State of California

Governor Gray Davis

Air Resources Board
Alan C. Lloyd, Ph.D.
Chairman

Office of Environmental Health Hazard Assessment
Joan E. Denton, Ph.D.
Director

October 9, 2003

To Interested Parties:

AIR RESOURCES BOARD RECOMMENDED INTERIM RISK MANAGEMENT POLICY FOR INHALATION-BASED RESIDENTIAL CANCER RISK

The Office of Environmental Health Hazard Assessment (OEHHA) recently released the Air Toxics Hot Spots Program Guidance Manual for the Preparation of Health Risk Assessments (HRA Guidance Manual). The HRA Guidance Manual was prepared pursuant to the requirements of Health and Safety Code section 44300 et seq. and contains a description of the calculations, recommended exposure parameters, and cancer and noncancer health values needed to perform a health risk assessment (HRA) for air toxics. The HRA Guidance Manual supercedes the risk assessment methods previously presented in the 1993 California Air Pollution Control Officer's Association Risk Assessment Guidelines.

State law requires the use of the new HRA Guidance Manual for implementing the requirements of the Hot Spots (AB 2588) Program. The Air Resources Board (ARB) recommends that the tiered-approach to risk assessment, methods, and health values found in the HRA Guidance Manual also be used to assist risk managers in permitting and project approval decisions for activities with air toxics. However, OEHHA is evaluating further refinements to the exposure assessment methods that may result in significant changes to exposure estimates for the breathing (inhalation) pathway for residential receptors. Therefore, we recommend that the enclosed ***ARB Recommended Interim Risk Management Policy for Inhalation-Based Residential Cancer Risk*** be used to augment the HRA Guidance Manual where a single cancer risk value (rather than a range of risk) is needed or prudent for characterizing risk or where a single risk value is used for risk management decision-making for residential receptors.

The ARB's Interim Policy was established in consultation with OEHHA. OEHHA supports the ARB's efforts to provide clear, health protective guidance that addresses the risk management of air toxics. OEHHA believes the ARB's Interim Policy is consistent with the methods included in OEHHA's HRA Guidance Manual and, based on current health risk and exposure information is protective of public health.

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption. For a list of simple ways you can reduce demand and cut your energy costs, see our Website: http://www.arb.ca.gov.

This interim policy recommends determining the range of potential cancer risk by using the mean (65th percentile for the breathing pathway) and the high-end (95th percentile) exposure values or by using the full data distributions of exposure, as outlined in the HRA Guidance Manual. However, where a single cancer risk value for a residential receptor is needed for risk management decisions, we recommend the cancer risk estimate for the breathing pathway be based, at a minimum, on the midpoint (80th percentile) value of the percentile range between the mean and high-end points of exposure. Based on existing exposure information, the interim use of the 80th percentile value for the breathing pathway will continue to give health protective estimates for a residential receptor that are consistent with previous risk methods and provides continuity for the regulated community during the period of forthcoming changes to the risk assessment exposure methodology. Further description of this new policy is attached. ARB and OEHHA believe this to be an appropriate interim policy until OEHHA completes the updates to its risk assessment methodologies.

If you have any questions regarding ARB's Interim Policy, please contact Mr. Dan Donohoue, Chief, Emissions Assessment Branch, Stationary Source Division, ARB at (916) 322-6023. If you have any questions regarding OEHHA's HRA Guidance Manual, please contact Ms. Melanie Marty, Ph.D., Chief, Air Toxicology and Epidemiology Section, OEHHA at (510) 622-3154.

Sincerely,

Catherine Witherspoon
Executive Officer
Air Resources Board

Sincerely,

Joan E. Denton, Ph.D.

Joan E. Denton, Ph.D., Director
Office of Environmental Health
Hazard Assessment

Enclosure

cc: Dan Donohoue, Chief
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AIR RESOURCES BOARD
RECOMMENDED INTERIM RISK MANAGEMENT POLICY
FOR INHALATION-BASED RESIDENTIAL CANCER RISK
(October 2003)

In an ongoing commitment to use the best available scientific data, the Air Resources Board (ARB) recommends that the risk assessment methods and health values found in the Office of Environmental Health Hazard Assessment (OEHHA) Air Toxics Hot Spots Program Guidance Manual for the Preparation of Health Risk Assessments (HRA Guidance Manual) be used to characterize health impacts associated with exposure to toxic air contaminants. Health and Safety Code section 44360 requires that health risk assessments prepared for the Air Toxics Hot Spots Program (AB 2588) be developed in accordance with the guidelines established by OEHHA. The ARB recommends that the tiered-approach, methods, and health values found in the HRA Guidance Manual also be used to assist risk managers in permitting and project approval decisions for activities with air toxics emissions and for estimating health impacts in ambient air. We further recommend that this interim policy be used to augment the HRA Guidance Manual where a single cancer risk value (rather than a range of risk) is needed or prudent for characterizing residential cancer risk or where decisions based on a single cancer risk value for a residential receptor are required.

ARB is recommending this interim policy to address two issues. The first issue is the evolving nature of risk assessment and the potential for changes to the HRA Guidance Manual in the near future. OEHHA is evaluating further refinements to exposure assessment methods that may result in significant changes to exposure estimates for the breathing (inhalation) pathway for residential receptors. OEHHA anticipates that the new exposure information will be released over the next few years. Since all risk assessments include the breathing pathway, the ARB believes that this interim guidance is timely and prudent.

The second issue is the ongoing need to use a single cancer risk value to address some risk management situations. Current district programs often rely on a single cancer risk value to trigger specific actions (e.g., notification, risk reduction audit and plans, installation of toxics best available control technology, and project permitting). Because of this ongoing need, ARB believes that interim guidance is appropriate and necessary.

Therefore, the ARB, in consultation with OEHHA, is recommending an interim policy that utilizes the HRA Guidance Manual's range of exposure for determining potential cancer risk at the mean (65th percentile for the breathing pathway) and high-end (95th percentile) values. For the breathing pathway, this policy further recommends the use of the midpoint value of the percentile range (i.e., the 80th percentile) between the mean and high-end as the minimum exposure level for risk management decisions where a single cancer risk value must be used for a residential receptor.

Based on existing exposure information, the ARB, with concurrence from OEHHA, is recommending the interim use of the 80th percentile value (breathing pathway) for risk management decisions for residential receptors. This will continue to give health protective estimates that are consistent with previous risk assessment methods and provides continuity for the regulated community during the period of forthcoming changes to the risk assessment exposure methodology. The use of any single risk assessment result that is based on exposures less than the 80th percentile is not considered to be health protective nor prudent public health policy. The ARB will reconsider this interim risk management policy in its entirety as new scientific data (e.g. exposure information) are released by the ARB or OEHHA. At that time, all data, full exposure distributions, and methods that are published by the ARB or OEHHA will be used to determine future policies that are protective of public health.

For all new carcinogenic risk assessments that are based on the breathing (inhalation) exposure pathway only, we recommend that the following interim policy be used when presenting information in risk assessments and making risk management decisions where a single cancer risk value must be used for residential receptors. All exposure information included in a Tier-2 and Tier-4 risk assessment should be approved by OEHHA. See the attached table for a summary of the interim policy.

- For a Tier-1 or Tier-2 risk assessment, the potential cancer risk should be reported using the high-end (95th percentile), mean (65th percentile), and the 80th percentile breathing rate. When a single cancer risk value is required for a risk management decision (e.g., permitting or the Hot Spots Program), the potential cancer risk should be based, at a minimum, on the breathing rate representing the 80th percentile. If a Tier-2 risk assessment includes site-specific exposure adjustments other than changes to the breathing rate, then the breathing rate based on the 95th percentile should be used for the risk management decision.

- For a Tier-3 or Tier-4 (stochastic) risk assessment, the potential cancer risk should be reported using the entire breathing rate distribution; however, specifically highlighting the 95th, 80th, and 65th percentiles. When a single cancer risk value is required for a risk management decision (e.g., permitting or the Hot Spots Program), the potential cancer risk should be based, at a minimum, on the breathing rate representing the 80th percentile. If a Tier-4 risk assessment includes site-specific exposure adjustments other than changes to the breathing rate, then the breathing rate based on the 95th percentile should be used for the risk management decision.

For all new carcinogenic risk assessments that are based on multiple exposure pathways (multipathway assessment), we recommend that the following interim policy be used when presenting information in risk assessments and making risk management decisions where a single cancer risk value must be used for residential receptors. All exposure information included in a Tier-2 and Tier-4 risk assessment should be approved by OEHHA. See the attached table for a summary of the interim policy.

- For a Tier–1 or Tier–2 multipathway risk assessment, the potential cancer risk should be reported using the derived cancer risk method outlined in the OEHHA HRA Guidance Manual and secondly, the derived cancer risk that uses the 80th percentile breathing rate. The derived cancer risk that uses the 80th percentile breathing rate is referred to as the derived (adjusted) cancer risk. When a single cancer risk value is required for a risk management decision (e.g., permitting or the Hot Spots Program) or for presenting ambient air toxics data, the potential cancer risk should be based, at a minimum, on the derived (adjusted) cancer risk. If a Tier-2 multipathway risk assessment includes site-specific exposure adjustments other than changes to the breathing rate, then the derived cancer risk method outlined in the OEHHA HRA Guidance Manual should be used for the risk management decision.

- For a Tier-3 or Tier-4 (stochastic) multipathway risk assessment, the potential cancer risk should be reported for the full distribution of exposure from all pathways included in the risk assessment. When a single cancer risk value is required for a risk management decision (e.g., permitting or the Hot Spots Program) or for presenting ambient air toxics data, the potential cancer risk from a Tier-3 or Tier-4 multipathway risk assessment should be based on the 95th percentile cancer risk.

In light of this interim policy, the ARB does not feel it is necessary to recalculate the potential cancer risk of new or historical ambient data that are based on the breathing pathway unless there are new or updated cancer health values (i.e., cancer potency factors and unit risk factors). If cancer potency and unit risk factors were unchanged, existing published results that are based on the breathing pathway would not change significantly when recalculated using the breathing rate that is based on the 80th percentile for residential receptors. However, if the risk manager determines the presentation appropriate, then the range of potential cancer risk based on point-estimates corresponding to the high-end (95th percentile), mean (65th percentile), and the 80th percentile breathing rate can be presented.

Updates to Hot Spots risk assessments should be conducted in accordance with Air Pollution Control or Air Quality Management District (District) procedures and the AB 2588 regulatory requirements. While this risk management policy pertains primarily to cancer risk assessment, the District also needs to ascertain whether the latest Reference Exposure Levels for non-cancer toxicological endpoints were utilized in the risk assessment. For information on current cancer potency factors, unit risk factors, and non-cancer acute and chronic Reference Exposure Levels see the tables on OEHHA's website at http://www.oehha.ca.gov/air/hot_spots/index.html. If the values used in the previous risk assessment are not the same as in these tables, the risk assessment should be updated. If there is a new health value for an emitted chemical for which there was previously no value, the risk assessment should be updated.

The HARP software can perform all of the calculations described in the OEHHA HRA Guidance Manual and those needed to implement this Interim Risk Management Policy. The HARP software will be released in late 2003. Information regarding the HARP software can be found on ARB's website at http://www.arb.ca.gov/toxics/harp/harp.htm.

If you have policy questions regarding this interim policy, please contact Mr. Dan Donohoue, Chief, Emissions Assessment Branch, Stationary Source Division, at (916) 322-6023. If you have technical questions regarding this interim policy, please contact Mr. Richard Boyd, Manager, Emissions Evaluation Section, at (916) 322-8285, or Mr. Greg Harris of his staff, at (916) 327-5635. If you have questions regarding ambient data presented in the Almanac or on the ARB's website, please contact Ms. Marcella Nystrom, Staff Air Pollution Specialist, Air Quality Analysis Section, Planning and Technical Support Division, at (916) 323-8548. If you have any questions regarding OEHHA's HRA Guidance Manual, please contact Dr. Robert Blaisdell, Chief, Exposure Modeling Unit, Air Toxicology and Epidemiology Section, Office of Environmental Health Hazard Assessment, at (510) 622-3142.

Attachment Summarizing the ARB's Interim Risk Management Policy for Residential Receptors (October 2003)[1]

Exposure Pathway(s) Included in the Risk Assessment	Analysis Method[2]	Adjustment(s) to the Breathing Pathway of Exposure[3]	Minimum Exposure Information Reported in Risk Assessment[4]	Recommended Percentile, Risk Level, or Method to Use for Risk Management Decisions Requiring A Single Cancer Risk Value[5]
Inhalation Only	Tiers 1 & 2	No Change	High–end, Mean, and 80th Percentile	80th Percentile/Cancer Risk
	Tier-2	New Breathing Rate Only		
		Other than a New Breathing Rate	High–end, Mean, and 80th Percentile	High-end (95th) Percentile/Cancer Risk
	Tiers 3 & 4	No Change	Entire Distribution; Highlight the High–end, Mean, and 80th Percentile Exposures	80th Percentile/Cancer Risk
		New Breathing Rate Distribution Only		
	Tier-4	New Breathing Rate Distribution Only		
		Other than a New Breathing Rate Distribution	Entire Distribution; Highlight the High–end, Mean, and 80th Percentile Exposures	High-end (95th) Percentile/Cancer Risk
Multipathway	Tiers 1 & 2	No Change	Derived (OEHHA) Cancer Risk and Derived (Adjusted) Cancer Risk	Derived (Adjusted) Cancer Risk[6]
	Tier-2	New Breathing Rate Only		
		Other than a New Breathing Rate	Derived (OEHHA) Cancer Risk and Derived (Adjusted) Cancer Risk	Derived (OEHHA) Cancer Risk[7]
	Tiers 3 & 4	No Change	Entire Distribution from all Exposure Pathways	95th Percentile of Cancer Risk
		New Breathing Rate Distribution Only		
	Tier-4	New Breathing Rate Distribution Only		
		Other than a New Breathing Rate Distribution		

1. Applies to all new health risk assessments when a single cancer risk value is required for a risk management decision for a residential receptor (e.g., permitting or the Hot Spots Program).
2. The OEHHA Guidance Manual recommends a four-tiered approach to risk assessment. The OEHHA Guidance Manual requires that a Tier-1 risk assessment be included with all Tier-2 through Tier-4 risk assessments. Tiers 1 and 2 use point estimates of exposure. Tiers 3 and 4 use data distributions of exposure.
3. OEHHA should review and approve all the data that supports the site-specific exposure assumptions used in a Tier 2 and Tier 4 risk assessments.
4. The high-end breathing rate is defined the as the 95th percentile of the distribution; the mean for this distribution falls on the 65th percentile.
5. All exposures are based on lifetime exposure (70-year). The HARP software can perform all identified calculations.
6. The 80th percentile of exposure is used for the breathing pathway only. All other exposure pathways included in the assessment use the point estimates of exposure identified in the OEHHA HRA Guidance Manual. The Derived (Adjusted) Cancer Risk uses the derived calculation method outlined in the OEHHA HRA Guidance Manual.
7. Methodology outlined in the OEHHA HRA Guidance Manual.