Meeting Minutes

Air Toxics Science Advisory Committee
Meeting No. 9

Sept. 16, 2015 (8 am to Noon, PDT)
Conference Room EQC-A, 10th Floor, DEQ HQ
811 S.W. Sixth Avenue
Portland, Oregon 97204

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DEQ is a leader in restoring, maintaining and enhancing the quality of Oregon's air, land and water.

List of Attendees

Committee members present: Bill Lambert, Dean Atkinson, David Farrer, Bruce Hope, Dave Stone. Max Hueftle attended by phone. Kent Norville was absent.

Oregon Department of Environmental Quality (typically referred to as DEQ) staff present: Sue MacMillan (Air Toxics Science Advisory Committee lead), Sarah Armitage, Jeffrey Stocum, Phil Allen, Justin Haynes, Kevin Downing, Anthony Barnack.

Introduction

Bill Lambert was running late. MacMillan offered to start the meeting by discussing some of the planned topics. She welcomed everyone to the meeting and explained that Lambert would be there within 20 minutes. She also directed people to view the agenda for today.

Proposal for use of average toxic equivalency factors in conversion of PAH results

Sue MacMillan discussed the fact that a decision needs to be made about the Ambient Benchmark Concentration (also referred to as an ABC) to use for total polycyclic aromatic hydrocarbons (now recommended to be based on a list of PAHs that are more directly related to PAH toxicity in air).

Originally, the proposal that Bruce Hope presented at the June and July ATSAC meetings included the recommendation to use the upper-bound value of the range of TEFs available for each PAH. Each upper-bound value of a TEF range would then be used to convert concentrations of each individual PAH to concentrations that represent their toxicity relative to benzo(a)pyrene. The ranges of TEFs were provided by EPA in their 2010 External Review draft document. However, instead of using the upper-bound value of a TEF to convert a PAH, Sue MacMillan requested that the average of each TEF range be used as the TEF used to convert PAH concentrations. Using the average value of each TEF range will make our protocol consistent with how EPA and other state agencies use this information. The result of using an average rather than the upper-bound TEF value is a slightly lower summed concentration once you adjust all the PAHs, which in turn means that the total PAH concentration is slightly less likely to exceed the ABC. But this is the approach most other agencies use. Sue MacMillan suggested that the committee vote on this proposal once Bill Lambert arrives.

Diesel particulate matter

Sue MacMillan then began a presentation that summarized previous discussions on diesel particulate matter. Diesel particulate matter is a complex mixture, and there is no way to directly measure it. We use surrogate compounds, such as black carbon, and modeling estimates to come up with estimates of concentrations of diesel particulate matter in air.

The original ABC for this compound, which is 0.1 micrograms per cubic meter (or ug/m^3), was recommended by the ATSAC in 2005, and was incorporated into rule in 2006. Since then, very few studies have become available which actually provide a protective, quantified, numeric value that can be used in our diesel particulate matter discussions. The value that was chosen back in 2005/2006 was the upper-bound value of the range of the World Health Organization values that were available in a 1996 reference at that time. At the same time there was also a value available from the Office of
Environmental Health Hazard Assessment in California (typically referred to as OEHHA) which was much more stringent: 0.003 ug/m^3.

The more-stringent OEHHA value was available in 2005, and was originally published in 1998. But there was a lot of controversy surrounding the technical credibility of this number. At least one author whose data had been used by OEHHA showed up at OEHHA's commentary meetings and told OEHHA not to use his data, because OEHHA was using it incorrectly and inappropriately, and the unit risk estimate OEHHA had calculated was not credible. Furthermore, this was not the only complaint of this type made by outside researchers. This is why the ATSAC did not choose the OEHHA value back in 2005, and why they are re-reviewing it so carefully now.

As the committee discussed how to deal with this complexity, Bruce Hope explained that he had suggested pooling all of the available estimated numbers from multiple authors to calculate a geometric mean, which would be representative of the data as a whole. He emphasized that not many of these studies are available, and that credible researchers had used similar data to start with, but then used varying methods to interpret the data. There doesn't seem to be a reason to exclude any of the few studies we do have from being used to generate a geometric mean value. A geometric mean is an arithmetic way of "smoothing out" the wide range of results from these credible studies.

Sue MacMillan stated that it should be pointed out that there are no standard or consensus-based approaches for the ATSAC to follow that would enable them to choose an ABC for diesel particulate matter. So, use of a geometric mean is a new way to arrive at an ABC that is credible and that the ATSAC feels comfortable supporting on a technical basis. Additionally, as part of this proposed approach, only epidemiological studies will be considered. Rodent studies that looked at diesel particulate matter toxicity have very different characteristics from those of human studies. The way the toxic effects of diesel particulate matter impact a rodent, the way that rodents are dosed in the laboratory, and their short life span, are all very different from the way diesel particulate matter impacts the human system. Sue MacMillan presented slides showing which studies were considered for inclusion in the calculation of draft geometric means. The pool of unit risk estimates (cancer-based toxicity values) as presented in the slides were obtained from modeling that OEHHA conducted on risk ratios obtained from the epidemiological studies being considered for inclusion. Unfortunately, almost all of the other studies being considered presented results as risk ratios, which cannot be directly used; first it takes a modeling effort to obtain unit risk estimates from risk ratio values.

Woman in audience asked if Sue MacMillan and the committee were familiar with the studies being discussed, and specifically the Vermeulen study done in 2014. She guessed that, over time, studies would get better, and so the 2014 study should be important to consider. She wanted to know why the Vermeulen study was eliminated from the pool of studies being considered for generation of a geometric mean. Bruce Hope explained that Vermeulen had simply used data already provided in earlier studies, and treated it a bit differently in coming up with a risk estimate. For every paper that's been written in regard to diesel particulate matter toxicity, there is a matching paper produced by equally credible people, saying that results of the original study are wrong. So it is very difficult to parse out which studies to include.

A woman in the audience asked Bruce Hope if other effects of diesel particulate matter exposure, such as cardiovascular disease, are being considered. He responded that only lung cancer was being considered in the ATSAC's current discussion. Sue MacMillan pointed out that if you protect for cancer effects, which at a 1-in-1-million cancer risk level occur at the lowest concentrations, then by default you are also going to protect for other adverse effects like cardiovascular disease that require exposure to higher concentrations.

Bruce Hope clarified a comment made earlier about a geometric mean being a way to smooth out skewed data. He stated that the data being used to calculate a geometric mean is not actually skewed. Rather, these data span three to four orders of magnitude, and the geometric mean is a much better representation of the midpoint of this expanse of data than anything arithmetic, such as an arithmetic mean. We're not talking about a distribution here -- we're just talking about a wide range of values. The geometric mean is a way of representing the midpoint of this wide range. And if you treated this range arithmetically, the vast majority of these numbers are going to be slammed up against the Y-axis of the graph and you wouldn't be able to tell what's going on, nor would you be able to see what the mean is or what the central tendency is. So that's why Bruce Hope is proposing going with the geometric mean.

Bill Lambert arrived. He reiterated that it is very difficult to look at a variety of scientific studies, which have all interpreted the data in different ways, and then come up with a single number that is protective. Also, in our case, we are looking at studies of different kinds of workers, exposed for varying time periods, and living in different kinds of places. In fact, the World Health Organization looked at the same studies and results that the committee is currently considering, and in 1996 came up with some protective values that they published, and then withdrew, due to the complexity of the technical issues. The ATSAC is now attempting to go where others have not been willing to go, and so we need to figure out a way to take advantage of this breadth of information and reduce it to a single number.

The rationale for this particular approach is to rely upon 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. Bill Lambert said that papers for the diesel exhaust miner studies published in 2012 need to be added to the pool of studies being considered. All of these studies tend to have more quantitative representations of the exposure estimate (in other words, numeric values), and each represents a group of predominantly male workers who were healthy enough to hold a job, a situation commonly referred to as "the healthy worker effect". 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.

Bill Lambert pointed out that whether it's four studies or all the studies as presented by Sue MacMillan in her slides, when we tinker with calculating a geometric mean using different combinations of these studies, in all cases the resulting geometric mean value falls between 0.001 ug/m^3 and 0.003 ug/m^3. This is good news; it means that somewhere between the concentrations of 0.001ug/m^3 and 0.003 ug/m^3 is a potentially robust single number that could be usable as a protective level.

Bill Lambert also pointed out that the majority of the unit risk estimates associated with each study as shown in Sue MacMillan's slides (and which were used by Sue MacMillan and the ATSAC to generate draft geometric means) were actually calculated by OEHHA circa 1998. OEHHA modeled these unit risk estimates from available risk ratio results in each study. He asked that if the committee is critical of OEHHA's 1998 unit risk estimate value (with an associated protective concentration of 0.003 ug/m^3), then why would the committee find

OEHHA's modeled unit risk estimates for each of these studies credible? Because of this, Bill Lambert feels that the committee needs to review the studies being considered to understand the details of where the numbers came from, rather than trusting OEHHA's calculations. The committee needs to make sure that it calculates a unit risk estimate value that makes sense, and one that they find to be technically acceptable – in other words, an empirically-based ABC for diesel particulate matter that would be generated by the committee. Otherwise, maybe the committee should just default to use of the OEHHA 1998 unit risk estimate, although he doesn't believe this is a robust approach.

Bruce Hope responded by saying that, based on all of the information he has read over the past few weeks, he thinks even less of OEHHA's 1998 unit risk estimate than he did previously. It appears to Bruce Hope that OEHHA chose this value primarily for political reasons, and then just ran with it. This happened in spite of the fact that Garshick himself showed up at one of their public meetings, and told OEHHA that they couldn't use his study data to calculate their unit risk estimate, as their protocol was inappropriate and not scientifically credible. In light of this information, Bruce Hope would prefer that the committee go with the approach that Bill Lambert suggested: carefully review the basis of the numbers, collapse them to a single value for each study, and then generate a geometric mean. This would also involve committee-generated rules for choosing to include or exclude the various studies. Bruce Hope explained that the reason he doesn't think the committee should simply default to using the OEHHA 1998 unit risk estimate is because he thinks it's extremely important for the committee to have a well-thought-out approach that it feels comfortable with. He suggested that the committee should think about calculating their own unit risk estimate values, based on the risk ratio results available in most of the studies being considered.

Bill Lambert agreed that the committee should calculate its own unit risk estimate values. A committee member warned that doing this could be a complex undertaking. Bill Lambert agreed, and segued into discussing his slides that present work by Robert Park (of the Risk Evaluation Branch, NIOSH CDC, Cincinnati Ohio). Park presented this material at the Health Effects Institute's Diesel Epidemiology Workshop held on March 6, 2014 in Boston, which might offer another way to look at risk related to diesel particulate matter.

Bill Lambert explained that the Health Effects Institute 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. Typically, HEI receives half of its core funds from the U.S. Environmental Protection Agency and half from the worldwide motor vehicle industry. Other public and private organizations periodically support special projects or certain research programs. Lambert then
presented slides from that talk. The link to some of the presentations from the HEI workshop can be accessed here: http://www.healtheffects.org/Workshops/DieselWorkshop2014/DieslEpiWorkshop2014.html.

Park talked in particular about the challenges related to measuring exposure in worker populations and estimating risk. This makes sense because his population of concern is occupational workers. Park looked at the diesel exhaust miner study information, including publications by Hatfield and Silverman published in 2012, which estimated health risks based on a 45-year working life. The risk level of concern for workers that Park refers to, which is a one-in-a-thousand risk (and used by NIOSH as a standard risk assessment specification), is different than the one-in-a-million lifetime risk that we apply to the involuntarily exposed public, including sensitive populations. Bill Lambert summarized Park's back-of-the-envelope calculation of risk, folding in the excess lifetime risk from exposure at an acceptable level of one-in-a-thousand risk of excess lung cancers, resulting in a concentration of respirable elemental carbon of 0.42 ug/m^3. Parks also estimated a respirable elemental carbon concentration of 0.1 ug/m^3, based on an exposure of 24 hours per day, seven days a week. Park used the data from the miner studies, which are considered to be superior because the studies controlled well for smoking. Also, the miner studies prospectively collected exposure data on the workers. Park's calculations result in a recommended exposure concentration for occupational workers based on a 45-year lifetime working exposure duration. Workers are exposed to much higher levels of toxics than the environmental level observed in communities. Park calculates an excess relative risk that represents cumulative risk for these cumulative years of exposure, 649 ug/m^3 -years.

This simple calculation, as rough as it is, relates to what we see in terms of exposure in the population, and also for the railroad workers, trucking workers, miners, dock workers, and the range of exposures at least in the 1990's under the old diesel mixture of the fleet. This approach might be one that the committee can use to take the relative risk estimates from different studies and convert them to concentrations that are protective to a one-in-a-million risk, which would be appropriate pool of data from which to obtain an ambient benchmark concentration for diesel particulate matter.

Bill Lambert pointed out the papers that had received the greatest amount of attention from the panel of experts at the diesel workshop, which was a panel made up of university researchers and individuals who have in the past been critical of these studies, including Kenny Crump and Paul Morfield. For any of these studies referred to by Park, particularly where the toxicological endpoint is the development of cancer, a lag time of 5 to 15 years needs to be included and the cancer effects documented, as in many cases that is how long it takes for cancer to develop post-exposure. It's also important to note that in the U.S., we will continue to see lower and lower levels of diesel in the environment as the new-technology cars and truck fleets come in. In addition, we also know that the toxicity (or potency) of diesel particles emitted from the new fleet will tend to be lower than that assessed in animal studies. So, Park warned that future diesel studies will need to be hundreds of times larger than the studies done in the miners group, and these kinds of studies probably won't occur in the next ten years. In light of this, Park is suggesting that alternative approaches could be used to try to identify non-adverse levels of diesel. Bill Lambert believes that this presentation by Park is useful for the committee to consider, and could provide the committee some ability mathematically to calculate a value, or suggest an approach that we might be able to use in coming up with a risk estimate based on available worker studies.

Bruce Hope cautioned that care should be taken in extrapolating from Park's concentration-based on a one-in-a-thousand risk to a value that is protective at a one-in-a-million risk, because the concentrations may not be consistent with a linear response at the low-dose end of the effects range. He pointed out that if the committee were to perform this extrapolation right now, and assume that the dose-effect relationship is linear, the result would be a concentration that is in the same range as the lower numbers the committee has already discussed today: 0.001 to 0.003 ug/m^3. Bill Lambert agreed, and said that if the committee can see convergence between the geometric mean approach and the Park calculations, it may help the committee to choose a range of values with which it feels comfortable.

Bruce Hope reminded the committee that it is advising DEQ about a shifting area of technical knowledge that has a lot of uncertainty associated with it. He would like to see the committee be able to answer the question with a rigorous statistical approach, but which type of statistical approach to use is hard to determine. If the committee recommends "X" concentration as the ABC, and DEQ adopts "X" as the ABC, and the program runs on the basis of that ABC, then the problem is that ten years from, now someone will say that the ABC chosen by the ATSAC in 2015 is still protective enough. Hope suggested that a range of values, rather than a single value might be more appropriate for the committee to consider. Then, this approach could be "backstopped" with a memorandum that explains why the committee identified a range of values to use as an ABC for diesel particulate matter.

Bill Lambert added that whatever approach the committee chooses must be scientifically defensible and transparent. He doubts that there will be any new studies on diesel within the next 10 years that will allow the committee to finally see whether or not it "chose correctly" in 2015, because the use of an older engine fleet will have faded away by that time. This is all the more reason to document exactly why we will make the choices we will make now. He said the committee needs to lay out the steps, and in part that's been the difficulty with interpreting the OEHHA 1998 approach, because detailed descriptions of how they made their decisions are not available. In the end, if the committee can recommend a number that's based empirically on the data, and then also considers some of the limitations of the interpretation of that number, then we will have done our job.

Bill Lambert volunteered to come up with a draft proposal that would consider how to calculate unit risk estimates from each study, and provide recommendations about how to choose which studies to include. He said that once these steps are completed, we can then calculate a geometric mean from the data we generate. Farrer stated that this sounded like a lot of work, but is a good idea.

Dean Atkinson said the one thing that he would push back on is the likely geometric mean values that Bruce Hope mentioned earlier, ranging from 0.001 to 0.003 ug/m^3. Dean Atkinson thinks the range should be from 0.001 to 0.1 ug/m^3, in order to include the ABC value chosen for diesel particulate matter in 2005.

Bruce Hope clarified his earlier statement, saying that he was simply referring to the fact that no matter which of the studies we've discussed today are grouped together in order to generate a geometric mean, all of the resulting values fall into the range of 0.001 to 0.003 ug/m^3. One benefit of ending up with a geometric mean of this size is that the number we choose would be concurrent with the OEHHA 1998 unit risk estimate, a choice which would be advantageous from a policy perspective. Right now, California uses the OEHHA 1998 unit risk estimate in their programs, as do certain other states such as Washington, which adopted the OEHHA 1998 unit risk estimate.

Bill Lambert agreed, and said that he feels the committee has been appropriately skeptical of the OEHHA process and the resulting unit risk estimate. If the committee can generate their own unit risk estimates from a chosen pool of studies, the results can provide reassurance to us as scientists, that the number we choose as the ABC for diesel particulate matter is in the ballpark of other, similar values. If our final number falls within the range of 0.001 to 0.003 ug/m^3, then that value will be 100 times more stringent than the current ABC of 0.1 ug/m^3.

Bruce Hope said he's not debating the number; but he wants to be clear. He would feel much better if the committee members came up with the number themselves, so that it is a number that the committee can explain in regard to how it was generated. If it happens that the number generated by the committee turns out to be the same number as the OEHHA unit risk estimate, that's fine. But in this case, the number we generate will be a number that we feel is credible, rather than simply defaulting to the OEHHA value, which we don't trust.

Bill Lambert pointed out that the ATSAC's earlier discussion about diesel particulate matter in 2005 resulted in the committee choosing a value that really was at the upper bound of a range of estimates published by the World Health Organization in 1996, and which included both animal and epidemiological studies. That's what the committee was comfortable with at the time. But since then – about 10 years --- the World Health Organization data from 1996 that relied partly on rodent studies conducted in the mid-1980s have become less reliable in terms of allowing credible extrapolation to human effects. He thinks the committee's old ABC certainly has aged and is now behind the current state of the science.

Bruce Hope said that in 1998, EPA itself came up with the concentration of 0.1 micrograms per cubic meter as an upper-bound of a range of values. They later withdrew this value from their

Integrated Risk Information System, but nonetheless, both the World Health Organization and the EPA agreed on this value back in the day. For him, it is a matter of updating the science, and providing DEQ with a number that the committee can support, because the committee members will have worked it out themselves. He thinks a number based on more than one study is a stronger number.

Bill Lambert said that everyone on the committee will be tasked with reviewing his draft diesel particulate matter memorandum, which he will need to create fairly quickly if it's to be discussed at the October 2015 ATSAC meeting. He thinks that deciding on this approach shows real progress, and that the committee can be proud of its work on diesel over the past three months.

Sue MacMillan brought up her previous proposal in regard to which TEFs to use to convert individual PAH concentrations prior to summing the results to get a concentration of total PAHs. She wants the committee to use the average TEF in each case, instead of the upper-bound value of the range of TEFs originally proposed by Bruce Hope. This change would make the ATSAC's recommended approach for the ABC for total PAHs consistent with use of TEFs for PAHs by other federal and state agencies, including DEQ's Cleanup Program. Bill Lambert asked whether this change would only alter the way we would calculate PAH sample results, but not the ABC itself, and.
Sue MacMillan responded that the ABC that the ATSAC voted unanimously to accept at the July ATSAC meeting would not change. Sue MacMillan also explained that benzo(a)pyrene and pyrene had been added to the list, while perlyene was removed, in order to be consistent with the typical list of 16 PAHs that EPA generally refers to.

Bill Lambert then reiterated that the recommendation from the DEQ is that we use the average TEF value for each PAH as the best estimate of potency relative to benzo(a)pyrene, as opposed to the upper-bound TEF value. He then asked the committee to vote on this change. The committee unanimously voted to accept the proposed change.

Bill Lambert then checked in with attending DEQ staff to ask them if they had any comments on the committee's deliberations so far, particularly in regard to the diesel particulate matter discussion. There were no comments from DEQ staff.

Formaldehyde

Bill Lambert and Max Hueftle had been tasked with presenting current toxicity information that is available for formaldehyde. Max Hueftle explained that the current ABC for formaldehyde is 3 ug/m^3, which was based on the 2000 OEHHA Reference Exposure Level value. The EPA Integrated Risk Information System database IRIS (typically referred to as IRIS) currently lists an inhalation unit risk factor of 1.3×10^{-5} per ug/m^3, which, when converted to a concentration that is protective of human health at a risk target of 1×10^{-6}, is 0.08 ug/m^3.

Max Hueftle went on to explain that for non-cancer effects, OEHHA revised its Reference Exposure Level in 2008 to 9 ug/m^3, based on some additional studies and evaluation of the data. Formaldehyde previously had been estimated to have one of the highest cancer risks, based on information from EPA's national air toxics assessment program; and based on the pre-public review of the 2011 data, formaldehyde will still have one of the highest cancer risks estimated. Hueftle is not sure which benchmark value EPA used to estimate that risk, but the modeled value from EPA is 17.8 excess incidents of cancer risk over a lifetime, in a population of one million people for Oregon statewide. This is an estimate similar to what's been calculated for formaldehyde in Lane County, Oregon. So, it's very important to determine safe protective levels for formaldehyde in air.

Max Hueftle recommended using the OHHEA cancer value of 0.2 ug/m^3 as the ABC for formaldehyde. By default, because the cancer value is more stringent than the non-cancer values, this recommended value would also be protective of non-cancer effects. Bill Lambert thanked him and added that the current IRIS unit risk estimate (which converts to a protective concentration of 0.08 ug/m^3) and OEHHA unit risk estimate (which converts to a protective concentration of 0.17 ug/m3, which in turns rounds up to 0.2 ug/m^3) are both based on a rat inhalation study conducted by Kerns, et al. back in 1983. This was a rat inhalation study that IRIS felt provided reliable information, and later on California OEHHA also utilized it. It should be noted that US EPA classified formaldehyde as a Class B1 (probable human) carcinogen, while the International Agency for Research on Cancer classifies formaldehyde as a 2A (probable human) carcinogen.

Bill Lambert added that in 2014, in the National Toxicology Program's *13th Report on Carcinogens (RoC)*, formaldehyde was classified as a known human carcinogen. Cancer is induced at levels much lower than levels at which we see non-cancer effects, such as irritation of the mucus membranes and inflammation of the respiratory track. In May 2014, EPA held a formaldehyde workshop and it was convened in order to consider other health outcomes, as well as the evidence supporting concern about the induction of leukemia and lymphomas due to exposure to formaldehyde. No consensus publication resulted from that workshop. There is some discussion of leukemia and lymphoma in the National Toxicology Program's RoC, but IRIS and OHHEA benchmarks for formaldehyde are based on the endpoint effects of nasal cancers.

Max Hueftle clarified that the reason for his uncertainty in regard to the IRIS value for formaldehyde was because the IRIS file states that an inhalation unit risk value was "not evaluated" in its front-end summary of information on formaldehyde, but an inhalation unit risk value of 1.3×10^{-5} per ug/m^3 is presented in the text of the file, along with a related value of 0.08 ug/m^3, which is the concentration at which people would be protected at a target excess cancer level of 1×10^{-6}.

Bill Lambert mentioned that, as he understands it, the endogenous (or inside-the-body) production of formaldehyde was being considered, because although formaldehyde is a naturally-occurring substance outside the body, it is also produced inside the body, which means it's always present and people are always being exposed to it at some level. This type of mechanism infers that that a certain threshold concentration probably exists, and that's what the current scientific discussion is about. The other concern that was being discussed at the meeting was in regard to formaldehyde exposure causing leukemia, lymphomas, and hepatotoxicity (liver toxicity). However, there appear to be some animal studies related to this question, but at this point in time his understanding is that there is not yet a lot of hard evidence, although studies are in progress. Interest and funding for formaldehyde toxicity research was spurred by the unfortunate situation that occurred with the FEMA trailers deployed after Katrina to New Orleans. After they were no longer needed in New Orleans, those trailers weren't destroyed, but instead were resold. These trailers continue to be used for housing, unfortunately, around the United States,
particularly in the Midwest. The formaldehyde released to air from these trailers is still occurring at levels that cause adverse health effects, although over time the concentration of formaldehyde in air in these trailers has decreased to about 15 parts per million. Because of all this, new formaldehyde research is in the process of being published, but it's not available right now.

A committee member presented some information from the National Toxicology Program's Report on Carcinogens. The Report on Carcinogens is a science-based, public health document prepared by the National Toxicology Program that identifies substances in our environment considered to be cancer hazards. The Report on Carcinogens considered human, animal, and mechanistic studies published through November 8, 2013 that focused on the potential for formaldehyde exposure to cause nasopharyngeal cancer. Based on these findings, the National Toxicology Program committee concluded that formaldehyde is *known to be a human carcinogen* based on sufficient evidence of carcinogenicity from studies in humans and supporting data on the mechanisms of carcinogenicity. The committee member explained that, in worker studies, we see an outcome of nasopharyngeal cancers, squamous cell cancers, and other dysplasias related to formaldehyde exposure, and intermediate endpoints of dysplasias in the epithelium of the naso-turbinate and pharyngeal passages. The unit risk estimate being considered for use as an ABC by the committee is based on the study by Kerns et al. in 1983, which was conducted with 120 rats exposed for a six-month period, six hours a day, at *environmental* levels of exposure, rather than occupational worker exposure levels.

As the discussion on formaldehyde concluded, Bill Lambert summarized the information presented. He recommended that the OEHHA value of 0.2 ug/m^3 be used as the ABC for formaldehyde, although the IRIS unit risk estimate is lower (0.08 ug/m^3 and was based on the same study that OEHHA reviewed. It is the committee's policy to choose the higher (less stringent) protective value, when both value choices are based on the same study. Therefore, he also recommended (in agreement with Max Hueftle) that the committee choose the concentration of 0.2 ug/m^3 as the ABC for formaldehyde. This recommended ABC is about an order of magnitude more stringent than the current ABC of 3 ug/m^3.

The committee voted unanimously to recommend an ABC of 0.2 microgram per cubic meter for formaldehyde.

Bill Lambert then added that there was something he wanted to put on the record: OEHHA, under the Children's Environmental Health Protection Act in 2001, specifically assessed formaldehyde as a hazard for asthma development and exacerbation in children. They found that higher levels of formaldehyde were necessary in order to induce respiratory health effects related to asthma in kids. In light of this, then, the cancer-based benchmark value of 0.2 ug/m^3 is still the appropriate concentration to recommend as the ABC for formaldehyde.

n-Hexane

David Farrer and Dave Stone then began the discussion of toxicity information for the chemical n-hexane. The current ABC for n-hexane is 7,000 ug/m^3, which is based on the 2000 OEHHA Reference Exposure Level. Dave Farrer explained that n-hexane is a simple mid-length carbon chain used to extract vegetable oils from seeds, such as sunflower seeds or safflower seeds. It's also used as an industrial solvent, and is a common component of gasoline. So when gasoline is spilled, there will be a lot of n-hexane in the air. This chemical also has neurological effects, with the critical endpoint in most studies being peripheral neuropathy. David Farrer recommended that the committee choose the IRIS inhalation reference concentration of 700 ug/m^3 as the ABC for n-hexane, as he referred to a slide showing a summary table of n-hexane toxicity values (the other two available values were the OEHHA chronic Reference Exposure Level of 7,000 ug/m^3, and the ATSDR chronic Minimal Risk Level of 2,100 ug/m^3, listed by the Agency for Toxic Substances and Disease Control (also known as ATSDR).

David Farrer pointed out that the IRIS value is the most recent toxicity value available. The number came from a study done by Huang et al. 1989, using four dose groups of eight mice each. The mice were dosed for 12 hours a day, seven days a week, for 16 weeks. The study measured some biochemical endpoints, including changes the in nervous-system-specific proteins neuron-specific enolase and beta S-100. The researchers weren't sure what to do with this information, so the toxicological point of departure they chose to use was based on the velocity of motor neuron conductance. On the summary table presented by Farrer on the projector, it could be seen that points of departure for all three studies were similar, at concentrations of 204, 205, and 215 milligrams per cubic meter. But due to different applications of uncertainty factors, the three studies came up with different toxicity values.

Dave Stone agreed that the IRIS number seemed to him to be the most credible toxicity value. The personal stories that Dave knows of researchers who were very active in toxicology labs back in the1960s and 1970s, and who used n-hexane before we knew some of the things we know now about it, used n-hexane without gloves. Many of them have very painful peripheral neuropathy now and they attribute it to those days in the lab.

Bill Lambert summarized the discussion of n-hexane by repeating the key study in this case is the one by Huang et al. 1989, on which the IRIS inhalation reference concentration of 700 ug/m^3 is based. He then called for a vote.
The committee voted unanimously to recommend 700 ug/m^3 as the ABC for n-hexane, which is an order of magnitude more stringent than the current ABC for n-hexane of 7,000 ug/m^3.

Methyl chloroform aka 1,1,1-trichloroethane

Dean Atkinson presented toxicity information for methyl chloroform, also known as 1,1,1-trichloroethane. He explained that methyl chloroform, which is actually better known as 1,1,1-trichloroethane, is used as a solvent, and is a colorless liquid with a fairly high vapor pressure. Although Atkinson did not create a summary table, the two toxicity values he thinks should be considered as possible choices for the ABC for 1,1,1-trichloroethane are 1 ug/$m^3$and 5 ug/m^3.The current ABC is 1,000 ug/m^3 (which is equivalent to 1 *milligram* per cubic meter, or 1 mg/m^3). Back in 2006, when the committee chose the current ABC, there was no IRIS value available, so the committee went with the 2000 OEHHA reference exposure level, which was the same toxicity value used by NATA to estimate air risks in 1999. In 2007, IRIS came out with a chronic inhalation reference concentration, and also sub-chronic, short-term, and acute inhalation reference concentrations based on animal studies, but consistent with all the human studies. All epidemiological studies identified effect endpoints that are associated with decreases in cognitive response.

In addition, the experimental literature suggests that chronic exposure to 1,1,1-trichloroethane induces hepatocellular hypertrophy at concentrations of 1,370 to 1,460 milligrams per cubic meter, and that these effects do not appear to progress in severity or incidence with exposure duration and are considered a physiological rather than adverse response. So it’s not even clear whether it’s really a chemical response or a physiological response. Atkinson pointed out that, either way, 1,1,1-trichloroethane is not a particularly toxic compound. He explained that the committee has one of two ways to go in choosing an ABC: Either recommend a new concentration of 5 milligrams per cubic meter as the ABC in order to be congruent with the IRIS value, or retain the current ABC for 1,1,1-trichloroethane of 1 milligram per cubic meter. He thinks it unlikely that monitored concentrations of 1,1,1-trichloroethane will exceed either of the two chronic-exposure-based levels that are being considered, and there’s only a difference of a factor of five between the two values, which is less than a difference of one order of magnitude. Atkinson is on the fence about which of these values to recommend as the ABC for 1,1,1-trichloroethane, but feels that, overall, the current ABC should be revised to a value of 5 milligrams per cubic meter, because that’s the value that IRIS uses.

One committee member mentioned that some of the technical information available for this chemical indicates that the chronic studies indicate a protective target value that is even higher than the 5 milligrams per cubic meter value we just discussed. But at the time these studies were performed, a value protective of acute exposures was found to be lower (more stringent) than the protective chronic level; so the researchers basically lowered the chronic level down to match the acute level, because it just seemed counterintuitive that chronic exposure would be less bad than acute exposure. Acute exposure levels are nearly always less stringent than chronic exposure levels, due to the shorter exposure duration that occurs with acute exposure.

Another committee member said that two studies were conducted for 1,1,1-trichloroethane to look for cancer outcomes. But the rats used in the studies didn’t survive long enough to determine whether or not cancer would occur, so 1,1,1-trichloroethane was deemed a Class D carcinogen because the data was considered inadequate.

Dean Aktinson asked if the final recommendation was to increase the current ABC of 1,000 ug/m^3 to 5,000 ug/m^3, or 5 milligrams per cubic meter, to be consistent with IRIS. Bill Lambert responded that it was the value of 5,000 ug/m^3.

Lambert called for a vote on this revision, and the committee voted unanimously to recommend a new ABC of 5,000 ug/m^3 for methyl chloroform/1,1,1-trichloroethane.

Items for next meeting

Bill Lambert then suggested that the committee plan their work for the October 2015 ATSAC meeting. He asked Sue MacMillan if she had gotten approval from the committee by email to approve the meeting minutes for the May 2015 ATSAC meeting. She said that yes, they had been approved by the committee, and were in the process of being formatted for posting to the ATSAC website. Bill Lambert said that additional meeting minutes for the June and July ATSAC meeting would be coming to the committee soon for review. Bill Lambert committed to sending the committee a draft approach for the diesel unit risk estimate calculations in enough time for them to review it prior to the October meeting, and then the committee can discuss the approach at the October meeting.

Dean Atkinson asked whether the committee plans on giving any guidance to DEQ about how diesel should actually be measured. Bill Lambert responded that the committee could have a discussion on guidance that we might recommend to DEQ in regard to measuring and modeling of diesel in air. One approach might be to measure or model elemental carbon, for example. Bruce Hope pointed out that this would be a modeling discussion, but that the question is really about how diesel particulate matter should be measured in the field. He said that he's unclear on whether an established method exists that can accurately measure diesel particulate matter. For that reason, Bruce Hope thinks that the committee needs to recommend an approach to DEQ that will help guide the way to consistently and accurately measure this compound.

Sue MacMillan stated that it wouldn't hurt for the ATSAC to give their opinion on monitoring and modeling protocols, but in the end this is an issue that DEQ will probably have to figure out. Bill Lambert acknowledged this fact, but stated that the committee has strong feelings about the technical aspects of measuring and modeling diesel particulate matter, and so will want to make recommendations to DEQ about how to do this. Bill Lambert suggested that the committee review three more chemicals in addition to the planned discussion on diesel, and work in pairs as usual, in preparation for the October ATSAC meeting.

Sue MacMillan, with Max Hueftle's assistance, requested that the committee review hydrogen cyanide, hydrogen sulfide, elemental mercury, and white phosphorus, based on an earlier screening conducted by Sue MacMillan. Bruce Hope asked why white phosphorus needed to be reviewed. Sue MacMillan explained that she had retained white phosphorus for review because the notes for it in the 2010 ABC table are a little unclear. She wanted to be sure that the committee was aware of this, and that the committee should decide whether or not to review it.

Dean Atkinson asked if separate ABCs were available for elemental mercury and for methyl mercury. Sue MacMillan pointed out that the 2010 ABC tables indicate that only elemental mercury has an assigned value. On that basis, Bill Lambert suggested that the committee focus on elemental mercury for its review. Bruce Hope stated that the ATSAC had earlier looked at multiple pathways of exposure related to elemental mercury being present in air, especially in light of the fact that elemental mercury becomes methylated in biological systems to produce methyl mercury, which is a bioaccumulative compound. Earlier modeling conducted by DEQ demonstrated that the ABC chosen for elemental mercury at that time was protective of both direct exposure to mercury and indirect exposure, which occurs via "downstream" exposure to mercury through exposure pathways other than inhalation of air – for example, ingestion by humans of fish which end up containing methyl mercury in their tissues.

At the October 2015 ATSAC meeting, Bruce Hope and Dave Stone will provide information on hydrogen sulfide; hydrogen cyanide will be reviewed by Max Hueftle and Kent Norville; Bruce Hope will do a brief review of white phosphorus, and Dean Atkinson and David Farrer will review elemental mercury. Lambert will work on creating a draft approach memorandum detailing a committee-specific calculation of unit risk estimates and a geometric mean for diesel particulate matter. The October ATSAC meeting will be held from 9 a.m. to noon on Oct. 21, 2015, in conference room EQC-A at the DEQ headquarters building.

Comments from the audience

Dale Feik began with a number of comments unrelated to what the ATSAC had discussed during the meeting, and Lambert politely directed Feik to limit his comments to those which were relevant to ATSAC issues. Feik then said that the committee's concern with significant digits doesn't make a whole lot of difference, in the end. Feik then urged the committee to err on the side of protecting public health by using a more conservative risk factor for formaldehyde, since studies have shown that workers exposed to formaldehyde have developed amyotrophic lateral sclerosis (more commonly referred to as ALS, or Lou Gehrig's Disease). Feik then asked the committee how they were going to look at nanotechnology, which puts very tiny particles into the air – again, to protect public health. Feik urged the committee to use the "precautionary principle", which basically says to make conservative assumptions when a chemical or an activity is thought to cause adverse effects, even if the connection is not fully established scientifically.

Bill Lambert responded that the committee does use the precautionary principle, as in the case of formaldehyde ABC, which the committee just voted to decrease to a concentration of 0.2 ug/m^3, which is an order of magnitude more stringent than the original ABC of 3 ug/m^3. The committee DOES err on the side of stringency, based on the amount of uncertainty attached to the studies being reviewed for a particular chemical. So the committee is already meeting the intent of Dale Feik's charge. Also, the committee is grappling with diesel as a complex mixture, which includes assessment of ultrafine particles.

John Krallman, an attorney for Neighbors for Clean Air and an adjunct professor at Lewis and Clark Law School, made a number of comments:
He is glad that multi-media exposure pathways will be included in the discussion of elemental mercury at the next ATSAC meeting; it is important that this consideration be rolled into the ABC decision.

He brought up an issue he had in regard to the ABC for methyl chloroform. Although he doesn't consider it a grave concern, a standing rule of this committee was to not change a value if two values being considered as a potential ABC were less than an order of magnitude apart. He thought the committee, on that basis, shouldn't change the ABC for methyl chloroform.

He believes that the current ABC for diesel particulate matter is not protective. Krallman urged the committee to choose a lower number. And maybe add uncertainty factors to the number that is chosen as the ABC for diesel particulate matter to preemptively protect ourselves from diesel exposure 10 years from now. DPM contains other toxic chemicals such as lead, which hasn't been discussed very much. And we'll probably identify other concerns as our knowledge about diesel particulate matter increases; so adding uncertainty factors to the number would be more likely to be protective even in the future.

Bill Lambert stated that the next ATSAC meeting will be held at the usual time, from 9 am to Noon on Oct. 21, 2015, in this same location. He then adjourned the meeting.

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