



STATE OF WASHINGTON  
DEPARTMENT OF AGRICULTURE  
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Dockets Management Branch (HFA - 305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Comments on the Juice HACCP Hazards and Controls Guidance - First Edition

To Whom It May Concern:

The Washington State Department of Agriculture is pleased to submit our comments on the referenced guidance document. We appreciate the opportunity to offer suggestions to improve this document and make it useful for both industry and state food safety officers.

If you have any questions, please contact me at 360-902-1905.

Sincerely,

Claudia G. Coles  
Food Safety Program Manager  
Washington State Department of Agriculture

cc: file (Juice HACCP)

02D-0333

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**Washington State Department of Agriculture Comments  
on the Juice HACCP Hazards and Controls Guidance - First Edition (9/12/02)**

**General Comments**

1. Corporation size should not be the deciding factor of whether a facility is required to follow the HACCP regulations. The deciding factor should be based on product volume.
2. The guide is too vague. There is a need for a grid showing specific hazards associated with specific fruits (e.g., apples, pears, oranges) and specific processes (e.g., fresh squeezed, concentrating, juice from concentrate).
3. A chart showing time/temperature requirements for achieving a 5-log reduction by different methods is needed. It should cover the general hazards listed in Footnote #9 on the draft guide, with the time/temp requirements shown for the each hazard to control. The processor would then determine the pertinent organism to be controlled for the specific product being produced. There is a need for more baseline data.
4. Any other data regarding the 5-log reduction (such as UV, high pressure, etc.) should also be published in the Hazard Guide. This would provide a single recognized source for information that would be helpful to regulators and industry. Food Safety Officers (FSOs) want a chart that would have a minimum baseline. The FSO needs more criteria before they could approve a process or approve equipment. FSOs will need training on UV equipment and process.

**II. Terms and Definitions (p. 6 - 9)**

Culled definition needs clarification regarding terminology i.e. processing vs. fresh pack. Definition for field run and or fresh pack sorts out. Need definition for Single Strength Juice, Juice or reconstituted juice. Exemption language needs clarification (i.e., shelf stable product what is a single thermal processing step and a thermal concentration process? Define these terms. Reconstituted juice in a multiple stage process is this exempted.) What is a "Single thermal Process" and what is FDA's intent for including this?

**III. Overview of the Juice HACCP Regulation**

**A. Compliance required for all juice processors**

**3.0 Juice Importers (p. 9)** – This should be the responsibility of the FDA. State inspectors shall determine if the correct documentation is available upon request during an inspection.

**C. Basic Steps of the Hazard Analysis**

**1.23 Allergens and Food Intolerance Substances Added to Juice as Ingredients (p. 15)** - Allergens added is it still considered Juice? IE lactose? How can that be considered 100% juice? **(p. 16)** - Clarify the possibility of translocation of lead into root crops vs. translocation of lead into tree fruits. Is there an issue? What is the threshold for additives and preservatives (i.e., Sulfites)? When does the product change from 100% juice to a beverage?

#### **D. Exemptions and items not subject to the regulation**

**1.0 Retail Business (p. 11)** -- Clarification must be made regarding who is a "retailer" and who is a "wholesaler". For example, if Costco processing its juice at a central kitchen for distribution entirely within the Costco retail chain, is this considered "retail" or "wholesale"?

#### **IV. Juice Hazard Analysis**

##### **C. Basic Steps of the Hazard Analysis**

**1.22 Undeclared food allergens in juice due to cross contact from shared processing equipment (p. 15 - 2<sup>nd</sup> paragraph after the allergen list)** -- section IV. C. 3.2. is cited for discussion about CCP vs. SSOP, however section IV. C. 3.3 applies more to the discussion about when FDA recommends use of a CCP vs. an SSOP for contaminants from food contact surfaces than the existing section. Recommend changing 3.2 to 3.3.

**3.3 Hazards related to facility sanitation (p. 20 - 2<sup>nd</sup> paragraph)** -- What would make a control measure 'necessary' or 'not necessary'? Clarification is needed.

#### **V. Control Measures**

##### **C. Control Measures for Biological Hazards**

**1.2 Shelf life and moderate temperature abuse conditions (p. 25)** --What are you getting at? Site better example of excessive temperature abuse. Product internal temperature (maybe)? What is 'temperature abuse'? Give FSOs a temperature and time, be specific.

##### **2.0 Location of juice extraction, processing, and packaging (p. 26)**

Will processors need to show a before and after sample? What if the counts on the incoming product from another processor are so low that achieving a 5-log reduction is not possible. ( i.e. Concentrate from a firm who uses an HTST is made into juice by basically adding water).

Regarding exemptions -- it looks like if you use High Brix concentration when blending at another facility need a HACCP plan but don't need heat step for the 5-log reduction, as by the guide it has already been satisfied. What about cross contamination at 2<sup>nd</sup> facility as Listeria is environmental? Is a concentrate necessarily a shelf stable product? Is there a fixed Brix level that constitutes shelf stability, lets say apple concentrate. You may extract juice from fruit in one location. How does the juice plant guarantee that the untreated juice at the 2<sup>nd</sup> facility would be processed for a 5 log reduction as when it leaves their facility it is no longer their process. Is labeling / bill of lading or other documentation adequate?

Regarding paragraph 1 and 4 -- want clarification of 5-log pathogen reduction and the exemptions, they are too vague and confusing. Examples would be a good. Need better clarification and definition of exemptions.

Clarification of concentrate blends of several different blends of juices that had already been through JH once. Does this mean that concentrates even through you are adding water, are not required for additional 5 log reduction but must have a system plan in place when at a final packaging facility. Another interpretation is that it must go through juice HACCP again as, all ingredients were not heated prior to final packaging. Is this based on the bulk transportation documentation requirements? **No 120.24** Process Controls not included Hazard analysis and CCP systems dated 1-18-01.

**4.1 Heat treated shelf stable juices and concentrates (p. 28)** -- Processing what about batch pasteurization currently all reference has been given to HTST or HHST and aseptic processing. What about time and temp for batch pasteurizing, or is the 160 degrees for 6 seconds adequate for all equipment for crypto. Need more guidance and baselines. FSOs want reference materials. What is "concentration process"? What does FDA mean? How does brix equate to water activity?

**4.4 Other non-thermal treatments for juice (p. 29)** --Which chemicals are approved by FDA and at which levels?

**5.1 Process authority (p. 30)** --Who does industry reference as a process authority? How do we as regulators determine if they are credible?

**5.31 Pasteurizing equipment (p. 31)** -- Who is performing the testing and sealing of the timing pump for flow rate for verification? How often does this equipment needed to be tested is semi annually necessary what about yearly. Are these pasteurizer tests completed by the regulatory authority or industry consultants? Who is liable if the regulatory accepts the plan including the pasteurizing unit and an equipment failure occurs? Is there any scientific data available for a temperature only kill for cryptosporidium? Instead of time and temperature? Process authority - who does industry reference as a process authority? How do we as regulators determine if they are credible?

#### **D. Control Measures for Chemical Hazards**

**1.1 Hazard Analysis (p. 35)** -- What is the maximum period of time that apples may be stored, depends on condition of fruit and type of storage any guide lines? When is a patulin study going to be included in the guide? FDA has been testing levels for years. Is Patulin required to be a CCP if SSOPs are adequate then why not a control point, i.e. through supplier guarantee or small cider operation that has total control of fruit harvest and processing. Warehouses need clarification as to exemption.

**E. Control Measures for Physical Hazards (p. 38)** -- The guide has no specific requirements. It is based on the results of the Hazard Analysis as to the control of physical hazards such as glass +/-or metal.

## **V.I. Preparing for HACCP**

### **B. HACCP Training and HACCP Resource Materials**

**1.0 Juice HACCP Alliance Training Curriculum (p. 43)** -- "Other curricula that are equivalent in coverage..." could the inspector determine whether the curricula is equivalent or would FDA need to make that determination? What is considered equivalent curricula? Is training required? Will FDA conduct training for states and industry? How will FDA provide training assistance and funding with state counterparts? How will FDA provide training to small processors?

**V.I.I. – Example Documents (p. 43+)** -- Looks very similar to the fish format. Provide more detail in processing steps (such as times, temps, hand contact, etc). Table formatting should be fixed. Tables should be set as landscape documents.

#### **Table 4.**

**Hazard Analysis Summary Table (for Not-from-concentrate Pasteurized Orange Juice) (p. 55+)** - #1. Receiving/staging raw fruit & #11. Receipt of unpasteurized juice in tankers & column (5) What preventive measures... -- Pasteurization is listed as a preventative measure in steps #1 and #11, but it is not listed as a CCP in the pasteurization step (should be #13). It should be listed as a CCP to control pathogens. It is also listed as CCP 1 in the HACCP plan. Change formatting to landscape.

#### **Table 7.**

**Excerpts from Summary HACCP Plan (p. 63+)** - CCP 1 - Pasteurization - critical limits should state "a minimum of 160 deg. F". Corrective action does not address the cause on Table 7 -- Adjust pasteurizer to achieve critical limit. Change format to landscape.