

April 25, 2016

Mr. Eric Shaw

Environmental Manager

Standards & Assessments Section

Florida Department of Environmental Protection

2600 Blair Stone Road, MS 6511

Tallahassee, FL

32399-2400

Dear Mr. Shaw:

These formal public comments by Larry E. Fink, M.S., Owner and Principal, Waterwise Consulting, LLC, are submitted to the Environmental Regulation Commission (ERC) in opposition to the proposed revisions to the Human Health-Based Water Quality Criteria as public noticed by the Florida Department of Environmental Protection (FDEP) for public comment at the July 26, 2016, meeting of the ERC. The proposed changes to the way FDEP derives Water Quality Criteria (WQC) to protect human health from exposure to non-carcinogens and known, likely and suspect human carcinogens in fresh and salt water fish and shellfish involve the use of a new, less protective, probabilistic approach that replaces the old, more protective, deterministic approach still used by the U.S. Environmental Protection Agency (EPA) in the derivation of national WQC guidance.

Proposed Revisions to Human Health-Based Water Quality Criteria

<http://www.dep.state.fl.us/water/wqssp/health.htm>

<http://www.dep.state.fl.us/water/wqssp/docs/health/HHC-FAQ.pdf>

http://www.dep.state.fl.us/water/wqssp/docs/health/Coded_62-302_072616.pdf

http://www.dep.state.fl.us/water/wqssp/docs/health/HH_TSD.pdf

<https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table>

I am a recognized expert in deriving, applying and peer reviewing the derivation and application of toxic substances Water Quality Criteria (WQC) to protect aquatic life and human health, Total Maximum Daily Loads based on those WQC, and Programmatic and Project-Specific Environmental Impact Statements for toxic substances. That experience includes revising, defending, and applying toxic substances Water Quality Standards (WQS) for non-carcinogens and carcinogens for the State of Michigan and co-authoring the book Regulating Toxic Substances in Surface Waters with Jeff Foran. My curriculum vitae is Appendix I. Appendix II is a copy of the abstract I submitted to the 6th International Conference of the Society of Environmental Toxicology and Chemistry in Orlando on the need to include the dose-response relationship in probabilistic risk assessment to ensure an adequate margin of safety in the derivation of human health protection criteria. Appendix III contains additional relevant references to support my concerns.

INTRODUCTION

On the one hand, FDEP is to be commended for initiating triennial review and revision of its WQS for toxic substances without U.S. Environmental Protection Agency Region 4 having to be sued first. On the other hand, the proposed changes weaken rather than strengthen the toxic substances WQC for Class I and III fresh and salt waters. Market basket dilution of exposure of the Florida public to toxic substances in fish and shellfish using Monte Carlo Simulation is not the solution to pollution.

This is no time to take the protection of public health less seriously, when as much as one-third of all cancers in the U.S. can be attributable to environmental factors, including exposure to carcinogens in air, water, food and fresh and salt water fish and shellfish.

<http://www.scientificamerican.com/article/how-many-cancers-are-caused-by-the-environment/>

According to the National Cancer Institute (NCI), in the period 2008-2012 the number of new cancers reported annually is about 455 per one hundred thousand. <http://www.cancer.gov/about-cancer/understanding/statistics> The incidences of certain age-adjusted cancers in humans are on the increase, including a 0.6% per year increase in cancers in children to age 14 between 2007 and 2011. http://www.oralcancerfoundation.org/facts/pdf/Us_Cancer_Facts.pdf

This may also be true of one of the most aggressive forms of cancer of the prostate. "The researchers -- who were looking for evidence to support a return to widespread prostate cancer screening -- found that cases of metastatic prostate cancer — the type that has started to spread in the body — nearly doubled in men aged 55 to 69 since 2004. The reason is not yet clear." <http://www.nbcnews.com/health/mens-health/cases-aggressive-prostate-cancer-rise-research-finds-n612661>

Since July 1984, when the national policy of zero discharge in the Clean Water Act (CWA) of toxic substances was effectively rescinded by administrative fiat and replaced by EPA with an acceptable lifetime increased risk for exposure to substances of commercial origin. Since then

you, your children, your grandchildren, and all future generations have been enrolled in a cancer lottery without your or their knowledge or consent. Their only crime is breathing the air, drinking the water, and eating the raw and processed foods necessary for life that are unnecessarily contaminated with carcinogens and carcinogenic amplifiers of unnatural origin.

This national policy shift was rationalized as acceptable by EPA, the environmental Non-Government Organizations, and the regulated industries, because the compounded margin of safety in the derivation of each WQC for each carcinogen was such that the realized increased cancer incidences were well below the legal threshold of administratively insignificant or legally *de minimis*. This was an unproven assumption for each carcinogen, let alone in all possible combinations, amplified by other unnatural chemicals in the diet. This convenient unproven assumption allowed commerce to socialize more risk to privatize more profit.

Instead of adopting technology-forcing regulations to protect human life, as was the intent of Congress under the CWA and was the case with seat belts, air bags, roll bars and crash-absorbing front ends and sides, the industries manufacturing, using, or disposing of carcinogenic substances of unnatural origin expended less and less on treatment technology R&D and more and more on lobbying the Executive and Legislative Branches of government to further deregulate by any means. This is the latest pseudo-scientific effort in this regard.

If you don't trust government, no issue should give you greater pause than the cancer lottery into which we and all future generations have been enrolled without their knowledge or approval. Your unconditional right to a quantity and quality of life granted to you by your creator now comes with conditional fine print in trade for the benefits of our modern lifestyle.

EXECUTIVE SUMMARY

The proposed revisions to the derivation of WQC for Class I and III fresh and salt waters are:

- arbitrary and capricious, because the set of revisions omits well-studied carcinogens like 2,3,7,8-TCDD without a sound scientific rationale.
- administratively deficient, because there is insufficient public notice of the effect of the proposed revisions on public health and no Federal or Florida Programmatic Environmental Impact Statement (PEIS) or Finding of No Significant Impact (FONSI) was public noticed prior to the proposed rulemaking.
- scientifically deficient, because it uses outdated fish consumption data from a 1994 survey, does not properly calculate the combined exposure pdf when the individual exposure pdfs are conditionally correlated, ignores the pdfs for other factors governing internal exposure, and omits the pdfs governing non-carcinogenic toxicity and carcinogenic potency.
- uncertain as to the margin of safety lost in the revised WQC for each toxic substances in the transition from a deterministic to a probabilistic approach.
- unnecessary, because the 2015 changes in EPA guidance regarding WQC derivation using the probabilistic approach are not binding.

- unsafe, because it increases lifetime cancer risks above the administratively insignificant or legally *de minimis* threshold, the administrative process does not provide the due process required to take the quality or quantity of human life at random in the future for the crime of drinking carcinogen-contaminated water and eating carcinogen-contaminated fish and shellfish today.
- unfair, because it creates a new second-class citizen for the nearly two million Floridians more exposed than the 90th percentile and disproportionately burdens those minorities who subsist on fresh and salt water fish and shellfish with increased cancer risks, for some of which they are already more susceptible by virtue of genetics or lifestyle, contrary to the principle of environmental justice.
- immoral, because it sacrifices human health on the altar of private profit, contrary to the proscriptions in the Old and New Testaments.
- costly, because as little as a 10% increase in the annual incidences of all cancers among Floridians relative to the pre-rule changes amounts to about \$850 million in additional annual health care costs, even if the increase is otherwise indistinguishable from the epidemiological noise.
- unlawful, because it undermines the anti-degradation and anti-backsliding provisions and the implicit margin of safety requirement of the Clean Water Act Federal and violates the equal protections provided for by the 14th Amendment.
- unwise, for all of the above reasons.

It is true that “DEP’s proposed criteria take into account how, and how much, Floridians eat seafood, drink, shower and swim, and set the limits necessary to protect Floridians from adverse health effects. The criteria consider a range of environmental variables and account for the most at-risk populations, including young children, pregnant women and those whose diets comprise primarily of Florida seafood.” However, taking into account does not equate to greater human health protection for the most exposed, most susceptible at-risk populations. According to FDEP, it used a cut-off of the 90th percentile exposure rather than the 50th percentile exposure used by EPA to derive its WQC to ensure the protection of these at-risk populations, but that still leaves nearly two million Floridians exposed without the same margin of safety provided to the average Floridian.

According to the chart submitted by the Florida Clean Water Network, which I incorporate in my comments by reference, for all but one of the 81 proposed changes did the human health WQC derived using the probabilistic approach decrease, i.e., fluoranthene, or stay the same, i.e., acrolein, while the rest were higher, and, therefore weaker. These increases range for Class III waters range from 6.7% for beryllium to +1300% for the category of polycyclic aromatic compounds: benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoranthene, benzo(k)fluoranthene, chrysene, indeno(a,c)anthracene, and indeno(1,2,3-cd)pyrene. Nor does the increase in the number of carcinogens included in the proposed changes to the set of carcinogen WQC for Class I and Class III waters equate to greater human health protection for the carcinogens it has updated. This is public relations sleight-of-hand.

ISSUES

Administrative Deficiencies

The proposed revisions to the human health WQC using the probabilistic approach are arbitrary and capricious, because they omit revisions for well-studied carcinogens like 2,3,7,8-TCDD without a sound scientific rationale.

The proposed revisions to the human health WQC using the probabilistic approach are administratively deficient, because there has been insufficient public notice of the likely effect of the proposed revisions on public health, especially highly exposed, highly susceptible subpopulations. Instead, the public has been given a false assurance by FDEP that the proposed changes do not weaken existing WQC and are adequately protective of the public health.

A policy change of this magnitude requires a Federal Programmatic Environmental Impact Statement (PEIS) or Finding of No Significant Impact (FONSI) was public noticed prior to the proposed rulemaking.

Scientific Deficiencies

The Denger Study upon which FDEP based its probability distribution functions (pdfs) for Florida population salt and freshwater fish and shellfish dietary preferences was conducted in 1994 and is outdated.

The diet lipid weighted composite bioaccumulation factor (BAF) for each toxic substance in each of the three coastal regions have been systematically underestimated, as have the WQC upon which they are based, because lipid content is not a scientifically valid predictor of T2, T3 or T4 BAFs from BCFs or Kows in the absence of measured values with the ample margin of safety required to protect the public health in general or for TMDL application using the implicit approach in particular. No effort was made to compensate for those likely underestimates by using upperbound confidence levels from the predictive empirical equations or mechanistic models.

The correlations/conditional probabilities between the fish size pdf, fish contaminant concentration pdf, and diet preference pdfs for each species of fish are lost for each region using this crude version of Monte Carlo Simulation, so it systematically underestimates human exposure via the consumption of contaminated fish based on a composite BAF based solely on a diet weighted-average lipid content for all the fish species in the market basket for each coastal region or inland region.

There was inadequate analysis, acknowledgement and display of the uncertainties in the WQC calculated using the probabilistic approach or the known and potential consequences of the various sources of uncertainty, individually and compounded, contrary to the consensus of the HHPRC. There was no sensitivity analysis to identify those uncertainties of such great consequence that they warrant Florida-specific fresh or salt water monitoring of water, fish and shellfish to reduce the propagated uncertainties in the estimates of T2, T3 and T4 fish BAFs to acceptable levels for purposes of ensuring an ample margin of safety in the protection of human health.

No effort was made to develop corresponding pdfs for dose-response relationships, either for non-carcinogens or carcinogens, because it was the consensus of the HHPRC that it was beyond standard practice. While it is true that it is not now standard practice, it is not beyond technological feasibility or relevance for the derivation of WQC using the probabilistic approach to properly gauge the margin of safety provided for the least advantaged and the most exposed. Support for this includes my analysis of the erosion of the margin of safety in Florida's use of EPA's 0.3 ppm WQC as the water quality target used to derive and report Florida's statewide mercury TMDL.

With a less complicated approach and the methylmercury WQC as an example, using low, medium and high values for fresh and salt water fish consumption rates, umbilical cord blood:mother's blood ratios, and the mother's methylmercury half-life, I was able to demonstrate with a one-compartment time-dependent model that the margin of safety in the methylmercury no observable adverse effect level was lost for a woman in the compounded high-risk category, despite the fact that FDEP pronounced the 0.3 ppm fish flesh WQC for methylmercury safe using the probabilistic approach to exposure assessment, because high and low exposures average out over a woman's lifetime. But the fetus only experiences one nine-month period of exposure based on the mother's fish consumption and physiology undiluted by average future behavior. A few large, highly contaminated fish consumed from a nearby lake, river or canal over that nine-month period is all that the fetus experiences, but it may be enough to do irreversible damage to its cognitive development. I presented these results at the 11th International Conference on Mercury as a Global Pollutant in Edinburgh, Scotland, in 2013.

<http://www.mercury2013.com/full-program/>

http://www.waterwiseconsulting.com/yahoo_site_admin/assets/docs/F5-1115-FINK_CORRECTED.338225226.pdf

Uncertain

There is already great uncertainty in the amount of realized lifetime increased cancer incidence from externalizing the pollution and socializing the risks than internalizing the pollution and privatizing the risks. There is greater uncertainty as to the margin of safety lost in the revised WQC for each toxic substance in the transition from a deterministic to a probabilistic approach. The public notice is insufficient in this regard, because it overstates the case for scientific certainty that the public health is being adequately protected when no scientific case exists.

Unnecessary

While there is ample reason to revise Florida's toxic substances WQC at this time, there is no reason to adopt a probabilistic approach at this time. The probabilistic approach has been available to EPA since the Clean Water Act Amendments of 1977 and the 2015 changes in EPA guidance regarding WQC derivation using the probabilistic approach are not binding.

Unsafe

There is no evidence of compounded conservatism in the derivation of WQC using the deterministic approach. To the contrary, the National Research Council has criticized EPA for not having sufficient margins of safety to protect the most physiologically, immunologically or genetically susceptible subpopulations. As a consequence of further eroding the compounded margin of safety using the probabilistic approach, the proposed revisions to the human health WQC are unsafe, because they increase the lifetime increased cancer risk for each carcinogen above the administratively insignificant or legally *de minimis* threshold of 10^{-6} adopted by the ERC and applied by FDEP in the derivation of the revised set of WQC for carcinogens. The administrative process does not provide the due process required to take the quality or quantity of human life at random in the future for the crime of drinking carcinogen-contaminated water and eating carcinogen-contaminated fish and shellfish today,

Unfair

The proposed revisions to the human health WQC using the probabilistic approach are unfair. This is because it creates a new second-class citizen for the nearly two million Floridians more exposed than the 90th percentile and disproportionately burdens those minorities who subsist on fresh and salt water fish and shellfish with increased cancer risks, for some of which they are already more susceptible by virtue of genetics or lifestyle, contrary to the principle of environmental justice.

Immoral

The proposed revisions to the human health WQC using the probabilistic approach are immoral, because the revised WQC sacrifice human health on the altar of private profit, contrary to the proscriptions in the Old and New Testaments. This is true whether one worships the Golden Calf or Mammon. Taking the quality or quantity of human life at random at some unspecified time in the future does not make it less immoral. Allowing commerce to socialize more cancer risk to privatize more profit makes it more immoral, not less.

Costly

According to the National Cancer Institute (NCI), in the period 2008-2012 the number of new cancers reported annually is about 455 per one hundred thousand. <http://www.cancer.gov/about-cancer/understanding/statistics> According to the NCI We spend \$125 billion on cancer treatment annually in 2010. Florida's proportional share of that annual cost was 6.7% of that or \$8.35B. An otherwise avoidable 10% increase in the annual cancer incidence in Florida as a result of weakening WQC for carcinogens would cost the Florida economy roughly \$835M, even if the increase is otherwise indistinguishable from the epidemiological noise.

Unlawful

The proposed revisions to the human health WQC using the probabilistic approach are unlawful. This is because they undermine both the anti-degradation and anti-backsliding provisions of the Clean Water Act Federal regulations. They also undermine the use of the implicit approach in

calculating TMDLs with the ample margin of safety required by Section 303(d)(1)(C) of the Clean Water Act and violates the equal protections provided by the 14th Amendment.

Unwise

Florida's proposed revisions to the human health WQC using the probabilistic approach are unwise. This is because the proposed revisions are administratively and scientifically deficient, uncertain, unnecessary, unfair, immoral, costly and unlawful.

FINDINGS

The administrative process does not provide the due process required to take the quality or quantity of human life at random in the future for the crime of drinking carcinogen-contaminated water and eating carcinogen-contaminated fish and shellfish today.

Whatever the realized increased cancer risks from this shift from privatizing to socializing more risk since 1984, the proposed change from a deterministic to a probabilistic approach for exposure to carcinogens on fish and shellfish erodes the compounded margin of safety to such an extent that the realized lifetime increased incidences of cancers in Florida's exposed populations can no longer be assured to be *de minimis*.

ERC no longer has the required reasonable assurances that carcinogens that are present in fish and shellfish at concentrations equivalent to their proposed revised WQC are not present in toxic amounts, contrary to the narrative WQC precluding same and the general mandate to protect the public health, safety and welfare from unreasonable risks of natural origin, like communicable diseases and pathogens in our food supply, and of unnatural origin from contamination in our fish and shellfish.

CONCLUSIONS

The WQC derivation process is administratively deficient and the WQC derived using that process are scientifically deficient, uncertain, unnecessary, unsafe, unjust, immoral, costly, unlawful, and unwise.

RECOMMENDATIONS

Rescind the set of toxic substances WQC derived using the proposed probabilistic approach to modeling diet-weighted exposures to salt and fresh water fish and shellfish native to Florida.

Update the 1994 Denger Study upon which FDEP based its Florida population salt and freshwater fish and shellfish dietary preferences.

Replace this statistical composite of modeled exposures with measured exposures using measured values in scans for heavy metals, metalloids, organometallics, and volatile, semi-volatile and non-volatile organics in sets of representative volume-weighted composites of water and diet-weighted composites of T2, T3 and T4 fish and shellfish collected from a representative set of locations in each of the three coastal regions and each of the five inland waters regions used by FDEP in its statewide mercury monitoring program. Twenty-one water, fish and shellfish samples composited and with the homogenate analyzed five times should allow one to calculate the 95th percentile upperbound estimates of the diet-weighted average combined T2, T3 and T4 fish BAFs with which to backcalculate the equivalent WQC.

If FDEP insists on using a probabilistic approach to exposure assessment, also include a probabilistic approach to toxicity assessment to account for physiologically, immunologically or genetically compromised susceptible subpopulations. Otherwise, this one-sided approach to probabilistic risk assessment will remain pseudo-scientific mumbo jumbo.

Draft and public notice a PEIS for these proposed changes to the method for deriving non-carcinogenic and carcinogenic WQC using either the statistical or physical diet-weighted average approach to WQC derivation. The statement of impact in the Technical Support Document is not sufficient in this regard.

Thank you for this opportunity to make formal public comment in opposition to FDEP's proposed revisions to ERC rules including Florida's human health WQC.

Sincerely,

Larry E. Fink, M.S.

Owner and Principal

Waterwise Consulting, LLC

<http://www.waterwiseconsulting.com/>

APPENDICES

APPENDIX I: Curriculum Vitae, Larry Edward Fink, M.S., Owner and Principal, Waterwise Consulting, LLC

Appendix II: Abstract Accepted for 6th International SETAC Conference

Appendix III: References

Appendix I: Curriculum Vitae, Larry Edward Fink, M.S., Owner and Principal, Waterwise Consulting, LLC

http://news.caloosahatchee.org/docs/Curriculum_Vitae_160405.pdf

“Inclusion of Physiological, Metagenetic and Genetic Susceptibility Distributions in Exposed Human Populations for Probabilistic Risk Assessment.

Abstract

The U.S. Environmental Protection Agency (EPA) is responsible for ensuring the protection of the water quality of the nation's waters by reviewing and approving or rejecting and issuing for each state an enforceable Water Quality Standard (WQS) for each priority substance or mixture in each pollutant category for each fresh and salt water body based on a set of narrative and numerical Water Quality Criteria (WQC) to protect various human uses of those waters. Unless affirmatively demonstrated otherwise by a Use Attainability Analysis, all waters are assumed to be able to support and are protected for fishable and swimmable uses by humans. This requires that the fish and shellfish populations supported by those waters can be safely consumed by humans. A WQC to protect human health is derived by translating a reference dose (RfD) or cancer potency factor (CPF) with an ample margin of safety into an equivalent water concentration based on a set of reference human exposure assumptions. The EPA guidance for WQC derivation uses national average exposure assumptions, but states may choose state average exposure assumptions if they are more protective of human health than the national average exposure assumptions. The derivation of WQC using probabilistic risk assessment (PRA) generally focuses on the probability distributions functions (pdfs) for body weight, eating rate as a function of age, sex, and body weight, the proportions of various fish and shellfish species in the diet by age, sex, ethnicity, and region, and contaminant concentrations in each fish and shellfish species, without or with conditional influences of size or age, while holding the RfD or CPF constant. This is a one-sided approach to PRA. To comport with the recommendations of the National Academy of Sciences to EPA on the regulatory applications of risk assessment, this presentation considers the other side of the equation: the known distributions of physiological, metagenetic, and genetic susceptibilities to carcinogenic toxic effects endpoints by gender, race and country of origin and those inferable from the cumulative pdfs for age of onset. This is a more rigorous way to derive an ample margin of safety (AMOS) to protect the representative most sensitive citizen. This will avoid a class action lawsuit based on government-sanctioned minority discrimination and ensure an AMOS for states that use the implicit approach to calculate Total Maximum Daily Loads for water quality-impaired waters.”

APPENDIX III: References

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