

Oregon Department of Environmental Quality

Toxic Air Contaminant Review and Update Rulemaking

8: DEQ's Proposal for the Diesel Particulate Matter Cancer Toxicity Reference Value

Framing Document for DEQ's Air Toxics Science Advisory Committee

1. Executive Summary

DEQ proposes that the Oregon Department of Environmental Quality (DEQ) cancer toxicity reference value (TRV) for inhalation exposure to diesel particulate matter (DPM) should be changed from 0.1 μ g/m³ to 0.0033 μ g/m³. DEQ and Oregon Health Authority (OHA) are seeking feedback from the Air Toxics Science Advisory Committee (ATSAC) on this proposal. Refer to <u>ATSAC Document 1: Overview of TRV Review</u> for more information about agency roles and the TRV review and update process.

Table of Contents

1. Executive Summary	1
2. Overview of DEQ's DPM TRVs	
3. DEQ's Request for ATSAC Members	3
4. Background on Exposure to Diesel Emissions and Cancer	4
5. CalEPA's Cancer TRV for DPM	6
6. Recent Epidemiological Evidence for Diesel Emissions Quantitative Risk Assessment	10
7. Other Options for the DEQ Cancer TRV and DEQ Conclusions	12
References	13
Appendix A. Brief History on Previous Oregon ATSAC	16
Appendix B. ATSAC Discussion Questions	16

2. Overview of DEQ's DPM TRVs

The Oregon DEQ and OHA are currently reviewing the inhalation TRVs used in DEQ's air quality programs. DEQ's Oregon Administrative Rules (OARs), adopted by the Oregon Environmental Quality Commission, specify sources of toxicity information considered to be authoritative in terms of their scientific rigor and comprehensive methods for deriving TRVs (OAR 340-247-0030) and include a table of existing TRVs (OAR 340-247-8010 Table 2). There are four authoritative sources in rule: the U.S. Environmental Protection Agency (EPA), U.S. Agency for Toxic Substances and Disease Registry (ATSDR), California's EPA (CalEPA), and Oregon DEQ in consultation with the ATSAC. DEQ uses the term TRV when referring to similarly derived health-based toxicity values developed by other agencies. ATSAC members can find more details on DEQ's authoritative sources and TRV definitions in the document titled *Proposed TRV Update and Selection Process for ATSAC Review*.

Because DPM exposure is prevalent in Oregon and can have a significant impact on public health, DEQ and OHA believe it is important to have an ATSAC discussion specific to DPM TRVs. **This framing document provides**

summary information for ATSAC members to prepare for a discussion on the DPM TRVs, specifically the cancer TRV.

DEQ is proposing to change DEQ's cancer TRV for chronic inhalation exposure to DPM. Hereafter, this TRV is referred to as the "**cancer TRV**". Currently, DEQ's cancer TRV is $0.1 \,\mu\text{g/m}^3$ and is calculated from the World Health Organization (WHO)'s inhalation unit risk (IUR), which was published in 1996. This value was adopted in 2018 by DEQ based on the recommendation from a previously convened ATSAC. However, the WHO cancer TRV has been withdrawn and not replaced. DEQ has been unable to find documentation from the WHO on why this value was withdrawn.

Cancer TRV Terminology

Throughout this document, DEQ will talk about cancer TRVs as being derived by authoritative sources. DEQ is referring to cancer TRVs that DEQ calculated at one-in-one-million risk using inhalation unit risks (IURs) developed by those authoritative sources.

DEQ's normal process for reviewing and updating inhalation TRVs is to check all the authoritative sources in OAR for relevant TRVs. DEQ's authoritative sources are listed in Table 1. When multiple authoritative sources have TRVs for the same TAC, DEQ considers the derivation information behind each value and selects the most scientifically robust option. Only one of DEQ's authoritative sources has a cancer TRV for DPM; California's Environmental Protection Agency (CalEPA) has a cancer TRV of 0.0033 µg/m³ (CalEPA 1998a) based on an IUR of 0.0003 (µg/m³)⁻¹, which was co-developed by the California Air Resources Board (CARB) and the Office of Environmental Health Hazard Assessment (OEHHA). Therefore, by default, DEQ proposes to select CalEPA's cancer TRV for DPM. DEQ acknowledges that this cancer TRV includes uncertainties, which are described in this framing document.

DEQ is not proposing to change the noncancer TRV for chronic inhalation exposure to DPM from what was adopted into DEQ rule in 2018 (5 μ g/m³). Hereafter, this TRV is referred to as the "**noncancer chronic TRV**". DEQ is only proposing to change the TRV source attribution from OEHHA (an office within CalEPA) to U.S. Environmental Protection Agency (EPA; Table 1). CalEPA published their value in 1998, and it is equivalent to and references the EPA Integrated Risk Information System (IRIS) program value (CalEPA 1998a). The EPA IRIS noncancer chronic TRV was originally published in 1993 and updated in 2003, with the TRV staying the same at 5 μ g/m³ (EPA 2003). No other noncancer chronic DPM TRVs are available from DEQ's authoritative sources (Table 1). DEQ also does not currently have a noncancer TRV for short-term (acute) inhalation exposure to DPM; hereafter, this TRV is referred to as the "**acute TRV**". In this TRV review process, DEQ did not identify an acute TRV to propose for DPM.

Table 1. Summary of DPM TRVs available from DEQ's authoritative sources as well as DEQ's current and proposed DPM TRVs.

		Cancer	Noncancer Chronic	Noncancer Acute
Current DEQ TRV (Adopted in 2018)		0.1 μg/m³ WHO*	5 μg/m³ ΟΕΗΗΑ	
	U.S. Environmental Protection Agency (EPA)		5 μg/m³ <u>EPA 2003</u>	
DEQ Authoritative	U.S. Agency for Toxic Substances and Disease Registry (ATSDR)		1	
Authoritative Source	California Environmental Protection Agency (CalEPA)	0.0033 μg/m³ <u>CalEPA 1998</u>	5 μg/m³ <u>CalEPA 1998</u>	
	Oregon DEQ in Consultation with ATSAC			
DEQ Proposal		0.0033 µg/m³ CalEPA	5 μg/m³ EPA	

[&]quot;--" Indicates that a TRV is not available.

Diesel Exhaust (DE) vs. Diesel Particulate Matter (DPM)

Organizations not only use the term "DPM", but also often use the term "diesel exhaust" in their documents. These terms are different. The EPA stated in their Diesel Engine Exhaust Chemical Assessment Summary,

"Diesel engine exhaust (DE) is a complex mixture of airborne particles and gases. Diesel particulate matter (DPM), composed of elemental carbon particles and adsorbed organic compounds, is the most frequently determined measure of DE and the measure reported in toxicological studies of diesel engine exhaust." (EPA 2003).

The EPA is specific that their noncancer chronic value is based on the lung deposition of DPM. A review article also reported,

"For older technology diesel engines, these [health] effects are mainly associated with the particulate fraction of the exhaust, making DEP [diesel exhaust particles or DPM] a good exposure indicator candidate" (Taxell and Santonen 2017).

DEQ currently lists DPM as a toxic air contaminant and is proposing to maintain this nomenclature. DEQ defines DPM as the particulate fraction, both filterable and condensable. In this document, DEQ uses the term "diesel exhaust" when referring to the entire complex mixture of airborne particles and gases released from diesel engines. DEQ also uses "DPM" when specifically referring to the particulate fraction of diesel exhaust, usually in reference to toxicological studies and TRVs.

3. DEQ's Request for ATSAC Members

DEQ is seeking feedback from ATSAC on DEQ's proposed DPM TRVs, especially the cancer TRV. DEQ will carefully consider all ATSAC comments on DPM. DEQ requests that ATSAC members:

- 1. Read this framing document for background on DEQ's initial proposal for the DPM cancer TRV.
- 2. Prepare answers to the diesel-related questions in Appendix B of this document.

^{*} The WHO cancer TRV (0.1 µg/m³) has been withdrawn and not replaced.

4. Background on Exposure to Diesel Emissions and Cancer

4.1. Diesel engines and emissions overview

Diesel engines have a wide variety of uses including passenger cars, buses, heavy goods vehicles, construction equipment, trains, ships, mining equipment, and electricity generators (IARC 2014). Diesel engines emit complex mixtures, which include chemicals in the gas phase (e.g., carbon monoxide, nitrogen oxides, benzene, and formaldehyde) as well as very small carbon particles, coated with numerous compounds including metals, known as DPM (CARB 2024; IARC 2014; Weitekamp et al. 2020). According to CARB, "diesel exhaust contains more than 40 cancer-causing substances, most of which are readily adsorbed on to the soot particles" (CARB 2024). Other common contaminant groups, such as polycyclic aromatic hydrocarbons (PAHs) and nitroarenes, are distributed within both the gas and particle phases of diesel emissions (IARC 2014). The portion of diesel emissions that contains particles is the most frequently determined measure of diesel emissions and most frequently reported in toxicological studies (EPA 2003). Further, because DPM is a complex, variable mixture that can have significant health impacts as a mixture it is evaluated differently from other toxic air contaminants. In response to public comments in 1998, CARB and OEHHA staff wrote why they evaluated diesel exhaust as a mixture rather than as individual air contaminants:

"In our review of diesel exhaust, we are examining the overall toxicity of the exhaust. The reason we are doing this is because the exposure experienced in most health studies, particularly the human studies, has been to the overall exhaust. The International Agency for Research on Cancer, the National Institute for Occupational Safety and Health, and the United States Environmental Protection Agency have also evaluated diesel exhaust in this way. Until more research is done to identify specific causes of toxicity in diesel exhaust, we believe this approach provides the best public health protection. We have also made it clear that our exposure analysis is based primarily on exposures to diesel exhaust particulate matter" (CalEPA 1998c).

There are a number of other factors that can affect the composition of emissions from diesel engines, such as type and age of the engine, fuel, maintenance of the engine, patterns of use, and use of emission controls (IARC 2014). Additionally, diesel engine technology has also changed over time in response to regulations to control engine emissions – these changes include both innovations to engine performance as well emissions reduction systems, including particulate filters and oxidation catalysts, all of which can lead to reductions in pollutant emissions and potential differences in DPM composition. Currently, there is a lack of sufficient toxicological information to assess how these factors may affect health outcomes. It is important to consider exposure and related health effects from both new and older diesel engines because older diesel engines and vehicles can remain in service for long periods of time (i.e., slow rate of turnover) (HEI 2015; Health Canada 2016). The Health Effects Institute (HEI; a nonprofit research organization that receives funding from both the U.S. EPA and motor vehicle industry), has estimated that the turnover to cleaner diesel engine technology is expected to take one to two decades in the U.S. (HEI 2015).

4.2. Diesel engine emissions and cancer

Over the past several decades, epidemiological and toxicological studies have reported associations between short-term and long-term exposures to diesel exhaust and a range of adverse health effects, including lung cancer (HEI 2015). As the CARB explains, "several factors exacerbate the health risks of diesel PM exposure:

- Diesel PM is often emitted close to people so high exposures occur
- Diesel PM is in a size range that readily deposits in the lung
- Diesel PM contains compounds known to damage DNA and cause cancer" (CARB 2024).

Certain populations can be more vulnerable and susceptible to health effects from toxic air contaminants, such as DPM. For example, children can be at greater risk from exposure to DPM emissions than adults because children are growing and breathe more air per pound of body weight. In addition, children's natural defenses for responding to exposure to toxic chemicals are less developed; for example, toxic air contaminants breathed in through the nose can more easily reach the lungs in children than adults (EPA 2024a).

This DEQ document is focused on cancer; however, information on noncancer health effects can be found in a 2017 review article in *Toxicological Sciences* (Taxell and Santonen 2017) and the EPA's IRIS report (EPA 2003). For cancer health effects, a recent journal article authored by Dr. Silverman concludes: "In the aggregate, experimental, epidemiologic, and mechanistic findings provide clear evidence that diesel exhaust causes lung cancer in humans" (Silverman 2018). Dr. Silverman is a researcher at the U.S. National Cancer Institute who has done extensive research on diesel exhaust and cancer.

Comprehensive reviews of the scientific evidence by several organizations have reported mounting evidence supporting a causal association between exposure to DPM and lung cancer (Table 2). In 2012, the International Agency for Research on Cancer (IARC) reclassified diesel exhaust from Group 2A (probably carcinogenic to humans) to Group 1 (carcinogenic to humans) due to additional evidence of lung cancer in humans (IARC 2014). Beyond lung cancer, the IARC working group also noted a positive association between diesel exhaust exposure and increased risk of bladder cancer (IARC 2012). While IARC did identify DPM exposure as a hazard, IARC did not conduct an exposure-response assessment, which is the next step necessary for deriving a TRV. The National Toxicology Program (NTP) and EPA also have not derived a cancer TRV for DPM.

Table 2. A summary of some of the organizations that have made statements on the carcinogenicity of DPM. A carcinogen is any substance that causes cancer.

Agency	Year	Findings	Documentation
World Health Organization (WHO) International Agency for Research on Cancer (IARC)	2012, 2014	Carcinogenic to humans (Group 1)	IARC Press Release (IARC 2012) IARC Working Group Lancet Summary (Benbrahim-Tallaa et al. 2012) Full IARC Monograph
			(IARC 2014)
National Toxicology Program (NTP)	2011	Reasonably anticipated to be a human carcinogen	Excerpt From NTP's Report on Carcinogens (NTP 2011)
U.S. EPA	2003	Likely to be carcinogenic to humans	EPA IRIS Report (EPA 2003)

There is a lack of information on the health effects of emissions from relatively newer diesel engines. According to a review article, "No human studies related to the health effects of new technology DE [diesel exhaust] were found. Moreover, the data on the effects of new technology DE in animals are still rather limited" (Taxell and Santonen 2017). Further, Dr. Silverman stated, "the safety of emissions from new-technology engines, however, has not been thoroughly evaluated, particularly for cancer risk" (Silverman 2018). One study of chronic

exposure of rodents to new technology diesel emissions, found no evidence of carcinogenicity (McDonald et al. 2015). More research on new-technology engines is greatly needed.

5. CalEPA's Cancer TRV for DPM

5.1. Derivation documentation for CalEPA's cancer TRV

CalEPA has a large amount of documentation on their cancer TRV for DPM from their original rulemaking. CARB wrote the documents related to diesel emissions and exposure and OEHHA wrote the documents related to the diesel exhaust health risk assessment. Table 3 contains links to key CalEPA documentation. As with other proposed TRVs derived by DEQ's authoritative sources, DEQ and OHA rely on the expertise of those authoritative sources. DEQ and OHA do not recreate or independently recalculate cancer TRV derivation information produced by authoritative sources. However, Table 3 provides links to all the detailed derivation information behind CalEPA's cancer TRV for DPM along with documentation of the public and technical process they followed to generate the TRV.

Table 3. A summary of key documentation from CalEPA on their cancer TRV for DPM. These resources can all be found on the 1998 CARB website titled <u>Rulemaking Identification of Particulate Emissions from Diesel-Fueled Engines as a Toxic Air Contaminant</u>.

Resource Title & Brief Description	Date	Link & Citation
Findings of the Scientific Review Panel (SRP) on the Report on Diesel Exhaust as Adopted at the Panel's April 22, 1998, Meeting 9 pages • This document summarizes the findings from the SRP in response to CARB's/OEHHA's diesel exhaust report	April 1998	Scientific Review Panel Report (CalEPA 1998a)
CARB Initial Statement of Reasons for Rulemaking Staff Report		
 33 pages This staff report summarizes the scientific basis for the proposed regulation and includes a discussion of the environmental and economic impacts of the proposal 	June 1998	Staff Report (CARB 1998)
 Part B: Health Risk Assessment for Diesel Exhaust by OEHHA 453 pages This document is part of Appendix III of the Rulemaking Staff Report and includes extensive background on the health effects of diesel exhaust and OEHHA's quantitative cancer risk assessment work. This document was revised in response to public comments and SRP comments. Chapter 7 provides details on their quantitative estimates of the risk of humans developing cancer due to the inhalation of diesel exhaust. Section 7.2.5. (pages 7-12 to 7-15) contains a list of the sources of uncertainty in the quantitative risk estimates, based on the Garshick et al. studies. 	May 1998	Health Risk Assessment Report (OEHHA 1998b)

Resource Title & Brief Description	Date	Link & Citation
California's Responses to Comments for the June 1994 Comment Period 14 pages & 178 pages	1994	CARB Responses (CARB 1994) OEHHA Responses (OEHHA 1994)
California's Responses to Comments for the May 1997 Comment Period 14 pages & 153 pages & 77 pages	1997- 1998	CARB & OEHHA Responses (CalEPA 1998b) OEHHA Responses PDF 1 OEHHA Responses PDF 2 (OEHHA 1997)
California's Responses to Comments for the February 1998 Comment Period 40 pages & 109 pages	1998	CARB & OEHHA Responses (CalEPA 1998c) OEHHA Responses (OEHHA 1998a)

There has been criticism of the CalEPA cancer TRV for DPM in the research community. Namely, a biostatistician, Dr. Crump, criticized CalEPA's cancer TRV in journal articles and letters over the years. In addition, the author of the critical studies used by CalEPA to develop the cancer TRV for DPM (Dr. Garshick) had communicated concerns about the use of his studies in TRV development in letters to both the U.S. EPA and CalEPA. Staff at CalEPA have responded to many of Dr. Crump's and Dr. Garshick's comments. DEQ assembled a table of the key dates and documents relevant to the CalEPA cancer TRV for DPM (Table 4).

Table 4. Summary of key commentary between CalEPA staff and other researchers and statements from other organizations on the CalEPA cancer TRV for DPM.

Year	Description and Link to Reference (If Available)			
	Garshick et al. Railroad Workers Studies			
1987- 1988	 CalEPA used concentration-response information from the following two studies on U.S. railroad workers to derive their cancer TRV for DPM Critical Study #1 Title: A case-control study of lung cancer and diesel exhaust exposure in railroad workers Author: Garshick et al. Published: American Review of Respiratory Disease (Garshick et al. 1987) Critical Study #2 Title: A retrospective cohort study of lung cancer and diesel exhaust exposure in railroad workers Author: Garshick et al. 			
	 Published: American Review of Respiratory Disease (Garshick et al. 1988) 			
	Dr. Crump Assessment of Risk from Exposure to Diesel Engine Emissions			
	Title: Assessment of risk from exposure to diesel engine emissions			
1991	Author: Crump KS, Lambert T, Chen C			
	Published: Report to U.S. Environmental Protection Agency. Contract 68-02-4601 (Work			
	Assignment No. 182, July). Office of Health Assessment, U.S. Environmental Protection			
	Agency, Washington, DC.			

Year	Description and Link to Reference (If Available)				
	DEQ has been unable to find a copy of this report.				
	Letter from Dr. Garshick to EPA				
1001	Cited in US EPA 2002 as "letter from Garshick, Harvard Medical School, to Chao Chen, U.S.				
1991	EPA, dated August 15, 1991."				
	DEQ has been unable to find a copy of the original letter.				
	Series of written communications between Dr. Dawson at OEHHA and Dr. Crump on				
1994	interpretation of data from Dr. Garshick and colleagues				
-1998	Several of these written communications are included or summarized in the rulemaking				
	documentation linked in Table 3 above				
1994	CalEPA Risk Assessment Documentation During Rulemaking Process				
-1998	See Table 3 above				
	HEI Special Report on Diesel Emissions and Lung Cancer				
	Title: Diesel Emissions and Lung Cancer: Epidemiology and Quantitative Risk Assessment,				
1999	A Special Report of the Institute's Diesel Epidemiology Expert Panel				
	Author: HEI Diesel Epidemiology Expert Panel Author: HEI Diesel Epidemiology Expert Panel				
	Published: <u>HEI Website</u> (HEI 1999)				
	Dr. Crump's Reanalysis of Dr. Garshick's Railroad Worker Studies				
1000	Title: Lung cancer mortality and diesel exhaust: Reanalysis of the retrospective cohort				
1999	study of U.S. railroad workers				
	Author: Crump Published International Technology (Community 1992) and a few transfer of the community				
	Published: Inhalation Toxicology (Crump 1999) note: full text not online				
	OEHHA Journal Article Title: Multi Stage Model Estimates of Lung Cancer Bick from Europeure to Diesel Europeure				
2001	Title: Multi-Stage Model Estimates of Lung Cancer Risk from Exposure to Diesel Exhaust, Based on a U.S. Railroad Worker Cohort				
2001	Author: OEHHA Staff, Dawson & Alexeeff				
	 Published: Risk Analysis (Dawson and Alexeeff 2001a) note: full text not online 				
	Dr. Crump's Commentary in Response to OEHHA Journal Article				
	Title: Invited Commentary: Modeling Lung Cancer Risk from Diesel Exhaust: Suitability of				
2001	the Railroad Worker Cohort for Quantitative Risk Assessment				
2001	Author: Crump				
	Published: Risk Analysis (Crump 2001) note: full text not online				
	OEHHA's Response to Dr. Crump on Multistage Models				
	Title: Response to Dr. Crump's Commentary on "Multi-Stage Model Estimates of Lung"				
2001	Cancer Risk from Exposure to Diesel Exhaust, Based on a U.S. Railroad Worker Cohort"				
	Author: OEHHA Staff, Dawson & Alexeeff				
	Published: OEHHA Website (Dawson and Alexeeff 2001b)				
	U.S. EPA's Final Report on Diesel Engine Exhaust				
2002	Title: Health Assessment Document for Diesel Engine Exhaust (Final 2002)				
	Author: U.S. EPA				
	Published: <u>U.S. EPA Website</u> (EPA 2002)				

Ramboll Environ US Corporation (an environmental consulting firm) prepared a white paper for Moffatt & Nichol (an engineering firm) on behalf of the Port of Seattle. This paper, titled *White Paper on Diesel Exhaust Quantitative Health Risk Assessment Values for Lung Cancer* (Ramboll Environ 2016), provides summary information for the key publications related to the cancer TRV options for DPM.

5.2. Additional CalEPA cancer TRV strengths

One key reason DEQ is proposing to use CalEPA's cancer TRV for DPM is because it is a result of following DEQ's normal process for updating inhalation TRVs. This is the same process DEQ has followed for setting and reviewing all several hundred other inhalation TRVs in the program. Generally, DEQ collects detailed information on the available TRVs from authoritative sources, ensures the information goes through a quality control process, and shares the information with the ATSAC. If there is more than one chronic TRV option, DEQ proposes to select the TRV option with more preferred TRV attributes such as the TRV that includes a new critical study or includes modern point of departure methods, as described in DEQ's document titled *Updates to the TRV Update and Selection Process after the ATSAC Meeting on January 20, 2023*. In the case of the DPM cancer TRV, **the only external DEQ authoritative source that has a cancer TRV option is CalEPA** (0.0033 µg/m³).

DEQ is also proposing to use CalEPA's cancer TRV because California has extensive, publicly available documentation related to their cancer TRV for DPM (Table 3). DEQ relies on documentation from its authoritative sources when reviewing and updating all TRVs. In this case, CalEPA agencies developed robust, comprehensive documents on the development of the quantitative cancer TRV. CalEPA also has hundreds of pages available where they responded to three iterations of public comment on this value. OEHHA also defended their value outside of their rulemaking process in journal articles and other venues (Table 4). While DEQ acknowledges that this TRV, like all TRVs, comes with associated uncertainties, DEQ considers CalEPA's cancer TRV to be protective of health and well justified by CalEPA with robust and detailed documentation of supporting arguments responding to multiple public comments opposing the cancer TRV.

CalEPA requires this cancer TRV be used in every health risk assessment in the Air Toxics Hot Spots Program (OEHHA 2015). Washington State also uses this cancer TRV (WA DOE 2008). For example, in a <u>Diesel Engine Exhaust Particulate Matter Health Risk Assessment Report</u> in Washington, the risk assessors use the unit risk factor from CalEPA (Landau Associates 2018). In addition, while EPA might not have made their own cancer TRV for DPM through IRIS, EPA risk assessment practitioners in the Superfund Program use the CalEPA cancer TRV. The CalEPA cancer TRV is listed in the EPA's Regional Screening Level (RSL) tables used in risk assessments for Superfund Sites (EPA 2024c). The RSL tables provide comparison values to screen chemicals at Superfund sites and promote national consistency (EPA 2024b).

5.3. Additional CalEPA cancer TRV uncertainties

DEQ acknowledges that the CalEPA cancer TRV has uncertainties. For example, the exposure to DPM in the critical study is not well defined; personal exposure to DPM was estimated using information related to job positions, activities, and locations rather than using air sampling measurements, and Garshick et al., Crump et al., and OEHHA all proposed different approaches for estimating exposure in place of job information (HEI 1999). In general, air sampling data is preferred when analyzing the relationship between exposure levels and health response; however, not having exposure data is an issue with many epidemiological studies looking back in time. In general, cancer studies on people are challenging because of the long time period (i.e., several decades) between when exposure first occurs and when cancer develops.

There are other limitations and uncertainties in this cancer TRV, which are not unique to just this TRV. All TRVs have some degree of uncertainty, which is accounted for by the integration of safety buffers (i.e., uncertainty factors) when deriving a TRV. The 1999 HEI report describes a wide variety of the potential sources of uncertainty when using the Garshick et al. critical studies for quantitative risk assessment (HEI 1999). For example, one source of uncertainty in CalEPA's cancer TRV is that the critical study on primarily healthy male workers, which does not encompass the variability in the human population. As the 1999 HEI report states

"One more possible source of bias in these data is the "healthy worker survivor effect" (Arrighi and Hertz-Picciotto 1994). That is, workers who are "healthier" and less susceptible to disease might stay in the work place longer, so that those employed for longer periods might show a smaller elevation in risk than those employed for a shorter duration." (HEI 1999)

This is not just the case for this TRV; many TRVs are based on occupational studies where many of the workers were healthy males (<u>ATSAC Workbook 2: TRV Derivation</u>). To deal with this, safety buffers are integrated into the TRV to protect the health of a larger population, including vulnerable populations such as children and those with health conditions.

As described in section 4, another complicating factor is that diesel engines have changed over time. Workers were exposed to DPM in the critical studies for the CalEPA cancer TRV through 1980, with older diesel engine technology used by the railroad industry (Garshick et al. 1987; 1988). However, more recent epidemiological evidence that could be used to develop cancer TRVs, also were based on exposure to older diesel engine technology (see section 6). In addition, turnover of old diesel engines takes a long time (HEI 2015), meaning people are currently being exposed to diesel exhaust from older diesel engines. We also do not have much information on health effects from exhaust from newer diesel engine technology (Taxell and Santonen 2017; Silverman 2018). DEQ needs to protect Oregonians health from DPM exposure, and in the absence of better information, DEQ finds that the CalEPA cancer TRV is the best option.

6. Recent Epidemiological Evidence for Diesel Emissions Quantitative Risk Assessment

There has been interest in looking at recent epidemiological studies (such as the studies that IARC used to reclassify diesel exhaust as carcinogenic to humans) to see if that evidence can be used to derive a TRV for the quantitative estimation of lung cancer risk. One organization in particular, HEI, summarized these relevant epidemiological studies and their potential use in quantitative risk assessment in a formal report (HEI 2015). The HEI stated in their report,

"This report is a careful review by an independent scientific panel of two major epidemiological studies of historical exposures to diesel exhaust, the Diesel Exhaust in Miners Study (DEMS) and the Trucking Industry Particle Study (Truckers) to assess whether these studies could provide the basis for quantitative risk assessment" (HEI 2015).

A high-level summary of these two major epidemiological studies and where to read more about them is in Table 5.

Table 5. Summary of the two recent major epidemiological studies evaluated by the 2015 Health Effects Institute (HEI) Diesel Epidemiology Panel.

Study Name	High Level Study Details Summarized by the HEI	Original Study Publications	Where to Find the HEI Study Summary
Diesel Exhaust in Miners Study (DEMS)	A cohort and nested case-control study designed to study associations between retrospective estimates of exposure to diesel exhaust (represented by respirable elemental carbon, REC), and health outcomes in 12,315 miners (mostly white males) working in eight underground non-metal mines in the U.S.	The Diesel Exhaust in Miners Study: A Nested Case-Control Study of Lung Cancer and Diesel Exhaust (Silverman et al. 2012) The Diesel Exhaust in Miners Study: A Cohort Mortality Study with Emphasis on Lung Cancer (Attfield et al. 2012) & ("Erratum" 2014)	Report Title Diesel Emissions and Lung Cancer: An Evaluation of Recent Epidemiological Evidence for Quantitative Risk Assessment Publisher and Date HEI Diesel Epidemiology Panel, November 2015
Trucking Industry Particle Study (Truckers)	Researchers examined risk of lung cancer in relation to quantitative estimates of personal exposure to submicron elemental carbon (SEC) in 31,135 workers in trucking facilities across the U.S.	Lung Cancer and Elemental Carbon Exposure In Trucking Industry Workers (Garshick et al. 2012)	Links and Citations Full Special Report (HEI 2015)

The HEI Panel did not derive a cancer TRV. Overall, the HEI "Panel concluded that the DEMS and data from both the Truckers study and the DEMS can be usefully applied in quantitative risk assessments. The uncertainties within each study should be considered in any attempts to derive an exposure–response relationship." (HEI 2015). Here are some of the other conclusions in the HEI Executive Summary:

- "In the Panel's view, both the Truckers and DEMS were well designed and well-conducted studies and each made considerable progress toward addressing a number of the major limitations that had been identified in previous epidemiological studies of diesel exhaust and lung cancer. These limitations related particularly to the need for metrics more specific to diesel, better models of historical exposures, and ultimately for quantitative estimates of historical exposures to diesel exhaust. They both also demonstrated many of the attributes of high quality epidemiological studies that scientists and regulators value in evidence used to support quantitative risk assessments." (HEI 2015).
- "The detailed evaluations of these studies by IARC, the HEI Panel, and other analysts lay the groundwork for a systematic characterization of the exposure–response relationship and associated uncertainties in a quantitative risk assessment, should one be undertaken. In addition, the Panel has identified the challenges that should be confronted in extrapolating the results from these studies to different populations and time

periods, particularly given the rapid changes in diesel technology and its deployment around the world." (HEI 2015).

HEI praised the quality of the more recent diesel studies in Table 5 above and, in section 5.2, described considerations for future quantitative risk assessments of diesel exhaust. HEI states that it is unlikely that a single study or statistical model will provide the sole basis for characterizing the exposure-response relationship for diesel exhaust and lung cancer (HEI 2015).

Researchers differ in approaches to calculating inhalation unit risk values for DPM. In 2014, Dr. Vermeulen and colleagues conducted a meta-analysis to develop an exposure-response curve based on a log-linear regression model using relative risk estimates (Vermeulen, Silverman, et al. 2014). These authors have affiliations with Utrecht University, the U.S. National Cancer Institute, VA Boston Healthcare System, and Emory University. Vermeulen et al. used data from three case-control studies (Garshick et al. 2012; Silverman et al. 2012; Steenland, Deddens, and Stayner 1998) to estimate excess lifetime risk of lung cancer mortality in the U.S. in the workplace and in the ambient environment (Vermeulen, Silverman, et al. 2014). In response, Crump et al. criticized the methods (specifically related to lag times) used in the Vermeulen et al. meta-analysis in an *Environmental Health Perspectives* commentary (Crump 2014); Crump's commentary was funded by a coalition of several trade organizations including the Truck and Engine Manufacturers Association, American Petroleum Institute, European Automobile Manufacturers Association. Alongside Crump's commentary, Vermeulen and colleagues published a commentary in response to Crump where they state that they "firmly stand with the conclusions of our original paper" (Vermeulen, Portengen, et al. 2014).

In 2015, Dr. Morfeld and Dr. Spallek (with associations to Cologne University, the Institute for Occupational Epidemiology and Risk Assessment, Goethe University Frankfurt, and the European Research Group on Environment and Health in the Transport Sector) reanalyzed Vermeulen's 2014 meta-analysis data with different modeling approaches (Morfeld and Spallek 2015). The researchers stated that "The findings of Vermeulen et al. 2014 should not be used without reservations in any risk assessments. This is particularly true for the low end of the exposure scale." (Morfeld and Spallek 2015). However, the authors of the Ramboll Environ white paper on diesel exhaust chose to use the relative risk estimates in Vermeulen et al.'s original paper (Vermeulen, Silverman, et al. 2014) and commentary (Vermeulen, Portengen, et al. 2014) to calculate and present inhalation unit risk values (see Table 1 in Ramboll Environ 2016).

7. Other Options for the DEQ Cancer TRV and DEQ Conclusions

DEQ and OHA no longer recommend retaining its current cancer TRV that has been withdrawn by the WHO due to a lack of scientific support. Other than adopting CalEPA's cancer TRV for DPM, there are other options that DEQ and OHA could consider, including deriving a new cancer TRV or not having a cancer TRV. As discussed in the previous section, there are recent epidemiology studies that have the potential to be used to derive a cancer TRV. However, 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 will continue to closely monitor other organizations that generate TRVs and follow any developments on DPM TRVs. If other options arise, DEQ and OHA will thoroughly review the alternate TRVs for consideration at subsequent TRV rulemakings.**

Another option is that DEQ could not have a cancer TRV. However, DPM exposure in Oregon is prevalent and updated IARC conclusions make it clear that DPM is hazardous (i.e., exposure to DPM can lead to lung cancer), and without a cancer TRV in place, DEQ will not have oversight or authority to regulate DPM emissions to reduce

this potential public health risk. DEQ and OHA also consider it important to acknowledge the impact DPM exposure can have on cancer with a quantitative TRV, even if that TRV incorporates uncertainty. In OEHHA's response to Dr. Crump's commentary (Crump 2001), staff at OEHHA wrote

"In the face of considerable uncertainties, the assumptions in our paper involve judgment. We maintain that where risk numbers are needed, as they are in California procedures for identifying toxic air contaminants, our upper confidence limits are appropriately health protective in that our assumptions permit the estimation of reasonable upper values for human risk." (Dawson and Alexeeff 2001b).

Overall, DEQ and OHA acknowledge that while there is uncertainty in CalEPA's cancer TRV for DPM, DEQ and OHA support CalEPA's overall process and conclusions related to their cancer TRV. DEQ and OHA believe it is important to have a cancer TRV for DPM exposure and find that CalEPA's cancer TRV is a health protective option. DEQ proposes that the DEQ cancer TRV for inhalation exposure to DPM should be changed from $0.1 \,\mu\text{g/m}^3$ (the WHO withdrawn value) to $0.0033 \,\mu\text{g/m}^3$ (the CalEPA value). DEQ and OHA are seeking feedback from the ATSAC on this proposal.

References

- Attfield, Michael D, Patricia L Schleiff, Jay H Lubin, Aaron Blair, Patricia A Stewart, Roel Vermeulen, Joseph B Coble, and Debra T Silverman. 2012. "The Diesel Exhaust in Miners Study: A Cohort Mortality Study with Emphasis on Lung Cancer." *Journal of the National Cancer Institute* 104 (11): 869–83.
- Benbrahim-Tallaa, Lamia, Robert A Baan, Yann Grosse, Béatrice Lauby-Secretan, Fatiha El Ghissassi, Véronique Bouvard, Neela Guha, Dana Loomis, and Kurt Straif. 2012. "Carcinogenicity of Diesel-Engine and Gasoline-Engine Exhausts and Some Nitroarenes." *The Lancet Oncology* 13 (7): 663–64.
- CalEPA. 1998a. "Findings of the Scientific Review Panel on the Report on Diesel Exhaust as Adopted at the Panel's April 22, 1998, Meeting." California EPA Scientific Review Panel (SRP). https://ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/de-fnds.pdf.
- ——. 1998b. "Part C in Response to 1997 Draft Version: Public Comments and ARB/OEHHA Staff Responses to Part A and Part B of the Proposed Identification of Diesel Exhaust as a Toxic Air Contaminant Report Public Comment and SRP Version." California Environmental Protection Agency (CalEPA). https://ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/ptcmay97.pdf.
- ———. 1998c. "Part C: Public Comments and ARB/OEHHA Staff Responses to Part A and Part B of the Proposed Identification of Diesel Exhaust as a Toxic Air Contaminant Report." California Environmental Protection Agency (CalEPA).
 - https://ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/ptcfeb98.pdf.
- CARB. 1994. "Part C: Summary of Comments for the Diesel Exhaust Part A Report." California Air Resources Board (CARB). https://ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/ptcjun94.pdf.
- ———. 1998. "CARB Initial Statement of Reasons for Rulemaking Staff Report: Proposed Identification of Diesel Exhaust as a Toxic Air Contaminant." California Air Resources Board (CARB). https://ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/staffrpt.pdf.
- ——. 2024. "Summary: Diesel Particulate Matter Health Impacts." California Air Resources Board (CARB). https://ww2.arb.ca.gov/resources/summary-diesel-particulate-matter-health-impacts.
- Crump. 1999. "Lung Cancer Mortality and Diesel Exhaust: Reanalysis of a Retrospective Cohort Study of US Railroad Workers." *Inhalation Toxicology* 11 (1): 1–17.
- ———. 2001. "Invited Commentary: Modeling Lung Cancer Risk from Diesel Exhaust: Suitability of the Railroad Worker Cohort for Quantitative Risk Assessment." *Risk Analysis: An International Journal* 21 (1).
- ——. 2014. "Meta-Analysis of Lung Cancer Risk from Exposure to Diesel Exhaust: Study Limitations." Environmental Health Perspectives 122 (9): A230–A230. https://doi.org/10.1289/ehp.1408482.

Dawson, and Alexeeff. 2001a. "Multi-stage Model Estimates of Lung Cancer Risk from Exposure to Diesel Exhaust, Based on a US Railroad Worker Cohort." Risk Analysis 21 (1): 1–18. —. 2001b. "Response to Dr. Crump's Commentary on 'Multi-Stage Model Estimates of Lung Cancer Risk from Exposure to Diesel Exhaust, Based on a U.S. Railroad Worker Cohort." California Office of Environmental Health Hazard Assessment (OEHHA). https://oehha.ca.gov/air/document/multi-stagemodel-estimates-lung-cancer-risk-exposure-diesel-exhaust. EPA. 2002. "Health Assessment Document for Diesel Engine Exhaust (Final 2002)." U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment 2002. https://iris.epa.gov/document/&deid=29060. —. 2003. "Diesel Engine Exhaust: IRIS Chemical Assessment Summary." U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS). https://iris.epa.gov/static/pdfs/0642 summary.pdf. 2024a. "Children Are Not Little Adults!" Environmental Protection Agency (EPA). https://www.epa.gov/children/children-are-not-little-adults. —. 2024b. "Regional Screening Levels (RSLs)." U.S. Environmental Protection Agency (EPA). https://www.epa.gov/risk/regional-screening-levels-rsls. — 2024c. "Regional Screening Levels (RSLs) - Generic Tables as of November 2024." U.S. Environmental Protection Agency (EPA). https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables. "Erratum." 2014. JNCI: Journal of the National Cancer Institute 106 (8): dju192. https://doi.org/10.1093/jnci/dju192. Garshick, Eric, Francine Laden, Jaime E Hart, Mary E Davis, Ellen A Eisen, and Thomas J Smith. 2012. "Lung Cancer and Elemental Carbon Exposure in Trucking Industry Workers." Environmental Health Perspectives 120 (9): 1301-6. Garshick, Eric, Marc B Schenker, Alvaro Muñoz, Mark Segal, Thomas J Smith, Susan R Woskie, S Katharine Hammond, and Frank E Speizer. 1987. "A Case-Control Study of Lung Cancer and Diesel Exhaust Exposure in Railroad Workers." American Review of Respiratory Disease 135 (6): 1242–48. ——. 1988. "A Retrospective Cohort Study of Lung Cancer and Diesel Exhaust Exposure in Railroad Workers." American Journal of Respiratory and Critical Care Medicine 137 (4): 820–25. Health Canada. 2016. "Health Canada: Human Health Risk Assessment for Diesel Exhaust." https://publications.gc.ca/collections/collection 2016/sc-hc/H129-60-2016-eng.pdf. HEI. 1999. "Diesel Emissions and Lung Cancer: Epidemiology and Quantitative Risk Assessment, A Special Report of the Institute's Diesel Epidemiology Expert Panel." Health Effects Institute (HEI). https://www.healtheffects.org/publication/diesel-emissions-and-lung-cancer-epidemiology-andquantitative-risk-assessment.

——. 2015. "Special Report 19, Diesel Emissions and Lung Cancer: An Evaluation of Recent Epidemiological Evidence for Quantitative Risk Assessment." Health Effects Institute (HEI) Diesel Epidemiology Panel.

https://www.healtheffects.org/system/files/SR19-Diesel-Epidemiology-2015_0.pdf.

IARC. 2012. "IARC Press Release: Diesel Engine Exhaust Carcinogenic." World Health Organization. https://www.iarc.who.int/wp-content/uploads/2018/07/pr213_E.pdf.

- ———. 2014. "Diesel and Engine Exhausts and Some Nitroarenes." *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* 105:9.
- Landau Associates. 2018. "Revised Diesel Engine Exhaust Particulate Matter Health Risk Assessment Report Quincy, Washington." Landau Associates. https://ecology.wa.gov/getattachment/d5f02053-2e41-4c14-8417-bb437fc5a010/20180806HealthRiskDieselDataCenter.pdf.
- McDonald, Jacob D, Melanie Doyle-Eisele, J Seagrave, Andrew P Gigliotti, Judith Chow, Barbara Zielinska, Joe L Mauderly, Steven K Seilkop, Rodney A Miller, and HEI Health Review Committee. 2015. "Part 1. Assessment of Carcinogenicity and Biologic Responses in Rats after Lifetime Inhalation of New-

- Technology Diesel Exhaust in the ACES Bioassay." 184. Advanced Collaborative Emissions Study (ACES): Lifetime Cancer and Non-Cancer Assessment in Rats Exposed to New-Technology Diesel Exhaust. Boston, MA: Health Effects Institute.
- Morfeld, Peter, and Michael Spallek. 2015. "Diesel Engine Exhaust and Lung Cancer Risks-Evaluation of the Meta-Analysis by Vermeulen et al. 2014." Journal of Occupational Medicine and Toxicology 10:1–18.
- NTP. 2011. "Report on Carcinogens, Fifteenth Edition: Diesel Exhaust Particulates." National Toxicology Program (NTP) Department of Health and Human Services.
 - https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/dieselexhaustparticulates.pdf.
- OEHHA. 1994. "Responses by OEHHA Staff to Health Effects Related Comments on the June 1994 Draft Technical Support Document (Including Part B) for Identification of Diesel Exhaust as a Toxic Air Contaminant." Office of Environmental Health Hazard Assessment (OEHHA).
 - https://ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/nwpc5 97.pdf.
- -. 1997. "Responses by the Staff of OEHHA to the March, 1997 Draft Technical Support Document For Identification of Diesel Exhaust as a Toxic Air Contaminant." Office of Environmental Health Hazard Assessment (OEHHA). https://ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/partc-1.pdf.
- -. 1998a. "OEHHA's Responses to Comments on the Public and Scientific Review Panel Draft Version of Part B: Health Risk Assessment for Diesel Exhaust, Feb. 1998." Office of Environmental Health Hazard Assessment (OEHHA). https://ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/pc_5_98.pdf.
- —. 1998b. "Part B: Health Risk Assessment for Diesel Exhaust." Office of Environmental Health Hazard Assessment (OEHHA) California Environmental Protection Agency (CalEPA).
 - https://ww2.arb.ca.gov/sites/default/files/barcu/regact/diesltac/partb.pdf.
- -. 2015. "Air Toxics Hot Spots Program: Appendix D, Guidance Manual for Preparation of Health Risk Assessments." Office of Environmental Health Hazard Assessment (OEHHA). https://oehha.ca.gov/media/downloads/crnr/2015gmappendicesaf.pdf.
- Ramboll Environ. 2016. "Appendix B: White Paper on Diesel Exhaust Quantitative Health Risk Assessment Values for Lung Cancer." Ramboll Environ US Corporation.
- Silverman, Debra T. 2018. "Diesel Exhaust and Lung Cancer—Aftermath of Becoming an IARC Group 1 Carcinogen." American Journal of Epidemiology 187 (6): 1149–52.
- Silverman, Debra T, Claudine M Samanic, Jay H Lubin, Aaron E Blair, Patricia A Stewart, Roel Vermeulen, Joseph B Coble, Nathaniel Rothman, Patricia L Schleiff, and William D Travis. 2012. "The Diesel Exhaust in Miners Study: A Nested Case-Control Study of Lung Cancer and Diesel Exhaust." Journal of the National Cancer Institute 104 (11): 855-68.
- Steenland, Kyle, James Deddens, and Leslie Stayner. 1998. "Diesel Exhaust and Lung Cancer in the Trucking Industry: Exposure–Response Analyses and Risk Assessment." American Journal of Industrial Medicine 34 (3): 220-28.
- Taxell, Piia, and Tiina Santonen. 2017. "Diesel Engine Exhaust: Basis for Occupational Exposure Limit Value." Toxicological Sciences 158 (2): 243–51.
- Vermeulen, Portengen, Silverman, Garshick, and Steenland. 2014. "Meta-Analysis of Lung Cancer Risk from Exposure to Diesel Exhaust: Vermeulen et al. Respond." Environmental Health Perspectives 122 (9): A230-31. https://doi.org/10.1289/ehp.1408428R.
- Vermeulen, Roel, Debra T Silverman, Eric Garshick, Jelle Vlaanderen, Lützen Portengen, and Kyle Steenland. 2014. "Exposure-Response Estimates for Diesel Engine Exhaust and Lung Cancer Mortality Based on Data from Three Occupational Cohorts." Environmental Health Perspectives 122 (2): 172–77.
- WA DOE. 2008. "Department of Ecology Air Quality Program: Concerns about Adverse Health Effects of Diesel Engine Emissions White Paper." State of Washington Department of Ecology. https://apps.ecology.wa.gov/publications/documents/0802032.pdf.

Weitekamp, Chelsea A, Lukas B Kerr, Laura Dishaw, Jennifer Nichols, McKayla Lein, and Michael J Stewart. 2020. "A Systematic Review of the Health Effects Associated with the Inhalation of Particle-Filtered and Whole Diesel Exhaust." *Inhalation Toxicology* 32 (1): 1–13.

Appendix A. Brief History on Previous Oregon ATSAC

In 2005 and 2017, previous ATSACs discussed the cancer TRV from OEHHA.

A.1. Background on Previous ATSACs Compared to the Current ATSAC

Compared to the current ATSAC, previous versions of ATSAC had a different scope and were comprised of people with expertise in a variety of fields other than toxicology, such as experts in Oregon air emissions monitoring and air dispersion modeling. In practice, the prior ATSAC did considerable TRV review work and presented TRVs as recommendations to DEQ. In 2021, the EQC adopted Oregon Administrative Rule changes that revised the ATSAC rules to: clarify it is a non-decision-making body; sharpen its focus on advising DEQ on updating DEQ TRVs and not developing TRV proposals itself; and require that all ATSAC members have experience relevant to the development and review of toxicity reference values.

A.2. Previous ATSAC Decision

In 2005 and 2017, previous ATSACs decided not to recommend the cancer TRV from OEHHA for several reasons including that EPA did not calculate a cancer TRV (even though OEHHA's cancer TRV was available at the time) and that Dr. Garshick, the lead author of the critical study used to derive CalEPA's cancer TRV, publicly argued against CalEPA's value.

ATSAC documentation from 2005 and 2017 also summarizes the available epidemiology studies and acknowledges the scientific uncertainty and significant resource requirements as barriers to Oregon calculating its own cancer TRV for DPM. Overall, prior ATSACs did not develop alternate TRVs. Prior ATSACs decided to recommend the WHO cancer TRV for DPM (0.1 μ g/m³), even though the WHO TRV had already been withdrawn during 2017 ATSAC discussions.

A.3. Current DEQ Response to Previous ATSAC Recommendations

DEQ and OHA do not recommend using a cancer TRV that has been withdrawn by the agency that derived it – the World Health Organization value of $0.1 \,\mu\text{g/m}^3$. DEQ and OHA acknowledge that the cancer DPM TRV from CalEPA has uncertainties. However, having assessed both the critiques of the CalEPA TRV and CalEPA's rationales defending the TRV, DEQ is proposing to use the CalEPA cancer DPM TRV of $0.0033 \,\mu\text{g/m}^3$.

Appendix B. ATSAC Discussion Questions

Directions: DEQ and OHA request that ATSAC members come to the next series of ATSAC meetings prepared to discuss the questions in this document. The agencies will also email ATSAC members an editable version of Appendix B. The agencies would appreciate a copy of ATSAC member's answers after the ATSAC meeting concludes.

- 1. Do you see additional uncertainties with the proposed cancer TRV not already covered in the DPM Framing Document?
- 2. It appears Ramboll Environ (see Table 1 of Ramboll Environ's white paper) calculated an inhalation unit risk (IUR) for Vermeulen et al. 2014 using an excess lifetime cancer risk of 17 per 10,000 at a DPM-proxy

(elemental carbon) concentration of 1 μ g/m³ (see Table 2 of Vermeulen et al. 2014). What do you think about Ramboll's approach and DEQ's interpretation of where that IUR came from?

- 3. Is there another IUR from the Ramboll paper (or average of some or all of them) (Table 1 of Ramboll Environ's white paper) that you believe is more scientifically sound than CalEPA's IUR for DPM?
- 4. What other questions or concerns do you have related either to the proposed DPM cancer TRV or to the DPM Framing Document?
- 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?

Contact

Oregon Department of Environmental Quality Cleaner Air Oregon Program <u>cleanerair@deg.oregon.gov</u>

Prepared by

This document was prepared by Oregon Department of Environmental Quality and Oregon Health Authority. Authors:

J.R. Giska, MS, PE Cleaner Air Oregon Program Manager Holly Dixon, PhD

Public Health Toxicologist David Farrer, MS, PhD

Public Health Toxicologist

Dana Crosby, MPH
Environmental Health Assessment Program Coordinator



Non-discrimination statement

DEQ does not discriminate on the basis of race, color, national origin, disability, age or sex in administration of its programs or activities. Visit DEQ's <u>Civil Rights and Environmental Justice page.</u>

Translation or other formats

<u>Español</u> | <u>한국어</u> | <u>繁體中文</u> | <u>Pусский</u> | <u>Tiếng Việt</u> | <u>800-452-4011</u> | TTY: 711 | deginfo@deg.oregon.gov

