# NSF/ANSI Standard 61

## Revisions to Standard 61 Section 3

Drinking Water Additives Joint Committee

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## Presentation Outline

### Revisions to Standard 61 Section 3.2 and Table 3.1

- Clarifications to emphasize information requirements and formulation dependant analyte selection procedure
- Simplification of diluted surface area approach
- Setting deminimus level for ingredients in formulations
- Format and reorganization of test parameters and renamed test requests
- Added components to metals
- Added silicone, tetrafluoroethylene, quartz and polyvinylidene fluoride toTable 3.1
- Added test parameters to concrete and polyurethane
- Add requirement to use minimum size GC/MS library

## Clarifications to emphasize information requirements and formulation dependant analyte selection procedure CURRENT

**Current: 3.2 Information and formulation requirements**

The following information shall be reviewed to determine the appropriate analytical testing and to ensure that the potential health effects of products and materials are accurately and adequately identified:

– the **product section(s**) under which the product, component, or material is covered and the intended function or end use of the product or the material;
– for assembled products or components, a **list of all of components and materials** and their corresponding surface areas that come into direct contact with water;
– when appropriate, the **total volume of water** that the product can hold when filled to capacity;
– the **expected service life** of the product;
– the anticipated minimum, maximum, and average **volumes of water** that come into contact with the product, component, or material during a 24-h period;

## Clarifications to emphasize information requirements and formulation dependant analyte selection procedure CURRENT

**Current: 3.2 Information and formulation requirements**

- **complete formulation information** for each water contact material as applicable;
– the **composition of the formulation** (e. g., percent or parts by weight for each chemical in the formulation or reference to a standardized material specification);
– a **chemical abstract number (CAS no.), name, trade designation, and supplier** for each chemical present in the formulation and a Material Safety Data Sheet (MSDS), when available; and
– an indication as to whether the chemical is an ingredient, reactant, or processing aid.
– when available, a list of the known or suspected impurities within the product or material and the maximum percent or parts by weight of each impurity;
– when available, the solubility, hydrolysis products, and extraction rates of chemicals within the product or material; and

Clarifications to emphasize information requirements and formulation dependant analyte selection procedure
CURRENT

## 3.3.1 Formulation-dependent analysis selection

For all water contact materials, **the formulation information described in 3.2 shall be reviewed,** and formulation-dependent analytes shall be identified for each water contact material. The criteria for selection of a formulation-dependent analyte shall include, but not be limited to, the following:

– known or suspected toxicity of the substance or its byproduct(s);

– high water solubility of the substance;

– monomer(s) of polymeric ingredients;

– high probability of extraction of a substance or its byproduct(s) at toxicologically significant concentrations; and

– extraction or migration information for the substance provided by the manufacturer.

Clarifications to emphasize information requirements and formulation dependant analyte selection procedure
PROPOSED

- complete formulation information **(equal to 100.0%),** for each water contact material as applicable' including a chemical name, chemical abstract number (CAS no.), trade designation, and supplier for each chemical present in the formulation

- ***A material is defined as a combination of ingredients used to: manufacture (mold, extrude, stamp, cast, machine, mix etc.) a part or component used in the assembly of a device. To include but not be limited to plastics, elastomers, metallic components, media, lubricants, adhesives, process aid, preservatives, coatings and surface treatments.***

- **a complete formulation shall result in the identity by CAS# or chemical name each component of the formulation including but not limited to the activators, antioxidants, antimicrobials, co-solvents, fillers, initiators, peroxides, pigments, plasticizers, process aids, solvents, stabilizer, surfactants and terminators at the chemical name and CAS# level;**

## Clarifications to emphasize information requirements and formulation dependant analyte selection procedure PROPOSED

- **when the chemical composition of an ingredient or component cannot be determined based on the information submitted by the material supplier, the information shall be obtained by the certifier from the ingredient supplier prior to determining all formulation dependant analytes.**

  **For non-organic based materials, percent or parts by weight for each chemical in the formulation or reference to a national or international standardized material specification is acceptable for metallic materials (e.g. copper alloy specifications);**

## Simplification of diluted surface area approach

- Current: NOTE – The complete formulation information may be omitted for a component material if the generic material type is contained in Table 3.1 and its diluted surface area in the application is less than or equal to 0.001 or 0.0001 for static or flowing conditions respectively.
- Proposed: NOTE – The complete formulation information may be omitted for a component material if the generic material type is contained in Table 3.1 and it is used in a high flow device exclusively used at water treatment plants that will treat or pump a minimum of 100,000 gallons of water per day. High flow devices include pumps (high volume), chemical feeders, pressure gas injection system pumps, vacuum injection systems, disinfection generators (chlorine dioxide, hypochlorite, ozone and ultraviolet), aeration technologies, clarifiers, electrodialysis technologies, microfiltration technologies, mixers, reverse osmosis technologies, screens, strainers and ultrafiltration technologies.

## Setting deminimus level for ingredients in formulations

- Note: No testing is required for activators, antioxidants, antimicrobials, co-solvents, fillers, curing agents, initiators, peroxides, inorganic pigments, polymers, plasticizers, process aids, solvents, surfactants, stabilizer and terminators or their impurities, degradation products and hydrolysis products when present at less than 0.10 % of the formulation.

- No testing is required for antimicrobials or organic pigments or their impurities, degradation products and hydrolysis products when present at less than 0.010 % of the formulation.

## Added components to metals

- Current Metals: antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, selenium, and thallium.

- Proposed Metals: antimony, arsenic, barium, beryllium, cadmium, chromium (III and VI), copper, lead, mercury, selenium, thallium, nickel, zinc, bismuth.

Added polytetrafluoroethylene, quartz, silicone and tetrafluoroethylene toTable 3.1

- polytetrafluoroethylene
  - perfluoro octanoic acid, GC/MS, VOC
- polyvinylidene fluoride
  - GC/MS, VOC, vinylidene fluoride
- quartz
  - metals
- silicone
  - 2,4-dichlorobenzoic acid, GC/MS , VOC

Added test parameters to concrete and polyurethane

- Concrete testing parameters were changed to match the requirements for cements
- polyurethane (PUR) and polyurethane coatings: GC/MS1, VOCs, metals, OCE-3: 1,6,11-trioxacyclo pentadecane, OCE-4: 1,6,11,16-tetraoxacyclo-pentadecane, OCE-5: 1,6,11,16,21-pentaoxacyclo-pentadecane, OCE-6: 1,6,11,16,21,26-hexaoxacyclo-pentadecane, 1,4-butanediol and cyanurate hydrolysis products.

Add requirement to use minimum size GC/MS library to 473,000 compounds

- **B.7.4.2.1 General requirements for GC/MS analysis**–
- Current - If commercially available mass spectral libraries are used a minimum size of 100,000 compounds shall be required.

- Proposed - Commercially available *NIST-EPA-HIH (*163,000 unique spectra) *and Wiley* (310,000 unique spectra) mass spectral libraries with a total size of 473,000 unique spectra compounds shall be utilized.

## Action Requested

Ballot the proposed changes