

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-024

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:

Alignment of the Food Code with the FDA Juice HACCP Retail Definition

Issue you would like the Conference to consider:

The sale of packaged, raw, untreated, or cold pressed juices is allowed under the 2013 FDA Food Code by a retail food establishment. However, the FDA Food Code does not address where a retail food establishment may sell untreated packaged juice. The FDA Juice Hazard Analysis and Critical Control Point (HACCP) regulation and associated guidance does have specific conditions under which packaged untreated juice may be sold under the retail exemption, specifically that any offsite sales must be conducted at a location owned by the retail establishment. Retail regulators operating under FDA Food Code are being challenged by food establishments that want to package untreated juice and then sell it "offsite" via a cooperative arrangement with a health club, health food store or a vending unit as an extension of the retail establishment. A clear link needs to be established in the Food Code & 21 Code of Federal Regulations (CFR) 120 Juice HACCP sections regarding retail sales.

Public Health Significance:

Providing a link between the FDA Food Code and 21 CFR part 120 Juice HACCP requirements for the sale of packaged juice allows for regulators to apply the same criteria when evaluating the safety of a proposed packaged juice process in regards to the retail exemption. Industry benefits from the uniform application of the retail exemption for treated juice by not having differing sets of standards from jurisdiction to jurisdiction. The need to treat packaged juice and the public health risk associated with consumption of untreated packaged juice has been cited in many studies.

Annex 3 of the FDA Food Code in Section 3-801.11 states: There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as *Cryptosporidium*, Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Vibrio cholera*.

The Summary in *the Federal Register / Vol. 66, No. 13 / Friday, January 19, 2001 / Rules and Regulations for Juice* states the need for the treatment of packaged juice.

"The Food and Drug Administration (FDA or the agency) is adopting final regulations to ensure the safe and sanitary processing of fruit and vegetable juices. The regulations mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of these foods. HACCP is a preventive system of hazard control. FDA is taking this action because there have been a number of food hazards associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products are safe."

In a September 22, 2005 *Guidance for Industry Letter to State Regulatory Agencies and Firms That Produce Treated (but not Pasteurized) and Untreated Juice and Cider*, the FDA stated the concern regarding continuing outbreaks of foodborne illness associated with the consumption of treated (but not pasteurized) and untreated juice and cider. The letter reminds regulators and industry of actions that the FDA recommends processors take to enhance the safety of these products with the following reason:

"Recent illness outbreaks due to treated (but not pasteurized) and untreated apple cider occurred in Ohio in 2003, and in New York state in 2004. In addition, a multi-state illness outbreak associated with treated (but not pasteurized) orange juice occurred this year. These outbreaks highlight the need for processors to ensure that they are taking all appropriate steps to comply with applicable food safety requirements."

References:

Federal Register CFR 21 Part 120:

<https://www.federalregister.gov/articles/2001/01/19/01-1291/hazard-analysis-and-critical-control-point-haccp-procedures-for-the-safe-and-sanitary-processing-and>

Guidance for Industry Letter to State Regulatory Agencies and Firms:

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm072508.htm>

Hazard Analysis Critical Control Point (HACCP), National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Recommendations:

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm073540.htm>

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the 2013 FDA Food Code be amended to include the following (new language is in underline format):

3-404.11 Treating Juice.

JUICE PACKAGED in a FOOD ESTABLISHMENT shall be:

(A) Treated under a HACCP PLAN as specified in ¶¶ 8-201.14(B) -(E) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; ^P or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance: ^{Pf}

(1) As specified under § 3-602.11, ^{Pf} and

(2) As specified in 21 CFR 101.17(g) Food labeling, warning, notice, and safe handling statements, JUICES that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and person with weakened immune systems." ^{Pf}

(C) And only at locations that are considered to be retail by the definition of a retail establishment as specified in 21 CFR 120.3 (l) and qualify for the retail exemption as specified in 21 CFR 120.3 (j) (2) (ii).

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Supporting Attachments:

- "CFR 120.3"

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.