**Conference for Food Protection**
**2016 Issue Form**

**Issue: 2016 I-024**

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

*All information above the line is for conference use only.*

**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-haacp-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).

**Submitter Information:**


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| Name: | Sandra D. Craig |
| Organization: | SC Dept. of Health and Environmental Control |
| Address: | 2600 Bull Street |
| City/State/Zip: | Columbia, SC 29201 |
| Telephone: | 803-896-0614 |
| E-mail: | craigsd@dhec.sc.gov |


**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.*

**§120.3 Definitions.**

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, §101.9(j)(18)(vi) of this chapter, and parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.
(b) *Control* means to prevent, eliminate, or reduce.
(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.
(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.
(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with §120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.
(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.
(i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.
(j)
(1) *Processing* means activities that are directly related to the production of juice products.
(2) For purposes of this part, processing does not include:
(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and
(ii) The operation of a retail establishment.
(k) *Processor* means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.
(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. “Provides” includes storing, preparing, packaging, serving, and vending.
(m) *Shall* is used to state mandatory requirements.
(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.
(o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.
(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.
(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

[66 FR 6197, Jan. 19, 2001, as amended at 80 FR 56167, Sept. 17, 2015]