

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF WATER STANDARDS AND FACILITY REGULATION**

**RATIONALE FOR THE DEVELOPMENT OF
AMBIENT WATER QUALITY CRITERIA
FOR HUMAN HEALTH**

Ambient water quality criteria are numeric values limiting the amount of chemicals present in our nation's waters. A water quality criterion is the highest concentration of a pollutant in water that is not expected to pose a significant risk to, or adversely impact, in this case, human health protection. Water quality criteria are based solely on the best available scientific data and scientific judgments on pollutant concentrations and environmental or human health effects. These water quality criteria are developed under Section 304(a) of the federal Clean Water Act of 1972. Section 304(a)(1) of the Clean Water Act requires that the Administrator, U.S. Environmental Protection Agency (EPA), develop criteria for water quality that accurately reflects the latest scientific knowledge. Section 303(c)(2) requires states to adopt criteria for all toxic pollutants listed pursuant to section 307(a)(1) of this Act for which criteria have been published under section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses.

The following criteria for toxic substances have been recommended by EPA since the previous triennial review, which was finalized in April, 2010:

- acrolein and phenol
- 1,2,4 and 1,3,5 trimethylbenzene,
- cis-1,2-dichloroethene,
- acrylamide,
- strontium,
- molybdenum
- 1,4 dioxane
- bromine and bromate
- styrene
- cadmium
- benzyl chloride
- 2-butoxyethanol

ACROLEIN and PHENOL:

Human health criteria - acrolein and phenol in May, 2009 (EPA-822-F-009-001).

The criteria for phenol and acrolein are being updated with more recent reference doses available from EPA's Integrated Risk Information System (IRIS). IRIS is an electronic data base maintained by the EPA that provides chemical-specific risk information on the relationship between chemical exposures and estimated human health effects. Risk assessment information contained in IRIS, except as specifically noted, has been reviewed and agreed upon by an interdisciplinary group of scientists representing various Program Offices within the Agency and represents Agency-wide consensus. Therefore, these updated values reflect the most current science.

In order to be consistent with the National criteria, the Department proposes to incorporate the updated human health criteria for phenol to 10400 ug/L and acrolein to 6.0 ug/L.

CRITERIA DEVELOPED BY THE DEPARTMENT

Other human health criteria for toxic substances to be included in this review are for criteria that were developed by the Department at the request of staff from one or more of the Departments regional offices. These compounds have been found in effluent discharges throughout PA and are need by the Department's permit engineers to set discharge limits to maintain compliance with the NPDES program. These proposed criteria were developed using the current best available toxicity data. The compounds will be added to Chapter 93, Table 5 (relating to water quality criteria for toxic substances). The threshold human health (THH) criteria are calculated using the EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health – 2000. The compounds and the toxicity data are as stated below:

1,2,4 and 1,3,5 Trimethylbenzene

Trimethylbenzene is a byproduct from the petroleum refining process. It is also used as a solvent in coatings; cleaners; pesticides and inks. Sub-chronic toxic effects to human health include alterations in blood clotting, anemia and asthmatic bronchitis. (US EPA OPP, August 1994) Because this toxic compound is widely used in PA and numeric water quality criteria have been requested by staff, the Department has calculated threshold human health criteria. The toxicity data used to calculate 1,2,4 trimethylbenzene (TMB) and 1,3,5 - TMB was obtained from the Risk Assessment Program and is a Tier 2, Provisional Peer Reviewed Toxicity Value (PPRTV).

The Department calculated threshold human health criteria for 1,2,4 and 1,3,5 trimethylbenzene based on toxicity data from a PPRTV, which was obtained from a peer reviewed, Risk Assessment Issue Paper, *Derivation of a Provisional RfD for 1,2,4-Trimethylbenzene (CASRN 95-63-6) and 1,3,5-Trimethylbenzene (CASRN 108-67-8)* and the Risk Assessment Information System (RAIS – 6/30/99). Because of the similarity in the structure of 1,2,4- and 1,3,5-TMBs it was determined in this paper that the two isomers can be used as surrogates for the other, therefore the same toxicity data is used to calculate the human health criteria for each.

The threshold human health (THH) criteria for 1,2,4 –TMB and 1,3,5-TMB was calculated using the following toxicity data:

.05 mg/kg-day - Oral RfD (reference dose) - Risk Assessment Information System (RAIS)
70 kg - body weight
2 L - drinking water intake
0.0175 kg/day - fish intake
439 L/kg - Bioconcentration factor (BCF), US EPA OPP, Chemical Summary for TMB, (EPA 749-F-94-022a)
0.2 - default relative source contribution (RSC)

The Department is proposing to adopt the calculated human health criteria for both 1,2,4 TMB (72 ug/L) and 1,3,5 TMB (72 ug/L).

cis-1,2-dichloroethylene (DCE)

Dichloroethylene occurs in two form, cis-1,2-DCE and trans-1,2-DCE. Trans-1,2-DCE is on EPA's list of priority pollutants and is currently listed in Chapter 93 (relating to water quality standards), Table 5. Cis-1,2 DCE is used as a solvent in waxes, resins, in the extraction of rubber, as a refrigerant and the manufacture of pharmaceuticals. (US EPA, Basic Information about cis-1,2-DCE) On 9/30/10, US EPA posted toxicity data in IRIS for developing human health criteria for cis-1,2-DCE. The Department is therefore proposing a threshold human health criterion for cis-1,2-DCE.

The THH criterion for cis-1,2 -DCE was calculated using the following toxicity data:

.002 mg/kg-day - Oral Chronic RfD for cis-1,2-DCE – IRIS
70 kg - body weight
2 L - drinking water intake
0.0175 kg/day - fish intake
23 L/kg - Bioconcentration factor (BCF), (US EPA, Basic Information about cis-1,2-DCE, Factsheet)
0.2 - default relative source contribution (RSC)

The calculated human health criterion for cis-1, 2- DCE is 12 ug/L.

1,4-Dioxane

On 8/11/10, EPA provided new toxicity data for 1,4-dioxane in the IRIS database. 1,4-dioxane is currently in Chapter 16 as a site specific criterion with a cancer risk level (CRL) of 3.0 ug/L. It has become evident to the Department that this toxic substance has statewide application. The Department is proposing to incorporate the human health and aquatic life criteria for this toxic substance into Chapter 93, Table 5 for statewide use. Based on the most current toxicity data in IRIS the new proposed human health CRL for 1,4-dioxane is 0.35 ug/L.

Acrylamide

Acrylamide is used a coagulant aid in the drinking water process; it is also used to improve production from oil wells; in making organic chemicals and dyes; in sizing of paper and textiles; in ore processing and in the construction of dam foundations and tunnels. (ATSDR Toxicological profile for acrylamide) The Department is proposing to incorporate a statewide human health criterion for acrylamide. Currently the Department has a site-specific CRL for

acrylamide of .008 ug/L in Chapter 16, Table 1A (relating to site-specific water quality criteria for toxic substances). On 3/22/10, EPA provided new toxicity data for acrylamide in IRIS. Acrylamide is classified as likely to be carcinogenic to humans by EPA. Based on the most current toxicity data in IRIS the Department is proposing an acrylamide human health CRL of .07 ug/L.

Strontium

Strontium has been identified in many hazardous waste sites that have been proposed for inclusion on the EPA National Priorities List (NPL) (HazDat 2003). The release of strontium to surface water and groundwater results from the natural weathering of rocks and soils and from the discharge of waste water directly into streams and aquifers. Strontium products are used in ceramics and glass products; pyrotechnics; paint pigments and fluorescent lights to name a few (ATSDR Toxicological profile for strontium). Based on the current toxicity data in IRIS and the Strontium Toxicological Profile, (ATSDR, April 2004) the Department is proposing a human health criterion of 4200 ug/L.

The THH criteria for strontium is calculated using the following toxicity data:

0.6 mg/kg-day - Oral RfD (reference dose) – IRIS

70 kg - body weight

2 L - drinking water intake

0.0175 kg/day - fish intake

1 L/kg - Bioconcentration factor (BCF), Strontium Toxicological Profile, (Agency for Toxic Substances and Disease Registry – ATSDR, April 2004)

0.2 - default relative source contribution (RSC)

Benzyl Chloride

The Department is proposing to incorporate a statewide human health criterion for Benzyl chloride. It is used as an intermediate in the processing of dyes, pharmaceuticals and perfumes. It can also be used in the production of synthetic tannins and as a gum inhibitor in petrol. (National Library of Medicine HSDB Database) EPA has labeled benzyl chloride as a probable human carcinogen. According to the current data available in IRIS, EPA has provided a cancer slope factor of 1.7×10^{-1} mg/kg-day. The cancer risk criterion to protect at a 1 in one million exposure level is 0.2 ug/L. The Department is therefore proposing a CRL of 0.2 ug/L.

Cadmium

The Department is proposing to incorporate a human health criterion for cadmium. Cadmium is a priority pollutant and the Department currently has criteria for aquatic life protection in Chapter 93, Table 5. The US Department of Health and Human Services – National Toxicity Program (NTP) has listed cadmium as a carcinogen in their 11th report. “Human findings in the report are supported by studies in experimental animals demonstrating that cadmium and cadmium compounds by multiple routes of exposure cause malignant tumor formation at various sites in multiple species of experimental animals”. In accordance with Chapter 16, at section 16.33 (relating to nonthreshold effects) the Department will incorporate and additional margin of

safety (10) with the threshold toxicity data to develop a cancer risk level for cadmium. The Department used toxicity data obtained from the National Recommended Water Quality Criteria: Human Health Criteria Calculation Matrix (November 2002). A CRL was calculated based on a threshold human health criterion.

The CRL for cadmium was calculated using the following toxicity data:

.0005 mg/kg-day - RfD – IRIS
70 kg - body weight
2 L - drinking water intake
0.0175 kg/day - fish intake
64 L/kg - Bioconcentration factor (BCF), US EPA, 1980 Cadmium document
0.25 - relative source contribution (Human Health Criteria Calculation Matrix (November 2002))
10 – margin of safety to protect against cancerous effects

Based on the above toxicity data the proposed CRL human health criterion for cadmium is 0.28 ug/L.

Cyclohexylamine

Cyclohexylamine is used in boiler water treatment as a corrosion inhibitor, in rubber and plastic synthesis, agricultural chemicals and as an emulsifying agent. (Hazardous Substance Data Bank - HSDB, 2002) Based on toxicity studies in IRIS, cyclohexylamine has been shown to cause reproductive damage. The Department is proposing to incorporate a human health criterion for cyclohexylamine. Toxicity data obtained from IRIS was used to calculate a human health criterion of 1000 ug/L.

The THH criterion for cyclohexylamine was calculated using the following toxicity data:

.2 mg/kg-day - RfD – IRIS
70 kg - body weight
2 L - drinking water intake
0.0175 kg/day - fish intake
3 L/kg - Bioconcentration factor (BCF), National Library of Medicine, Hazardous Substance Databank.
0.2 - relative source contribution (RSC)

2-Butoxyethanol

The Department is proposing to incorporate a human health criterion for 2-butoxyethanol. Based on studies recorded in the IRIS data base 2-butoxyethanol has been shown to cause damage to the liver. 2-butoxyethanol is used as a solvent in spray lacquers, enamels, varnishes, and latex paints and as an ingredient in paint thinners and strippers, varnish removers, and herbicides. (Agency for Toxic Substances and Disease Registry – ATSDR, Toxicity Profiles) The Department used toxicity data obtained from IRIS, to calculate a human health criterion for 2-butoxyethanol of 700 ug/L.

The THH criteria for 2-butoxyethanol was calculated using the following toxicity data:

.1 mg/kg-day - RfD – IRIS
70 kg - body weight
2 L - drinking water intake
0.0175 kg/day - fish intake
2 L/kg - Bioconcentration factor (BCF), Agency for Toxic Substances and Disease Registry – ATSDR, Toxicity Profiles
0.2 - relative source contribution (RSC)

Styrene

The Department is proposing to incorporate a CRL human health criterion for styrene. Based on toxicity studies present in IRIS, styrene causes central nervous system damage. The Department has calculated a CRL based on a threshold human health criterion. The US Department of Health and Human Services – National Toxicity Program (NTP) has listed styrene as reasonable anticipated to be a human carcinogen in their 10th report. The International Agency for Research on Cancer has also listed styrene as a possible human carcinogen. Therefore, the Department will incorporate an additional margin of safety (10) with the threshold toxicity data to develop a protective human health criterion.

The CRL criterion for styrene was calculated using *EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health – 2000* and the following toxicity data:

.2 mg/kg-day - RfD – IRIS
70 kg - body weight
2 L - drinking water intake
0.0175 kg/day - fish intake
14 L/kg - Bioconcentration factor (BCF), US EPA Office of Pollution Prevention and Toxics (OPPT) – Chemical Fact Sheet, December 1994.
0.25 - relative source contribution (Human Health Criteria Calculation Matrix (November 2002))
10 – margin of safety to protect against cancerous effects

Based on the above toxicity data, the proposed CRL human health criterion for styrene is 100. ug/L.

Molybdenum

The Department has collected toxicity data in several water bodies in PA indicating molybdenum concentrations that are high enough to have acute effects on aquatic life and human health. Molybdenum toxicity data collected at PA water quality network (WQN) stations since 2007 has revealed an average detectable acute concentration for Mo of 4028 ug/L. The highest acute concentration recorded is 15400 ug/L. Waterbodies displaying high concentrations of Mo were found in Dauphin, Bradford, Washington counties. At the request of our regional office permit engineers, and based on the WQN data, it has been determined it is appropriate to incorporate statewide human health criteria for molybdenum.

The Department has calculated a threshold human health criterion for molybdenum based on the most current scientific information and data including the publication by the National Academies Press, “*Dietary Reference Intakes for Vitamin A ... Molybdenum ... 2000*, which supplements scientific information and data currently found in IRIS. The molybdenum criterion was calculated in accordance with the Department policy found in § 16.32 (relating to threshold level toxic effects), using EPA’s *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health – 2000*.

The calculated water quality based threshold human health criterion for molybdenum is 210 ug/L. The data and methodology used to develop this criterion were provided to EPA Region 3 and Headquarters Office of Water staff for review and confirmation. EPA staff reviewed and concurred that the Department used the appropriate data, and methodologies to develop the proposed recommended human health criterion for molybdenum.

This calculated human health criterion of 210 ug/L for molybdenum replaces the threshold human health criterion of 175 ug/L that was previously provided to the Department’s Southwest Regional Office prior to September 2006.

The threshold human health criterion for molybdenum was calculated using *EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health – 2000* and the following toxicity data:

- **RfD Equivalent** for molybdenum – **NOAEL/UF** (0.03 mg/kg-day)
 - **NOAEL** – No Observed Adverse Effect Level (0.9 mg/kg-day) (National Academies Press, 2000)
 - **UF** – Uncertainty factor (30: 10 for extrapolation from animal to human studies, and 3 for inter-species variations)
- **RSC** – Relative Source Contribution - .20 (accounts for the non-water sources of exposure.) (EPA, 2000)
- **BW** – Body weight (70 kg) (25 Pa Code § 16.32(b))
- **DI** – Drinking Water Intake (2.0 Liter) (25 Pa Code § 16.32(b))
- **FI** – Fish consumption Rate (17.5 g/day - increased from the previous 6.5 g/day) (EPA, 2000)
- **BAF** – Bioaccumulation factor for Mo - 1.0