

APPENDIX M – CDC (2014e), Personal communication with Dr. V. Kapil to WVTAP team (March 26, 2014)

The following are written responses to written questions posed to the CDC regarding MCHM and PPH. Specifically, the responses were provided by Dr. Vikas Kapil (Chief Medical Officer & Associate, Director for Science, National Center for Environmental Health & Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention).

I) WV TAP MCHM QUESTIONS

In the media, we see reference to a 50 ppb (microgram per liter) MCHM level, such as: “...Centers for Disease Control and Prevention (CDC) said that levels of MCHM below 50 parts per billion did not pose a public health concern”. The official CDC Drinking Water “Advisory Level” or “short-term screening level” for MCHM is 1 mg/L (or 1000 ppb) based on the “CDC Information about MCHM 2014 West Virginia Chemical Release” (<http://emergency.cdc.gov/chemical/MCHM/westvirginia2014/mchm.asp>).

WVTAP MCHM Question 1) Is 50 ppb level for MCHM an advisory level of any sort (such as for pregnant women, children or infants)?

CDC Response: The short-term drinking water screening level CDC established for MCHM is 1 part per million (1 ppm, (1000 parts per billion or ppb). As stated in the Summary Report of Short-term Screening Level Calculation and Analysis of Available Animal Studies for MCHM, a level of 1ppm or below is not likely to be associated with any adverse health effects. CDC has not suggested any other water screening levels.

Few studies of the health effects of MCHM have been conducted and most of those have been in animals. CDC scientists used the limited information from those studies to estimate how much MCHM a person could ingest without experiencing adverse health effects. Using a widely accepted and commonly used approach in public health and risk assessment, CDC calculated this level by extrapolating from the available animal toxicity studies. The calculation used uncertainty factors to take into account the differences between animals and people and to consider possible effects on vulnerable populations, including pregnant women and children. Finally, an additional uncertainty factor was applied to account for the limited availability of data.

In a letter to Secretary Bowling on January 15, 2014, CDC Director Dr. Tom Frieden stated that, “due to the limited availability of data, and out of an abundance of caution,

you may wish to consider an alternative drinking water source for pregnant women until the chemical is at non-detectable levels in the water distribution system.”

At the time, the lower limit of detection for MCHM in tests being conducted on water in some areas was approximately 50 ppb. Later tests were able to detect levels as low as 10 ppb and still later at 2 ppb.

WVTAP MCHM Question 2) Has anyone stated that water with concentrations less than 50 ppb is "safe"?

CDC Response: CDC has consistently stated that concentrations of MCHM in drinking water below the detection limit of 50 ppb are appropriate for use by everyone, including pregnant women. The detection limit for MCHM in drinking water in areas affected by the spill has continued to decline over time. CDC officials stated that the water could be used in mid-January when the MCHM detection limit was 50 ppb, and subsequently when even lower levels were detectable.

WVTAP MCHM Question 3) What is or was the reason that (or source of) 50 ppb is being cited as “not considered a public health risk”?
(<http://www.louisvilleky.gov/LWC/News/2014/Louisville+Drinking+Water+is+Safe.htm>)

CDC Response: The basis for this statement is that the 50 ppb level is far below the short-term drinking water advisory level (screening level) of 1 ppm. That is, the lower limit of 50 ppb is 1/20th of the 1 ppm screening level. Similarly, levels of MCHM detected in the water of 10 ppb or 2 ppb are even further below the screening level, at 1/100th or 1/500th of the screening level, respectively.

WVTAP MCHM Question 4) Is there any other official DW advisory level other than 1 mg/L (1000 ppb) for MCHM from the CDC
(<http://emergency.cdc.gov/chemical/MCHM/westvirginia2014/mchm.asp>) ?

CDC Response: Other than the 1 ppm (1000 ppb) level from the CDC, we are not aware of any short-term drinking water advisory level for MCHM.

II) WV TAP PPH QUESTIONS

The drinking water advisory level has been set by the CDC at 1.2 mg/L (1,200 ppb) for PPH (<http://emergency.cdc.gov/chemical/MCHM/westvirginia2014/pph.asp>). The drinking water advisory level for PPH was calculated using a 40 mg/kg/day “No Observed Adverse Effect Level” (NOAEL). Several studies cite higher (less conservative) NOAELs of, for example, 113 mg/kg/d or 180 mg/kg/d (<http://www.chem.unep.ch/irptc/sids/OECD/SIDS/770354.pdf>).

WVTAP PPH Question 1) What was the specific study and citation for the more conservative 40 mg/kg/day?

CDC Response: The specific study and citation for the 40 mg/kg/day developmental toxicity endpoint is the Dow Chemical Company’s Chemical Safety Report, Substance Name 1-phenoxypropan-2-ol, July 9, 2010 (2010-09-07 CSR-PI-5.2.1).

No substance-related effects were noted in fetuses from dams receiving 160 or 40 mg/kg of PPH per day in this rat study. The NOAEL for maternal toxicity was 40 mg/kg per day; the NOAEL for prenatal developmental toxicity was 160 mg/kg per day. No substance-induced teratogenicity was seen up to 640 mg/kg per day.

WVTAP PPH Question 2) Why was this NOAEL for PPH chosen over other NOAELs considered by the interagency working group?

CDC Response: Of the available studies, this NOAEL of 40 mg/kg/day represents the most conservative level for dams and their offspring.

WVTAP PPH Question 3) Were any more conservative NOAEL or NOELs considered by the working group and/or the CDC? If yes can you give us the references for these other studies?

CDC Response: No other more conservative NOAELs or NOELs were considered. We did consider all of the relevant studies available. However the other NOAELs or NOELs in the available studies were all higher.

WVTAP PPH Question 4) Which agencies were involved in the interagency work group led by the CDC in January to consider and help establish this DW Advisory level for PPH?

CDC Response: The Federal interagency expert workgroup included scientists from the National Institute of Environmental Health Sciences, the National Toxicology Program, the National Library of Medicine, the Environmental Protection Agency, and CDC/ATSDR.