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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. The changes from Draft 1 are shown with strikeout and new text is bold and underlined.]

NSF/ANSI Standard for Drinking Water Additives —

Drinking water treatment chemicals – Health effects

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3 General Requirements

3.9 Product Security

Products certified under this standard shall be protected to maintain the quality required by this standard. Reasonable, effective measures shall be made to control access to products at all points of manufacturing, blending, diluting, packaging, repackaging, storage, shipping and handling and to provide the manufacturer and the purchasing user of product with the ability to detect tampering.

- **3.9.1 Definition of tamper-evident packaging** Packaging having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.
- **3.9.2 Security requirements for packaged products** Packaged product shall be stored, shipped, and delivered in tamper-evident packaging as defined in Section 3.9.1. Properly constructed, labeled, and sealed multi-wall containers such as bags and fiber drums constitute two forms of acceptable tamper-evident packaging.
- **3.9.2.1 Bags and super sacks** Packages for product shipped without reusable openings shall be constructed and properly sealed to make opening or substitution obvious to the purchaser. The packages

shall employ unique printed markings (e.g., <u>a pattern</u>, manufacturer's name, trademark, logo, etc.) so that the packaging cannot be readily duplicated. <u>. The packages shall display the company's name, and employ seals that are destroyed upon opening, or that make resealing unlikely (e.g. serialized tags), or other equivalent tamper evident measures so that once opened, the tamper-evident feature of the seal the packaging cannot be restored nor readily duplicated.</u>

- 3.9.2.2 Drums and small containers Drums and small containers used for product shall be constructed and properly sealed to make opening or substitution obvious to the purchaser. Openings in the containers shall be sealed with tamper-evident seals with unique printed markings (e.g., a pattern, manufacturer's name, trademark, logo, etc.) so that once opened, the tamper-evident feature of the seal cannot be restored nor readily duplicated. and the packages shall display the company's name. Packages shall employ seals that are destroyed upon opening, or that make resealing unlikely (e.g. ultrasonic seals), or other equivalent tamper evident measures so that once opened, the tamper-evident feature of the seal cannot be restored nor readily duplicated
- 3.9.3 Security requirements for bulk shipments Bulk shipping containers 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 quantities of product shall be secured during storage and distribution by employing one or more of the following security measures. These requirements are applicable to a single load delivered to one or multiple locations.
- **3.9.3.1 Tamper-evident seals** Bulk shipping containers may be sealed with a uniquely numbered, non-reusable, tamper-evident seal on each opening in the shipping container. If tamper-evident seals are used, the seals shall remain in place until removed at the point of delivery. Seal numbers 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.
- **3.9.3.2 Chain of custody** A continuous chain of custody may be used to document secure distribution of product. Maintaining a continuous chain of custody requires that the product is under the control of responsible individuals, that direct access to the product is restricted to those individuals, and that the shipping container is sealed or locked at all times during shipping. If chain of custody is used, a copy of a completed, signed chain of custody form showing continuous and secure custody between the certification holder and purchaser shall be provided to the purchaser at the time of delivery and kept available for review by the certification body.
- 3.9.3.3 Alternative method An alternative method or methods agreed upon by the certification holder and the purchaser may be used for bulk shipments if the alternative method provides protection against

tampering that is equivalent to this standard. If alternative methods are used, the agreement with the purchaser and description of the alternative methods shall be in written form and kept available for review by the certification body.

3.9.4 Tamper-evident integrity – The tamper-evident features employed on all final product packaging, seals, and bulk shipping containers shall be designed to remain intact when handled in a reasonable manner during manufacture, storage, shipment and delivery to the purchaser.

Notes to reviewers:

- 1. The DWA Task Group on Conformity Assessment (formerly Annual Recertification Task Group) developed this proposed section for consideration by the Joint Committee on Drinking Water Additives to address issues related to product security and potential tampering.
- 2. The proposed section is based on tamper-evident language from AWWA, 2009 and the Code of Federal Regulations 21 CFR 211.132, *Tamper-Evident Packaging Requirements for Over-the-Counter (OTC) Human Drug Products.* Both of these source documents are posted on the NSF workspace for convenience.