

VIRGINIA INHALATION TOXICOLOGY ADVISORY GROUP

MINUTES-UNAPPROVED DRAFT

SECOND MEETING FEBRUARY 19, 2009

TIME AND PLACE: 9:00AM – 12:00 PM

DEQ Central Office
629 E. Main Street
Richmond, VA 22469
Conference Room A

PRESIDING: Patricia McMurray, DEQ Risk Assessor Program Manager

MEMBERS PRESENT:

Chris Bednar, Smurfit-Stone, (VMA)
Robert Corley, Ph. D., Virginia State University
Jim Gould, Sierra Club
John Morris, Ph.D., University of Connecticut (SOT)-by phone
Debbie Mulrooney, Dupont (VMA)
Kevin Wallace, M. D., University of Virginia-by phone
Kimber White, Ph. D., Virginia Commonwealth University

STAFF PRESENT:

Patty Buonviri, Air Toxics
Kyle Newman, Risk Assessor, Office of Remediation Programs (Recorder)

An attempt to use NetMeeting to tie-in the participants on the phone was not successful.

The meeting agenda was reviewed. The intent was to discuss non-cancer toxicity factors and come to consensus on a process and begin to discuss cancer toxicity factors if time allowed.

The meeting minutes from the first meeting were approved without changes. The group liked the level of detail of the minutes. The final minutes will be posted on the Virginia Town Hall within three days of approval. See <http://www.townhall.state.va.us/L/meetings.cfm> for the minutes from the last meeting.

Power Point presentations from the meetings will be sent to the group.

ACTION:DEQ

The draft decision tree from the last meeting was reviewed. The group discussed the options for addressing chemicals for which the toxicity values from CalEPA and U. S. EPA are less than three times different. One member asked about the rationale for choosing three times as the criterion for designating a value as essentially the same. The three times is based on the uncertainty factors applied to a point of departure. The group decided to maintain the three times criterion. The options were to choose: the most conservative (protective), the most recently reviewed, the most recent study, CalEPA value, U. S. EPA value, or an average value. It was suggested that the most recent review would reflect the best science and recent approaches. The group agreed. One member cautioned that study bias should be considered. This would involve going back to the original papers. It was later agreed that this would only be necessary for the chemicals with values that differ by greater than three.

CONSENSUS: For chemicals with values that differ by less than 3 times, DEQ should choose the value based on the most recent review.

DEQ began review of the chemicals that varied by greater than 3 times due to CalEPA and U. S. EPA choosing different critical studies. Most of the studies are inhalation but there may be a few by drinking water, no injection studies were noted.

Acrolein: CalEPA had the most recent review. The value was based on a newer study with a NOAEL rather than just a LOAEL.

Carbon Tetrachloride: U. S. EPA had the most recent review based on a newer study. One member questioned why we needed to look at the non-cancer value since carbon tetrachloride is a carcinogen. DEQ noted that for chemicals that are both we will need to develop both numbers to demonstrate which endpoint is the driver. (Most of the time, the carcinogenic effect will drive.)

Chloroform: CalEPA had the most recent review. Cal picked an animal study over a human study because the human study that U.S. EPA used had confounding factors of viral hepatitis and jaundice in the subjects. (A confounding factor is a variable that could mask an association between a chemical and an effect or that could suggest an effect is caused by the chemical when it's really not. Other examples are tobacco and alcohol use and Tylenol.)

Ethylene dichloride: U. S. EPA had the most recent review. CalEPA disagreed with the study that U. S. EPA used because it had a free-standing NOAEL and did not adjust for continuous exposure. The CalEPA study also used a more sensitive critical effect (liver enzymes.)

Methylene chloride: The reviews were done the same year. It is not clear why U.S. EPA did not use the human study used by CalEPA. It was noted that sometimes an animal study may be preferred because it can be better controlled. The timeframe for measurement (end of shift) in a human study may also impact the result.

Toluene: U. S. EPA had the most recent review. CalEPA used a rat study over a human study because the rat study had a more sensitive endpoint.

Xylenes: U. S. EPA had the most recent review. U. S. EPA picked a rat study over a human study because they had concerns with the human study such as self-reporting, lack reporting of exposure duration, and no clear dose-response.

The reasons for choosing one study over another may be difficult to fit into a decision tree. One member suggested that since there were a limited number of chemicals, the VINTAG could review and provide recommendations. It was also suggested that chemicals with differences that rounded to 3 or less could be eliminated.

DEQ could provide the U. S. EPA and CalEPA support documents and the papers that describe the critical study. Each VINTAG member could be the primary reviewer for 1 or 2 chemicals. At the next meeting they could report back to the group with recommendations. Criteria for reviewing the chemicals would be needed. The approach could work for the current list of chemicals with different values but it could be a problem for future reviews. Options would be to reconvene the group periodically or for DEQ to do periodic reviews internally. DEQ would probably want outside experts for controversial chemicals.

One member questioned whether sulfides would be covered. DEQ currently uses the EPA HAPs list. Sulfides aren't listed as a group but a few (hydrogen sulfide, carbon disulfide) are on the list. A method for adding chemicals to the list can be discussed.

One member noted that we are going to have 4 sets of chemicals to review and it may be too time consuming to look at all. DEQ has already looked at the cancer list and there are about 14 or 15 that differ by 3 or more times. One member also noted that we may want to have a different panel to look at carcinogens. Based on DEQ review so far, the carcinogens require a lot more professional judgment and therefore a panel review may be a good approach.

One member noted that we couldn't do a detailed review of all references but they can be skimmed for a general idea. We can do a triage and see if there are any that will need a more detailed review. We can eliminate hydrogen cyanide, chloroform, epichlorohydrin, ethyl chloride, naphthalene, and methylene chloride since they round to less than 3 times difference.

The members agreed to split the remaining nine chemicals. One member will be the primary reviewer of each. They will also try to at least skim the others. The members that do not have a strong toxicology background may get help from toxicologists in their organization if needed. DEQ will provide the CalEPA and U. S. EPA documents to the group as well as the critical study papers. A primary reviewer was assigned for acetaldehyde, acrolein, carbon tetrachloride, ethylene dichloride, mercury, tetrachloroethylene, toluene, triethylamine, and xylenes. The majority of these had differences due to different study selection. However, mercury was based on different

uncertainty factors and acetaldehyde was based on a different point of departure from the same study.

ACTION: DEQ will provide support documents and critical study papers.

It was suggested that the group should have standard criteria for review. We need consensus on terminology like “external validity” (how relevant is a rat inhalation study to human inhalation.) One member volunteered to draft a list of study criteria to consider.

ACTION: DEQ will distribute draft criteria and coordinate comments.

One member asked if the values will go out for public comment. They will be subject to public comment if/when they are added to the regulations.

One member suggested that we look at the New Jersey numbers as a check of our process.

ADJORN FOR BREAK

It appears that New Jersey has chosen the most conservative number for non-carcinogens. This may have been a policy decision.

ACTION: DEQ will look into whether NJ has a documented rationale for choosing their numbers.

DEQ noted that there may be occasions that industries will want to petition the department to use alternate values. DEQ will need input from the VINTAG on what the minimum requirements would be for deviating from the selected numbers. One member suggested that they would need to have good quality human data. One member gave an example from the water regulations. Companies could calculate their own bioconcentration factor but they had to agree to use it even if it were to their disadvantage. It’s not exactly relevant to air but may be able to do something similar. We could look at other states. Texas allows facilities to challenge their ESL but their numbers are not in the regulation so the process is more flexible.

DEQ noted that the process will also need to address whether it is acceptable to use draft value. TCE is an example. EPA has issued a draft document but is still using the older CalEPA value.

The decision tree will need to have an approach to uncertainty.

The group began the discussion of cancer toxicity values. We may need to bring in experts for particular chemicals. The cancer evaluations will require more expertise to evaluate such issues as the relevance of mutagenicity and animal receptors.

A draft handout was distributed of the carcinogens that differ by 3 times or greater. DEQ noted that most of the chemicals that differed were older and the documentation was not always clear.

Chloroform may be controversial. It's a question of using the linear multistage model vs. a non-threshold model. The current panel is not expert in that type of judgment. We could take a simplistic approach and just use the most conservative number. This could be a problem for chemicals that differ by orders of magnitude, such as formaldehyde. Formaldehyde is a unique case. The number used by the EPA Office of Air Toxics is a value developed by the Chemical Industry Institute of Toxicology (CIIT) based on a fluid dynamic/two stage clonal growth model. DEQ would definitely need experts to evaluate.

One member suggested that it would make sense to use a 10 times factor for the cancer evaluation. Other members were comfortable with that since low-dose extrapolation is imprecise and the uncertainty can be an order of magnitude or more.

It was noted that the cancer toxicity factors are unit risk factors not air concentrations. The acceptable risk divided by the unit risk will give the acceptable air concentration. The acceptable risk level will be a management decision at DEQ.

If we use a 10 times factor for carcinogens there would only be two compounds that would need to be evaluated in detail.

Another option would be to select the more conservative number if they differ by more than 10 times and to select the most recent if they differ by less than 10 times. Industry groups could petition DEQ if they wanted to use a less conservative number. Citizen groups could also petition. This would probably be workable if we are only talking about two chemicals. If there are more in the future, it could be resource intensive for DEQ. DEQ needs to discuss this option internally.

ACTION: DEQ

The next meeting was scheduled for April 9, 2009 at 9:00 am. Members can choose the method for presenting their assigned chemicals. There is no need to prepare a formal presentation.

One member asked if the VINTAG can bring new studies to the attention of the group. While the intent is to choose values that have already been peer reviewed through U. S. EPA or Cal/EPA we can look at other relevant information. The study would need to be peer reviewed in an acceptable journal. We don't expect anyone to do a literature review.

The group felt that the process was moving forward.

The meeting adjourned early.