FLORIDA DEPARTMENT OF
Environmental Protection

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January 23, 2019

Mrs. Susan P. Gibson
DOD Regional Environmental Coordination
60 Forsyth Street, SW Rm 9M-15
Atlanta, GA 30303

Re: Perfluoroalkyl substances (PFAS), Department requirements/expectations for addressing PFAS

Dear Mrs. Gibson,

The Department appreciated the opportunity to speak with you and other Department of Defense (DOD) representatives during our November 1, 2018, conference call regarding the investigation of aqueous film-forming foam (AFFF) sources and Per- and Polyfluoroalkyl Substances (PFAS) at military installations in Florida. The DOD is already assessing PFAS based on federal policy and practice at your installations in the State of Florida. As discussed in the call, this letter is intended to summarize our discussions and clarify our state requirements and expectations for addressing PFAS at those Florida installations.

The Department would like to make you aware that the requirements for site rehabilitation under Chapter 62-780, F.A.C., apply to PFAS contamination and requests these contaminated sites be incorporated into Site Management Plans or Corrective Action Management Plans, and RCRA Permits (collectively referred to as “management plans”), as applicable, for each military installation identifying how PFAS contamination is to be addressed and remediated. The management plan should specify a list of actions to be conducted, reports to be prepared and submitted, and a schedule to complete those tasks.

To aid in the assessment and remediation of PFAS contamination in the State of Florida the Department, per Rules 62-780.150 and 62-780.650, F.A.C., has derived provisional groundwater cleanup target levels (GCTLs) and soil cleanup target levels (SCTLs) for PFOA and PFOS (attached). Remediation pursuant to these provisional CTLs ensures compliance with remediation requirements of Chapter 62-780, F.A.C. These provisional CTLs were generated using the process established in this publicly promulgated rule. As we discussed during our conference call, while DOD as the person responsible for site rehabilitation, has the option to propose alternative CTLs for PFOA and/or PFOS, that proposed alternative would have to be evaluated against statute and rule.

Again, we appreciate the opportunity to discuss the investigation of PFAS sources at Florida's military installations and our expectations for addressing PFAS in accordance with our state requirements. The Department is committed to continuing to work collaboratively with the DOD and its military components, as well as EPA and public water systems to ensure safe water supply for Floridians. Please do not hesitate to call or contact me at (850) 245-8790 or Teresa.Booeshaghi@floridadep.gov if you have questions or need clarification regarding this letter.

Sincerely,

Tim J. Bahr, Acting Director
Division of Waste Management

Attachments:
{*Calculation of an AGTL for PFOA/PFOS protective of sensitive lifestages*}
{*Development of alternative soil cleanup target levels for PFOA and PFOS*}

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April 16, 2018

Brian Dougherty, PhD
Program Manager
District and Business Support Program
Division of Waste Management
Florida Department of Environmental Protection
2600 Blair Stone Road
Tallahassee, FL 32399-2400

Re: Development of alternative soil cleanup target levels for PFOA and PFOS

Dear Dr. Dougherty:

At your request, we have developed alternative soil cleanup target levels (ASCTLs) for perfluorooctanoic acid (PFOA; CAS# 335-67-1) and perfluorooctane sulfonate (PFOS; CAS# 1763-23-1). PFOA and PFOS are perfluoroalkyl substances (PFASs). PFASs are used to make products resistant to stains, grease, and water. Before production was phased out at the end of 2015, PFOA was used in carpets, leathers, textiles, upholstering, and as a waterproofing or stain-resistant agent (USEPA, 2016a). In 2002, the only major US manufacturer of PFOS agreed to phase out production. However, PFOA and PFOS degrade slowly and are persistent in the environment. Most contamination by PFOA and PFOS is a result of releases from manufacturing sites, industrial sites, fire training areas, and waste sites where these chemicals were disposed (USEPA, 2016a & 2016b). Derivation of the ASCTLs for each chemical is described below.

Perfluorooctanoic Acid (PFOA)

The United States Environmental Protection Agency (USEPA) summarized toxicity studies for PFOA in the Drinking Water Health Advisory for PFOA (USEPA, 2016a). For reference dose (RfD) development, several candidate studies and health effect endpoints were evaluated (Perkins et al., 2004; Lau et al., 2006; Wolf et al., 2007; White et al., 2009; DeWitt et al., 2008; Butenhoff et al., 2004). A total of six candidate RfDs were considered based upon endpoints including increased liver weight and necrosis in rats, decreased pup weight from gestational exposure in mice, immunosuppression in mice, reduced ossification and accelerated male puberty in offspring of mice, and reduced body weight and increased kidney weight (relative and absolute) in rats. For each animal toxicity study, human equivalent average serum PFOA concentrations were derived using a pharmacokinetic model by Wambaugh et al. (2013). An oral reference dose (RfD) was derived for each human equivalent no observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL) using study-specific uncertainty factors. Three endpoints resulted in a RfD of 2E-05 mg/kg-d (the lowest calculated RfD). Among these, reduced ossification of the proximal phalanges and accelerated puberty in offspring from treated dams in the study by Lau et al. (2006) were selected as the critical effect(s). Other studies producing the same or similar RfD values are considered supportive. Data were not considered adequate to derive a reference concentration (RfC) for inhalation exposure.

In the Lau et al. (2006) study, pregnant CD-1 mice were dosed with 1, 3, 5, 10, 20, or 40 mg/kg PFOA by oral gavage daily from gestational day 1 to 17. Decreased ossification of pup (both sexes) proximal phalanges and accelerated preputial separation were seen at 1 mg/kg PFOA. The USEPA calculated a human equivalent point of departure of 5.3E-03 mg/kg-d for these endpoints. An uncertainty factor of 300 (3 for extrapolation from animal to human, 10 for extrapolation from LOAEL to NOAEL, and 10 for sensitive individuals) was applied to derive an oral RfD of 2E-05 mg/kg-d. Greater than 95% of PFOA is absorbed by the gastrointestinal tract (ATSDR, 2015). Therefore, a gastrointestinal absorption factor of 1 was used to extrapolate the toxicity to other routes of exposure.

PFOA is also carcinogenic and has been shown to be tumorigenic in the liver, testes, and pancreas of rats. In humans, there is epidemiological evidence for an association between serum PFOA and kidney and testicular tumors (USEPA, 2016a). The USEPA developed an oral cancer slope factor of 7E-02 per mg/kg-d based on the development of testicular tumors in rats. They concluded that the drinking water health advisory based on non-cancer effects was protective for the cancer endpoint. We also calculated ASCTLs based on the oral cancer slope factor of 7E-02 per mg/kg-d (ASCTLs not shown). These ASCTLs were higher than those protective of non-cancer endpoints confirming that ASCTLs based on non-cancer effects are protective of the cancer endpoint.

Direct exposure ASCTLs for residential and commercial/industrial scenarios were calculated using the formula presented in Figure 5 of Chapter 62-777, Florida Administrative Code (F.A.C.). The equation is shown in Figure 1. Default assumptions listed in Table 1 were taken from OSWER Directive 9200.1-120 (USEPA, 2014) and Table 3 of Chapter 62-777, F.A.C. Chemical-specific parameters are presented in Table 2. **The residential ASCTL for PFOA is 1.3 mg/kg and the commercial/industrial ASCTL is 25 mg/kg.** A leachability ASCTL was derived using the formula presented in Figure 8 of Chapter 62-777, FAC. The equation is shown in Figure 2 and inputs are listed in Table 1. **The ASCTL for leachability to groundwater is 0.004 mg/kg** (based on an alternative groundwater cleanup target level of 0.1 µg/L provided to you in a letter dated April 12, 2017).

Perfluorooctane Sulfonate (PFOS)

The USEPA summarized toxicity studies for PFOS in the Drinking Water Health Advisory for PFOS (USEPA, 2016b). Six candidate studies and seven endpoints were identified for the derivation of an RfD for PFOS (Seacat et al., 2002 & 2003; Luebker et al., 2005a & 2005b; Butenhoff et al, 2009; Lau et al., 2003). Candidate endpoints included: 1) increased liver weight and histopathology, decreased body weight, and thyroid hormone disturbances in monkeys; 2) increased liver weight and histopathology, and increased liver enzymes and blood urea nitrogen in serum in male rats; 3) decreased body weight of rat pups; 4) another study showing decreased body weight in rat pups; 5) decreased maternal body weight, gestation length, and pup survival in rats; 6) developmental neurotoxicity in rats; and 7) decreased pup survival and decreased maternal and pup body weight in rats. For each animal toxicity study, human equivalent average serum PFOS concentrations were derived using a pharmacokinetic model by Wambaugh et al. (2013). An oral RfD was derived for each human equivalent NOAEL or LOAEL using study-specific uncertainty factors. Data were not considered adequate to derive a reference concentration (RfC) for inhalation exposure. The USEPA selected reduced pup weight from a two-generation study in rats as the critical effect. Low body weight was considered to be a marker for developmental effects, including effects that may not be manifested until later in life. This effect is considered relevant to humans because PFOS has been measured in the blood of newborns, in breast milk, and in blood of older children.

The developmental toxicity study by Luebker et al. (2005a) resulted in a RfD of 2E-05 mg/kg-d (the lowest calculated RfD). In this study, male and female rats were dosed with 0, 0.1, 0.4, 1.6, or 3.2 mg/kg-d by gavage from six weeks prior to mating, during mating, and, for females, through gestation and lactation across two generations. Rat pup weight was significantly decreased at 1.6 mg/kg-d PFOS in the F1 generation. The USEPA calculated a human equivalent point of departure of 5.1E-04 mg/kg-d based on decreased rat pup weight in the F1 generation. An uncertainty factor of 30 (3 for extrapolation from animal to human and 10 for sensitive subpopulations) was applied to derive an oral RfD of 2E-05 mg/kg-d. No data are available regarding the gastrointestinal absorption of PFOS. Therefore, a gastrointestinal absorption factor of 1 was used to extrapolate the toxicity to other routes of exposure.

There is also suggestive evidence that PFOS is carcinogenic in humans based on chronic studies in rats that result in liver and thyroid adenomas. However, the tumor data lack a dose-response relationship and could not be used by the USEPA to develop a cancer slope factor. Therefore, the critical effect for PFOS is developmental toxicity.

Direct exposure ASCTLs for residential and commercial/industrial scenarios were calculated using the formula presented in Figure 5 of Chapter 62-777, Florida Administrative Code (F.A.C.). The equation is shown in Figure 1. Default assumptions listed in Table 1 were taken from OSWER Directive 9200.1-120 (USEPA, 2014) and Table 3 of Chapter 62-777, F.A.C. Chemical-specific parameters are presented in Table 2. **The residential ASCTL for PFOS is 1.3 mg/kg and the commercial/industrial ASCTL is 25 mg/kg.** A leachability ASCTL was derived using the formula presented in Figure 8 of Chapter 62-777, FAC. The equation is shown in Figure 2 and inputs are listed in Table 1. **The ASCTL for leachability to groundwater is 0.01 mg/kg** (based on an alternative groundwater cleanup target level of 0.1 µg/L provided to you in a letter dated April 12, 2017).

As with the PFOA and PFOS alternative groundwater cleanup target levels (AGCTLs) provided to you previously, these ASCTLs have been calculated using default equations and exposure assumptions from Chapter 62-777, F.A.C. (the ASCTLs also include updated exposure assumptions from OSWER Directive 9200.1-120). Recently, the USEPA and a number of states have modified their calculation of PFOA and PFOS criteria based upon the critical effects, which are developmental in nature, and/or the availability of serum concentration data for these chemicals. For example, the USEPA Health Advisories for PFOA and PFOS in drinking water are based upon a water consumption rate for a lactating woman to protect the breast fed infant rather than a standard adult drinking water consumption rate. This higher rate of consumption leads to a lower acceptable drinking water concentration (0.07 µg/L rather than 0.1 µg/L calculated with Chapter 62-777 F.A.C. assumptions). New Jersey and Minnesota have both used serum concentration data rather than the USEPA oral reference dose to derive acceptable concentrations of PFOA and PFOS in drinking water that are lower than the USEPA Health Advisories. The Minnesota approach specifically targets serum concentrations in the breast fed infant. Other than a general protection of children when developing SCTLs, Florida has not typically tailored calculation of cleanup target levels (CTLs) to address sensitive life stages when they have been identified. With increased attention to the issue of sensitive life stages in the context of PFOA and PFOS exposure, the Florida Department of Environmental

Protection (FDEP) may want to consider as a general matter when and to what extent sensitive life stages should be addressed in CTL development.

Please let us know if you have any questions regarding the development of these ASCTLs.

Sincerely,

Leah D. Stuchal, Ph.D.

Stephen M. Roberts, Ph.D.

References:

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USEPA (2016b) *Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS).* United States Environmental Protection Agency, Office of Water, Washington, DC.

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Figure 1 – Equation for Developing Acceptable Soil Cleanup Target Levels for Non-Carcinogens:

$$\text{SCTL} = \frac{THI \times BW \times AT}{EF \times ED \times FC \times \left[\left(\frac{1}{RfD_o} \times IR_o \times 10^{-6} kg/mg \times RBA\right) + \left(\frac{1}{RfD_d} \times SA \times AF \times DA \times 10^{-6} kg/mg\right)\right]}$$

Figure 2 – Equation for the Determination of SCTLs Based on Leachability:

$$\text{SCTL}\ (mg/kg) = GCTL(\mu g/L) \times CF(mg/\mu g) \times DF \times \left[K_{oc} \times f_{oc} + \frac{\theta_w + \theta_a \times H'}{\rho_b}\right]$$

Table 1 - Default values for the direct contact and leachability equations

Symbol	Definition (units)	Receptor	Default
BW	Body weight (kg)	child	15
		worker	80
IR_o	Ingestion rate, oral (mg/day)	child	200
		worker	50
EF	Exposure frequency (days/yr)	child	350
		worker	250
ED	Exposure duration (years)	child	6
		worker	25
SA	Surface area exposed (cm^2/day)	child	2373
		worker	3527
AT	Averaging time (days) (non-carcinogens)	child	2190
		worker	9125
AF	Adherence factor (mg/cm^2)	child	0.2
		worker	0.12
IR_i	Inhalation rate (m^3/day)	child	8.1
		worker	20
DA	Dermal absorption (unitless) (organics)		0.1
PEF	Particulate emission factor (m^3/kg)		1.24×10^9
TR	Target risk (unitless)		1×10^{-6}
CF	Conversion factor (µg/mg)		1000
DAF	Dilution attenuation factor (unitless)		20
f_{oc}	Fraction organic carbon in soil (g/g)		0.002
Θ_ω	Water-filled soil porosity (L_{water}/L_{soil})		0.3
Θ_α	Air-filled soil porosity (L_{air}/L_{soil})		0.13
ρ_β	Dry soil bulk density (g/cm^3)		1.5
ω	Average soil moisture content (g_{water}/g_{soil})		0.2 (20%)
η	Total soil porosity (L_{pore}/L_{soil})		0.43
ρ_σ	Soil particle density (g/cm^3)		2.65
CF	Conversion factor (µg/mg)		1000

Table 2 – Chemical-specific parameters for PFOA and PFOS

Chemical-Specific Variable	PFOA		PFOS	
	Value	Source	Value	Source
RfD_o	2E-05 mg/kg-day	USEPA	2E-05 mg/kg-day	USEPA
RfD_d	2E-05 mg/kg-day	extrapolated	2E-05 mg/kg-day	extrapolated
RfD_i	2E-05 mg/kg-day	extrapolated	2E-05 mg/kg-day	extrapolated
Diffusivity in air	2.3E-02 cm^2/s	calculated	1.7E-02 cm^2/s	calculated
Diffusivity in water	5.8E-06 cm^2/s	calculated	4.2E-06 cm^2/s	calculated
Molecular weight	414.09 g/mol	HSDB	500.13 g/mol	HSDB
Density	1.792 g/cm^3	HSDB	1.25 g/cm^3	Chemicaland21
Henry's Law Constant	Not measurable	EPIWIN	Not measurable	EPIWIN
log K_{ow}	4.81	HSDB	4.49	EPIWIN
K_{oc}	655.1 L/kg	EPIWIN	2562 L/kg	EPIWIN

USEPA – United States Environmental Protection Agency
HSDB – Hazardous Substances Data Bank
EPIWIN – Estimation Programs Interface for Windows v4.1.1

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August 16, 2018

Leah J. Smith
District and Business Support Program
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Florida Department of Environmental Protection
2600 Blair Stone Road
Tallahassee, FL 32399-2400

Re: Calculation of an AGCTL for PFOA/PFOS protective of sensitive lifestages

Dear Ms. Smith:

We have developed an alternative groundwater cleanup target level (AGCTL) for perfluorooctanoic acid (PFOA; CAS# 335-67-1) and perfluorooctane sulfonate (PFOS; CAS# 1763-23-1) protective of sensitive lifestages/receptors. We previously developed AGCTLs for PFOA and PFOS in letters to the Florida Department of Environmental Protection (FDEP) dated April 12, 2017. These AGCTLs incorporated updated toxicity values based on the USEPA Drinking Water Health Advisories for PFOA and PFOS (USEPA, 2016a & 2016b) and updated exposure parameters for adults listed in the 2011 Exposure Factors Handbook (USEPA, 2011). At that time, we were requested to use a drinking water ingestion rate applicable to a generic adult receptor, which is the approach used in the development of groundwater cleanup target levels (GCTLs) in Chapter 62-777, F.A.C. The resulting GCTL for both PFOA and PFOS was 0.1 µg/L.

The critical effects for both of these chemicals are developmental effects. For PFOA, the critical effects are decreased ossification of pup (both sexes) proximal phalanges and accelerated preputial separation. For PFOS, the critical effect is decreased pup weight in the F_1 generation. The F_1 generation is the first generation of pups born after parental exposure. Exposure usually takes place while pups are in utero and may last through lactation and weaning. Because the critical effects are development endpoints, adverse effects can result from short-term exposure during critical periods of development. The 90th percentile drinking water ingestion rate for lactating women (0.054 L/kg-d; USEPA, 2011) is used by the USEPA in the development of their drinking water criterion due to the potential increased susceptibility from higher drinking water rates during pregnancy and lactation (USEPA 2016a & 2016b). From a toxicological standpoint, it is more appropriate to use a drinking water ingestion rate applicable to the most sensitive lifestage/receptor in the development of a cleanup target level, than a default drinking water rate for an adult.

At your request, we have calculated AGCTLs for PFOA and PFOS protective of sensitive lifestages based on the 90th percentile drinking water ingestion rate of 0.054 L/kg-d for lactating women. For developmental effects, AGCTLs of 0.07 µg/L were derived for both PFOA and PFOS using the formula in Figure 2 of Chapter 62-777, FAC. The AGCTLs for these two chemicals are identical because their oral reference doses are also identical (2E-05 mg/kg-d). The calculation and exposure assumptions used are shown in Figure 1 below. Because of the similarity in adverse effects and potency of these chemicals, the USEPA recommends that, where PFOA and PFOS are co-located, the sum of the concentrations of these chemicals should be compared to the drinking water criterion (USEPA, 2016a & 2016b). Therefore, **the sum of PFOA and PFOS concentrations should be compared to the AGCTL of 0.07 μg/L.**

In deriving these AGCTLs, we note that the Agency for Toxic Substances and Disease Registry (ATSDR) has recently released for public comment a draft toxicological profile for perfluoroalkyl chemicals, including PFOA and PFOS. The proposed Minimal Risk Levels for PFOA and PFOS are an order of magnitude lower than their USEPA reference doses, prompting discussion within the scientific and regulatory community whether the USEPA reference doses should be re-visited and perhaps revised downward. We recommend following this discussion closely and making further modifications to the AGCTLs if warranted. Please let us know if you have any questions regarding the development of this AGCTL.

Sincerely,

Leah D. Stuchal, Ph.D.

Stephen M. Roberts, Ph.D.

References:

USEPA (2011) *Exposure Factors Handbook: 2011 Edition.* United States Environmental Protection Agency, National Center for Environmental Assessment, Office of Research and Development, Washington, DC.

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USEPA (2016b) *Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS).* United States Environmental Protection Agency, Office of Water, Washington, DC.

Figure 1 – Equation for the derivation of a GCTL for PFOA and PFOS

$$GCTL\ (\mu g/L) = \frac{RfD_o \times RSC \times CF}{WC}$$

where:

Parameter	Definition	Value
GCTL	Groundwater cleanup target level (µg/L)	--
RfDo	Reference dose (mg/kg-d)	2E-05
RSC	Relative source contribution	0.2
CF	Conversion factor (µg/mg)	1000
WC	Water consumption (L/kg-d)	0.054