



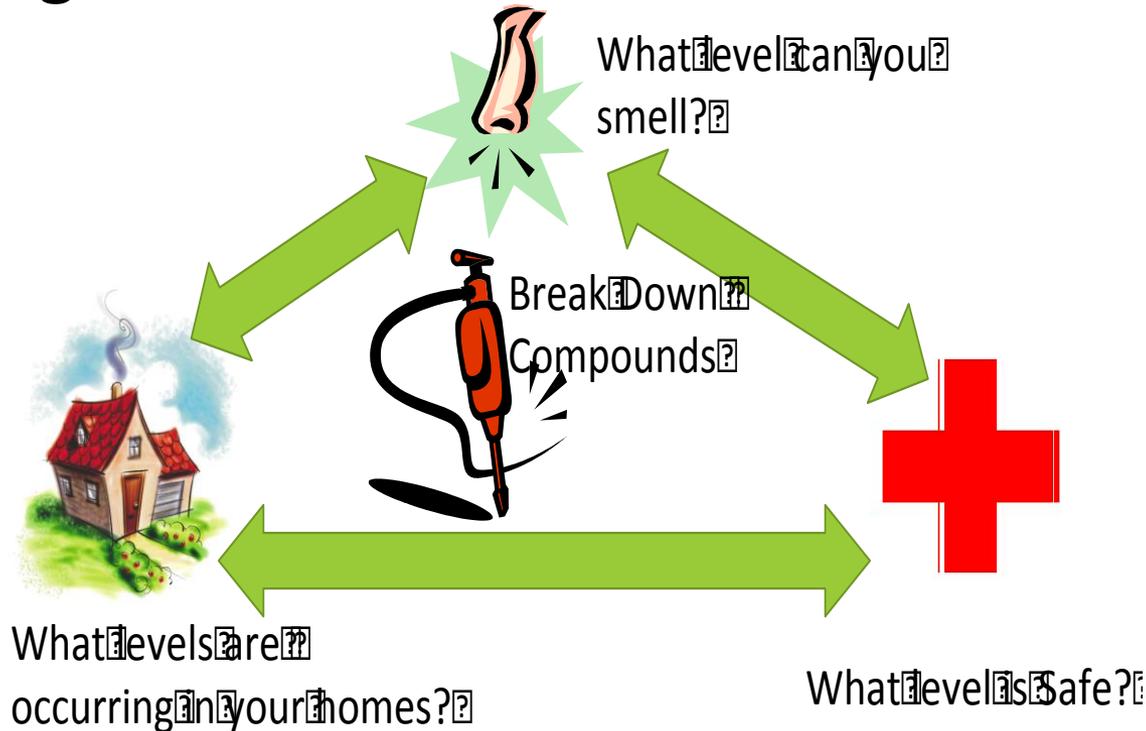
Preliminary Results of the Health Effects Expert Panel

Dr. Michael L. Dourson, Panel Chair
Toxicology Excellence for Risk Assessment (TERA)

April 1, 2014

The WVTAP Program Mission

- Provide independent scientific assessment of the spill of MCHM into the Elk River and its distribution throughout the 9 counties served by West Virginia American Water



Why Convene a Health Effects Expert Panel?

- To provide independent expert review of screening levels.
- Essential part of science
 - Evaluate by experts who are equivalent (that is “peers”) of those who did the work.
 - Review to ensure that results are scientifically sound.
- Complex issues require participation by diverse types of scientists.

Questions to Be Addressed by TAP Expert Panel

- **Review and discuss the available toxicology data** and the scientific support for the West Virginia 4-MCHM Screening Level established at 10 parts per billion (ppb).
- Initial starting value of 1 part per million (1,000 ppb) 4-MCHM established by the CDC and then **consider if the additional safety factor applied by the State of West Virginia was protective of public health**, based on available data.
- **Identify data gaps and make recommendations** for additional studies or analyses that could strengthen the screening level and reduce uncertainty.

THE Charge Questions

1. Given data now available, what would be appropriate screening levels for MCHM and PPH in drinking water?
2. What additional data, analyses, or studies might reduce uncertainty and provide greater confidence?
3. How should the presence of multiple chemicals in the release to the Elk River be considered?
4. Are the screening values protective for all potential routes of exposures (i.e., ingestion, dermal and inhalation)?
5. Please identify any additional scientific issues or questions that the panel should discuss.

WV TAP Expert Panel

(affiliations listed for identification purposes only)

- **Dr. Michael Dourson**, Toxicology Excellence for Risk Assessment, Cincinnati, Ohio
- **Dr. Shai Ezra**, Mekorot, Israel National Water Company Ltd, Tel Aviv, Israel
- **Dr. Paul Rumsby**, National Centre for Environmental Toxicology at WRc plc, United Kingdom
- **Dr. Stephen Roberts**, University of Florida, Gainesville, Florida USA
- **Dr. James Jacobus**, Minnesota Department of Health, Saint Paul, Minnesota USA

Panel's Thoughts on CDC Results

- CDC used traditional methods and reasonable assumptions to develop their screening levels.
- The panel chose to consider additional routes of exposure (inhalation and skin).
- The panel was not constrained to use any particular methods.
- The panel included international and US state experts.

Panel's Approach

- The Panel agreed with CDC on the choice of key toxicity data for MCHM, but not for PPH.
- The Panel agreed with CDC on the choice of uncertainty (safety) factors for MCHM, but had a different choice of factors for PPH.
- The Panel chose to consider additional routes of exposure (inhalation and skin).
- The Panel chose to calculate values based on the most highly exposed population (that is, formula-fed infants).

Exposure & Sensitive Groups

- The Panel considered the following exposures:
 - Direct ingestion of water, including formula-fed infants
 - Inhalation from showering and cooking
 - Skin exposure to water uses in the house
 - Incidental exposures, including brushing teeth, watering plants, etc.
- These exposures protect all populations, including:
 - Infants
 - Children
 - Pregnant Women

Preliminary Conclusions

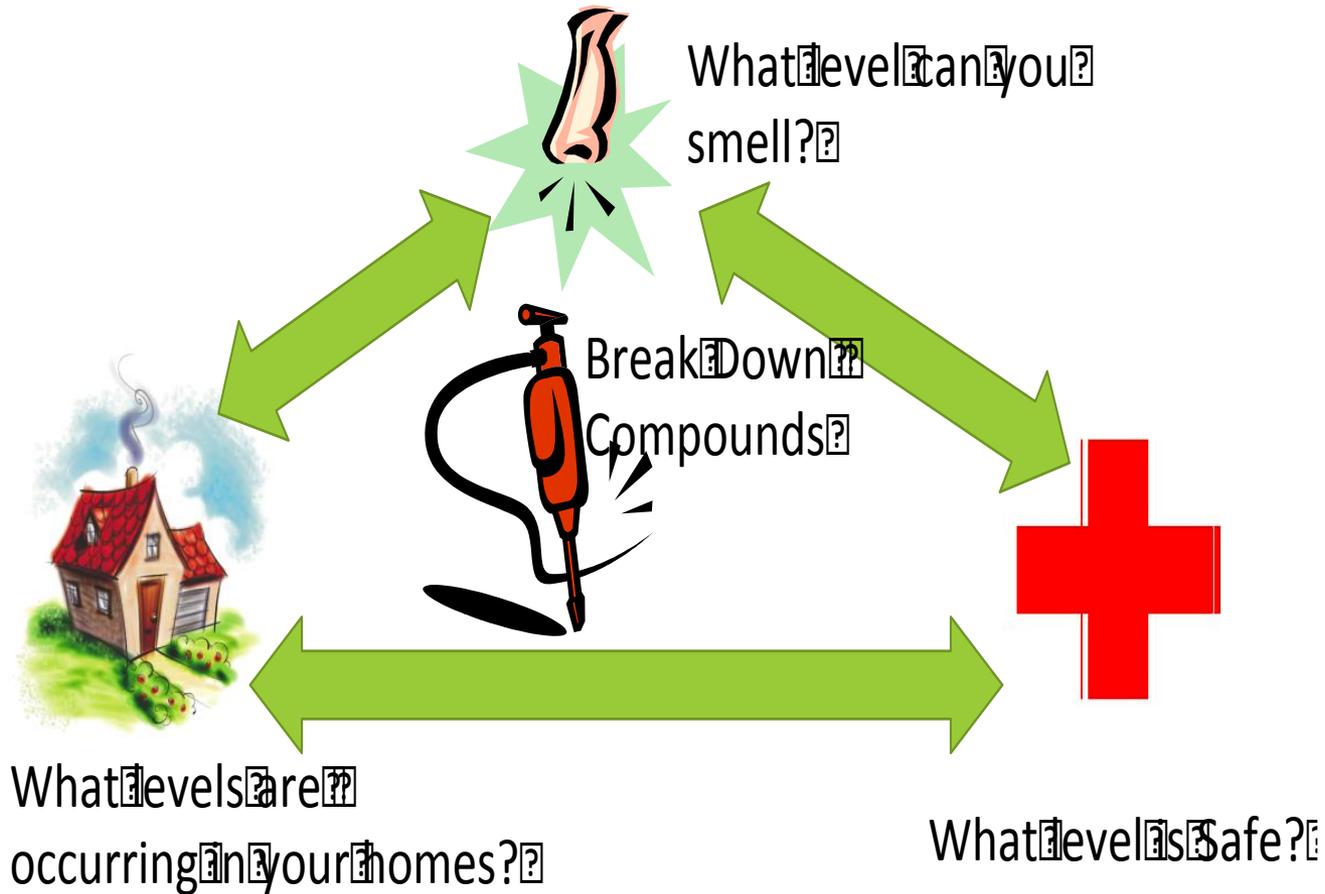
- The panel developed safe levels of exposure that are protective for all populations.
- These levels are averages for exposures up to 28 days:
 - 120 ppb for MCHM
 - 250 ppb for DiPPH
 - 850 ppb for PPH

Research Needs

1. Determine MCHM potential to cause skin irritation.
2. Conduct toxicology studies for MCHM in pregnant animals.
3. Organize all available data on exposures and health effects (from immediately following the spill) to facilitate the estimation of initial conditions.
4. Pending results of #2 and #3, consider the need for long term health effects study.
5. Determine chemical fate and transport within the treatment plant and water distribution system.

**The Panel thanks
you for the
opportunity to help.**

Summary



Data Postings

- We posted in the last few days
 - Integrated relational database (Access) with all sample results and relevant quality control data
 - Over 1300 pages (12,000 data points) of raw chemical analysis reports
- We will be posting in the next few weeks
 - Odor threshold results for consumer panel
 - Health Effect Expert Panel final report
 - Statistical design for larger sampling program
 - Final report integrating all the results together along with recommendations for next steps and suggested long term research programs.

Completing the WV Tap Program

- WV TAP anticipated ending in May 15
 - Final report summarizing all the results
 - Includes recommendations to State for short- and long-term activities



Thank you!

The WV Tap Program

Extra slides

CDC	Panel
No Observed Effect Level (NOEL) = 100 mg/kg-day	No Observed Effect Level (NOEL) = 71 mg/kg-day
Uncertainty Factor = 10H, 10A, 10D	Uncertainty (Safety) Factor = 10H, 10A, 10D (provision for refined factor possible)
Ingestion of water only	Ingestion, inhalation and skin
Exposure to 1-year old child	Exposure to formula-fed infant
Screening level = 1000 ppb	Screening (safe) level = 120 ppb

10H = 10x for human variability; 10A = 10x for animal to human extrapolation; 10D = 10x for data base sufficiency

CDC	Panel
No Observed Effect Level (NOEL) = 40 mg/kg-day	No Observed Effect Level (NOEL) = 146 mg/kg-day
Uncertainty Factor = 10H, 10A, 10D	Uncertainty (safety) Factor = 10H, 10A, 3D (provision for refined factor possible)
Ingestion of water only	Ingestion, inhalation and skin
Exposure to pregnant woman	Exposure to formula-fed infant (provision for pregnant woman available)
Screening level = 1200 ppb	Screening (safe) level = 850 ppb

10H = 10x for human variability; 10A = 10x for animal to human extrapolation; 10D = 10x for data base sufficiency

CDC Not Determined	Panel
	No Observed Effect Level (NOEL) = 146 mg/kg-day
	Uncertainty (safety) Factor = 10H, 10A, 10D (provision for refined factor possible)
	Ingestion, inhalation and skin
	Exposure to bottle fed infant (provision for pregnant woman available)
	Screening (safe) level = 250 ppb

10H = 10x for human variability; 10A = 10x for animal to human extrapolation; 10D = 10x for data base sufficiency