



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Juice HACCP Hazards and Controls Guidance, First Edition, Sept. 12, 2002

Dear Sir or Madam:

The Florida Citrus Processors Association ("FCPA"), a voluntary trade association representing the citrus juice manufacturers of Florida since 1931, respectfully submits the following comments and suggestions on the draft "Guidance for Industry, Juice HACCP Hazards and Controls Guidance, First Edition, released for comments on September 12, 2002, and internally identified with Document Number 02D-0333. FCPA is incorporated in the State of Florida, and headquartered in Winter Haven, Florida.

FCPA supports the concept that Guidance is not a set of binding requirements. However, concern is generated by some of the details and specific language. Processors, new to the concept of applying the concepts of HACCP, may be led to assume FDA has predetermined certain aspects of processor's hazard analysis, and HACCP planning. This concern is particularly strong as it applies to auditors/inspectors, new to the principles of juice HACCP, who demonstrate a tendency to apply the Guidance language and directives as not guidance, but requirements.

Consequently, FCPA is disappointed in finding language such as (from Section IV. C. 1.31) "...we anticipate that you will conclude..." The use of such language suggests that FDA will make determinations of hazards that are "reasonably likely to occur", and thus deny the concept that the guidance "is not a substitute for a processor's performance of its own hazard analysis as required by FDA's regulations." FCPA believes that Guidance statements should consistently emphasize the concept that "it is the ultimate responsibility of the juice processor to identify all hazards that are reasonably likely to occur and all appropriate controls for such hazards."

FCPA respectfully submits the following for your consideration:

- **Physical Hazards (Glass and Metal)** In the discussion of glass and metal fragments as potential hazards, FCPA recommends that the language in sections IV.C.(1.31) "Glass Fragments" be changed to read "If you pack your juice in glass, your hazard analysis may conclude that glass fragments are a hazard that is reasonably likely to occur, and you will establish controls for glass fragments in your HACCP plan. If

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your hazard analysis does not conclude that glass fragments are a hazard reasonably likely to occur, you must be prepared to provide appropriate documentation to justify your conclusion.”

In section IV. C. (1.32) “Metal Fragments” FCPA recommends a similar change in the language to read “If your process includes such operations, your hazard analysis may conclude that metal fragments are a hazard that is reasonably likely to occur, and you will establish controls for metal fragments in your HACCP plan. If your hazard analysis does not conclude that metal fragments are a hazard reasonably likely to occur, you must be prepared to provide appropriate documentation to justify your conclusion.”

- **Controls for Pathogens and Allergens Arising from Food Contact Surfaces** The Guidance, in its several sections of Part IV and in its Examples, with respect to declaring and controlling allergens, has created confusion with respect to when a SSOP, and when a CCP, is the appropriate choice for achieving control of the potential hazard(s). It appears that the distinction relies on the availability of appropriate validation mechanisms. What the Guidance does not clearly explain is what validation mechanisms, and for which allergens, are acceptable to FDA. Further clarification within the Guidance is needed.
- **Allergens and Food Intolerance substances Added to Juice** In an associated section, Section IV. C. (1.23), the Guidance lists four ingredients in addition to the eight allergens listed in Section IV. C. (1.22). No justification for this list is offered. FCPA recommends that no such list of “...some ingredients...” be included; the ingredients that might appear on such a list is extensive and changes often. Guidance suggesting proper hazard analysis and appropriate controls, such as labels, is sufficient. FCPA recommends striking the list and stopping the paragraph with the change to read “...Controls to ensure that the proper labels are used should be part of your hazard analysis.”
- **Process Authority** – further clarification or examples of appropriate (by FDA considerations) Process Authorities with regard to specific processes, is needed in the Guidance. What qualifications for a Process Authority does FDA envisage?
- **Record Keeping and Electronic Records** Section III.B.4.0 – further clarity is needed from FDA on whether or not a record that is printed from an electronic source is considered an “electronic record”
- **Exemptions and Items not Subject to the Regulation** Section III.D.1.0 – further comment is needed from FDA on defining retail vs. wholesale as it applies to a retail establishment unknowingly providing juice to an entity that resells the juice, thus creating a potential wholesaler out of the first entity.

Miscellaneous Recommendations

- In the Hazard Analysis examples for both fresh orange juice and NFC pasteurized orange juice, the phrase “locally grown” in describing the Incoming Materials should be deleted; the phrase is undefined and unnecessary.
- In the fresh juice model, step 13, the Metal Detector, under column (4), the detector is described as “eliminating” metal. The detector detects metal; it does not eliminate.
- In the Hazard Analysis example for NFC Pasteurized Orange Juice, under the Processing Steps, the step described as “Pulp is removed from the extracted juice by finishers and pumped to” needs to be changed to read “.....by finishers and the juice is pumped to.....”
- In the Table 4. Hazard Analysis Summary ...NFC Pasteurized Orange Juice, step 13 - Pasteurizer ---- no biological hazard is identified, and the step is not identified as a CCP. Column 2 should identify *Salmonella* as a Biological hazard, and the step should be an identified CCP under column 6. The associated table 7, “Excerpts from Summary HACCP plan” appears to be correct.
- Several of the columns within the pages describing the HACCP plans, summaries, etc., need to be formatted to display words completely, or properly hyphenated.

FCPA thanks the FDA in advance for your careful consideration of our comments and suggestions. If you find that we may be of further assistance on this matter, please do not hesitate to contact me, or Dr. Dan King, Director of Technical Services, FCPA.

Sincerely,



Lisa Young Rath
Executive Vice-President
Florida Citrus Processors Association