

Turning Science into Law: The Process for Setting Health- Based Exposure Limits

ACEC of North Carolina

Sean M. Sullivan

April 24, 2019

Topics

Safe Drinking Water Act

EPA's PFAS Action Plan

North Carolina's Default Rules for Surface Water and Groundwater Quality Limits

NC Science Advisory Board

Applicability of the 2L Rules to Emerging Compounds

Safe Drinking Water Act

Evaluation of Unregulated Contaminants

- Unregulated Contaminant Monitoring Rules (UCMR) – to develop data about unregulated substances in public water systems
 - Once every five years (next one due by 2021)
 - No more than 30 substances
- Candidate Contaminant List (CCL) – EPA uses toxicology information and information about prevalence of a substance in drinking water from the UCMR to develop the list of candidates to enter the Regulatory Determination Process
- Regulatory Determination (RD) – EPA must decide whether to regulate five substances on the CCL every five years (next one due 2021)
 - Potential health effects of the substance
 - Likelihood of substance being present at concentrations that can cause adverse health effects
 - In a significant number of public water systems
 - Good opportunity to reduce public health risk by regulating the substance

Safe Drinking Water Act

Two Key Concepts for Setting Standards

- Maximum Contaminant Level Goal (MCLG) – maximum concentration at which no known or anticipated health effects will occur, including an adequate margin of safety
 - Starting point for an MCL
- Maximum Contaminant Level (MCL) – enforceable concentration limit for a contaminant

Setting the MCLG

- Carcinogens – set at zero unless there is a dose that is known to be safe
- Non-carcinogens – set using the reference dose (concentration at which no adverse health effects are expected to occur based on a lifetime of daily exposure)

Setting the MCL

- MCL must be set as close to the MCLG as “feasible”
- If there is no reliable method to measure contaminant concentrations that is technically and economically feasible, EPA establishes a “treatment technique” instead

Safe Drinking Water Act

Feasible – the lowest concentration that can be achieved using:

- Best available technology or treatment approaches
- Other methods that EPA concludes are available (based on actual use in the field, not only in a lab)
- And, EPA can consider the costs of these methods in determining if a treatment method is feasible

Once EPA establishes the “feasible” concentration, EPA then performs a Health Risk Reduction and Cost Analysis (HRRCA)

- Analyze quantifiable and unquantifiable benefits of the feasible concentration versus increased costs from the feasible concentration
- Incremental costs and benefits of feasible concentration versus other levels
- Health effects on general population and sensitive subgroups
- Other factors (data quality, nature of the health risk from the contaminant)

If the benefits of the feasible concentration do not justify the costs, EPA can adjust the MCL to a level where the costs are justified by the benefits.

Safe Drinking Water Act

Implications of MCLs and MCLGs for Cleanups

- EPA policy is to adopt the MCLG as a groundwater cleanup target, as long as the MCLG is something other than zero.
- EPA uses the MCL in cases where the MCLG is zero.
- Strange federal dichotomy – If you're cleaning up a known/suspected carcinogen, your cleanup standard takes the cost of drinking water treatment into account. Otherwise, it doesn't.

Topics

Safe Drinking Water Act

EPA's PFAS Action Plan

North Carolina's Default Rules for Surface Water and Groundwater Quality Limits

NC Science Advisory Board

Applicability of the 2L Rules to Emerging Compounds

EPA's PFAS Action Plan

Short-Term Actions (completion within the next two years)

- Propose MCLs for PFOA and PFOS
- Improved analytical methods for drinking water
- New analytical methods for PFAS and precursors in other media
- Guidance on groundwater cleanups
- Final Toxicity Assessments
 - PFBS and GenX in 2019
 - Five additional PFAS in 2020

EPA's PFAS Action Plan

Long-Term Actions

- Consider requiring reporting for PFAS releases in TRI reports
- Consider establishing numerical surface water quality criteria
- Examine existing information and begin to send information requests to support development of ELGs for NPDES permits
- Include PFAS in next UCMR and use data to develop national prevalence information
- Continue studying ecological risk and atmospheric transport

Topics

Safe Drinking Water Act

EPA's PFAS Action Plan

North Carolina's Default Rules for Surface Water and Groundwater Quality Limits

NC Science Advisory Board

Applicability of the 2L Rules to Emerging Compounds

Default Rules for Surface Water and Groundwater Quality Limits

Surface Water Quality Standards

- 15A NCAC 02B.0208 – numerical approach for establishing surface water quality standards for toxic pollutants
 - Aquatic life – cannot cause chronic toxicity; in absence of direct measurements thereof, limit is:
 - Fraction of the the lowest LC50 that predicts no effect chronic level (using acceptable acute/chronic ratio); or
 - 0.05 or 0.01 X lowest LC50
 - Human Health – Cancer and non-cancer health effects
 - Non-cancer focuses on effects from consumption of fish tissue and water consumption
 - Fish tissue focuses on effects to 70kg adult based on average lifetime consumption
 - Water consumption focuses on effects to 10kg child consuming 1 liter of water per day
 - Cancer – focuses on not causing increase in lifetime risk greater than 1×10^{-6}
 - Based solely on consumption of fish. Cancer risk from water consumption is addressed in the WS classifications.

Default Rules for Surface Water and Groundwater Quality Limits

Water Supply Watersheds

- WS-I through WS-V classifications all require that surface waters meet applicable MCLs
 - 15A NCAC 02B.0212, 0214, 0215, 0216, 0218
- There are also specific standards for carcinogens and non-carcinogens for each class of water supply watersheds.
 - Standards are based on both water consumption and fish tissue consumption.

Default Rules for Surface Water and Groundwater Quality Limits

2L Rules – Groundwater – 15A NCAC 02L.0202(d&f)

- Standards must be set as “the least of”:
 - Systemic threshold concentration (non-carcinogenic effects) based on effects to 70kg human
 - Concentration corresponding to increase in lifetime cancer risk of 1×10^{-6}
 - Taste threshold limit
 - Odor threshold limit
 - Maximum Contaminant Level (MCL) established by EPA for drinking water from public water systems
 - National secondary drinking water standard – 15 contaminants directed towards odor, taste, color, etc.
- EMC can establish a standard that is less stringent than the MCL or the secondary standard if:
 - More recent data from certain sources supports a less stringent standard
 - It will not endanger human health or the environment
 - Compliance with the MCL or the secondary standard will “produce serious hardship without equal or greater public benefit”

Topics

Safe Drinking Water Act

EPA's PFAS Action Plan

North Carolina's Default Rules for Surface Water and Groundwater Quality Limits

NC Science Advisory Board

Applicability of the 2L Rules to Emerging Compounds

Re-Chartered in July 2017 to Assist DEQ and DHHS in Establishing Health-Based Exposure Limits for Environmental Contaminants

- Meets at least six times per year
- Makes recommendations on:
 - Need for reviews or evaluations of releases to the environment
 - How to regulate releases to the environment
 - Urgency of establishing such regulations
 - Consult with DEQ on regulation of releases, including establishment of acceptable exposure levels
 - Recommend acceptable concentrations of contaminants based on a “range of risks”
 - Evaluating multi-media effects of releases
 - Availability of new information about a contaminant and the implications for existing standards
 - DHHS’s efforts to establish health goals
 - Identifying emerging contaminants and need for evaluation of their health effects

Factors in making recommendations on “range of risk” concentrations:

- Have toxicological principles been appropriately applied in development of media-specific exposure concentration?
- Should substances with adverse reproductive / developmental effects “be treated with risk assessment factors”?
- Should synergistic effects of contaminant mixtures be considered?
- Should acceptable concentrations of contaminants be adjusted because of presence of multiple sources in a localized area?
- How should uncertainties be incorporated into the development and revision of acceptable concentration limits?

What isn't here? – **COST CONSIDERATIONS AND ACTUALLY SETTING THE STANDARDS**

Science Advisory Board

Recent Actions

- February 2019 – concurrence with DEQ’s proposed AAL for methyl bromide
- February 2019 – concurrence with DEQ’s recommended action levels for TCE in indoor air
- October 2018 – concurrence with DHHS’s proposed drinking water health goal for GenX

Ongoing Evaluations

- Hexavalent chromium

Science Advisory Board

Decision re GenX

- 140ppt standard is appropriate based on non-carcinogenic effects
- Insufficient information available to determine status as carcinogen

Consistency with Federal Approach

- Because the recommended health limit is based on non-carcinogenic effects, 140ppt is the equivalent of a NC-only MCLG for GenX
- Consistent with CERCLA and the NCP to use a non-zero MCLG as a cleanup target for GenX

Topics

Safe Drinking Water Act

EPA's PFAS Action Plan

North Carolina's Default Rules for Surface Water and Groundwater Quality Limits

NC Science Advisory Board

Applicability of the 2L Rules to Emerging Compounds

Applicability of the 2L Rules to Emerging Compounds

2L Rules – What if there's no established standard?

- 15A NCAC 02L.0202(c) – “Substances which are not naturally occurring and for which no standard is specified shall not be permitted in concentrations at or above the practical quantitation limit in Class GA or Class GSA groundwaters.”
- Practical Quantitation Limit – “lowest concentration of a given material that can be reliably achieved among laboratories within specified limits of precision and accuracy by a given analytical method during routine laboratory analysis.” 15 NCAC 02L.0102(15).
- According to DEQ – any detection of any non-natural substance above its PQL is a violation that can trigger corrective action under 02L.0106 unless there is an established standard for that substance
- Interim Maximum Allowable Concentration (IMAC) – 02L.0202(c) – allows any person to petition DEQ to establish an IMAC for a substance that does not have an established standard.
 - If DEQ establishes an IMAC, it must “initiate action” to consider adoption of a standard for that substance.

Applicability of the 2L Rules to Emerging Compounds

2L Rules – What if there’s no established standard? (cont’d)

- Establishing an IMAC appears to be the only way to avoid the conclusion that the detection of an unnatural substance without a standard constitutes a violation that establishes corrective action authority under 02L.0106.
- How do you establish an IMAC for an emerging contaminant? The whole idea is that we don’t have enough information about these contaminants to set a standard.
 - What would that IMAC petition look like?
 - DEQ is supposed to “initiate action” to consider a binding standard within three months of adopting an IMAC. Given the lack of information about an emerging contaminant, would DEQ really want to lock itself into having to initiate a rulemaking proceeding?
- If I were DEQ’s lawyer – I wouldn’t be in a hurry to establish a standard.
 - Promulgating a rule takes time and money, and it opens the door to someone seeking judicial review of it.
 - The current structure gives DEQ corrective action authority under the 2L rules for any detection above the PQL, so why limit yourself?
 - As more data comes in about a substance, you might learn that you need to reduce the standard again – more time and money, plus the political blowback of setting a standard that wasn’t stringent enough.

Applicability of the 2L Rules to Emerging Compounds

What is the PQL for an Emerging Compound?

- We are talking about parts per trillion in many cases, and sometimes less than 1ppt. Are lab results really that reliable?
 - Consider the potential for sample contamination – DEQ has established strict requirements for employees sampling for GenX (including limits on types of clothing and not eating fast food before taking samples).
 - Do we really know enough about these substances to know these precautions will be effective and produce a reliable, accurate result?

Chemours Consent Decree and Modified Title V Permit

Changing Understanding of Emissions of GenX from Fayetteville Works

- Original 2016 estimate – 66.6 lbs/year
- October 2017 revision to 2016 estimate – 594 lbs/year
- April 2018 calculation by DEQ – 2,758 lbs/year

Discovery of Atmospheric Deposition

- Early to mid-2017, GenX is primarily a surface water issue
- Mid to late 2017, DEQ discovers the extent of groundwater contamination and identifies air emissions as likely source
- January to April 2018, rainwater sampling identifies deposition as far as 20 miles from the facility

April 6, 2018 – DEQ sends a 60 day notice to Chemours of DEQ’s intent to modify the Facility’s Title V permit

Chemours Consent Decree and Modified Title V Permit

Basis for the 60-Day Notice

- 15A NCAC 02Q.0519(a)(2) – conditions under which the permit was issued have changed
- 15A NCAC 02Q.0519(a)(7) – modification necessary to carry out “the purpose of NCGS 143, Article 21B.”

Changed Conditions

- Stack testing determined significantly higher emissions of GenX than previously thought
- Emissions are resulting in atmospheric deposition of GenX
- GenX deposition is causing violations of NC groundwater quality standards

Purpose of NCGS 143, Article 21B

- NCGS 143-211 establishes “clear mandate” for environmental protection
- Statute endorses a “total environment of superior quality”
- Coordinated protection of air and water resources, including groundwater

Purposes of Article 21B?

“Total environment of superior quality”

- Chemours’ new Title V permit cites 02Q.0519(a)(7) (purposes of Article 21B) as the basis for requiring installation of a thermal oxidizer and reduction of GenX emissions by 99.99%
- Also provides the basis for requiring a shutdown/malfunction plan
- And provides the basis for establishing enhanced LDAR requirements

New annual emissions limit of 23.027 lbs/year

- My question – if any detection of GenX in groundwater is a violation, is this new limit sufficient to prevent any atmospheric deposition capable of causing a detection above the PQL?
- Seems more likely that it’s sufficient to prevent any detection above the health-exposure limit established by the SAB (140 ppt).
- If it’s the latter – seems like DEQ is exercising its enforcement discretion on the basis of an SAB opinion, which means the SAB recommendation is a de facto 2L standard for GenX that hasn’t gone through rulemaking at the EMC.

Bottom Line

The real action on emerging compounds in North Carolina is at the Science Advisory Board

- Unlikely DEQ is going to initiate rulemaking to establish a 2L standard quickly and petitioning to establish an IMAC isn't really feasible.
- Therefore – SAB recommendations are likely to guide DEQ's exercise of its enforcement discretion.

The regulated community needs to participate in the SAB's process!

Contact Information

Sean M. Sullivan

Troutman Sanders LLP

305 Church at North Hills Street

Suite 1200

Raleigh, NC 27609

(919) 835-4173

sean.sullivan@troutman.com