MEMORANDUM

TO: Joint Committee on Drinking Water Additives – System Components

FROM: France Lemieux, Chairperson

DATE: February 12, 2015

SUBJECT: Proposed revision to NSF/ANSI 61 – *Drinking water system components- Health effects* (61i120r1)

Draft 1 of NSF/ANSI 61 issue 120, is being forwarded to the Joint Committee for balloting. Please review the changes proposed to these standards and **submit your ballot by March 5, 2015** via the NSF Online Workspace.

When adding comments, please identify the section number/name for your comment and add all comments under one comment number where possible. If you need additional space, please upload a word or pdf version of your comments online via the browse function.

Purpose

The purpose of this ballot is to add an option to perform a full 90 days of exposure to establish the Day 90 contaminant concentration where Day 90 assessments are currently allowed.

Background

Currently under NSF/ANSI 61, when the normalized concentration of a contaminant exceeds or is expected to exceed its acceptable level, the determination of the contaminant leaching rate over time is considered using a multiple time point exposure protocol. The samples are analyzed and the results are extrapolated to establish a projected Day 90 value. In addition to the current protocol, section 4 also provides the option to expose the product for a full 90 days. The test takes longer but is much simpler. This ballot will allow a similar option for products covered under other sections of the standard. The selection of the protocol would be at the discretion of the manufacturer.

The issue was presented at the 2014 annual DWA-SC JC meeting on December 4, 2014, and the JC unanimously voted in favor of balloting the proposed revisions. Please see the attached meeting summary excerpt and the issue document (DWA-61-2014-1) for additional information.

Public Health Impact

This revision will have no negative impact on public health.

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

Chairperson, Joint Committee
c/o Monica Leslie
Joint Committee Secretariat
NSF International
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E-mail mleslie@nsf.org

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[Note – the changes are seen below using strikeout for removal of old text and gray highlights to show the suggested text. ONLY the highlighted text is within the scope of this ballot.]

NSF/ANSI Standard
for Drinking Water System Components – Health Effects

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4 Pipes and related products

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4.5 Extraction procedures

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4.5.7 Multiple time point conditioning/exposure protocols

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4.5.7.1 Cold application

Products that are intended to be in contact with only cold water shall be maintained at 23 ± 2 °C (73 ± 4 °F) for 19 d. During the 19-d period, the exposure water shall be changed at least 12 times, with a minimum period of 24 ± 1 h between water changes. At seven of these water changes, extraction water shall be collected for analysis after a 24-h exposure. For extrapolation and normalization purposes, the number of hours elapsed since the most recent water change (or sample collection) and the number of days elapsed since the initiation of the exposure shall be recorded at the time of each extraction water collection.

NOTE – Table 4.3 provides an example multiple time point conditioning/exposure protocol. Alternate protocols shall be permitted as long as the requirements of 4.5.7.1 are met.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be maintained at 23 ± 2 °C (73 ± 4 °F). Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 (representing 14 d of conditioning and 1 d of acute exposure), and after the final exposure terminating on Day 90 (representing 14 d of conditioning, 1 d of acute exposure, and 90 d of chronic exposure). The exposure water shall be changed at least weekly ~~4 d/wk~~ during the interval between the initial and final exposure~~s~~ and on at least 4 days during the final week of exposure. ~~Exposures that are used for the collection of extractant water for analysis shall not exceed 24 ± 1 h in duration.~~

4.5.7.2 Hot applications

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4.5.7.2.1 Intermittent hot water exposure

Products that are intended to be in intermittent contact with hot water shall undergo the cold application exposure according to 4.5.7.1. At the initiation of each exposure that will be collected for analysis, the product shall be exposed at the selected elevated temperature, either 60 ± 2 °C (140 ± 4 °F) or 82 ± 2 °C (180 ± 4 °F), for 30 ± 5 min. The product shall then be exposed at 23 ± 2 °C (73 ± 4 °F) for the duration of the exposure period. The exposure water shall not be decanted prior to the completion of the exposure period.

NOTE 1 – Table 4.3 provides an example multiple time point conditioning/exposure protocol. Alternate protocols shall be permitted as long as the requirements of 4.5.7.2.1 are met.

NOTE 2 – The stated duration of the conditioning period at the hot temperature does not include any time needed to elevate the product sample or exposure vessel to the required exposure temperature.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. At the initiation of each exposure that will be collected for analysis, the products shall be exposed at the selected elevated temperature, either 60 ± 2 °C (140 ± 4 °F) or 82 ± 2 °C (180 ± 4 °F), for 30 ± 5 min. The product shall then be exposed at 23 ± 2 °C (73 ± 4 °F) for the duration of the exposure period. The exposure water shall not be decanted prior to the completion of the exposure period. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 (representing 14 d of conditioning and 1 d of acute exposure), and after the final exposure terminating on Day 90 (representing 14 d of conditioning, 1 d of acute exposure, and 90 d of chronic exposure). The exposure water shall be changed at least weekly ~~4 d/wk~~ during the interval between the initial and final exposure and on at least 4 days during the final week of exposure. ~~Exposures that are used for the collection of extractant water for analysis shall not exceed 24 ± 1 h in duration.~~

4.5.7.2.2 Continuous hot water exposure

Products that are intended to be in continuous contact with hot water shall be maintained at the selected elevated temperature, either 60 ± 2 °C (140 ± 4 °F) or 82 ± 2 °C (180 ± 4 °F) for 19 d. During the 19-d period, the exposure water shall be changed at least 12 times with a minimum period of 24 ± 1 h between water changes. At seven of these water changes, extraction water shall be collected for analysis after a 24-h exposure. For extrapolation and normalization purposes, the number of hours elapsed since the most recent water change (or sample collection) and the number of days elapsed since the initiation of the exposure shall be recorded at the time of each extraction water collection.

NOTE – Table 4.3 provides an example multiple time point conditioning/exposure protocol. Alternate protocols shall be permitted as long as the requirements of 4.5.7.2.2 are met.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be maintained at the selected elevated temperature, either 60 ± 2 °C (140 ± 4 °F) or 82 ± 2 °C (180 ± 4 °F). Extraction water shall be collected for analysis at at least two time points: after Day 1 (representing 14 d of conditioning and 1 d of acute exposure), and after the final exposure terminating on Day 90 (representing 14 d of conditioning, 1 d of acute exposure, and 90 d of chronic exposure). The exposure water shall be changed at least weekly ~~4 d/wk~~ during the interval between the initial and final exposure and on at least 4 days during the final week of exposure. ~~Exposures that are used for the collection of extractant water for analysis shall not exceed 24 ± 1 h in duration.~~

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5 Barrier materials

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5.5 Extraction procedures

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5.5.5.5 Multiple time point exposure protocol

When the normalized concentration of a contaminant exceeds, or is expected to exceed, its acceptable concentration (see Annex A) when evaluated as a single time point (see 5.5.5.4), determination of the contaminant leaching rate as a function of time shall be considered. The relationship between contaminant concentration(s) and time shall be determined and plotted using a minimum of five data points. Table 5.5 summarizes the multiple time point exposure sequence. For contaminants of interest that do not require over time testing, extraction water shall be collected following the third exposure period (elapsed time 5 d). For paint/coating systems intended for immediate return to service, the first four days of the exposure will be eliminated and the water samples shall be collected at the conclusion of the first 24 hour period following conditioning.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be exposed at the selected application temperature (e.g. 23 $\pm$2 ^{o}C; 60 $\pm$2 ^{o}C; 82 $\pm$2 ^{o}C) for the full duration of the exposure. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 and after the final exposure terminating on Day 90. The exposure water shall be changed at least weekly during the interval between the initial and final exposure and on at least 4 days during the final week of exposure.

NOTE – Day 1 is defined as the time point at which extractant water for all contaminants is collected for analysis (5 d of elapsed time). Day 90 is defined as 90 d following this time point (95 d of elapsed time).

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Annex B

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B.3 Joining and sealing materials

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B.3.7 Multiple time point protocol

When the normalized concentration of a contaminant exceeds, or is expected to exceed, its acceptable level when evaluated as a single time point exposure, determination of the contaminant leaching rate using a multiple time point exposure shall be considered. For the purpose of contaminant concentration

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evaluation, Day 1 shall be defined as the time point at which extractant water is collected for analysis under the single time point exposure protocol. Day 90 shall be defined as 90 d after this time point. When over time data are used, the Day 1 concentration for the contaminant of concern shall meet the Short Term Exposure Level and Day 90 concentration shall meet the Total Allowable Concentration/Single Product Allowable Concentration respectively. When extrapolation is used, the relationship between contaminant concentration and time shall be determined and plotted using a minimum of five data points.

> NOTE – When a multiple time point protocol is employed in the evaluation of a contaminant, consideration shall be given to the availability of appropriate toxicity data to define an acute exposure limit for the contaminant, as required in Annex A, Section A.5, Data requirements for evaluating short-term exposures. Consideration shall also be given to the leaching characteristics of the contaminant. Short Term Exposure Levels shall not exceed the Total Allowable Concentration for nonmetallic contaminants listed in NSF/ANSI 61, Annex D, Table D1 (Drinking water criteria for contaminants regulated by the USEPA and established by Health Canada). Multiple time point analysis shall not be used for lead or any other metal contaminant listed in Table D1.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be exposed at the selected application temperature (e.g. 23 $\pm$2 ^{o}C; 60 $\pm$2 ^{o}C; 82 $\pm$2 ^{o}C) for the full duration of the exposure. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 and after the final exposure terminating on Day 90. The exposure water shall be changed at least weekly during the interval between the initial and final exposure and on at least 4 days during the final week of exposure.

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B.4 Mechanical devices

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B.4.5 Multiple time point protocol

When the normalized concentration of a contaminant exceeds, or is expected to exceed, its acceptable level when evaluated as a single time point exposure, determination of the contaminant leaching rate using a multiple time point exposure shall be considered. For the purpose of contaminant concentration evaluation, Day 1 shall be defined as the time point at which extractant water is collected for analysis under the single time point exposure protocol. Day 90 shall be defined as 90 d after this time point. When over time data are used, the Day 1 concentration for the contaminant of concern shall meet the Short Term Exposure Level and Day 90 concentration shall meet the Total Allowable Concentration/Single Product Allowable Concentration respectively. When extrapolation is used, the relationship between contaminant concentration and time shall be determined and plotted using a minimum of five data points.

> NOTE – When a multiple time point protocol is employed in the evaluation of a contaminant, consideration shall be given to the availability of appropriate toxicity data to define an acute exposure limit for the contaminant, as required in Annex A, Section A.5, Data requirements for evaluating short-term exposures. Consideration shall also be given to the leaching characteristics of the contaminant. Short Term Exposure Levels shall not exceed the Total Allowable Concentration for nonmetallic contaminants listed in NSF/ANSI 61, Annex D, Table D1 (Drinking water criteria for contaminants regulated by the USEPA and established by Health Canada). Multiple time point analysis shall not be used for lead or any other metal contaminant listed in Table D1.

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At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be exposed at the selected application temperature (e.g. 23 ±2 °C; 60 ±2 °C; 82 ±2 °C) for the full duration of the exposure. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 and after the final exposure terminating on Day 90. The exposure water shall be changed at least weekly during the interval between the initial and final exposure and on at least 4 days during the final week of exposure.

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B.5 Mechanical plumbing devices

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B.5.6 Multiple time point protocol

When the normalized concentration of a contaminant exceeds, or is expected to exceed, its acceptable level when evaluated as a single time point exposure, determination of the contaminant leaching rate using a multiple time point exposure shall be considered. For the purpose of contaminant concentration evaluation, Day 1 shall be defined as the time point at which extractant water is collected for analysis under the single time point exposure protocol. Day 90 shall be defined as 90 d after this time point. When over time data are used, the Day 1 concentration for the contaminant of concern shall meet the Short Term Exposure Level and Day 90 concentration shall meet the Total Allowable Concentration/Single Product Allowable Concentration respectively. When extrapolation is used, the relationship between contaminant concentration and time shall be determined and plotted using a minimum of five data points.

> NOTE – When a multiple time point protocol is employed in the evaluation of a contaminant, consideration shall be given to the availability of appropriate toxicity data to define an acute exposure limit for the contaminant, as required in Annex A, Section A.5, Data requirements for evaluating short-term exposures. Consideration shall also be given to the leaching characteristics of the contaminant. Short Term Exposure Levels shall not exceed the Total Allowable Concentration for nonmetallic contaminants listed in NSF/ANSI 61, Annex D, Table D1 (Drinking water criteria for contaminants regulated by the USEPA and established by Health Canada). Multiple time point analysis shall not be used for lead or any other metal contaminant listed in Table D1.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be exposed at 23 ±2 °C with the except for instant hot water dispensers, in which case the manufacturer's specified thermostat setting shall be used. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 and after the final exposure terminating on Day 90. The exposure water shall be changed at least weekly during the interval between the initial and final exposure and on at least 4 days during the final week of exposure.

Reason: Revised per 2014 DWA-SC JC meeting discussion (December 4, 2014) to provide a similar option for performing full 90 days of exposure as contained in Section 4.