

**Conference for Food Protection
2012 Issue Form**

**Internal Number: 034
Issue: 2012 I-026**

Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

All information above the line is for conference use only.

Title:

Hand Antiseptics

Issue you would like the Conference to consider:

An update to the language in the 2009 FDA Food Code, Section 2-301.16 Hand Antiseptics is needed to account for the regulatory procedures that can also be used to make a hand sanitizer compliant with the Food Code. Due to the absence of any specific regulation in FDA's 21 Code of Federal Regulations (CFR) for hand antiseptics and indirect food contact, the Food Code serves as the sole guidance for the use of hand antiseptics in retail food facilities. These procedures are already referenced in Annex 3 of the Food Code (Chapter 2- 301.16 Hand Antiseptics) and therefore updating the language in Chapter 2 would help avoid any confusion and misunderstandings by Inspectors in the field.

Public Health Significance:

Chemicals may be poisonous or toxic if not used properly and in accordance with FDA regulations. The lack of clear and explicit guidance surrounding the use of hand antiseptics in food facilities poses a risk and could contribute to the improper use of chemicals that may subsequently cause public health issues such as the adulteration of food, or potentially acute and chronic effects to both the consumer and the employee of the food facility.

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) ~~Comply with and 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 ~~as regulated for use as a food additive with conditions of safe use,~~^{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} ~~and~~ 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 ~~or a hand antiseptic solution used as a hand dip~~ 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}

Submitter Information:

Name: Dan Dahlman

Organization: Ecolab

Address: 370 Wabasha St N

City/State/Zip: St. Paul, MN 55102

Telephone: 651-225-3297

Fax:

651-225-3122

E-mail: dan.dahlman@ecolab.com

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.