

**American Fresh Juice Council  
457 Cardinal Oaks Ct.  
Lake Mary FL 32746**

November 8, 2002

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

Re Guidance for Industry, Juice HACCP  
Hazards and Controls Guidance, First Edition

To Whom It May Concern:

The American Fresh Juice Council (AFJC) appreciates the opportunity to comment on the first edition of the FDA's Guidance for Industry – Juice HACCP. The AFJC represents the interests of small-scale fresh and pasteurized citrus juice producers in the state of Florida.

Section V, part E addresses control measures for physical hazards. Part 1.2 of this section specifically addresses the occurrence of metal fragments in juices. Although a number of extraction technologies are employed within small-scale citrus juice operations, most producers utilize pinpoint or implorer style extractors. The AFJC is unaware of metal fragments ever finding their way into citrus juice produced with pinpoint or other extractor types. Several inquiries were made, and the AFJC has been unable to find information on any such occurrence. One manufacturer (pinpoint type), FMC, has verified that metal fragments have never been introduced into citrus juice in any of their worldwide machine installations. It appears that this is a non-issue and should be omitted from the Guidance Document. Producers are doing their due diligence in conducting thorough hazard analyses, but should not be forced to address contrived circumstances or add unnecessary CCP's..

Section V, part C (5.1) addresses the role of a process authority. This section does not clearly explain the required credentials of a process authority. The term "process authority" is new to many producers, and there is confusion whether state food safety inspectors, consultants trained under the Juice Alliance curriculum, etc., may be considered process authorities.

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Section V, part C (3.1) addresses "requirements to use tree-picked, culled fruit." This section requires that producers obtain a written guarantee from their supplier for each fruit shipment stating that only tree-picked fruit was supplied. There should be a provision in the guidance document for juice producers who grow and harvest their own

fruit. It is not reasonable to require that a grower provide a guarantee to himself. Additionally, the AFJC believes that it is unnecessary to require the establishment of a CCP and critical limit at the receiving step. First, mandating CCP's and critical limits runs contrary to the purpose and function of HACCP plan development and conducting a hazard analysis. The hazard analysis process will determine within each operation whether a CCP and critical limit are warranted at the receiving step. Second, many small scale citrus juice producers have one receiving line. This single line, supplies fruit to the fresh fruit packing line in addition to the juice operation. For these producers, the culls that precede the sanitation step and immediately prior to extraction are more important. To require a CCP and critical limit at receiving would be unnecessary and burdensome.

Section IV, part C (3.1) covers potential hazards that are "reasonably likely to occur." It is the opinion of the AFJC that this part (3.1) requires more consideration and modification. It is nonsensical to *tell* producers that if a "potential" hazard has a severe, acute public health impact, that the hazard not only presents a "significant risk", that it presents this risk *even* if the hazard is "extremely low in occurrence". Furthermore, the Guidance Document states that such a hazard is to be automatically considered "reasonably likely to occur". Surely, there would be no foreseeable end to "what-if" scenarios that could be enveloped into this loosely defined requirement. This places an extraordinary burden on the producer and also runs contrary to the concept, function and development of a HACCP plan.

Section II, terms and conditions, provides a new and very confusing definition to "culled". This definition still makes reference to a USDA grade standard (USDA Choice or higher) that does not exist. The note below this definition does mention that FDA is aware that this USDA standard is not in existence and that FDA will consider tree-picked, and undamaged citrus fruit to meet this definition of "culled" for purposes of compliance with the juice HACCP regulation. Although the clarification provided within this section is appreciated; the AFJC once again requests that FDA eliminate any reference to this USDA standard. It is confusing and unnecessary. The AFJC respectfully suggests that a simple reference to "the elimination of unwholesome damaged or decayed fruit" will suffice.

Finally, section IV, part C (1.23) addresses "Allergens and Food Intolerance Substances added to juice as ingredients." It is the opinion of the AFJC, that FDA strike part 1.23. As is indicted in part 1.23, allergens and intolerance substances are covered in applicable labeling regulations 21 CFR Part 101). The AFJC does not see a need to cover these substances in a HACCP plan. The definition of a food hazard reads "any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control". Food allergens listed in (1.22) could certainly be a hazard, if not controlled and/or declared. However, items listed in 1.23 (2-5) can be adequately addressed through labeling regulations.

Respectfully submitted,



J. Peter Chaires  
President