NSF HAB and JPRSC Pass/Fail Criteria Updates

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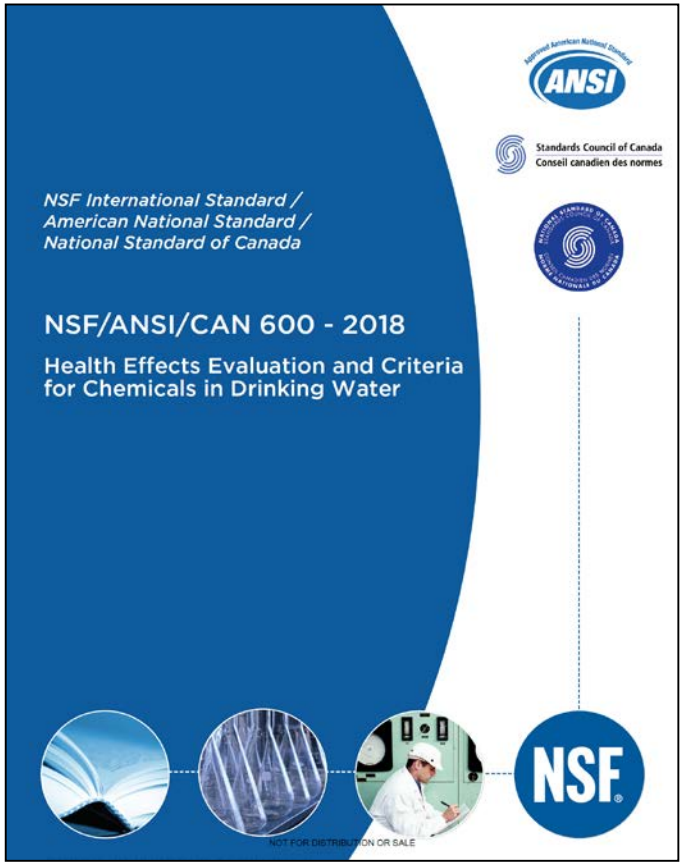
Goals of Presentation

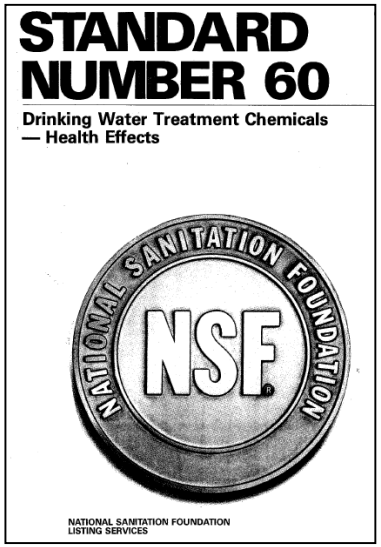
- **Introduce NSF/ANSI/CAN 600!!!!!**
  - Review Section 3 (formerly Annex A) changes
- **Review the types and sources of pass/fail criteria**
  - EPA, Health Canada, JPRSC, NSF International, etc.
- **Provide an update on HAB membership and JPRSC activities**
- **Provide an update on new and updated pass/fail criteria**
  - HAB Peer-Reviewed Assessments
  - JPRSC Reconciled Values

NSF/ANSI/CAN 600 – 2018

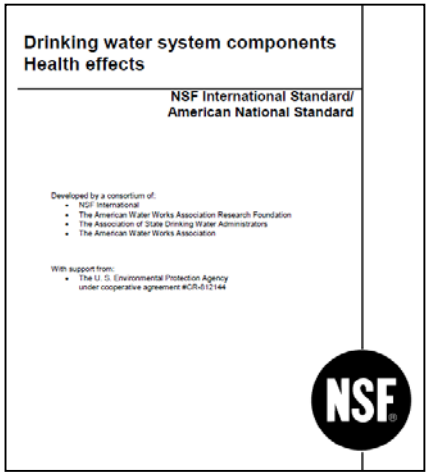
- Initially published in February 2019
- Purpose of NSF 600 is to create a single source for the pass/fail criteria that can be linked to multiple Standards
- Criteria tables from Annex C (NSF 60) and Annex D (NSF 61) are now in Section 4 (Table 4.1)
- Annex A (NSF 60/61) toxicology requirements now under Section 3



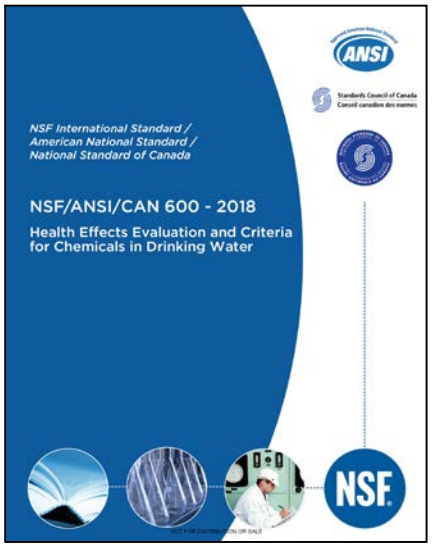
Toxicology Evaluation Updates



1980's
(pre-Annex A)



1990's



2019

Former Annex A of NSF 60/61 (circa 1999), now Section 3 of NSF 600, outlines risk assessment procedures for unregulated drinking water additives or contaminants.

- Annex A has never been systematically updated.
- Update strategy was developed at Spring 2016 HAB.
- First round of topics reviewed Fall 2016 HAB.
- Second round of topics reviewed Spring 2017

NSF/ANSI/CAN 600 – 2019

NSF/ANSI/CAN 600 – 2019, Published in August 2019

Updates to Section 3 (formerly Annex A) address the use of the following:

- Existing peer-reviewed assessments
- Secondary sources
- Updated drinking water intake and body weight values
- Life-stage susceptibility for carcinogens (mutagenic MOA)
- Surrogates/chemical classes
- Confidence in risk characterization (qualitative statement)
- Updated definitions and references

TAC/SPAC Water Intake Change

- **Prior Section 3 defaults for adults match historical EPA assumptions:**
  - Body weight (BW) of 70 kg
  - Drinking water intake (DWI) of 2 Liters per day
    - ➢Combined these equate to an ingestion rate (IR) of 0.028 L/kg-day
- **The 2011 USEPA Exposure Factors Handbook (EFH) considers new data and recommends a L/kg-day intake rate instead of separating BW and DWI.**
  - The new default is now the 90th percentile all ages IR of 0.033 L/kg-day.

STEL Water Intake Change

- **STEL Intake changes:**
  - Previously body weight (BW) of 10 kg
  - Drinking water intake (DWI) of 1 Liters per day
    - ➢Combined these equate to an ingestion rate (IR) of 0.1 L/kg-day

- **Using 2011 USEPA Exposure Factors Handbook (EFH) and depending on critical effect, intake rates for STEL may be the following:**
  - The default is now the 90th percentile for bottle-fed infant IR of **0.228 L/kg-day**.
  - Other intake rates that may be used include 0.056 L/kg-day (1 to <2 year-old child), 0.039 L/kg-day (pregnant woman) or 0.033 L/kg-day (adult)

Pass/Fail Criteria

- **TAC = Total Allowable Concentration**
  - The maximum concentration of a non-regulated contaminant allowed in a public drinking water supply
- **SPAC = Single Product Allowable Concentration**
  - The maximum concentration of a contaminant in drinking water that a single product is allowed to contribute
  - Generally 1/10th of the TAC value
- **STEL = Short-term Exposure Level**
  - A maximum concentration of a contaminant that is permitted in drinking water for an short-term exposure

Sources of Pass/Fail Criteria

- **US EPA & Health Canada Regulatory Values**
  - Maximum Contaminant Levels (MCL) – EPA
  - Maximum Acceptable Concentration (MAC) – Health Canada
- **US EPA Integrated Risk Information System (IRIS) Assessments**
- **Other U.S. or International Regulatory Values**
  - U.S. EPA, U.S. FDA, WHO, etc.
- **Risk Assessments Peer Reviewed by the NSF Health Advisory Board (HAB)**
- **JPRSC (Joint Peer Review Steering Committee) Reconciliations**
- **Threshold of Evaluation Assessments**

EPA MCL / Health Canada MAC updates - Uranium

- **Recent review of Health Canada MAC value for uranium confirmed an MAC value of 0.02 mg/L which differs from current US EPA MCL of 0.03 mg/L**
  - 0.03 mg/L is the current pass/fail criteria in NSF 600

- **NSF 600 Section 3 does not specify prioritization**
  - Consulted with HAB chair (Dr. Ed Ohanian, US EPA)
  - NSF facilitated meeting between US EPA and Health Canada

- **Representatives from Health Canada and U.S. EPA agreed to adopt the Health Canada MAC value for elemental uranium of 0.02 mg/L for NSF 600**

NSF International Health Advisory Board (HAB)

Mission and Charge

- **To provide expert peer review, advice and guidance on human health effects issues to the NSF Council of Public Health Consultants**
- **To provide consensus peer review of documents supporting derivation of NSF drinking water action levels**
- **To review and accept defined methods for performing scientifically-sound human health risk assessments for inclusion in NSF/ANSI 60 and 61, Annex A**

Spring 2020 HAB Membership

- Edward Ohanian, U.S. EPA, Chair
- Helen Goeden, State of Minnesota, Vice-Chair
- David Blakey, Health Canada (retired)
- Steven Bursian, Michigan State University
- Craig Farr, Craig Farr Consulting
- Robert Hinderer, Robert Hinderer Consulting
- Gene McConnell, ToxPath, Inc.
- Elaine Francis, Sandcastle Toxicology Associates
- Caroline English, NSF International (retired)
- Lynne Haber, University of Cincinnati – TERA
- John Lipscomb, U.S EPA, National Homeland Security Research Center (NHSRC) (retired)
- Douglas Wolf, Syngenta Corporation

FALL 2019 VALUES

Chemical Name	CAS#	Listed TAC/SPAC/STEL (µg/L)	TAC/SPAC/STEL (µg/L)
Chlorotrifluorotoluene (revised)	98-56-6	300 / 30 / 2000	3 / 0.3 / 3
TAME/TAEE/TAA CBEL (revised)	994-05-8 919-94-8 75-85-4	3 / 0.3 / 10 (TOE) 3 / 0.3 / 10 (TOE) Not Listed	**300 / 30 / 400 (total)**
(Hydroxycyclohexyl) phenyl methanone	947-19-3	Not Listed	80 / 8 / 500
Polyacrylic acid and polyacrylic acid copolymer	9003-01-4 40623-75-4	Not Listed	5000 / 2000 / 10000

FALL 2019 VALUES

Chemical Name	CAS#	Listed TAC/SPAC/STEL (µg/L)	TAC/SPAC/STEL (µg/L)
Triethylene glycol dimethacrylate (revised)	109-16-0	50 / 50 / 2000 (total)	**50 / 50 / 50**
Trimethylolpropane acrylate (revised)	15625-89-5	Not Listed	400 / 40 / 1000

SPRING 2019 VALUES

Chemical Name	CAS#	Listed TAC/SPAC/STEL (µg/L)	TAC/SPAC/STEL (µg/L)
Ammonium Carbamate	1111-78-0	Not Listed	7000 / 2000 / 7000
Cyclopentanone	120-92-3	3 / 0.3 / 10 (TOE)	8000 / 800 / 8000
2-Phosphonobutane-1,2,4-tricarboxylic acid	37971-36-1	3 / 0.3 / 10 (TOE)	**1000 / 300 / TBD**
Cyclotrisiloxane, hexamethyl	541-05-9	Not Listed	**50 / 50 / 500**

SPRING 2019 VALUES

Chemical Name	CAS#	Listed TAC/SPAC/STEL (µg/L)	TAC/SPAC/STEL (µg/L)
Polyethylene glycol	25322-68-3	Not Listed	**20000 / 2000 / 20000**
Methyl t-butyl ether (MTBE)	1634-04-4	Not Listed	60000 / 6000 / 60000
Isophthalic Acid (revised)	121-91-5	10 / 10	**600 / 60 / 9000**

FALL 2018 VALUES

Chemical Name	CAS#	Listed TAC/SPAC/STEL (µg/L)	TAC/SPAC/STEL (µg/L)
Poly(Hexamethylene) Biguanide (Revised)	28757-47-3	Not Listed	**2000 / 700 / 3000**
Rubidium (Revised)	7440-17-7	Not listed	**500 / 200**
Chloramine T	7080-50-4 127-65-1 70-55-3	Not listed	**100 / 100 / 2000**
Ethyl Carbonate	105-58-8	Not listed	500 / 50 / 1000

FALL 2018 VALUES

Chemical Name	CAS#	Listed TAC/SPAC/STEL (µg/L)	TAC/SPAC/STEL (µg/L)
Chloromethyl Propanol	558-42-9	Not listed	200 / 20 / 300
Sodium Persulfate	7775-27-1	Not listed	6000 / 6000 / 30000

SPRING 2018 VALUES

Chemical Name	CAS#	Listed TAC/SPAC/STEL (µg/L)	TAC/SPAC/STEL (µg/L)
Methyl Acetate	79-20-9	3 / 0.3 / 10 (TOE)	**30000 / 3000 / 30000**
Tinuvin P	2440-22-4	3 / 0.3 / 10 (TOE)	**4000 / 400**
Propylene Glycol Monomethyl Ether Propylene Glycol Monomethyl Ether Acetate	107-98-2 108-65-6	50 / 50	**2000 / 200 / 3000 (total)**
p-Benzoquinone	106-51-4	Not listed	0.09 / 0.009

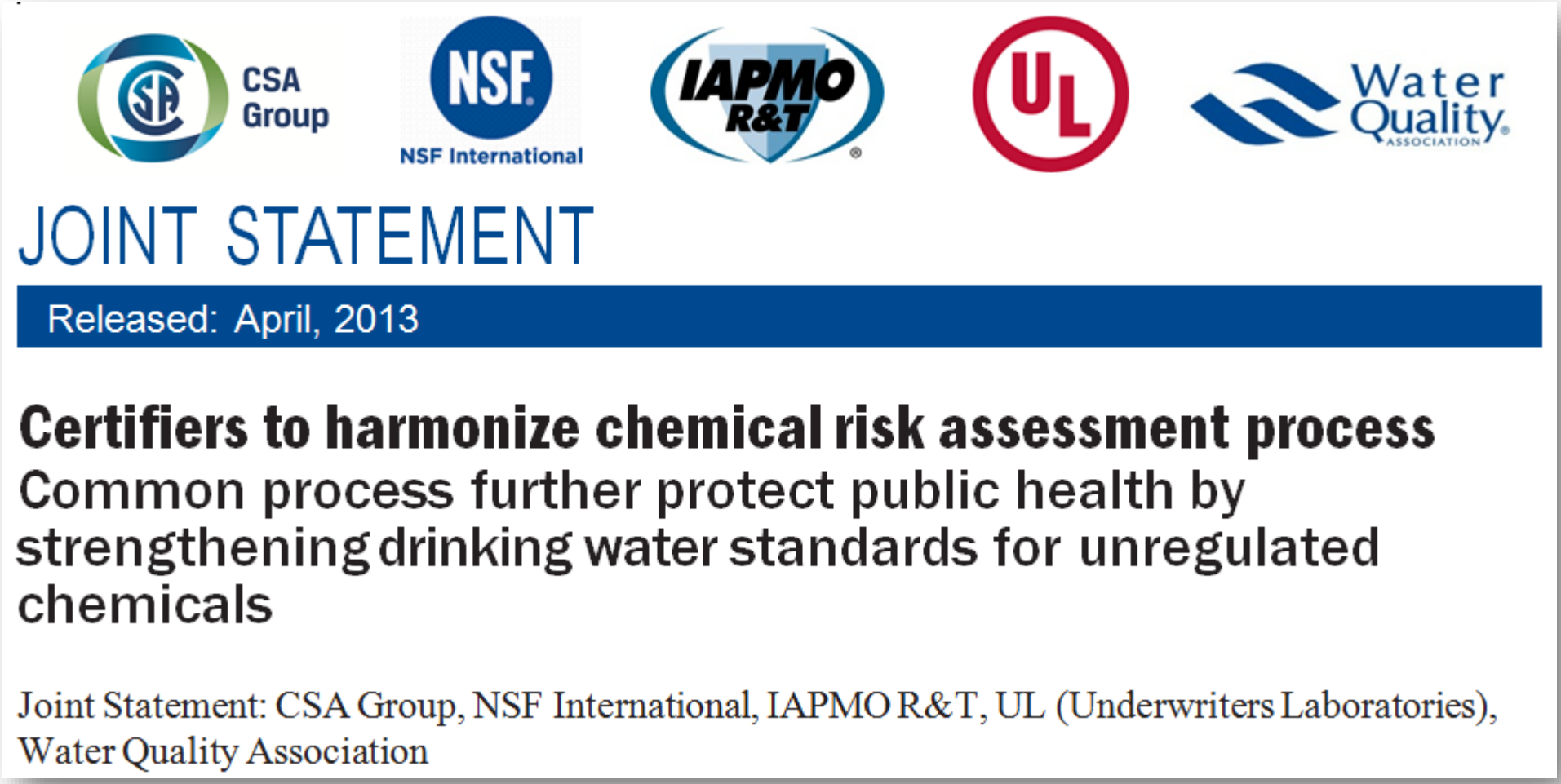
SPRING 2018 VALUES

Chemical Name	CAS#	Listed TAC/SPAC/STEL (µg/L)	TAC/SPAC/STEL (µg/L)
Alkyl Isothiocyanates (Class Based Evaluation Level)	Multiple	Not listed	40 / 4 / 60 (total)
Octylphenol Glycol Ethers (Class Based Evaluation Level)	58705-51-4 49796-75-0 38621-31-7 37806-81-7	3 / 0.3 / 10 (TOE)	**100 / 10 / 500 (total)**

Joint Peer Review Steering Committee

- **Established to consolidate efforts among ANSI accredited certification bodies to nominate/prioritize risk assessment documents for review by the NSF HAB**
- **Intended to reduce duplication in effort and to harmonize risk values when products are being certified to NSF/ANSI Standards**
- **Membership includes the Chairman of the NSF HAB and representatives from participating ANSI accredited certification bodies**

Joint Peer Review Steering Committee



- **New Member – ALS - Truesdail Laboratories**

START

Action levels based on Authoritative Body peer reviewed concentrations?

Yes

Any new relevant information?

No

Group 1: Certifiers adopt Authoritative Body values (HAB FYI)

Yes

NSF risk assessment approved by NSF HAB?

Yes

New information basis for an OC risk assessment ?

No

Group 2: Certifiers adopt NSF action levels

Yes

OC expert panel approved risk assessment available?

Yes

Simple majority agreement on action levels by JPRSC?

No

Group 3: Certifiers adopt action levels reconciled by HAB

Yes

Group 4: Document(s) presented to HAB

Group 5: FYI to HAB

Key:
OC = Other Certifiers;
JPRSC = Joint Peer Review Steering Committee;
HAB = NSF Health Advisory Board

FALL 2019 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
Ethyl acetate	141-78-6	Not Listed	5000 / 500
Benzaldehyde, 2-hydroxy-	90-02-8	3 / 0.3 / 10 (TOE)	10 / 10
Undecanoic acid	112-37-8	3 / 0.3 / 10 (TOE)	10 / 10
3-Hexyne-2,5-diol, 2,5-dimethyl-	142-30-3	3 / 0.3 / 10 (TOE)	10 / 10
Carbonyl sulfide	463-58-1	3 / 0.3 / 10 (TOE)	10 / 10

FALL 2019 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
2-Propanol, 1,1-oxybis-	110-98-5	Not Listed	10 / 10
Benzoic acid, 4-amino, ethyl ester	94-09-7	Not Listed	10 / 10
2-Cyclopentylidenecyclopentanone	825-25-2	3 / 0.3 / 10 (TOE)	10 / 10
Hexylene glycol	107-41-5	Not Listed	10 / 10
PEG stearyl ether	9005-00-9	Not Listed	10 / 10

SPRING 2019 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
n-Propyl acetate	109-60-4	3 / 0.3 / 10 (TOE)	10 / 10
Octadecanoic acid, 2,3-dihydroxypropyl ester	123-94-4	Not Listed	10 / 10
Octanal	124-13-0	Not Listed	10 / 10
2-Ethylhexenal	645-62-5	Not Listed	10 / 10
Propylparaben	94-13-3	3 / 0.3 / 10 (TOE)	10 / 10

SPRING 2019 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
Dimethyldecanedioate	106-79-6	3 / 0.3 / 10 (TOE)	10 / 10
Hexane-2,5-dione	110-13-4	3 / 0.3 / 10 (TOE)	10 / 10
2-Hydroxypropyl methacrylate	923-26-	3 / 0.3 / 10 (TOE)	10 / 10
Decyltetraglycol isomer	5703-94-6	Not Listed	10 / 10
5-Octadecene	7206-21-5	Not Listed	10 / 10

SPRING 2019 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
2,6,10,15,19,23-Hexamethyl-2,6,10,14,18,22-tetracosahexaene	7683-64-9	3 / 0.3 / 10 (TOE)	10 / 10
1,2-Dimethyoxypropane	7778-85-0	Not Listed	10 / 10
1-Pentadecene	13360-61-7	Not Listed	10 / 10
Hexanoic acid, 2-ethyl-, oxybis(2,1-ethanediyloxy-2,1- ethanediyl) ester	18268-70-7	3 / 0.3 / 10 (TOE)	10 / 10
Trimellictic anhydride	552-30-7	Not Listed	10 / 10

SPRING 2019 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
Triethylene glycol	112-27-6	Not Listed	10 / 10
Bis-(2-butoxyethyl) phthalate	117-83-9	Not Listed	10 / 10
Di(2-ethylhexyl) isophthalate	137-89-3	Not Listed	10 / 10
Glyceryl monolaurate	142-18-7	3 / 0.3 / 10 (TOE)	10 / 10
Ethanone, 1,1'-(1,3-phenylene)bis-	6781-42-6	3 / 0.3 / 10 (TOE)	10 / 10

SPRING 2019 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
Phenol, 2,4-bis(1,1-dimethylethyl)-6-methyl-	616-55-7	Not Listed	10 / 10
Furan, 2,5-dimethyl	625-86-5	Not Listed	10 / 10
2-ethylhexyl methacrylate	688-84-6	Not Listed	10 / 10
Gallium	7440-55-3	3 / 0.3 / 10 (TOE)	10 / 10
m-tert-Butyl phenol	585-34-2	Not Listed	10 / 10

SPRING 2019 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
2-Ethylhexyldiphenyl phosphate (EHDP)	1241-94-7	3 / 0.3 / 10 (TOE)	10 / 10
Amino tris(methylene phosphonic acid) and it sodium salts	2235-43-0 6419-19-8 20592-85-2 4105-01-5 7611-50-9 94021-23-5 15505-05-2	3 / 0.3 / 10 (TOE) Not Listed	10 / 10 (total)

Joint Peer Review Steering Committee

- **JPRSC has continued its reconciliation efforts**
  - 37 reconciled values presented at 2019 HAB meetings
  - 24 reconciled values presented at 2018 HAB meetings
  - The current focus of the JPRSC committee includes:
    - Evaluating the qualitative requirements of NSF 600
    - Increasing number of criteria reconciled
    - Streamlining review process
    - Increasing the number of risk assessment presented to HAB
    - Seek more balanced and timely contribution from members

Questions or Comments?

FALL 2018 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
Dihydro-5-pentyl-2(H)-furanone	104-61-0	3 / 0.3 / 10 (TOE)	1000 / 100
Heptanoic acid	111-14-8	3 / 0.3 / 10 (TOE)	200 / 20
Acetic acid, 1-methylethyl ester	108-21-4	3 / 0.3 / 10 (TOE)	10 / 10
Isobutyl acetate	110-19-0	Not Listed	10 / 10
Ethanol, 2-(2-methoxyethoxy)-	111-77-3	Not Listed	10 / 10

FALL 2018 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
2,5-Hexanediol, 2,5-dimethyl-	110-03-2	3 / 0.3 / 10 (TOE)	10 / 10
Decanedioic acid, dibutyl ester	109-43-3	Not Listed	10 / 10
Methyl salicylate	119-36-8	3 / 0.3 / 10 (TOE)	10 / 10
Cyclotetrasiloxane, octamethyl-	556-67-2	Not Listed	10 / 10
Benzoic acid, 2-ethylhexyl ester-	5444-75-7	Not Listed	10 / 10

FALL 2018 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
Methyl-3-hydroxybenzoate	19438-10-9	3 / 0.3 / 10 (TOE)	10 / 10
Methyl-4-hydroxybenzoate	99-76-3	3 / 0.3 / 10 (TOE)	10 / 10
2-Methylbenzaldehyde	529-20-4	3 / 0.3 / 10 (TOE)	10 / 10
3-Methylbenzaldehyde	620-23-5	3 / 0.3 / 10 (TOE)	10 / 10
4-methylbenzaldehyde	104-87-0	3 / 0.3 / 10 (TOE)	10 / 10

SPRING 2018 JPSRC Reconciled Values

Chemical Name	CAS#	Prior TAC/SPAC/STEL (µg/L)	Updated TAC/SPAC/STEL (µg/L)
1,3-Dichloropropane	142-28-9	Not Listed	100 / 10
2-Hexanone	591-78-6	Not Listed	40 / 4
3-Phenyl-2-propen-1-ol Cinnamaldehyde trans-Cinnamic acid Cinnamic acid trans-Cinnamaldehyde	104-54-1 104-552 140-10-3 621-82-9 14371-10-9	Not Listed	4000 / 400 (total)
Phenol, 4,4'-butylidenebis(2-(1,1-dimethylethyl)-5-methyl-	85-60-9	Not Listed	10 / 1
2,7-Naphthalenediol	582-17-2	Not Listed	10 / 10