**Conference for Food Protection**

**2012 Issue Form**

**Internal Number: 034**

**Issue: 2012 I-026**

**Title:**

Hand Antiseptics

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline and deleted language shown with strike-through):

**2-301.16 Hand Antiseptics.**

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

(1) Comply with one of the following:

(a) Be an approved drug that is listed in the FDA publication **Approved Drug Products with Therapeutic Equivalence Evaluations** as an approved drug based on safety and effectiveness; Pf or

(b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, Pf and

(2) Comply with one of the following:

(a) Have components that are exempted from the requirement of being listed in federal food additive regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles;Pf or

(b) Be listed in the following sections and used up to the maximum allowable concentration permitted by that regulation:

(i) 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers Pf or,

(ii) 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food, Pf or

(c) Have components that have been appropriately cleared for use as hand sanitizers with incidental food contact through GRAS notifications/ affirmations or a Food Contact Notification (FCN) with FDA, and,

(3) Be applied only to hands that are cleaned as specified under § 2-301.12. Pf

(B) If a hand antiseptic does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:

1. (1) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; Pf or
2. (2) Limited to situations that involve no direct contact with food by the bare hands. Pf

(C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine. Pf

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.