



February 12, 2015

# ORSANCO Human Health Temperature Criterion

Review of basis in comparison with EPA  
Ambient Water Quality Criteria (AWQC)  
Methodology

Lisa Yost, MPH, DABT



# Overview

- Background
- Basis for ORSANCO standard
- Comparison with EPA ambient water quality criteria (AWQC) methodological basis
  - Hazard identification
  - Toxicity assessment
  - Exposure assessment
  - Risk characterization
- Conclusions



# Background



# Overview of Thermal Criterion

- ORSANCO Ad Hoc Temperature Workgroup (Temperature Workgroup) recommended 116.5 degrees Fahrenheit (°F)
  - Health protective basis for human health temperature criterion
- ORSANCO set criteria at 110 °F
  - Maximum temperature where public access is possible in Ohio River (ORSANCO 2012)
  - Intended to protect people from contact with heated water (e.g., boating accidents)
  - Basis not clearly identified



# Human Health Temperature Criterion is Unusual, but Should Have Rigorous Technical Basis

- Human Health Temperature Criterion is quite unusual.
  - There are no EPA federal thermal human health criteria (U.S.EPA 2003b, ORSANCO005290).
  - Wisconsin 120 °F standard (WDNR 2013a,b) allows for site-specific exposure considerations.
  - Pennsylvania guideline of 110 °F is not enforceable.
  - No other state has this criterion.
- ORSANCO Temperature Criterion enforced under the Clean Water Act
  - Methodology should be as rigorous as other human health criteria (e.g., AWQC) (USEPA 2000).
  - EPA AWQC based on in-depth risk assessment



# Basis for ORSANCO Criteria



# Basis for Temperature Workgroup 116.5 °F Recommendation

- Consumer Product Safety Commission (CPSC) voluntary water heater guideline of 120 °F (CPSC 2012)
  - Widely used residential (bathwater) voluntary guideline
  - Protective of adults and children against potential scalding
  - Early study in animals (pigs) and human volunteers (Moritz and Henriques 1947)
- Temperature workgroup recommended 116.5 °F based on analysis by Diller (2006)
  - Considered (Moritz and Henriques 1947) thermal injury data at 120 °F
  - Recommended 116.5 °F to protect children, due to thinner skin



# Discussion in Temperature Workgroup

## 116.5 °F

- Exposure potential
  - Some Temperature Workgroup members expressed reservations about whether such a standard was needed given the low likelihood of exposure to water at the 116.5 °F temperature.
- Mixing Zone
  - Most Temperature Workgroup members agreed that the 116.5 °F should apply within a mixing zone, but others argued that it should instead apply outside the mixing zone consistent with other water quality criteria.



## ORSANCO Basis for 110 °F

- ORSANCO did not apply 116.5 °F recommended by the Temperature Workgroup
- ORSANCO set thermal criterion at 110 °F
  - Applied inside the mixing zone in contrast with all other standards
- Basis not clearly identified
  - Appears to be based on non-enforceable Pennsylvania guideline of 110 °F
- Pennsylvania guideline has unclear basis
  - Stated to be based on scalding, but not supported by data
  - Based instead on CPSC references to hot tub safety
- Hot tub basis not representative of Ohio River



# Some Temperature Workgroup Reactions to ORSANCO 110 °F Standard

- Temperature Workgroup members strongly disagreed with the ORSANCO 110 °F standard stating:

“Again, there is a lack of scientific data supporting either the 110 °F or 120 °F though the WHO recommendation is the closest to what ORSANCO’s TEC committee has discussed.”

“I suggest not picking a value just because it is something that one state already has on their books and is therefore convenient.”



# Comparison of Thermal Criterion with AWQC Basis

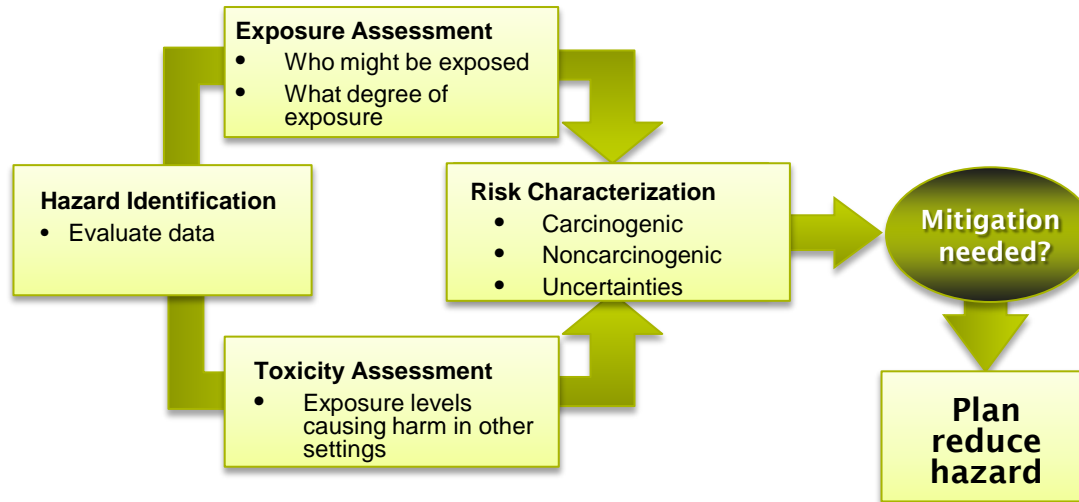


# Applicability of AWQC Methodology

- EPA human health AWQC primarily address chemicals in fish or water or both.
- ORSANCO Temperature Criterion and EPA human health AWQC are parallel because both are
  - Intended to protect public health regarding water quality, and
  - Dependent on a sufficient degree of exposure both in intensity and in duration, to result in harm.
- EPA AWQC methodology is a useful basis for evaluating the ORSANCO methodology and standard.
  - AWQC are based on risk assessment (USEPA 2000).



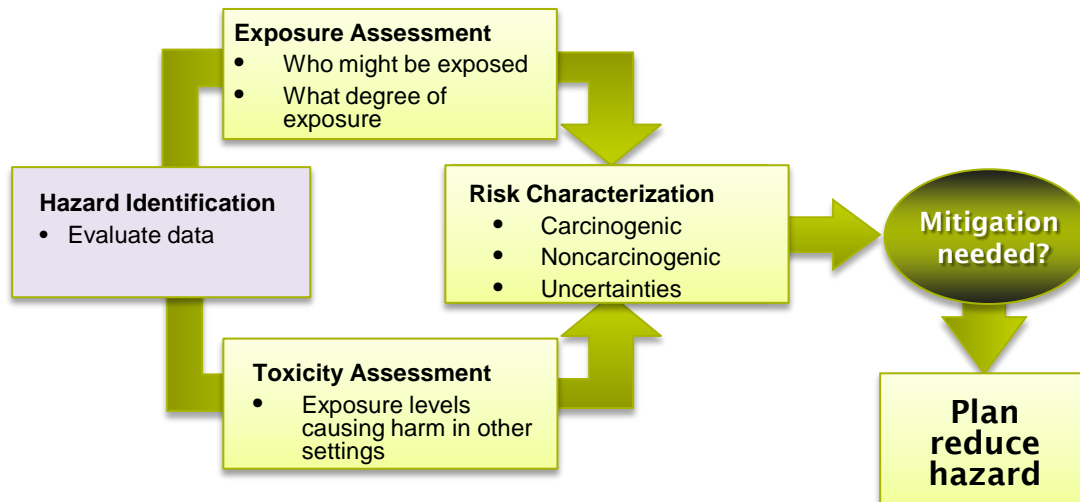
# Human Health Risk Assessment Model



- Risk assessment is a useful scientific tool that estimates whether chemicals might cause health effects under assumed exposure conditions
- Does not predict actual risks
- Incorporates health protective input assumptions intended to not underestimate risks and may overestimate risks
- *Temperature criterion basis considered here relative to AWQC risk assessment methodology (USEPA 2000)*



## Comparison of Thermal Criterion with AWQC Basis



## Hazard Assessment

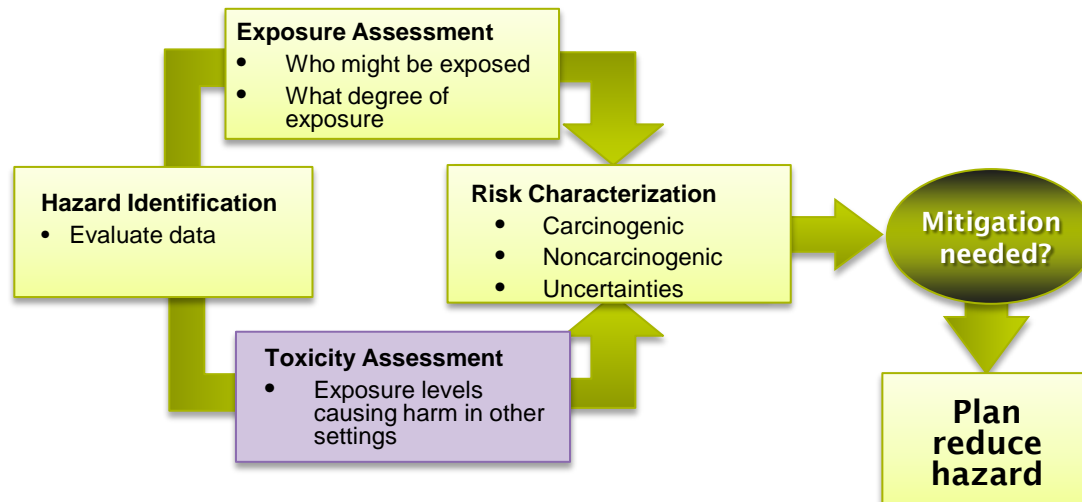


# Hazard Assessment

- Hazard assessment evaluates potential for harm related to exposure to the regulated material *in any setting*.
- ORSANCO 110 °F criterion development not based on thorough hazard evaluation in other settings
  - For example, 120 °F voluntary standard for residential hot water heaters
- Moreover, standard setting did not integrate what is known about Ohio River setting
  - Heated water has been released into the Ohio River for over 40 years.
  - No documented cases of accidental full-body immersion in a thermal mixing zone or record of injuries.



# Comparison of Thermal Criterion with AWQC Basis



## Toxicity Assessment



# Toxicity Assessment

- Toxicity assessments underlying AWQC are extensive.
  - Consider the relevance of the available data for the exposure setting of the standard.
- Temperature Workgroup 116.5 °F recommendation is protective.
  - Hot water heater temperature of 120 °F is adequate to prevent harm in home bathwater.
  - Workgroup reduced further to 116.5 °F
- ORSANCO thermal criterion 110 °F relies on studies used to set hot tub recommendations.
  - Hot tub exposure is greater in magnitude and in duration.
- ORSANCO did not provide sufficient basis that a standard of 110 °F is necessary to protect human health in the Ohio River.



# Temperature Workgroup 116.5 °F Recommendation is Protective (1 of 2)

- Hot water heater temperature of 120 °F is adequate to prevent harm in home bathwater.
  - Recommended by CPSC, plumbing industry groups, burn safety organizations (American Burn Association 2012), medical providers (Mayo 2013, U of WI Katchner et al. 1989)
  - In state statutes (Washington State Legislature. RCW 19.27A.060)
- Basis of 120 °F is Moritz and Henriques (1947)
  - Evaluated effects of controlled timed exposure to hot water in pigs and in human volunteers
- Temperature Workgroup recommended 116.5 °F based on Diller (2006) estimates for children



# Temperature Workgroup 116.5 °F Recommendation is Protective (2 of 2)

- Findings of Moritz and Henriques (1947)
  - Eight minutes of exposure to 120 °F resulted in a first degree burn (i.e., the level of a sunburn).
- A 120 °F temperature would be protective, and the 116.5 °F standard offers additional protection.
- Explaining the shift from 116.5 °F to 110 °F, ORSANCO stated:
  - “The 116 deg F temperature was to protect children from second degree burns with an 8 minute exposure. It was felt that protections should be stronger than to prevent second degree burns.” (ORSANCO0001395)
  - In contrast studies relied on by ORSANCO indicate mild injury after 8-minute exposures.



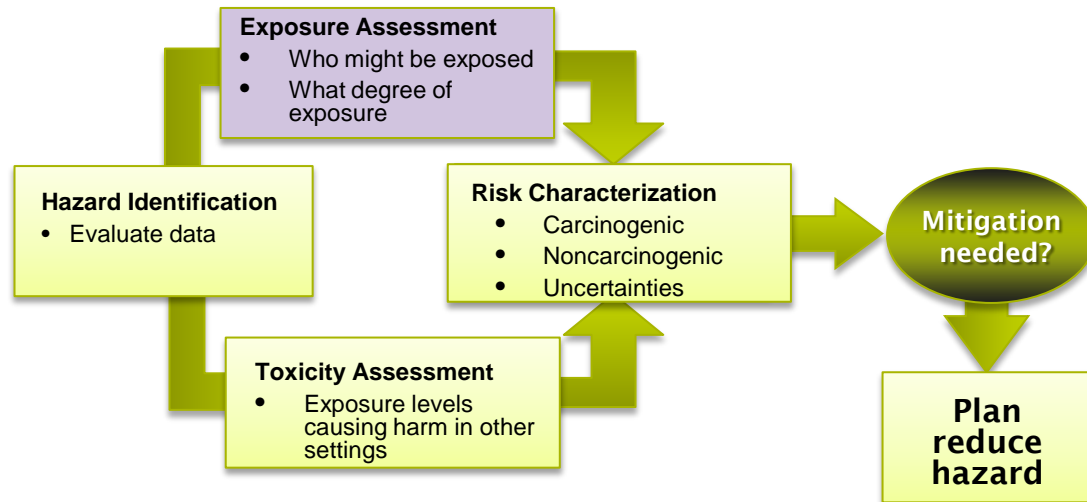
# ORSANCO Thermal Criterion of 110 °F

Preliminary Draft  
Privileged and Confidential  
Attorney-Client Communication

- The 110 °F criterion relies on PA guideline, which relies on hot tub recommendations.
  - “109.4 °F documented by WHO to cause death during prolonged exposure (primarily related to hot tubs).”  
ORSANCO
  - Consistent with WHO (2006) and CPSC discussion of risks related to soaking in hot tubs, particularly when alcohol is involved
- Hot tub exposure is greater in magnitude and in duration than unintentional temporary immersion in river.
- ORSANCO did not provide any estimate of how many cases of irreversible burns would be prevented by reducing the temperature criterion from 116.5 °F to 110 °F.



# Comparison of Thermal Criterion with AWQC Basis



## Exposure Assessment



# Exposure Assessment

- Exposure assessment considers whether current or potential future exposure could be sufficient to result in harm
  - Consider specific exposure (i.e., the Ohio River)
- EPA AWCQ exposure assessment is extensive
  - Estimates the potential for exposure in a relevant setting
  - EPA AWQC considers ‘reasonable maximum exposure’
- ORSANCO provided limited exposure discussion
  - Standard intended to protect a child exposed for 8 minutes to water uniformly heated to 110 °F
  - This assumed exposure is not consistent with site conditions
- ORSANCO standard is not relevant to exposure settings in the river.



# Potential for Exposure to Hot Water in the Ohio River is Limited

- Limits on exposure
  - Heated water is discharged into a discharge channel, which ultimately reaches the Ohio River.
  - Heated water is present in shallow layer
- Some facilities bar access to the mixing zone
- Many facilities deploy a warning “stay out” float in front of the thermal mixing zone
- Biological pathogens and cool air and water temperatures limit use

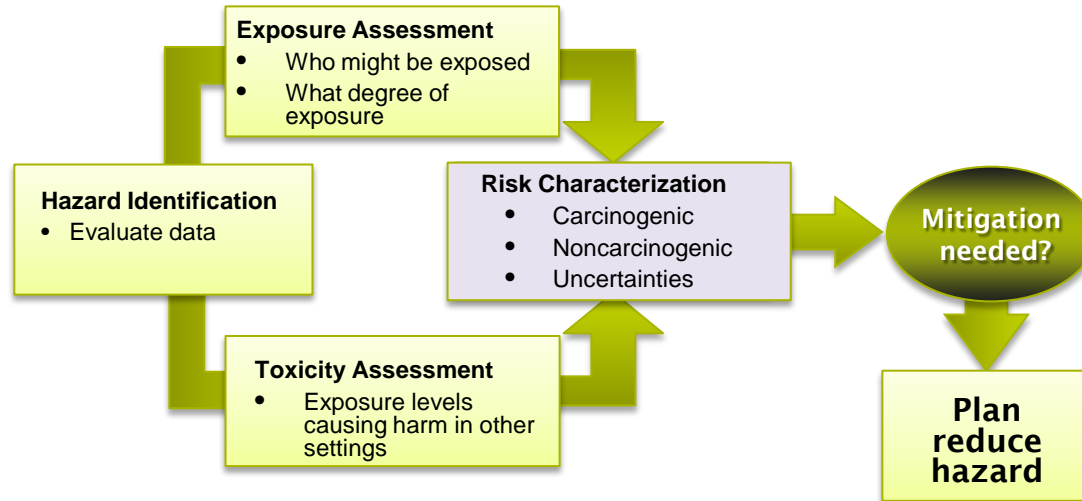


# ORSANCO Exposure Analysis Was Limited

- Exposure level assumed in ORSANCO standard is greater than “reasonable maximum exposure”
  - Criterion is intended to be protective for a child exposed for 8 minutes to water uniformly heated to 110 °F
- Site conditions and nature of heated plume limit exposures
  - Dangerous nature of river, submerged objects, limited visibility, current all limit intentional swimming
  - Brief accidental exposures
  - Fishing near plume is limited and is more likely in winter
  - Heated water would rapidly mix and cool if a person enters river
- ORSANCO standard assumed an exposure that is not representative of the river.



## Comparison of Thermal Criterion with AWQC Basis



## Risk Characterization



# ORSANCO Standard Setting Did Not Quantify Hazard

- In risk characterization, site data and information, exposure estimates, and toxicity estimates are brought together to derive a numeric estimate of risk.
  - Numeric estimates of risk are compared with acceptable risk levels identified by EPA (USEPA 1989).
- The ORSANCO Criterion did not include risk characterization stating:
  - “This has not been determined and the information is not necessary to promulgate the appropriate standard.” (ORSANCO0001396).
- EPA guidance stresses the importance of characterizing likelihood of harm.



# EPA Guidance Stresses Importance of Characterizing Likelihood of Harm

“Risk characterizations should include a summary of the key issues and conclusions of each of the other components of the risk assessments, as well as *describe the likelihood of harm.*” [USEPA 2000, Emphasis added.]

“Risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgments, and the use of default values or methods and *the use of assumptions in the risk assessment are clearly articulated.*” [USEPA 2000, Emphasis added.]

“Risk characterizations should be consistent in general format, but recognize the *unique characteristics of each specific situation.*” [USEPA 2000, Emphasis added.]



# Conclusions

- ORSANCO did not assemble adequate underlying hazard and exposure data nor conduct adequate analyses to serve as basis for the 110 °F temperature criterion for the Ohio River.
- Human Health Temperature Criterion is technically flawed both in the technical basis and the methodology
- Criterion should be reconsidered after a thorough risk assessment process that appropriately considers the potential for harm, potential for exposure, and characterizes potential hazards.