

DRAFT Meeting Minutes
Health Effects Subcommittee
New Jersey Drinking Water Quality Institute
March 30, 2009
401 E. State St., Trenton, NJ

Members present: Leslie McGeorge, Gloria Post, Perry Cohn; (by phone) David Pringle, Judith Klotz.

Also attending: Branden Johnson (BSDW-TA); (by phone) Keith Cooper (Rutgers).

The meeting was convened at 3 PM.

Health Effects Subcommittee Report and Basis and Background for SDW Rule

G. Post had earlier that day circulated two proposals by email to subcommittee members. The first was that all health-based maximum contaminant levels (HBMCLs) should be reported to two significant figures, although final MCLs would still be rounded to one significant figure. The second proposal was that the summary table of key health effects information used to generate revised HBMCLs, which had previously been distributed to the full DWQI for informational purposes, would be updated for inclusion in the HE Subcommittee Report. It was suggested that both revised HBMCLs and new HBMCLs be included in the Table.

The subcommittee quickly agreed that both proposals should be adopted, as providing consistency and a valuable summary of the committee's work. Comments on the table were requested from the Subcommittee members during the week following the meeting. The subcommittee also agreed to defer to G. Post and P. Cohn on proof-editing the final version of the Health Effects Subcommittee report, which will form Appendix A of the forthcoming DWQI report recommending new MCLs.

1,2,3-Trichloropropane

G. Post noted that she wrote most of the background of this draft analysis, while P. Cohn did the modeling of the cancer risk with help from California and USEPA scientists. Subcommittee members suggested focusing discussion on the modeling and the basis for the HBMCL recommendation, as they had no major questions or suggestions on earlier parts of the draft document. Minor comments on the entire document were provided in writing to G. Post by J. Klotz, L. McGeorge, and K. Cooper.

G. Post noted that it was most appropriate to base the recommendation on the National Toxicology Program cancer study, which found tumors at multiple sites early in life in both rats and mice. A year ago USEPA had issued a draft IRIS Toxicological Review document for peer review. In this document, the cancer risk assessment was based on rat tumors, rather than the mouse forestomach tumors used by California EPA in the risk assessment for its Public Health Goal. It is P. Cohn's understanding from discussions

with USEPA scientists that they are now considering moving closer to the California approach. G. Post noted that this draft IRIS document is still available online for review, so it can be provided as background.

P. Cohn said that USEPA is considering using the same assumptions and parameters as California, although this decision is not final. The California approach includes a focus on the mouse as the most sensitive species, and on forestomach tumors. The International Agency for Research on Cancer has extensive discussion of the relevance to human cancer risk of rodent forestomach tumors in its reports, and IARC information on this topic is cited in the 1,2,3-TCP document.

P. Cohn put considerable time and effort into development of the slope factor for 1,2,3-TCP. USEPA made its beta software to model time-to-tumor data available to New Jersey at no cost. This software, already used by both California and USEPA, is limited in this beta version by how it deals with tumor classification: all tumors must be considered to be fatal, or all must be considered to be incidental. In the approach used by California EPA for 1,2,3-TCP, and which P. Cohn and G. Post agreed to use for the New Jersey risk assessment, incidental tumors are those found when an animal is sacrificed according to schedule, while fatal tumors are those found upon death or sacrifice due to morbidity. Thus the software obtained by P. Cohn was incapable of carrying out the modeling using the desired approach. (The next version of the software should not have this limitation).

Both California EPA and USEPA independently ran New Jersey's desired inputs and assumptions for data from the NTP study using other software capable of carrying out the time-to-tumor modeling as desired. These two agencies obtained the same results.

L. McGeorge noted that even though the model was run by others, NJDEP still needs to provide sufficient information on the run so that there will be a transparent record of the basis for the modeling portion of the recommendation. P. Cohn suggested the model input and output could be sent to anyone who requested it; D. Pringle suggested that these be posted as an electronic appendix to the 1,2,3-trichloropropane report. G. Post suggested that this information be added as a second Appendix to the document, and this was agreed upon.

L. McGeorge noted that the California Public Health Goal from this model was 0.0007 ug/L, while New Jersey's recommended Health-based MCL is 0.0014 ug/L. G. Post explained that the slope factor is the same for both states' drinking water values, but that California EPA assumes that exposure from non-ingestion routes for VOCs (e.g. inhalation) is equal to ingestion exposure, resulting in a two-fold decrease of the drinking water concentration compared to New Jersey's conclusion. L. McGeorge suggested that the report should mention that the slope factor in the two analyses is the same, but different exposure assumptions explain the difference in the HBMCL.

Subsequent discussion concerned sentences which needed clarifying. The discussion of sensitivity analysis (p. 22) needed to clarify that the selected slope factor of 25

mg/kg/day⁻¹ (versus low and high values of 11 mg/kg/day⁻¹ and 180 mg/kg/day⁻¹ from the sensitivity analysis) was due to use of different assumptions as to classification of tumors as fatal or incidental. The tables on pp. 18-19 need to clarify that the total figures for multiple tumor types needed to specify “and/or” because some animals might have both types (e.g., both papillomas and carcinomas in the forestomach). The addition of the doses used in the NTP study in a footnote was confirmed. A short discussion of whether there is any available guidance on use of the multistage Weibull time-to-tumor model, or the degree to which choices are becoming convention in risk assessment practice, will be added.

K. Cooper suggested that a table be added by G. Post to summarize the subchronic, reproductive, and developmental effects; the NOAELs and LOAELs; and the most sensitive endpoints for these.

It was decided that G. Post will send the revised document to the Subcommittee for any further comments and for a vote of acceptance when all changes are incorporated.

Minutes of December 17, 2008 Meeting

These were approved.

Society of Toxicology Meeting

G. Post reported that the Hamner Institute has been conducting a chronic-exposure study of MTBE in drinking water for about a year, and reported at SOT that at higher doses water consumption was lower, and that the ratio of kidney to body weight increased in male rats. The highest dose used in this study is equivalent to doses used in the Belpoggi gavage study which showed tumor formation by MTBE. Because of issues with this study, the Belpoggi study was not used as the basis for calculating the NJDEP HBMCL for MTBE. No effects have yet been found in females in the Hamner Institute study. Whether MTBE is carcinogenic in this drinking water study is still unclear. K. Cooper expected that final results of the study will be available in 18-24 months from now.

G. Post reported that the PFOA poster presented at SOT by G. Post/NJDEP and K. Cooper/Rutgers University got a lot of attention and was well received. About 35 abstracts were presented at SOT on PFOA and related compounds, showing that this is an area of very active toxicology research. She attended a session on studies of immune effects of these chemicals. The C8 Science Panel presented results of its analysis of immune system effects in the study of 70,000 Ohio and West Virginia residents exposed to PFOA in drinking water. K. Cooper reported on posters about some developmental studies on PFOA being done by USEPA.

Two studies (one on rainbow trout (Tilton et al. (2008) *Env. Health Perspect.* 116: 1047-1055), and a more recent one on rodents, presented at SOT) now provide data relevant to the issue of whether liver tumors caused in rodents by PFOA are relevant to humans. This question is relevant to the mechanism of action for PFOA, but was not discussed by G.

Post in her presentation at the December HE meeting, due to lack of time. As the HE Subcommittee moves on to address PFOA, this issue will be presented and discussed in more detail.

Next Meeting

G. Post suggested that the subcommittee should deal with tertiary butyl alcohol before it deals with PFOA, because TBA can be assessed relatively quickly. She suggested that when a draft of the TBA document is available, the next meeting will be scheduled. This was agreed to by the subcommittee.

Adjournment

The meeting was adjourned at 4:05 PM.