Documentation of Diesel Particulate Matter Work Conducted by the 2014-2017 Air Toxics Science Advisory Committee

Submitted to: Ambient Benchmark Concentration Rulemaking site

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Executive Summary

This report provides details on the 204-2017 Air Toxics Science Advisory Committee's work on review of available toxicity information for diesel particulate matter, and the committee's final decision on identifying an Ambient Benchmark Concentration for DPM. The committee's complex discussions and intermediate decisions of DPM characteristics, toxicity, and health effects are described in detail.

Introduction and Overview

The Air Toxics Science Advisory Committee, commonly referred to as the ATSAC, is required by rule to meet every five years to review all ABCs in order to determine whether any new toxicological information has become available in the years since the last set of ABCs were identified. To this end, the ATSAC was reconvened beginning in December 2014 to review the existing 52 ABCs, as well as to identify ABCs for a few new compounds. Diesel particulate matter, or DPM, information took up the majority of five ATSAC meetings held in June, July, September, and October of 2015, and in March 2017. The current iteration of the ATSAC, or the 2014-2017 ATSAC, is made up of seven members: Dr. Bill Lambert, who serves as committee chair; Dr. Dean Atkinson, Dr. Kent Norville, Dr. David Farrer, Dr. Bruce Hope, Dr. David Stone and Mr. Max Hueftle. Ms. Sue MacMillan serves as the DEQ lead for the ATSAC.

Generally, for most compounds, the policy of the ATSAC is to utilize toxicity values already available from recognized authoritative bodies, such as EPA's Integrated Risk Information System, EPA's Provisional Peer-Reviewed Toxicity Values, California's Office of Environmental Health Hazard Assessment, or OEHHA; the Agency for Toxic Substance and Disease Registry, or ATSDR; the International Agency for Research on Cancer; and other trusted sources of best-science toxicity information. The committee evaluates the relevant documentation for a compound and then applies its best scientific skills to evaluate unique aspects regarding the protection of people being exposed to these compounds. The committee focuses on protection of human populations, including vulnerable and sensitive groups, and also considers other technical issues such as multi-pathway exposures. The committee then recommends an ABC to the DEQ with a supporting rationale and basis for the recommendation.

In 2005 the ATSAC chose a toxicity value from the World Health Organization (WHO 1996) to use as the basis of the ABC of 0.1 $\mu g/m^3$.The WHO document provided a range of Unit Risk Estimate, or URE, values based on both animal and epidemiological (human) studies. These values have since been withdrawn by the WHO, due to concerns with the uncertainty of the data. A URE of 5×10^{-6} per $\mu g/m^3$, published by the USEPA in IRIS around 2005 for DPM, and which converts to an ABC of approximately 0.2 $\mu g/m^3$, was also withdrawn.

OEHHA identified a cancer-based toxicity value for DPM (referred to by OEHHA as "Particulate Emissions from Diesel-Fueled Engines") in 1998 that converts to an ABC of 0.003 $\mu g/m^3$, which is two orders of magnitude lower (more stringent) than DEQ's current ABC for DPM of 0.1 $\mu g/m^3$. In 2005, the first convention of the ATSAC determined that the OEHHA value was not credibly calculated, and so dismissed the OEHHA toxicity value as an option for calculating an ABC for DPM. In 2015, the ATSAC and Ms. MacMillan, after reviewing documentation of the discussions held in California during the 1998 OEHHA process of identifying the toxicity value for DPM and during a lawsuit later filed by the trucking industry, do not feel that the OEHHA toxicity value for DPM has a credible technical basis, and so should not be used to calculate a revised ABC for DPM in Oregon. This decision confirms the earlier decision made by the ATSAC in 2005.

In May 2015, the committee heard from outside experts in regard to polycyclic aromatic hydrocarbons, or PAHs, and diesel particulate matter, or DPM, focusing on chemical characteristics and dispersion in the environment. In June 2015 the ATSAC talked about analytical considerations and ways in which to detect and measure DPM and related compounds including black carbon, elemental carbon, and organic carbon, and the ways in which these compounds are monitored. Also at the June meeting, Bill Lambert presented the epidemiological (human) evidence that is available for DPM. In July 2015, the committee continued their discussion about alternative approaches that might be used to develop a new ABC for DPM. In addition, Sue MacMillan and Bruce Hope presented a chronological listing of how risk related to DPM has been quantified, and the related human and animal studies used to that end. The committee also discussed using a geometric mean that could be generated from the combined studies in order to identify a cancer-based numeric URE. However, the ATSAC was concerned about the appropriateness of combining these studies, which have differing research designs and differing test species, and how credible the outcome of such an approach would be. The committee then decided to rely only on epidemiological data and not on animal data, as the mechanics of inhalation uptake of DPM by rodents does not accurately represent the same sort of uptake by humans. The discussion of these issues continued in the September 2015 meeting, with the committee coming to the conclusion that the only credible path to identifying a new ABC for DPM would be for the ATSAC to come up with their own calculations; but then all members immediately acknowledged that this was probably too complex and too time-consuming a task to attempt.

Nonetheless, Bill Lambert offered to attempt to generate URE value for DPM using some of the information he had obtained from Dr. Robert Parks during a conference in 2014, and produce a draft memorandum for the other ATSAC members to review and then discuss at a future committee meeting. However, this attempt took much longer than expected, as evidenced by a break in meetings of the ATSAC pending potential creation of the DPM memo, which began after the January 2016 ATSAC meeting and ended by the March 2017 ATSAC meeting. In the end, no DPM memorandum was forthcoming.

During the period from September 2015 through early 2017, people asked whether someone besides Bill Lambert could have completed the necessary calculations for creating a revised ABC for DPM, and the short answer is no. The ASTAC consisted of seven members, and those members had been together throughout the five ATSAC meetings where DPM was the main topic of discussion. None of the members aside from Bill Lambert were willing to try to calculate a new ABC for DPM. The ATSAC, and the scientific community in general, acknowledged the difficulty in calculating a new ABC for DPM, based on the limited information available to do so. Pulling in an expert from the outside was not practical because 1) it would have taken a large amount of time to orient that person to the DPM information that had already been provided for and presented to the ATSAC; 2) the process for finding a person with the appropriate technical skill set would have taken significant time; 3) that person would have had to have been willing to volunteer their time to the ASTAC; and 4) in the end, that person also might have decided that the task of calculating a new ABC for DPM was too difficult to attempt.
By March 2017, Dr. Lambert had determined that even the newer science behind the cancer toxicity of DPM was not developed enough to allow him to calculate a URE value, and the ATSAC then decided to retain the standing ABC for DPM of 0.1 $\mu g/m^3$until additional information for DPM becomes available in the future.

Descriptions of the Composition of DPM

Diesel exhaust is a complex mixture of individual compounds, including gases, ultrafine particles, nitrogen oxides, sulfur oxides, sulfate absorbed onto particles, carbon, volatile organic compounds, metals, and polycyclic aromatic hydrocarbons, or PAHs. Ultrafine particles have an average aerodynamic diameter of 0.1 micron in diameter or smaller, and these physical characteristics mean that ultrafine particles are able to reach the deeper parts of the lung. Although larger particles with an average aerodynamic diameter of 2.5 microns (referred to as $PM_{2.5}$) are also present in DPM, it is the ultrafine particles of $PM_{0.1}$ or smaller that are able to travel to the deep and more vulnerable parts of the lung, along with any toxic chemicals that have adsorbed to the surface of the particles.

The components in DPM which may actually cause the bulk of the compound’s toxicity include three primary components: 1) total carbon (largest component by mass), a category that includes elemental carbon, organic carbon, and ultrafine particles; 2) water-soluble metals such as iron, zinc, lead, copper, chromium, vanadium, nickel, cadmium, cobalt, and manganese; and 3) PAHs. Approximately 92 percent of the mass of a diesel particle is made up ultrafine particles. EPA is planning to assess the health effects of ultrafine particulates in the future, and is expected to identify a proposed standard. Based on current knowledge, the carbon component is not likely to be the primary carcinogenic element in a diesel particle; however, particles do cause inflammation on their own, and if a human or animal subject's lungs are loaded with enough particles through inhalation, there can be an initial inflammatory response that eventually results in the appearance of cancer in the tissue.

An important and potentially confusing aspect of diesel is the varying terminology surrounding the measurement of DPM, including terms such as organic carbon, elemental carbon, and black carbon. The committee discussed the competing definitions for these carbon types, as well as the idea of using size-fractionated particle matter mass as a potential tool to assess DPM toxicity. Many researchers measure elemental carbon and total particulate mass, and then say that elemental carbon is equivalent to the total particulate mass. However, using total mass carbon in this case results in an overestimation of the actual cancer potential. A better way to try to estimate cancer risk would be to measure the main components of diesel emissions.

There is no protocol at this time that allows the direct measurement of diesel particulates. One way to attempt to quantify the toxicity of diesel emissions is to use elemental carbon as a marker or surrogate compound for the exposure of lung tissue to diesel particulates; but the committee acknowledged that there is no universally recognized, single marker for diesel particulate matter. Given this situation, the committee looked both at monitoring and modeling capabilities related to the detection of DPM in order to better understand how actual exposure to emissions interacts with the potential toxicity of diesel.

Anthony Barnack, DEQ's coordinator for ambient air quality monitoring, mentioned that the DEQ laboratory does have some of its quartz air collection filters analyzed, so there is some data on elemental carbon for some areas of the state. He thought ratios could be developed for various areas based on historic collection data. DEQ could potentially apply a ratio factor to total PM2.5 in order to estimate elemental carbon amounts. There is also source-specific speciation, which could be apportioned in the Emissions Inventory to estimate amounts of elemental carbon or other chemicals. Speciation profiles are also used in source apportionment modeling. Black carbon is another compound that is collected by DEQ in air samples, although there is no available toxicological or epidemiological data for black carbon. Additionally, both elemental carbon and organic carbon are somewhat arbitrarily defined by their analytical testing methods. Organic carbon is not light-absorbing, and is volatilized using inert gas. Elemental carbon, on the other hand, is light-absorbing, and can be made to combust in a controlled oxidizing atmosphere. New analysis methods for elemental and organic carbons are being developed by the Desert Research Institute.

In regard to detecting elemental carbon separately from organic carbon, the analytical method provided by the National Institute of Occupational Safety and Health (NIOSH), which is NIOSH Method 5040, is referred to as "Elemental Carbon (Diesel Particulate)". The definition for elemental carbon as discussed by the committee was: Elemental carbon is a refractory carbon measured both optically and thermally, while black carbon is only measured optically. Another confusing phrase appears in the literature: "carbon black". Carbon black is mistakenly used in some cases to refer to black carbon or even elemental carbon. But carbon black is actually a man-made product, and not a combustion breakdown product like elemental carbon or black carbon. The committee talked about an analytical method called ECOC (which stands for elemental carbon/organic carbon) used to measure elemental carbon and organic carbon. The different types of ECOC methods include "IMPROVE ECOC", "NIOSH ECOC", and "STN". It appears that the IMPROVE ECOC method is most often used currently. Unfortunately, the analytical results for ECOC vary not only from method to method, but from laboratory to laboratory. This makes it very difficult to replicate results consistently. The analytical results for elemental carbon are frequently attributed to diesel, in cases where the sample was already known to have been collected near a diesel engine. This kind of correlation makes the committee leery of a method that requires prior knowledge of what the source is before the results can be correlated to it. The bottom line is that there is no way use elemental carbon results to produce credible estimates of DPM levels.

The committee is charged with developing health-based benchmark concentrations for chemical compounds that present a hazard to Oregon residents. Sometimes, the ABCs that the committee recommends to the DEQ are technology-forcing or policy-forcing, as the committee does its best to evaluate the relevant health information and make a recommendation that is technically workable. The committee is not charged with consideration of policy or cost related to their ABC recommendations, and in some cases it may not even be appropriate for the committee to consider technological feasibility. But the committee feels it should attempt to generate a benchmark concentration that has utility and works well for the protection of health.

For the eventual application of an ABC for DPM to air sample results, it could be useful to take measurements and then use an apportionment method to come up with a level related to diesel elemental carbon. This approach would be useful for air quality planning and management. Even though the method requires adjustment and the results have some uncertainty associated with them, an investment could be made in this area in order to address diesel as a concern for health.

There was general agreement that elemental carbon itself is measureable, but obtaining measurements of elemental carbon is pointless unless the results can be compared to a quantified toxicity level specific to elemental carbon. Measured elemental carbon may or may not be diesel, but diesel is always elemental carbon. Therefore, measurements of elemental carbon could be used to identify the upper-bound estimate of how much diesel is present. On the other hand, black carbon measurements are less expensive to obtain and more reliable than elemental carbon measurements.

The committee discussed the option of recommending a nuanced ABC for DPM, and could state in that recommendation that DPM is known to cause adverse health effects, while leaving the current benchmark in place or revising it. The committee could also specify that there are reasonable surrogates, such as elemental carbon or even black carbon that could be used as markers for DPM, until better options become available. Oregon rule language as it currently stands only refers to DPM as the chemical of concern, but perhaps this definition could be changed to fit a nuanced ABC for DPM. One committee member recommended that the committee differentiate between “uncontrolled diesel” and “diesel exhaust”. This suggestion is related to the fact that we already know that new-technology diesel engines are contributing far less emissions than the old-technology diesel engines.The two types of engine technologies have completely different chemical signatures in terms of air emissions. In addition, if the committee decides to recommend that DEQ monitor for elemental carbon rather than DPM, but all related modeling is still focused on DPM, then it will be very difficult to make apple-to-apple comparisons of air data and to use it appropriately in the models, which were built around assessing DPM. One committee member didn’t think that adjusting modeling assumptions to address the use of elemental carbon to represent DPM would be difficult to do. These issues of modeling and monitoring are more DEQ’s concern than the committee’s, but that discussion reflects the ATSAC’s technology-forcing and policy-forcing role in regard to certain ABCs.

Sources of DPM Emissions

A substantial amount of diesel activity takes place in the state of Oregon, which is a significant human health concern. The Emissions Inventory provides a general characterization of the distribution of diesel emissions around the state. Most of those which were found to occur in metropolitan areas, particularly in the Portland area. The committee was concerned about diesel exposure also because of the large numbers of people living in proximity to diesel emissions. The committee expects to continue to see growing truck and rail traffic and off-road activity, such as construction activities, that will utilize diesel engines.

In spite of the fact that a larger number of new-technology diesel engines will be in use in the future that will have a concurrent significantly lesser risk related to better-controlled diesel emissions, old-technology diesel engineers are still in use throughout Oregon, and the health impacts caused by these older engines are what the public needs to be protected against currently. The committee recognized that the use of new diesel engines and fuels, beginning in approximately 2007, has resulted in reduced emissions of toxic compounds. But information on how many of the older diesel engines are still in use in Oregon is incomplete, and the committee’s goal is to be protective of the emissions that people are actually experiencing. Older diesel engines are very durable, and because replacement of old engines with new ones is very expensive, we know that heavy-duty-vehicle fleet turnover will be slow. Thus, it must be assumed by the committee that old-technology diesel engines are still emitting unacceptable amounts of DPM into the air.

Kevin Downing, air quality planner and clean diesel coordinator for DEQ, presented a talk on diesel engines and related issues at the May 2015 ATSAC meeting. He stated that a variety of sources of diesel exhaust exist, including emissions from trucks, boats, on-road sources, short- and long-haul trucks, off-road sources, construction equipment, specialty equipment, and buses. The work DEQ is doing to improve school bus engine exhaust is helping a vulnerable group of kids. Diesel emissions from rail transport and train locomotives in various sectors of the city are important to consider, including emissions coming from train use and switching yards, as well as container facilities and emergency power generators. Kevin Downing also discussed turnover of fleets having old-technology diesel engines to the post-2007 new-technology diesel engines. The newer engines have much lower emissions that contain chemicals with less-toxic carcinogenic potency than the older engines, but the actual amount of engine turnover that has occurred in Oregon is unknown. The data is hard to gather, particularly in regard to the turnover of truck engines in Oregon. Generally, the lifetime nationally for a diesel engine is somewhere around eight years. Kevin Downing believes it would be reasonable to assume that long-haul trucks represent the newer engines, and that older diesel engines are probably continuing to be used for short-distance transport work around cities. On the interstates and major highways, newer engines are expected to dominate. As time goes on, the fleets will contain greater and greater numbers of the new-technology diesel engines.

Review of Relevant Scientific Literature

Significant review of the scientific literature around DPM and comprehensive discussion by the ATSAC over multiple meetings provided highly-detailed information about the carcinogenicity of DPM and the availability and potential applicability of the studies reviewed. Expanded descriptions of a number of related topics that were covered by the ATSAC in 2015 and 2017 are provided below.

ATSAC Dismissal of OEHHA URE for Use in Calculating a New ABC for DPM

As discussed earlier, the single currently available 1998 URE value of 0.0003 per µg/m^3 is from OEHHA, which is one of the authoritative bodies the ATSAC relies upon for toxicity value information. When this URE is converted to a concentration that is protective at a 1 in 1 million risk, the value of 0.003 µg/m^3 is obtained. This OEHHA value was available to the ATSAC in 2005, but there was a lot of controversy surrounding the technical credibility of the number.

The OEHHA 1998 URE value has been questioned for years by a number of technical agencies, including the International Agency for Research on Cancer, and by some of the researchers whose data was used to calculate the value. Dr. Eric Garshick, a well-respected DPM expert whose work in combination with other published studies was used by OEHHA to generate the OEHHA URE value, is on record informing OEHHA they shouldn’t use his study data to help calculate their URE value, as he considered their protocol to be inappropriate and not scientifically credible. This is why, in part, the ATSAC did not choose the OEHHA value back in 2005, and it is why the committee re-reviewed the basis of the 1998 OEHHA URE value so carefully in 2015 - 2017.

EPA and the World Health Organization both tried to calculate a URE value, but gave up because they considered the available data to be inadequate. No other agency or researcher has been able to replicate the California OEHHA value, which further detracts from its credibility. Although the OEHHA value has been adopted and used by Washington state and a metropolitan agency in Vancouver, B.C., it appears the number was chosen because no others were available. In addition, the OEHHA value is based on total particulate mass, which is most likely not the component in diesel exhaust that can cause cancer.

Dean Atkinson does not find the OEHHA URE value credible. He also posed the question that if this value is credible, why haven’t a larger number of agencies chosen to use it to make decisions about protection of human health? For example, EPA does not use the OEHHA URE value, and in fact has chosen not to identify a URE value for DPM. He also thinks that the OEHHA value overestimates actual risk from exposure to diesel particulates. The prior values recommended by USEPA and the World Health Organization (but now withdrawn), estimated the protective concentrations to be higher (less stringent) than the OEHHA URE value. The study behind the OEHHA value does not include an exposure response, which further detracts from the credibility of the California value. Kent Norville said that another concern is that the studies used to generate the OEHHA value showed a weak dose response for DPM in regard to both human and animal studies. Bruce Hope stated that he had been unable to find another regulatory agency that's even attempted to replicate OEHHA's work, much less tried to generate a separate quantitative value.

Because the committee wanted to be clear about why it is rejecting the OEHHA URE value, the ATSAC has once again carefully re-assessed the technical foundation of the value, and is documenting why it has rejected it a second time as a potential ABC for DPM. Because the OEHHA URE value is older (nearly 20 years old at this point, in 2017) and because the ATSAC has not been able to determine exactly how the value was calculated, the committee opts not to consider the OEHHA URE value as the basis for a new ABC for DPM.

Epidemiological Studies Relevant to DPM

One approach discussed by the ATSAC involved the idea of assembling and evaluating all studies that provide URE values, and then identifying a single representative URE value that could be used as a new ABC for DPM. Most of the DPM studies that would be useful to the ATSAC identify the primary health impact of DPM exposure as lung cancer, upon which the majority of DPM toxicity information is based at the present time. DPM exposure causes other health effects as well.

One committee member asked whether, in light of the fact that rodent respiratory systems aren't comparable to human respiratory systems, it would be possible to conduct a study where rats are exposed to diesel compounds via inhalation in a specialized chamber that would accurately simulate upper respiratory tract inhalation uptake by humans. Bill Lambert responded by saying that those types of studies have been attempted over time. But the particulate loading necessary to generate a cancer effect in those animal models was so high that they basically overloaded the rodents' respiratory tracts in a mechanical, rather than toxicological, sense. Thus, organ damage was observed long before the development of tumors, which was the effect that the study leaders were trying to simulate. So, the rat model doesn't work well as a representation of the human lung. This is why the Health Effects Institute, or HEI, closely evaluated the trucker and miner epidemiological studies, rather than animal studies. They have certified the quality of these studies, and determined that the retrospective assembly of a quantitative exposure estimate for DPM was done using established methods in a careful way and that these studies do establish a small excess risk of lung cancer in these workers. This is a very important result, because it establishes diesel exhaust as a human carcinogen.

Earlier studies evaluated by the previous ATSAC include Dawson and Alexeeff, 2001; Stayner et al. 1998 (epidemiological data); Stayner et al. 1998 (animal toxicity data); Pepelko, 1993; World Health Organization, 1996: USEPA, 1998; and California Office of Health Hazard Assessment, 1998. Since 2006, the Pepelko, World Health Organization, and USEPA studies have been withdrawn, due to inadequate data. Nothing newer in terms of a numeric value has become available since then.

Studies conducted by Silverman, Steenland, and Garshick measured PM 2.5 on a routine basis and then analyzed a subset of filters to come up with the related amounts of elemental carbon. The best data is retrospective workplace data (epidemiological data) that allows us to discern effect, and this shows an excess risk. But it is difficult to apply the results of occupational studies to an environmental situation that includes women and children. Uncertainty about the point of departure of the toxic effects is what undermines USEPA and other efforts to make progress.

The most-recent science on DPM became available in 2012 and after, and included epidemiologic studies done by Garshick, Silverman, and Attfield on miners and truckers. The results of these studies have been embedded in scientific journals, and the HEI convened an expert panel which generally endorsed the quality and validity of these approaches. A small excess risk of lung cancer was seen at the highest levels of the occupational exposures. However, the HEI did not generate a numeric URE value, which is what is needed to calculate a new risk-based concentration. Choosing not to identify a URE was related to concerns about extrapolating from the worker studies down to the community level, and how ambient levels of exposure to DPM might fit in. Also, uncertainty factors of some kind would have to have been applied to these worker study results in order to be able to use them to protect non-worker communities. The worker studies are impacted by what is referred to as the Healthy Worker Effect, which refers to the idea that someone who is healthy enough to work may be less vulnerable to disease conditions than someone in the general population. Therefore, safety factors would have to be researched that would allow application of worker-based results to potentially not-as-healthy vulnerable or sensitive populations groups.

Some DPM studies have been criticized because they are based on emissions from old diesel engines and old technology. But currently there are not enough new-technology diesel engines in use, nor has the new technology been in use long enough, to generate credible epidemiological results. These are important facts to consider, because there is a 10-to-15-year lag time between exposure to diesel and the development of lung cancer, and the new-technology diesel engines have not yet been in use for a long enough period of time to allow evaluation of lag time. Importantly, this means that a large segment of Oregon's population is still exposed to emissions from old-technology diesel engines, and therefore this is the type of exposure for which the committee must choose a protective value.

In human epidemiological studies, the effects can be more accurately assessed in terms of human exposure, because observational studies conducted in the occupational environment are the primary assessment tool. Exposure to chemicals in the occupational setting tends to be at fairly high concentrations, so it is not representative of the typically lower environmental levels experienced by the general population or by vulnerable subgroups such as women, children, the elderly, and people with chronic disease conditions. Thus, low-dose exposure information for these groups is extrapolated from the data obtained in the occupational setting. Therefore, when the committee considers using toxicity values from IRIS or other authoritative bodies, it prefers evidence that is quantitative rather than qualitative, and that provide measures of dose and response. The committee prefers to use human epidemiologic studies, if available, but if forced to rely upon animal studies, the committee would use those that demonstrate a response which is most like the response observed in humans. Studies that involve inhalation, which is the relevant exposure pathway in this case, are of course preferred over studies that assess other exposure routes. Studies of longer exposure durations and multiple exposure levels are also preferred, because they provide greater statistical confidence in the results.

In human epidemiological studies, effects specific to diesel have been notoriously difficult to quantify due to the complex composition of diesel particulates. Thus, in many of these occupational worker studies, we must rely upon quantification of exposure by job classification and the number of years in that job, as well as industrial hygiene measurements made to represent each level in the job exposure matrix. In other words, a lot of assumptions are made when numeric results are extrapolated from these studies, which automatically injects uncertainty into the process.

In regard to documented exposures of workers to diesel particulates, the exposure ranges associated with each worker group type are important to consider. Bill Lambert presented average exposure concentrations for each type of worker group, as obtained from the HEI Diesel Epidemiology Workshop that he attended on March 6, 2014: 5 $\mu g/m^3$ for long-haul truckers, 50 $\mu g/m^3$ for railroad workers, 100 $\mu g/m^3$ for underground mine workers, and 10 $\mu g/m^3$ for dock workers. The average ambient U.S. urban average ambient air exposure concentration is 1.0 $\mu g/m^3$. The estimated concentration for workers exposed to new-technology diesel engines is 0.1 $\mu g/m^3$. The studies upon which these values are based were conducted from the 1970s to the 1990s, and related exposures were essentially integrated across work-shift durations rather than over a lifetime, and discussed in terms of occurring over a *working* lifetime.

Railroad worker study data are currently being re-analyzed by the National Institute of Occupational Safety and Health, but are not yet available. The most useful study for the committee to use would be a study done conducted jointly by NIOSH and the National Cancer Institute, known as the Diesel Exhaust in Miners Study (also referred to as DEMS) on underground miners. But for now, the focus is on the data from the trucker studies.

The Garshick trucker study provides mortality ratios for exposure of workers to DPM. The study assessed two groups: a worker cohort which included workers of age 40 and older, including 2,000 mechanics, and a second group which did not include the mechanics. More than 30,000 workers are represented in this national data set. The exposure measurements were made at various locations around the United States, including a location in Portland, OR. In terms of units of micrograms per cubic meter-months, 122 lung cancer deaths were observed for workers that were exposed at the lowest level of less than 371 µg/m^3-months. The number of cancer deaths was the same whether the mechanics were included or not. Therefore, 371 µg/m^3-months will be considered the reference level, or the lowest level of exposure, and can be thought of as being ambient background. The next level of exposure at 371 to 860 µg/m^3-months showed an increase in the number of deaths: 193 in the group with mechanics, and 191 in the group without mechanics. This change from 122 to 193 lung cancer deaths is equivalent to a ratio of a 30% increase, which is equal to a Relative Risk of 1.3. So that's a 30% increase in cancer deaths at the higher concentration, which is statistically significant. This trend continues as the exposure concentrations increase.

The risk estimates also agree well with the estimates by Kyle Steenland published in 1995, and there's actually great consistency in the literature. In addition, there are individuals who might be very susceptible and develop cancer rapidly, while other individuals might not manifest a cancer effect until a greater amount of time has passed. By building in a five-year lag period, time is allowed for the process of pathogenesis to occur. Thus we are looking at exposures that occurred at least five years prior to a diagnosis of lung cancer.

The 2014 study by Vermeulen et al. is a meta-analysis, which indicates that it's an analysis of multiple earlier studies, or "a study of studies". It utilizes studies done by Garshick, Steenland, and Silverman. Groupings of the Relative Risks of lung cancer from all of these studies were presented, and were based on exposure to elemental carbon, which was used as a surrogate for diesel engine exhaust. However, focusing on cancer deaths, as the Vermeulen study did, does not take into account non-fatal incidents of cancer that occur. The Vermeulen study identifies a concentration of 0.8 µg/m^3 which is related to 21 cancer deaths within a general population of 10,000, a probability which can be arithmetically related to the more typical consideration of 1 additional incidence of cancer in a population of one million people. Performing this calculation, however, is not an apple-to-apple type of comparison, and a significant amount of uncertainty is associated with it.

These studies focus their evaluations on the number of lung cancer deaths caused by exposure to diesel emissions, rather than the number of cancer incidents that occurred, and cancer deaths are a less-sensitive parameter than the number of cancer incidents. However, in terms of epidemiologic research on lung cancer, deaths from lung cancer is a fairly unambiguous outcome which has been accurately characterized. There is some error in regard to cause of death listed on death certificates, certainly, but that error is believed to be small relative to the effects shown in the studies.

Proposal to Calculate a Geometric Mean from Epidemiological Studies

As the committee continued discussing how to deal with the complexity behind trying to choose a new ABC for DPM, Bruce Hope suggested pooling all relevant values from a number of scientific journal articles and using them to calculate a Geometric Mean value, which would be a single numeric representation of all the different information from a number of the DPM articles the committee has looked at. Using a Geometric Mean, rather than an Arithmetic Mean, or average, is an arithmetic way to "smooth out" data values from multiple studies which are orders-of-magnitude different from each other.

There were no standard or consensus-based protocols that the ATSAC could have used to choose a new ABC for DPM. Therefore, using a Geometric Mean was an approach proposed as a new way to arrive at an ABC for DPM that was credible and with which the ATSAC could feel comfortable. Thus, only epidemiological study results were used to generate a Geometric Mean. Studies based on rodent inhalation did not adequately reflect the inhalation mechanics and chemistry seen in human epidemiological studies, and so the ATSAC as a matter of policy chose not to include information from rodent studies in the calculation of a Geometric Mean for DPM. Multiple UREs based on epidemiological studies were calculated by the OEHHA from a number of published studies, based on their choice of toxicity information, statistical assumptions, and modeling required to obtain URE values from Relative Risk ratio values. Initially, the ATSAC meant to include these OEHHA-calculated UREs from other studies in the pool that would be used to calculate a Geometric Mean. But a committee member pointed out that if the committee had dismissed the OEHHA URE value as not credible, then the committee should not consider any interim calculations made by OEHHA. Therefore, the UREs generated by OEHHA from other studies were not included in the pool of values used to calculate a Geometric Mean.

Sue MacMillan and Bruce Hope presented a number of draft calculations of a Geometric Mean, using different combinations of relevant studies from the pool in each case. In all cases, the Geometric Mean values fell within the range of 0.001 $\mu g/m^3$ to 0.003 $\mu g/m^3$. Any value within this range, then, could be a potentially robust single number that might be usable as a protective level. However, based on further technical review of the parameters used in each study, it became apparent to the committee that only a small number of studies could reliably be used, and the number was too small to allow credible calculation of a Geometric Mean value. As a result, the committee discarded the idea to use a calculated Geometric Mean as the ABC for DPM.

ATSAC’s Attempt to Generate a URE Value for DPM

Until the toxicity behind DPM was reviewed by the ATSAC, the committee, according to established policy, had based their recommendations for revised ABCs on toxicity values already available from recognized authoritative bodies, including but not limited to IRIS, OEHHA, and ASTDR. However, the lack of any credible cancer-based toxicity value for DPM from any authoritative body presented a problem for the ATSAC, in light of the fact that DPM is an air toxic that causes a high degree of risk in Oregon and which is of very high concern to the public. The committee members agreed the ideal option would be to calculate their own URE value for DPM, but acknowledged quickly that attempting this could be a very complex and time-consuming undertaking. Bill Lambert discussed an approach used by a speaker from the National Institute of Occupational Safety and Health, or NIOSH, Robert Parks (Risk Evaluation Branch, NIOSH CDC, Cincinnati Ohio), at the HEI Workshop. Bill Lambert explained that the HEI is a nonprofit corporation chartered in 1980 as an independent research organization to provide high-quality, impartial, and relevant science on the health effects of air pollution.
Bill Lambert felt that the ATSAC should rely upon the more-recent studies by Garshick in 1987 and 1988, Steenland’s long haul truck driver study in 1998, and Stayner’s 1998 study of exposure of railroad workers. Papers for the diesel exhaust miner studies, published in 2012, should be added to the pool of studies being considered by the ATSAC. All of these studies tend to have more quantitative representations of the exposure estimate, and each study represents a group of predominantly male workers who were healthy enough to hold a job. In some cases there are concerns about retrospective assessment of smoking history or co-occurring exposures to radon or asbestos, which would confound the data being used.

The ATSAC is advising DEQ about a shifting area of technical knowledge that has a lot of uncertainty associated with it. Bill Lambert suggested that a range of values, rather than a single value, might be more appropriate for the committee to consider; this approach could then be “backstopped” with a memorandum that explains why the committee identified a range of values to use as an ABC for DPM. If the committee had seen a greater similarity between the geometric mean approach and the Parks calculations, it might have helped the committee to choose a range of values with which it could feel comfortable. If the committee can generate their own URE values from a chosen pool of studies, the results would provide reassurance to the committee as scientists that the number that might finally be chosen as the ABC for DPM is in the ballpark of other, similar values.

At the September 2015 ATSAC meeting, Bill Lambert volunteered to come up with a draft proposal that would consider how to calculate URE values from each relevant DPM study, and provide recommendations about how to choose which studies to include. Once these steps are completed, the committee can then calculate a geometric mean from the data generated. Dave Farrer stated that this sounded like a lot of work, but is a good idea.

Bill Lambert wanted to document an approach which would allow the committee to identify principle studies from which to obtain a mean estimate for a protective DPM concentration, specifically using elemental carbon as a surrogate. This would involve extrapolating from the available occupational studies of miners, long-haul truck drivers and others; thus a large number of studies are available, some from the 1980s and 1990s. Sue MacMillan had also assembled a list of potentially relevant studies to use. So, from this larger group of studies, the committee had the option to choose principle studies based on the quality of the study design, measurement of exposure, the outcomes considered, the way a study was conducted and if it was possible to calculate a quantifiable dose-response number from each study.

The committee can create a spreadsheet that reflects the information from all of these studies, which should help in deciding which studies are most relevant. Using these selected studies, an average value can be back-calculated, similar to the approach attributed to Parks discussed earlier. Sophisticated statistical boot-strapping methods or simulations can then be used to come up with a true 95 percent confidence interval value, which the committee can then use to identify a defensible best estimate.

Some of the papers that critiqued the studies that the committee was interested in were also of value. The committee reviewed the paper by Kenny Crump, 1991, and the one by Morfeld and Spalleck, 2015, which Bill Lambert distributed at the September ATSAC meeting to help the committee judge whether or not the proposed DPM approach will stand up to these types of critiques.

Bill Lambert stated that five studies by Silverman, Attfield, Garshick, and Steenland seemed to be of the highest quality, and were also the ones that could be related to elemental carbon. The other studies were more qualitative in their assessment of exposure, and did not appear to provide a credible measurement of what the diesel exhaust exposure received in those studies actually consisted of. The committee needed quantifiable numbers to be able to move forward.

Bill Lambert wanted to follow this study selection protocol because he was uncomfortable with just recommending a numeric standard for DPM without providing clear justification for how the number was calculated. The lack of clear justification in regard to the OEHHA approach and the related lack of transparency in regard to how the OEHHA calculated their number is what kept the committee from using the OEHHA value, and the committee didn’t want to repeat these weaknesses with their own DPM calculations.

Attempting to generate a credible URE value for DPM turned out to be a more complex task for Bill Lambert than initially expected. Due to other professional constraints that Bill Lambert had as an OHSU professor and researcher, it took him more than a year to attempt to identify an approach for identification of a DPM URE value that the ATSAC might be able to consider, involving the possible use of one or more Relative Risk values. Because the possibility of obtaining a credible URE for DPM was a huge opportunity that would have moved the state of the science forward not only in Oregon but also in larger venues, the wait was considered acceptable to the DEQ. Once it became apparent that the science around DPM was still not developed enough to support the calculation of a credible URE for DPM by the ATSAC, the committee was convened on March 22, 2017 to discuss this. At that meeting, the committee acknowledged that DPM is a recognized human carcinogen, but the committee lacks the quantitative data and method necessary to confidently calculate a related URE for DPM, which in turn prevents the ATSAC from calculating a new ABC value.

Dean Atkinson asked whether EPA and the World Health Organization had provided an explanation of why each agency withdrew its older DPM values from the literature. Bill Lambert and Sue MacMillan said that they had looked for this information, but had not found any related documentation. Dean Atkinson then commented that it was irresponsible of those agencies not to have provided an explanation for the withdrawn values, and recommended that the ATSAC not do the same thing. On this basis, he agreed that the ATSAC cannot recommend a revision of the current ABC for DPM at this time.

Currently, concentrations of DPM in air are not meeting the current ABC of 0.1 $\mu g/m^3$ for DPM in all parts of the Portland metropolitan area, or in other urban areas in the state. Retaining the current ABC for DPM is still considered protective, and is also useful as a screening tool that the DEQ can use to make decisions about the potential DPM hazards throughout communities, and then to prioritize areas for more-focused control of DPM and the protection of human health.

One committee member wondered if the moss studies used in 2015 to identify the presence of metals around the city of Portland could be used to detect DPM. Sue MacMillan said the moss method is able to identify metals and PAHs, so further use of this tool is being considered by DEQ. Moss studies will show that PAHs are present in moss tissue, but will fail to indicate whether the same PAHs are present in the air nearby, or where the PAHs are coming from. However, moss results could be used to determine where the best locations are to place air monitors.

Kevin Downing of DEQ thanked the committee for its hard work, and then made three observations: First, while it is difficult to identify particles specific to diesel engines through typical ambient monitoring techniques, it is incorrect to say that there are no chemical markers indicating unique exposure to diesel PM. At least two studies that he is aware of have reported a unique biomarker for human exposure to diesel exhaust, distinct from other combustion sources like tobacco smoke. Second, the suggestion that the NAAQS might be part of a complete protective strategy misses a critical point: while most of the criteria pollutants are distinctive chemicals, e.g., carbon monoxide, lead, sulfur oxides, not all DPM components are made up of single, named chemicals, and so cannot be compared to a protective value. Ozone is a secondary pollutant with a multitude of precursors among hydrocarbons, many of which have distinct and separate health endpoints, like benzene. Particulate matter consists of a variety of chemicals with varying toxicities that are nonetheless united by the fact that they are aerosols of a certain size. To the extent that NAAQS control strategies have reduced emission levels over time, at the same time it is not true that all risk from ozone precursors or the extensive range of material that qualifies as PM fine is also present at acceptable levels. The primary motivation behind looking at air toxics comes from trying to resolve this fundamental question and deliver the benefits that NAAQS standards were meant to address. Third, although DPM has limitations as a toxic from a monitoring perspective, it still has value as a screening measure as compared to the alternative, which would be whole diesel exhaust, which is the air toxic constituent that the International Agency for Research on Cancer (known as the IARC) concluded was a known human carcinogen. When considering protective strategies, the idea that whole diesel exhaust is the cancer-causing agent suggests that the effective control measure is to eliminate diesel exhaust in total. Instead, relying on DPM as the air constitute of concern suggests the use of strategies that substantially eliminate risk from DPM, while not explicitly removing diesel engines altogether.

Possible Future Methods for Identifying a New Benchmark for DPM

If new quantified toxicity information for DPM becomes available in the next few years, the ATSAC can review it to determine if a new ABC can be generated from it. However, in light of the fact that that no credible URE value for DPM is currently available, the committee chair proposed three other ways to approach the control of diesel emissions. Many of the details related to these three options had been discussed at earlier ATSAC meetings:

> 1) Use a constituent approach where, rather than pinpointing diesel toxicity, DPM might be controlled indirectly by evaluating the toxicity of related components, such as particles and gases. For example, PM 2.5 already has an available protective criterion in its National Ambient Air Quality Standard, and there are ABCs available for the PAHs. In addition, specific epidemiological data exists for these DPM-related compounds, with quantified, numeric results. So each component could be assigned its own ABC, and uncertainty factors could be applied to try to account for the unknown potential chemical interactions of these compounds with each other. The constituent approach discussed here is the method that is used currently by the federal government.

2) Set a standard for DPM based on what the appropriate marker compounds for DPM would be. As has been discussed previously, choosing an appropriate marker is extremely challenging, because no single chemical in the DPM mixture serves as a unique marker of actual DPM exposure. The more-recently published and credible occupational worker studies use elemental carbon as a measure, or marker, of DPM exposure. These occupational studies of truckers and miners are the studies the committee would rely on in its evaluation of DPM toxicity, as these studies offer a much better and valid assessment of human exposure than do earlier studies. These studies included evaluation of older populations, due to the fact that there is a lag time between exposure and the actual appearance of lung cancer. This is part of what is referred to as a "retrospective approach", which evaluates historical exposures of workers, reconstructs their dosage history, and then measures the occurrences of lung cancer. These types of occupational worker studies are based on human exposure that is higher than that observed in the general population when exposed to ambient levels of these toxins.

Many of these studies present their results in terms of Relative Risk, which is the measure of association of exposure levels with physical outcomes. Unfortunately, there is no defensible approach for using Relative Risk values and related hazard ratios to generate a credible Unit Risk Estimate for DPM. Relative Risk results in these studies are based on respirable elemental carbon levels, rather than DPM levels. The reason that elemental carbon was measured in these epidemiologic studies was because it occurred in situations where the primary exposure was already known to be due to the presence of diesel engines used by workers while driving, working in truck terminals, or working underground. In these studies, samples of respirable PM 2.5 particulate matter were analyzed, and a calculation subsequently performed to estimate what the concentrations of elemental carbon were. However, as was discussed in past ATSAC meetings, the measurement of elemental carbon is impractical currently, which means that the protocol related to the assumed measurability of elemental carbon is not very useful for the purposes of this committee.

As mentioned earlier, the committee has discussed the various thermo-optical methods used for measurement of respirable elemental carbon. However, there is too much uncertainty with using respirable elemental carbon as a marker for DPM to rely on this approach. There is still no method available that would allow the direct measurement of DPM in a way that is consistent and repeatable.

Also, use of the marker approach described above focuses on one particular health outcome: lung cancer. But new evidence is coming forward on exposure of populations to motor vehicle exhaust in general, which includes the recognition of new endpoints of concern, such as neurological impacts. Neurological impacts could be a more sensitive indicator of diesel exposure toxicity than lung cancer. But because this new evidence is still being developed, we are left for now with looking at lung cancer as the relevant outcome of diesel exposure.

3) Another way to look at DPM would be similar to the approach risk assessors use when evaluating Superfund sites or cleanup sites, and encounter a contaminant of concern for which no toxicological information is available. They don't include it in their quantitative estimates of total risk, but do explain that they think the contaminant is likely to be a health hazard, and acknowledge this uncertainty in another section of the risk assessment report as a kind of placeholder for when and if toxicological information for that contaminant does become available.

The committee discussed these options, but decided that at this point in time there is too much uncertainty associated with them for the ATSAC to feel comfortable in recommending any of them.

The committee discussed in May 2015 how diesel emissions would figure into EPA's National Air Toxics Assessment risk information, to be released later in the fall of 2015, which itself will be based on data from the 2011 Emissions Inventory. EPA does perform dispersion modeling of DPM, but does not attempt to estimate cancer risk associated with that diesel. EPA, via NATA, uses only a non-cancer Reference Concentration with which to evaluate potential non-cancer risks to human health from inhalation of DPM. The EPA acknowledges that DPM is a carcinogen, but since 2014 has chosen not to undergo the time- and resource-intensive work that would be required to identify a numeric toxicity value related to the carcinogenicity of DPM. Instead, EPA has opted to focus their efforts on reducing exposures to the chemical.

New diesel studies are underway , but the results of good epidemiologic research on lung cancer caused by diesel is probably 10 years away, including studies that are likely to be conducted on the new-technology diesel engines. Also, pending studies on the worker populations in the U.S. and China will likely provide some valuable information in the future. In addition, more-sophisticated studies in the future will likely focus on particulates with a diameter smaller than 2.5 microns – that is, ultrafine particles with a diameter of less than 1 micron, and smaller. As mentioned earlier, at this point in time, it is unknown if it's the mass of the particles or the total number of particles that is most relevant to health effects from diesel inhalation.

There are a variety of other health effects that have been measured as well, such as with children in Los Angeles who exhibit reduced lung growth, which results in smaller lung volumes and flows for those who are living within 1,500 feet of a roadway; asthma risks increase, as well. The newest information that's coming forward now is that there may be additional DPM exposure concerns for cognitive development in children; aspects related to dementia; and carbon soot particles have been found, during autopsies, to have been transported to not only the heart, but also into the brain, crossing the blood brain barrier. Thus, we are still in the process of learning a lot more new information about particles. Nonetheless, it is important to work toward the prevention of lung cancer, and so the current DPM for ABC represents a defensible position in regard to prevention of lung cancer.

Final Conclusion

In 2005, the ATSAC chose an ABC for DPM of 0.1 $\mu g/m^3$ and made a statement that, at the time, the committee's pick was a reasonable choice, particularly because the committee recognized that DPM was a carcinogen. The committee set the standard near the World Health Organization values that were available at that time. Other, newer information on DPM has become available since then, but so far none of the new information allows the current committee to quantitatively identify a new, numeric URE for DPM. Therefore, the committee voted unanimously in March 2017 to recommend that the current ABC of 0.1 $\mu g/m^3$ for DPM be retained.

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