture the overall mass loss between the hand and the mouth for indirect hand-to-mouth activities, including the effect of hand-washing during the period in which the product is used.

Default Values for Transfer Factors (f_{direct} and $f_{indirect}$)

Among the parameters needed to estimate lead intake from the hand-to-mouth exposure pathway using Equations 1 and 2, the transfer factors f_{direct} and $f_{indirect}$ are probably the least amenable to study, and the most uncertain. This is especially true for $f_{indirect}$, given the complexity of the multiple intermediate objects and transfer steps that could occur. Empirical measurements of representative samples would be extremely challenging to generate. If they are available and based on sound scientific methodology, they should be used. Modeled output with default values could be used when scientifically sound empirical data are not available.

The direct and indirect hand-to-mouth transfer factors used in Equations 1 and 2 depend on a number of factors, including the lead concentration on the surface of the hand (or the intermediate object), the chemical and physical nature of the lead being transferred, the chemical and physical nature of the intermediate object (for indirect hand-to-mouth transfer), the frequency, duration and pressure of the contact of the hand with the mouth (or the intermediate object), temperature, pH, and humidity. No empirical data in the scientific literature on the percentage of lead transferred from the hand to the mouth as a result of handling consumer products were identified by OEHHA.

In OEHHA's interpretive guideline for hand-to-mouth transfer of lead through exposure to fishing tackle products (OEHHA, 2008), 50% was selected as the direct hand-to-mouth transfer factor, f_{direct}. It is consistent with the best available study, *i.e.*, Camann *et al.* (2000). Camann *et al.* (2000) measured the fraction of

each of three pesticides (chloryrifos, pyrethrin I, and piperonyl butoxide) removed from the hands of three adult volunteers by gauze wipes moistened with human saliva. The empirical measurements indicate that the transfer efficiency from the hand to the mouth was approximately 50% for each of the three pesticides.

The study by Kissel *et al.* (1998), which measured total soil loading on the hand and soil transfer to the mouth from particular parts of the hand (*i.e.*, thumb; two fingers; palm) in four adults, was also reviewed in OEHHA (2008). This study provides the soil mass transferred to the mouth divided by the soil mass on the entire hand. Kissel *et al.* (1998) reported that the average percent of the total soil on the whole hand transferred to the mouth by thumb-sucking, finger mouthing, and palm licking was 10.1% (95% CI: 8.7 – 11.8%), 15.9% (95% CI: 13.8 – 18.4%) and 21.9% (95% CI: 20.5 – 23.4%), respectively. Since these fractions are based on removal from the entire hand rather than the portion of the hand in contact with the mouth, they should be considered as lower bound estimates of f_{direct}. This is because f_{direct} represents the fraction that is transferred to the mouth based on the amount loaded on the part of the hand touching the mouth, and not the fraction transferred to the mouth based on the amount loaded on the entire hand.

Other studies reviewed in OEHHA (2008) include those that derived estimates for a hand load transfer factor or transfer efficiency: Dubé *et al.* (2004, a published paper from an earlier 2001 Gradient report), Beyer *et al.* (2003), and the Consumer Product Safety Commission (CPSC, 2003). These studies discussed hand-to-mouth transfer in terms of average hand load ingested per day, and did not include hand-to-mouth contact frequency or the fraction of the hand in contact with the mouth to enable determination of hand-to-mouth transfer as defined here. Other studies reviewed, including Paull (1997), Zartarian *et al.* (2000), and U.S. EPA (2005), use different modeling approaches that are not applicable to the transfer factors defined here. Additional discussion of these studies is provided in OEHHA (2008).

A hand-to-mouth transfer efficiency value of 50% has been used by other agencies. CPSC used this value in estimating hand-to-mouth exposure to lead from children's PVC products (CPSC, 1997).   The U.S. EPA Office of Pesticide Programs used it as a default value for estimating hand-to-mouth exposure to pesticides (U.S. EPA, 2001). A California Department of Health Services exposure assessment of wood preservatives used 50% for arsenic, chromium and copper, while 100% transfer efficiency was assumed for pentachlorophenol (CDHS, 1987).

Hemond and Solo-Gabriele (2004) raised concerns regarding application of the 50% value from the pesticide studies of Camann *et al.* (2000) to the estimation of the hand-to-mouth transfer of arsenic from CCA-treated wood, considering 50% too low to represent dislodgeable arsenic because "the skin has higher permeability to oil-soluble materials like pesticides than to more polar inorganic

chemicals; saliva, being water-based, is expected to be an indifferent solvent for the hydrophobic chemicals." In assessing children's exposure to arsenic from CCA-treated wood, Hemond and Solo-Gabriele. (2004) assumed a hand-to-mouth transfer efficiency of 100%.

Selection of f_{direct}

As reviewed above, empirical data are not available on the percentage of lead transferred from the hand to the mouth as a result of handling consumer products. The only study available that provides empirical data on direct hand-to-mouth transfer is the controlled laboratory pesticide transfer study by Camann *et al.* (2000). In this study, the removal efficiencies (*i.e.*, f_{direct}) of chlorpyrifos, pyrethrin I, and piperonyl butoxide were found to be approximately 50%. In this interpretive guideline the value of 50% is selected as the default for f_{direct}, for lead in consumer products.

There are multiple sources of uncertainties associated with using the 50% value from the study of Camann *et al.* (2000) for f_{direct} for lead from all consumer products. These include the uncertainty with which the controlled laboratory conditions of the study reflect hand-to-mouth transfer under real world situations, the uncertainty with which the small number of study participants (n = 3) represent the variability within the human population, and the uncertainty associated with how well the three organic pesticides studied represent transfers of inorganic lead from various consumer products. Compared to lead, these pesticides are likely to have higher skin permeability and less availability for hand-to-mouth transfer, resulting in lower hand-to-mouth transfer efficiencies.

Selection of f_{loss} and $f_{indirect}$

In the absence of data, 50% is the default value selected for f_{loss}. f_{loss} takes into account the possible mass loss during the potentially multiple intermediate steps between loading on the hands and transfer to the mouth, such as the mass loss resulting from hand washing or wiping the hands on an item of clothing (*e.g.*, pants), then wiping an apple on the same area of clothing, and eating the apple. Since $f_{indirect}$ is given by $f_{direct} \times (1 - f_{loss})$, $f_{indirect}$ is therefore 25%, or 0.25 (= 0.5 × [1 − 0.5]).

These default values for f_{direct} and $f_{indirect}$ may be revised as new scientifically robust data become available.

Potential Data Sources for Selection of Values for SA_D, SA_I, λ_D, λ_I, and t

Scientific methods using representative samples collected under the specific use conditions associated with a given consumer product ideally should be used as the basis of parameter value selection. In the absence of such data, other information from closely related studies or other relevant sources may be used to

develop representative parameter values, based on the best available scientific knowledge. When limited data are available for a given parameter or when the data are highly variable, a health-protective value should be selected which takes into account the range of the potential values. Possible data sources for SA_D, SA_I, λ_D, λ_I, and t, as used in Equations 1 and 2, are discussed below.

Surface area (SA_D and SA_I)

The U.S. EPA Exposure Factors Handbook (U.S. EPA, 1997) provides representative hand surface area values for both adults and children in Chapter 6, General Factors for Dermal Route. Distributions of hand surface area (mean, standard deviation and percentile distributions) by gender and age are provided in Tables 6-2 to 6-8. Additional information on hand surface area for infants and children is provided in the U.S. EPA Child-Specific Exposure Factors Handbook (U.S. EPA, 2008; Tables 7-2 and 7-6). These data can be used as the basis for determining the hand surface area in contact with the mouth, adjusting for specific exposure scenarios for a given consumer product and for specific characteristics of the users.

From the U.S. EPA Exposure Handbook (U.S. EPA, 1997), the representative values of the surface area of both hands in adults are 750 cm^2 for women and 840 cm^2 for men. If the contact surface area is only limited to some fingertips, the representative hand surface area has to be multiplied by a reasonable value for the fraction of the fingertips in contact with the mouth (or the intermediate object). For example, for fishing tackle (OEHHA, 2008), it is assumed that SA_D is equal to three fingertips (conversion assumptions: fingertip ~30% of finger; finger ~10% of the palmar surface of one hand), corresponding to 17 and 19 cm^2 for women and men, respectively (or 2.3% of the total surface area of both hands). In another example, Cherrie *et al.* (2006) assumed for workers in occupational settings that the surface area of the hands contributing to the hand-to-mouth exposure pathway was 5% of the palmar surface of one hand, or 10 cm^2. In estimating children's exposures to pesticides by the hand-to-mouth pathway, the U.S. EPA (2001) uses a default surface area value of 20 cm^2. These values should be taken into consideration when selecting case-specific surface area values for a given product.

For indirect hand-to-mouth activities, the hand surface area contacting the material that eventually is introduced to the mouth can be larger than that directly contacting the mouth. This parameter may vary greatly depending on the activity pattern and the intermediate objects involved. For example, in the case of fishing tackle (OEHHA, 2008), two likely scenarios were presented as representative of indirect hand-to-mouth activities and two different values for SA_I were estimated. The numbers developed for fishing tackle (OEHHA, 2008) are not meant to be used for other consumer products without appropriate evaluation of the specific use patterns expected for those other products. It is often more challenging to derive representative values for SA_I than for SA_D.

Contact frequency (λ_D and λ_I)

The hand-to-mouth contact frequency may vary depending on many factors, including the use characteristics of the product (*e.g.*, garden hose *versus* lunch box), the users (*e.g.,* children *versus* adults; smokers *versus* non-smokers), and the setting in which the product is used (*e.g.*, outdoors *versus* home *versus* workplace).

For adults, very limited information is available on hand-to-mouth contact frequency. This may be because the hand-to-mouth exposure pathway is generally considered to be less important for adults as compared with young children. It is practically more challenging to obtain unbiased data on hand-to-mouth activity from adults, given that adults may alter such behavior if they are aware, through informed consent, that they are being observed or videotaped. In the one published study reporting adult hand-to-lip contact based on a small sample size of 10 adult volunteers, the average hourly contact rate was eight per hour (standard deviation: 8; range: 0 - 24 per hour) (Nicas and Best, 2008). In evaluating the importance of inadvertent ingestion of toxic substances in occupational settings, Cherrie *et al.* (2006) considered two different workplace scenarios. In the first scenario, a hand-to-mouth contact frequency of 10 contacts per hour was assumed for pesticide workers, while in the second, 5 contacts per hour was assumed for inorganic lead workers (Cherrie *et al.*, 2006).

Studies of hand-to-mouth activity patterns have mainly been conducted in children, with most children studied being under the age of six. There are various sources of information on hand-to-mouth contact frequency in children of different ages. The U.S. EPA Child-Specific Exposure Factors Handbook (2008) presents recommended age-specific values (average and 95th percentile estimates) for hand-to-mouth contact frequencies for infants and children (aged 3 months to < 11 years) in indoor and outdoor environments. These values (see Table 1) were taken from the meta-analysis of hand-to-mouth activity studies published by Xue *et al.* (2007). As shown in Table 1, there are large differences between the mean and the 95th percentile values within each age grouping. This reflects the variability among individuals, in addition to the variability of hand-to-mouth activity patterns within an individual. These recommended values may be used as a starting point for selecting the hand-to-mouth contact frequency for children when considering use scenarios for child-related consumer products. Adjustments can be made based on a case-by-case evaluation.

Table 1. Recommended values for hand-to-mouth frequency (contacts/hours) for children (U.S. EPA, 2008, extracted from Table 4-1)

Age group	Indoor		Outdoor	
	Mean	*95th%*	*Mean*	*95th%*
3 to < 6 months	28	65	-	-
6 to < 12 months	19	52	15	47
1 to < 2 years	20	63	14	42
2 to < 3 years	13	39	5	20
3 to < 6 years	15	54	9	36
6 to < 11 years	7	21	3	12

Exposure Duration (t)

Many studies have been carried out to characterize time spent in major microenvironments (*e.g.*, indoors at home, in transit) and activities (such as cooking or yard work). California-specific data were collected in two California Air Resources Board (ARB)-sponsored studies, one for California residents age 12 and above and the other for children age 11 and under (Wiley, 1991a and 1991b). Larger-scale studies were also undertaken to better understand the time activity patterns for exposure assessment, such as the National Human Activity Pattern Survey (NHAPS) with over 9,000 subjects interviewed (Klepeis *et al.*, 2001), and a study conducted in 1,000 children aged five to 12 from six states (Silvers *et al.*, 1994). However, not all activity durations are well characterized (*e.g.*, duration of a typical fishing event). The best available information on the specific consumer product use duration should be obtained or estimated using professional judgment, and based on other relevant available data or reasonable upper bound assumptions.

Summary

This interpretive guideline provides a general scientific framework to assess hand-to-mouth lead transfer from the use of consumer products. Lead intake from hand-to-mouth activity is the sum of intake from direct and indirect hand-to-mouth exposure. Equations are provided to estimate lead intake from direct hand-to-mouth contact (Equation 1) and from indirect hand-to-mouth contact (Equation 2).

$$Intake_{HM\ direct} = L_{hand-D} \times SA_D \times f_{direct} \times \lambda_D \times t \qquad \text{(Equation 1)}$$

$$Intake_{HM\ indirect} = L_{hand-I} \times SA_I \times f_{indirect} \times \lambda_I \times t \qquad \text{(Equation 2)}$$

A default value of 50% is provided for f_{direct} and 25% for $f_{indirect}$. For circumstances where good empirical data based on sound scientific studies provide better information than the defaults, alternative values should be used. Default values for other parameters used in the hand-to-mouth intake equations are not provided because of the many different settings, conditions and activities in which consumer products containing lead may be used. Guidance and discussion of existing scientific evidence relevant to the selection of representative values for these other parameters used in the equations has been provided. Case-specific assessment is recommended for estimating the hand-to-mouth transfer of lead from consumer products, taking into consideration the product's characteristics (*e.g.*, configuration, age, condition) and the specific use scenarios (use frequency and duration; microenvironments where it is used) in selecting representative values for equation parameters.

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