August 18, 2014

Dr. David Siegel
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Office of Environmental Health Hazard Assessment
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Sacramento, CA, 95814

SUBJECT: PROPOSED OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESMENT (OEHHA) HEALTH RISK ASSESMENT (HRA) METHODOLOGY FOR USE IN CONTROL OF AIR TOXICS

Dear Dr. Siegel:

The undersigned groups represent companies that operate industrial, commercial and manufacturing facilities which may be impacted by the implementation of OEHHA's proposed HRA methodology, developed pursuant to the Air Toxics "Hot Spots" Information and Assessment Act of 1987, otherwise known as AB 2588 (California Health & Safety Code § 44300 *et seq.)* and SB 25 (Health and Safety Code § 39660 *et seq.*). We offer these comments on the new draft Air Toxics Hot Spots Guidance Manual released for public comment on June 20, 2014.

Our comments necessarily address technical and policy issues that are likely to impact the majority of business sectors in California. As the California Air Pollution Control Officers Association (CAPCOA) has observed, the proposed HRA changes are likely to affect *thousands* of facilities, including many that previously were not subject to Hot Spots or local district air toxics regulatory requirements, regardless of any actual change in air toxics emissions from these facilities. The expectation that these guidelines will be used in other settings, such as a means of evaluating incremental air toxics risk for projects subject to the California Environmental Quality Act (CEQA), also introduces significant new hurdles for proposed facility expansions and new operations.

Bearing these practical realities in mind, we encourage both OEHHA and the Scientific Review Panel on Toxic Air Contaminants (SRP) in the course of their deliberations to consider further amendments to the guidelines to ensure that those who are responsible for implementing these changes -- facility operators and local air districts -- can do so in a manner that protects public health without undermining California's still fragile economic recovery.

The following comments are supplemented by the enclosed technical and scientific review prepared by Dr. Robert Scofield with the expert consulting firm GSI, which we incorporate by reference. Taken together, these documents respond to OEHHA's request to focus on areas where further clarity is needed, relevant information is omitted or errors exist which should be addressed before the document is finalized and used in any regulatory context.

In particular, the undersigned groups would like to highlight the following two major concerns:

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

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

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

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

[1] Air Toxics Hot Spots Program Risk Assessment Guidelines, The Air Toxics Hot Spots Program Guidance Manual for the Preparation of Health Risk Assessments, Public Review Draft, OEHHA, June 2014.
[2] See Comments on June 20, 2014 Draft Air Toxics Hot Spots Program Guidance Manual, GSI Environmental Inc., August 12, 2014, at p.2.
[3] This assumption is referred to as Age Specific Factors (ASF) which increase the cancer potency value for younger people.
[4] Applying the ASF values over a 70-year lifetime results in a cancer risk value that is 1.7 times greater, *see* p. 62 of the OEHHA Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to all for early life stage exposures, May, 2009.
[5] 15 – 9.1 = 5.9; 5.9/9.1 x 100 = 65%.

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

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

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

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

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

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

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

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

A primary objective of AB2588 is to communicate the results of facility health risk assessments (HRAs) to potentially affected individuals.[7] A successful risk communication program provides accurate information to stakeholders that they can understand and use to make informed decisions.[8] To achieve this objective, the Legislature concluded the HRA results must be both accurate and complete:

[6] OEHHA, 2014, Table 5.6 at p. 5-25.
[7] H&SC § 44362(b).
[8] Improving Risk Communication, National Research Council, Committee on Risk Perception and Communication, National Academy of Sciences, 1989; see pp. 26-29, 80-83.
[9] Health & Safety Code (H&SC) § 44360(b)(3).

> "The [risk assessment] guidelines established pursuant to paragraph (2) shall impose only those requirements on facilities subject to this subdivision that are necessary to *ensure that a required risk assessment is accurate and complete* ..."[9] *(emphasis added)*

The obvious rationale for accurate and complete HRA's in the context of risk communication is to avoid misleading and confusing the public. As noted by the NRC "good risk communication cannot always be expected to improve a situation, poor risk communication will nearly always make it worse."[10] Presentation of a single point estimate of facility risk based on a series of worst case assumptions, ranging from the highly unlikely to the outright false, does not further the statutory objective of accurate risk communication. More importantly, this approach is in direct conflict with Health and Safety Code section 44360(b)(3).

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

Recommendations:

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

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

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

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

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

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

[10] *Op. cit.* National Research Council, 1989 at p.3. We strongly urge OEHHA reconsider this policy as it will hinder good risk communication by the Districts

Respectfully Submitted By:

Agricultural Council of California
Almond Hullers and Processors Association
American Chemistry Council
Associated General Contractors- California
Associated General Contractors- San Diego
Building Industry Association of Fresno and Madera County
California Building Industry Association
California Business Properties Association
California Chamber of Commerce
California Cement Manufacturers Environmental Coalition
California Construction and Industrial Materials Association
California Cotton Ginners Association
California Cotton Growers Association
California Farm Bureau Federation
California Fresh Fruit Association
California League of Food Processors
California Manufacturers and Technology Association
Can Manufacturers Institute
California Metals Coalition
California Refuse Recycling Council
California Small Business Alliance
California Trucking Association
Chambers of Commerce Alliance of Ventura and Santa Barbara Counties
Chemical Industry Council of California
Coastal Energy Alliance
Construction Industry Air Quality Coalition
Dairy Cares
Inland Empire Economic Partnership
Industrial Environmental Association
Kern County Farm Bureau
Los Angeles County Business Federation
Manufacturers Council of the Central Valley
Metal Finishing Association of Northern California
Metal Finishing Association of Southern California
Milk Producers Council
NAIOP- Southern California
National Federation of Independent Business
National Tank Truck Carriers, Inc.
Orange County Waste & Recycling
Rural County Representatives of California
San Bernardino County Solid Waste Management Division
San Gabriel Valley Economic Partnership
Solid Waste Association of North America
Styrene Information & Research Center
Valley Industry and Commerce Association
West Coast Lumber & Building Materials Association
Western Agricultural Processors Association
Western Growers
Western Plant Health Association
Western States Petroleum Association
Western United Dairymen
Western Wood Preservers Institute

Enclosure

cc: Matthew Rodriquez – Cal-EPA Secretary
George Alexeeff – OEHHA Director
Richard Corey – CARB Executive Officer
Members, California Air Pollution Control Officers Association

Comments on June 20, 2014

Draft – Air Toxics Hot Spots Program Guidance Manual

Prepared by Robert Scofield, D. Env.
15 August 2014

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The Office of Environmental Health Hazard Evaluation (OEHHA) has issued a new guidance manual, "Air Toxics Hot Spots Program Guidance Manual for the Preparation of Risk Assessment" (Guidance Manual) designed to improve the way the state estimates lifetime health risks from toxic air contaminants. In their notice of a public comment period for the new Guidance Manual, OEHHA stated that the methodologies in the new Guidance Manual were intended to "seek to develop more accurate estimates of the risks from emissions of air toxics." In the same announcement, OEHHA reported that responding to legislative requirement (SB25) to consider the special susceptibility of children was a major impetus for issuing the new Guidance Manual. In the introductory chapter of the new Guidance Manual itself, OEHHA provides another guiding principle for their Guidance Manual in a discussion of the importance of consistency in risk assessment approaches to support the use of risk assessment as a tool for comparing sources of emissions and for prioritizing concerns.

GSI Environmental has prepared comments on the new draft Air Toxics Hot Spots Guidance Manual released for public comment on June 20, 2014. We understand that the new Guidance Manual is based on three previously published Technical Support Documents. We also understand that the underlying science in the new Guidance Manual has already been the subject of public comment and that OEHHA is currently seeking comments on the clarity of the new document and on issues related to implementing the information presented in the three TSDs and on specific points identified in OEHHA's June 20, 2014 announcement of the release of the new Guidance Manual for public comment. Accordingly, our comments focus on points of clarification for implementing the new guidance in the preparation of risk assessments and for the use of the risk assessment prepared under the new guidance in support of risk management decisions and risk communication. In particular, we provide comments on the effect that following the new guidance would have on undermining accuracy and consistency of risk assessments, two aspects of the risk assessment process that OEHHA has stated they value.

As relevant background for our comments, we note that the new Guidance Manual is explicitly intended for use in the Air Toxics Hot Spots program, which has both risk management (e.g., mitigation) elements and risk communication (e.g., public notification) elements. Air Districts across the State generally require the Hot Spots risk assessment guidelines to be followed for risk assessments submitted for air permit applications as well. In addition, the guidance documents prepared by Air Districts for risk assessments prepared in support of the California Environmental Quality Act (CEQA) also closely follow OEHHA's Air Toxics Hot Spots guidance. Thus, when considering the implementation of the new Guidance Manual, questions about the effects of the proposed changes for risk management and risk communication under not only Hot Spots, but under permitting and CEQA applications are also raised.

Young Animals are More Sensitive than Adults to Only Some Chemicals

The primary factors cited by OEHHA as motivating the risk assessment changes included in the draft OEHHA Guidance Manual are new science about increased childhood exposure to and childhood sensitivity to air toxics as well as the legislation noted above requiring that special susceptibility of infants and children to air toxics be taken into account. While the legislature did express concern about childhood sensitivity to toxic air contaminants, their finding expressed concern that **certain** (not all) toxic air contaminants may pose a greater risk to children than

adults.[1] OEHHA's response to these motivating factors was the adoption of higher breathing rates for children than had previously been recommended under Hot Spots guidance and the adoption of default Age Sensitivity Factors (ASFs). The rationale cited for the adoption of the default ASFs was the observation that "young animals are more sensitive than adults to some carcinogens". OEHHA noted that the USEPA had also adopted a set of ASFs in response to the observation that young animals were more sensitive than adult animals to some carcinogens.

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

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

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

[1] As noted in California Health and Safety Code 39669.5. "The Legislature finds and declares that certain toxic air contaminants may pose risks that cause infants and children to be especially susceptible to illness and that certain actions are necessary to ensure their safety from toxic air contaminants."

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

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

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

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

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

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

Value to Characterizing a Range of Risks

In general, much of the need for clarification in the new OEHHA Guidance document stems from the conflict created by the use of quantitative risk assessment as a basis of risk management

decisions and as a basis of risk commination. The use of conservative assumptions or procedures in a risk estimate used as the basis of a risk management decision can improve confidence that health risks have not been underestimated. Use of conservative assumptions and methods in support of risk management decisions is often rationalized as assuring that the risk estimate and associated decision have "erred on the side of protecting public health".

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

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

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

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

Recommended Clarifications to the Draft Guidance Manual

It is not clear from the new Guidance Manual, however, how the use of ASFs would be used in the presentation of risks for the three exposure durations. It is reasonable to expect that many, if not most, adults who have lived in their current residence for 9 or even 30 years moved to their current residence after the age of 16. Accordingly, it would be misleading to present them only

with a risk assessment estimate based on the assumption that they had lived in that location from the last trimester of gestation through age 9 or age 30. We recommend that the range of risks presented for the assumed exposure durations of 9, 30 and 70 years include the assumption of 9 and 30 years of exposure as an adults as well as ages -0.25 to 9, -0.25 to 30, and -0.25 to 70. The use of all five exposure durations would not capture all of the permutations of exposure durations, but would provide risk estimate reference points relevant to many more people than would be provided if exposure beginning with the last trimester of gestation were assumed for all people living near a facility.

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

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

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