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Subject: Assessing cumulative risk of PFAS using Cycle 11 PFAS recommendations for public health enforcement standards

Dear Ms. Haag and Mr. Elmore:

On November 6th, 2020, the Department of Health Services (DHS) released its Cycle 11 Groundwater Recommendations to the DNR. In Cycle 11, DHS developed a combined recommended standard for the following per- and polyfluoroalkyl substances (PFAS): PFOA (Cycle 10), PFOS (Cycle 10), NEtFOSE, NEtFOSAA, NEtFOSA, and FOSA.[1] Twelve additional PFAS were identified as having sufficient toxicological information available to develop individual recommended standards per Chapter 160, Wis. Stats.[2] Data from ongoing PFAS investigations show it is common to detect mixtures of PFAS in environmental samples. To evaluate human health risks posed by these mixtures, DHS will use a cumulative risk assessment method called a hazard index (HI), taking into consideration all PFAS that have a recommended groundwater enforcement standard.

DHS is choosing a hazard index approach because:

1) **PFAS identified in Cycle 11 groundwater recommendations have reproductive and/or developmental health effects and PFAS typically occur as mixtures in groundwater.** Toxicological studies of PFOA, PFOS, PFHxS, PFNA, PFDA, PFTeA, PFUnA, PFDoA, and PFODA all had observed critical effects based on a developmental and/or reproductive endpoint that were used to develop the recommended groundwater standards.[3] Although the groundwater standard recommendations for PFBS, HFPO-DA, PFBA, DONA, and PFHxA were not developed from critical effects based on

[1] https://www.dhs.wisconsin.gov/water/gws-cycle11.htm
[2] https://docs.legis.wisconsin.gov/statutes/statutes/160
[3] https://www.dhs.wisconsin.gov/publications/p02807.pdf

reproductive and/or developmental endpoints, each of these PFAS had other peer reviewed studies that identified critical reproductive/developmental effects (see Table 1).[4]

2) **Using a hazard index approach is appropriate for assessing risk of compounds with similar health effects as it uses the assumption of dose additivity to assess the noncancer health effects of a mixture of PFAS compounds**.[5,6] The hazard index approach is used or recommended by a number of agencies including the Agency for Toxic Substances and Disease Registry (ATSDR), the American Conference of Governmental Industrial Hygienists (ACGIH), and the Environmental Protection Agency Office of Research and Development (EPA ORD) among other national and international organizations.[7] DHS has also utilized a hazard index approach for other groundwater contaminants such as pesticides and volatile organic compounds (VOCs). As applied by DHS, the hazard index is the summation of individual hazard quotients (HQ). The HQ is the ratio of the exposure doses for DONA, PFBS, PFHxS, PFNA, PFDA, PFTeA, PFUnA, PFDoA, PFODA, HFPO-DA , PFBA, PFHxA, and the combined recommended standard to N-EtFOSE, NEtFOSAA, NEtFOSA, FOSA, PFOA, and PFOS divided by their respective recommended public health enforcement standard.

$$Hazard\ Quotient\ (HQ) = \frac{observed\ concentration\ (OC)}{recommended\ public\ health\ enforcement\ standard\ (ES)}$$

If the hazard index is less than 1.0 (see Table 2), it is unlikely that significant additive or toxic interactions would occur; so no further evaluation is necessary. If the hazard index is greater than 1.0, concern for the potential hazard of the mixture increases.

$$Hazard\ Index\ (HI) = \sum_{i=1}^{n} \frac{OC_i}{ES_i} \quad or \quad Hazard\ Index = \frac{OC_1}{ES_1} + \frac{OC_2}{ES_2} + \frac{OC_3}{ES_3} + \cdots + \frac{OC_n}{ES_n}$$

When a hazard index value is equal to or exceeds 1.0 (see Table 3), DHS recommends the following:

- Bottled water or another safe alternative water source should be used for drinking and preparing food, preparing infant formula, watering fruit and vegetable gardens, and for drinking water for pets.

- Because PFAS do not easily enter the body through skin, tap water can be used for showering, bathing, and washing hands. However, children and infants should be

[4] https://www.dhs.wisconsin.gov/publications/p02807.pdf
[5] https://www.epa.gov/sites/production/files/2014-11/documents/chem_mix_1986.pdf
[6] https://www.atsdr.cdc.gov/interactionprofiles/ip-ga/ipga-c1-c5.pdf
[7] https://www.atsdr.cdc.gov/interactionprofiles/ip-ga/ipga.pdf

monitored to discourage swallowing of bath or shower water. Tap water may also be used for doing laundry, washing dishes, brushing teeth, and filling a swimming pool.

Please note that the inclusion of site-specific exposure parameters may be appropriate for this determination when using this approach. Therefore, DHS should be consulted prior to proceeding with the use of a hazard index approach. If you have any questions regarding the information contained in this letter, please contact me at the email address below.

Sincerely,

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Enclosures
1. Cycle 11 Recommended PFAS Enforcement Standards for Groundwater and Associated Reproductive and/or Developmental Health Effects
2. Example of Hazard Index below 1.0
3. Example of Hazard Index equal to or greater than 1.0

cc: Bridget Kelly, Program Coordinator for Emerging Contaminants
Bruce Rheineck, NR Program Manager
Judy Fassbender, NR Program Manager

Table 1. Cycle 11 Recommended PFAS Enforcement Standards for Groundwater and Associated Reproductive and/or Developmental Health Effects

PFAS Compound	Recommended Enforcement Standard ng/L (ppt)	Developmental/ Reproductive Study	Developmental/ Reproductive Health effects from Animal Studies[2]
PFOA, PFOS, NEtFOSE, NEtFOSAA, NEtFOSA, FOSA	20	Goulding et al., 2017; Chen et al., 2017; Song et al., 2018; Van Esterik et al., 2016; Lai et al., 2017 & 2018	Developmental delays, birth defects, newborn deaths, reduced serum testosterone and sperm count, reduced size of corpora lutea in the ovaries, decreases in body weight gain in offspring
PFBS	450,000	Liebers et al., 2009; Feng et al., 2017	Developmental delays in offspring, decreased testicular sperm count, decreased body weights in female offspring, decreased pup survival, increased abnormal sperm cells.
PFBA	10,000	Das et al., 2008	Developmental delays, increase in full litter loss
PFDA	300	Harris and Birnbaum 1989	Decreased body weight in offspring, decreased fetal survival, increased percentage of resorptions per litter
PFDoA	500	Shi et al., 2009; Shi et al., 2010	Decreased body weight and testosterone in males, change in testes structure, decreased progesterone
PFHxS	40	Chang et al., 2018	Increased anogenital distance, reduced mean live litter size
PFHxA	150,000	Loveless et al., 2009	Decreased body weight/body weight gain, decreased weight gain in 1st week of pregnancy, decreased overall body weight gain, decreased mean weight during lactation
PFNA	30	Wolf et al., 2010; NTP, 2019	Decreased body weight gain, decreased survival , developmental delays,

PFODA	400,000	Hirata-Koizumi et al., 2012	Increased testes weight, decreased body weight and food consumption, decreased body weight gain and body weight in offspring, decreased corpora lutea and implantation sites, decreased total number of offspring born and live offspring
PFTeA	10,000	Hirata-Koizumi et al., 2015	Decreased seminal vesicle weight, lower body weight in offspring, lower body weights in pregnant females
PFUnA	3,000	Takahashi et al., 2014	Decreased body weight in offspring
HFPO-DA/GenX[1]	300	Blake et al., 2011	Decreased placenta weight and increased placental lesions
DONA	3,000	Gordon et al., 2011	Decreased litter size, decreased body weight gain and food consumption

[1]GenX is the trade name for HFPO-DA
[2]This is not an exhaustive list of reproductive/developmental health effects

Table 2. Example of Hazard Index below 1.0

PFAS Compound	Recommended Standard	Detectable Private Well Result	Hazard Quotients
PFBA	10,000	2.4	0.00
PFHxA	150,000	0.75	0.00
PFNA	30	0.9	0.03
PFDA	300	3.5	0.01
PFUnA	3000		0.00
PFDoA	500		0.00
PFTeA	10,000		0.00
PFODA	400,000		0.00
PFBS	450,000	1.3	0.00
PFHxS	40	0.54	0.01
HFPO-DA (GenX)	300		0.00
DONA	3,000		0.00
FOSA+NEtFOSE+NEtFOSA+ NetFOSAA+PFOS+PFOA	20	5	0.25
		Hazard Index	**0.3**

Table 3. Example of Hazard Index equal to or greater than 1.0

PFAS Compound	Recommended Standard	Detectable Private Well Result	Hazard Quotients
PFBA	10,000	2.4	0.00
PFHxA	150,000	7.7	0.00
PFNA	30	1.1	0.04
PFDA	300	3.6	0.01
PFUnA	3000		0.00
PFDoA	500		0.00
PFTeA	10,000		0.00
PFODA	400,000		0.00
PFBS	450,000	1.3	0.00
PFHxS	40	1.5	0.04
HFPO-DA (GenX)	300		0.00
DONA	3,000		0.00
FOSA+NEtFOSE+NEtFOSA+ NetFOSAA+PFOS+PFOA	20	18.4	0.92
		Hazard Index	**1.0**