## **Oregon Department of Environmental Quality**



# **ATSAC Written Responses to Diesel Particulate Matter Discussion Questions**

The purpose of this document is to compile ATSAC member feedback on the cancer toxicity reference value (TRV) for diesel particulate matter (DPM) during the DEQ Toxic Air Contaminant Review and Update Rulemaking.

# **Background**

This DEQ and OHA requested written responses from ATSAC members to all questions in the <u>Diesel Particulate</u> <u>Matter Framing Document</u>. These written responses were submitted to OHA in May 2025 and compiled in this document.

### **Related Resources**

<u>Diesel Particulate Matter Framing Document</u>

<u>ATSAC Meeting #8 PowerPoint Slides</u>

<u>ATSAC Meeting #8 Agenda</u>

## **Discussion Questions and Responses**

_	1. Do you see additional uncertainties with the proposed cancer TRV not already covered in the DPM Framing Document?	
ATSAC	Response:	
Member: John Budroe	The DPM Framing document did a commendably thorough job of discussing the uncertainties	
	associated with adopting the OEHHA diesel particulate matter (DPM) inhalation unit risk (IUR) for use in developing a cancer TRV. The only area that might benefit from some additional discussion	
Daisy Dong	would be early-life sensitivity (infants and children).  I do not see any additional uncertainties.	
John Stanek	Overall, the framing document is well organized and clearly presented. The document could benefit from additional discussion highlighting the various uncertainties outlined in the CalEPA risk assessment report and the Ramboll white paper.	
Susan Tilton	<ul> <li>Primary uncertainties are:</li> <li>Lack of dose-dependency in studies used to derive TRV (i.e. risk did not increase with duration of employment or age in railroad worker studies from 1987 &amp;1988) - likely due to         <ul> <li>the fact that the study used job title as a surrogate for DPM exposure, which likely led to misclassification</li> <li>the year when exposures began is unknown as diesel technology was just gradually being introduced through 1950s</li> <li>lack of information on other occupational exposures</li> <li>also method of analysis resulted in different outcomes by different groups</li> </ul> </li> <li>Diesel exhaust from past epidemiological studies would not be consistent with exposure to current technologies</li> </ul>	

	<ul> <li>US EPA (2002) concluded that even though the scientific evidence support an association between DPM and lung cancer, the available data were too uncertain to be used as the basis of a quantitative dose-response analysis and subsequent derivation of cancer unit risk for diesel exhaust</li> <li>One way to address uncertainty related to causality in epidemiological studies is using the Hill Criteria – this was addressed by CalEPA and recommend to include in the framing document</li> </ul>
John	The DPM Framing Document (2025) appropriately identifies and discusses in a balanced manner
Vandenberg	uncertainties evaluated by several organizations that have conducted extensive work to understand
	and apply state-of-the-art risk assessment methods to derive a quantitative cancer potency estimate for DPM.
	A consideration not discussed in the DPM Framing Document is that none of the existing DPM
	cancer potency assessments appear to consider age as a risk factor. The Supplement to the 2005
	USEPA Guidelines for Carcinogen Risk Assessment identifies the potential for additional risk to
	children due to a variety of biological and exposure differences with adults, hence Age Dependent
	Adjustment Factors (ADAF) are applied to carcinogens that have a mutagenic mode of action, which is relevant for DPM (see IARC). I am not proposing that ADAFs be applied to the OEHHA (1998) or
	other assessments, but that this consideration be more explicitly discussed in the DPM Framing
	Document.

ATSAC Member:	nboll's approach and DEQ's interpretation of where that IUR came from?  Response:
John Budroe	DEQ's interpretation of how Ramboll Environ developed a DPM-proxy (elemental carbon; EC) IUR from the Vermeulen et al. (2014) data appears to be accurate. The approach taken by Ramboll could eventually be the starting point for developing a DPM IUR, but a number of details (e.g. conversion of an EC IUR to a DPM IUR) would have to be worked out in order to produce a useable DPM IUR from the Vermeulen et al. (2014) data. The DPM Framing Document states: "DEQ and OHA do not support deriving a new DEQ cancer TRV at this time because this would take a considerable amount of toxicology resources (staff, time, and money), and even with recent higher quality studies available, considerable uncertainties remain and a derivation effort at this time may not result in an alternate, more robust cancer TRV." DEQ and OHA are entirely correct.
Daisy Dong	DEQ's interpretation of Vermeulen 2014 is correct.
John Stanek	It appears that DEQ's interpretation of Ramboll's approach and calculation of an IUR from Vermeulen is correct based upon the information provided.
Susan Tilton	<ul> <li>In the Ramboll white paper, a range of risk values were identified due to the high uncertainty associated with the different methods to develop quantitative estimates from the more recently published diesel miners and truckers studies. The Vermeulen paper itself was a meta-analysis of 3 studies – which was subsequently modified based on comments and reanalyzed by others (Crump and Morfield and Spallek) using different methods. The primary conclusion is that a consensus does not exist for the analysis of these datasets.</li> <li>However, the strength of the Ramboll white paper is that it relies on newer studies that HEI recommends for use in quantitative risk assessment and, therefore, are a good comparator to values calculated by CalEPA.</li> </ul>

John	Table 2 of Vermeulen et al (2014) shows estimates of lifetime risk per 10,000 for the general public
Vandenberg	ages 5-80 years, and for workers exposed at ages from 20 to 65 years. The estimate for the general
	public is most appropriate to evaluate and for an average exposure of 0.8 ug/m³ the risk from age 5
	through age 80 is 21 per 10,000. To calculate the risk URE for an exposure of 1 ug/m³, the risk is
	21/(1/0.8) = 16.8 which rounds to 17 per 10,000, as shown in Table 1 of the Ramboll Environ white
	paper as $1.7 \times 10^{-3}$ per ug/m <sup>3</sup> . The DEQ characterization of the derivation shown in the Ramboll
	Environ white paper appears to be correct. However, the derivation by Ramboll Environ does not
	include consideration of Age Dependent Adjustment Factors applied to ages 0-2 and 2-6 from the
	Supplement to the 2005 EPA Guidelines for Carcinogen Risk Assessment. This is an important
	omission in the Ramboll Environ white paper.
	Web address for Ramboll Environ white paper: https://www.portseattle.org/sites/default/files/2018-03/T5_FEIS_volume_II_Appx_B.pdf

ATSAC	white paper) that you believe is more scientifically sound than CalEPA's IUR for DPM?  Response:
Member:	
John Budroe	At this point in time, there is no DPM IUR contained in the Ramboll white paper that is more appropriate for use by DEQ and OHA to develop a DPM cancer TRV than the OEHHA DPM IUR.
Daisy Dong	I prefer to select the high end of the IUR of the proposed range (10 <sup>-3</sup> -10 <sup>-5</sup> ) from Ramboll Environ 2016 white paper, that's to say use the IUR = 1 x 10 <sup>-3</sup> per μg/m³, which translates to a cancer TRV of 0.001 μg/m³ for DPM based on the excess risk of 1 in a million. My rationales are listed below: OEHHA's TRV is based on Garshick et al. 1988, which is an old study judged by WHO, EPA, and HEI as in adequate for the developmental of a quantitative estimate of human risk for cancer. This study also came with many limitations highlighted in DEQ's framing document. Currently there are more recent and better designed studies (Steenland et al., 1998; Silverman et al., 2012; and Garshick et al., 2012) and these studies were considered adequate to derive a quantitative estimate by HEI. Although Crump 2014 and Morfeld and Spallek 2015 criticized the methodology used by Vermeulen et al. 2014, I don't see why these criticisms made the Vermeulen 2014 values less uncertain than OEHHA's IUR based on an old and less robust study. I also think Vermeulen 2014 response made a good argument to dispute some of those criticisms.
John Stanek	Based on the sources of information provided, there is not another more scientifically sound IUR presented in the Ramboll paper. The CalEPA value proposed for selection by DEQ is within both the range of values suggested by Ramboll and the range of values determined in other analyses presented in Table 1. This evaluation taken together with additional discussion concerning uncertainty could further strengthen the rationale for selecting the CalEPA IUR for DPM.
Susan Tilton	Since DEQ is not developing their own TRV based on these studies, I would recommend comparing your reported TRV to others that have been reported by various methods to show that they are within a similar range or level of protection for public health. This approach will build confidence in the CalEPA IUR developed from the older studies, but is within range of values reported from newer studies using different methods.
John Vandenberg	The Ramboll Environ white paper and the DPM Framing Document identify and appropriately summarize the scientific strengths and uncertainties that affect estimation of inhalation unit risk factors from various published studies (except lack of ADAF consideration). Arguments can be presented to support alternative IUR calculations, most notably the Vermeulen (2014) study and response to Crump letter to the editor which conducted a meta-analysis with improved exposure

assessment including lag period adjustments. The IUR from Vermeulen (2014) at $1.7 \times 10^{-3}$ is about 6 times more potent than the OEHHA factor of $3 \times 10^{-4}$ ug/m <sup>3</sup> (or, about 4 times more potent based on Vermeulen response to Crump letter to the editor).
It is notable that the IUR values shown in Table 1 of the Ramboll Environ white paper are rather similar, despite differences in data and estimate methods employed. This adds confidence that the CalEPA IUR is a scientifically reasonable approach for derivation of TRVs.

4. What other	4. What other questions or concerns do you have related either to the proposed DPM cancer TRV or to the	
DPM Framing Document?		
ATSAC	Response:	
Member:		
John Budroe	None noted.	
Daisy Dong	None except what I indicated above.	
John Stanek	As other committee members noted, the application of age-dependent adjustment factors (ADAFs)	
	should be considered and, if warranted, a discussion/rationale provided.	
Susan Tilton	It would be helpful to summarize how the DEQ TRV is derived from the CalEPA IUR. (e.g. reporting	
	the IUR value, cancer slope factor, range of values with 95% confidence interval)	
John	No additional comments.	
Vandenberg		

	5. Do you agree with CalEPA's inhalation unit risk DEQ proposes to adopt to calculate a cancer TRV? If not, do you have an alternative suggestion?	
ATSAC	Response:	
Member:		
John Budroe	OEHHA used cancer data from two well-described and well-conducted railroad worker occupational studies (Garshick et al. 1987; 1988) to develop a DPM IUR using appropriate methodology. The OEHHA DMP IUR received multiple rounds of public comments and peer review, and was revised in response to received comments. US EPA has sufficient confidence in the OEHHA DPM IUR that it has listed it in the EPA's Regional Screening Level (RSL) tables for use in Superfund site risk assessment. Additionally, the states of Washington and New Jersey also use the OEHHA DPM IUR as the basis of a diesel exhaust cancer TRV. It would be entirely appropriate for DEQ and OHA to use the OEHHA DPM IUR as the basis for a cancer TRV.	
Daisy Dong	See my response to Question 3.	
John Stanek	Yes, I agree with CalEPA's IUR that DEQ proposes to adopt for calculating cancer TRVs. I do not have an alternative selection.	
Susan Tilton	<ul> <li>I support using the CalEPA IUR for deriving the DEQ TRV compared to the proposed alternatives of either deriving a new TRV (not possible due to resources) or not having a cancer TRV (which would limit authority to regulate DPM emissions to reduce public health risk).</li> <li>This value has been adopted by other states (e.g. Washington DEQ) and is well documented, also follows the standard process of using DEQ authoritative sources</li> <li>It is important that DEQ/OHA continue to monitor other organizations that generate TRVs and consider new data</li> </ul>	
John	I agree with the selection of CalEPA's inhalation unit risk DEQ that proposes to adopt to calculate a	
Vandenberg	cancer TRV for diesel particulate matter. The CalEPA document was based on strong science and underwent extensive peer review. The CalEPA products are considered "authoritative" and I support DEQ and OHA using the CalEPA value which would be consistent with using such assessments as the basis for TRV derivation.	

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