

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 III-005

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

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Issue History:

This is a brand new Issue.

Title:

HHC 3 - Definition for "Antiseptic Hand Rub"

Issue you would like the Conference to consider:

The CFP Hand Hygiene Committee (HHC) was charged to ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.

The Hand Antiseptic section of the 2013 FDA Food Code; 2-301.16 (A) states "A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall..."

The HHC identified specific areas in the Food Code where amendments and definitions can provide further clarity to regulators and retail food stakeholders. The HHC identified that defining "Antiseptic Hand Rub" was necessary to eliminate ambiguity between an "antiseptic hand rub" and the other items listed in the section; hand antiseptic solutions used as hand dips and hand antiseptic soaps.

Prevention of cross-contamination is essential in foodservice, and explicitness in the Food Code can help reduce potential risk.

Public Health Significance:

The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food, or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses.

Regulators and retail food service stakeholders reference the Food Code for guidance and clarity on appropriate approaches for removal or reduction of potential pathogens from hands. Therefore, the Food Code should be inclusive of clarifying language to assure the reader understands intent.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (using underlining for language additions):

1. Add a definition for "ANTISEPTIC HAND RUB."

"ANTISEPTIC HAND RUB" An antiseptic hand hygiene product applied to the hands and rubbed until dry, used to reduce the transient microorganisms on the hands.

2. Add reference to ANTISEPTIC HAND RUB to Section 2-301.16, Hand Antiseptics.

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, ANTISEPTIC HAND RUB, 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 be listed in:

(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

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

(B) If a hand antiseptic, ANTISEPTIC HAND RUB, 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) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; ^{Pf} or

(2) Limited to situations that involve no direct contact with food by the bare hands. ^{Pf}

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