

The Office of Environmental Health Hazard Assessment

Response to Public Comments

Submitted to the California Air Resources Board

On July 19, 2002

Comments of Julio A. Salinas, Ph.D., Biochem.D.

Comments on the manual were received from Dr. Julio Salinas, acting as a private resident of the State of California, in a letter dated July 5, 2002 to Mr. Jim Behrmann of the California Air Resources Board, the liaison to the Scientific Review Panel on Toxic Air Contaminants.

Paragraph A:

Upon a thorough review, I concluded that the Manual is scientifically unsupported, it is insufficient, and it is inappropriate as a guide for preparing risk assessments. The methods and practices are inconsistent with current understanding of risk assessment, and do not reflect risk assessment practices in California and the U.S. EPA. The Manual reads as a regulatory document and it incorporates a large number of regulatory policies presented as assumptions or scientific practices. The Manual is presented as a compilation of four previous reports prepared by OEHHA over the last ten years, but the document reads as unfamiliar with the topics, it is redundant, incomplete, and needs extensive editing. The methods proposed to estimate risks to human health are conservative to the point of being scientifically unsupported. The Manual is presented as a multi-media risk assessment approach, but it does not provide the scientific basis for being applicable to a multiple exposure pathways except for the inhalation route, and therefore it should be limited to the *health risk assessment of air* emissions from stationary primary sources. Although the Manual is introduced as an update and new version to the CAPCOA Risk Assessment Guidelines (1993), the improvements are unclear and in effect it leaves a number of unanswered questions. If approved as presented, the Manual will significantly affect the risk assessment and risk management activities in the State of California. For these reasons, I ask the California Environmental Protection Agency not to approve this document.

Response to Paragraph A:

The Guidance Manual is a compilation of four Technical Support Documents (TSDs) developed for the Air Toxics Hot Spots program, all of which underwent extensive internal review, public comment, and review by the Scientific Review Panel on Toxic Air Contaminants. The four TSDs are:

The Air Toxics Hot Spots Program Risk Assessment Guidelines; Part I; Technical Support Document for the Determination of Acute Reference Exposure Levels for Airborne Toxicants, Office of Environmental Health Hazard Assessment, March 1999.

The Air Toxics Hot Spots Program Risk Assessment Guidelines; Part II; Technical Support Document for Describing Available Cancer Potency Factors, Office of Environmental Health Hazard Assessment, April 1999.

The Air Toxics Hot Spots Program Risk Assessment Guidelines; Part III; Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels, Office of Environmental Health Hazard Assessment, April 2000.

The Air Toxics Hot Spots Risk Assessment Guidelines; Part IV; Technical Support Document for Exposure Assessment and Stochastic Analysis, Office of Environmental Health Hazard Assessment, September 2000.

The Guidance Manual contains a list of SRP-reviewed and OEHHA-adopted Acute Reference Exposure Levels (RELs) (Table 6.2) from Part I TSD, Chronic RELs (Table 6.3) from the Part III TSD, and cancer potency factors (Table 7.1) from the Part II TSD. The fate and transport and

exposure algorithms, and exposure variates and distributions are from the Part IV Technical Support Document (with the minor exception of worker breathing rate). The methodology for the point estimate and stochastic approaches are also explained in the Part IV TSD. All four of these TSDs underwent extensive internal peer review, public comment with concomitant response by OEHHA staff and mandated peer review by the State's Scientific Review Panel on Toxic Air Contaminants. The documents were then formally adopted by the Director of OEHHA. The Part IV TSD was developed by OEHHA using an internal working group consisting of people from all four technical Sections within OEHHA as well as ARB staff, and in consultation with an External Advisory Group composed of OEHHA staff, industry representatives, environmental group representatives, and academic representatives. Thus, the claim that the Guidance Manual contains information that has not been internally reviewed is incorrect.

The Guidance manual addresses airborne air pollution from stationary sources. These pollutants include metals, dioxins and polycyclic aromatic hydrocarbons (PAHs). These substances exist wholly (metals) or in part (PAHs, dioxins) as particles when emitted into the air by stationary sources. As particles they are subject to deposition onto soil, plants and adjacent water bodies. The plants may be directly contaminated by deposition onto leaves or indirectly by root uptake from the soil. People can then be exposed directly by consuming contaminated plants, contaminated water and soil. They can also be secondarily exposed by consuming mother's milk or home raised meat, eggs or milk. Scientific criteria for inclusion were developed in Appendix E of the Part IV TSD. Fate and transport algorithms for estimating fate and transport of these pollutants are similar if not identical to those in U.S.EPA's Risk Assessment Guidance Document for Superfund Sites, 1987.

Paragraph B:

I am very surprised that OEHHA has taken the path of releasing to the public documents that have not been internally reviewed within OEHHA, other than by its authors. The Integrated Risk Assessment Section (IRAS) at OEHHA, that has the expertise and provides scientific assistance in multiple environmental media exposure assessment for all Cal/EPA BDOs, was not informed on this Manual nor it was consulted for review. Risk assessment practices at IRAS/OEHHA may be significantly affected by the approval of this Manual.

Response to Paragraph B:

The Guidance manual has undergone internal peer review by the Air Resources Board staff and Managers, as well as within OEHHA by Dr. George Alexeeff, Deputy Director for Scientific Affairs, and has undergone a public comment period and will be peer reviewed by the State's Scientific Review Panel on Toxic Air Contaminants. As indicated above, all of the content of the manual came from four TSDs that underwent extensive internal peer review, public comment with concomitant response by OEHHA staff and mandated peer review by the State's Scientific Review Panel on Toxic Air Contaminants. Decisions concerning the need for additional internal review are the prerogative of OEHHA management. The risk assessment practices in the Guidance Manual are already being used by Cal/EPA BDOs including IRAS in OEHHA because the TSDs 1-4 have already been adopted by the Director of OEHHA.

Comment:

My comments are organized as follows:

A. General comments

1. Lack of scientific consistency with current risk assessment practices
2. Updating and upgrading of CAPCOA Guidelines
3. Purpose and contents of the Manual are unclear.
4. The proposed air dispersion model is inappropriate for the risk assessment
5. The proposed approach does not support the multi-media, multi-exposure pathway approach
6. Tier approach to levels of complexity in risk assessment approach is inconsistent and unsupported
7. Proposed Probabilistic risk assessment practices are inconsistent with current practices and scientifically unsupported
8. Incorporation of methods and procedures that are scientifically unsupported
9. Use of exposure factors normalized to body weight is scientifically unsupported
10. Presentation of the Uncertainty in Health Risk Assessment is unsupported
11. Uses and limitations of the proposed approach
12. Level of conservatism of the proposed approach is unsupported
13. The document confuses science, policies, and generic-unsupported statements
14. Purpose of the Hot Spots Analysis and Reporting Program (HARP) Software is unclear
15. The Manual is a biased regulatory guideline
16. The document requires extensive editing
 - 16.1. Use of terminology
 - 16.2. Format
 - Repetitive (examples)
 - General format and contents of the Manual
 - Unnecessary material included in the document
 - 16.3. Unnecessary explanations

B. CONCLUSIONS AND RECOMMENDATIONS

A. GENERAL COMMENTS

Comment 1a:

Lack of scientific consistency with current risk assessment practices. There are numerous instances in which the Manual departs from current risk assessment practices. A few of these are mentioned here as examples.

- a. In Section 2.1 - The Model for Risk Assessment, the Manual cites the National Academy of Sciences 1983 and 1994 paradigms for risk assessment, however there is no other reference to these documents anywhere else in the Manual, not any evidence that its materials were used in the Manual.

Response 1a:

As regards the manual departing from current risk assessment practices, the comment is surprising since the guidance manual describes current risk assessment practice in the California Air Toxics Hot Spots program. In addition, the information in this guidance document is used in whole or part by a

number of other state regulatory agencies within California and in other states, and is largely consistent with standard practices at U.S.EPA.

Comment 1b:

b. In Section 8.1 - Risk Characterization for Cancer Health Effects, the Manual proposes a risk characterization using a default algorithm that consists of two terms: a variable, the inhalation dose normalized to body weight (mg/kg day), and a constant, the cancer potency slope ([mg/kg day]). The variable and the constant have reciprocal units, so they cancel out. This is a regression in risk assessment practices, since as explained below, the procedure proposed for estimating the dose is a default one. A question is why a computer software (HARP, see below) would be needed for this oversimplification? The time component (frequency, duration, length), the bioavailability coefficient, the retention (absorption) coefficient, and the body weight have been eliminated and replaced by "recommended" and "mandatory" values. This looks more like a mandatory, regulatory, overly conservative approach, and is an unsupported scientific approach for protecting human health.

Response to 1b:

First, it is not clear what the point of the comment is, other than expressing concerns that the regulatory approach is too conservative. Second, as regards to "eliminating body weight", we have expressed the exposure variable, breathing rate as L/kg-day and this is used to estimate dose on a body weight basis. Of course when you estimate risk by multiplying cancer potency factor in reciprocal dose units by dose, the units cancel and the result is a unitless probability of cancer. The HARP program greatly simplifies the risk assessors' task by having a computer make all calculations starting with the air dispersion model through the estimates of dose and risk by all relevant pathways of exposure.

The Guidance manual does recommend variates and risk assessment procedures for the Air Toxics Hot Spots program, a public-right-know-act. However, facilities have always been able to provide supplemental risk assessment information. Tier 2 and Tier 3 provide guidance for use of variates not specified by OEHHA.

The HARP program performs a number of useful functions for the Hot Spots program. In addition to calculation of inhalation risk, the risk for other pathways may be calculated. HARP also contains emissions inventory modules, and will perform air modeling using an integrated version of ISCST3.

Comment 1c:

The Dose-Response and the Risk Characterization Sections mentions profusely the *Acute Reference Exposure Levels*, *Chronic Reference Exposure Levels*, *Chronic Oral (Non-inhalation) Reference Exposure Levels*, *Inhalation Cancer Potency Factor*, and *Oral Cancer Potency Factor*, however it ignores the Oral Reference Dose, and the Inhalation Reference Concentration used by the State of California and the U.S. EPA. It would be only fair to compare how different are the outputs from the Reference Exposure Levels and the Reference Dose approach.

Response 1c:

The Toxic Air Contaminant legislation specifically mandates that all risk assessment procedures including health values be prepared by OEHHA, be publicly reviewed, and peer reviewed and endorsed by the State's Scientific Review Panel on Toxic Air Contaminants (SRP). The health values used in the Hot Spots program are in some cases the same as those used by U.S.EPA. In cases where they are different, it may be due to differences in scientific opinion or a more recent evaluation by OEHHA utilizing more recent literature. This issue is discussed on an on-going basis with the SRP as new health values are developed. There are minor differences in risk assessment methodologies between U.S.EPA and OEHHA. The guidance we have received from the SRP is to develop and present the most scientifically supportable health values based on our risk assessment practices. The SRP has expressed reservations on numerous occasions regarding rubber-stamp approval of U.S. EPA health values. While OEHHA works closely with U.S. EPA in many arenas, and strives to come to consensus with U.S. EPA on health values, there is no requirement for consistency between health values, nor is there any point in complicating risk assessment by asking facilities to use U.S.EPA values in addition to our own.

Comment 1d:

d. In Section 5 - Exposure Assessment, the Manual describes that as a "minimum, three receptors are evaluated in the] Hat Spots health risk assessment," namely: the Point of Maximum Impact (PMI), the Maximally Exposed Individual Resident (MEIR), and the Maximally Exposed Individual Worker (MEIW). The Manual confuses the concept of Point of Contact with Receptor of Concern: these are not equivalent. The Point of Maximum Impact (PMI) is not a receptor, but a geographical location generated by the air dispersion model, and is where the air emissions are maximum at ground level. The Maximally Exposed Resident or Worker are "maximal" because in addition of spending significant time at the PMI, depends on the assumed human exposure factors, time factors, and a number of chemical-related variables (e.g., bioavailability, environmental fate, reactivity). The U.S. EPA no longer recommends the Maximally Exposed Individual (MEI) scenario, because the composite additivity of the factors results in a non-plausible overly conservative exposure and risk levels. Instead, the U.S. EPA recommends an upper-end exposure scenario, typically using human exposure factors between 90-99"" percentiles. This receptor is interpreted as the maximum likely risk value. As described in the Manual, the three "Maximal" values are overly conservative and unsupported.

Response 1d:

Firstly, the U.S.EPA recommendation is not what drives risk assessment in the Air Toxics Hot Spots program. Secondly, the EPA recommendation of using upper-end exposure scenarios is exactly what we have done in the Air Toxics Hot Spots program. This is described in the fourth TSD. Thus, we are fairly consistent. It is not clear what the commentator means by "the three 'maximal values' are overly conservative", as he provides no support for the claim. Third, the commenter is confused regarding the language on receptor points in the guidance manual, which OEHHA believes is clear.

Comment 1e:

e. The Criteria for Exposure Pathway Evaluation, Section 5.2, is unsupported. It confuses contaminant with migration pathway. For example, it reads: "Two steps are used to determine if a substance should be evaluated for multipathway impacts: (1) see if the substance or its group is listed; (2) determine if the substance has an oral reference exposure level... or an oral cancer slope factor..."

Why oral... for air emissions? Why the manual does not explain that a migration or exposure pathway should be supported by scientific evidence such as sampling and analysis, or air dispersion modeling, or migration in soil or groundwater? The Manual does not provide any support for the environmental migration of contaminants.

Response 1e:

We are not sure what the comment's point is. Dioxins, PAHs and metals emitted from stationary facilities are subject to deposition onto the soil because they exist wholly or in part as particles. These toxicants can also be deposited directly onto plants or taken up by roots from soil, or deposited onto surface waters used for drinking or fishing. The plants can then be consumed by animals or directly by people. People can be exposed by consuming home raised meat, produce, eggs, cow's milk, fisher caught fish or contaminated water. Infants may be exposed to lipophilic toxicants in mother's milk. The scientific criteria for inclusion of substances for multipathway consideration in the risk assessment guidance are in Appendix E of the Part IV TSD. The fate and transport algorithms, also described in the Part IV TSD and presented in the Guidance Manual, are similar to those in the Risk Assessment Guidance for Superfund Sites, 1987.

Comment 1f:

The human exposure factors and time factors assumed in the exposure assessment section are questionable. For example, the proposed approach mandates the use of 9, 30, or 70 year of exposure. There is no rationale for the selected values.

Response 1f:

The justifications for the selection of the 9, 30 and 70 year exposure durations are explained in Section 11 of the Part IV TSD. The Guidance Manual repeatedly refers the reader to the Parts 1-4 TSDs as a reference for the basis for procedures and values.

Comment 1g:

g. In Section 7.2.1- Description of the Inhalation Cancer Potency Factor, the Manual describes that "breathing rates expressed in [L/kg bw.day] can be coupled with air concentrations to estimate dose in [mg/kg.day}. This allows for estimation of average, high-end, and distributions of cancer risk." This is a default methodology in exposure assessment that is unsupported. In Section 8.2.4, is explained that the oral dose expressed in mg/kg.day multiplied by the oral slope factors in (mg/kg.day)", results in the "Potential Cancer Risk" (what is potential risk?), According to the Manual, "To convert this to theoretical cancer risks or chances per million, multiply the potential cancer risk by 10⁶." This is clearly wrong, and contradicts the expression of the multistage risk at low doses, $R = q d$, where risk is directly related to dose in mg/kg.day and CPS, in [mg/kg.day]", no need to multiply by 10⁶. The Manual, without realizing the error, describes, "This result is useful as a risk communication tool." This is plain ludicrous and the entire Section must be rewritten.

Response 1g:

The scientific justification for the selection of the methodology of multiplying the breathing rate (L/kg BW-day) times the inhalation cancer potency factor (mg/kg BW-day)⁻¹ is in Sections 1 and 3 of the Part IV TSD. The word potential has been removed from "potential cancer risk".

Cancer risk, which is expressed as a probability, can be converted into chances per million by multiplying cancer risk times 10⁶. For example, a cancer risk of 5 X 10⁻⁶ when multiplied by 10⁶ gives a value of 5 "chances per million" of contracting cancer from the exposure. This is commonly used in risk communication by the California Air Resources Board, as it is easily understood by the laymen. Most people do not understand negative exponents.

Comment 2a:

Updating and upgrading of CAPCOA Guidelines a. In the Notice to Interested Parties, the announcement explain that "We are not seeking comments on the information in the guidance Manual that has already undergone public and peer review, approval by the Scientific Review Panel, and adoption by OEHHA." This is a questionable, non-scientific procedure, since: (a) the Manual was not internally reviewed at OEHHA prior to its release in the OEHHA Website, in particular by other Programs that may be affected by the "approval" of these guidelines; (b) the Manual does not unambiguously identify what has been "approved" or "adopted" by OEHHA; and (c) There is no justification whatsoever to dictate that OEHHA produces documents that are "written in stone for posterity." Science is a dynamic intellectual activity, and true scientists will always question or ask themselves whether the available science is based on scientific evidence and whether new evidence may support a different hypothesis. The process used in preparing and releasing the Manual is deceptive to our primary stakeholders and the public.

Response 2a:

The Guidance Manual incorporated information from the Parts 1-4 TSDs. OEHHA could not entertain public comments on all the material in the four TSD previously approved by the Panel, as that process has already been completed. The Part 1-4 TSDs and the Guidance Manual will be periodically revised, and when revision occurs, the documents will individually receive public comment and Scientific Review Panel peer review. This is very much a dynamic process. New chronic RELs are being individually considered by the Scientific Review Panel and added to the list of approved RELs, for example. When the individual documents are reconsidered, new scientific data will be incorporated. OEHHA has not identified any documents as "written in stone".

Comment 2a (sic):

The Manual is described as a "compilation" of information presented in the previous four Technical Support Documents prepared by OEHHA, and it was supposed to replace and update the CAPCOA Risk Assessment Guidelines (1993). From my review, I concluded that the proposed Manual is not significantly different and shows the same information that was presented in the original South Coast Air District report for multipathway exposure and risk assessment prepared in 1984 by Clement Associates and used as the basis for the CAPCOA approach. The exposure pathways and algorithms are the same, but the single difference in the current proposed Manual is that exposure factors have been normalized to body weight, further introducing conservatism and uncertainty to the CAPCOA (1993) guidelines.

Response 2a:

Most of the exposure and fate and transport variates in the Guidance Manual have been updated compared to the 1993 CAPCOA Risk Assessment Guidance. This process took place during the development of the Parts 1-4 TSDs. Some values from 1984 Clement document were retained when newer better studies were not available. The Part IV TSD contains a detailed documentation of these changes. The incorporation of body weight issues is discussed in response to Comment 1b. Conservatism or uncertainty would not be introduced by this procedure.

Comment 2b:

b. The Manual provides a four-tier approach to conducting risk assessments, in circumstances that risk assessment practices only recognize three levels of complexity;

Response 2b:

OEHHA staff do not understand why the Guidance manual cannot allow for a defined four Tier approach. We do not agree that three levels of complexity are standard required practice.

Comment 2c:

c. The Manual contains a Hot Spot Analysis and Reporting Program (HARP) software, which is described as the "recommended model for calculating and presenting HRA results for the Hot Spots Program." Unless this software is intrinsic part of the Manual and is subject to public review, it is not acceptable to accept "black boxes."

Response 2c:

The HARP program performs the calculations specified in the Guidance manual. It is not a "black box" as it uses all of the exposure parameters, algorithms, distributions, Reference Exposure Levels, and Cancer Potency Factors that have been approved for use in the Air Toxics Hot Spots program. The data files are viewable. If a user wished to confirm that the calculations are being performed properly, an independently programmed spreadsheet could be used. OEHHA and ARB staff used hand calculators to confirm that calculations were being performed properly.

Comment 2d:

d. The Manual is described as containing "relatively little new information... since the previously adopted Technical Support Documents form the basis of the Guidance Manual." One problem with the Manual is that it does not reflect current advances in risk assessment, and insufficiently describes a large number of topics that are supposed to be explained in detail in a document presented as "Guidance Manual for Preparation of Health Risk Assessments:" Since the Manual is a compilation, the authors failed in preparing a sound document.

Response 2d:

OEHHA disagrees with the comment that the document does not reflect current advances in risk assessment. In fact, the evaluation of exposure factors is more current than what was being used in

California and is still being used elsewhere. As far as the comment that “large numbers of topics that are supposed to be explained in detail” in the Guidance Manual, we have repeatedly referred the reader to the more detailed Technical Support Documents for further information. A guidance manual is supposed to be able to be used by the average risk assessor, and is more of a “cookbook”.

We fully intend to update the Guidance Manual and associated Technical Support Documents as new science becomes available and resources permit.

Comment 3a:

Purpose and contents of the Manual are unclear.

a. The purpose of the Manual - and the intrinsically incorporated "HARP software" - is described as "to provide consistent risk assessment procedures" and "methods and report presentation". The benefits are described as "expediting the preparation and review of HRAs, minimizing revision and resubmissions of HRAs, allowing for a format for facility comparisons, and cost-effective implementation of HRAs and the Not Spot Program." indeed, this purpose corresponds to a procedure for *standardization and* automatization of preparation and reporting of health risk assessment activities, concept that is fundamentally different from consistency. This is not appropriate. The Manual does not explain the purpose and the basis for "comparing facilities", since most likely, the composition, conditions of the emissions, exposure scenarios, etc., would be site-specific and different for each facility.

Response 3a:

The comment appears to disagree with the risk assessment process that has been utilized in the Air Toxics Hot Spots program. The purpose of the guidelines is to provide consistency across the state for evaluating facilities subject to the Act while making provision for site-specific information. The consistency in the document is in the air modeling, exposure, fate and transport algorithms, variates (e.g. fish bioconcentration, breathing rates), and Reference Exposure Levels and Cancer Potency Factors developed in Parts 1 through 4 Technical Support Documents and provided in the Guidance Manual. Emissions estimates, chemicals and pathways evaluated, the meteorological data selected and certain site-specific parameters will be specific for an individual facility for all Tiers. This is clearly spelled out in the Guidance manual.

Risk comparison between facilities to prioritize risk management efforts are not possible without a consistent methodology. Facilities are required to notify the population exposed to unacceptable risk levels defined by the District. A consistent yardstick allows a fair determination of the facilities that need to notify.

Comment 3b:

There is a Section 1.1, Risk Assessment Review Process. The Manual should clarify that a HRA produced according to the Manual, may be reviewed by CARB Local District as a lead regulatory agency, and by OEHHA acting as a scientific assistance agency. OEHHA has no role in proposing or reviewing policies that belong to CARB.

Response 3b:

The responsibilities for Districts, ARB and OEHHA are specified in the Hot Spots legislation. OEHHA is mandated by law to provide risk assessment guidelines that all facilities must use in the Air Toxics Hot Spots program, and review the health risk assessments and communicate our findings by letter to the Districts. The Districts are responsible for reviewing the emissions estimates and air modeling portion of the risk assessment. The guidelines were developed in consultation with the ARB and CAPCOA, the guidelines do not propose nor review policies that belong to CARB.

Comment 3c:

Section 1.1 states that "OEHHA provides comments on the technical accuracy *and* completeness of the health risks reported in the HRA." This is an insufficient and inappropriate description of the risk assessment review process. The Manual's approach relies heavily on the HARP software and therefore the output results are no more accurate and complete than the HARP model. The Manual describes a review of the *health risks reported* which is significantly different from a review of a *HRA* report. The peer and scientific review is not and should not be limited to verifying the numerical values produced by the model. A sound scientific review of a HRA for air emissions should include, as a minimum: (a) verifying that all evidence related to the primary source, sampling and analysis, environmental migration and fate, point of contact, and location of receptors; (b) verifying that the scientific and technical methods and practices used are acceptable and in use by the State of California and comparable to those from the U.S.EPA; (c) verifying that human health is *reasonably* (that is, is not unreasonably conservative and it biologically plausible) protected; (d) the HRA report is verified for scientific and technical merits, consistency, appropriateness of statistical analysis. This Section should be extensively revised.

Response 3c:

See response to Comment 3b. The risk assessment review process is specified in the Health and Safety Code for the program. There is no requirement in the Hot Spots legislation for scientific methods and practices to be comparable to U.S.EPA. Many of the scientific methods and practices are similar because both agencies work together and arrive at similar scientific public health protective conclusions. It should be emphasized that the Hot Spots program uses emissions estimates, air modeling and fate and transport modeling for risk assessments. Only rarely is monitoring data used in addition to air modeling. Occasionally source testing at stacks is used instead of emissions factors. This approach has been utilized by ARB and CAPCOA and does not require "verifying that all evidence related to the primary source, sampling and analysis, environmental migration and fate, point of contact". There are thousands of facilities subject to the emissions reporting and risk assessment requirements; such verification would be exceedingly expensive and would prevent the program from evaluating all the facilities subject to the program.

Comment 3d:

d. Section 5 - Exposure Assessment appears to advocate the use of air dispersion modeling instead of sampling and analysis. Some statements are unclear, for example:

"It is standard risk assessment practice when monitoring results are reported both above and below the LOD (level of detection) to use one-half the LOD for those sample concentrations reported below the LOD" (page 5-3). Please rewrite and discuss the topic of "statistical analysis of censored data."

"The algorithms in this chapter are also used to calculate media concentrations and dose in the rare instances for the Hot Spots program when monitoring equipment were used rather than an air dispersion modeling to obtain a receptor's substance-specific GLC (ground level concentration)."

Response 3d:

In the Air Toxics Hot Spots program, emissions estimates and air dispersion and environmental fate modeling serve as the basis of the risk assessment. It is not feasible to require stack testing of all of the tens of thousands of facilities subject to the Act in California. The ARB's Emissions Inventory and Guidelines Regulation provide the requirements for emissions estimation for the Air Toxics Hot Spots program. All emissions estimates are reviewed and approved by the ARB and the Districts.

The comment requests a discussion of the statistical analysis of censored data. This is clearly beyond the scope of a risk assessment guidance manual.

Comment 4a:

The proposed air dispersion model is inappropriate for the risk assessment.

a. The information in Section 4 - Air Dispersion Model, is described as an abbreviated version of Chapter II, Part IV - Exposure Assessment and Stochastic Analysis Technical Support Document, Air Toxics Hot Spots Risk Assessment Guidelines (OEHHA, 2000). The abbreviation was excessive. The Manual does not discuss the modeling approach for deposition of air particles (flyash), although the risk assessment is presented as multi-media. This deficiency is critical since Particulate matter deposition (i.e., fly ash) is the single mechanism for incorporation of head metals and semi-volatiles in surface soil or surface water. Without an appropriate, validated model for particles deposition, the proposed multi-media approach is unsupported, and should be limited to the inhalation of contaminated air.

Response 4a:

The air models discussed in Chapter 4 are designed to model particle deposition. A section discussing deposition was inadvertently omitted from the document. We will restore the section to the Guidance Manual.

Comment 4b:

Section 4 ambiguously states that outputs from the SCREEN3 and ISCST3 air dispersion models can be used as input for the CARB HARP software. However, the SCREEN3 air dispersion model selected does not provide analysis of deposition of particulate matter, therefore invalidating the multi-media pathway approach of the entire proposed approach, which should be limited exclusively to the inhalation pathway. Particle deposition is a function of particulate size, which is not modeled by SCREEN3.

Response 4b:

The local districts are responsible for reviewing and approving modeling protocols. When multipathway pollutants are emitted, deposition modeling is required. Thus, the facility cannot use a modeling paradigm that does not include deposition.

Comment 4c:

Section 4 fails in identifying the sampling approach and the analytical methods necessary for the characterization of air emissions. It appears that the proposed risk assessment approach prefers the use of default assumptions on emissions inventory data (what chemicals, in what concentration, exit temperature, humidity, etc.).

Response 4c:

The Hot Spots program only very rarely uses air monitoring data. ARB's Emissions Inventory and Guidelines Regulation specifies the basis for the emissions estimates and mandates source testing for some sources (e.g., incinerators). Suggested changes to this approach should be directed to ARB during the next round of revision for the Emissions Inventory and Guidelines Regulation. Ground Level Concentrations are typically estimated using air modeling, therefore there is no need for a detailed discussion of sampling approach and analytical methods necessary for the characterization of air emissions. The emissions inventory is specific for each facility, and the engineering parameters that feed into the air modeling are specific to each facility.

Comment 4d:

Section 4.1 - Air Dispersion Modeling in Exposure Assessment: Overview, does not explain the basis for relying on a mathematical modeling instead of or in addition to air monitoring data as the basis for the exposure assessment. The advantages and disadvantages of each of these should be presented in detail and the rationale for the selection clearly stated.

Response 4d:

ARB's Emissions Inventory and Guidelines Regulation specifies the basis for the emissions estimates and mandates source testing for some sources (e.g., incinerators). Suggested changes to this approach should be directed to ARB during the next round of revision for the Emissions Inventory and Guidelines Regulation. Air monitoring is very expensive and could not be used in the routine assessment of ground level concentrations for the tens of thousands of facilities in California that must report emissions inventories under this program. A discussion of the advantages and disadvantages of monitoring and modeling is clearly beyond the scope of a Guidance Manual.

Comment 4e:

Section 4.6.1 Zone of Impact, defines a zone of impact as "the area surrounding the facility where receptors have a potential multipathway (inhalation and non-inhalation exposure) cancer risk greater than 10^{-6} (one in a million), an acute (inhalation) hazard index (H.I.) of 1.0, and/or a chronic multipathway HI of 1.0." This definition is unsupported for the following reasons:

- A zone of impact is the region within which a target risk level is exceeded.
 - For the screening mode, the area may be *surrounding* a source, but for a refined mode because there is a prevalent wind direction, the zone of impact is a down wind location;
 - The area of impact is at a distance from the source, depending on emission parameters (height, rate), topography, meteorological conditions, etc. Very rarely the impact area is contiguous or adjacent to the source;
 - For stationary gas and vapor sources, a multiple exposure pathway is unlikely; only the inhalation pathway is supported. Even if gas/vapors and flyash are emitted together, the "zone of impact" is still limited to the air emissions, since a potential "area of concern" would depend on fate and migration in surface soil, subsurface soil, surface waters, and groundwater, for all contaminants from all exposure pathways that are not and cannot be considered with the proposed approach.
 - Air dispersion models allow for the plotting of contaminant concentration or cumulative risk isopleths, which are linear contours for similar values of either output. Isopleths can assume any value, as needed. However, target risk or hazard levels are a prerogative of the regulatory agency, not OEHHA.
 - The proposed approach does not support the *requirement of* submitting maps indicating risk or hazard isopleths for exposure pathways other than inhalation route. The Manual only provides limited support for some aspects of the inhalation risk (see Section 8, below),
- g. Section 4.2 does not explain in what part of the vapor or a gas emission phase you would expect to find heavy metals (mercury, chromium, arsenic, cadmium, beryllium, lead, nickel).

Response 4e:

In a refined air modeling analysis based on local meteorological, data wind direction can vary daily or seasonally; it therefore quite possible for the zone of impact to surround the facility. The zone of impact will typically be skewed in the direction of the prevailing winds. The comment ignores the sections on air dispersion modeling and appears to over-interpret the words "surrounding the facility" to mean that the isopleths are circles around the facility.

There is a very limited subset of chemicals that are emitted by stationary facilities that are subject to multipathway evaluation under the Hot Spots program. These include heavy metals, PAHs and dioxins. These chemicals are widely acknowledged to exist in the air wholly or partially in the particle phase and be subject to deposition. Exposure to these chemicals can potentially occur through multiple noninhalation pathways.

The risk and exposure to receptors has been commonly modeled through air modeling and fate and transport models for many years by multiple agencies. We are, of course, aware that the models can plot concentration isopleths; they can also plot cancer risk isopleths and hazard index isopleths. The level of significant risk is determined by the Districts in the Hot Spots program. Typically the level of significant risk has been set at a 1×10^{-5} cancer risk and hazard index of 1, or in some cases 0.5. The commentator should refer to Chapter 5 for a description of chemicals considered as multipathway. The Guidance manual does not recommend assessment of the ground water pathway because typically insufficient amounts of metals or semivolatile organic compounds are deposited onto soil from airborne sources to appreciably contaminate ground water. For hazardous waste sites with heavily contaminated soils, however, there are many instances of resulting groundwater contamination.

Comment 5a:

The proposed approach does not support the multi media, multi-exposure pathway approach.

- a. The Manual is described as a "multi-media" approach for health risk assessment, but it does not present the basis and evidence that air emissions could be transported in soil and food products. The air dispersion model does not explain how vapor, gas, and particulate emissions are dispersed in the atmosphere and could become incorporated in soil, water, animals, and plants.
- b. Migration of VOCs in subsurface soils should not be considered in this Manual, as no appropriate modeling is presented;
- c. The proposed Manual mentions applicability to landfill sites. Did the authors contact the California Integrated Waste board for their input on this topic? Solid waste landfill sites are typically capped, and no vapor or gases are released to the atmosphere.

Response 5a-c:

The Guidance manual is not intended to provide the basis and evidence that air emissions of a limited subset of chemicals are subject to deposition and could therefore contaminate soil water, animals and plants. This discussion is provided in the Part 4 TSD in Chapters 1, 4, 7 and Appendix E. The Guidance Manual does, however, supply the multipathway algorithms necessary to calculate contaminant concentrations in various media.

The migration of VOCs in subsurface soils is not mentioned or considered in this Guidance manual. Landfills are subject to the Hot Spots program and risk assessments have been performed on landfills (e.g. BKK in Los Angeles). In addition, a separate legislative requirement mandating air monitoring around landfills has resulted in data which is available for use in the Air Toxics Hot Spots program to use in place of emissions estimates.

Comment 6a-d: Tier approach to levels of complexity in risk assessment approach is inconsistent and unsupported

- a. Section 2.5.3 -Tiered Approach to Risk Assessment is limited to a paragraph less than one-third of a page, which indicates the importance attributed to the topic. This Section should be revised and expanded to reflect current knowledge on the topic.
- b. The Manual does not explain the basis for the Tier approach, the requirements for proceeding to the next higher level of complexity, nor the information necessary for starting at above Level 1. The text is unsupported and inappropriate, and should be replaced with material that is already available.
- c. Although cited as a reference in Section 2.1, the Manual ignored and did not make use of any of the extensive information presented in Appendix J- A Tiered Modeling Approach for Assessing the Risks Due to Sources of Hazardous Air Pollutants, Science and Judgment in Risk Assessment (NAS, 1994) (pages 537-582).
- d. The Manual describes a four-tiered approach to risk assessment. Risk assessment practitioners, regulatory agencies (U.S. EPA), scientific literature, and IRAS/OEHHA, only recognize a three-levels of complexity tier in risk assessment, namely:

Level 1: Screening, deterministic, non-site specific approach. This is based on limited information on the site or contamination problem, and for this reason it assumes conservative values.

Purpose of a Level 1 is to "red flag" a contamination problem, or to provide a No Action Needed to risk managers. Because of its built-in uncertainty (conservatism), it should NOT be used as a basis for prioritizing risks or for other risk management action.

Level 2: Detailed, deterministic, problem-specific approach. This is a detailed risk assessment that makes use of site- or contamination problem-specific assumptions and discrete values. This Level requires a detailed Conceptual Site (or Contamination Problem) Model, exposure scenarios, multi-contaminant (if supported), multi-migration and -exposure pathway, multi-receptor approach.

Level 3: Detailed, probabilistic, problem-specific approach. This is the highest Level of complexity, and is similar to Level 2, except that it makes use of input Probability Density Functions (PDFs) for the human exposure factors (representing variability) and other input PDFs (representing pseudo-uncertainty, such as certain environmental migration parameters, time factors, or factors such as bioavailability). The approach requires use of uncertainty analysis software (also described as error propagation); the most frequently used being Monte Carlo method. The output is an overall PDF for health risk (cancer or hazard), and depending on whether a one-dimensional or a two-dimensional analysis is conducted, it allows estimating the contribution of variability and uncertainty on the overall risk estimate. It also allows for sensitivity analysis, that is, the relative contribution of each input PDF to the overall variance, information of great value for risk assessors and risk managers,

e. A scientifically supported Tier approach should replace the proposed approach for air emissions risk assessment. Level 4 has not been recognized as a sound, widely used practice, and there are no detailed discussions and interpretations available in the literature. Level 4 is presented in the Manual as a combination of stochastic and deterministic approach, which limits the use and interpretation of the results, and would be extremely complex to run.

Response 6a-e:

The Tiered approach is described in detail in the Part 4 TSD. The Guidance Manual is not meant to repeat all the information from the four TSDs. The reader is referred to the four TSDs repeatedly in the Guidance Manual for more detailed information. The Tiers described briefly in the Guidance manual are tailored to the needs of the Hot Spots program. The comment refers to methods and language used by U.S.EPA, and confuses this with the approved risk assessment methods for the Air Toxics Hot Spots program. The level 1, 2 or 3 approaches described in the comment easily fit within the four Tiers described for the Hot Spots program. It is clear that the comment does not recognize that Tier 4 is the same as Tier 3 but allows use of site-specific information. Facilities have always had the option of presenting alternative risk assessment information. The Tiered approach presented in the Guidance manual is intended to provide some direction to alternative risk assessments.

Comment 7a:

The proposed probabilistic risk assessment practices are inconsistent with current practices and scientifically unsupported.
Section 2.5.2 - Stochastic Exposure Assessment is limited to a half a page, which is inappropriate for a "Guidance Manual" document. It should be replaced by text that actually describes and reflects current practices in risk assessment.

Response 7a:

A detailed discussion of stochastic analysis and current risk assessment practices is beyond the scope of the Guidance manual, but some discussion of the issues is available in Chapter 1 of the Part IV TSD. Also, the comment implies that stochastic risk assessment is widely used; while use of these approaches is growing, OEHHA is not aware of such widespread use at least within the toxics regulatory arena.

Comment 7b:

The Section mentions the use of probability density functions (PDFs) (they are not "distributions" as referred in the Manual) for describing variability. The Manual does not mention that in probabilistic risk assessment, variability and uncertainty can be analyzed as single or combined input variables. A one-dimensional analysis is available for analysis of variability, and a two-dimensional analysis can be conducted to analyze the contribution of variability and uncertainty in the final risk estimate. The Manual fails to explain this topic, which may be more important to CAR8 titan to OEHHA, since *quasi-* or pseudo-uncertainty (not true uncertainty) analyzed in a two-dimensional Monte Carlo simulation generates information such as engineering, modeling, emission rate variables of interest, which cannot be achieved with a one-dimensional Monte Carlo analysis. Clearly, the authors are unfamiliar with these topics.

Response 7b:

The term distribution is commonly used interchangeably with pdf as in "lognormal distribution". A discussion of uncertainty and variability is in Chapter 1 of the Part IV TSD. The two-dimensional Monte Carlo analysis referred to in the comment which is meant to incorporate uncertainty, is not widely practiced primarily because it relies upon assumptions about uncertainty that cannot be validated (due to lack of data). There was much discussion of this type of analysis during our public comment period on the Part IV TSD. The Scientific Review Panel agreed with OEHHA in rejecting this type of analysis for the Air Toxics Hot Spots program risk assessments.

Comment 7c:

The second paragraph in this Section describes the extraordinary, unnecessary effort redeveloping PDFs from original raw data in circumstances that the information has been already available for some years ("paralysis by analysis"). Attempting extreme precision and accuracy in probabilistic risk assessment suggests poor understanding of risk and uncertainty.

Response 7c:

The distributions (pdf's) that were developed from raw data were not available in literature. In cases where distributions (pdfs) were available in the literature (e.g. tap water consumption), OEHHA simply described and incorporated the use of the existing distributions (pdfs).

Comment 7d:

The Manual ignores the availability of the following documents that are widely used by risk assessment practitioners:

- U.S. Environmental Protection Agency (1999). *Risk Assessment Guidance for Superfund: Volume 3 - Part A, Process for Conducting Probabilistic Risk Assessment (RAGS 3A)*. Draft Revision No: 5. Washington, DC: Office of Solid Waste and Emergency Response. EPA 000-0-99-00; OSWER 000.0-000; P899-000000.
- U.S. Environmental Protection Agency (1998). *Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs*. Draft. Washington, D.C.: USEPA, Office of Pesticide Programs, Health Effects Division.
- U.S. Environmental Protection Agency (1997). *Policy for Use of Probabilistic Analysis in Risk Assessment at the U.S. Environmental Protection Agency*. Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development.
- U.S. Environmental Protection Agency (1997). *Exposure Factors Handbook, Volume I: General Factors; Volume II: Food Ingestion Factors; Volume III: Activity Factors*. Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development. EPA/600/P-95/002Fa, EPA/600/P-95/002Fb, and, EPA/600/P-95/002Fc.
- U.S. Environmental Protection Agency (1997). *Guiding Principles for Monte Carlo Analysis*. Washington, DC: U. S. Environmental Protection Agency, Risk Assessment Forum, Office of Research and Development. EPA/630/R-97/001.
- U.S. Department of Energy (1996). *Characterization of Uncertainties in Risk Assessment with Special Reference to Probabilistic Uncertainty Analysis*. Washington, DC: U.S. Department of Energy, Office of Environmental Policy and Assistance. EH-413-068/0496.
- U.S. Environmental Protection Agency (1995). *Use of Monte Carlo Simulation in Performing Risk Assessments*. Denver, CO: U.S. Environmental Protection Agency, Region VIII Superfund Technical Guidance.
- U.S. Environmental Protection Agency (1994). *Use of Monte Carlo Simulation in Risk Assessment*. Region 111 Technical Guidance Manual Risk Assessment. Hazardous Waste Management Division, Office of Superfund Programs. Philadelphia, PA. EPAI903/F-94/001.

At the same time, the manual cites obscure documents, such as "Hausch C., Leo AJ, Medchem Project Issue No. 26, Claremont, CA, Pomona College (1985). I could not find this referenced document in the text.

Response 7d:

Some of the documents cited are cited in the Part 4 TSD. Many of the documents are not of practical use in the Air Toxics Hot Spots program.

Comment 8a:

Incorporation of methods and procedures that are scientifically unsupported.
Appendix D: Risk Assessment Procedures to Evaluate Particulate Emissions from Diesel Fueled Engines. This material is limited to cancer and non-cancer toxicity criteria, both that have been developed by OEHHA based on whole gas plus particulate matter diesel exhaust together. This is scientifically unsupported. Because of the different chemical composition, and the gaseous or solid nature of the emissions components, the gas/vapor phase and the solid phase are expected to have different toxicity properties. Assuming that particulate emissions from a facility (any facility) are similar to diesel particulates is unsupported.

Response 8a:

The comment suggests that all particulates emitted from any facilities will be treated as diesel particulates; this is not the case. There are sources of diesel particulate in stationary facilities which use diesel engines. Diesel engine emissions fall under the Hot Spots program. In addition, it is important to point out that the derivation of the unit risk factor and Reference Exposure Level for diesel engine exhaust used particulate matter as the surrogate measure for exposure to whole diesel exhaust.

Comment 8b:

Appendix F. Overview of the Lead Risk Assessment Procedures, describes risk management policies, blood levels, a Tiered approach, percentage of children with certain blood levels, information that is interesting but marginal, since the Manual does not explain how to conduct an exposure and risk assessment for environmental lead.

Response 8b:

In regard to 8b, lead is handled differently from other toxics. Appendix F is only an overview of the lead evaluation. The procedure is described in the Air Resources Board's Risk Management Guidelines for New, Modified, or Existing Sources of Lead (March 2001), and is based on the risk assessment of lead carried out by OEHHA as part of the identification of lead as a Toxic Air Contaminant in California.

The procedures described in Appendix D can be used to estimate the percentage of children in a zone of impact whose lead blood levels will be increased above 10 µg/dL by a facility's emissions. The lead level of 10 µg/dL has been used as the level of concern in California's air toxics program. The risk assessment procedures in Appendix D are consistent with the health effects assessment of lead conducted under the TAC program and approved by the Scientific Review Panel.

Comment 9A:

Use of exposure factors normalized to body weight is scientifically unsupported. This is an issue that I have discussed for several years with many colleagues at Cal/EPA, including the authors of the Manual who seem not to understand the scientific basis for the error. I will be presenting an original work at the Annual Meeting of the International Society of Epidemiology and Exposure Analysis

(ISEEA), in August 2002, because I am concerned about this problem. My point is that inhalation rate (m^3/day), inadvertent soil ingestion (mg/day), dermal contact with soil (mg/day), water ingestion (L/day), food intake (kg/day), and similar, are variables that are independent from body weight (bw). The former are "dynamic" functions (continuously changing), but body weight is "static" (changes very slowly overtime). Others argue that the human exposure factors are related and are a function of body weight. My argument is that: (1) the relationship seen is a spurious relationship, that is, only apparent; there is no mathematical function that establishes the association of one over the other physiological function; (2) respiration rate, water ingestion, food ingestion, and body weight are physiological processes that are regulated by neuronal and endocrine body functions and in turn, are not related to body weight; (3) inadvertent soil ingestion that occurs while one works in the backyard, can hardly be described as "related to body weight", and pica ingestion (soil, hair, paper, plants, etc.) in children is a behavioral problem that has no relationship whatsoever with body weight. Like these, there are many additional arguments against an association between exposure factor and body weight. Nevertheless, some believe that there is a relationship and they divide the exposure factor by the body weight that is normalizing the exposure factor to body weight. Expressions such as that normalized inhalation rate ($\text{m}^3/\text{kg bw}\cdot\text{day}$), normalized inadvertent soil ingestion ($\text{mg soil}/\text{kg bw}\cdot\text{day}$), dermal contact with soil ($\text{mg}/\text{kg bw}\cdot\text{day}$), water ingestion ($\text{L}/\text{kg bw}\cdot\text{day}$), food intake ($\text{kg}/\text{kg bw}\cdot\text{day}$). These expressions are wrong, because, for example, inhalation rate is a two-dimensional probability density function and body weight is also a two-dimensional probability density function. Dividing a two-dimension by another two-dimension variable does not result in a point estimate as shown in the Manual. The same applies to the other human exposure factors. Therefore the normalizing procedure produces a loss of information, which translates in an increase in uncertainty.

One problem with these newly created numbers is that they have not been validated, verified, discussed nor peer reviewed in scientific journals, and therefore users cannot compare the values, and there is no source to validate the numbers. For example, the point estimated for daily breathing rate for a 9-year exposure duration is average = 452, and high end = 581 $\text{L}/\text{kg bw}\cdot\text{day}$. I challenge the authors to explain the meaning of these values and discuss whether they are typical or conservative. In my opinion they are meaningless.

The other problem with these numbers is that because they have an inherent increased uncertainty, the result is a significantly tamer dispersion of the risk estimates. This is one of my observations that will be presented at the ISEEA meeting. Larger values of high-end risk estimates will lead to lower levels of environmental contaminants that will need to be remediated or controlled in the air emissions. It is possible that we may be requiring clean up or control to levels technically impractical or unfeasible, at extremely high costs. All of this because of an unsupported conceptual error.

Response 9A:

OEHHA staff disagree with this analysis. OEHHA staff believe that there is a relationship between body weight and breathing rate. They are neither totally independent nor totally dependent, but are related (e.g., partially correlated). In evaluating data used as the basis for our breathing rates, OEHHA normalized breathing rates measured in individuals performing specific activities to their individual body weights. Interestingly, much of the variability in breathing rate for specific activities could be explained by variability in body weight. The alternative approach is to determine the correlation between breathing rate and body weight and use separate distributions of body weight and breathing rates with a rank correlation coefficient to generate a distribution of breathing rates per unit body

weight. This seemed more cumbersome so OEHHA decided to produce a breathing rate distribution with the body weight term integrated (L/kg BW-day). This was facilitated by the availability of individual body weights in the studies of breathing rates. The breathing rate distribution is part of the Part IV TSD that has already been adopted by OEHHA. The data are provided in Chapter 3 of the Technical Support Document on Exposure Assessment and Stochastic Analysis. Much of the data was collected by University of California faculty at Berkeley and Davis under contract to the ARB, and reported in the peer-reviewed literature.

The point estimates for daily breathing rate for a 9-year exposure duration of average = 452, and high end = 581 L/kg bw-day and their derivation can be found in Chapter 3 of the Part IV Technical Support Document on Exposure Assessment and Stochastic Analysis, which underwent two public comment periods, was subsequently reviewed by the SRP, and adopted by the Director of OEHHA. In addition, the breathing rate distributions were validated against energy expenditure literature. This analysis is provided in Appendix K of the Part IV TSD. A peer-reviewed paper on the breathing rates has been accepted for publication in Human and Ecological Risk Assessment.

Food intake does constantly vary; however, average daily intake of food or a particular food, usually over a long period of time is the metric that is of importance to the risk assessor. Caloric intake is clearly related to body weight. A large adult tends to consume more calories than a small adult in order move his or her body because the work involved is greater. Therefore, some of the variability in food intake can be described by differences in body weight. There are two approaches that can be taken to deal with this correlation between a parameter such as food intake and body weight. The first is to use a separate distribution (pdf) for body weight and food intake and determine the correlation between the two. A rank order correlation coefficient can be used to generate a distribution of food intake per kg body weight when food intake is divided by body weight using Monte Carlo methods. The second approach is to divide food intake by body weight for each individual in a food survey and produce a distribution (pdf) of food intake expressed as g/kg body weight. If the distribution of g/kg BW is less variable (smaller standard deviation) than the corresponding distribution of g/day, then part of the variation is likely explained by body weight. In our hands using the CSFII database, body weight is correlated with food consumption.

OEHHA did not endorse a distribution for soil ingestion (Part 4, TSD), nor did we imply that soil ingestion is correlated to body weight. We simply used an average soil ingestion rate divided by a time weighted average body weight to give a point estimate in terms of mg soil ingested/kg BW for the purposes of calculating dose by ingestion of contaminated soil.

Comment 10a:

Presentation of the Uncertainty in Health Risk Assessment Is Insufficient and Unsupported. Section 1.1- Uncertainty in Risk Assessment, states that "OEHHA has striven to use the best science available in developing these risk assessment guidelines" sounds self-indulgent. The Manual ignores the availability of a large number of documents widely used by risk assessment practitioners (see Section 2.5.2, below). It is surprising that although OEHHA attended some of these U.S.EPA-organized meetings, there is no mention of these activities or the documents produced from these meetings. This is an unacceptable omission.

Response 10a:

Comment noted. Describing OEHHA participation in U.S.EPA organized meetings is not appropriate for the Guidance manual. The Part 4 TSD cites general risk assessment literature. The implication that there is widespread use of uncertainty analysis in regulatory risk assessment is not supported.

While OEHHA is aware of USEPA activities, the Scientific Review Panel urged OEHHA to not rely solely or exclusively on USEPA because many of its documents were produced in house and had not received external peer review. Also, OEHHA has a legislative mandate specifically for the Hot Spots program, which is unlike any federal program. (Staff note that two members of the Committee on Risk Assessment of Hazardous Air Pollutants of the National Research Council, which produced the 1994 document Science and Judgment in Risk Assessment, have had input to our documents. Drs. Hanspeter Witschi and James Seiber were members of the ARB's Scientific Review Panel on Toxic Air Contaminants, and reviewed Parts I through IV Technical Support Documents, which are the source of the information provided in the Guidance Manual.)

Comment 10b:

It is critical and scientifically sound that risk assessment practitioners understand the difference between uncertainty and variability, which is not made clear in the Manual. Uncertainty is defined in the Manual as "what is not known and may be reduced with further scientific studies." This is inconsistent with the previous sentence that advocates the use of assumptions that err on the side of conservatism. How conservative the approach should be to avoid underestimation of risk to the public? This topic should be explained in this Section. For example, the Manual cites uncertainty in the estimation of the emissions and in the air dispersion models, but it does not explain the type of studies to reduce this uncertainty.

Response 10b:

The Part 4 TSD contains a discussion of uncertainty and variability, the differences between the terms, and our use of the terms in the Air Toxics Hot Spots Risk Assessment Guidelines. Risk assessment requires both science and judgment, as recognized in the title of the aforementioned 1994 NAS document. In the presence of insufficient data, we make a judgment favoring public health. When the scientific data demonstrate the actual variability and thus reduce the uncertainty, we use the science to assign a parameter value. The variability in exposure parameters is discussed at length in the Exposure Assessment and Stochastic Analysis Technical Support Document.

Comment 10c:

"Interactive effects of exposure to more than one carcinogen or toxicant are also not necessarily *quantified* in the HRA." There is no methodology for dealing with interaction (i.e., synergism, antagonism) in risk assessment. The practice and policy is to consider that hazards and risks of chemicals are additive in terms of their contribution to the overall health hazard or risk. It is unclear what is the meaning of the expression "not necessarily quantified." Delete the rest of the paragraph, since it is speculative.

Response 10c:

The discussion of interactive effects of toxicants in the Guidance Manual and TSDs simply describes synergistic, additive and antagonistic interactions between toxicants and explains that risk assessment procedures simply regard interactions as additive. In the case of synergistic or antagonistic interactions the risk will be underestimated or overestimated, respectively. The comment appears to agree with what we have stated.

Comment 10d:

According to the Manual, other examples of "underestimation or overestimation" of risk is from "exposure estimates where little or no data are available" and it gives examples of soil half-life and dermal penetration from soil matrix. These exposure pathways are unlikely for vapors and gases in air. Please delete or provide non-speculative examples.

Response 10d:

The Guidance manual does not recommend assessing the dermal pathway for gases or vapors.

Comment 10e:

Please delete the paragraph in page 1-6 starting with "Factors including..." This is a generic presentation of factors that are related to dose-response. The Manual is not intended for the development or changes in toxicity criteria, so that this discussion is irrelevant. What the Manual fails in describing is specific examples of uncertainty and variability.

Response 10e:

OEHHA will retain the paragraph on uncertainty. The sources of uncertainty discussed are important in risk assessment. The reader should realize that health guidance values may change if better data become available and thus the reader should check regularly for updates.

Comment 10f:

Some explanations are ludicrous and unnecessary, such as not including *children of short age* in the worker population. If one assumes that children of short age do not work, is this a source of uncertainty?

Response 10f:

Comment noted. We have assumed a 40-year work-life occurring between the ages of 18 and 65. However, child labor laws allow children as young as 14 to be employed at some work-sites, and even younger children may be at work in agriculture in areas where Hot Spots facilities, for example, plants processing fresh produce, are located.

Comment 10g:

The manual explains that "risk estimates generated by an HRA should not be interpreted as the expected rates of disease in the exposed population but rather as estimates of potential risk."

Response:

Comment noted. It is not clear what the issue is.

Comment 10h:

h. Risk assessment is described as "best used as a ruler to compare one source with another and to prioritize concerns." This conservative ruler can only be used to compare among risk estimates developed with the same approach. Risk prioritization belongs to risk management and should not be based only on risk estimates.

Response 10h:

This risk assessment methodology described in the Guidance Manual is the common, health-protective ruler to be used to assess and compare risk from facilities in the Air Toxics Hot Spots program. Risk management does take into account other inputs besides the assessment of risk such as technical feasibility and economic considerations.

Comment 11a: Uses and limitations of the proposed approach.

In Section 1.1, Use of the Guidance Manual, it is explained that the Manual 'should be used in conjunction with emissions data collected and reported and approved' by the Air Pollution Control or Air Quality Management District. The emissions reported are routine or predictable and include continuous and intermittent releases and predictable process upsets or leaks. Therefore the Manual is not applicable to unpredictable releases or to compounds that have not been identified in the emissions.

Response 11a:

The Hot Spots program does not address unpredictable releases. Each risk assessment is specific to the facility and only includes chemicals emitted by the facility in question that are covered by the Hot Spots program list of substances.

Comment 11b:

The Manual fails to explain the type of sampling necessary to characterize the gas emissions from any primary or secondary source.

Response 11b:

The ARB is responsible for source test protocols. These are contained in the ARB's "Emissions Inventory Guidelines and Regulation".

Comment 11c:

The Manual fails to explain the type of analysis necessary to characterize the gas emissions from any primary or secondary source.

Response 11c:

The ARB is responsible for source test protocols. These are contained in the ARB's "Emissions Inventory Guidelines and Regulation". As noted above the vast majority of facilities subject to the Air Toxics Hot Spots program are not required to conduct stack testing.

Comment 11d:

Section 3.1 - The Air Toxics Hot Spots List of Substances and Emissions Inventory explains that the air contaminants considered in the Air Toxics Hot Spots Program are only those listed in the ARB's Emission Inventory Criteria and Guidelines Regulations, and the Emissions Inventory Criteria and Guidelines Report. It can be concluded that the proposed approach is not applicable to stationery sources of air emissions such as solid waste incinerators, hazardous waste incinerators, medical waste incinerators, and solid waste landfills. These are complex emissions that require sampling and analysis, not just comparison against a list of emissions.

Response 11d:

The Hot Spots program is applicable to solid waste incinerators, hazardous waste incinerators, medical waste incinerators and solid waste landfills. Risk assessments under the Hot Spots program have been performed on solid waste incinerators, solid waste landfills and medical waste incinerators. Emissions estimates from incinerators are generally based on stack testing in the Air Toxics Hot Spots program. These requirements are contained in the ARB's "Emissions Inventory Guidelines and Regulation".

Comment 11e:

The Manual describes chemical substances listed in the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") as included in the Air Toxics Hot Spots List of Substances and Emissions inventory (emphasis added). The rationale is only applicable to the contaminant prior to its release into the air, but not to incorporation to soil, water or plants. Contaminants in gas or vapor phase in normal conditions have different physico-chemical properties from those soluble in solid (soil) or liquid (water) phases.

Response 11e:

Comment noted. It is not clear what the issue is.

Comment 11f:

Section 3.1 - The Air Toxics Hot Spots List of Substances and Emissions inventory explains that the air contaminants considered in the Air Toxics Hot Spots Program are only those listed in the ARB's Emission Inventory Criteria and Guidelines Regulations, and the Emissions Inventory Criteria and Guidelines Report. It can be concluded that the proposed approach is not applicable to stationery sources of air emissions such as solid waste incinerators, hazardous waste incinerators, medical waste incinerators, and solid waste landfills. These are complex emissions that require sampling and analysis, not just comparison against a list of emissions.

Response 11f:

Comment is identical to 11d. Thus, we reiterate that the Hot Spots program is applicable to solid waste incinerators, hazardous waste incinerators, medical waste incinerators and solid waste landfills. Risk assessments under the Hot Spots program have been performed on solid waste incinerators, solid waste landfills and medical waste incinerators. Emissions from incinerators are generally based on stack testing in the Air Toxics Hot Spots program. These requirements are contained in the ARB's "Emissions Inventory Guidelines and Regulation".

Comment 11g:

The Manual describes chemical substances listed in the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") as included in the Air Toxics Hot Spots List of Substances and Emissions Inventory (emphasis added). The rationale is only applicable to the contaminant prior to its release into the air, but not to incorporation to soil, water or plants. Contaminants in gas or vapor phase in normal conditions have different physico-chemical properties from those soluble in solid (soil) or liquid (water) phases.

Response 11g:

Comment is identical to 11e. Comment noted

Comment 12a:

Level of conservatism of the proposed approach is unsupported. According to the Manual, "The assumptions used in these guidelines are designed to err on the side of health avoid underestimation of risk to the public." This is not the best science available, but instead constitutes a policy. Composite conservative assumptions may lead to unreasonable and biologically non-plausible situations. Prior to making this type of decisions, the authors should analyze the uncertainty introduced by the *intentional bias* and attempt to estimate the magnitude of the change in risk uncertainty. Human health is not protected by simply inflating numbers.

Response 12a:

Comment noted. We believe the guidelines have tried to avoid being overly conservative by limiting the number of high-end exposure variates used in the multi-pathway modeling. This is discussed in the Part IV TSD and also in the Guidance Manual.

Comment 12b:

The Manual proposes: "a health-protective assumption is to assume that *all individuals* within a large radius of the source are exposed to the maximum *concentration*" (emphasis added). The Manual does not explain that if the screening risk assessment population risk estimates exceed target risk values, then a Level 2, more detailed approach should be used. Otherwise the use of unsupported scientific procedures and evidence would be an unusual and unacceptable procedure for "protecting human health."

Response 12b:

Facilities have the option of submitting a more refined analysis, and generally work with local Districts to determine when a more-refined analysis is warranted.

Comment 13a:

The document confuses science, policies, and generic-unsupported statements. The Manual makes numerous sweeping, unsupported, and unexplained generalizations. For example, Section 4.6.2 - Screening Population Estimates for Risk Assessments, starts with the following: "Not all health risk assessments require refined population exposure assessments and at times a screening estimate may be appropriate." Explain the basis for such statement.

Response 13a:

The statement in the Guidance Manual is addressed to risk managers at the air districts who may decide, for example, that a facility that only impacts five or six people may not need to do a refined population exposure assessment. Calculating the cancer burden in such instances does not provide much additional insight. The Guidance Manual must balance between striving for consistency in methodology and providing for flexibility in risk assessment and risk management. If a facility does not pose a significant health risk using a screening risk assessment, then there is no need to be concerned about the population around the facility. A screening population estimate is adequate in, for example, parts of the Mojave Desert Air District where there is little population now and probably in the near future also.

Comment 13b:

The Manual mentions facilities with "high, intermediate, or low priority" to prepare an HRA, but there is no description on the differences on each and the rationale for each. The priority level is a risk management decision, which should not be included in a risk assessment guidance.

Response 13b:

Determinations of facilities with high, intermediate, or low priority are made by the air district staff using the Air Toxics Hot Spots Facility Prioritization Guidelines (available at

www.arb.ca.gov/ab2588/RRAP-IWRA/priguide.pdf). Determination of a priority score is a risk assessment exercise. The separation into high, intermediate, or low priority is a risk management decision to make the process manageable and to comply with the law.

Comment 14: Purpose of the Hot Spots Analysis and Reporting Program (HARP) Software is unclear. The Manual relies heavily on the Hot Spots Analysis and Reporting Program (HARP) Software for the calculations and reporting of results described in the Manual. The Manual, however, did not include the software in order to compare these two work products. This is not a transparent process.

Response 14:

The HARP program performs the calculations specified in the Guidance manual. It is not a “black box” as it uses all of the exposure parameters, algorithms, distributions, Reference Exposure Levels, and Cancer Potency Factors that have been approved for use in the Air Toxics Hot Spots program. The data files are viewable. If a user wished to confirm that the calculations are being performed properly, an independently programmed spreadsheet could be used. OEHHA and ARB staff used hand calculators to confirm that calculations were being performed properly.

Comment 15a:

The Manual is a biased regulatory guideline.

a. In Section 5.2 - Criteria for Exposure Pathway Evaluation, it can be found the following statement: "Table 8.2 identifies the residential and worker receptor exposure pathways that are mandatory and those that are dependent on the site-specific decisions." It is extremely unusual to find a Manual that describes mandatory inclusion of contaminants and exposure pathways for maximally exposed receptors, - regardless of the evidence otherwise - unless there is a preconceived effort to exaggerate the estimated risks. This is unscientific, and it can hardly be considered an approach to protect human health. The mandatory exposure pathways shown in Table 8.2 (page 8-6) are inhalation, soil ingestion, dermal exposure, and maternal milk consumption. The site/route dependent exposure pathways include homegrown produce ingestion, fish ingestion, drinking water ingestion, dairy (cow's) milk ingestion, and meat (beef, pork, chicken, and egg) ingestion.

Response 15a:

OEHHA has assumed that persons residing or working within the isopleth of a facility will breathe and therefore the inhalation pathway should be evaluated for all facilities. We also assume that if chemicals that can be deposited in the soil are emitted by the facility, then people in the zone of impact can inadvertently ingest contaminated soil and can be exposed dermally from contact with contaminated soil. Such contact may occur from playing in the dirt or gardening. A resident mother who lives in the isopleth of the facility may decide to breast feed her infant. A facility could present compelling evidence that these activities were not occurring in a supplemental risk assessment, and then the District and OEHHA would consider this information during review of the assessment. However, it is difficult to see how requiring that these pathways be evaluated constitutes a preconceived effort to exaggerate the estimated risks.

Comment 15b:

In Section 8 - Risk Characterization, at the end of the first paragraph, a statement reads: "Note, for the Hot Spots Program, the 70-year exposure duration should continue to be used as the basis for estimating risk." This policy has no basis. It is irrational to expect that a person would be seating with his/her nose in the air at the same location for 70 years, except for a biased effort to exaggerate risk levels. This approach is unsupported and should be revised.

Response 15b:

The acceptable cancer risk levels set by the District (generally 10^{-5}) assume 70-year exposure duration. The theoretical cancer burden from facility emissions remains the same irrespective of residential turnover. The basis for the 70-year exposure duration is that at least until recently it was considered to be an average human life span (not high end). Although people do not sit in the same place for 70 years, some people do stay in the same general area for most of their life. The 70-year duration is a useful measuring stick to compare facilities. The cancer risk based on 9 and 30-year durations of exposure can also be presented so that a person can gauge his risk from that facility versus the time he has lived in his residence. (As an aside, even if he decides to move, he will not find a place where there is no risk. Thus, a person could cumulate a number of 10^{-5} risks when moving from one place to another if shorter durations of exposure were the basis of risk estimates. The Hot Spots legislation specifically authorizes consideration of cumulative impact.)

While we will never be able to calculate the "true" risk, we at least can compare the relative risk of different types of facilities. And just as there are reasons to opine that these risk assessment methods overestimate risk, there are ways in which the risk may be underestimated, such as not accounting for synergistic effects and not estimating risks for chemicals known to be emitted but lacking approved Reference Exposure Levels and cancer potency factors.

The exposure duration issue was debated during the public and peer review of the Part 4 TSD, and the SRP agreed that the 70 year exposure duration continue to be the basis of risk estimates from facility emissions.

Comment 16a:

The document requires extensive editing.

a. Regarding use of terminology

- The Manual should clarify early in the document that throughout the Manual, the expression "emissions" mean "air emissions" or "emissions into the atmosphere." There are also emissions into surface soils, subsurface soils, surface waters, or ground waters.
- Change "noncancer" to non-cancer, and "non inhalation" to non-inhalation.
- Comment on Section 4.6.4 - Sensitive Receptor Locations. The term "sensitivity" refers to allergic responses, of an immunity nature. The term 'hypersusceptible' refers to individuals that respond to a chemical stressor with a response higher than the typical response (and which are addressed in the Reference Doses). The Manual should clarify that it refers to the second.

The manual shows expressions such as (mg/kg/day) and (mg/kg-day). Decide for one.

- "Lipophilic (fat-loving)." Have they heard about soluble in fat?

Response 16a:

OEHHA will continue to use the term “emissions”. Although there are other types of emissions, the use of the word is clear in this context.

As for the terms noncancer and noninhalation, the Random House College Dictionary, Revised Edition, 1984, is replete with hundreds of compound words such as nonappearance, noncompliance, nonconformist, and nonpartisan, which do not contain a dash. Thus noncancer and noninhalation should be acceptable spellings.

The term sensitive receptor is defined in the document; we will continue to use it. We will adopt a standard expression for (mg/kg-day).

The term lipophilic is a standard scientific term, and will continue to be used in the manual.

Comment 16b:

Repetitive (examples)

- Section 2 - Overview of Health Risk Assessment provides an unnecessary, repetitive overview of the risk assessment process and of the rest of the document. Carefully edited, this Section should become part of Section 1- Introduction.
- Section 6 - Dose-Response Assessment for Non-carcinogens, and Section 7 - Dose-Response Assessment for Carcinogens, can be condensed in one single Section, since the procedures are similar among different chemicals and exposure pathway. There is no need to explain how toxicity criteria are developed.
- Often, the Manual uses expressions such as "Chronic Oral (Non-inhalation)". It is sufficient with chronic oral; there is no need to explain what it is not (e.g., white [non-black]),

Response 16b:

It is customary in government documents to provide an overview or executive summary in order to help the less technically sophisticated reader. The Hot Spots program is a public-right-to-know act. This overview or executive summary will cover the same material as is covered else where in the document.

The different chapters in the Guidance manual are designed so that reader will not have to read the entire document to understand the parts. This means that there will be some repetition of material. The use of “chronic oral (noninhalation)” is useful in helping the less technically sophisticated reader.

Comment 16c:

Unnecessary explanations.

The Manual contains a large number of "explanations" that are unnecessary. For example, in the first paragraph of Section 4.10.1- SCREEN3, it reads: "The dispersion algorithms used in SCREEN3 are consistent with ISCST3. (With the implementation of AERMOD, which is expected in the future, SCREEN3 may need to be superceded with a model that is compatible with AERMOD.)"

Response 16c:

Comment noted. However, we do not agree that the explanations in the document are unnecessary.

Comment 16d:

There is no comment 16d.

Comment 16e:

Unnecessary material included in the document

- Appendix B: Health and Safety Code Related to the Air Toxics Hot Spots Program. This is unnecessary, and the Manual should focus on the actual preparation of risk assessments, not the historical background.
- Section 4.2.1.1.1- Molecular Weight Adjustments for the Emissions of Metal Compounds is unnecessary, since any undergraduate student should know how to adjust fraction of total molecular weight. However, the Manual does not describe other similar calculations necessary for estimating the concentration and emission rates of chemicals for exposure assessment, and these include, e.g., adjustments of composition for temperature and humidity. An engineer, who is the expert professional responsible for the task, should conduct these adjustments.

Response 16e:

The Health and Safety Code is important in understanding the legal basis of the Hot Spots program.

The Section on molecular weight adjustment is present because people with differing technical backgrounds are expected to use the manual. OEHHA staff note that engineers at the air districts are responsible for reviewing the emission estimates of Hot Spots facilities, including making molecular weight adjustments if needed.

Emission factors and their derivation are beyond the scope of this document. These are, however, discussed in ARB's "Emissions Inventory Guidelines and Regulation".

Comment 16f:

General format and contents of the Manual. In the title page, five names are listed as Editors, Project Leads, and Contributing Authors. Clarify the role of each. Only one name is shown as Departmental Reviewer. It would have been preferable a Review Committee or Panel of scientists with experience in the field of risk assessment.

Response 16f:

The terms editors, project leads and contributing authors are self-explanatory. The internal review of the Guidance manual is the prerogative of OEHHA management. The Guidance document is a compilation of four previous TSDs that underwent extensive internal review, as well as public review and review by the Scientific Review Panel on Toxic Air Contaminants. OEHHA has had many formal and informal meetings and discussions with representatives of facilities and with experts in the various

areas of risk assessment while developing these guidelines. The Health and Safety Code specifies that the SRP is appropriate body for peer review of the Guidance Manual.

B. CONCLUSIONS AND RECOMMENDATIONS

Comment: The Air Toxics Hot Spots Program Guidance Manual for Preparation of Health Risk Assessments is a scientifically unsupported document, is inconsistent with risk assessment practices in California and the U.S., it includes mandatory values, policies, and methods that make it a de facto regulatory document, and it could have a significant effect on a number of risk assessment and risk management activities in the State of California. The proposed approach is insufficient and inappropriate for its intended use. The document is both redundant and insufficient, and needs extensive editing. An experienced reader will conclude that the document reads as unfamiliar with the topics. This is a document with a strong emphasis in conservatism, default procedures, and many extreme assumptions that lead to unsupported risk estimates and increased uncertainty. There is no doubt in my mind that the proposed approach applied to any facility with air emissions would generate significant risk levels. What is unclear to me is what is the purpose of doing this?

If the Manual is approved, it could have significant impact on the risk management decisions used by CARB, and it may impact other Cal/EPA BDOs that rely on risk assessment guidelines prepared by the State. As presented, this document cannot and should not be accepted nor approved by the California Environmental Protection Agency. Further, the Manual describes risk assessment practices that doubtfully would be protective of human health. Human health cannot be protected by pushing science to irrational levels.

OEHHA has invested ten years to comply with this mandate, passed by legislators in 1992. It still does not make sense. I would like to suggest the Scientific Review Panel on Toxic Air Contaminants, California Air Resources Board, and the California Environmental Protection Agency, submit the five-volume Technical Support Documents to a higher level of review and recommendations, such as the National Academy of Sciences. The problems contained in these documents have not been able to be recognized by previous reviewers, and it would take an external higher level of scientific expertise to conclude how valid they are.

Response:

Comments noted. The Guidance manual provides guidance for the preparation of risk assessments in the Hot Spots program. The Guidance manual is a compilation of information contained in the Parts I-IV Technical Support Documents which underwent extensive internal, public, and peer review. Much of this information is already in use for risk assessment activities in OEHHA and other California Boards and Departments. Most facilities in the Hot Spots program are not required to do risk assessments under the prioritization schemes developed by the Districts. Only a small fraction of facilities required to do risk assessments under these new Guidelines will show significant risks. This is predictable on the basis of OEHHA's review of over 900 risk assessment using the previous CAPCOA guidelines. The Guidance manual is not by law approved by Cal/EPA. The Health and Safety code states that it is to be peer reviewed by the Scientific Review Panel and then adopted by the Director of OEHHA. The National Academy of Sciences is not designated to review the Guidance Manual.

