Responses to Public Comment on the Draft Air Toxics Hot Spots Guidance Manual

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

September, 2014

On June 20, 2014, the Office of Environmental Health Hazard Assessment (OEHHA) released the draft document, *Air Toxics Hot Spots Program Guidance Manual for the Preparation of Risk Assessments* (Guidance Manual) to solicit public comment. Responses to comments received on the draft *Guidance Manual* are provided here.

Background

The *Guidance Manual* was developed by OEHHA, in conjunction with the Air Resources Board, for use in implementing the Air Toxics Hot Spots Program (Health and Safety Code Section 44360 et. seq.). The *Guidance Manual* is a user manual for the preparation of health risk assessments. The manual combines the critical information from three Technical Support Documents (TSDs) developed by OEHHA, which provide the scientific basis for numeric values used in assessing health risks from exposures to facility emissions. The TSDs underwent public and peer review, were approved by the State's Scientific Review Panel on Toxic Air Contaminants, and adopted by OEHHA for use in the Air Toxics Hot Spots program. The Guidance Manual will also undergo review by the Scientific Review Panel. The guidance covers:

- Non-cancer risk assessment in the *Technical Support Document for the Derivation of Noncancer Reference Exposure Levels* (OEHHA 2008),
- Derivation of cancer potency factors in the *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures* (OEHHA 2009), and
- Exposure assessment methodology including stochastic risk assessment in the *Technical Support Document for Exposure Assessment and Stochastic Analysis* (OEHHA, 2012).

OEHHA solicited public comments on the guidance itself including clarity, and on items related to implementing the information in the three TSDs. These items are related to the mechanics of conducting the risk assessment. OEHHA did not seek comments on

the underlying scientific information that originally appeared in the TSDs, which are finalized documents.

The June 20 notice[1] specifically sought comments on a set of items not directly addressed in the three TSDs, or clarified in the *Guidance Manual*, reproduced verbatim here:

- Chapter 4
  - In Section 4.3.1 and 4.11.1.2, the text clarifies examples of "release types" for point, area, or volume sources and modeling selection related to screening or refined air dispersion modeling.
  - In Section 4.7.3, the text clarifies the method for spatial averaging at a fence line receptor when a portion of the grid is within the facility boundary.
- Chapter 5
  - In Section 5.3.2, the text clarifies that in Tier 1 assessments, for pathways involving dermal exposure to contaminated soil or soil ingestion, the concentration in soil reflects accumulation over 70 years.
  - In Section 5.3.4.4, we provide guidance on how to use the mother's milk biotransfer coefficients shown in Table 5.5.
  - In Table 5.4, footnotes were added to clarify how to use intake point estimates for food animals in the food animal pathway.
  - In section 5.4.1.4 (and again in Chapter 8, Section 8.3.4), the text clarifies application of the 8-hour Reference Exposure Levels for offsite workers and residences, and for continuously emitting versus non-continuously emitting facilities.
  - In section 5.4.2.1, there is a small correction in the equation for calculating dermal dose. There was an extra parameter (year) in the equation in the 2012 TSD; it has now been removed.
  - In the 2012 TSD for Exposure Assessment, there were no equations shown to determine the weighted average dose used for calculating a chronic noncancer hazard quotient for the non-inhalation pathways of exposure. This needs to be done across age-groupings to estimate a chronic Hazard Quotient. Algorithms were added (pp. 5-40-42, 5-44-45, 5-47-48, 5-53-54, 5-57-58, 5-60-61) to make this clearer.
- Chapter 6
  - On page 6-7, we clarified that for determining Hazard Index by target organ system, reproductive and developmental toxicants are combined into one Hazard Index.
- Chapter 8
  - In section 8.2.7, we clarified that for estimating non-inhalation pathway cancer risk for the mother's milk pathway, the exposure duration is one year in the 0 < 2yr age groups and 2 years for the other non-inhalation pathways.

[1] Available online at: http://oehha.ca.gov/air/hot_spots/riskguidancedraft2014.html

  - In section 8.2.10, we included more detailed text regarding cancer risk assessment for short-term projects, relative to the description on page 61 in the May 2009 *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures* (available at: http://www.oehha.ca.gov/air/hot_spots/tsd052909.html) . This issue is also discussed in Chapter 11, pages 11-17 and 11-18 of the *Technical Support Document for Exposure Assessment and Stochastic Analysis* (available here: http://www.oehha.ca.gov/air/hot_spots/tsd082712.html).
- Appendix E
  - We added language on page E-2 regarding estimating noncancer impacts from unspeciated polychlorinated biphenyl mixtures.

Commenters on the Draft Guidance Manual

Comments were received from:

- California Chamber of Commerce (CalChamber), representing a group of business organizations identified below. The CalChamber comments also included supplemental comments by Robert Scofield of GSI Environmental Inc.
- California Council for Environmental and Economic Balance (CCEEB)
- County Sanitation Districts of Los Angeles County
- Construction Industry Air Quality Coalition, which provided a letter asking OEHHA to consider amendments provided by CalChamber and does not provide any additional comments. Thus, responses to the CalChamber comments below address this group's comment.

Organizations that signed the CalChamber comment letter were:

Agricultural Council of California
Almond Hullers and Processors Association
American Chemistry Council
Associated General Contractors-California
Associated General Contractors- San Diego
Building Industry Association of Fresno and Madera County
California Building Industry Association
California Business Properties Association
California Chamber of Commerce
California Cement Manufacturers Environmental Coalition
California Construction and Industrial Materials Association
California Cotton Ginners Association
California Cotton Growers Association
California Farm Bureau Federation
California Fresh Fruit Association
California League of Food Processors
California Manufacturers and Technology Association
Can Manufacturers Institute
California Metals Coalition
California Refuse Recycling Council
California Small Business Alliance

California Trucking Association
Chambers of Commerce Alliance of Ventura and Santa Barbara Counties
Chemical Industry Council of California
Coastal Energy Alliance
Construction Industry Air Quality Coalition
Dairy Cares
Inland Empire Economic Partnership
Industrial Environmental Association
Kern County Farm Bureau
Los Angeles County Business Federation
Manufacturers Council of the Central Valley
Metal Finishing Association of Northern California
Metal Finishing Association of Southern California
Milk Producers Council
NAIOP- Southern California
National Federation of Independent Business
National Tank Truck Carriers, Inc.
Orange County Waste & Recycling
Rural County Representatives of California
San Bernardino County Solid Waste Management Division
San Gabriel Valley Economic Partnership
Solid Waste Association of North America
Styrene Information & Research Center
Valley Industry and Commerce Association
West Coast Lumber & Building Materials Association
Western Agricultural Processors Association
Western Growers
Western Plant Health Association
Western States Petroleum Association
Western United Dairymen
Western Wood Preservers Institute

Responses to Comments Received from CalChamber

CalChamber Comment 1:

"Overly Conservative Assumptions Produce a Risk Estimate That Undermines Responsible Risk Communication and Risk Management

"The Hot Spots exposure assessment guidance[1] identifies a series of conservative default assumptions and corresponding inputs that are required to be used in deriving a single "Tier I" point estimate of risk for exposed individuals. One such assumption that has a substantial impact on the risk estimate is that ALL carcinogens present a higher risk in early life stages -- e.g., the fetus, infants and children -- than in adults.[2] This assumption is patently wrong. As noted in the attached GSI review, not all carcinogens behave in this manner. In fact, some actually present a lower cancer risk in early life stages than for adults[3]. Even in isolation, this assumption can increase cancer risk estimates by 70% for each chemical. [4]

"For example, if only Chemical A has evidence demonstrating greater sensitivity during early life stages, then assuming the default ASFs apply to all four chemicals artificially inflates risk estimates by nearly 70%.[5] The practical impact of using default ASFs across the board is that a facility will be required to notify the public because an unwarranted increased calculation of cancer risk exceeds the air district notification threshold of 10 per million. By contrast, when the default ASF is applied only to those chemicals that have data demonstrating a likelihood of increased sensitivity in early life stages, the facility estimated cancer risk will surpass the actionable threshold only when warranted."

Chemical	Cancer Risk with ASF Applied to ALL Chemicals	Cancer Risk with ASF Applied only to Chemicals Having Evidence For Greater Risk in Early Life Stages
Chemical A	**0.1 per million**	**0.1 per million**
Chemical B	**5 per million**	**3 per million**
Chemical C	**5 per million**	**3 per million**
Chemical D	**5 per million**	**3 per million**
Total	**15 per million**	**9.1 per million**

[1] Air Toxics Hot Spots Program Risk Assessment Guidelines, The Air Toxics Hot Spots Program Guidance Manual for the Preparation of Health Risk Assessments, Public Review Draft, OEHHA, June 2014.

[2] See Comments on June 20, 2014 Draft Air Toxics Hot Spots Program Guidance Manual, GSI Environmental Inc., August 12, 2014, at p.2.

[3] This assumption is referred to as Age Specific Factors (ASF) which increase the cancer potency value for younger people.

[4] Applying the ASF values over a 70-year lifetime results in a cancer risk value that is 1.7 times greater, see p. 62 of the OEHHA Technical Support Document for Cancer Potency Factors:

Methodologies for derivation, listing of available values, and adjustments to all for early life stage exposures, May, 2009.

[5] 15 – 9.1 = 5.9; 5.9/9.1 x 100 = 65%.

Response to CalChamber Comment 1:

The basis for the Age Sensitivity Factors (ASFs) in the Air Toxics Hot Stops risk assessments is discussed in the OEHHA TSD, *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures*[2]. As noted above, this TSD went through public review and extensive scientific peer review by the State's Scientific Review Panel before it was finalized in April 2009. This issue was considered during the development of the TSD and was considered during the review by the SRP. Thus, we are not re-considering the ASFs during this current public review process. However, for transparency we are providing a response to the comment.

The analyses conducted by OEHHA in our 2009 TSD show that in general, early life exposures to carcinogens increase the cancer risk relative to later life exposures. Further, early life exposures provide a longer time for cancer to manifest than later life exposures (e.g., cancer appears to increase with approximately the 3rd power of age). Even for the same chemical, the sensitivity of an individual to a chemical changes with lifestage, and thus the potency of the carcinogen can be observed to vary dramatically depending on whether and at what point there is exposure in utero, in the early postnatal period, during the teenage years or during adulthood (see Appendix J of the TSD for Cancer Potency Derivation).

Humans are exposed *in utero* and over their lifetimes to carcinogens emitted from industrial and other sources. Thus, there is exposure to these environmental contaminants during any and all windows of susceptibility. The data presented in our analyses (see OEHHA (2009) link above) clearly indicate increased sensitivity for many carcinogens during early life. The data gaps in this regard are large, even for well-studied carcinogens. Thus OEHHA made a science-informed policy choice to include the increased susceptibility of early life exposures, which is supported by both human and animal data, albeit for a limited number of agents. This choice was reviewed by the SRP and approved in 2009. Finally, we note that these ASFs are default values to be used in the absence of good evidence to the contrary.

CalChamber Comment 2:

"Among other conservative assumptions include exposure duration and behavioral patterns that affect individual exposures. We support OEHHA's recommendation to use

[2] located at: http://www.oehha.ca.gov/air/hot_spots/2009/AppendixJEarly.pdf

a 30-year estimate for residential exposure in lieu of the traditional 70-year assumption. It is a health-protective refinement as most of the population actually lives in the same residence for less than 30 years. It is an example of how more representative data can be used to improve the accuracy and validity of Tier I risk assessments for risk communication and risk management purposes. However, this estimate still assumes that some exposed individuals are present at home 24 hours per day, seven days per week, and 365 days per year, have very high breathing rates, and are outdoors at all times (e.g., time spent indoors provides no reduction in the concentration of a given pollutant present in the outdoor air). Such embedded assumptions can, in and of themselves, drive significantly higher risk estimates.

"For example, use of the 95th percentile inhalation rate rather than the average breathing rate will result in exposure estimates nearly 60% higher over a 70-year lifetime.[6]"

Life Stage	**Mean Breathing Rate (L/kg BW-day)**	**95 Percentile Breathing Rate (L/kg BW-day)**	**Difference in Exposure**
3rd Trimester	225	361	60%
Birth < 2 years	658	1090	66%
2 years to < 16 years	452	745	65%
16 years to 70 years	185	290	57%
Average Over Lifetime			59%

"Compounding these multiple worst case assumptions and presenting them as a single point estimate of risk conveys a message that is entirely detached from reality for the vast majority of the exposed populations, including infants and children.

"Simply combining assumptions from the above examples artificially inflates risk estimates by 270%."

Conservative Assumption	**Risk Increase**
ASF Applies to Chemical	**1.7 times**
High Inhalation Rates	**1.59 times**
Compound Increase	**2.7 times**

[6] OEHHA, 2014, Table 5.6 at p. 5-25.

Response to CalChamber 2:

Note that the comment is referring to issues that were discussed at length during the public comment and scientific peer review of the *Technical Support Document for*

Exposure Assessment and Stochastic Analysis[3] before it was approved by the SRP and finalized in 2012. While this is not an issue under consideration during this review, for transparency we are providing a response to the comment.

The new guidance allows the use of adjustment for time at home for various age groups. Further, both the new and previous guidelines allowed for people to be away 2 weeks per year, the typical vacation time in the U.S. Thus, we do not make the automatic assumption that people are in the same place 24 hours per day, 365 days per year.

OEHHA recommends using the high end (e.g., 95th percentile) breathing rates to calculate cancer risk for risk management decisions in Tier I Air Toxics Hot Spots risk assessments because the high end breathing rates represent those at greatest risk in the population from the inhalation pathway.

The Hot Spots program also evaluates maximum one hour air concentrations at the PMI, residential Maximum Exposed Individual (MEI) and worker MEI. The resident or worker could also be outside at the time of the modeled maximum one hour concentration, therefore it is public health protective to simply assume the modeled maximum one hour represents the exposure concentration from facility emissions.

CalChamber Comment 3:

"The problem with OEHHA's proposed approach is that it has the potential to mislead the public about the actual risks posed by a particular facility. Moreover, if the assumptions incorporated into the risk estimate are known to be false, then the policy outcomes – risk communication actions, risk management responses and operational and economic impacts on actual facilities – are indefensible."

Response to CalChamber Comment 3:

The risk assessment methodology presented in the draft Guidance Manual is contained in the TSDs and has undergone public comment and scientific peer review by the SRP before it was finalized. We believe the assumptions used are appropriate and public health protective, and are scientifically defensible.

OEHHA has striven to use the best science available in developing the risk assessment methodology. However, there is a great deal of uncertainty associated with the process of risk assessment. The uncertainty arises from lack of data in many areas

[3] available at: http://www.oehha.ca.gov/air/hot_spots/tsd082712.html

necessitating the use of assumptions. The assumptions used in the TSDs and Guidance Manual are designed to be health protective in order to avoid underestimation of risk to the public.

CalChamber Comment 4:

"A Misleading Point Estimate of Risk Will Not Further the Objectives of the Hot Spots Program

"A primary objective of AB2588 is to communicate the results of facility health risk assessments (HRAs) to potentially affected individuals. A successful risk communication program provides accurate information to stakeholders that they can understand and use to make informed decisions. To achieve this objective, the Legislature concluded the HRA results must be both accurate and complete:

> "The [risk assessment] guidelines established pursuant to paragraph (2) shall impose only those requirements on facilities subject to this subdivision that are necessary to *ensure that a required risk assessment is accurate and complete* ..."*(emphasis added)*

"The obvious rationale for accurate and complete HRA's in the context of risk communication is to avoid misleading and confusing the public. As noted by the NRC "good risk communication cannot always be expected to improve a situation, poor risk communication will nearly always make it worse." Presentation of a single point estimate of facility risk based on a series of worst case assumptions, ranging from the highly unlikely to the outright false, does not further the statutory objective of accurate risk communication. More importantly, this approach is in direct conflict with Health and Safety Code section 44360(b)(3).

"We expect OEHHA would prefer to endorse effective risk communication practices rather than to institutionalize poor ones that could make a difficult situation even worse. Therefore, we recommend that OEHHA revise the draft guidance to emphasize a preference for using actual data over default assumptions whenever possible and presenting risk estimates in Tier I HRAs as a range of values rather than as single point estimates. This approach will yield a more accurate reflection of risk for a given population."

Response to CalChamber Comment 4:

The main objective of the Air Toxics Hot Spots program is to understand emissions from stationary sources, evaluate the potential public health impacts, and reduce exposures

where appropriate. A “right-to-know” provision is also included in the law. Risk communication is important, but it is not the focus of the Risk Assessment Guidance Manual. The comment appears to muddy the distinction between risk assessment and risk communication. Risk communication should reflect the results of a risk assessment, rather than drive decisions as to how the risk assessment is conducted.

The pertinent portion of Health and Safety Code section 44360(b) referred to in the comment reads as follows:

> (2) Health risk assessments required by this chapter shall be prepared in accordance with guidelines established by the Office of Environmental Health Hazard Assessment. The office shall prepare draft guidelines which shall be circulated to the public and the regulated community and shall adopt risk assessment guidelines after consulting with the state board and the Risk Assessment Committee of the California Air Pollution Control Officers Association and after conducting at least two public workshops, one in the northern and one in the southern part of the state. The adoption of the guidelines is not subject to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The scientific review panel established pursuant to Section 39670 shall evaluate the guidelines adopted under this paragraph and shall recommend changes and additional criteria to reflect new scientific data or empirical studies.
>
> (3) The guidelines established pursuant to paragraph (2) shall impose only those requirements on facilities subject to this subdivision that are necessary to ensure that a required risk assessment is accurate and complete and shall specify the type of site-specific factors that districts may take into account in determining when a single health risk assessment may be allowed under subdivision (d). The guidelines shall, in addition, allow the operator of a facility, at the operator's option, and to the extent that valid and reliable data are available, to include for consideration by the district in the health risk assessment any or all of the following supplemental information:
>
> (A) Information concerning the scientific basis for selecting risk parameter values that are different than those required by the guidelines and the likelihood distributions that result when alternative values are used.
>
> (B) Data from dispersion models, microenvironment characteristics, and population distributions that may be used to estimate maximum actual exposure.
>
> (C) Risk expressions that show the likelihood that any given risk estimate is the correct risk value.
>
> (D) A description of the incremental reductions in risk that occur when exposure is reduced.

The tiered approach to complete an Air Toxics Hot Spots risk assessment satisfies the requirement of Health and Safety Code section 44360(b)(3). The tiered approach provides for a consistent methodology to be used across facilities, and provides data-based values for exposure variates that are to be used in a Tier 1 or 3 risk assessment. Tier 1 uses a point estimate approach to characterize risk, and all facilities are required to conduct an analysis using the Tier 1 approach. The Tier 2 approach allows a facility to use site-specific parameters when justified for the risk assessment. This is entirely in keeping with Health and Safety Code Section 44360(b)(3). In addition, the Tier 3

approach allows a facility to present a range of risks based on the distributional analyses OEHHA conducted using data to derive a distribution of values for exposure variates (intake rates). Tier 4 allows a facility to use justified distributions of exposure variates to present a range of risks. This is also in keeping with Health and Safety Code Section 44360(b)(3).

CalChamber Comment 5:

"Recommendations:

"Given the above noted concerns, the undersigned recommend that OEHHA make the following changes to the draft HRA guidelines:

"1. Support use of a range of risk estimates.

"In light of the many factors and assumptions used in risk assessment, each with its own range of probability, OEHHA should expressly allow if not recommend the use of a range of risk in addition to, or in lieu of, Tier I point estimates. This approach will facilitate more accurate and meaningful risk communication and better inform risk management actions necessary to protect public health, including potentially sensitive populations.

"2. Reconsider Adoption of the default Age Specific Factors (ASFs).

"OEHHA and the SRP should reconsider the adoption of ASFs as they have been proposed. Given the complicated and controversial nature of the proposed changes, the substantial practical impacts the default ASFs would have on the regulatory agencies and the regulated community, as well as the confusion that would be created in the public arena by incorporation of default ASFs into some state regulatory programs and not others, an independent, peer-review should be undertaken to address the adequacy of the basis for adopting ASFs and whether their adoption would result in net public health benefits relative to current approaches to risk assessment. At a minimum, OEHHA should incorporate into the final guidelines a procedure for developing ASFs based on chemical-specific data that can be used in Tier I HRAs.

"These recommendations are entirely consistent with OEHHA's statutory mandate to use current principles, practices, and methods in establishing threshold exposure levels and non threshold health values for specific toxic air contaminants and in considering the need for changes to health risk assessment guidelines to ensure protection of infants and children."

Response to CalChamber Comment 5:

Recommendation 1: The guidelines support the use of risk ranges in Tier 3 and 4 risk assessments and provide guidance for making the calculations. A facility may do a Tier 3 or 4 risk assessment as well as a Tier 1 assessment. This would meet the needs of the recommendation. (See the response to comment 4 above for an explanation of the tiers.) However, a facility is only required to do a Tier 1 assessment. Further, a facility may also present a point estimate using justified site-specific values for exposure variates (Tier 2) or present a range of risk based on site-specific distributions of values for exposure variates (Tier 4). Thus, the guidelines already allow a distributional approach, and in fact OEHHA spent much effort and resources developing data-based distributions for such an approach.

Recommendation 2: As explained above in response to CalChamber comment 1, issues involving the use of ASFs in the Air Toxics Hot Stops risk assessments went through public review and review by the State's Scientific Review Panel. We are not seeking comments on that issue.

Regarding the comment that OEHHA should incorporate a procedure for developing ASFs based on chemical-specific data, OEHHA does allow the use of chemical-specific ASFs that are science-based and defensible. As noted in our Guidance on page 8-4 and 8-5,

> "*In the absence of chemical-specific data, OEHHA recommends a default ASF of 10 for the third trimester to age 2 years, and an ASF of 3 for ages 2 through 15 years to account for potential increased sensitivity to carcinogens during childhood. For specific carcinogens where data indicate enhanced sensitivity during life stages other than the immediate postnatal and juvenile periods, or for which data demonstrate ASFs different from the default ASFs, the chemical-specific data should be used in order to adequately protect public health*."

Note that in our 2009 Cancer TSD[4], we state that *"In cases where there are adequate data for a specific carcinogen of potency by age, we would use the data to make any adjustments to risk*."

[4] *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures*

CalChamber Comment 6 (supplemental comment by GSI Environmental Inc.):

"Young Animals are More Sensitive than Adults to Only Some Chemicals

"The primary factors cited by OEHHA as motivating the risk assessment changes included in the draft OEHHA Guidance Manual are new science about increased childhood exposure to and childhood sensitivity to air toxics as well as the legislation noted above requiring that special susceptibility of infants and children to air toxics be taken into account. While the legislature did express concern about childhood sensitivity to toxic air contaminants, their finding expressed concern that certain (not all) toxic air contaminants may pose a greater risk to children than adults (As noted in California Health and Safety Code 39669.5. "The Legislature finds and declares that certain toxic air contaminants may pose risks that cause infants and children to be especially susceptible to illness and that certain actions are necessary to ensure their safety from toxic air contaminants."). OEHHA's response to these motivating factors was the adoption of higher breathing rates for children than had previously been recommended under Hot Spots guidance and the adoption of default Age Sensitivity Factors (ASFs). The rationale cited for the adoption of the default ASFs was the observation that "young animals are more sensitive than adults to some carcinogens". OEHHA noted that the USEPA had also adopted a set of ASFs in response to the observation that young animals were more sensitive than adult animals to some carcinogens.

"Even though young animals were observed to be more sensitive than adults to SOME carcinogens, OEHHA developed default ASFs for ALL carcinogens. Even though OEHHA's (2009) evaluation of prenatal sensitivity of 14 carcinogens showed an enhanced tumor response from prenatal exposure to several carcinogens, it also showed an essentially equivalent response to prenatal and adult exposure for a few carcinogens; and it showed a REDUCED response from prenatal versus adult exposure to several carcinogens (See Figure 6 in OEHHA May 2009a). Nonetheless, OEHHA adopted an ASF of 10 to be applied to the last trimester of gestation for ALL carcinogens. The approach adopted by OEHHA differs from the USEPA approach in that the default ASFs adopted by the USEPA only applied to SOME carcinogenic chemicals (i.e., those that cause cancer via a mutagenic mechanism); and no ASF is applied to prenatal exposures under the USEPA approach.

"While it has been documented that young animals are more sensitive than adults to SOME carcinogens, it has also been documented that young animals are LESS sensitive than adults to SOME chemicals. This phenomenon has been observed

empirically and is often a result of the fact that young animals eliminate some chemicals more quickly than adult animals and the fact that young animals do not metabolize some noncarcinogenic parent compounds into carcinogenic metabolites as quickly as adults or at all. While results from cancer studies documenting the difference between the sensitivity of young and adult animals to carcinogens is relatively scarce, the available data suggest that children are more sensitive than adults to about as many chemicals as they are less sensitive than adults. (See discussions in: OEHHA, 2009a , Becker, 2005 . Charnley and R. Putzrath, 2001, Barton et al, 2005)."

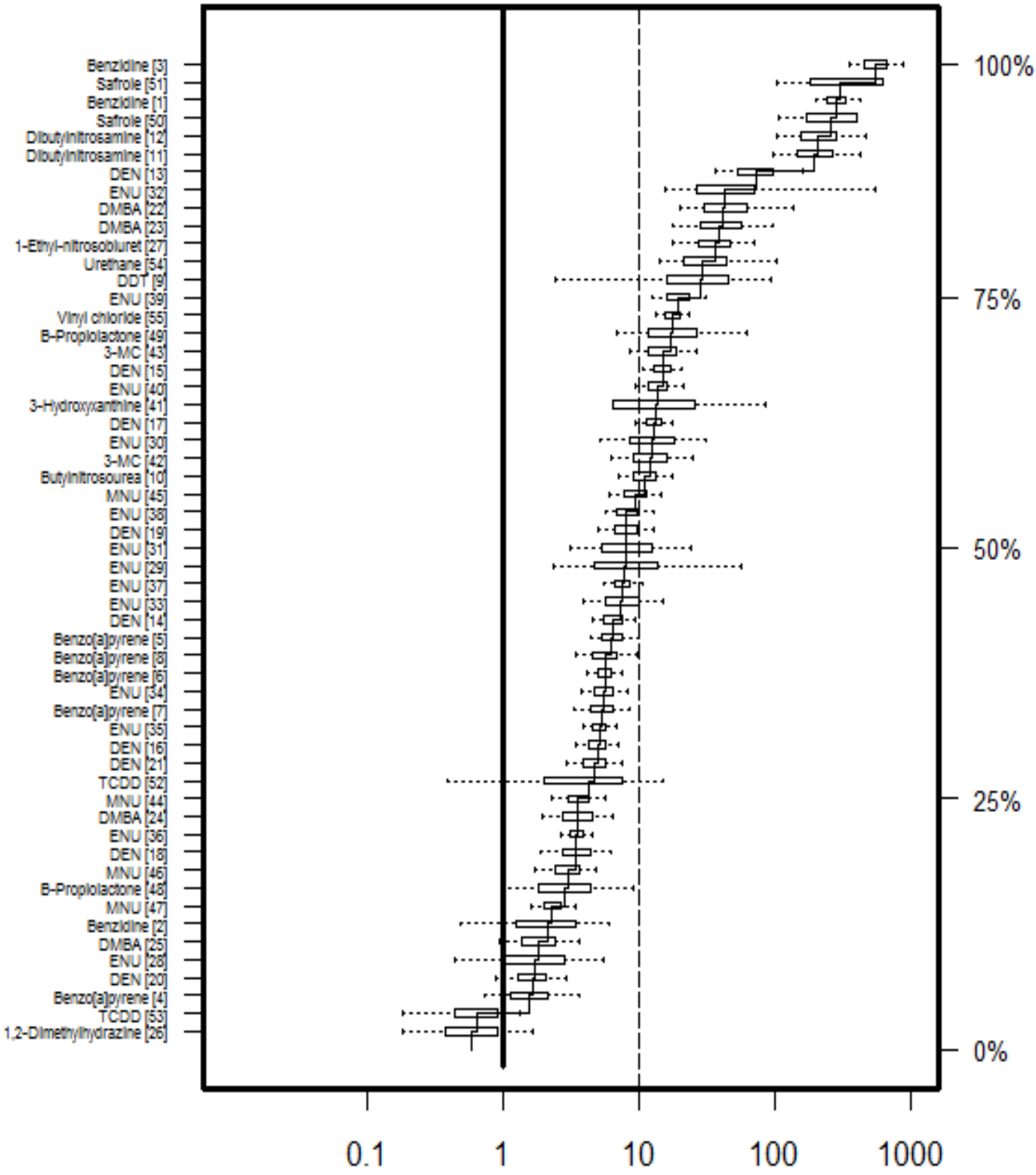
Response to CalChamber Comment 6:

As noted in response to CalChamber comments 1 and 5 above, issues involving the use of ASFs in the Air Toxics Hot Stops risk went through public review and review by the State's Scientific Review Panel before the cancer TSD[5] was finalized in April 2009, and we are not re-considering the ASFs during this current public review process as indicated in the announcement for the public review of the *Guidance Manual.*

OEHHA based the default ASF of 10, which is applied to exposures during the third trimester to age 2 years, on postnatal rodent experiments and describes our rationale in OEHHA (2009) (see figure below). The rodent's immediate postnatal period is more akin developmentally to the third trimester of human gestation. The US Environmental Protection Agency's (USEPA) method does not consider prenatal exposure at all. This method essentially takes the view that there is no risk from prenatal exposures and that risk starts to accrue only following birth. This is not appropriate in our view, based on the animal data we analyzed as part of the development of the Technical Support Document, as well as on some information in humans. This is detailed in Appendix J of the 2009 TSD[6] Finally, OEHHA chose a default ASF approximating the median of our ASF distribution. Thus, it may overestimate risk for some carcinogens but underestimate risk for other carcinogens from early-in-life exposure. Again, all of these issues were reviewed and approved by the SRP in 2009.

The following figure is from Appendix J showing the postnatal ASF cumulative frequency profile. The median of the postnatal ASF mixture distribution is 13.5. The dotted line denotes the default ASF of 10 for weighting risk for carcinogen exposures to humans between the third trimester and 2 years of age.

[5] *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures*
[6] available at: http://www.oehha.ca.gov/air/hot_spots/tsd052909.html


Benzidine [3]
Safrole [51]
Benzidine [1]
Safrole [50]
Dibutylnitrosamine [12]
Dibutylnitrosamine [11]
DEN [13]
ENU [32]
DMBA [22]
DMBA [23]
1-Ethyl-nitrosobiuret [27]
Urethane [54]
DDT [9]
ENU [39]
Vinyl chloride [55]
B-Propiolactone [49]
3-MC [43]
DEN [15]
ENU [40]
3-Hydroxyxanthine [41]
DEN [17]
ENU [30]
3-MC [42]
Butylnitrosourea [10]
MNU [45]
ENU [38]
DEN [19]
ENU [31]
ENU [29]
ENU [37]
ENU [33]
DEN [14]
Benzo[a]pyrene [5]
Benzo[a]pyrene [8]
Benzo[a]pyrene [6]
ENU [34]
Benzo[a]pyrene [7]
ENU [35]
DEN [16]
DEN [21]
TCDD [52]
MNU [44]
DMBA [24]
ENU [36]
DEN [18]
MNU [46]
B-Propiolactone [48]
MNU [47]
Benzidine [2]
DMBA [25]
ENU [28]
DEN [20]
Benzo[a]pyrene [4]
TCDD [53]
1,2-Dimethylhydrazine [26]
100%
75%
50%
25%
0%
0.1
1
10
100
1000

CalChamber Comment 7 (supplemental comment by GSI Environmental Inc.):

"In addition, the placenta is known to act as a barrier reducing or eliminating exposure to a fetus to some, but certainly not all, carcinogens (Lehman-McKeeman, 2013). Accordingly, application of default ASFs would be incorrect for roughly half of the carcinogens to which it is applied. Cancer risks estimated by applying default ASFs to chemicals that are not more potent for young animals than adults would be incorrect and misleading. Resources expended to mitigate risks attributable to incorrectly applied ASFs would not be expended addressing the problem they were ostensibly directed to correcting (i.e., incremental risk attributable to age-specific sensitivity) because no such incremental risk was present in the first place. Similarly, denial of permits in response to risk estimates based on incorrect default ASFs would represent a lost business opportunity with no corresponding benefit of mitigating an incremental risk attributed to age sensitivity. Risk communication would be compromised because incorrect and misleading estimates of incremental risk would be communicated to the public for some chemicals."

Response CalChamber Comment 7:

See above response to CalChamber Comment 6. OEHHA chose a default ASF approximating the median of our ASF distribution. Thus, it may overestimate risk for some carcinogens but underestimate risk for other carcinogens from early-in-life exposure. Again, all of these issues were underwent public comment and were reviewed and approved by the SRP in 2009. As noted in response to CalChamber Comments 1 and 5, where there is good evidence to support an alternative ASF for a specific chemical, the alternative can supplant the default.

Risk management considerations embedded in the comment are not the subject of the Risk Assessment Guidance Manual.

CalChamber Comment 8 (supplemental comments by GSI Environmental Inc.):

"Apparently in recognition of the fact that the default ASFs do not apply to some chemicals, the new OEHHA Guidance Manual (page 8-4) includes the following statement allowing the use of chemical-specific ASFs for chemicals to which the default ASFs are not applicable:

> "For specific carcinogens where data indicate enhanced sensitivity during life stages other than the immediate postnatal and juvenile periods, or for which data demonstrate ASFs different from the default ASFs, the chemical-specific data should be used in order to adequately protect public health."

"Presumably, this statement applies to the use of ASFs of 1.0, or possibly less than 1.0, for those chemicals to which young animals are not more sensitive than adults. Clarification is needed to understand how ASFs other than the defaults would be developed and applied. In addition to clarification on the technical factors and criteria to be considered when developing ASFs different from the defaults, procedural considerations should be clarified. For example, would there be an OEHHA review or peer review process for chemical-specific ASFs?"

Response CalChamber Comment 8:

The risk assessments generated under the Air Toxics Hot Spots Act are reviewed by OEHHA. If a risk assessor had the data indicating there are no windows of susceptibility early in life or that a different ASF should be used for a specific carcinogen and wanted to use these data, OEHHA would review the material as part of the review of the risk assessment. We have included the following language in Section 8.2.1 of the Guidance Manual clarifying this point:

"The risk assessments generated under the Air Toxics Hot Spots Act are reviewed by OEHHA. If a risk assessor had data indicating there are no windows of susceptibility early in life or that a different ASF should be used for a specific carcinogen and wanted to use these data, OEHHA would review the material as part of the review of the risk assessment."

CalChamber Comment 9 (supplemental comments by GSI Environmental Inc.):

"When using risk estimates based on the use of ASFs and when communicating risks estimated using ASFs, it important to keep in mind that the knowledge that some individuals and some age groups, such as children, are more sensitive than others is not new science and has already been taken into account by the standard, conservative approach of using upper bound estimates of potency when developing cancer potency factors to be used in risk assessment. In the discussion of the cancer potency factors recommended by OEHHA (2009b) in the TSD (page 24), for example, OEHHA includes the note that:

> "The risk assessment procedures used aim to include the majority of variability in the general human population within the confidence bounds of the estimate, although the possibility that some individuals might experience either lower or even no risk, or a considerably higher risk, cannot be excluded."

"We recognize that it is difficult to quantify the degree to which the already conservative approach to developing cancer potency factors accounts for the range of additional sensitivities of young animals to some chemicals. Nonetheless, it is important to expand the discussion of the ASFs to more clearly address the fact that at least some of the additional sensitivity of young animals has been accounted for in the standard risk assessment procedures in the past and that the issue of childhood sensitivity has not been ignored in the past. A concise discussion of these assumptions and uncertainties is needed for the risk managers in the air districts, for example, who will be making decisions and providing risk communication based on risk assessments that incorporate the new OEHHA default ASFs, but who may not themselves be versed in the basis of the ASFs and in the uncertainties associated with ASFs. For example, it would be useful for air district staff and others to know which specific chemicals are young animals or prenatal animals NOT more sensitive than adults when they are using the results of risk assessments for risk management decisions or for risk communication."

Response to CalChamber Comment 9:

As noted in response to CalChamber comments 1, 5 and others above, issues involving the use of ASFs in the Air Toxics Hot Stops risk went through public review and review by the State's Scientific Review Panel before the cancer TSD[7] was finalized in April 2009, and we are not re-considering the ASFs during this current public review process as indicated in the announcement for the public review of the *Guidance Manual.* This particular issue was also considered in 2009.

The typical animal cancer bioassay, which serves as the basis for many cancer potency factors, does not include exposures prior to sexual maturity. Further, most epidemiological studies of cancer have been in occupationally exposed adults. Thus, there is nothing inherent in the studies upon which the cancer potency estimates are based that informs risk for exposures early in life.

The practice of taking the 95th-percent upper confidence limit on the slope of the dose-response curve from these studies does not in fact do anything to explicitly protect children. This practice only really accounts for variability in the population studied, usually the population of about 50 adult experimental animals; experimental animals are

[7] *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures*

typically much more similar to one another than the heterogeneous human population. The other common practices of using bioassay data for the most sensitive species, gender, and site also do not explicitly account for early-in-life exposures. Thus, the contention that these conservative methods already account for increased sensitivity of early life stages is unfounded.

CalChamber Comment 10 (supplemental comments by GSI Environmental Inc.):

"Value to Characterizing a Range of Risks

"In general, much of the need for clarification in the new OEHHA Guidance document stems from the conflict created by the use of quantitative risk assessment as a basis of risk management decisions and as a basis of risk commination. The use of conservative assumptions or procedures in a risk estimate used as the basis of a risk management decision can improve confidence that health risks have not been underestimated. Use of conservative assumptions and methods in support of risk management decisions is often rationalized as assuring that the risk estimate and associated decision have "erred on the side of protecting public health".

"The use of conservative assumptions comes at a price, however, when the same risk estimate is used for risk communication because risks have been deliberately overestimated through the use of multiple conservative assumptions. This is because assumptions and methods used to assure that risks are not underestimated and to "err on the side of protecting public health" result in the overstating of health risk when communicating the level of risk associated with a given source; and the overstating of risks can cause unwarranted concern and an unwarranted erosion in the communities sense of well-being.

"The use of a single, upper bound estimator for a factor where there may be a great deal of variability also has the benefit of streamlining the risk estimation process and risk communication is usually simplified by producing a single risk estimate. Even though risk assessment guidelines (e.g., NRC 1983) emphasize the importance of characterizing identifying and characterizing uncertainties, risk assessment reports rarely effectively and explicitly communicate the fact that some individuals are more sensitive than others to a given level of chemical exposure or that some people have greater levels of risk than others to a specific level of exposure. Consequently, the public is generally presented with an overstated level of risk in which the several conservative assumptions and methods on which the risk estimate is based are not well explained.

"OEHHA's proposed application of ASFs trigger this conflict between the practical benefits of adding assurance that estimated risks will not underestimate actual risks and erosion of the value of the risk assessment for supporting risk communication and helping people understand their actual risk."

Response to CalChamber Comment 10:

The Risk Assessment Guidance Manual is a user manual for conducting a health risk assessment. It does not deal with issues of risk communication or risk management.

As stated in the response to Comment 4, risk communication should reflect the results of a risk assessment rather than drive decisions on how a risk assessment is conducted. Risk assessors typically use conservative assumptions to avoid underestimation of health risks. These assumptions normally are explained as part of the risk-communication process so that the public understands how the health risks were estimated, as well as the limitations and uncertainties contained in the risk assessment. Effective risk communication helps prevent unwarranted public concern or overreaction to the results of a risk assessment.

CalChamber Comment 11 (supplemental comments by GSI Environmental Inc.):

"In recognition of the need for effective risk communication, the new Guidance Manual includes the recommendation to present a range of risks by estimating and presenting risks based on three assumed exposure durations (9 years, 30 years, and 70 years). The concept of characterizing a range of risks is consistent with OEHHA guidance for using probabilistic risk assessment procedures to characterize the range of risks posed by any given facility. While probabilistic estimates of risk have the advantage of presenting a more complete range of risks than are provided by a single risk estimate, it can be difficult for individuals to understand where they fall in the risk spectrum. The use of risk isopleths, or the presentation of risks associated with specific exposure scenarios, can help people to better understand the level of risk associated with their specific situation. Accordingly, presentation of risks under assumed exposure durations of 9, 30 and 70 years would be a valuable addition to the standard risk assessment practice."

Response to CalChamber Comment 11:

The practice of preparing risk estimates for 9, 30 and 70 years is not new to this Guidance Manual. The 2003 guidelines also provided for this, based on average (9

years) and high-end (30 years) estimates of the length of residency time at a single location, as well as lifetime exposure (70 years). For the current Guidelines, we are recommending using a 30-year estimate for assessing residential exposure, but also recommend presenting the 9- and 70-year individual risks as well. A 70-year estimate will also be used to assess population exposure. Chapter 4 (Air Dispersion) of the Guidance Manual goes into considerable detail about the application of isopleths for Health Risk Assessments. For example, Section 4.6.1. states that, "As part of the estimation of the population exposure for the cancer risk analysis, it is necessary to determine the geographic area affected by the facility's emissions. An initial approach to define a "zone of impact" surrounding the source is to generate an isopleth where the total excess lifetime cancer risk from inhalation exposure to all emitted carcinogens is greater than 10^{-6} (one in 1,000,000). For noncarcinogens, a second, third, and fourth isopleth (to represent the chronic, 8-hour, and acute impacts) should be created to define the zone of impact for the hazard index from both inhalation and noninhalation pathways greater than or equal to 1.0. For clarity these isopleths may need to be presented on separate maps in the HRA."

Additional risk isopleths to represent one-in-10,000 and one-in-100,000 risk are also added, if relevant.

CalChamber Comment 12 (supplemental comments by GSI Environmental Inc.):

"Recommended Clarifications to the Draft Guidance Manual

"It is not clear from the new Guidance Manual, however, how the use of ASFs would be used in the presentation of risks for the three exposure durations. It is reasonable to expect that many, if not most, adults who have lived in their current residence for 9 or even 30 years moved to their current residence after the age of 16. Accordingly, it would be misleading to present them only with a risk assessment estimate based on the assumption that they had lived in that location from the last trimester of gestation through age 9 or age 30. We recommend that the range of risks presented for the assumed exposure durations of 9, 30 and 70 years include the assumption of 9 and 30 years of exposure as an adults as well as ages -0.25 to 9, -0.25 to 30, and -0.25 to 70. The use of all five exposure durations would not capture all of the permutations of exposure durations, but would provide risk estimate reference points relevant to many more people than would be provided if exposure beginning with the last trimester of gestation were assumed for all people living near a facility.

"Based on discussion in the call for comments on the new Guidance Manual and in the new Guidance Manual itself, OEHHA expresses the value they place on accuracy and consistency. We agree that these are worthwhile goals for any risk assessment. We are, however, concerned that the use of default ASFs have at least the potential to undermine both accuracy and consistency. The use of default ASFs introduces inaccuracies by assuming young animals are more sensitive than adults to all chemicals. Inaccuracies associated with the use of default ASFs could be mitigated by a more clear discussion of the assumptions and uncertainties associated with the use of the ASFs as they have been proposed by OEHHA, and clearer guidance for use of chemical-specific ASFs when available. In addition, the assumption that people living for 9 and 30 years in the vicinity of a source have lived there from the last trimester through age 9 or 30 would introduce a substantial amount of inaccuracy to estimated risks. Attenuation of the inaccuracy could be achieved by also presenting risks for 9 and 30 years of exposure after age 16."

Response to CalChamber Comment 12:

A facility may present whatever risk estimates it considers appropriate as long as it conducts a Tier 1 assessment using OEHHA's default approach. The OEHHA Tier 1 default approach includes 9- and 30-year exposure scenarios for residential exposures that start in the third trimester to capture risks from early life exposures.

Regarding the comment that use of default ASFs introduces inaccuracies by assuming young animals are more sensitive than adults to all chemicals, OEHHA chose a default ASF approximating the median of our ASF distribution (see ASF cumulative frequency profile figure in Response 6). Thus, it may overestimate risk for some carcinogens but underestimate risk for other carcinogens from early-in-life exposure. Again, all of these issues were reviewed and approved by the SRP in 2009.

CalChamber Comment 13 (supplemental comments by GSI Environmental Inc.):

The use of default ASFs raised particular concerns for the issue of consistency because the Hot Spots Guidance Manual can affect risk assessments prepared under regulatory programs other than the Hot Spots program itself (e.g., CEQA and Proposition 65).

Response to CalChamber Comment 13:

The Hot Spots Guidance Manual was developed for the Air Toxics Hot Spots Program. Other programs considering whether to use the Guidance Manual would have to determine if the methodology is appropriate for their programs.

Response to comments received from the California Council for Environmental and Economic Balance (CCEEB)

CCEEB Comment 1:

"CCEEB understands that OEHHA is required to provide a margin of safety to adequately capture the variable effects of air toxics on heterogeneous human populations, particularly for infants and children, as mandated by SB 25 (Escutia, 1999). However, the proposed changes in the guidance overstate risk from exposure without recognizing the large range in risk variables or the degree of uncertainty built into the process. This needs to be properly characterized in the guidance and in any risk communication by the air agencies and sources seeking to comply with public notification requirements."

Response to CCEEB Comment 1:

OEHHA spent a good deal of time deriving distributions of intake rates (breathing rates, drinking water rates, etc.) for use in risk assessments where the facility wanted to derive a range of risks. These were described in the *Technical Support Document for Exposure Assessment and Stochastic Analysis*, which underwent public and scientific peer review by the SRP in 2012. Thus, the concern that OEHHA' guidelines do not recognize the range in risk variables is incorrect; the distributions are explicit expressions of ranges of values.

The guidance for doing a Tier 1 assessment provides default parameters for a health conservative point estimate of cancer risk. A Tier 2 assessment may also be done which also provides a point estimate of cancer risk, but site-specific parameters may be used when they are sufficiently documented. A Tier 3 assessment is also available using stochastic methodology and default parameter distributions. This method will provide a range of estimated cancer risk that can be used to evaluate the large range in risk variables or the degree of uncertainty built into the process. Finally, there is a Tier 4 assessment available using stochastic methodology and site-specific parameter distributions when they are sufficiently documented.

CCEEB Comment 2:

"CCEEB is concerned that, lacking adequate risk communication and in light of the significant increase in risk estimates under the new guidance, the public will be overwhelmed and likely confused by new warnings, resulting in message fatigue, or worse, false alarm. A well-prepared rollout of this information is critical to ensure public understanding of the new analytical techniques. We recommend a coordinated approach among all parties, with the opportunity to provide input and feedback, on materials being prepared for distribution. We will continue to work with OEHHA, ARB, and the air districts on this important issue of risk communication."

Response to CCEEB Comment 2:

We agree that a coordinated communication strategy and individual plans are necessary to provide the public information on the assessments as they are released. ARB, the air districts and the California Air Pollution Control Officers Association (CAPCOA) are currently working together to provide information to the public. The ARB and OEHHA are also coordinating to release the updated HARP (the Hot Spots Analysis and Reporting Program) when the Hot Spots Guidance Manual is finalized.

CCEEB Comment 3:

"Reconsider the 9-year Minimum Exposure Requirement"

"Some projects that must undergo assessment are short in duration, such as construction or remediation work that lasts only a year or two. For those projects, the 9-year minimum exposure requirement for modeling cancer health risk makes little sense. OEHHA should explicitly include in their guidelines the ability for air districts to evaluate health risk for short-term projects using the expected length of exposure when the project applicant is able to stipulate a finite duration of source activity."

Response to CCEEB Comment 3:

OEHHA has changed the requirement that a minimum duration of exposure of 9 years be used for short term projects. This was described in the TSD for Exposure Assessment and Stochastic Analysis, which underwent public and scientific peer review by the SRP before it was approved by the SRP and finalized in 2012. Such guidance is discussed in the Guidance Manual, in section 8.2.10, "Cancer Risk Evaluation of Short Term Projects."

CCEEB Comment 4:

"Greater clarification is needed on applying Age-Sensitivity Factors (ASFs)

"CCEEB has questions regarding how age-sensitivity factors would be applied, particularly when data for a specific chemical is known to be different than OEHHAs default ASFs. For example, some chemicals may have scientific evidence that infants and children have less (not greater) sensitivity than adults. It is unclear by what process a project could have the best available science reviewed and approved as part of its risk assessment. Further, we believe that ASFs should be applied only where there are data that clearly demonstrates an enhance sensitivity."

Response to CCEEB Comment 4:

As noted in response to CalChamber comments 1 and 5 above, this topic is discussed in the *Technical Support Document for Cancer Potency Factors*, which underwent public review and scientific peer review by the SRP before it was approved by the SRP and finalized in 2009. OEHHA will not revisit the ASFs in the current public comment period, as indicated when we released the Guidance Manual for public review. The derivation of the ASFs is discussed in the technical support document starting on page 32. OEHHA's position on how they are to be used related to the comment is explained in a paragraph on page 51:

> *The ASFs will be applied to all carcinogens, regardless of the theorized mode of action. While U.S. EPA currently intends to apply weighting factors only to those carcinogens with "a mutagenic mode of action" (U.S.EPA, 2005), OEHHA notes that there is evidence that early life is a susceptible time for carcinogens that are thought to act via non-mutagenic mode of action (DES is a prime example). Defining a mutagenic mode of action may be problematic if approached narrowly (ERG, 2008). Further, carcinogens may have multiple modes of action and one mode may predominate over other modes at different life stages. The complexity of carcinogenesis argues against restricting the ASF to chemicals acting via a mutagenic mode of action.*

The type of data needed to adequately show that no windows of susceptibility occur during development through adolescence does not generally exist, even for well-studied chemicals. It would be imprudent and not in the interests of the public's health to assume there is no increased sensitivity in the absence of data. Thus, OEHHA chose a value consistent with US EPA's for the ASFs that is informed by the available science. Note that the value is representative of a median rather than a mean. As noted above,

this is all discussed and was debated during the open public process and peer review back in 2009.

Also as noted in responses to CalChamber comments above, OEHHA does allow the use of chemical-specific ASFs that are science-based and defensible. As noted in our Guidance on page 8-4 and 8-5,

> "*For specific carcinogens where data indicate enhanced sensitivity during life stages other than the immediate postnatal and juvenile periods, or for which data demonstrate ASFs different from the default ASFs, the chemical-specific data should be used in order to adequately protect public health*."

Also, note that in our 2009 Cancer TSD[8], we state that "*In cases where there are adequate data for a specific carcinogen of potency by age, we would use the data to make any adjustments to risk.*"

CCEEB Comment 5:

"Greater clarification is needed in applying the Tiered Approach to Risk Assessment

"OEHHA proposes a tiered approach for risk assessment whereby *all* projects must utilize OEHHA determined defaults for point estimates of exposure variates (Tier 1), although some projects *might* be able to utilize *additional* site-specific point estimates (Tier 2) and/or distributions of exposure variates (Tier 4), but only with the prior approval of OEHHA and the responsible air district. The process and criteria by which a project could seek and obtain approval to utilize Tier 2 or Tier 4 approaches is not well defined, nor is it clear why a Tier 1 approach is needed if other approaches provide better and more scientifically sound site-specific data."

Response to CCEEB Comment 5:

We have added the verbiage to section 2.5.3, *Tiered Approach to Risk Assessment*, to clarify how site-specific information can be included in Tier 2 and 4 risk assessments and why everyone needs to do a Tier 1 risk assessment. An extensive summary of the tiered approach is also presented in Section 8.1.1. Regarding Tier 1 and 2, Tier 1 evaluations are required for all health risk assessments (HRAs) prepared for the Hot Spots Program. Tier 1 is a standard point estimate approach using the recommended point-estimates presented in Hot Spots Guidance Manual. If site-specific information is

[8] *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures*,

available to modify some point estimates developed in the *Technical Support Document for Exposure Assessment and Stochastic Analysis* (OEHHA, 2012) and is more appropriate to use than the recommended point-estimates in this document, then Tier 2 allows use of that site-specific information.

As discussed in the *Technical Support Document for Exposure Assessment and Stochastic Analysis* (OEHHA, 2012), if the risk characterization results from a Tier 1 assessment are above a regulatory level of concern, the risk assessor may want to proceed with more site-specific analysis as described in Tier 2, or use a more resource-intensive stochastic modeling effort described in Tier 3 and Tier 4 (for cancer risk). While further evaluation may provide more information to the risk manager on which to base decisions, the Tier 1 evaluation is useful in comparing risks among a large number of facilities and must be included in all HRAs.

We have also added language in Section 8.1.1 regarding use of Tier 2 and 4 for small footprint facilities (e.g., gas stations). For example, alternative breathing rates (point estimates or distributions) may be used as part of Tier 2 or Tier 4 risk assessments with appropriate supporting justification in the case of a very small zone of impact. OEHHA would work with risk managers at ARB and the Districts to review the alternative estimates in such an assessment.

OEHHA had a tiered approach in our 2003 guidelines. Further, we presented the tiered approach again in our Technical Support Document for Exposure Assessment and discussed the approach during the open public process in 2012. The 2012 TSD underwent scientific peer review and received approval from the SRP. In that document, OEHHA discussed the tiered assessment approach and indicated that site-specific values can be presented if they are justified. The Districts and OEHHA would review any risk assessment that uses site-specific exposure parameter values. Note that it takes considerable effort to identify and analyze data for determining exposure intake rates. OEHHA performed those extensive analyses to derive the point estimates.

Response to comments from the County Sanitation Districts of Los Angeles County (LASanDistricts)

LASanDistricts Comment 1:

"It is not clear if OEHHA intends users to apply metrics for the 95th threshold to every receptor for the purposes of calculating cancer burden. It seems to us that applying 95th percentile breathing rates to the entire population is statistically inappropriate. Furthermore, it seems that the choice of what percentile to use is the role of the risk manager and not the risk assessor (OEHHA). If that is the choice that OEHHA is recommending, please provide justification for risk managers so they can defend the results."

Response to LASanDistricts Comment 1:

OEHHA has recommended that the user use the 95th percentile breathing rate when calculating a point estimate of risk. This is to ensure that the more highly exposed individuals are included in risk assessment. This recommendation was already subject to public and scientific peer review and adopted after SRP approval when OEHHA developed the *Technical Support Document for Exposure Assessment and Stochastic Analysis* (OEHHA, 2012).

We also developed distributions of breathing rate by age groups if a facility wants to include an analysis based on a distribution of risks to provide additional information to the risk managers. These distributions are also included in the Technical Support Document and were subject to the public and peer review noted above.

LASanDistricts Comment 2:

"Although the usability of the Guidance is important, the usability of HARP is of greater concern. Please consider coordinating with ARB to simultaneously obtain public comment on a beta version of HARP with the associated OEHHA Guidance. Such a vetting process using the tool that implements the Guidance should glean more meaningful feedback."

Response to LASanDistricts Comment 2:

The update of HARP by ARB is ongoing. ARB is coordinating with OEHHA on the update as they need to input changes based on the three approved Technical Support Document and the Guidance Manual. We need to provide a public comment period on the Guidance Manual prior to finalizing the manual. Thus, a simultaneous public comment period is not possible. However, both ARB and OEHHA are working together to release an updated version of HARP at the same time the Guidance Manual is finalized.

LASanDistricts Comment 3:

"Section 1.2. Please indicate that OEHHA doesn't have a role in permitting, nor does OEHHA review HRAs for those purposes."

Response to LASanDistricts Comment 3:

There is not a mandate for OEHHA to review permitting decisions or any of the scientific analyses that go into a permitting decision. However, we do provide advice to the Districts when requested on any of the risk assessment methods or health values they have used. Language to this effect has been added to the Preface.

LASanDistricts Comment 4:

"Please clarify that facility HRAs under AB2588 are based on actual, routine and predictable emissions, and not potential to emit or worse case scenarios."

Response to LASanDistricts Comment 4:

The Air Toxics Hot Spots Act is chaptered in the California Health and Safety Code Section 44300 et seq. The statute defines "air releases, which are the subject of the emissions inventory and risk assessment as follows:

> *"Section 44303. "Air release" or "release" means any activity that may cause the issuance of air contaminants, including the actual or potential spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing of a substance into the ambient air and that results from*

> *the routine operation of a facility or that is predictable, including, but not limited to, continuous and intermittent releases and predictable process upsets or leaks."*

Thus, the law addresses not just actual, routine and predictable emissions, but also "potential" releases. Note, however, that the emissions inventories for the typical facility under the Hot Spots program are based on what is known about the actual releases, both routine and process upsets, at a facility. Under a permitting scenario, of course, the facility is not yet built and thus the emissions are by definition potential emissions.

Air Toxics Hot Spots Act California Health and Safety Code Section 44300 et seq. can be found in Appendix B of the Hot Spots Guidance Manual.

LASanDistricts Comment 5:

"Section 1.4, item 8. Please state that cumulative risks from other facilities are not part of AB2588 and are not discussed further in this document."

Response to LASanDistricts 5:

The wording in the section pertains to the HARP software and its potential functions. In item 8, the word "facility" was replaced with the words "emission sources".

In the Health and Safety Code Section 44301, the legislative findings refer to "cumulative health risks". In 44301(d):

> "These releases may create localized concentrations or air toxics "hot spots" where emissions from specific sources may expose individuals and population groups to elevated risks of adverse health effects, including, but not limited to, cancer and contribute to the cumulative health risks of emissions from other sources in the area. (Emphasis added.) In some cases where large populations may not be significantly affected by adverse health risks, individuals may be exposed to significant risks."

In practice, however, individual facilities are responsible for assessing the risk posed by their emissions, not the emissions of other facilities nearby.

Air Toxics Hot Spots Act California Health and Safety Code Section 44300 et seq. can be found in Appendix B of the Hot Spots Guidance Manual.

LASanDistricts Comment 6:

"Section 4.1. For the benefit of risk managers in their consideration of new health-protective risk thresholds, please mention the numerous areas where conservatism is built into the various RELs and cancer potency factors."

Response to LASanDistricts Comment 6:

OEHHA has striven to use the best science available in developing these risk assessment guidelines. However, there is a great deal of uncertainty associated with the process of risk assessment. The uncertainty arises from lack of data in many areas necessitating the use of assumptions. The assumptions used in these guidelines are designed to be health protective in order to avoid underestimation of risk to the public.

The risk managers from the air pollution control districts are familiar with our Technical Support Documents which underlie the Guidance Manual. Indeed, CAPCOA reviewed the Technical Support Documents prior to public review. These TSDs describe the methods by which RELs and Cancer Potency Factors are derived, as well as describe the underlying data and analyses for deriving exposure variable values (e.g., long-term breathing rates), including point estimates and distributions. A discussion of "conservatism" does not belong in the Guidance Manual, which is a user manual of how to conduct a risk assessment. The Guidance Manual does not discuss risk management. Further, "conservatism" in risk assessment is not well-defined either in the comment or generally, and is not readily quantifiable. In fact, we have not recommended conservative values for a number of parameters (e.g., the default Age Sensitivity Factors which hover around the median of a skewed distribution; the use of a 30 year residency time; the fraction of time spent at home; improved modeling with spatial averaging).

LASanDistricts Comment 7:

"Section 4.1 . Please include a consideration of the land use as one of the HRA steps."

Response to LASanDistricts Comment 7:

A discussion of land use is covered under the subject of "identifying the terrain type". Terrain type and land use are discussed in more detail in Section 4.4.

LASanDistricts Comment 8:

"Section 4.2.1.2. Please include clear guidance on capped stacks and non-vertical stacks. Air districts are giving inconsistent recommendations for these non-traditional release points."

Response to LASanDistricts Comment 8:

The OEHHA guideline has included general guidance for raincap on stack (see Section 4.13.5). Currently, U.S. EPA provides a BETA option for capped stacks (source type = POINTCAP) and horizontal releases (source type = POINTHOR) in AERMOD. (For details, see U.S. EPA - AERMOD ADDENDUM USER'S GUIDE FOR THE AMS/EPA REGULATORY MODEL, released February 2012, the link: ttp://www.epa.gov/ttn/scram/models/aermod/aermod_userguide_addendum_v11059_draft.pdf.). Note that the BETA option is a non-DFAULT option, and will be overridden if the DFAULT option is specified. The local air districts should be consulted before modeling capped stacks and horizontal releases.

LASanDistricts Comment 9:

"Section 4.2.1.3. Please clarify that operation schedules for AB2588 purposes are based on routine and predictable operation, and not extreme cases."

Response to LASanDistricts Comment 9:

Comment addressed and text clarified.

LASanDistricts Comment 10:

"Section 4.3.1.2. Please expand the explanation regarding what circumstances non-motor vehicles become subject to Hot Spots reporting and HRAs. This inclusion seems to have occurred recently without being fully vetted with stakeholders and was not mentioned in the previous (2003) Guidance."

Response to LASanDistricts Comment 10:

The text in Section 4.3.1.2 has been clarified in response to the comment. Mobile sources that operate within the facility boundary, which do not meet the definition of

motor vehicles, should be included in emission inventory reports. This has been required since 1989. See the Emission Inventory Criteria and Guidelines (2007) and the link to a memo from 1989 http://www.arb.ca.gov/ab2588/motorv.pdf.

LASanDistricts Comment 11:

"Section 4.3.1.3. Area-wide modeling of portable equipment within a facility for cancer and chronic risks should be allowed as this represents the routine and predictable use of this equipment."

Response to LASanDistricts Comment 11:

Routine and predictable emissions should always be included in the emission inventory and risk assessment. Portable equipment, depending on its use and release configuration, may or may not be best represented as an area source. Therefore, a general statement will not be added to the text since this is a case by case determination. Contact the local district or reviewing authority for additional discussion of a specific situation.

LASanDistricts Comment 12:

"Section 4.6.1. It's not clear why a separate "zone of impact" is needed if an affected area is already being defined by the cancer burden isopleth. An example may explain better OEHHA's recommendation. If OEHHA is anticipating examples where the non-cancer hazard indices may be more impactful than cancer burden, please state so more clearly."

Response to LASanDistricts Comment 12:

Zone of impacts should be presented for both cancer and noncancer impacts. Section 4.6.1 separately discusses presenting the zone of impact from carcinogens and noncarcinogens. There is no intent to imply or state that one type of impact is more important that another impact. All impacts must be clearly presented in the risk assessment.

LASanDistricts Comment 13:

"Overall, Chapter 4. Please consider eliminating isopleth requirements where the critical isopleths fall entirely within a facility boundary."

Response to LASanDistricts Comment 13:

The general elimination of onsite impacts is not appropriate. Some facilities may have onsite receptors. Zones of impact should be shown where receptors of concern are located. Discussion of onsite receptors is presented in Section 4.7.1. If there is a question, consult with the local air district or reviewing authority for a case by case determination.

LASanDistricts Comment 14:

"Section 4.7.1. Some air districts have yet to establish clear guidance on the conditions where on-site receptors should be considered for HRAs. Some guidance from OEHHA would be helpful here."

Response to LASanDistricts Comment 14:

We do provide guidance when and how onsite receptors should be considered. Any locations on the facility property that the public has regular access to may be considered an onsite receptor. We note in Section 5.4.1.2 that onsite daycare centers should also be included in risk assessments.

Regarding how onsite receptors should be considered for emission exposure, our Guidelines in Section 8.4 say: "When a receptor lives and works on the facility, site, or property, then these receptors should be evaluated and reported under both residential and worker scenarios and the one that is most health protective should be used for risk management decisions. The cancer risk estimates for the onsite residents may use a 30-year exposure duration while the 25-year exposure duration is used for a worker. Under a Tier 2 analysis, alternate exposure durations may be evaluated and presented with all assumptions supported. See section 8.2.10 for more discussion of short term exposures." This statement will also be added to Section 4.7.1 for more clarity on the issue.

The District or reviewing authority should be consulted on the appropriate evaluations for the risk for all onsite receptors. This is already noted in Section 4.7.1.

LASanDistricts Comment 15:

"Section 4.7.1. Clarify the treatment for off-site worker exposure for unstaffed operations like oil derricks or pump stations. It seems like cancer/chronic risks should not apply in these cases."

Response to LASanDistricts Comment 15:

If there are no off-site workers, then the Maximum Exposed Individual Worker (MEIW) receptor cannot be determined. As noted in Section 4.7.1,

> "Some facilities will not have off-site workers in the vicinity of the facility and will not need to evaluate worker exposure. The approval to omit the MEIW receptor is a case-by-case situation and should be verified in writing with the District or reviewing authority and the written approval to not evaluate a worker receptor included in the HRA."

However, a determination for short-term chronic exposures to emissions should be considered if there is the occasional presence of off-site workers to these areas (See Section 8.2.10). In addition, these sources may need to be evaluated for acute noncancer MEIW impacts if workers are present for an hour or more.

LASanDistricts Comment 16:

"Section 4.7.1.1. Please clarify whether flag-pole receptors were discussed in the Exposure Assessment TSO and if/when these are recommended. The default has always been ground-level concentrations."

Response to LASanDistricts Comment 16:

The text in Section 4.7.1.1 has been clarified in response to the comment. These were discussed in Section 2.7.1.1 of the Exposure Assessment and Stochastic Analysis Document (August 2012). The ground level (0 meters) is appropriate for noninhalation pathways. A breathing zone of 0 to 1.8 meters may be appropriate for the inhalation pathway. The air district or reviewing authority should be consulted for final approval.

LASanDistricts Comment 17:

"Section 4.8. Please encourage the use of pre-processed meteorological data compiled and reviewed by air district staff. Users should only attempt to process their own data in unusual circumstances as most users will have difficulty processing and verifying these data. Please also encourage local air districts and the ARB to provide these data for the updated HARP software."

Response to LASanDistricts Comment 17:

The ARB does understand that processing meteorological data may be difficult. ARB will be providing AERSCREEN inputs and AERMOD-ready meteorological data for California as it can be developed or becomes available.

LASanDistricts Comment 18:

"Section 4.8. Please clarify with an example the discussion regarding early morning low mixing heights."

Response to LASanDistricts Comment 18:

As the sun goes down, the atmospheric temperature near the surface starts to fall, usually faster than the temperature in the upper atmosphere causing a temperature inversion layer to form and extend downward. This inversion layer usually sustains throughout the night, and remains until the next morning till the sun heats up the lower atmosphere enough to break it. Because of the inversion (cold air sitting on warm air at the top of the inversion layer), pollutant vertical mixing is very low in the morning.

LASanDistricts Comment 19:

"Section 4.11.1.2(b). Please state that discussions of 1-meter resolution of AERMOD results may provide a misleading picture of the accuracy of the model results. Also please note that such a resolution represents a highly unusual case."

Response to LASanDistricts Comment 19:

The text in Section 4.11.1.2(b) has been clarified in response to the comment. The area source algorithm in AERMOD estimates source emission strength by integrating an area upwind of the receptor location. Receptors may be placed within the area itself, downwind of the area, or adjacent to the area. However, since the vertical distribution

parameter (σ_z) goes to zero as the downwind distance goes to zero, the plume function solution is infinite for a downwind receptor distance of zero. In order to avoid such singularity in the plume function solution, the AERMOD model arbitrarily sets the plume function to zero when the receptor distance is less than one meter. As a result, the area source algorithm will not provide reliable solutions for receptors located within or adjacent to very small areas, with dimensions on the order of a few meters across. In these cases, the receptor should be placed at least one meter outside of the area.

LASanDistricts Comment 20:

"Section 4.11.1.2(c). Please explain what is meant by "initial distribution" of volume source emissions."

Response to LASanDistricts Comment 20:

When modeling volume source emissions, one needs to provide initial horizontal (σ_{y0}) and vertical (σ_{z0}) dimensions as accurate as possible so that pollutant buoyancy and dispersion are also calculated accurately. US EPA's AERMOD User Guide (i.e., Table 3-1) provides suggested procedures to estimate these initial dimensions based on source type.

LASanDistricts Comment 21:

"Section 4.11.1.2(d). Please state that the presence of a major freeway, like that of a large building, can affect the plume by introducing additional mixing. This effect is ignored in AERMOD and introduces more conservatism into the model results that is not mentioned in the Guidance."

Response to LASanDistricts Comment 21:

The presence of a major freeway may cause some initial vertical dispersion, which could be estimated based on wind speed, wind angle, roadway orientation, roadway width, etc. This could be a complex estimation and needs very adept modeling skills. We suggest that for this special case modeling scenario the local air quality district is consulted for their recommendations.

LASanDistricts Comment 22:

"Section 4.11.1.2(g). Please clarify your point about diurnal considerations with an example."

Response to LASanDistricts Comment 22:

For a facility, operation hours could be different during a day. For example, a facility may just operate for daytime hours (e.g., 8 am to 5 pm) or may operate 24 hours per day. Even so, hourly emission rates may be different due to different loadings. From a prospective of meteorology, diurnal meteorological conditions are also different (for details, see Section 4.11.1.2(g)). For these reasons, it is especially important to simulate facility emissions with an hourly diurnal pattern reflective of source activity so that the risk assessment is representative of daily conditions.

LASanDistricts Comment 23:

"Section 4.15.1. In many cases, the modeler cannot know ahead of time the PMI/MEIR/MEIW until after the model is run. If the model cannot be run until after the modeling protocol is approved, then please correct this apparent conundrum."

Response to LASanDistricts Comment 23:

Text revised. Note that text covering this same subject in Chapter 9 was also revised.

LASanDistricts Comment 24:

"Section 5.4.1.1(A)(a). Appears that text is missing, please revise."

Response to LASanDistricts Comment 24:

We thank the commenter for pointing out the error. We have corrected the text in Equation 5.4.1.1 (a)1 to say: "{BR/BW} = Daily breathing rates by age groupings, see Table 5.6 (point estimates) and Table 5.7 (parametric model distributions for Tier III stochastic risk assessment). For Tier 1 residential estimates, use 95th percentile breathing rates in Table 5.6."