Assessment of the Revisions to Human Health-Based Water Quality Criteria by the Florida Department of Environmental Protection (FDEP)

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Overall Assessment

I am an aquatic scientist with more than 30 years of experience in assessment of water pollution impacts in freshwaters, estuaries, and marine coastal waters (curriculum vitae attached). I am also experienced in research involving toxin impacts on mammals. I was requested to assess the FDEP revisions to human health-based water quality criteria for Florida, and submit this assessment accordingly.

FDEP has proposed revisions to the state of Florida's human health-based water quality criteria (human health criteria, HHC – 62-302 and 62-303 F.A.C.). Criteria for some substances were based on exposure via consumption of finfish and shellfish (seafood) in Class II (designated use - shellfish propagation or harvesting), Class III (fish consumption, recreation, and propagation and maintenance of a healthy, well-balanced population of fish and wildlife), and Class III-Limited waters (fish consumption, recreation or limited recreation, and/or propagation and limited maintenance of a limited population of fish and wildlife). For Class I (potable water supplies) and Class I-Treated waters (treated potable water supplies), both seafood consumption and drinking water exposure were considered in developing substance criteria.

The agency asserts that its proposed HHC for 81 harmful chemical substances reflect up-to-date national recommendations and state-specific information, and that the "vast majority" of Floridians" will be protected by the revised criteria FDEP 2016a, p.iv). Both assertions are incorrect. FDEP used Monte Carlo probability modeling to develop the revised criteria, despite the fact that the model has several major impediments which prompted the U.S. Environmental Protection Agency (EPA) (2015a) to advise *against* its use for deriving HHC. An old adage among modelers is that "a model is only as good as the data used to build it." FDEP's probability modeling lacked the information needed for many key parameters. Some were estimated based on little or no data about Florida waters or Floridians, and based on sparse data even at the national level. Others were estimated by omitting important information that would have resulted in more protective HHC.

FDEP then used its Monte Carlo probability modeling results as a blanket rationale for rejecting, for most of the chemical substances, the more protective, up-to-date recommendations of the U.S. EPA (2015b). The draft HHC produced by FDEP's model would weaken the regulations, that is, would allow higher toxic substance limits to be deemed "acceptable," for 24 harmful chemicals discharged into Florida surface waters, including various known human carcinogens. Moreover, *the resulting draft HHC for ~80% to 95% of the chemicals (depending on the water Class) exceed the levels recommended by the U.S. EPA (2015b)*. FDEP asserts that its probabilistic model errs on the side of conservatism. That assertion is seriously misleading: The model emphasizes average adult Floridians. The conservative steps that were included fall far short of the overall conservative approach needed to protect the health of average adult Floridians, or the health of sensitive groups such as children, the elderly, immunocompromised people, and subsistence fishers.

FDEP also proposes inadequate assessment of compliance, wherein only three water samples collected per year would be required to calculate average annual concentrations of these toxic substances. That small number of samples per chemical substance will not enable calculation of an accurate annual average. The unreliable estimates of annual averages, along with several other weaknesses in FDEP's present plan for sampling/assessment of these harmful substances, will jeopardize the health of all Floridians.

My overall assessment is that FDEP's probability modeling does not reliably predict safe exposure to these toxic substances and, therefore, FDEP's proposed revisions to Florida's HHC, as well as the agency's proposed assessment of compliance and enforcement, would fail to protect the designated use of Class I and I-T waters as potable water supplies of sufficient quality to safeguard human health. The points considered in reaching that conclusion are explained in more detail below, and should be considered together with the following facts as background:

* While deaths from some cancers are decreasing, the incidence of many cancers is dramatically increasing in the U.S., including Florida (American Cancer Society 2012, FDOH 2016 – and see p.3 of this assessment);

Table 1. From FDOH (2016).

The Five Most Common Types of Cancer in Florida (Age-adjusted Incidence Rates per 100,000 Population for Select Cancer Sites by Sex in 2012)	
Females	
All Cancers	396.5
Breast	116.7
Lung & Bronchus	54.5
Colorectal	32.2
Uterine	22.3
Non-Hodgkin's Lymphoma	14.1

Males	
All Cancers	462.3
Prostate	92.98
Lung & Bronchus	72.4
Colorectal	41.4
Bladder	33.5
Head & Neck	26.8

*Excludes non-melanoma skin cancers
Data Source: Florida Cancer Data System (FCDS)

* Many dangerous, toxic chemical contaminants in drinking water have been linked to diseases like cancer which can take years to develop (Nadler and Zurbenko 2013). According to a recent *New York Times* investigative report (Duhigg 2009a,b), what have become extremely common cancers (e.g., breast cancer, prostate cancer) are among the cancers that have sharply increased in frequency for the human population of this nation;

* Research indicates that the increasing frequency of these cancers is tied to pollutants such as those found in drinking water – not only the source water but also the finished drinking water at the tap (Duhigg 2009a). Analysis of U.S. EPA data has shown that Safe Drinking Water Act violations have occurred in parts of every state, and that the Safe Drinking Water Act is poorly enforced (Duhigg 2009b);

* Sensitive populations such as children, the elderly, and those with a weakened immune system are especially at risk for long-term carcinogenic effects (Centers for Disease Control and Prevention [CDC] 2012, Agency for Toxic Substances and Disease Registry [ATSDR] 2014); and

* The dramatically increasing incidence of cancers indicates that allowance of considerable discharges of these substances while also attempting to protect human health is out of balance, such that human health is not being adequately protected.

Specific Comments

A. *Present Florida Environment*

1. *Cancers are dramatically increasing in Florida. As explained above, research has linked*

many of these cancers to chemical contaminants in drinking water.

According to the FDOH, ***Florida has the second highest cancer burden in the nation*** (FDOH 2016) (Table 1). As of 2011-2012, cancer is the leading cause of death for Floridians, with more than 42,0000 cancer deaths per year and more than 100,000 new cancer reports per year (FDOH 2016).

Cancers are affecting males more than females: for every 100,000 males, ~462 new cancers were diagnosed in 2012 compared to 397 new cancers for every 100,000 females (FDOH 2016). One sector of the population that is being substantially affected is children. The most common childhood cancers are leukemia, brain tumors, and lymphomas (FDOH 2016). Amin et al. (2010) found evidence for two large cancer clusters among children located in the southern and northeastern regions of Florida, and a smaller cancer cluster in central Florida. Children in those areas were almost three times more likely to be diagnosed with cancer as elsewhere in the state. Another sensitive group, the elderly in Florida, has been well-represented in incidences of esophagus, stomach, colon, rectum, and bladder cancers (Morris 1995).

Scientists working at various states across the nation, including Florida, have linked many common cancers to chemical contaminants in drinking water (e.g. Morris 1995, Costas et al. 2002, Cantor et al. 2006, CDC 2012, Liu-Mares et al. 2013). Cancers are generally known as insidious diseases, often requiring a lag period (years) to manifest (Cantor et al. 2006). This information collectively suggests a pressing need for Florida to err on the side of caution (that is, to err conservatively) in developing HHC that protect human health. Although FDEP states in its fact sheet (FDEP 2016b) and supporting information (FDEP 2016a) that the agency used a conservative (protective) approach in developing the draft HHC, the analysis below shows that FDEP failed to use a protective approach, and that *FDEP's draft HHC will not protect many people in Florida from serious drinking water-related disease*.

2. *Carcinogenic substances can interact with other carcinogens, and with non-carcinogenic harmful substances, to adversely impact human health. Such interactions were not adequately accounted for by FDEP.*

FDEP has proposed revised or new HHC for non-carcinogenic harmful substances as well as for carcinogens. As FDEP (2016a) repeatedly emphasizes, each chemical substance was separately considered. Yet, these substances do not occur alone and they do not act alone in adversely affecting human health. Instead, many of these substances are known to **co-occur** in industrial effluents and source drinking waters. They also are known to interact. The resulting effect can be antagonistic, that is, the presence of harmful compound A and harmful compound B results in less of an overall toxic effect than would happen if each compound was acting alone. More commonly, harmful substances act together to cause *additive* impacts (effects of compound A acting alone + effects of compound B acting alone, for example). They can also cause *synergistic* impacts; that is, the adverse effects of such co-occurring compounds are much worse than the impacts from each compound if acting alone (U.S. EPA 2007, Goodson et al. 2015). Thus, as the authors of a major review entitled, "Combined Toxic Exposures and Human Health: Biomarkers of Exposure and Effect" emphasized, *solid evidence shows that carcinogens and non-carcinogenic substances can produce additive or synergistic effects* (Silins and Högberg 2011).

Mixtures of harmful chemicals that are not individually carcinogenic additionally can act together to be procarcinogenic, that is, capable of producing carcinogenic synergies (Goodson et al. 2015). After review of the available scientific information, a large body of more than 150 scientists recommended that cumulative risk assessment of carcinogens and non-carcinogens is of paramount importance, and that such assessments should anticipate synergisms with non-carcinogenic compounds (Goodson et al. 2015).

FDEP (2016a) asserts that the [high] potential for chemical interactions was accounted for by inclusion of various conservative exposure assumptions used in its risk evaluation. Its information sheet for the general public even includes the remarkable claim, in bold, that "Each and every criterion protects Floridians." Yet, toward the end of its TSD explaining the derivation of the draft HHC, FDEP (2016, p.77) stated, "It is conceivable that exposure could occur to more than one contaminant at the same time, and that these contaminants could produce a cumulative or even synergistic toxicity." FDEP further states that many of the chemical substances for which draft HHC were developed affect the same organ, such as the liver, making cumulative effects more likely. FDEP (2016, p.78) then dismisses the subject with a general statement acknowledging that its analysis of individual chemical effects alone, omitting any consideration of impacts from mixtures of these chemicals (and many other unknown chemicals – see below) "could underestimate" risks. Nothing more is done to address this major problem in FDEP's analysis. As shown below, the conservative assumptions that were included in FDEP's analysis are overwhelmed by the many factors omitted from consideration which would result in much lower, more protective HHC.

3. ***Many other potentially harmful chemical substances being released by industries have not been identified for the general public, are not monitored by any entity, and exacerbate the lack of accounting for hazardous substance interactions by FDEP in developing its draft HHC.***

The Government Accounting Organization (GAO) (2009) reported the following information: There are about 80,000 chemicals already on the U.S. market, and the burden of obtaining information about them falls to the U.S. EPA as unfunded mandates, rather than to the companies that produce the chemicals. A very small percentage has been even partially tested for human health effects. The Toxic Substances Control Act requires the U.S. EPA to demonstrate certain health or environmental risks before the companies are required to further test the chemicals, so the U.S. EPA does not (cannot) routinely assess risks of the industrial chemicals that are already in use. About 700 new chemicals are introduced into U.S. commerce each year, and about 85% of the accompanying notices from chemical companies provide no health or safety test data. In many cases, industries do not (even) have to provide the general public with the names of the chemicals being discharged. FDEP is surely aware of this serious problem, as the agency wrote a compelling description of it:

> As of August 2007, more than 32 million substances were registered with the American Chemical Society's Chemical Abstract Service, with over 15 million of them being commercially available….Unfortunately, regulatory controls only exist for approximately 250,000 (1.6%) of these substances. Therefore, ~98% of the commercially available compounds are NOT

inventoried and are essentially unregulated substances, [many] having a high degree of uncertainty associated with their environmental fate, transport, and toxicological effects. In less than two years (August 2005 to August 2007), more than 5 million new chemicals were added to the registry, and 5 million additional chemicals became commercially available….At the current rate of chemical development, the fraction of unregulated to regulated chemicals will continue to increase exponentially. Once available in the marketplace, many of these substances are eventually released into the environment, where they pose an unknown level of risk to humans, animals, and plants. – FDEP (2008, p.1).

A large body of peer-reviewed, published research has shown that there are major gaps in knowledge about the identified chemicals being released from various industries. For example, the FDEP draft criteria include various disinfection byproducts (DBPs). The U.S. EPA (2015b) regulates 11 of them, but more than 600 DBPs have been reported in the science literature (Richardson et al. 2007). Only a small number of them has been assessed for quantitative occurrence in the environment, or for human health impacts. As Richardson et al. (2007) noted in their extensive review, "nothing is known about the potential toxicity of many of the DBPs present in drinking water." As another example, in a joint U.S. EPA - U.S. Geological Survey (USGS) survey, 18 unregulated chemicals and 3 regulated chemicals were detected in drinking water from more than one-third of 25 U.S. water utilities surveyed. The substances included 11 perfluorinated compounds, an herbicide, two solvents, caffeine, an antibacterial compound, a metal, and an antidepressant (Furlong et al. 2013).

This overall situation illustrates the pressing need for FDEP to err on the side of conservativism in taking all necessary steps to ensure that HHC for drinking water and seafood consumption will protect the people of Florida from disease and death due to exposure to chemical contaminants. As this assessment explains, FDEP has failed to do so; the few conservative exposure assumptions that FDEP included in its analysis are far out-weighed by many factors that were omitted from consideration which would have resulted in much lower, more protective HHC.

Specific Comments II. The Draft HHC

1. ***Most of the draft HHC proposed by FDEP are much less protective than U.S. EPA recommendations to safeguard human health. In addition, many toxic chemicals for which the U.S. EPA has recommended safe levels in drinking water are not considered in the draft HHC.***

The U.S. EPA repeatedly has indicated the need for more protective drinking water criteria to safeguard human health (e.g., U.S. EPA 1995; Duhigg 2009a,b; Pressman et al. 2010). The FDEP draft HHC mostly fail to reach that goal, as shown by the following analysis of FDEP's revised and new HHC for Classes I and I-Treated waters, and for Classes II, III, and III-Limited waters, considered separately here because they are based on drinking water + biota (seafood consumption) exposure (Classes I and I-T) versus only biota exposure (Classes II, III, III-L), for which the U.S. EPA has two different sets of recommendations.

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Classes I and I-T waters - FDEP has proposed revisions of HHC for 44 harmful chemical substances, and has newly proposed HHC for 37 additional harmful substances (basis: documents on the FDEP website, http://www.dep.state.fl.us/water/wqssp/health.htm, as of 12 October 2016). Considering the "revised" grouping (Tables 2 and 3 below), 7 of the 44 substances were previously grouped together as polycyclic aromatic hydrocarbons (PAHs), so previous criteria did not exist for the substances considered separately. Of the remaining 37 substances, the revised draft criteria were *increased* – that is, the draft criteria would enable FDEP to consider higher concentrations of these harmful chemicals as acceptable – for 24 (65%) of the substances (Tables 2 and 3). Furthermore, comparison of the draft revised FDEP criteria to levels recommended by the U.S. EPA to protect human health shows that *the draft revised FDEP criteria exceed U.S. EPA recommendations for 35 (80%) of the 44 chemical substances* (Tables 2 and 3). Thus, FDEP has proposed less protective revised criteria than recommended by the U.S. EPA for most of the 44 substances.

Of the 37 chemical substances for which FDEP has proposed *new criteria* in Class I and IT waters, *36 (92%) are less protective than recommended by the U.S. EPA to safeguard human health* (Table 4)*. Some exceed U.S. EPA recommendations by ten-fold, or an order of magnitude*. FDEP informed the people of Florida that the state's HHC need to be updated because the present standards do not reflect current national recommendations (FDEP 2016a,b). Yet overall, 80% of the agency's draft HHC for Class I and IT waters fail to reflect national recommendations by the U.S. EPA (2015b) – instead, they are substantially less protective.

Classes II, III, and III-L waters - FDEP has proposed revisions of HHC for 41 harmful chemical substances, and has newly proposed HHC for 39 additional harmful substances (basis: documents on the FDEP website, http://www.dep.state.fl.us/water/wqssp/health.htm, as of 12 October 2016). Considering the "revised" grouping (Tables 5 and 6 below), 8 of the 41 substances were previously grouped together as PAHs, so previous Florida criteria did not exist for the substances considered separately. For one substance, cyanide, the draft HHC were revised to change annual averages to maxima (same quantities). Of the remaining 32 substances, the revised draft criteria were *increased* – that is, the draft criteria would enable FDEP to consider higher concentrations of these harmful chemicals as acceptable – for 17 (53%) of the substances (Tables 5 and 6). Comparison of the 41 draft revised FDEP criteria for Class II, III and IIIL waters to levels recommended by the U.S. EPA to protect human health revealed that *the draft revised FDEP criteria exceed U.S. EPA recommendations for 38 (93%) of the substances* (Tables 5 and 6). Thus, FDEP has proposed less protective revised criteria in Class II, III, and III-L waters than recommended by the U.S. EPA for most of the 41 substances.

Considering the "new" grouping (Table 7), of the 39 chemical substances for which FDEP has proposed new criteria in Class II, III, and III-L waters, 31 (*79%) are less protective than recommended by the U.S. EPA to safeguard human health*. Thus, similarly as for the Class I, II, and II-T proposed HHC, overall for Class II, III, and III-L water bodies, most of the proposed HHC fail to reflect up-to-date national recommendations by the U.S. EPA (2015b) – instead, they are substantially less protective. As another important point, the draft HHC do not include ~25 harmful chemical substances for which the U.S. EPA (2015b) has developed recommendations for safe levels. These compounds would not be regulated; that is, criteria to safeguard human health would not be available in Florida.

Table 2. The 44 chemical substances for which FDEP has proposed **revised** water quality human health criteria (HHC – annual averages in micrograms per liter [μg/L] for **Class I and Class IT waters (based on drinking water and seafood consumption)** unless otherwise indicated; max = maximum; see (http://www.dep.state.fl.us/water/wqssp/health.htm - 62-302.530 F.A.C., Table: Surface Water Quality Criteria), and comparison with U.S. EPA recommended HHC for these same chemicals (recommendations for primary drinking water standards at [https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table], except for fluorides [recommendation for secondary drinking water standard at https://www.epa.gov/dwstandardsregulations/secondary-drinking-water-standards-guidance-nuisance-chemicals]. Note that the range given for U.S. EPA recommendations for benzene reflects the upper and lower cancer slope factors (CSFs; U.S. EPA 2015 BENZENE, p.15); and for beryllium, 4 μg/L given by the U.S. EPA is the Maximum Contaminant Level (MCL) goal. Asterisks (*) indicate substances with proposed criteria in excess of the EPA recommendations (36 of 44 substances, or 82%).

Chemical Substance	U.S. EPA (≤)	Previous (FDEP, ≤)	Proposed (FDEP, ≤)	Proposed (FDEP) relative to U.S. EPA
44 substances - FDEP proposed revised criteria for Class I and Class I-T waters				
*Acenaphthene	70	1.2	110	increased; 1.6x higher
*Aldrin	0.00000077	0.00013; max 3.0	0.0000038	decreased; 4.9x higher
*Anthracene	300	9.6	540	increased; 1.8x higher
Antimony	5.6	14	2.4	decreased ; 2.3x lower
*Benzene	0.58 to 2.1	1.8	2.0	increased; 3.4x higher to ~equal
*Benzo(a)anthracene	0.0012	within PAHs	0.012	-----; 10.0x higher
*Benzo(a)pyrene	0.00012	within PAHs	0.0012	-----; 10.0x higher
Benzo(b)fluoranthene	0.0012	within PAHs	0.0012	-----; equal
*Benzo(k)fluoranthene	0.012	within PAHs	0.12	-----; 10.0x higher
*Beryllium	4 (MCL)	0.0077	0.11	increased; 2.75x higher
*Beta-hexachlorocyclohexane (b-**HCH**)	0.008	0.014	0.018	increased; 2.25x higher
*Bromoform	7.0	4.3	15	increased; 2.1x higher
*Carbon tetrachloride	0.4	0.25; max 3.0	0.95	increased; 2.4x higher
*Chlordane	0.00031	0.00058; max 0.0043	0.0010	increased; 3.2x higher
*Chlorodibromomethane	0.80	0.41	1.8	increased; 2.25x higher
Chloroform	60	5.67	60	increased; equal
Chlorophenoxy herbicide (2,4-D)	1,300	100	1,200	increased; 1.1x lower
*Chlorophenoxy herbicide (2,4,5-TP; Silvex)	100	10	160	increased; 1.6x higher
*Chrysene	0.12	within PAHs	1.2	-----; 10.0x higher
Cyanide	4	5.2	3.7; max 5.2	decreased; 1.1 lower
*Dibenzo(a,h)anthracene	0.00012	within PAHs	0.0012	-----; 10.0x higher
*Dichlorobromomethane (bromodichloromethane)	0.95	0.27	2.1	increased; 2.2x higher
*Dieldrin	0.0000012	0.00014; max 0.0019	0.0000054; max 0.0019	decreased; 4.5x higher
Fluoranthene	20	0.3	18	increased; 1.1x lower
*Fluorene	50	1.3	77	increased; 1.5x higher
Fluorides	2.0 (2ndary std)	1.5 (Class 1)	1.5 (Class I); 10 (Class I-T)	no change except Class I-T higher; 1.3x lower to 5.0x higher
*Heptachlor	0.0000059	0.00021; max 0.0038	0.000025; max 0.0038	decreased; 4.2x higher
*Hexachlorobutadiene	0.01	0.45	0.018	decreased; 1.8x higher
*Indeno(1,2,3-cd)pyrene	0.0012	within PAHs	0.012	-----; 10.0x higher
*Methoxychlor	0.02	0.03	0.023	decreased; 1.15x higher
*Methylene chloride (dichloromethane)	20	4.65	36	increased; 1.8x higher
Pentachlorophenol	0.03	0.28; max 30	0.0067; max 30	decreased; 4.5x lower
*Polychlorinated biphenyls (PCBs)	0.000064	0.000044; max 0.014	0.000098; max 0.014	increased; 1.5x higher
p,p'-dichlorodiphenyltrichloroethane (DDT)	0.000030	0.00059; max 0.001	0.00015; max 0.001	decreased; 5.0x higher
*Pyrene (individual PAH)	20	0.96	43	increased; 2.15x higher
*Tetrachloroethylene (perchloroethylene or 1,1,2,2-tetrachloroethene)	10	0.8; max 3.0	23	increased; 2.3x higher
*Trichloroethylene (TCE)	0.6	2.7; max 3.0	1.3	decreased; 2.2x higher
1,1-dichloroethylene	300	0.057; max 7.0	300	increased; equal
*1,1,2,2-tetrachloroethane	0.2	0.17	0.35	increased; 1.75x higher
2-chlorophenol	30	120	30	decreased; equal
*2,4-dichlorophenol	10	93	16	decreased; 1.6x higher
*2,4-dinitrophenol	10	0.0697	12	increased; 1.2x higher
*2,4-dinitrotoluene	0.049	0.11	0.11	no change; 2.2x higher
*2,4,6-trichlorophenol	1.5	2.1	3.3	inceased; 2.2x higher

Table 3. Summarized information from Table 1, showing general trends.

Chemical substance	FDEP change	Comparison to U.S. EPA recommendation
FDEP proposed revised criteria for Class I and Class I-T waters (44)		
Acenaphthene	increased	1.6x higher
Anthracene	increased	1.8x higher
Benzene	increased	3.4x higher to ~equal
Beryllium	increased	2.75x higher
Beta-hexachlorocyclohexane (b-BHC)	increased	2.25x higher
Bromoform	increased	2.1x higher
Carbon tetrachloride	increased	2.4x higher
Chlordane	increased	3.2x higher
Chlorodibromomethane	increased	2.25x higher
Chlorophenoxy herbicide (2,4,5-TP; Silvex)	increased	1.6x higher
Dichlorobromomethane (Bromodichloromethane)	increased	2.2x higher
Fluorene	increased	1.5x higher
Fluorides	no change (Class I); or increased (Class I-T)	1.3x lower (Class I); 5.0x higher (Class I-T)
Methylene chloride (dichloromethane)	increased	1.8x higher
Polychlorinated biphenyls (PCBs)	increased	1.5x higher
Pyrene (individual PAH)	increased	2.15x higher
Tetrachloroethylene (perchloroethylene or 1,1,2,2-tetrachloroethene)	increased	2.3x higher
1,1,2,2-tetrachloroethane	increased	1.75x higher
2,4-dinitrophenol	increased	1.2x higher
2,4,6-trichlorophenol	increased	2.2x higher
Chloroform	increased	equal
1,1-dichloroethylene	increased	equal
Chlorophenoxy herbicide (2,4-D)	increased	1.1x lower
Fluoranthene	increased	1.1x lower
2,4-dinitrotoluene	no change	2.2x higher
Aldrin	decreased	4.9x higher
Dieldrin	decreased	4.5x higher
Heptachlor	decreased	4.2x higher
Hexachlorobutadiene	decreased	1.8x higher
Methoxychlor	decreased	1.15x higher
p,p'-dichlorodiphenyltrichloroethane (DDT)	decreased	5.0x higher
p,p'-dichlorodiphenyltrichloroethane (DDT)	decreased	2.2x higher
2,4-dichlorophenol	decreased	1.6x higher
2-chlorophenol	decreased	equal
Antimony	decreased	2.3x lower
Cyanide	decreased	1.1x lower
Pentachlorophenol	decreased	4.5x lower
Benzo(a)anthracene	previously in "PAHs"	10x higher
Benzo(a)pyrene	previously in "PAHs"	10x higher
Benzo(k)fluoranthene	previously in "PAHs"	10x higher
Chrysene	previously in "PAHs"	10x higher
Dibenzo(a,h)anthracene	previously in "PAHs"	10x higher
Indeno(1,2,3-cd)pyrene	previously in "PAHs"	10x higher
Benzo(b)fluoranthene	previously in "PAHs"	equal

Table 4. The 37 chemical substances for which FDEP has proposed **new** water quality HHC for **Class I and Class I-T waters (basis: drinking water and seafood consumption** - see (http://www.dep.state.fl.us/water/wqssp/health.htm - 62-302.530 F.A.C., Table: Surface Water Quality Criteria), and comparison with U.S. EPA recommended HHC for these same chemicals (recommendations for primary drinking water standards [https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table]. Asterisks indicate substances with proposed criteria in excess of the EPA recommendations (35 of 37 substances, or 95%).

Chemical Substance	U.S. EPA (≤)	Proposed (FDEP, ≤)	Proposed (FDEP) relative to U.S. EPA
37 substances - FDEP proposed new criteria for Class I and Class I-T waters			
Acrolein	3	3	equal
*Acrylonitrile	0.061	0.13	2.1x higher
*Benzidine	0.00014	0.00031	2.2x higher
*Bis(2-chloroethyl) ether	0.20030	0.066	2.2x higher
*Bis(2-chloro-1-methylethyl) ether	200	240	1.2x higher
*Bis(2-ethyl-hexyl) phthalate	0.32	1.5	4.7x higher
*Butylbenzyl phthalate	0.1	0.29	2.9x higher
*Chlorobenzene	100	110	1.1x higher
*Diethyl phthalate	600	770	1.3x higher
*Dimethyl phthalate	2,000	2,400	1.2x higher
*Di-n-butyl phthalate	20	35	1.75x higher
*Ethylbenzene	68	80	1.2x higher
*Heptachlor epoxide	0.000032	0.000098	3.1x higher
*Hexachlorocyclopentadiene	4	4.7	1.2x higher
*Hexachloroethane	0.1	0.24	2.4x higher
*Isophorone	34	76	2.2x higher
*Methyl bromide	100	120	1.2x higher
*Nitrobenzene	10	12	1.2x higher
*Pentachlorobenzene	0.1	0.14	1.4x higher
Toluene	57	56	slightly lower
*Trans-1,2-dichloroethylene (DCE)	100	120	1.2x higher
*Vinyl chloride	0.022	0.048	2.2x higher
*1,1,1-trichloroethane	10,000	12,000	1.2x higher
*1,1,2-trichloroethane	0.55	1.2	2.2x higher
*1,2,4-trichlorobenzene	0.071	0.14	2x higher
*1,2-dichlorobenzene	1,000	1,400	1.4x higher
*1,2-dichloroethane	9.9	22	2.2x higher
*1,2-dichloropropane	0.90	2.0	2.2x higher
*1,2-diphenylhydrazine	0.03	0.077	2.6x higher
*1,3-dichlorobenzene	7	8.3	1.2x higher
*1,3-dichloropropene	0.27	0.59	2.2x higher
*1,4-dichlorobenzene	300	340	1.1x higher
*2,4-dimethylphenol	100	120	1.2x higher
*2-chloronaphthaline	800	960	1.2x higher
2-methyl-4,6-dinitrophenol	2	1.8	1.1x lower
*3,3'-dichlorobenzidine	0.049	0.11	2.2x higher
*3-methyl-4-chlorophenol	500	540	1.1x higher

Table 5. The 41 chemical substances for which FDEP has proposed **revised** water quality human health criteria (HHC – annual averages in micrograms per liter [μg/L] for **Class II, Class III, and Class III-L waters (basis - seafood consumption)**. The criteria for fluorides were not revised for these Classes. Florida did not previously have biota (seafood)-only criteria for herbicide 2,4-D, or herbicide Silvex, so they are listed in Table 7. Max = maximum; see (http://www.dep.state.fl.us/water/wqssp/health.htm - 62-302.530 F.A.C., Table: Surface Water Quality Criteria), and comparison with U.S. EPA recommended HHC for these same chemicals (recommendations for primary drinking water standards at [https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table]. Note that the range given for U.S. EPA recommendations for benzene reflects the upper and lower cancer slope factors (CSFs; U.S. EPA 2015 BENZENE, p.15); and for beryllium, 4 μg/L given by the U.S. EPA is the Maximum Contaminant Level (MCL) goal. Asterisks (*) indicate substances with proposed criteria in excess of the EPA recommendations (38 of 41 substances, or 93%).

Chemical Substance	U.S. EPA ($\leq$)	Previous (FDEP, $\leq$ for Class II, Class III)	Proposed (FDEP, $\leq$ for Class II, Class III, Class III-L)	Proposed (FDEP) relative to U.S. EPA
41 substances - FDEP draft revised criteria - Class II, Class III, and Class III-Limited Waters				
*Acenaphthene	90	2.7 (Class III)	130 (all classes)	increased; 1.4x higher
*Aldrin	0.00000077	0.00014; max 1.3 (Cl II, III-mar); max 3.0 (Cl III-frw)	0.0000038; max same as previous	decreased; 4.9x higher
*Anthracene	400	110	540	decreased; 1.35x higher
Antimony	640	4,300	240	decreased ; 2.7x lower
*Benzene	16-58	71.28	53.0	decreased; 3.3x higher (10⁻⁶ level)
*Benzo(a)anthracene	0.0013	within PAHs	0.014	-----; 10.8x higher
*Benzo(a)pyrene	0.00013	within PAHs	0.0014	-----; 10.8x higher
*Benzo(b)fluoranthene	0.0013	within PAHs	0.0014	-----; 1.1x higher
*Benzo(k)fluoranthene	0.013	within PAHs	0.14	-----; 10.8x higher
*Beryllium	4 (MCL)	0.13	0.64	increased; 6.3x higher
*Beta-hexachlorocyclohexane (b-HCH)	0.014	0.046	0.033	decreased; 2.35x higher
*Bromoform	120.0	360	260	decreased; 2.2x higher
*Carbon tetrachloride	5	4.42	10	increased; 2.0x higher
*Chlordane	0.00032	0.00059; max 0.0040 (Cl II, III-mar), max 0.0043 (Cl III-frw)	0.0010; max same as previous	increased; 3.1x higher
*Chlorodibromomethane	21	34	44	increased; 2.1x higher
*Chloroform	2,000	470.8	2,300	increased; 1.2x higher
*Chrysene	0.13	within PAHs	1.4	-----; 10.8x higher
Cyanide	400	1.0 (Cl III, III-mar); 5.2 (Cl III-frw)	1.0 max (Cl II, III-mar, III-L-mar); 5.2 max (Cl III-frw, Cl III-L -frw)	annual avgs. changed to maxima; 76.9 to 400x lower
*Dibenzo(a,h)anthracene	0.00013	within PAHs	0.0014	-----; 10.8x higher
*Dichlorobromomethane (bromodichloromethane)	27	22	57	increased; 2.1x higher
*Dieldrin	0.0000012	0.00014; max 0.0019	0.0000054; max 0.0019	decreased; 4.5x higher
Fluoranthene	20	0.370	19	increased; 1.1x lower
*Fluorene	70	14	94	increased; 1.3x higher
*Heptachlor	0.0000059	0.00021; max 0.0036 (Cl II, III-mar); max 0.0038 (Cl III-frw)	0.000025 - Cl III-frw, Cl III-L-frw); 0.00025 (Cl III-mar, Cl III-L-mar)	increased; 4.2x to 42.4x higher
*Hexachlorobutadiene	0.01	49.7	0.018	decreased; 1.8x higher
*Indeno(1,2,3-cd)pyrene	0.0013	within PAHs	0.014	-----; 10.8x higher
*Methoxychlor	0.02	0.03	0.023	decreased; 1.15x higher
*Methylene chloride (dichloromethane)	1,000	1,580	2,300	increased; 2.3x higher
*Pentachlorophenol	0.04	0.28 (Cl III-frw, Cl III-L-frw); 7.9 (Cl II, Cl III-mar, Cl III-L-mar)	0.11 (Cl II, Cl III-mar, Cl III-L-mar); 0.11, max 30 (Cl III-frw, Cl III-L-frw)	decreased; 2.75x higher
*Polychlorinated biphenyls (PCBs)	0.000064	0.000045; max 0.03	0.000098; max 0.03 (Cl II, Cl III-mar, Cl III-L-mar); max 0.014 (Cl III-frw, Cl III-L-frw)	increased; 1.5x higher
*p,p'-dichlorodiphenyltrichloroethane (DDT)	0.000030	0.00059; max 0.001	0.00015; max 0.001	decreased; 2.3x higher
*Pyrene (individual PAH)	30	within PAHs	49	-----; 1.6x higher
*Tetrachloroethylene (perchloroethylene or 1,1,2,2-tetrachloroethene)	29	8.85	66	increased; 2.3x higher
*Trichloroethylene (TCE)	7	80.7	15	decreased; 2.1x higher
1,1-dichloroethylene	20,000	3.2	16,000	increased; 1.25x lower
*1,1,2,2-tetrachloroethane	3	10.8	5.9	decreased; 2.0x higher
*2-chlorophenol	800	400	860	increased; 1.1x higher
*2,4-dichlorophenol	60	790	65	decreased; 1.1x higher
*2,4-dinitrophenol	300	14.26	330	increased; 1.1x higher
*2,4-dinitrotoluene	1.7	9.1	3.5	decreased; 2.1x higher
*2,4,6-trichlorophenol	2.8	6.5	6.6	increased; 2.4x higher

Table 6. Summarized information from Table 5, showing general trends.

Chemical Substance	FDEP Change	Comparison to U.S. EPA Recommendation
41 substances - FDEP draft revised criteria - Class II, Class III, and Class III-Limited Waters		
*Acenaphthene	increased	1.4x higher
*Beryllium	increased	6.3x higher
*Carbon tetrachloride	increased	2.0x higher
*Chlordane	increased	3.1x higher
*Chlorodibromomethane	increased	2.1x higher
Chloroform	increased	1.2x higher
*Dichlorobromomethane (bromodichloromethane)	increased	2.1x higher
*Fluorene	increased	1.3x higher
*Heptachlor	increased	4.2x to 42.4x higher
*Methylene chloride (dichloromethane)	increased	2.3x higher
*Polychlorinated biphenyls (PCBs)	increased	1.5x higher
*Tetrachloroethylene (perchloroethylene or 1,1,2,2-tetrachloroethene)	increased	2.3x higher
*1,1-dichloroethylene	increased	1.25x higher
*2-chlorophenol	increased	1.1x higher
*2,4-dinitrophenol	increased	1.1x higher
*2,4,6-trichlorophenol	increased	2.4x higher
Fluoranthene	increased	1.1x lower
*Aldrin	decreased	4.9x higher
*Anthracene	decreased	1.35x higher
*Benzene	decreased	3.3x higher (10^{-6} level)
*Beta-hexachlorocyclohexane (b-HCH)	decreased	2.35x higher
*Bromoform	decreased	2.2x higher
*Dieldrin	decreased	4.5x higher
*Hexachlorobutadiene	decreased	1.8x higher
*Methoxychlor	decreased	1.15x higher
*Pentachlorophenol	decreased	2.75x higher
*p,p'-dichlorodiphenyltrichloroethane (DDT)	decreased	2.3x higher
*Trichloroethylene (TCE)	decreased	2.1x higher
*1,1,2,2-tetrachloroethane	decreased	2.0x higher
*2,4-dichlorophenol	decreased	1.1x higher
*2,4-dinitrotoluene	decreased	2.1x higher
Antimony	decreased	2.7x lower
*Benzo(a)anthracene	previously in "PAHs"	10.8x higher
*Benzo(a)pyrene	previously in "PAHs"	10.8x higher
Benzo(b)fluoranthene	previously in "PAHs"	1.1x higher
*Benzo(k)fluoranthene	previously in "PAHs"	10.8x higher
*Chrysene	previously in "PAHs"	10.8x higher
*Dibenzo(a,h)anthracene	previously in "PAHs"	10.8x higher
*Indeno(1,2,3-cd)pyrene	previously in "PAHs"	10.8x higher
*Pyrene (individual PAH)	previously in "PAHs"	1.6x higher
Cyanide	annual avg. changed to max.	76.9 to 400x lower

Table 7. The 39 chemical substances for which FDEP has proposed **new** water quality HHC (**Class II, Class III, and Class III-Limited waters – based on seafood consumption**) (http://www.dep.state.fl.us/water/wqssp/health.htm - 62-302.530 F.A.C., Table: Surface Water Quality Criteria), and comparison with U.S. EPA recommended HHC for these same chemicals (recommendations for primary drinking water standards [https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table]. Note that the two herbicides, 2,4-D and Silvex, were added. Asterisks indicate substances with proposed criteria in excess of the EPA recommendations (31 of 39 substances, or 79%).

Chemical Substance	U.S. EPA ($\leq$)	Proposed (FDEP, $\leq$)	Proposed (FDEP) relative to U.S. EPA
39 substances - FDEP proposed new criteria for Class II, Class IIII, and Class III-L waters			
Acrolein	400	300	1.3x lower
*Acrylonitrile	7.0	11 (Class III)	1.6x higher
*Benzidine	0.011	0.020	1.8x higher
*Bis(2-chloroethyl) ether	2.2	4.1	1.9x higher
Bis(2-chloro-1-methylethyl) ether	4,000	4,000	equal
*Bis(2-ethyl-hexyl) phthalate	0.37	2.1	5.7x higher
*Butylbenzyl phthalate	0.10	0.29	2.9x higher
*Chlorobenzene	800	970	1.2x higher
*Chlorophenoxy herbicide (2,4-D)	12,000	13,000	1.1x higher
*Chlorophenoxy herbicide (2,4,5-TP; Silvex)	400	570	1.4x higher
*Diethyl phthalate	600	840	1.4x higher
*Dimethyl phthalate	2,000	2,400	1.2x higher
*Di-n-butyl phthalate	30	36	1.2x higher
*Ethylbenzene	130	140	1.1x higher
*Heptachlor epoxide	0.000032	0.000099	3.1x higher
*Hexachlorocyclopentadiene	4	5	1.25x higher
*Hexachloroethane	0.1	0.27	2.7x higher
*Isophorone	1,800	3,600	2.0x higher
Methyl bromide	10,000	10,000	equal
Nitrobenzene	600	570	1.1x lower
*Pentachlorobenzene	0.1	0.15	1.5x higher
*Toluene	520	610	1.2x higher
Trans-1,2-dichloroethylene (DCE)	4,000	3,900	~equal
*Vinyl chloride	1.6	3	1.9x higher
1,1,1-trichloroethane	200,000	190,000	1.1x lower
*1,1,2-trichloroethane	8.9	20	2.2x higher
*1,2,4-trichlorobenzene	0.076	0.15	2.2x higher
*1,2-dichlorobenzene	3,000	3,900	1.3x higher
*1,2-dichloroethane	650	1,200	1.8x higher
*1,2-dichloropropane	31	63.0	2.0x higher
*1,2-diphenylhydrazine	0.2	0.48	2.4x higher
*1,3-dichlorobenzene	10	18	1.8x higher
*1,3-dichloropropene	12	23	1.9x higher
*1,4-dichlorobenzene	900	1,110	1.2x higher
2,4-dimethylphenol	3,000	2,800	1.1x lower
*2-chloronaphthaline	1,000	1,400	1.4x higher
2-methyl-4,6-dinitrophenol	30	29	~equal
*3,3'-dichlorobenzidine	0.15	0.34	2.3x higher
*3-methyl-4-chlorophenol	2,000	2,700	1.35x higher

for safe levels. These compounds would not be regulated; that is, criteria to safeguard human health would not be available in Florida.

2. *Monte Carlo simulations (probabilistic modeling), used by FDEP to develop the draft HHC, is not recommended for such use by the U.S. EPA because of major limitations in the modeling approach that can lead to biases, misinterpretations, and overestimates.*

Two terms merit definition here as background for this section. First, "parameters" refer to the constants characterizing the probability density function or cumulative distribution of a random variable in Monte Carlo simulations (U.S. EPA 1997a,b). The term can also refer to the constants and independent variables that define mathematical equations used in the model (U.S. EPA 1997b). Second, it should be stressed that, according to FDEP (2016a), human health water quality criteria (HHC) are established at the *highest* concentration of a pollutant in water that protects against a significant risk of adverse health effects over a lifetime. That is, HHC should provide adequate protection to the general population over a lifetime of exposures, and to special subpopulations (i.e., people with high water or fish intake rates, or higher sensitivities) that have an increased risk of receiving a dose that would elicit adverse effects.

As further background, Monte Carlo simulations require initial selection of risk management targets for each chemical substance. The standard U.S. EPA (2000a) methodology for determining criteria for carcinogens was used by FDEP, and is within the range of 10^{-4} to 10^{-6}, that is, form one person affected per one ten thousand (10^{-4}, least protective) to one person affected per one million (10^{-6} level, most protective). Monte Carlo simulations can be used to produce multiple risk descriptors. In this statistical modeling technique, a quantity of interest is calculated repeatedly using randomly selected "what if" scenarios for each calculation (U.S. EPA 1997a,b; 2015a). The goal is that the results approximate the full range of possible outcomes and the probability of each. When Monte Carlo simulations are used in risk assessment, risk is depicted as a frequency distribution graph (rather than a single-point estimate; see below) that is "user-friendly" to non-statisticians. Monte Carlo simulations are a type of probability risk analysis that can provide more information about the range and likelihood for risk from exposure to harmful chemical substances. According to U.S. EPA (2014a), analyses such as Monte Carlo are widely used as *a tool* to improve understanding of uncertainties and variability. Probability risk analysis has *not* yet been relied upon for *formal decision analysis* by U.S. EPA decision makers because PRA has certain major limitations that have not yet been reliably accounted for (U.S. EPA 2014a, 2015a).

The U.S. EPA (2014a) has developed simplified deterministic approaches, used by the states except for this recent effort by FDEP, to characterize risks from environmental exposures to harmful chemical substances, using point estimates for key parameters (variables) such as body weight, fish consumption rate, and drinking water intake. Deterministic risk assessment has procedural consistency; there are established procedures regarding its use, and the resulting assessments are feasible and tractable (U.S. EPA 2014a). Deterministic approaches produce point estimates of risk (e.g., 10_{-5}, a lifetime probability of cancer risk of one individual in 100,000), and the point estimates are usually established conservatively at the 90th percentile to attempt to protect high-risk individuals. Site-specific regional risk assessments typically present risk as a single number (single-point estimate), along with a qualitative discussion of uncertainty (Smith 1994, U.S. EPA 2015a). Uncertainties are addressed primarily through the incorporation

of predetermined default values and conservative assumptions, included in an attempt to yield protective estimates of risk (e.g. U.S. EPA 1989, 1991). Variability is addressed by combining input parameters intended to represent higher-end exposure. The intent is to implicitly provide a margin of safety; that is, the deterministic approach is considered conservative (protective) because it is more likely to overestimate than underestimate risk (U.S. EPA 2014a).

PRAs such as Monte Carlo simulations, in contrast, create *thousands of parameters (variables)* that are used to calculate (estimate) the health effects of exposure to a lifetime of toxic chemicals by considering average body weight (BW), drinking water ingestion rate (DW), finfish and shellfish consumption rate (FCR), and the fat content of fish (important because fatty tissues absorb most of the toxins in seafood). Unfortunately, *the cumulative or overall uncertainty factor in estimating human health risk using these simulations can easily be as high as several orders of magnitude* (U.S. EPA 2015a). The information needed for reliable estimates of many parameters needed for the modeling effort is sparse, lacking, or sometimes poorly applicable (e.g., extrapolation of short-term laboratory trials with mice to long-term impacts on human health from environmental exposures.

Following guidance from the National Research Council (2009), the U.S. EPA (2014a, 2015a) has recommended a tiered approach to risk assessment using *both* deterministic and probabilistic tools. Given the present status of knowledge, the U.S. EPA has encouraged development of multiple risk descriptors from PRA *as supporting information for protective single-point risk estimates*. As more data become available to accurately parameterize probability models such as Monte Carlo, the models will describe more completely the uncertainty surrounding (deterministic) single-point risk estimates, and provide the general public and resource managers with more complete information on the likelihood (probability) of various risk levels. At present, however, the information needed for reliable estimates of many parameters is sparse or lacking.

Thus, the U.S. EPA (2015a) identified *four major limitations* in Monte Carlo simulation which have discouraged the agency from accepting it as the sole or preferred risk assessment tool: (1) Monte Carlo software treats uncertainty (lack of quantitative information for a given parameter) as if it were variability (quantitatively well-described differences in a given factor), which *can lead to misleading or unrealistic predictions.* (2) Ignoring (or guesstimating) correlations among exposure variables can bias Monte Carlo calculations, but is usually done because actual empirical, quantitative information on these correlations is usually not available. (3) Exposure factors developed from short-term studies with large populations [e.g., with human surrogates such as mice or rats] may not accurately represent long-term conditions in relatively small sub-populations [such as human subsistence fishers]. (4) The "tails" (low and high areas of the ranges) in the risk distributions, which are of most interest to regulators, are very sensitive to the shape of the input distributions and, thus, can easily be inaccurately depicted. Because of these limitations, U.S. EPA has not recommended Monte Carlo simulation as the sole, or even primary, risk assessment method (U.S. EPA 2015a). The deterministic approach (single-point risk estimates) is recommended, while multiple descriptor methods such as Monte Carlo are considered helpful as a secondary tool that can provide insights about the uncertainty and variability surrounding single-point estimates (U.S. EPA 2015a).

FDEP (2016a, p.7) describes the deterministic approach as "often criticized…due to compounded levels of conservativism…," and that key variables can be left to best professional judgment. FDEP asserts that the probabilistic approach allows the focus of the analysis to be the "true concern," that is, the risk of exceeding the reference dose (RfD) for non-carcinogens, or the Cancer Slope Factor (CSF) for carcinogens. As shown below, both the RfD and the CSF are characterized by **high** uncertainty, to such an extreme that for many chemical substances, the RfD and CSF are, at best, gross estimates, thought to be inaccurate by one or more orders of magnitude. Calculation of RfDs, for example, includes poorly defined "uncertainty factors," arbitrarily selected based on best professional judgment; if inclusion of such nebulous factors does not appear to reduce the RfD enough for the number to make sense, yet more arbitrary factors, this time referred to as "multiplication factors," are added it, based on best professional judgment (see p.17 of this assessment).

There are many uncertainties in attempting to set HHC, regardless of the approach, because of data inadequacies needed to define the behavior of many chemical substances in the natural environment and in humans. Accordingly, the U.S. EPA (2015a) recommended erring on the side of conservatism in order to focus on what is and should be the true concern, namely, protection of human health from serious disease or death due to exposure to these chemical substances. FDEP's dependence only on the Monte Carlo probability model to set HHC is a less conservative approach, and resulted in draft HHC that are substantially higher than U.S. EPA recommendations for most of the chemical substances under consideration. FDEP asserts that its model represents a more sophisticated approach. The fact remains that use of this model as the sole means of developing HHC is premature given the present status of available data and knowledge.

3. ***The Monte Carlo model yielded unreliable predictions of safe concentrations of harmful substances because it is based on sparse or poor data (even no data) for many factors, resulting in estimates for various parameters that are inaccurate by orders of magnitude.***

The key data used in calculating the HHC for carcinogenic and non-carcinogenic substances are the parameters shown in the following equations and defined below:

Class I and I-T waters (consumption of water and biota) -

Non-carcinogens:
$$SWQC(\mu g/L) = \frac{\left[RfD \left(\frac{mg}{kg \cdot d}\right) \times RSC\right] \times BW \text{ (kg)} \times 1{,}000 \text{ (}\mu g/mg\text{)}}{DI \text{ (L/d)} + \Sigma_{i=2}^{4}\left[FCR_i \left(\frac{kg}{d}\right) \times BAF_i \left(\frac{L}{kg}\right)\right]}$$

Carcinogens:
$$SWQC(\mu g/L) = \frac{\left[Risk/CSF \left(\frac{mg}{kg \cdot d}\right)\right] \times BW \text{ (kg)} \times 1{,}000 \text{ (}\mu g/mg\text{)}}{DI \text{ (L/d)} + \Sigma_{i=2}^{4}\left[FCR_i \left(\frac{kg}{d}\right) \times BAF_i \left(\frac{L}{kg}\right)\right]}$$

Class II, III, and III-L waters (consumption of biota only) –

Non-carcinogens:
$$SWQC(\mu g/L) = \frac{\left[RfD \left(\frac{mg}{kg \cdot d}\right) \times RSC\right] \times BW \text{ (kg)} \times 1{,}000 \text{ (}\mu g/mg\text{)}}{\Sigma_{i=2}^{4}\left[FCR_i \left(\frac{kg}{d}\right) \times BAF_i \left(\frac{L}{kg}\right)\right]}$$

Carcinogens:
$$SWQC(\mu g/L) = \frac{[Risk/CSF\ (mg/_{kg \cdot d})]\ \times\ BW\ (kg)\ \times\ 1{,}000\ (\mu g/mg)}{\Sigma_{i=2}^{4}[FCR_i\ (kg/_{d})\ \times\ BAF_i\ (L/_{kg})]}$$

wherein:

SWQC = Surface water quality criteria (HHC; units, milligrams per liter - mg/L; note, however, that FDEP [2016a; also see 62-302.530 F.A.C., Table: Surface Water Quality Criteria] presents the draft HHC for most of the chemical substances under consideration in units of micrograms per liter, µg/L);

RfD = Parameter-specific reference dose, that is, the natural background (oral dose) concentration in humans (units, milligrams per kilogram-day, mg/kg-day, usually extrapolated from laboratory tests on rats, mice, or dogs – see FDEP 2016a, Appendix C);

RSC = Relative source contribution, a factor used in an attempt to account for non-water sources of exposure (exception - not used for linear carcinogens, that is, for carcinogens characterized by an incremental increase in impact directly proportional to the change in dose); may be either a percentage or an amount, depending on the calculation method used;

BW = Body weight of a person (units, kg);

CSF = Cancer slope (potency) factor, that is, the proportion of the human population affected per mg contaminant per kg BW-day (units, mg/kg-day), usually extrapolated from laboratory tests on rats, mice, or dogs; see FDEP (2016a, Appendix C). [Note that for three substances (1,2-dichlorobenzene, 1,3-dichlorobenzene, and 1,4-dichlorobenzene), FDEP (2016a) used minimal risk levels (MRLs) instead, following U.S. EPA (2015a).]

Risk = Incremental life-time increased cancer risk (10_{-6} to 10_{-5}, that is, the targeted level of 1 person affected per 1 million (1,000,000) or 1 person affected per 100,000);

DI = Drinking water consumption rate (units - liters per day, L/d);

FCR_i = Fish consumption rate for aquatic TLs 2, 3, and 4 (kg/day; note that the letter *i* refers to the specific TL considered);

BAF_i = Bioaccumulation factor (a BAF should be developed for each TL (TLs 2, 3, and 4 – units, L/day); and

$\Sigma_{i=x}^{4}$ = Summation of values for aquatic trophic levels (TLs), where the letter *i* refers to the TLs considered (x = TL2, 3, and 4).

As further background, the equations for non-carcinogens do not include a risk factor. That is, it is technically feasible to prepare probabilistic analyses of "safe" doses for health effects from non-carcinogens (Baird et al. 1996), but the results of such assessments typically are estimates of the likelihood of risk using a hazard index – not an actual measure of risk (National Research Council 1994). Therefore, it has been cautioned that careful consideration should be given to appropriate use of these techniques for non-carcinogen risk models (Thompson and Graham 1996). The U.S. EPA (2015b) includes an *implicit assumption* that the majority (approximately 90%) of the target human population will not be exposed to contaminant levels that exceed the *RfD* – but the validity

of that assumption depends upon the accuracy of the estimated *RfD*, which is highly problematic (see below). To impose a risk factor, FDEP (2016a) ran the Monte Carlo simulations to calculate surface water HHC and then set the criteria at the 10th percentile of the Monte Carlo results. The RfDs, CSFs, RSCs, and BAFs (or substitute values for BAFs; see below) were entered into the Monte Carlo model as point values. A distribution (that is, a range of values for "average adults" reflecting several geographic regions of Florida), rather than a point measurement, was used for FCR, DI, and BW.

Examples of the flawed assumptions used by FDEP and the major uncertainties in key parameters are given below:

RfD – The reference oral dose is poorly known or unknown for most of these chemical substances, to the extent that FDEP (2016a, p.43) described the RfD as an estimate associated "with uncertainty spanning perhaps *an order of magnitude*" (that is, the estimate typically are thought to be inaccurate by a factor of ten-fold or [usually] more – see Appendix C) of a daily oral exposure to humans that is likely to be without an appreciable risk of adverse effects over a lifetime. It is usually derived from a laboratory animal (rat, mouse, or dog – FDEP 2016a, Appendix C) dosing study using the no-effect level or point of departure (no observed adverse effect level, NOAEL), lowest observed adverse effect level (LOAEL), or benchmark dose (BMD) for the most sensitive known toxicity endpoint, that is, the toxic effect that occurs at the lowest dose or at a pre-specified level (e.g., 5th percentile). The data, usually very limited, are then extrapolated to estimate a relevant dose for humans.

Due to the **high** uncertainty in estimating RfDs, the "point of departure" number (that is, the average harmful dose level for the lowest effect or no-effect level in the animal studies, extrapolated to humans) is divided by "uncertainty factors" (1, 3, or 10 based on a log or half-log scale, assigned using "best professional judgment," that is, expert's educated guess) in *an attempt* to ensure that the final RfD is set at a level that will protect the human population, including sensitive groups (but see below). These uncertainty factors of 1, 3, or 10 are applied to all uncertainties, no matter the type. The total uncertainty factor (UF) is equal to the individual uncertainty factors multiplied together. If the resulting dose still is regarded, again based on best professional judgment, as too "uncertain," it is divided by a yet another factor, a "modifying factor" (MF, based, again, on best professional judgment). The total product of the UFs and MF "must" be less than or equal to 3,000 according to FDEP (2016a, p.43 – supporting rationale not given). [Note: Evidently, however, the derivation of the RfD for one chemical substance in FDEP's analysis, pentachlorobenzene, was characterized by such high uncertainty that the total UF alone was 10,000 – see FDEP 2016a, Appendix C.] Clearly, even the procedure for estimating RfDs exemplifies extreme uncertainty.

RSC – The relative source contribution is supposed to account for [all] other, non-water-based sources of the chemical substance (U.S. EPA 2000a, 2015b). It is considered as a percentage of the RfD, the percentage attributed to ambient water and fish consumption (limited by FDEP to finfish and shellfish from Florida inland and nearshore waters – but see below) when there are other potential exposure sources. Not considered in the RSC are exposure to pollutants from other fish (e.g., fish imported from other states or countries), non-fish food consumption, or dermal and respiratory exposures.

Reliable data are needed to calculate RSCs (FDEP 2016a) – *but if the data are insufficient, "default assumptions" can be used in a decision tree to estimate RSCs* (U.S. EPA 2000a, Krishnan and Carrier 2013). FDEP (2016a,b) informed Floridians that a major reason for having revised the HHC was that they needed to be based on Florida conditions. For this key parameter in FDEP's Monte Carlo model, however, FDEP used national U.S. EPA RSCs for the non-carcinogen substances because "robust" (= sufficient good-quality) data on Florida exposures from drinking water, surface water, and fish tissue concentrations could not be found.

The U.S. EPA requires RSCs to range from 20% to 80%; the 80% ceiling is set as an addition UF resulting in a lower criterion, in an attempt to ensure protection of individuals whose total exposure to a given contaminant is actually higher than indicated by available data. Sufficient Florida data were not available to enable calculation of RSCs for most of the chemical substances based on ambient exposures for drinking water, surface water, and fish tissue concentrations, so FDEP used national-level data.

FCR - Many Federal and State agencies, including FDEP, use default values for FCR based on general per capita estimates to describe fish-consuming populations and to set HHC based on such per capita estimates (Holloman and Newman 2012, and references therein). Although this is standard practice, it is fundamentally in error to compare mean fish consumption of fish consumers with means of general populations that include both consumers and non-consumers of fish (Holloman and Newman 2012).

Moreover, *in FDEP's analysis, the exclusion of fish from areas other than Florida resulted in substantial underestimates of the RSC parameter for many Floridians*, based on evidence presented in a Government Accounting Organization (GAO 2011) report. The Food and Drug Administration was reported to inspect less than 1% of imported seafood. The State of Florida has detected evidence of prohibited harmful substances from screens of imported fish (GAO 2011). By 2011, Florida had run out of funds to continue inspections, but as an example, in 2007 state officials found that nearly 20% of the imported catfish tested were positive for fluoroquinolones. Across the U.S., including Florida, more than 80% of the fish people eat is imported (GAO 2011). FDEP (2016a) also admitted that the 2012 draft of its TSD "clearly demonstrated that available Florida fish stocks were insufficient to sustain the assumed fish consumption rate over the entire population. These rates can only be sustained through significant importation." Clearly, despite knowing otherwise, in deriving its draft HHC, FDEP (2016a) unrealistically assumed that all seafood consumed by Floridians comes from local waters and has a lipid profile consistent with native fish. FDEP (2016a) stated that because the agency assumed that all consumed seafood had come from local waters, "the criteria are clearly protective of the population of Florida freshwater and estuarine fish consumers." The problem lies in the fact that relatively few Floridians consume only Florida fish. *By ignoring the strong evidence of substantial chemical contaminants in imported seafood that Floridians are consuming as the source of the majority of their seafood, FDEP failed to develop HHC that protect Floridians' health.*

The same assumption renders invalid FDEP's (2016, pp.77-78) additional assertion that:

> The [draft HHC] criteria are more than sufficiently stringent for the general

population who may only occasionally consume Florida seafood. Therefore, the risks presented herein actually overstate the risk of adverse health risk to the general Florida Population. The actual risk experienced by individual consumers is dependent on their particular balance of Florida and imported seafood as well as the level of contamination in imported products. Note: risk associated with imported seafood is assumed to be controlled by regulations in place in the State of origin and through FDA inspections programs…. Assumption: the distribution of all freshwater and estuarine fish is representative of this group [i.e., people who eat fish in Florida] regardless of the seafood source (i.e., state waters, interstate waters, international importation, or aquaculture).

The above statements by FDEP are, at best, highly misleading, except for the third sentence. FDEP is aware that the FDA inspects only 1% of imported seafood; that seafood imported to Florida, as elsewhere in the U.S., has a serious chemical contamination problem; and that seafood contamination varies substantially depending on the source (Ahmed 1991, GAO 2011). Accordingly, FDEP acknowledges in the third sentence of the above quote that the actual risk differs markedly from the risk depicted in its analysis which artificially and completely unrealistically "forces" all Floridians to only consume Florida seafood.

CSF – The oral CSF is an upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime oral exposure to a stressor (EPA 2000a). FDEP used national (that is, nation-wide) CSF values from the Integrated Risk Information (IRIS) of the U.S. EPA as the source for the CSFs used in its analysis, because *sufficient data were not available for Florida*. The CSF is calculated as the slope of a line with a 0 (zero) intercept (that is, zero = no dose and no effect or risk). The slope of the line is defined as the $0.1/LED_{10}$, wherein LED_{10} is the lower 95% confidence interval on a dose associated with at 10% extra risk of tumor incidence or tumor precursor development. If the LED_{10} value was based on animal studies (e.g., rats or mice), it is adjusted to equivalent human doses if appropriate data for humans are available. *Usually, however, sufficient data are <u>not</u> available* to enable reliable "translation" of the dose data for rats or mice to dose data for humans (FDEP 2016a). Lacking sufficient data for human exposures, "default assumptions" are used to estimate a CSF for humans based on the data for rats or mice:

"equivalent human oral dose" = scale daily applied oral doses over a lifetime in proportion to the body weight of the test animal, raised to the ¾ power ($BW_{3/4}$).

This "adjustment factor" is used some metabolic rates have been found to be related to body weight in this way (U.S. EPA 2000a). Clearly, however, the lack of appropriate data for humans, and use of a simple "adjustment factor" to relate the body weight/dose for a rat or mouse to the body weight/dose for a human is a major generalization that imparts <u>high</u> uncertainty to the derivation of the key parameter, CSF. This is the reality because rats and mice are markedly different from humans in many metabolic functions that cannot be simplistically related (e.g. Csanády et al. 1992, Jewell and Miller 1999, Johnson 2012 and references therein). Thus, simple scale-up based on a body weight factor should be expected to

produce, at best, rough estimates of the CSF for humans. Anisimov et al. (2005) summarized the problem as follows:

> Whereas laboratory rodents (namely mice and rats) are similar to humans in some respects, there are important differences…that make valid interpretation and extrapolation of the results from rodent cancer experiments to humans problematic. …Mammary tumours are common in rodents [but] there are not rat or mouse strains that exhibit a high incidence of spontaneous carcinomas of the stomach or colon [as in humans]….The spontaneous regression of tumours is a rare phenomenon in adult humans, whereas it is common in mature laboratory rodents….Few rodent carcinogens were established as clearly carcinogenic to humans. Similarly, some human carcinogens are not carcinogenic to rodents. This creates a significant problem for interpreting the results of animal experiments with carcinogens in relation to humans. *These and other differences warn against the simple extrapolation of the results of rodent experiments to humans…to reliably predict cancer risks* [emphasis added]….

As noted above (see p.15), minimum risk level (MRL) values, developed by the Agency for Toxic Substances and Disease Registry, were used by FDEP (following U.S. EPA 2015a) in place of CSFs for three benzene derivative substances. A MRL is defined as an *estimate* of the daily human exposure to a hazardous substance that is *likely* to be without *appreciable* risk of adverse non-cancer health effects over a specified duration of exposure. It has been used to screen contaminant levels and to identify contaminants and potential health effects as hazardous waste sites. The italicized portions of the above definition indicate the potential for high uncertainty in attempts to use MRLs in place of CSFs to derive protective HHC. Note, as well, that MRLs were devised for use in assessment of non-cancer health effects, rather than carcinogenic effects. Additional explanation about the use of MRLs in deriving HHC for these three chemical substances is lacking in the TSD (FDEP 2016a).

BAF – Bioaccumulation is the uptake and retention of a chemical substance by an aquatic organism from the entire surrounding environment (water, sediments, food etc.; U.S. EPA 2003). In developing HHCs, BAFs are used to account for potential bioaccumulation of chemicals in finfish and shellfish (seafood). Values are considered to represent steady-state equilibrium between uptake, elimination, growth (biodilution), and biotransformation. BAFs inherently consider all uptake routes (diffusion, diet, etc.), and should be developed for three trophic levels in the food web of interest.

BAFs, ideally estimated directly from data in the natural environment, are known to vary depending on the chemical substance, the trophic level, the ecosystem, the waterbody, and the site within the waterbody. *Sufficient field data to estimate BAFs are not available for most of the chemical substances for which FDEP developed HHC.* Lacking those data, BAFs were estimated using a bioconcentration factor (BCF), which FDEP described as a measure of uptake via diffusion across gill membranes. Bioaccumulation by organisms such as fish can be much higher than bioconcentration, especially for persistent, hydrophobic (relatively insoluble) chemicals. *BCFs are usually lower than BAFs* and, thus, unreliable in estimating BAFs. Their use typically results in less protective criteria (EPA 2000b). *For organic substances with low*

or unknown metabolism, BAFs have been estimated a third way, using the K_{ow} approach (K_{ow} multiplied by a *"food chain multiplier," FCM*). FCMs are calculated as "the ratio of a baseline BAF for an organism of a given trophic level (whatever laboratory data were available) to the baseline BCF." FDEP "derived" them using a food web model; in other words, *a model was used in attempt to estimate what the "food chain multipliers" should have been, had actual data been available to calculate them.*

The italicized information above indicates **major uncertainties** in attempts to estimate BAFs, which are (or should be) critically important to the process of developing protective HHC. FDEP used U.S. EPA national (rather than Florida-specific) laboratory and field data to develop BAFs, but such data were only available for 11 of the 81 chemical substances. FDEP used less reliable BCFs to estimate BAFs for 4 substances; and FDEP used the K_{ow} approach for 59 substances. The remaining substances had insufficient laboratory or field data across all three trophic levels, and the K_{ow} approach was inappropriate for use. So, FDEP estimated field environmental exposure BAFs for those substances using limited laboratory BCF data.

Insufficient data were available for calculating BAFs for bis(2-ethylhexyl) phthalate, butylbenzyl phthalate, diethyl phthalate, dimethyl phthalate, and di-nbutyl phthalate. FDEP calculated "alternative BAFs" for those five phthalates as geometric means across the trophic levels for which there were sufficient data, and the resulting numbers were applied as single values similar to BCFs. It is well known, however, that geometric means nearly always yield lower values than averages or medians (Parkhurst 1998, Sokal and Rolff 2012). Thus, this FDEP decision biased the "alternative BAFs" low. In other words, rather than acting conservatively (= use of medians), FDEP elected to use geometric means which resulted in lower estimates of bioaccumulation, leading in turn to higher, less protective HHC for these six chemical substances.

Insufficient data were available, as well, for six benzene-related substances including indeno(1,2,3-cd)pyrene, benzo(b)fluoranthene, benzo(k)fluoranthene, chrysene, dibenzo(a,h)anthracene, and benzo(a)anthracene. FDEP based BCFs for those substances on the laboratory-measured BCF for benzo(a)pyrene, which has been thought to be a good indicator of the presence of pyrogenic PAHs in the environment because it may similarly concentrate in fish and shellfish.

Clearly, there are **major uncertainties** in all of the above estimates. FDEP then decided that the resulting BAFs and BCFs were not representative of Florida conditions and "further modified" them using Florida-specific *general averages* for dissolved organic carbon (DOC), particulate organic carbon (POC), and general trophic-level estimates for the lipid content of Florida finfish and shellfish. The tacit assumption was that the DOC/POC ratio represents the fraction of a chemical substance that is available for uptake by aquatic organisms – which may or may not be valid for some of the chemical substances, and is invalid for others. Consider, for example, that many of these substances are stored in the bottom sediments, and are roiled up into the water column following bottom disturbance such as fish feeding. Taking a water-column sample, measuring the dissolved and particulate organic carbon, and assuming that the ratio represents anything about actual availability of the chemical substance produces highly unreliable results for many chemical substances because such compounds actually are more

abundant in the bottom water and surficial sediments (MacDonald et al. 2000, Wetzel 2001 and references therein).

POC measurements were <u>not</u> taken, however: *No POC data for Florida were available.* Therefore, FDEP estimated POC as equal to TOC – DOC (that is, total organic carbon minus dissolved organic carbon). This may *seem* to have been a scientifically defensible approach; the particulate organic carbon *should* equal the total organic carbon minus the dissolved organic carbon. But the quality of the data for TOC and DOC clearly was compromised because there in various cases the DOC was higher than the TOC measurements for the same sample (paired data), which would have been *impossible* if the measurements had been made using good quality control and careful consistency. FDEP decided to exclude all DOC/TOC ratios when the fraction equaled or exceeded 120%. In other words, the DOC could be up to 20% higher than the TOC before FDEP excluded the data. FDEP (2016a, p.29) explained that "Fractions between 100-119% were considered to be within the analytical noise and uncertainty." That decision alone conveyed as much as a ~20% uncertainty factor to the analysis.

In summary, the DOC/POC fraction as used in estimating BAFs is important in developing protective HHC. Yet, FDEP (i) provided no supporting information to justify the (unrealistic) assumption that this ratio represents the fraction of a chemical substance that is available for uptake by biota; (ii) had no data for POC, and estimated all of the POC concentrations; (iii) considered, as acceptable, DOC data that exceeded the TOC data by as much as ~20%, and used those data to estimate the BAF; and (iv) used medians of the "derived" DOC/POC ratios across water body identification numbers, despite the fact that true BAFs are known to vary depending on the waterbody and sites within it (FDEP 2016a, p.28). Further scrutiny of the technical support document for these HHC (FDEP 2016a, Table 3-4) revealed that four DOC/POC ratios were developed, one each for [all] coastal waters, [all] estuaries, [all] streams, and [all] lakes.

For lipid-soluble chemicals, the biota lipid (fat) content and trophic level transfer can strongly influence the bioaccumulation potential and, thus, the BAF. The U.S. EPA (2016) recommended nationwide BAFs for such chemical substances, standardized to lipid contents of 1.9%, 2.6%, and 3.0% for trophic levels 2, 3, and 4, respectively. FDEP argues that the lipid content of fish in Florida are substantially lower than the national values for trophic levels 3 (1.5%) and 4 (2.0%). FDEP then used the final baseline BAF values reported in U.S. EPA (2016), together with the Florida estimates for DOC, POC, and trophic-level lipid content to estimate Florida BAF values. Importantly, these percentages represent broad generalizations for each trophic level, as the percentage of fatty tissue in a given fish species varies greatly with age, sex, and physiological condition (e.g. Love 1970, Henderson and Tocher 1987). Larger percent lipid content of biota from higher trophic levels would result in potentially more bioaccumulation of lipid-soluble substances and, thus, higher BAF values which, in turn, would result in more protective HHC. In contrast, FDEP's use of smaller lipid percentages in the tissues of biota from higher trophic levels 3 and 4 biased the analysis in favor of smaller BAFs and less protective HHC.

These points are included as examples of the high uncertainty inherent in key parameters used in FDEP's analysis. *Overall, the BAFs used in FDEP's analysis are characterized by*

uncertainty so great that there is no scientific basis for FDEP to assert, for nearly all of the chemical substances, that the BAFs approximated actual field conditions even in a general sense, much less that they were "specifically" applicable to Florida waters.

Contaminant Sources – Throughout its explanation for how contaminant contributions from various sources were estimated, FDEP (2016a) repeatedly revealed high uncertainty in the numbers used. The emphasis consistently was on mean concentrations, which biased the analysis against yielding protective criteria for the population sectors exposed to contaminant concentrations that were higher than the mean. Consider the example of toluene (FDEP 2016a, p.145-). In estimating toluene exposure from treated drinking water, FDEP (2016a, p.147) related the weighted mean toluene concentration in treated surface water (0 μg/L), groundwater (0.00093 μg/L), and all treated water (0.00053 μg/L). FDEP used the "all treated water" weighted mean in its calculations. This approach would not adequately protect Floridians who obtain their treated drinking water from groundwater; the contamination concentration used for toluene was only about half of what it should have been.

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The above examples were included in this assessment to illustrate the *very high uncertainties* in the estimates for key factors that were used by FDEP to develop the draft HHC. FDEP asserts that its analysis built overall "uncertainty factors" of two to three orders of magnitude into the calculations, which erred on the side of conservatism. The reality, instead, is that the "corrective uncertainty factors" were much too low to enable calculation of protective HHC, because they failed to adequately account for the very high uncertainties which characterized the development of each key parameter. Overall, much higher corrective "uncertainty factors" would have been needed to accomplish a conservative analysis which yielded HHC that safeguard Floridians' health.

4. ***The uncertainty factors used by FDEP to adjust (decrease) RfDs and CSFs to estimate more conservative HHC, and other conservative assumptions, were inadequate to account for the high uncertainties in many key parameters used in the Monte Carlo simulations.***

FDEP (2016a) followed U.S. EPA (2000a) guidance to include "uncertainty factors" (UFs) to adjust modeled HHCs downward in an attempt to set more conservative, protective criteria. FDEP (2016a, e.g. p. 75) asserted that the uncertainties in the criteria calculations are "balanced" by the UFs that were inserted into the analysis, and by other conservative assumptions. As corrective information, the many uncertainties that characterize the key parameters used in FDEP's analysis overwhelmed the UFs and led to higher HHC that will not safeguard human health.

In FDEP (2016a), Appendix C consists of a table with up-to-date information about the UFs that were applied in estimating RfDs (oral reference doses - non-carcinogens) and CSFs (oral cancer slope factors - carcinogens), key parameters for derivation of the draft HHC. The UF for each harmful chemical substance, as well as the weight of evidence and the confidence in the analysis, summarized as follows (excluding endosulfan as indicated in the appendix):

Carcinogens: Overall UF = 3 (1 chemical substance); UF = 30 (3 substances); UF = 100

(8 substances); UF = 300 (6 substances); UF = 1,000 (13 substances); UF = 3,000 (1 substances). No UF for 12 (27%) of 45 substances listed.

Confidence indicated in the analysis: Low (1 substance), low to medium (5 substances), medium (10 substances), medium to high (4 substances), high (1 substance), "multiple" (1 substance, trichloroethylene). No indication of any confidence level for 23 (51%) of the 45 substances.

Non-carcinogens: Overall UF = 3 (1 chemical substance); UF = 10 (1 substance); UF = 25 (1 substance); UF = 100 (14 substances); UF = 300 (1 substance); UF = 1,000 (12 substances); UF = 3,000 (10 substances); and UF = 10,000 (1 substance). No UF for 6 (15%) of 41substances.

Confidence indicated in the analysis: Low (8 substances), low to medium (11 substances), medium (5 substances), medium to high (2 substances), high (1 substance), "multiple" (1 substance, trichloroethane). No indication of any confidence level for 13 (32%) of 41 substances.

As Appendix C illustrates, 12 (27%) of the 45 carcinogens and 6 (15%) of the 41 non-carcinogens, or a total of 21% (18) of the 85 substances, had no UF applied to the analysis. Confidence in the analysis was described as "high" for only 1 carcinogen and 1 non-carcinogen (total, 2, or 2%) of the 86 substances listed. The "Confidence" box in the table was *blank* for fully half (51% - 23 substances) of the carcinogens, and for ~one-third (32% - 13 substances) of the non-carcinogens, or more than half (54% - 36 substances) of the chemical substances analyzed. That is, there was no indication of any degree of confidence by FDEP, even low confidence, for half of the carcinogens and one-third of the non-carcinogens for which FDEP developed CSFs and RfDs, respectively. In correction of FDEP's (2016a,b) repeated assertions, for many of the harmful substances, the UFs and other conservative assumptions included in the analysis were *inadequate* to "balance" (account for or "cancel out") the many, major uncertainties characterizing the quantities estimated for these two key parameters in FDEP's modeling effort.

This assessment has pointed out ***many*** *major uncertainties for various other key parameters* used in FDEP's Monte Carlo simulations as well. The conservative assumptions and UFs inserted for the RfD and CSF parameters are inadequate to "balance" the major uncertainties characterizing those two parameters, and cannot reliably account for the major uncertainties in the other key parameters. This information collectively affords no confidence that the draft HHC will protect the designated uses of Class I, I-T, II, III, and III-L waters in safeguarding Floridians' health.

5. ***Risks to children, the elderly, and immunocompromised people were poorly considered in FDEP's analysis, and the draft HHC will fail to protect them from serious health impacts.***

The draft HHC are given as long-term annual averages not to be exceeded (FDEP 2016a, pp. 69-71). The probability risk analysis set the target risk (1 person in 1 million, 100,000, or 10,000) to be achieved at the arithmetic mean of the 90th percentile distribution. FDEP asserts that "because the risk distributions [from the Monte Carlo simulations] are log-normal and skewed, the mean value [i.e., the average value used to derive the HHC] represents greater than 50% of the population."

As FDEP (2016a, pp. 76-77) acknowledged, risks to children were only qualitatively addressed; hence, the agency's statement (p.77) is misleading that "…children eat less fish at home than adults on an *absolute weight basis* but on a per-kilogram-body-weight basis the risk estimates *could be* higher than for adults [emphasis added]." *Of course*, children eat small fish meals (absolute weight) than adults. But children generally are also much smaller than adults. Based on *what matters here* regarding their exposure to harmful substances, on a per-body-weight basis, *children are well known to have much higher risk than adults to a given concentration of harmful substance*. FDEP made a point of noting that body weight was used as a distribution, rather than a single "point" value, in its Monte Carlo simulations. This did not mean, however, that FDEP used smaller body weight values representative of children. Instead, FDEP simply used average adult weights for several different regions of Florida in its analysis. Moreover, as FDEP (2016a, p.77) acknowledged, drinking water ingestion rates "may be" (in fact, have been found to be) *much higher* for children per unit body weight. FDEP's (2016a, p.77) second seriously misleading statement on this issue is that "it is possible that the risk distributions derived for adults underestimate risks for children." It is not only "possible" – *it is certain that children are not sufficiently protected* by including them under HHC for "average adults."

FDEP (2016a, p.77) asserted that children are sufficiently protected by the draft HHC because the risk assessments are supposed to represent average exposures over a lifetime. In correction of that false assertion, children are inadequately protected by the draft HHC because, for many of the harmful chemical substances, early life developmental affects are the most sensitive endpoints; thus, "average lifetime" exposures are insufficient to protect children. In further attempting to "explain away" inadequate protection for children by the draft HHC, FDEP (2016a, p.77) y reiterated its assertion that the uncertainty factors applied in estimating RfDs and CSFs would "ensure full protection for children." That assertion is also false, considering the information presented on pp.23-24 of this assessment.

Elderly and immunocompromised people are also known to be much more sensitive than "average adults" to the impacts of harmful chemical substances (CDC 2012, ATSDR 2014). Similarly as for children, the draft HHC will fail to protect their health. These groups form major sectors of the Florida population. As of 2010, people aged 65 and over were reported by the U.S. Census Bureau to represent more than 20% of the Florida population (see http://www.census.gov/quickfacts/table/PST045215/12). Regarding the immunocompromised population, recall that Florida is second among the states in incidence of cancers (see p.3 of this assessment), and Florida is number one among the states in new cases of HIV (Bousquet and Auslen 2016).

6. *The draft criteria underestimate the fish consumption rate (FCR) for subsistence fishers and other groups who consume fish at a subsistence fisher rate, resulting in non-protective HHC linked to environmental injustice issues.*

FDEP's analysis assumed that the fish consumption rate for subsistence fishers was 142.4 g/day (uncooked), or 5 oz/day, based on U.S. EPA (2014b) national recommendations. This value underestimates the fish consumed by subsistence fishers, based on updated information (e.g., see Holloman and Newman 2012), and considering that *subsistence fishers and their*

families rely almost entirely on fish for their diet. For example, a recent study of African American women (ages 16-49 years) in the southeastern U.S. were surveyed to assess the reproducibility and consistency of fish consumption rates. Although the women in that community were not subsistence fishers, they were subsistence fish consumers. Their average FCR was 147.8 g/day, with a maximum of 185.8 g/day. Moreover, numerous researchers have reported that African Americans have higher fish consumption rates and associated chemical contaminant exposures than the general U.S. population or other sub-populations (e.g. Burger et al. 1999, 2001; Mahaffey et al. 2004, 2009; Gibson and McClafferty 2005; Derrick et al. 2008; McGraw and Waller 2009, Holloman and Newman 2010; Shilling et al. 2010).

This accumulating body of information suggests that FDEP's draft HHC may be especially non-protective of African Americans. Compounding the problem, in the Holloman and Newman (2012) study, the sources of the fish items consumed by African-American women were mainly from commercial sources (grocery stores or fish markets), not non-commercial sources (fishing). In other words, as previously explained (see p.17), FDEP completely ignored all sources of fish other than Florida waters in its entire analysis of FCRs and associated contaminant levels. This lack of accounting for contaminants in a major source of fish contaminated by harmful chemical substances led to the development of non-protective HHC for many Floridians, prominent among them, African Americans, many of whom are not subsistence fishers but consume fish at a subsistence fisher rate. As Holloman and Newman (2012, pp. 118-119) noted,

> Narrow perceptions and incorrect assumptions of fish consumption and contaminant exposure for many U.S. sub-populations has led to serious issues of environmental injustices regarding risk management and communication, whereby non-protective standards and policies have been implemented (and communicated), and the burden of exposure reduction has been placed solely on the individual and population (NEJAC [National Environmental Justice Advisory Council] 2002)….[There is a] potential environmental injustice issue arising from current perceptions of subsistence fish consumption held by many charged with assessing and regulating exposure to contaminated fish [by] viewing subsistence fish consumption only in relation to items fished for, instead of purchased….

In its analysis of additional risks for subsistence fishers in Florida, FDEP (2016a) used the same inputs for body weight (BW), drinking water consumption (DI), BAFs, BCFs, CSFs, and criteria as for the "average" Florida population. The only key parameter that was altered (and underestimated, based on the above information) was the fish consumption rate (FCR). FDEP provide no data in support of this general assumption. Yet, it is generally accepted that subsistence fishers are poor, and that they are characterized by a high proportion of minority groups and the elderly (Tyson 2012). As an advisory council to the U.S. EPA noted nearly 15 years ago, consumption of contaminated fish "is an especially pressing concern for many communities of color, low-income communities", whose members may consume fish in greater quantities than the general population (National Environmental Justice Advisory Council 2002). This information collectively indicates that FDEP erred in making the general assumption given above, *leading to unreliable claims by the agency that subsistence fishers (and other groups who consume fish at a subsistence fisher rate) will be "sufficiently protected" by the draft HHC.*

7. *Assessment of compliance with the HHC would be inadequate.*

There are several serious weaknesses in FDEP's plan for sampling that, if not improved, will jeopardize the health of all Floridians. First, various industries in Florida discharge toxic substances into surface waters daily based on permits. The industries self-report on their success at meeting discharge goals in the permits, and corrective actions are seldom required. The major burden of detecting violations of the HHC historically has fallen, and would continue to fall, on public utilities, many of which likely lack the substantial resources that are necessary. Moreover, the draft HHC are based upon an underlying expectation that water utilities would have to remove the higher levels of harmful chemicals which industries would be allowed to discharge into Florida waters. Many potable water treatment plants in Florida presently do not include expensive carbon filters in their treatment processes (see the FDEP Drinking Water Database at http://www.dep.state.fl.us/water/drinkingwater/download.htm) which, when properly maintained, ensure effective reduction/removal of harmful chemicals in finished drinking water (Burkholder et al. 2010). Second, about four million Floridians rely upon private wells for their drinking water (Mr. B. Bibler, former bureau chief of the FDOH, pers. comm., August 2016). None of these wells would be tested to assess contamination after substantially higher levels of these chemical substances were allowed in Florida surface waters.

Third, FDEP (2016a) would consider compliance assessment to be acceptable based on an average of *only three samples per year*, with samples taken in different quarters of the same year, which is seriously inadequate to calculate a reliable average because such an extremely low sampling frequency would easily miss events that resulted in elevated concentrations of the harmful substances. Much higher uncertainty in estimating the mean occurs when the sample number is below five (Sokal and Rohlf 2012, pp. 135-137). A minimum of monthly sampling is recommended to assess compliance in water quality assessment (e.g. Robertson and Roerish 1999, Stansfield 2001). In addition, for small sample sizes, the median is a better measure of central tendency in water quality data, which usually do not follow a normal distribution (Sokel and Rolff 2012).

Recommendations

The following corrective actions are needed to strengthen the draft HHC so that they protect the designated uses of Florida Class I, I-T, II, III, and III-L waters and safeguard human health:

- The more protective, conservative recommendations of the U.S. EPA (2015b) for most of these chemical substances should be followed in setting HHC for Florida waters until the many major uncertainties in various factors used to parameterize the Monte Carlo probability model can be substantially reduced.

- HHC should be developed for 4,4′-DDE. FDEP (2016a, p.48) specified that criteria were not added for this harmful substance because it is a banned pesticide. That rationale is inconsistent with FDEP's inclusion of HHC for DDT, which is also a banned pesticide. Moreover, the banning of pesticides does not prevent threats to drinking water quality from concentrations of these pesticides that remain on the Florida landscape from previous use.

- Protective HHC additionally should be developed for ~25 chemical substances for which recommended protective levels are available from the U.S. EPA (2015b).

- Toward strengthening the Monte Carlo probability model for future use, the model should be modified to include more protective parameters for sensitive groups. Sensitive groups should be expanded to include groups that consume fish at high levels similar to those of subsistence fishers. Fish consumption should be expanded to capture the reality of sources of seafood for Floridians, which include a high proportion of aquaculture and imported products.

- Assessment of compliance should be based on seasonal medians from data collected at least monthly. Medians are more appropriate for use because they are considered a better indicator generally of the "mid-range" especially for smaller sample sizes (Sokal and Rohlf 2012). Only three samples cannot be used to reliably estimate an average annual concentration.

- The state of Florida should take appropriate steps to ensure that potable water treatment plants have adequate funding support to enable effective reduction/removal of increased concentrations of harmful chemicals in potable source waters, allowed by these draft HHC, so that the finished drinking water is safe for human consumption.

- The state of Florida should routinely test private wells for many of these harmful chemicals which, as a direct result of the draft HHC, would be expected to increase in the potable waters depended upon by about four million Floridians.

- Until the above recommendations are implemented, EPA should disapprove of the proposed revisions to Florida's human health-based water quality criteria as failing to protect the designated uses of Florida's waters, and of failing to safeguard human health.

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