NSF/ANSI/CAN Standard 60
Joint Committee Issue Papers from Blake Stark for 2019 Meeting
US EPA FIFRA Requirements (1 of 3)

• The US EPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is the U.S. Federal regulation that governs the sale, registration, distribution, and end use of pesticides.

• Objective is to ensure that use of a chemical (when applied as instructed) does not cause unreasonable risk to human health or the environment.

• FIFRA registration includes chemical label registration as well as other parameters such as product efficacy claim verification.

• Although the scopes of product evaluation (between FIFRA and Standard 60) do not overlap, many of the drinking water treatment chemicals are subject to FIFRA registration.
US EPA FIFRA Requirements (2 of 3)

• Drinking water treatment chemicals (under Standard 60) used as disinfectants, algicides, bactericides, and molluscicides are also subject to EPA FIFRA registration.

• The US EPA Office of Pesticides has requested a review by the Standard 60 Joint Committee, relative to FIFRA reference.

• Should NSF/ANSI/CAN Standard 60 be updated to include a normative reference to EPA FIFRA registration, which would establish FIFRA registration as prerequisite for Standard 60 compliance (for those chemicals with end use functions that are subject to FIFRA)?
Other Considerations:

- Standard 60 is used internationally, whereas FIFRA is a U.S. requirement.

- A FIFRA normative reference would add steps to the Standard 60 certification process (for chemicals that are subject to FIFRA) that do not relate directly to the current scope of Standard 60.
Product Security/Tamper Evident Packaging (Section 3.9 of Standard 60)

• 3.9.2.1 Bags and super sacks employ seals that are destroyed upon opening, or that make re-sealing unlikely.

• 3.9.2.2 Drums and small containers used for product shall be constructed and properly sealed to make opening or substitution obvious to the purchaser.

• 3.9.3 Bulk shipments (including large totes) shall employ:
  – 3.9.3.1 Tamper evident seals; or
  – 3.9.3.2 Chain of custody; or
  – 3.9.3.3 Alternative method of providing equivalent protection.
Tamper Evident Packaging (TEP) requirements for bulk chemical shipments

- Section 3.9.3 addresses “Security requirements for bulk shipments and large reusable containers (totes)”, whereby TEP compliance can be achieved by TE seals (3.9.3.1), chain-of-custody (3.9.3.2), or alternate method (3.9.3.3).

- 3.9.3.1 TEP compliance currently requires that TE seals are uniquely numbered and disclosed on documentation given to the end/user purchaser.

- Proposal to include “unique company identifier or logo” as an for labeling each tamper-evident seal for bulk shipments.

- Large totes (>1000L) are forms of bulk shipments.
Product Security Requirements
(NSF/ANSI/CAN 60 Section 3.9)
3.9.3 Security requirements for bulk shipments and large reusable containers (totes)

3.9.3.1 Tamper-evident seals.

Containers used for bulk shipments shall have tamper protection provided at all openings capable of loading or unloading chemicals. Vents shall have tamper protection provided, unless they are protected by construction that makes them incapable of receiving chemicals. Bulk containers may be sealed with a uniquely numbered, non-reusable tamper-evident seal, or a tamper-evident seal which contains a unique company identifier or logo, on each opening in the container. If tamper-evident seals are used, the seals shall remain in place until removed at the point of delivery. Seal numbers, or the unique company identifier or logo, shall be recorded and disclosed on shipping documents provided to the purchaser at the time of delivery and kept available for review by the certification body. If tamper-evident seals are used in milk run deliveries, a new seal shall be applied after each partial off-loading and noted in the consignment records after each partial delivery.
Required Labeling for Hypochlorite Bleach (1):

AWWA B300 (Hypochlorites) includes Recommendations for the Handling and Storage of Hypochlorite solutions, to control decomposition of bleach and limit formation of perchlorate and chlorate over time.

B300 recommendations include dilution of bleach in storage, reducing storage temperature, pH 11-13 range, control of metal ions, and bleach age limitation. In addition:

- Standard 60, Section 6.3.3 requires the manufacturing date and (if applicable) the repackaging date to be included on documentation supplied with any shipment of a bleach product.

- This provides key information to end users of bleach.
Required Labeling for Hypochlorite Bleach (2):

- At present, Standard 60 Section 6.3.3 also requires a reference to the AWWA B300 recommendations on all documentation supplied with bleach products which references Standard 60.

- Bills of lading, Certificates of Analysis, Safety Data Sheets, and other product data sheets are common documents used to convey reference to Standard 60 compliance of the bleach.

- As B300 is primarily utilized by water utilities (bleach end users), it is proposed that the reference to B300 be changed from a Standard 60 literature requirement to an informational reference.

- This change would help clarify the requirements for hypochlorite product vendors versus guidelines for water utilities.
6.3.3 Required labeling for sodium hypochlorite products (production dates and repackaging dates)

6.3.3.1 Manufacturers use instructions

Because aged solutions of sodium hypochlorite may contain elevated levels of chlorate and perchlorate, Certification Listings and the manufacturer’s use instructions, or documentation supplied with the product that reference this Standard, shall reference the recommended handling and storage practices contained in AWWA B300-Hypochlorites.

6.3.3.2 Production dates and repackaging dates.

For sodium hypochlorite products, the manufacturing date, and if applicable the repackaging date, for the product shall be included on the documentation supplied with the product. This alerts the end user of the bleach product age, as aged solutions of sodium hypochlorite may contain elevated levels of chlorate and perchlorate. Reference the AWWA B300 Appendix Recommendations for the Handling and Storage of Hypochlorite solutions for additional information.
NSF/ANSI Standard 223
Annual Audit/Test Frequency requirements in Standard 60

1.) Historically, audit and test frequencies have been specified in certifiers’ policies, and not Standard itself.

2.) A California CCR (March, 2008) requires annual recertification of chemicals used to treat public drinking water.

3.) In addition, in 2009, minimum annual audit and annual test frequencies added in 60 Section 3.8 (conformity assessment section of Standard 60).
1.) NSF/ANSI 223 (2012) for Standard 60 certifiers.

2.) Includes all compliance monitoring elements of Standard 60 Section 3.8, with some additional detail.

3.) Intended as supplemental criteria to ISO 17065 (could be audited criteria by accreditation bodies).
Standard 223 Audit Scope

• The scope of the formulation audit is open to multiple interpretations. NSF has observed auditing the formulation as:
  – Beginning reaction mixture
  – End reaction product
  – Intermediary steps in production
  – Repackage of an intermediary step

5.1 Facility audit requirements

Facility audits shall include, but not be limited to the:

- on-site review of a facility’s Quality Management or Product Stewardship Program;
- visual inspection of production, process and equipment
- collection of samples pursuant to 4;
- validation of formulations from ingredient entry to the facility to final product;
- validation of approved suppliers from ingredient purchase to final product;
- review of analytical procedures and methods (if applicable);
Current required monitoring audit frequencies in 223 (Section 5.2: Facility audits during surveillance):

a.) Minimum audit frequency=1 per year (Section 5.2.1).

b.) Quarterly audits (for 3-year minimum) required for those facilities with significant Standard 60-related deficiencies (Section 5.2.2). Examples are given in the 223 annex.
c.) Twice/year minimum audit frequency for facilities in countries scoring <50.0 on TI CPI (Section 5.2.3):

Compliant plants that are registered to ISO 9001, ISO 14001, ACC-RCMS, or NACD Responsible Distribution programs may remain on 1/year freq.

Audit frequency for other plants may be reduced to 1/year upon 3 years of successful compliance history.
Transparency International Corruption Perceptions Index (TI CPI)

TI Corruption Perception Index (CPI) is constructed to aid international businesses in understanding the conditions they will face in the different countries in which they do business.

The index has been constructed since 1995 at the University of Passau. Process sources 16 independent surveys of countries.

A score of 50 or lower on the CPI indicates that corruption is a significant factor in doing business in that country, where oversight may be relaxed, and where it must be maintained.

TI CPI is updated on an annual basis and is maintained at: https://www.transparency.org/cpi2018
Standard 223 Audit Frequencies

d.) Distributors of noncertified products (where source chemical originates from a country that is <50 TI CPI) have twice/year minimum audit frequency (Sec 5.2.4).

Inspection frequency can be reduced to 1/year if:

- Supplier facility also receives audits to Standard 60 by an accredited certification body.

or

- Distributor has an alternate method (acceptable to certification body) which provides a mechanism to verify that no changes have been made to the supplied product and continues to be provided identical product.

Proposed change is to remove the words “blend” and “blender” from the scope of 5.2.4 (scope clarification).
5.2 Facility audits during surveillance

5.2.4 Facilities that blend, dilute, dissolve, re-label, repackage, or transfer non-certified products that are supplied by a facility that is located in a country with a TI CPI <50 shall have an audit frequency of twice per calendar year. The certification body has the option to reduce the inspection frequency to once every 12 months if the supplying facility meets one of the following criteria:

a.) The supplier to the facility also receives audits from a certification body that is accredited by an International Accreditation Forum signatory, according to the requirements of this Standard.

b.) The blender, diluter/dissolver, re-labeler, repackager, or transfer facility has an alternate method that is acceptable to the certification body, which provides a mechanism to verify that no changes have been made to the supplied product and continues to be provided identical product.
NSF/ANSI Standard 223

1.) Blends receive technical review, whereby each ingredient, supplier, and % level are disclosed to the product certifier in confidence for product evaluation.

2.) A blend may include any number of ingredients/constituents, but each must be identified in the confidential documentation provided to the certifier.

3.) Audits of the blending facility are conducted, at a frequency specified in Section 5.2.3.

4.) TI CPI score would apply to the blending location site (as opposed to each ingredient production site).