Why the need for the white paper?

- Under the United States Clean Water Act (CWA) (33 U.S.C. Sections 1251-1387), EPA is required to take a number of actions to protect and restore the ecological integrity of the Nation's water bodies.
- Under Section 304(a) of the CWA, EPA must develop and publish ambient water quality criteria. Ambient water quality criteria (AWQC) are levels of individual pollutants, water quality characteristics, or descriptions of conditions of a water body that, if met, should protect the designated use(s) of the water.
- AWQC for aquatic life (aquatic life criteria, ALC) developed under Section 304(a) reflect the "latest scientific knowledge" concerning "all identifiable effects" of the pollutant in question.

Why the need for the white paper?

- In 1985, EPA published *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (hereafter referred to as the "*Guidelines*"; Stephan et al. 1985)
- The *Guidelines* have provided uniformity and transparency in the derivation methodology of ALC for a large number of compounds among several classes of chemicals.
- The majority of EPA's currently recommended ALC have been derived using the methods outlined in the *Guidelines*.

Why the need for the white paper?

- While the *Guidelines* remain the primary instrument the Agency uses to meet its broad objectives for the development of ALC, there have been many advances in aquatic sciences, aquatic and wildlife toxicology, population modeling, and ecological risk assessment that are relevant to deriving ALC.
- Some of the advances have been addressed through supplemental guidance on the derivation or site-specific modification of criteria (Prothro 1993; U.S. EPA 1994a), while others have been incorporated directly into derivation of individual ALC for certain chemicals (e.g., saltwater chronic ALC for tributyltin, U.S. EPA 2003).
- Recently, considerable attention has been generated by a widely ranging group of chemicals termed contaminants of emerging concern (CECs).

Why the need for the white paper?

- Criteria development for CECs is needed
- CECs challenge the traditional derivation methods because of their toxicological properties not previously encountered and a general lack of toxicity data
- Adaptation of the guidelines is warranted to accommodate these issues but should still maintain the technical rigor of the 1985 Guidelines

What is a Contaminant of Emerging Concern?

- Have no regulatory standard
- Recently “discovered” in natural streams
- Potentially cause deleterious effects in aquatic life at environmentally relevant concentrations
- Pollutants not currently included in routine monitoring programs
- Not necessarily new chemicals

What is a Contaminant of Emerging Concern?

- CECs include several types of chemicals:
  - Persistent organic pollutants (POPs)
  - Pharmaceuticals and personal care products (PPCPs)
  - Veterinary medicines
  - Endocrine-disrupting chemicals (EDCs)
  - Nanomaterials

Why the concern about CECs?

- Widespread
- Some indication of environmental persistence
- Indications of effects in natural systems
- Public concerns
- ALC not yet developed for many CECs

General Purpose of the white paper

- The white paper is meant to provide supplemental guidance that will facilitate the derivation of ALC for CECs
- Evaluate application of the guidance with the model CEC Ethinylestradiol

General Organization of white paper

- Part I
  - Introduction
  - Current Aquatic Life Criteria Methodology
    - Summarize current methodology and identify areas in which procedures might be modified to address CECs
  - Implications for Criteria Development
    - Discuss specific CEC characteristics as they affect ALC procedures
    - Paths forward to address issues raised
  - Summary and Recommendations
- Part II
  - Illustrate the recommendations with the model CEC Ethinylestradiol

General nature of feedback desired from SAB Reviewers

- Comment on the scientific merits of the recommendations
- Comment as to what issues may have been missed
- Comment on any perceived implementation difficulties