

Joint Committee on Drinking Water Additives – Treatment Chemicals Joint Committee on Drinking Water Additives – System Components

5/2/2024

Proposed revision to NSF/ANSI/CAN 600 – Health Effects Evaluation and Criteria for Chemicals in Drinking Water (600i12r1)

Revision 1 of NSF/ANSI/CAN 600, issue 12 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by May 23, 2024** via the NSF Online Workspace.

Please review all ballot materials. When adding comments, please include the section number applicable to your comment and add all comments under one comment number whenever possible. If you need additional space, please use the attached blank comment template in the reference documents and upload online via the browse function.

Purpose

This ballot includes the following proposed revisions to NSF/ANSI/CAN 600. Importantly, implementation periods for adoption of PFAS criteria into product specific standards will be determined separately.

- Updates to the criteria for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) to align with the U.S. EPA Final Rule (89 FR 32532, April 26, 2024) that provides maximum contaminant levels of 4.0 ppt for each compound. A TAC of 4 ppt and a SPAC of 0.4 ppt is proposed based on the regulation. As the SPAC of 0.4 ppt may not be feasible to achieve in all cases based on varying normalization parameters for specific products, the footnote "10" is maintained for the SPAC, which reads: "¹⁰ Limitations in analytical methods may preclude detection at levels sufficient to report these compounds at or below the SPAC. To the maximum extent possible, testing laboratories shall seek the lowest detection limits via both sample exposure and analysis."
- Addition of individual criteria for perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), and hexafluoropropylene oxide dimer acid (HFPO-DA; or Gen X) based on the US EPA Final Rule (89 FR 32532, April 26, 2024) that provides individual maximum contaminant levels for PFHxS, PFNA, and HFPO-DA of 10 ppt each when compounds are observed to extract individually. A TAC of 10 ppt and a SPAC of 1 ppt is proposed for each compound based on the regulation. As the SPAC of 1 ppt may not be feasible to achieve in all cases based on varying normalization parameters for specific products, the footnote "10" is maintained for

the SPAC, which reads: "10 Limitations in analytical methods may preclude detection at levels sufficient to report these compounds at or below the SPAC. To the maximum extent possible, testing laboratories shall seek the lowest detection limits via both sample exposure and analysis."

- Addition of individual criteria for PFBS of 2000 ppt based on the US EPA Health Based Water Concentration provided within the US EPA Final Rule (89 FR 32532, April 26, 2024). Although the US EPA regulation does not provide for an individual MCL for PFBS, PFBS will be measured during extractives testing and criteria for PFBS will be required when this compound is observed to extract individually.
- Addition of criteria for perfluorohexanoic acid (PFHxA) of 2000 ppt when observed to extract as an individual compound based on the final US EPA IRIS assessment that provides an RfD of 5 x 10⁻⁴ mg/kg-day. The criteria was calculated based on the drinking water intake rate for a lactating woman of 0.0469 L/kg and a relative source contribution of 20%.
- Addition of a hazard index approach based on the US EPA Final Rule (89 FR 32532, April 26, 2024) and advisement from US EPA and Health Canada that should be applied when two or more of PFHxA, PFHxS, PFNA, HFPO-DA and/or perfluorobutane sulfonic acid (PFBS) are observed to extract together as a mixture. Footnote "11" is added to clarify how the hazard index should be applied, which reads:

¹¹ The hazard index (HI) approach is applied to account for dose-additive health effects that may occur when a person is exposed to multiple compounds having a similar mode of action in the body but varying in potency. A hazard index of 1 is used to protect against health concerns associated with exposure to chemical mixtures and is calculated as follows referencing the observed concentration in water for each extracting chemical divided by its individual TAC. Where a compound is not observed to occur in water, its associated fraction may be removed from the equation:

$$HI\ TAC: \left(\frac{HFPO-DA\ ppt}{10\ ppt}\right) + \left(\frac{PFBS\ ppt}{2000\ ppt}\right) + \left(\frac{PFHxA\ ppt}{2000\ ppt}\right) + \left(\frac{PFHxS\ ppt}{10\ ppt}\right) + \left(\frac{PFNA\ ppt}{10\ ppt}\right) \leq 1$$

Background

Updates to the drinking water criteria are based on the US EPA final rule for PFAS compounds and continued efforts of the Health Advisory Board (HAB) and the Joint Peer Steering Committee (JPRSC). New contaminants, as well as changes made to existing contaminants for total allowable concentration (TAC) and single allowable product concentration (SPAC) levels are shown in the ballot using strikeout for removal of old text and gray highlights to show the updated text.

The proposed updates were presented at the recent DWA JC meetings on November 29th and 30th, 2023, contingent up on finalization of the US EPA final rule. Please refer to the

DWA JC meeting summary excerpts, the JC presentation, and the original information paper under the referenced items for additional background information.

If you have any questions about the technical content of the ballot, you may contact me in care of:

France Lemiuex, Chair, Joint Committee on Drinking Water Additives c/o Amy Jump, Joint Committee Secretariat

T (313) 426-4918

E ajump@nsf.org@nsf.org

[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of strikeout and additions by grey highlighting. Rationale Statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication.]

NSF/ANSI Standard for Drinking Water Additives –

Health Effects Evaluation and Criteria for Chemicals in Drinking Water

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Table 4.1 Drinking water criteria

(previously NSF/ANSI 60 Annex C, NSF/ANSI 61 Annex D)

Substance	CAS#	MCL/MAC or TAC (mg/L)	SPAC (mg/L)	STEL (mg/L)	Source of supporting documentation 1, 2, 3, 4, 5, 6, 7	Additional information
•						
•						
•						
perfluorohexanoic acid (PFHxA)	307-24-4	0.002	0.0002	_	Derived from the oral RfD on the U.S. EPA IRIS database with a default 20% RSC for drinking water. Verification date: 2023-04-10	Detections shall be evaluated to individual criteria, or according to the hazard index approach ¹¹ when observed with: CAS#s: 45187-15-3, 72007-68- 2, 108427-53-8 and/or 122499-17-6
•						
perfluorooctanoic acid (PFOA)	335-67-1	0.0000040 0.00007 (total)	0.0000040 ¹⁰ 0.000007 (total) ¹⁰	_	40 C.F.R. § 141.60, 40 C.F.R. § 141.61 U.S. EPA Lifetime Drinking Water Health Advisory. Issue date: 2016	Detections shall be summed with the following chemical: CAS# 1763-23-1.
Perfluorooctane sulfonic acid (PFOS)	1763-23-1	0.0000040 0.00007 (total)	0.0000040 ¹⁰ 0.000007 (total) ¹⁰		40 C.F.R. § 141.60, 40 C.F.R. § 141.61 U.S. EPA Lifetime Drinking Water Health Advisory. Issue date: 2016	Detections shall be summed with the following chemical: CAS# 335-67-1.

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(previously NSF/ANSI 60 Annex C, NSF/ANSI 61 Annex D)

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Substance	CAS#	MCL/MAC or TAC (mg/L)	SPAC (mg/L)	STEL (mg/L)	Source of supporting documentation 1, 2, 3, 4, 5, 6, 7	Additional information
perfluorobutane sulfonic acid (PFBS)	45187-15-3	0.002	0.0002	_	40 C.F.R. § 141.60, 40 C.F.R. § 141.61 (Health-Based Water Concentration)	Detections shall be evaluated to individual criteria, or according to the hazard index approach ¹¹ when observed with: CAS#s: 307-24-4, 72007-68-2, 108427-53-8 and/or 122499-17-6
perfluorononanoic acid (PFNA)	72007-68-2	0.00001	0.00000110	_	40 C.F.R. § 141.60, 40 C.F.R. § 141.61 (Health-Based Water Concentration)	Detections shall be evaluated to individual criteria, or according to the hazard index approach ¹¹ when observed with: CAS#s: 307-24-4, 45187-15-3, 108427-53-8 and/or 122499-17-6

Table 4.1 Drinking water criteria

(previously NSF/ANSI 60 Annex C, NSF/ANSI 61 Annex D)

Substance	CAS#	MCL/MAC or TAC (mg/L)	SPAC (mg/L)	STEL (mg/L)	Source of supporting documentation	Additional information
perfluorohexane sulfonic acid (PFHxS)	108427-53- 8	0.00001	0.00000110	-	40 C.F.R. § 141.60, 40 C.F.R. § 141.61	Detections shall be evaluated to individual criteria, or according to the hazard index approach ¹¹ when observed with: CAS#s: 307-24-4, 45187-15-3, 72007-68-2, and/or 122499-17-6
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-						
hexafluoropropylene oxide dimer acid (HFPO-DA; Gen X)	122499-17- 6	0.00001	0.00000110	_	40 C.F.R. § 141.60, 40 C.F.R. § 141.61	Detections shall be evaluated to individual criteria, or according to the hazard index approach ¹¹ when observed with: CAS#s: 307-24-4, 45187-15-3, 72007-68-2, and/or 108427-53-8
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¹ The references for criteria based on US primary drinking water regulations are from the US Code of Federal Regulations, Title 40 (Protection of Environment), revised as of July 1, 2011. This document is available on-line at <www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>. Issue dates are given for criteria based on Health Canada guidelines. Additional information on the guidelines for these chemicals is available at <hc-sc.gc.ca/ewh-semt/pubs/water-eau/index-eng.php#tech_doc.>.

² NSF action levels have been derived according to the requirements of Section 3.

Table 4.1 Drinking water criteria

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Substance	CAS#	MCL/MAC or TAC (mg/L)	SPAC (mg/L)	STEL (mg/L)	Source of supporti	ng documentation	Additional information
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³ Criteria are derived from the oral RfD on the U.S. EPA IRIS database adjusted for a drinking water intake rate for an adult and a default relative source contribution from drinking water of 20%.

Other criteria have been used directly, unless otherwise noted.

Van den Berg et al., 1998. Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and Wildlife. Environmental Health Perspectives 106(12):775:792.

US Environmental Protection Agency. 2000. Chapter 9: Toxic Equivalency Factors (TEFs) for Dioxin and Related Compounds. From Exposure and Human Health Risk Assessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. Part II: Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds. NCEA-I-0386. September 2000. SAB Review Draft. www.epa.gov/ncea/pdfs/dioxin/part2/fm-chap9.pdf

- ⁶ For the chemicals listed in this table under the threshold of evaluation (TOE), the evaluation criteria are 0.003 mg/L under static conditions, and 0.0003 mg/L under flowing conditions. If any of these chemicals are detected at concentrations exceeding the TOE, toxicity data shall be reviewed to determine whether specific TAC and SPAC values can be established, prior to using TOE to determine compliance with the standard.
- ⁷ Effective April 17, 2013, CSA Group, NSF International, IAPMO R&T, UL, and the Water Quality Association use harmonized procedures outlined in Section 3 (previously Annex A of NSF/ANSI/CAN 60 and NSF/ANSI/CAN 61) to develop action levels for unregulated drinking water contaminants. The Joint Peer Review Steering Committee (JPRSC) was established by the aforementioned certifying agencies to consolidate current pass/fail criteria and to harmonize the external per review process for future risk assessments. As part of the consolidation process, pass/fail criteria may be adopted following consensus approval of the members of the JPRSC. Sources of the pass/fail criteria approved by the JPRSC may include risk assessments submitted by each certifying agency as well as assessments based upon authoritative agencies (i.e., U.S. EPA, Health Canada).
- ⁸ TT = treatment technique. For NSF/ANSI/CAN 61 only, the lead and copper rule requirement that defines corrosion control optimization for large systems is based on the difference between the 90th percentile lead level and the source water lead concentration being less that the practical quantitation level of 5 ppb (Code of Federal Regulations 40 C.F.R. Part 141.81(b)(3)).
- ⁹ For NSF/ANSI/CAN 61, Section 9 products other than supply stops, flexible plumbing connectors, and miscellaneous components, a Q statistic value of 5 μg or 1 μg of lead is used as the evaluation criterion when the product is evaluated to the requirements of Section 9.5.1, or Section 9.5.1.1.1, respectively. For supply stops, flexible plumbing connectors, and miscellaneous Section 9 devices, a Q statistic value of 3 μg or 0.5 μg of lead is used as the evaluation criterion when the product is evaluated to

⁴ The IRIS verification date represents the date the oral RfD or the cancer risk assessment was peer reviewed by the U.S. EPA. Refer to the online IRIS database for the complete update and revision history of the IRIS files. <www.epa.gov/IRIS>

⁵ Toxic equivalency factors (TEFs) have been established as a means to compare the potency of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) to individual congeners of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs). The U.S. EPA uses an approach to dioxin risk assessment methodology in which levels of dioxins and furans are analytically determined, the concentration of each congener is multiplied by its respective TEF value, and all the products are totaled to a single 2,3,7,8-TCDD equivalent.

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(previously NSF/ANSI 60 Annex C, NSF/ANSI 61 Annex D)

Substance	CAS#	MCL/MAC or TAC (mg/L)	SPAC (mg/L)	STEL (mg/L)	Source of supporting documentation	Additional information
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the requirements of Section 9.5.1, or Section 9.5.1.1.1, respectively.

$$HITAC: \left(\frac{HFPO-DA\ ppt}{10\ ppt}\right) + \left(\frac{PFBS\ ppt}{2000\ ppt}\right) + \left(\frac{PFHxA\ ppt}{2000\ ppt}\right) + \left(\frac{PFHxS\ ppt}{10\ ppt}\right) + \left(\frac{PFNA\ ppt}{10\ ppt}\right) \le 1$$

¹⁰ Limitations in analytical methods may preclude detection at levels sufficient to report these compounds at or below the SPAC. To the maximum extent possible, testing laboratories shall seek the lowest detection limits via both sample exposure and analysis.

¹¹ The hazard index (HI) approach is applied to account for dose-additive health effects that may occur when a person is exposed to multiple compounds having a similar mode of action in the body but varying in potency. A hazard index of 1 is used to protect against health concerns associated with exposure to chemical mixtures and is calculated as follows referencing the observed concentration in water for each extracting chemical divided by its individual TAC. Where a compound is not observed to occur in water, its associated fraction may be removed from the equation: