Issues relevant to deriving Surface Water Quality Standards

(Groundwater standards issues are separated)

Priority: Supply supportive materials to develop scientifically based WQS for surface waters to be approved by EPA under CWA

The information requested is based on the requirements set forth in current NC regulations for Surface Waters (15A NCAC 02B .0200s – specifically.0208)

1. AQUATIC LIFE PROTECTION (15A NCAC 02B .0208 (a) (1))

a. Identification of scientifically sound aquatic toxicology studies to obtain the following information for individual chemicals (or chemical groups if deemed appropriate by the SAB):
   - **Lethal Concentration at 50% (LC50 values)** for fully aquatic or aquatic-dependent species (preference for species native to NC surface waters)
   - **NOEC & LOEC values** for the calculation of chronic values for fully aquatic or aquatic-dependent species (preference for species native to NC surface waters)
   - **Acute/chronic ratios** for fully aquatic or aquatic-dependent species (preference for species native to NC surface waters)

b. Information on the **half-life** or **log octanol:water (log P) values** for individual chemicals

2. HUMAN HEALTH PROTECTION (excerpt/abbreviated from: 15A NCAC 02B .0208 (a)(2)):

Highlights indicate areas that the SAB could offer assistance/guidance and advice on maintaining the level of protection with respect to the PFAS or adding additional layers of protection.

Human health standards: the concentration of toxic substances shall not exceed the level necessary to protect human health through exposure routes of fish tissue consumption, water consumption, or other route identified as appropriate for the water body. Fish tissue consumption includes the consumption of shellfish;

(A) For **non-carcinogens**, these concentrations shall be determined using a Reference Dose (RfD) as published by the US EPA pursuant to Section 304(a) of the Clean Water Act as amended or an RfD issued by the US EPA in the Integrated Risk Information System (IRIS) file or a **RfD approved by the Director after consultation with the State Health director.....:**

(i) Fish tissue consumption {only} Note: this derived non-cancer standard protects Class C waters. Class C waters are the basic level of human health protection.

WQS = (RfD x RSC) x Body Weight / (FCR x BCF)

where:

WQS = water quality standard or criteria;

RfD = reference dose;

RSC = Relative Source Contribution;

FCR = fish consumption rate (based upon 17.5 gm/person-day);

BCF = bioconcentration factor, or bioaccumulation factor (BAF), as appropriate.

Pursuant to Section 304(a) of the Clean Water Act as amended BCF or BAF values, literature values, or site specific bioconcentration data approved by the Commission or its designee are based on US EPA; FCR values are average consumption rates for a 70 Kg adult for the lifetime of the population; alternative FCR values may be used when it is considered necessary to protect localized populations that may be consuming fish at a higher rate; RSC values, when made available through US EPA publications pursuant to Section 304(a) of the Clean Water Act to account for non-water sources of exposure may be either a percentage (multiplied) or amount subtracted, depending on whether multiple criteria are relevant to the chemical;

(ii) Water consumption (including a correction for fish consumption): Note: Applies to all waters bodies designated as "Water Supplies" (WS Classification). All highlights as noted above plus "Water Consumption Rate""

WQS = (RfD x RSC) x Body Weight / [WCR+(FCR x BCF)]

where:

WQS = water quality standard or criteria;

RfD = reference dose;

RSC = Relative Source Contribution;
FCR = fish consumption rate (based upon 17.5 gm/person-day);
BCF = bioconcentration factor, or bioaccumulation factor (BAF), as appropriate;
WCR = water consumption rate (assumed to be two liters per day for adults).

Note: the following section indicates provisions to protect a child. Advice is requested on modifying these sections for future consideration, as well as applying the rule to the current need for PFAS protective concentrations.

To protect sensitive groups, exposure is based on a 10 Kg child drinking one liter of water per day. Standards may also be based on drinking water standards based on the requirements of the Safe Drinking Water Act .....the equations listed in this Subparagraph shall be used to develop water quality based effluent limitations on a case-by-case basis for toxic substances that are not presently included in the water quality standards. Alternative FCR values may be used when it is considered necessary to protect localized populations that may be consuming fish at a higher rate;

(B) For **carcinogens**, the concentrations of toxic substances shall not result in unacceptable health risks and shall be based on a Carcinogenic Potency Factor (Oral Slope Factor). An unacceptable health risk for cancer shall be considered to be more than one case of cancer per one million people exposed (10-6 risk level). The CPF is a measure of the cancer-causing potency of a substance estimated by the upper 95 percent confidence limit of the slope of a straight line calculated by the Linearized Multistage Model or other appropriate model according to US EPA Guidelines .....

To summarize areas of need for human health:

1. **Studies of sufficient strength and confidence to recommend a Point of Departure (POD) and suggestions for the use of Uncertainty Factors; or a recommended RfD or provisional RfD which could be used until additional studies or reevaluations can be made**
2. **RSC determinations (if possible); the SAB could also recommend the use of a default**
3. **CPF/OSFs (as appropriate)**
4. **Recommendations on modifying the current default assumptions for FCR, BW, WCR, exposure timeframe**
5. **Need to address other sensitive subpopulations?**

Issues relevant to deriving Groundwater Quality Standards

Priority: Supply supportive materials to develop scientifically based WQS for groundwaters to be approved by the NC Environmental Management Commission

The information requested is based on the requirements set forth in current NC regulations for Surface Waters (15A NCAC 02L .0200s – specifically.0202)

Current regulations for protection of groundwater (15A NCAC 02L .0202) (excerpt/abbreviated)

Highlights indicate areas that the SAB could offer assistance/guidance and advice on maintaining the level of protection with respect to the PFAS or adding additional layers of protection.

(b) The groundwater quality standards for contaminants specified in Paragraphs (h) and (i) of this Rule are as listed, except that:

(2) Where two or more substances exist in combination, the Director shall consider the effects of chemical interactions as determined by the Division of Public Health and may establish maximum concentrations at values less than those established in accordance with Paragraphs (c), (h), or (i) of this Rule. In the absence of information to the contrary, in accordance with Paragraph (d) of this Rule, the carcinogenic risks associated with carcinogens present shall be considered additive and the toxic effects associated with non-carcinogens present shall also be considered additive.

(c)..... Any person may petition the Director to establish an interim maximum allowable concentration {IMAC} for a substance for which a standard has not been established under this Rule. The petitioner shall submit relevant toxicological and epidemiological data, study results, and calculations necessary to establish a standard in accordance with Paragraph (d) of this Rule.....

(d) Except as provided in Paragraph (f) of this Rule, groundwater quality standards .....are established as the least of:

(1) Systemic threshold concentration calculated as follows: [Reference Dose (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganics; .20 for organics)] / [2 liters/day (avg. water consumption)];{As noted with respect to the Surface Water standards – these default assumptions are currently in rule – but, the Department requests advice on modifying them with respect to the PFAS or other chemicals}

(2) Concentration which corresponds to an incremental lifetime cancer risk of 1x10-6;

(3) Taste threshold limit value;

(4) Odor threshold limit value;

(5) Maximum contaminant level; or

(6) National secondary drinking water standard.

(e) The following references, in order of preference, shall be used in establishing concentrations of substances which correspond to levels described in Paragraph (d) of this Rule.

(1) Integrated Risk Information System (IRIS) (U.S. EPA).

(2) Health Advisories (U.S. EPA Office of Drinking Water).{the use of the term HA here is specific to the US EPA}

(3) Other health risk assessment data published by the US EPA.

(4) Other relevant, published health risk assessment data, and scientifically valid peer-reviewed toxicological data.

To summarize areas of need with respect to Groundwater standards:

1. **Derive applicable RfDs, CPF, etc, factors to allow the Division to adopt an IMAC (interim)/standard for groundwater.**
2. **Note that there is language relating to mixtures in 15A NCAC 02L .0202; is this useful for the PFAAs?**
3. **Note that GW doesn't currently have language addressing infants or children**

Overall Health Protection Target Issues

If carcinogenic, would the Board suggest the DEQ maintain a 1 in a million-increased lifetime cancer risk? Or perhaps modify the recommendation for a sub-population (Wilmington area?). This would aid risk management decisions and risk communications.

Is a state-wide criterion warranted? Or is the situation more suited to a site-specific criterion?

If non-carcinogenic, a RfD derived by the Board could include the descriptor of applied uncertainty factors (UFs), so that the public can be better informed as to the strength of the health studies.

Relative Source Contribution:

US EPA recommends the use of between 20 and 80%. The application of an RSC lowers the Human Health Water Quality Criteria to account for exposures from other sources such that the total exposures do not exceed toxicity thresholds. Advice/demonstration on a proper choice of an RSC is requested.

The use of an RSC has been questioned when used in conjunction with derivation of a criterion protective of a bottle-fed infant (where ~100 % of consumption of chemical is assumed to be from the bottle). If suggested, documentation on the reasoning would be appreciated.

Bioaccumulation Factors:

In order for the State to derive criteria for the protection of humans consuming potentially contaminated fish, it would be helpful if the Board could obtain information on the bioaccumulation potential of the per/poly fluorinated compounds, as well as other examined chemicals.

Drinking water intake rates:

Current state regulations assume a 2 liter/day consumption for adults. EPA now suggests an increase to 2.4 L/day is warranted.

As noted above, groundwater standards are not written to protect children, WQS are written for children, but, not infants. Advice on modifying the current regulation for intake rates and sensitive populations is requested.