COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF POINT AND NON-POINT SOURCE MANAGEMENT

RATIONALE FOR THE DEVELOPMENT OF AMBIENT WATER QUALITY CRITERIA FOR THE PROTECTION OF

HUMAN HEALTH USE

(Revised February 2013)

Ambient water quality criteria are numeric values limiting the amount of chemicals present in our nation's waters. A water quality criterion is the minimum or maximum 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. These water quality criteria are based solely on the best available scientific data and scientific judgments on pollutant concentrations and environmental or human health effects.

The Department uses the provisions stated in PA Code, Chapter 16 (relating to the statement of policy), Sections 16.32 and 16.33 to develop human health criteria. The primary source used to obtain relevant risk assessment values is the Environmental Protection Agency's, (EPA's) Integrated Risk Information System (IRIS). IRIS is an electronic data base maintained by the EPA's National Center for Environmental Assessment (NCEA) that contains summaries of adverse health effects that result from lifetime (chronic) exposure to chemical substances. The summaries in IRIS contain health effects information, including reference doses (RfD's) for non-cancer effects resulting from oral exposures, cancer weight of evidence designations and cancer slope factors. EPA uses an ongoing screening-level review of scientific literature for chemicals in IRIS. (EPA, *Screening-Level Review of the Recent Health Effects for IRIS Chemicals*) 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. The screening-level review, consists of:

- Identifying recent toxicological secondary source documents prepared by EPA and other authoritative scientific organizations
- Conducting literature searches to identify relevant health effects literature published since the IRIS assessment for a given chemical was completed and posted on IRIS
- Sorting literature and evaluating the new health effects information and determining if this information could potentially produce a significant change in IRIS toxicity values.
  (EPA, *Screening-Level Review of the Recent Health Effects for IRIS Chemicals*)

Authoritative Secondary Sources Considered for Screening Level Review:

- Agency for Toxics Substances and Disease Registry (ATSDR) Toxicological Profiles
- Health Canada assessments
- International Agency for Research on Cancer (IARC) Monographs
- World Health Organization/International Programme on Chemical Safety (WHO/IPCS) - Environmental Health Criteria
- National Toxicology Program (NTP) Cancer Bioassay
- NTP report on Carcinogens
- Office of Pesticide Programs (OPP) Reregistration Eligibility (RED) documents
- NCEA Provisional Peer-reviewed Toxicology Values
- Documents submitted to IRIS Submission Desk
- World Health Organization/International Programme on Chemical Safety (WHO/IPCS) – Concise International Chemical Assessment Document (CICADS) (EPA, *Screening-Level Review of the Recent Health Effects for IRIS Chemicals*)

The Department is proposing criteria, that will protect human health uses, for the following toxic substances. This list also contains toxic substances that have been recommended by EPA since the completion of Pennsylvania's previous triennial review, which was finalized in April, 2010:

- acrolein and phenol
- acrylamide
- benzyl chloride
- 2-butoxyethanol
- cis-1,2-dichloroethylene
- cyclohexylamine
- resorcinol
- strontium
- 1,2,4 and 1,3,5 trimethylbenzene

CRITERIA DEVELOPED BY EPA

Acrolein and Phenol

Acrolein and phenol are priority pollutants and are currently listed on the federal 304(a) list of the National Recommended Water Quality Criteria. The criteria for phenol and acrolein are being updated because of more recent reference dose's (RfD) available from the EPA, IRIS database.

Because recalculation of these two criteria resulted in significant changes, EPA published notice in the Federal Register on September 15, 2008 (73 FR 53246) in order to solicit scientific views. EPA indicated, however, in that Federal Register notice that they did not intend to subject this recalculation to additional peer review concerning the RfD because the IRIS RfD's being updated in the subject draft partial criteria update had been previously peer reviewed. EPA published notice of final criteria for acrolein and phenol in the Federal Register on June 10, 2009 (74 FR 27535), which supersedes earlier criteria published by EPA. Human health criteria - acrolein and phenol, May, 2009 (EPA-822-F-009-001).

Acrolein is a widely used product. It is used in the preparation of polyester resin, polyurethane, propylene glycol, and acrylic acid. It is also used as an herbicide to control submersed and floating weeds and algae in irrigation canals. Phenol was first extracted from coal tar, and its major uses involve its conversion to plastics or related materials. Phenols are used in creating polycarbonates, epoxies, nylon, detergents, herbicides and pharmaceuticals.

In order to be consistent with the national criteria recommendations, based on this latest scientific information on reference doses, the Department recommends that the Environmental Quality Board (EQB) proposes to incorporate the updated, recalculated human health criteria for phenol to 10400 ug/L, and for acrolein to 6.0 ug/L.

CRITERIA WITH CANCER RISK LEVELS (CRL) LISTED IN IRIS

Benzyl Chloride

Benzyl chloride 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 gasoline. (National Library of Medicine HSDB Database) EPA has labeled benzyl chloride as a probable human carcinogen. Toxicity data in IRIS reveals that benzyl chloride affects the thyroid causing cancerous cells to develop.

Based on the most current data available in IRIS and the exposure assumptions in the Department's statement of policy, the calculated cancer risk level is 0.2 ug/L. The Department is therefore recommending that the EQB propose to adopt the IRIS calculated CRL for benzyl chloride. (0.2 ug/L)

CRITERIA DEVELOPED BY THE DEPARTMENT

These proposed criteria were developed using the current best available toxicity data. The sources the Department uses to obtain relevant risk assessment values to calculate criteria to protect human health are found in Chapter 16 (relating to guidelines for development of human health-based criteria). The main sources are:

The EPA agency-wide supported data system known as IRIS.
Maximum contamination level goals (MCLG),
The EPA CWA § 304(a) health criteria listed under the National Toxics Rule in 40 CFR 131.35 and other final criteria published by the EPA and the Great Lakes Initiative Clearinghouse.
Teratology and other data that have been peer-reviewed.

Depending on the toxicity data available the criteria are developed either as threshold toxics or non-threshold (cancerous) toxics. Both the threshold human health (THH) and non-threshold cancer risk level – (CRL) criteria are calculated using the EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health – 2000. The substances and the toxicity data used to calculate the criteria for each substance are as stated below:

Acrylamide

Acrylamide is an industrial chemical used mainly in the production of polyacrylamides, which are used as flocculants for clarifying drinking water and treating municipal and industrial effluents. 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)

On March 22, 2010, EPA provided new toxicity data for acrylamide in the IRIS database. The carcinogenicity assessment in IRIS has acrylamide labeled as, "likely to be carcinogenic to humans". An oral slope factor of 0.5 mg/kg-day has been established to determine a cancer risk. In addition to the exposure assumptions found in Chapter 16, the toxicity data was used to calculate the criterion.

Based on the most current toxicity data in IRIS the Department is recommending that the EQB propose an acrylamide human health CRL of .07 ug/L.

2-Butoxyethanol

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). It is also used as a bulk additive in the hydro-fracking process. Based on studies recorded in the IRIS data base 2-butoxyethanol has been shown to cause damage to the liver.

The Department used toxicity data obtained from IRIS, to calculate a human health criterion for 2-butoxyethanol.

In addition to using the exposure assumptions found in Chapter 16, the THH criteria for 2-butoxyethanol was calculated using the following toxicity data:

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

Based on the most current toxicity data in IRIS, the Department is recommending that the EQB propose a THH criterion for 2-butoxyethanol of 700 ug/L.

cis-1,2-dichloroethylene (DCE)

Dichloroethylene occurs in two forms, cis-1,2-DCE and trans-1,2-DCE. 1,2-DCE is used as a solvent for waxes, resins, polymers, fats, and lacquers. It is also used as an intermediate in the preparation of other chlorinated solvents. 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. Because cis-

1,2-DCE is an isotope of DCE, and there is newly developed toxicity data available in IRIS, the Department is proposing to incorporate the human health criterion for cis-1,2-DCE into Chapter 93, Table 5. Cis-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) The criterion for trans-1,2-DCE was also reviewed but there was no update to the national recommendation.

On September 30, 2010, US EPA posted toxicity data in IRIS for developing human health criteria for cis-1,2-DCE. The THH criterion for cis-1,2 –DCE was calculated using the following toxicity data in addition to the exposure assumptions found in Chapter 16:

.002 mg/kg-day - Oral Chronic RfD for cis-1,2-DCE – IRIS
23 L/kg - Bioconcentration factor (BCF), (US EPA, National Primary Drinking Water Regulations Technical Factsheet on cis-1,2-DCE)
0.2 - default relative source contribution (RSC)

The proposed calculated cis-DCE criterion is more stringent than the trans-DCE isotope that is currently listed as a priority pollutant. Therefore, the Department is recommending that the EQB propose the cis-DCE criterion and place it in Table 5 with its isotope, trans-DCE. The calculated human health criterion for cis-1,2- DCE is 12 ug/L.

Cyclohexylamine

Cyclohexylamine is listed as an extremely hazardous substance according to Section 302 of the US Emergency Planning and Community Right- to -Know Act. It 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. Cyclohexylamine is very toxic by ingestion and is readily absorbed through the skin.

The THH criterion for cyclohexylamine was calculated using the following toxicity data in addition to the exposure assumptions found in Chapter 16:

.2 mg/kg-day - RfD – IRIS
3 L/kg - Bioconcentration factor (BCF), National Library of Medicine, Hazardous Substance Databank. US EPA, Health and Environmental Effects Document for cyclohexylamine, Office of Health and Environmental Assessment, 500ECAOCING017
0.2 - relative source contribution (RSC)

The Department is recommending that the EQB propose 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.

Resorcinol

Beazer East, Inc. (Beazer) implemented environmental investigations and remediation at sites in Butler and Armstrong Counties, Pennsylvania in cooperation with the Department of Environmental Protection (Department) and United States Environmental Protection Agency (U.S. EPA). Currently, with respect to surface water, there is no ambient water human health criteria for resorcinol.

The Beazer sites are located within an area approximately 60 square miles in size that has been designated by the Department under the Hazardous Sites Cleanup Act (HSCA) as the "Bear Creek Area Chemical Site" (BCACS). The Department has determined that environmental media (i.e. soil and groundwater) within the BCACS have been impacted by sulfonate compounds (the sulfonate compounds include meta-benzene disulfonic acid (m-BDSA), benzene monosulfonic acid (BSA), p-phenol sulfonic acid (p-PSA)), resorcinol and other hazardous substances. Resorcinol is used as a chemical intermediate for the synthesis of pharmaceuticals and other organic compounds. It is used in the production of dyes and plasticizers and as a UV absorber in resins. The Department developed a resorcinol ambient water quality criterion for the protection of human health since it was discovered during this evaluation of water quality criteria that human health is the most sensitive use to be protected.

The Department, calculated a threshold human health criterion using EPA's approved methodology, 2000 and toxicity data from Resorcinol – Concise International Chemical Assessment Document 71, which was published in 2006 under the United Nations Environment Programme, the International Labour Organization, and the World Health Organization. The Department also used information from the Data Analysis and Test Plan for Resorcinol, INDSPEC Chemical Corporation, May 2004. The Department is recommending that the EQB propose a human health criterion for resorcinol (2700 ug/L) which was developed using the exposure assumptions found in Chapter 16 and following equation, variables, and sources of data:

AWQC (ug/L) = NOAEL/ UF x RSC x (BW/DI + (FI x BCF)) x 1000, where:

- **RfD Equivalent** for resorcinol – **NOAEL/UF** (0.4mg/kg-day)
    - **NOAEL** – No Observed Adverse Effect Level (50 mg/kg-day) (*Concise International Chemical Assessment Document 71*, 2006)
    - **UF** – Uncertainty factor (100, 10 –intra species, 10 – inter species variations) (*Concise International Chemical Assessment Document 71*, 2006)
- **RSC** – Relative Source Contribution - .20 (Accounts for the non-water sources of exposure.) (EPA, 2000)
- **BCF** – Bioconcentration Factor – 3.162.0 L/kg (INDSPEC Chemical Corporation)

Strontium

Strontium has been identified in many hazardous waste sites that have been proposed for inclusion on the EPA Superfund National Priorities List (NPL) (HazDat 2003). Strontium is a naturally occurring metal and can enter the waterways in a variety of forms. It can be released to surface water and groundwater as a result of the natural weathering of rocks and soils and from the discharge of wastewater directly into streams and aquifers. Strontium is used in ceramics and glass products; pyrotechnics; paint pigments and fluorescent lights to name a few (ATSDR

Toxicological profile for strontium). It is also a component of the effluent from natural gas production. The absorption of strontium in the body is similar to that of calcium. Strontium will migrate to the bones. Excess strontium causes problems with growing bone. For this reason, children are more susceptible to the effects of strontium than adults who have mature bone. (Agency for Toxic Substances and Disease Registry (ATSDR). 2004)

The THH criteria for strontium is calculated using the exposure assumptions found in Chapter 16 and the following toxicity data:

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

Based on the current toxicity data in IRIS and the Strontium Toxicological Profile, (ATSDR, April 2004) the Department is recommending that the EQB propose a human health criterion of 4200 ug/L.

1,2,4 and 1,3,5 Trimethylbenzene (TMB)

TMB is a byproduct from the petroleum refining process. It is also used as a solvent in coatings; cleaners; pesticides and inks. The TMB's are lipophilic and tend to accumulate in fatty tissue. Most of the chemical will adhere to red blood cells. TMB is labeled a central nervous system depressant. Once metabolized, TMB has been shown to cause anemia, asthmatic bronchitis, alterations in blood clotting. (US EPA OPP August 1994)

The toxicity data used to calculate 1,2,4 -TMB and 1,3,5 - TMB was obtained from the EPA Risk Assessment Program Tier 2, Provisional Peer-Reviewed Toxicity Value (PPRTV) assessment. 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). In the PPRTV risk assessment paper it was determined that the structure of 1,2,4- and 1,3,5-TMB is similar, therefore the two isomers can be used as surrogates for the other. The same toxicity data was therefore 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 exposure assumptions found in Chapter 16 and the following toxicity data:

.05 mg/kg-day - Oral RfD (reference dose) - Risk Assessment Information System (RAIS)
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 recommending that the EQB propose to adopt the calculated human health criteria for both 1,2,4 TMB (72 ug/L) and 1,3,5 TMB (72 ug/L).

REFERENCES USED IN THIS EVALUATION:

General Reference:
IRIS (US EPA, Integrated Risk Information System) A-Z list of substances
http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList&list_type=alpha

EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health – 2000*. (EPA-822-B-00-004)

25 Pa Code Chapter 16 Water Quality Toxics Management Strategy – Statement of Policy. Commonwealth of Pennsylvania.

U.S. Environmental Protection Agency (1994). Water Quality Standards Handbook. Second Edition. EPA 823-0-94-005A, August, 1994.

Chemical-Specific References:

Acrolein and Phenol - May, 2009 Human health criteria (EPA-822-F-009-001).
Acrylamide – EPA IRIS
Acrylamide - Chemical Summary, (1994) US EPA Office of Pollution Prevention and Toxics, (EPA – 749-F-94-005a)
Benzyl chloride – EPA IRIS
2-butoxyethanol – EPA IRIS
2-butoxyethanol – ATSDR, Toxicity Profiles (tp118-c5[1].pdf)
cis-1,2-dichloroethylene (DCE) – IRIS
cis-1,2-DCE – BCF, (US EPA, National Primary Drinking Water Regulations Technical Factsheet on cis-1,2-DCE)
Cyclohexylamine – IRIS
Cyclohexylamine – US EPA, Health and Environmental Effects Document for cyclohexylamine, Office of Health and Environmental Assessment, 500ECAOCING017
Resorcinol – Concise International Chemical Assessment Document 71, 2006, United Nations Environment Programme, the International Labour Organization, the World Health Organization.
Resorcinol, Data Analysis and Test Plan for, (May 2004), INDSPEC Chemical Corporation.
Strontium – EPA IRIS
Strontium, Toxicological Profiles, ATSDR, April 2004
1,2,4 and 1,3,5 Trimethylbenzene:
Risk Assessment Issue Paper for: *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).
Chemical Summary for TMB, US EPA OPP August 1994 (EPA 749-F-94-022a)