1 Introduction

The Air Toxics "Hot Spots" Information and Assessment Act (AB 2588, Connelly, stat. 1987; Health and Safety Code Section 44300 et seq.) is designed to provide information on the extent of airborne emissions from stationary sources and the potential public health impacts of those emissions. Facilities provide emissions inventories of chemicals specifically listed under the "Hot Spots" Act to the local Air Pollution Control and Air Quality Management Districts (Districts) and ultimately to the state Air Resources Board. Following prioritization of facilities by the Districts, facilities may be required to conduct a health risk assessment.

Health risk assessment involves a comprehensive analysis of the dispersion of the specific facility's air emissions, and the extent of human exposure via all relevant pathways (exposure assessment), the toxicology of those chemicals (dose-response assessment), and the estimation of cancer risk and noncancer health impacts to the exposed community (risk characterization). Most "Hot Spots" risk assessments are conducted by contractors for the facility; some are conducted in-house and some by the local air districts. AB-2588 mandates the Office of Environmental Health Hazard Assessment (OEHHA) to review Hot Spots risk assessments and the findings are conveyed to the District by letter. The District may require the facility to notify the impacted public if the risk assessment shows risks above a level deemed acceptable by the District.

The Air Toxics "Hot Spots" Act was amended to require that the Office of Environmental Health Hazard Assessment (OEHHA) develop risk assessment guidelines for the Air Toxics "Hot Spots" program (SB 1731, Calderon, stat. 1992; Health and Safety Code Section 44360(b)(2)). The amendment specifically requires OEHHA to develop a "likelihood of risks" approach to health risk assessment. Therefore, the OEHHA developed a stochastic, or probabilistic, approach to exposure assessment to fulfill this requirement. The previous version of this document, the *Technical Support Document for Exposure Assessment and Stochastic Analysis,* was final in September 2000 (OEHHA, 2000a). This revision of the document updates OEHHA (2000a) by incorporating scientific advances in the field of exposure assessment, and newer data on exposure variates. Exposure variates are consumption estimates for various media and values for fate and transport modeling such as fish bioaccumulation factors.

All facilities are required to conduct a point estimate risk assessment using OEHHA's recommended exposure variates. Facilities may choose to also conduct a stochastic assessment of exposure (and risk) to provide more information to the risk managers and the public. The stochastic approach described in this document provides guidance to the facility operators who want to conduct a stochastic risk assessment, and facilitates use of supplemental information to be considered in the health risk assessment. It provides a method for quantification of the portion of exposure variability for which sufficient data exist to permit estimation. This document does not present an approach for quantification of uncertainty in exposure assessment.

OEHHA has developed a series of documents describing the information supporting the dose-response assessment for "Hot Spots" chemicals and the exposure assessment methodologies. The Children's Environmental Health Protection Act (SB-25) was passed in 1999 and mandated that OEHHA ensure that our risk assessment procedures were protective of children's health. OEHHA developed the methodology presented in the *Air Toxics Hot Spots Risk Assessment Guidelines Technical Support Document for the Derivation of Non-cancer Reference Exposure Levels* (RELs) (OEHHA, 2008) to ensure that our procedures for REL development were protective of children. The 2008 document supersedes the earlier documents for acute RELS, (OEHHA 1999a) and chronic RELS (OEHHA, 2000b). However, RELs developed under the previous OEHHA Guidance (1999a and 2000b) that have not undergone re-evaluation under the OEHHA (2008) updated methodology remain in effect for the Hot Spots program. New and revised RELs are being developed using the 2008 Guidelines and periodically released for public comment and review by the State's Scientific Review Panel on Toxic Air Contaminants (SRP).

OEHHA also developed 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) after the passage of SB-25 to ensure that cancer dose-response takes into account the vulnerability of children. The 2009 document supersedes the *Technical Support Document for Determining Cancer Potency Factors* (OEHHA, 1999b).

This revision of the *Technical Support Document for Exposure Assessment and Stochastic Analysis* describes the exposure algorithms, and point estimates and distributions of key exposure variates that can be used for the exposure analysis component of Air Toxics "Hot Spots" risk assessments. OEHHA reassessed exposure variates for children to ensure they would not underestimate exposure under our SB-25 mandate. We also incorporated advances in the field of exposure assessment since the previous version of the document. The document includes a description of the point estimate and stochastic multipathway exposure assessment approaches and a brief summary of the information supporting the selection of default assumptions. OEHHA developed this document in consultation with the Air Resources Board (ARB) and the California Air Pollution Control Officers Association (CAPCOA). The ARB provided Chapter 2 and associated appendices describing the air dispersion and deposition modeling.

A tiered approach to risk assessment, which allows for both consistency and flexibility, is described in Section 1.4. OEHHA's proposed algorithms, default point estimates and distributions of variates for each major exposure pathway are described in Chapters 3 through 10. The algorithms, with one exception, are identical to the previous version of this document (OEHHA, 2000). We condensed portions of the algorithm for dermal absorption, simplifying the equation and calculation. The algorithms used in our exposure model are largely consistent with the U.S. EPA (1991) Risk Assessment Guidance for Superfund Sites, with some modifications. The point estimates and distributions were updated based on newer data.

Finally, we are updating the *Air Toxics 'Hot Spots' Risk Assessment Guidance Manual* (OEHHA, 2003). This updated document, which will be available soon for public comment and peer review by the SRP, contains the essential information to conduct a health risk assessment based on the three technical support documents described above.

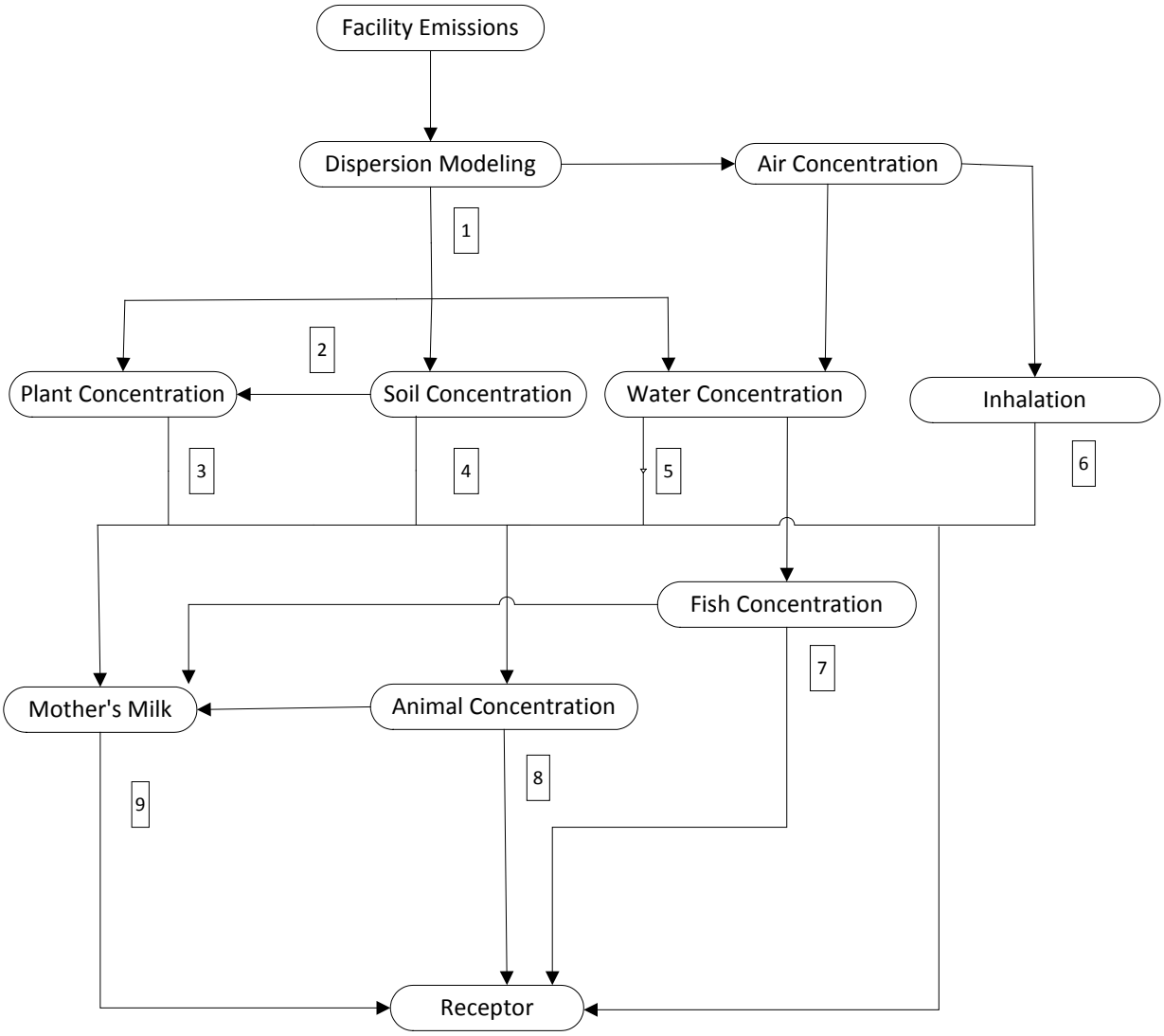
1.1 Multipathway Nature of Exposure Assessment

Exposure assessment of airborne emissions includes not only an analysis of exposure via the inhalation pathway, but also noninhalation pathways of indirect exposure to airborne toxicants. There are data in the literature demonstrating that for some compounds, significant exposure occurs following deposition of airborne material onto surface water, soils, edible plants (both food, pasture and animal feed), and through ingestion of breast milk. Examining both direct inhalation and indirect noninhalation exposure pathways reveals the full extent of exposure to airborne emissions (see Figure 1.1).

However, only certain chemicals are evaluated via the multipathway approach in the Air Toxics "Hot Spots" risk assessments. In general, there is a higher potential for indirect exposure to chemicals which tend to bioconcentrate or bioaccumulate (e.g., lipophilic semi-volatile organics), or otherwise accumulate in the environment (e.g., metals). Semi-volatile and non-volatile organic and metal toxicants can be directly deposited onto surface waters, soil, leaves, fruits and vegetables, grazing forage, and so forth. This is particularly important when these chemicals are associated with particulate matter. Cows, chickens, and other food animals can become contaminated through inhalation, and ingestion of contaminated surface water, pasture, feed and soil. Fish can become contaminated via bioconcentration from water and bioaccumulation from their food. Produce can become contaminated via root uptake from soils and direct deposition. Thus, humans can be exposed through ingestion of contaminated meat, fish, produce, water and soil, as well as from breathing contaminated air, and via dermal exposure. In addition, nursing infants can be exposed via breast milk.

The exposure variates are presented by chapter in this Document roughly in order of importance to an Air Toxics Hot Spots facility risk assessment. The breathing rate (Chapter 3) is the most important pathway; all chemicals must include an inhalation assessment. The breathing rate chapter is followed by chapters discussing the pathways that are automatically included if a risk assessment finds semi- or non-volatile Hot Spots chemicals: the soil ingestion pathway (Chapter 4), the mother's milk pathway (Chapter 5), and the dermal exposure pathway (Chapter 6). The remaining chapters contain the pathways that are only presented in a risk assessment in cases where it has been shown that these exposure pathways exist: the home-produced food pathway (Chapter 7), the water intake pathway (Chapter 8), and the fish consumption pathway (Chapter 9).

Figure 1.1 Exposure Routes



1. Deposition
2. Root Uptake by plants.
3. Human Consumption of Leafy, Protected, Exposed and Root Produce. Animal consumption of pasture and feed.
4. Soil Ingestion by humans and animals, and dermal exposure to soil.
5. Water consumption from surface water sources
6. Inhalation by humans and animals
7. Fish consumption
8. Consumption of beef, chicken and pork.
9. Mother's milk consumption.

Inhalation exposure is assessed for all “Hot Spots”-listed chemicals which have either Cancer Potency Factors and/or Reference Exposure Levels (see the Technical Support Documents mentioned in paragraph 2 for information on these values (OEHHA,2008, 2009), available at http://www.oehha.ca.gov/air/hot_spots/index.html). The noninhalation exposures are assessed only for semivolatile organics and metals listed in Appendix E, Table E.2. These chemicals have oral RELs and/or oral cancer potency factors. Appendix E contains a description of the process used to decide which chemicals should be evaluated by multipathway exposure assessment.

Only the exposure pathways which exist at a particular site need to be assessed in the Air Toxics Hot Spots program. For example, if a fishable body of water is impacted by facility emissions, then exposure through consumption of angler-caught fish is assessed. Otherwise, that pathway may be omitted from the risk assessment. Likewise if no backyard or local commercial produce or animals are raised in the impacted area, then the risk assessment need not consider dose through the ingestion of animal food products or produce. The “Hot Spots” program does not currently assess run off into surface drinking water sources because of the complex site-specific information required. The water consumption of surface waters pathway is rarely invoked in the “Hot Spots” program.

All risk assessments of facilities emitting chemicals listed in Table E.2 need to include an evaluation of exposure from breast milk consumption, soil ingestion, and dermal absorption from soil, since these exposure pathways are likely to exist at all sites. Table E.3 lists the chemicals that should be evaluated by the breast milk exposure pathway. The determination of the appropriate exposure pathways for consideration in the risk assessment should be made in conjunction with the local Air Pollution Control or Air Quality Management District. Justification for excluding an exposure pathway should be clearly presented.

1.2 The Point Estimate Approach

The point estimate approach (sometimes referred to as deterministic) is the traditional approach for site-specific risk assessments in the Hot Spots program. In the point estimate approach, a single value is assigned to each variate in the model (e.g., a breathing rate in L/kg BW-day). The point estimates chosen sometimes represent upper-end values for the variate and sometimes reflect a mean or central tendency estimate. The outcomes of a point estimate model are single estimates of either cancer risk or of the hazard index for noncancer effects. The point estimates of risk are generally considered near the high-end of the range of estimated risks, based on variability in exposure; quantitative information on population variability is generally lacking. However, the older point estimate approach to exposure assessment left open the question of variability in exposures of the general population. For example, it was unclear what percentage of the population would breathe more or less than a 20 m^3/day inhalation rate. The research stimulated by the desire to incorporate population variability in stochastic approaches has allowed informed selection of point estimates

that cover a defined percentage of the population, within the limitations and uncertainties of the available scientific data.

1.2.1 Need for Exposure Variates for Specific Age Groupings

In the previous exposure guideline, we presented distributions and point estimates for use in exposure assessment for children less than 12 years of age and for adolescents and adults up to age 70 years. Risk assessments were conducted for different durations of exposure based on estimates of how long people live at a single location (9 years for the average, 30 years for a high end estimate, and 70 years for a lifetime).

This update retains the evaluation of the 9, 30 and 70 year exposure durations, which represent approximately the mean, 90th percentile and lifetime of residence time. However, *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) concludes that the potency of carcinogens, and thus cancer risk, varies based on the lifestage at exposure. To address this concern, OEHHA applies a weighting factor to early life exposures, termed the Age Sensitivity Factor (ASF) (see OEHHA, 2009 for details). Cancer risk is multiplied by an ASF of ten to weight lifetime risk from exposures occurring from the third trimester of pregnancy to age less than 2. Likewise, for exposure from age 2 to less than 16 years, an ASF of three is applied.

Using these Age Sensitivity Factors (ASFs) requires a different approach to calculation of cancer risk from the traditional methods. Accounting for effects of early-in life exposure requires accounting for both the increased potency of early in life exposure to carcinogens and the greater exposure on a per kg body weight that occurs early in life due to behavioral and physiological differences between infants and children, and adults.

The lifetime risk is a summation of risks from the third trimester to age 2 yrs, 2 to age 16 and 16 to age 70 years. Similarly, when estimating cancer risk for a 9 year (average duration living at given residence) exposure to facility emissions or a 30 year (high-end duration living at a given residence) exposure to facility emissions, the cancer risks are similarly summed, starting with early-in-life exposures. These calculations are as follows:

9-year exposure duration - Calculation of Cancer Risk from the Third Trimester to Age Nine:

$$\text{Cancer Risk} = [(ADD_{\text{third trimester}} \times CPF \times 10) \times 0.3\ \text{yrs}/70\ \text{yrs}] + [(ADD_{0\ \text{to}\ <2\text{yrs}} \times CPF \times 10) \times 2\ \text{yrs}/70\ \text{yrs}] + [(ADD_{2\ <\ 9\text{yrs}} \times CPF \times 3) \times 7\ \text{yrs}/70\ \text{yrs}]$$

30-year exposure duration - Calculation of Cancer Risk from Third Trimester to Age 30:

$$\text{Cancer Risk} = [(ADD_{\text{third trimester}} \times CPF \times 10) \times 0.3 \text{ yrs}/70 \text{ yrs}] + [(ADD_{0 \text{ to } <2\text{yrs}} \times CPF \times 10) \times 2 \text{ yrs}/70 \text{ yrs}] + [(ADD_{2 < 16\text{yrs}} \times CPF \times 3) \times 14 \text{ yrs}/70 \text{ yrs}] + [(ADD_{16 < 30\text{yrs}} \times CPF \times 1) \times 14\text{yrs}/70 \text{ yrs}$$

Lifetime (70 year) exposure duration - Calculation of Cancer Risk from Third Trimester to Age 70:

$$\text{Cancer Risk} = [(ADD_{\text{third trimester}} \times CPF \times 10) \times 0.3 \text{ yrs}/70 \text{ yrs}] + [(ADD_{0 \text{ to } <2\text{yrs}} \times CPF \times 10) \times 2 \text{ yrs}/70 \text{ yrs}] + [(ADD_{2 < 16\text{yrs}} \times CPF \times 3) \times 14 \text{ yrs}/70 \text{ yrs}] + [(ADD_{16 < 70\text{yrs}} \times CPF \times 1) \times 54 \text{ yrs}/70 \text{ yrs}$$

where:

ADD = Average Daily Dose, mg/kg-d, for the specified time period (estimated using the exposure variates presented in the TSD)
CPF = Cancer Potency Factor $(\text{mg/kg-d})^{-1}$
Age Sensitivity Factor third trimester to less than 2 years = 10
Age Sensitivity Factor age 2 to less than 16 years = 3
Age Sensitivity Factor age 16 to less than 70 years = 1

Exposure from all pathways evaluated by the Hot Spots program tends to be greater for children per kilogram body weight, particularly for the third trimester to less than age 2 years. Therefore exposure variates are needed for the third trimester (mother's exposure), ages 0 to <2 years, 2 to <9 years, 2 < 16 years,16 to <30 years, and 16 to 70 years in order to properly estimate cancer risk for the age ranges specified in OEHHA (2009) as well as the residential exposure duration periods (9, 30, and 70 years). This document presents intake rates for the necessary age groupings for inhalation, food consumption, drinking water consumption, breast milk consumption, inadvertent soil ingestion, and dermal exposure useful to estimate exposure and thus cancer risk.

Estimating dose for the fetus during the third trimester of pregnancy is not easy because it will vary from chemical to chemical depending on the toxicokinetics. An approximation of the dose during the third trimester can be made by assuming the dose (mg/kg body weight) is the same as the mother's dose (mg/kg-body weight). The mother is assumed to fall into the age range sixteen to less than thirty. This approximation is uncertain and will over or underestimate dose in some instances. The dose during the third trimester tends to be considerably less than the dose during ages zero to less than two, so separate calculations of dose during the third trimester and ages zero to two years are needed.

The point estimate approach has the advantages of simplicity and consistency, and in the Air Toxics "Hot Spots" program consistent application across the state is critical to comparing risks across facilities for the notification and risk reduction provisions of the statute. Risk communication is relatively straightforward with a point estimate approach. However, a single point estimate approach does not provide information on

the variability in the dose or risk estimates. Some Information about the potential range of risks in the population can be presented as average or high-end point estimates of risk.

1.3 The Stochastic Approach ("Likelihood of Risks" Approach)

As noted earlier, the amended Act specifically requires OEHHA to develop a "likelihood of risks" approach to health risk assessment. Therefore, the OEHHA developed a stochastic, or probabilistic, approach to exposure assessment to fulfill this requirement. The stochastic approach to Hot Spots risk assessment developed by OEHHA estimates the population variability in cancer risk resulting from variability in intake rates such as breathing rate, infant breast milk ingestion, and meat and produce ingestion. The data on variability in risk assessment variates are largely limited to intake rates of contaminated media. Data are particularly sparse on the variability in fate and transport variates (e.g., soil half life). Therefore only a portion of the overall variability in exposure can be characterized in our model. However, for the less complicated pathways such as the inhalation pathway, the variability in breathing rate probably represents a major portion of the overall variability in exposure.

As noted in U.S. EPA (1995), true uncertainty represents lack of knowledge about a variate or factor that impacts risk which may be reduced by further study. There are uncertainties associated with measurement, with models of environmental fate (e.g., air dispersion models), and with dose-response models. Uncertainty may stem from data gaps that are filled by the use of assumptions. Although methods such as expert elicitation have been occasionally used to try to quantify true uncertainty in individual risk assessments, the cost of such methods is outside the scope of what would be reasonable for the Hot Spots program.

Variability can be measured empirically in data describing an exposure variate. Variability arises from true heterogeneity in characteristics of a population such as differences in rate of intake of various media (air, water, food, soil). The stochastic analysis approach presented in this document attempts to quantify some of the variability in exposure in the risk estimates by using measured variability in data describing key exposure variates. A parametric model (e.g., lognormal) can be fit to measures of, for example, food consumption in a representative sample of a population in order to characterize the variability of that variate for a population. The stochastic approach uses a distribution of values, or a parametric model for the distribution, as input for one or more variates in the model. Risk estimates can be expressed as a distribution by propagating the variance of exposure variates through the model using Monte Carlo simulation. This allows estimation of some of the variability in exposure in the risk estimate.

The primary benefits of stochastic analysis are the quantitative treatment of some of the variability in risk estimates and the increase in information on which to base decisions. The risk manager can determine what percentage of the population would be protected if emissions were reduced by a certain amount. However, it can be difficult to

communicate the results of a stochastic risk assessment to the public and risk managers.

Better characterization of total variability in exposure would require more research. Typical intake rates for various age ranges and longitudinal data on the same individuals over time are not usually available. Short term survey data on representative samples of populations of interest are all that are available for many variates. Such data can overestimate exposure particularly in the upper percentiles when considerable intraindividual variability occurs. Some important exposure variates such as soil ingestion lack sufficient data to characterize variability.

Neither the stochastic approach nor the point estimate approach to exposure assessment presented in this document deals with uncertainty or variability in the dose-response assessment. While human variability in response to toxicants is an increasingly active area of research, more data are needed to better account for human interindividual variability in risk assessments. We have evaluated the impact of age-at-exposure on carcinogenic potency (OEHHA, 2009). As noted above, that analysis resulted in application of ASFs to account semi-quantitatively for variability in response to carcinogens due to age. OEHHA also modified the methodology for developing Reference Exposure Levels (OEHHA, 2008) to more explicitly account for potential sensitivity of infants and children.

OEHHA carefully evaluated the available literature characterizing variability for important exposure variates. Even though in some cases there were studies presenting valid parametric models for exposure variates in the literature, the age ranges did not correspond to our current needs. In other cases, we obtained unpublished raw data from published studies or performed our own analyses on publically available databases such as the Continuing Survey of Food Intake for Individuals (CSFII) or the National Health and Nutrition Examination Survey (NHANES). The methodology is described in the individual chapters in this document as well as in the peer reviewed scientific literature for some variates. If the data or studies were not adequate to characterize variability in a variate (e.g., soil ingestion) point estimates are recommended.

We have taken the approach that enough data must be available to adequately characterize a distribution. While some papers in the risk assessment literature make speculative assumptions about the shape of an input distribution in the absence of data, this cannot be readily justified in most cases. Additional assumptions regarding a distribution in the absence of data may increase uncertainty and may not improve the knowledge about the range of risks in a population.

Distributions of exposure variates are presented in this document for the age ranges needed to assess cancer risk using the age sensitivity factors for specific age groups.

Thus, estimation of dose using the stochastic approach for the various age groupings is similar to the point estimate approach. The intake distributions for ages 16 to 30 years are generally used for women in their third trimester of pregnancy if intake data specific

for this group is lacking. Distributions for the ages specified In Section 1.2.1 above should be used to determine the dose ranges.

1.4 Tiered Approach to Risk Assessment

During the development of risk assessment guidelines for the Hot Spots program, a number of stakeholders wanted the option of using non-default site-specific point estimates and distributions for assessing exposure where more appropriate. Thus OEHHA developed a tiered approach to accommodate this concern (Table 1). The first Tier is the simplest point estimate approach to estimating exposure to facility emissions. In Tier 1, the risk assessor must use the point estimates developed by OEHHA for all exposure variates, other than obvious site-specific parameters such as the volume of a body of impacted water. Tier 2 allows use of site-specific point estimates of exposure variates as long as these estimates can be justified. The risk assessor must supply the data and methods used for the site-specific estimates, and the site-specific estimates must be reproducible and justified, and approved by OEHHA. Tier 3 allows use of OEHHA-derived distributions of a number of exposure variates so that a “likelihood of risks” approach can be utilized, as called for in the statutory language. This allows one to estimate risk based on a distribution of exposures, rather than a single point estimate. Tier 4 allows use of site-specific distributions of exposure parameters as long as they can be justified and are approved by OEHHA. The risk assessor must supply the data and methods used for the site-specific distributions for exposure variates, and the site-specific estimates must be reproducible and justified.

Most facilities in the Air Toxics “Hot Spots” program may not require a complicated stochastic analysis for sufficient characterization of risks from emissions. In order to allow the level of effort in a risk assessment to be commensurate with the importance of the risk management decision, a tiered approach to risk assessment is recommended. The tiers are meant to be applied sequentially to retain consistency across the state in implementing the Air Toxics “Hot Spots” program while allowing flexibility.

The benefits of a tiered approach to site-specific risk assessment include consistency across the state, comparability across facilities, and flexibility in the approach to assessing risks. A simple health-protective point estimate risk assessment will indicate whether a more complex approach is warranted, and will help prioritize limited resources. The tiered risk assessment approach facilitates use of site-specific supplemental information in the risk assessment to better characterize the risks. Finally, more information is available to risk managers and the public when a tiered approach is fully utilized.

TABLE 1 – THE TIERED APPROACH TO RISK ASSESSMENT

Tier	Description	When Applied
Tier 1	Utilizes OEHHA default point estimates of exposure variates	All risk assessments must include a Tier 1 assessment
Tier 2	Utilizes site-specific point estimates for exposure variates (justified, and approved by OEHHA)	If desired by risk assessor, a Tier 2 approach may be presented in addition to Tier 1
Tier 3	Utilizes OEHHA distributions of exposure variates	A Tier 3 approach may be presented in addition to Tier 1
Tier 4	Utilizes site-specific justified distributions of exposure variates (justified, and approved by OEHHA)	A Tier 4 approach may be presented in addition to Tier 1

1.4.1 Tier 1

Tier 1 is the first step in conducting a comprehensive risk assessment with a point estimate approach, using algorithms and point estimates of input values presented in the following chapters. Each facility conducts a Tier 1 risk assessment to promote consistency across the state for all facility risk assessments and allow comparisons across facilities.

Condensed guidance, including tables of the point estimate values recommended by OEHHA in the following chapters, is given in the companion document *Air Toxics Hot Spots Risk Assessment Guidance Manual*, which we are in the process of updating. Site-specific values (e.g. the volume of water in an impacted lake) have to be provided by the risk assessor.

Mean and high-end point estimates for key exposure variates were estimated by OEHHA from available data. To be health-protective, high-end estimates for the key intake exposure variates are used for the dominant pathways in Tier 1.

If a risk assessment involves multipathway exposures, then the risk assessor needs to evaluate which pathways are dominant by conducting an initial assessment using the high-end point estimates for those key intake variates, that have been evaluated by OEHHA. Dominant pathways are defined for these purposes as the two pathways that contribute the most to the total cancer risk estimate when using high-end estimates of key intake variates. High-end estimates for key intake variates for the two dominant pathways and mean values for key variates in the exposure pathways that are not dominant are then used to estimate risks. If the food pathway is the dominant pathway, then the highest single produce or meat type (e.g., exposed produce) using the high

end estimates should be determined. The risk for the other food pathways then should be estimated using the average intake values.

This approach will lessen the problem of compounding high-end exposure estimates while still retaining a health-protective approach for the more important exposure pathway(s). It is unlikely that any one person would be on the high-end for all the intake variates. It is our experience that inhalation is generally a dominant pathway posing the most risk in the Air Toxics "Hot Spots" program; occasionally risks from other pathways may also be dominant for lipophilic compounds or metals. Therefore, for many facilities emitting volatile chemicals, the inhalation pathway will be the only pathway whose risks are assessed using a high-end intake estimate. For the Air Toxics "Hot Spots" program, the point of maximum impact for cancer risks is the location with the highest risks using this method.

OEHHA is recommending the hazard index (HI) approach to assess the potential for noncancer health impacts (OEHHA, 2008). The hazard index is calculated by dividing the concentration in air by the Reference Exposure Level for the substance in question and summing the ratios for all chemicals impacting the same target organ (OEHHA, 2008).

There may be instances where a noninhalation pathway of exposure contributes substantially to a noncancer chronic hazard index. In these cases, the high-end estimate of dose is appropriate to use for the two dominant pathways' noninhalation hazard indices. The point of maximum impact for noncancer chronic health effects is the modeled point having the highest non cancer chronic hazard index (adding noninhalation and inhalation hazard indices when appropriate for systemic effects). The inhalation chronic HI calculation does not involve a high end and average inhalation rate, as the airborne concentration is divided by the REL to calculate an HI (OEHHA, 2008).

There are 8-hour RELs for a number of chemicals. These RELs can be used in different exposure scenarios, such as, to evaluate noncancer risk to offsite workers (and other offsite receptors impacted routinely by facility emissions) who are repeatedly exposed for approximately eight hours at the workplace. The 8 hr RELs may also be useful for assessing impacts to residents when assessing the emissions from a non-continuously operating facility (see Chapter 2). In cases where there are only chronic RELs for a chemical, the Hazard Index for offsite workers can be calculated by adding the Hazard Quotient for a chemical with an 8-hour REL to a chemical where only a chronic REL is available. Eventually 8-hour and chronic RELs will be developed for all Hot Spots chemicals as OEHHA completes its evaluation of RELs under SB-25. There are no noninhalation pathways to consider in calculation of acute hazard indices.

The relatively health-protective assumptions incorporated into the Tier 1 risk assessment (e.g., high-end values for key variates in the driving pathways) make it unlikely that the risks are underestimated for the general population. If the results indicate that a facility's estimated cancer risk and noncancer hazard are below the level

of regulatory concern, further analysis may not be warranted. If the results are above a regulatory level of concern, the risk assessor may want to proceed with further analysis as described in Tier 2 or a more resource-intensive stochastic modeling effort described in Tiers 3 and 4 to provide the risk manager with more information on which to base decisions. While further evaluation may provide more information to the risk manager, the Tier 1 evaluation is useful in comparing risks among a large number of facilities.

1.4.2 Tier 2

The risk assessor may want to analyze the risks using point estimates more appropriate for the site being evaluated. This second tier approach would replace some of the defaults recommended in this document with values more appropriate to the site. A Tier 2 risk assessment would use the point estimate approach with justifiable point estimates for important site-specific variates. Use of this supplemental site-specific information may help to better characterize the risks.

Certain exposure variates such as breast milk consumption or inhalation rate would not be expected to vary much from site to site. Other variates for which OEHHA has provided point estimates may vary significantly from site-to-site. If the facility has data indicating that an OEHHA point estimate value is not appropriate in their circumstance, they may provide an alternative point estimate value. For example, if there are data indicating that consumption of fish from an impacted fishable body of water is lower than the OEHHA-recommended fish consumption rate, then the facility can use those data to generate a point estimate for fisher-caught fish consumption from that body of water.

If site-specific values are substituted, the values need to be justified. All data and procedures used to derive them should be clearly documented, and reasonable justification should be provided for using the alternative value. The Districts and OEHHA should be able to reproduce the point estimate from the data presented in the risk assessment. As noted above, OEHHA must approve the site-specific point estimates.

In a Tier 2 approach, the risk assessor may want to present multiple alternative point estimate scenarios with several different assumptions encompassing reasonable “average” and “high-end” exposures for important pathways. This may be an issue in the case where data on a key exposure variate for that particular site are lacking. For example, in a case where soil ingestion is a dominant pathway, if a key variate in the model is the number of days children spend outdoors in contact with soil, it may be most appropriate to run the model more than once using several different assumptions about the exposure frequency. Such scenario development is easily communicated to the risk manager and the public, and serves as a semi-quantitative analysis of the exposure variability using a point estimate approach to risk assessment. In any risk assessment where alternative point estimates representing different exposure scenarios are presented, all information used to develop the point estimates needs to be presented clearly in the risk assessment. Also, a justification for the exposure scenarios needs to be included.

If the risk is below a level of regulatory concern, further analysis may not be warranted. If the risk estimate is still above a level of concern, then the risk assessor may want to proceed with a more complex stochastic analysis as described in Tier 3 to get a fuller characterization of the variability in the exposure estimate.

1.4.3 Tier 3

The third tier risk assessment involves stochastic analysis of exposure using algorithms and distributions for the key exposure variates specified in this document. Point estimates specified in this document for those exposure variates without distributions should be used. Since a stochastic approach to risk assessment provides more information about the range and probability of risk estimates, Tier 3 can serve as a useful supplement to the Tier 1 and 2 approach. In the third tier, variance propagation methods (e.g., Monte Carlo analysis) are used to derive a range of risk estimates reflecting the known variability in the inputs as described in the distributions characterized in this document. Recommended distributions for use in a stochastic analysis and the scientific bases for these distributions are provided in Chapters 3 through 9 of this document.

OEHHA is recommending that a stochastic analysis be performed for cancer risk assessment only. OEHHA has not currently identified a stochastic approach to the exposure part of noncancer risk assessment that would provide value. OEHHA is recommending a point estimate approach only for assessing the impact of AB-2588 facilities on workers employed at nearby work sites (i.e., the offsite worker). We have not developed a breathing rate distribution that would be appropriate for a stochastic offsite worker risk assessment.

Commercial software is available that can be used to conduct a stochastic analysis. The Air Resources Board has developed the Hot Spots Analysis and Reporting Program (HARP) that can perform Tier 3 stochastic analyses as well as Tier 1 risk assessments. The HARP software includes an air modeling module and emissions reporting modules.

1.4.4 Tier 4

OEHHA's stochastic model is based on the best available scientific data that have undergone public comment and peer review. However, a fourth tier risk assessment could also be conducted if site-specific conditions suggest that alternative or additional distributions (and point estimates) for variates may be more appropriate than those provided by OEHHA. In a Tier 4 risk assessment, the risk assessor could characterize the distribution of variates that are important to the overall calculation of risk for which OEHHA provides only a point estimate. Or, the risk assessor may wish to use distributions other than those supplied by OEHHA for important variates that impact the risk. The scientific basis and documentation for alternative and additional distributions should be presented clearly in the risk assessment. Clear, reasonable justification

would need to be provided in the risk assessment for using alternative distributions or point estimates, and OEHHA must approve the site-specific distributions. Such distributions would be based on data from the literature or site-specific data gathered by the facility.

The quality of data would need to be sufficient to reasonably justify the selection of the parametric model (e.g., normal, lognormal, etc.) used to characterize the empirical distribution. It is not necessary, however, that the data fit a given parametric model as defined by conservative statistical criteria such as the Kolmogrov-Smirnoff test. If a distribution is nonparametric, it may be used as a custom distribution in a variance propagation model such as a Monte Carlo simulation.

In each case where alternate distributions or point estimates are used, it is important that the results be compared with the results obtained using any point estimates and/or distributions recommended in this document by OEHHA (e.g., the Tier 1 and 3 risk assessments). This is necessary to identify the contribution of the new information to the risk assessment. The District and OEHHA staff and any interested parties should be able to easily verify the assumptions, and duplicate the results.

1.5 Exposure Assessment Pathways

Chapters 3 through 10 are organized by exposure pathway, and present the algorithms used for both the point estimate and stochastic approach to exposure assessment. The scientific basis for each recommended point estimate and distribution for key variates is presented. In the instances where the variate is site-specific (e.g., volume of a body of water), default point estimates or distributions are not provided. In general, key studies used in evaluating a point estimate value or distribution are briefly discussed along with procedures used to characterize the distribution. OEHHA procedure for significant figures is to round at the end of any calculation. Thus the exposure variates are generally rounded to 2 or 3 significant figures. The risk estimates are generally rounded to 1or 2 significant figures in the risk assessments conducted by facilities.

1.6 Individual Risk, versus Population Risk, and Duration of Exposure to Facility Emissions

In past practice, the risk managers generally made decisions on the lifetime cancer risk to the “Maximally Exposed Individual” at the site of highest modeled concentration(s) of carcinogen(s). However, relying on estimated cancer risk to the maximally exposed individual is problematic for scenarios where there may be a risk of cancer that falls below the typical risk management threshold of 10^{-5}, but a large number of people are exposed at that level. Facilities with cancer risks estimated above 10^{-5} but that expose few people may face risk management actions, but a facility that exposed thousands of people just below the risk management threshold would not. Both the concept of population risk and individual risk are important for public health protection (discussed in Chapter 11).

In trying to resolve this dilemma, OEHHA reconsidered the issues of individual risk, population risk, duration of time at a single residence and activity patterns. The previous recommendation for risk managers was to rely on the 70 year risk estimate without consideration of whether or not people resided at the same address for 70 years, or were away from home parts of the day. The previous guidelines also suggested estimating cancer risk for shorter residence times (9 and 30 years, based on EPA analyses of duration of residence at a single address). Thirty years is approximately the 90^{th} percentile of residency in California, according to newer data and is consistent with estimates of thirty years for the 90^{th} percentile of residency duration nationally, and is thus a more realistic portrayal of the maximum reasonable length of exposure that would occur at the residential point of maximal impact. The previous recommendation of relying on the cancer risk estimate to the maximally exposed individual for a 70 year exposure duration contained an element of protection for the population since individual exposure was defined as an entire lifetime, although the risk was likely spread over different individuals living at the maximally exposed location since very few people live at the same address longer than 30 years. Presenting individual cancer risk as a thirty year risk rather than a seventy year risk is easier from a risk communication standpoint because it is a more realistic exposure scenario. OEHHA is thus suggesting that the risk manager when making a decision based on cancer risk to the MEIR use the risk estimated for a 30 year exposure scenario. However, this lessens the element of protection for the population – someone is always living around a given facility. Thus, OEHHA makes a recommendation to consider population risk separately in assessing public health impacts (Chapter 11).

In the example above, there will be more theoretical cancer cases when a larger facility with estimated cancer risk just under the 10^{-5} threshold has a large populated zone of impact, than for the small facility impacting a few people with a cancer risk estimate just over the 10^{-5} threshold. The public health impacts may not be adequately addressed if the cancer risks at the residential or worker point of maximum impact are below the level of significant risk determined by the District. It is important to look at improved methods of assessing the public health impact of facilities with more diffuse emissions impacting larger areas with large impacted populations. Therefore, OEHHA recommends that the number of people residing within the 1×10^{-6} and greater cancer risk isopleths be determined using census data and that the risk managers use this information to decide on appropriate risk management. This is in addition to simply basing a risk management decision on the cancer risk to the maximally exposed individual without regard to the size of the zone of impact and the population exposed. Strengthening population protection will help protect public health.

1.7 SB-352

SB-352 was passed in 2003 and requires California school districts to perform a risk assessment for proposed school sites located within 500 feet, or 150 m, of a freeway or busy roadway. SB-352 specifies that OEHHA's Hot Spots risk assessment guidance procedures be used for the assessment. School children and staff are present at the school site for less than 24 hours so hourly breathing rates that reflect playground activities and classroom activities are appropriate for such assessments. We have included recommended breathing rates in Chapter 3 of this document for appropriate age ranges for elementary, junior high and high school and staff at such schools for such assessments. The age ranges provided also allow for early-in-life exposure age ranges. The South Coast Air Quality Management District has a document that discusses air quality concerns when selecting school sites (SCAMD, 2005).

1.8 Summary

This revision of the Exposure Assessment and Stochastic Analysis Document allows estimation of exposure for age ranges of children. In addition we have incorporated advances in the field of exposure assessment since the last revision and new point estimates and distributions of exposure variates, based on new data. The Exposure Assessment and Stochastic Analysis document retains the option of tiered risk assessment so that site-specific factors can be taken into account.

OEHHA has reviewed and incorporated the extensive body of exposure assessment literature that has been published since the 2000 Exposure and Stochastic Analysis Technical Support Document in order to refine our exposure assessment model.

1.9 References

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SCAQMD (2005) South Coast Air Quality Management District (SCAQMD) Air Quality Issues in School Site Selection Guidance Document June 2005 www.aqmd.gov/prdas/aqguide/doc/School_Guidance.pdf

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