



**November 11, 2002**

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

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

Dear Sir or Madam:

National Juice Products Association ("NJPA") appreciates the opportunity to comment on the draft Juice HACCP Hazards and Controls Guidance, First Edition, published September 12, 2002. NJPA is a trade association of juice and juice beverage processors incorporated in the State of Florida with its headquarters located in Tampa, Florida. Regular members of the association consist of 58 processor companies located throughout the United States, Canada, Europe, and South and Central America. Its regular members include major packers and distributors of a wide variety of fruit and vegetable juices, juice beverages and drinks. NJPA represents a significant majority of the juice and juice beverage processors in the United States.

As a general comment, NJPA members appreciate the enormous effort and wealth of information contained in the guidance document. However, we are somewhat concerned that the detail of this guidance document suggests that, despite disclaimers, FDA intends to control juice processors in their conduct of hazard analyses and evaluations of their processing operations using HACCP principles. The juice HACCP rule (21 CFR Part 120) provides that the processor is responsible for the performance of its own hazard analyses. We anticipate that this underlying premise will not be lost on enforcement and inspection personnel, who might be inclined to audit processing operations against the detailed and specific guidance contained in this document.

Having made this general observation, the following are areas in the document in which NJPA members recommend modification:

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**Physical Hazards (Glass and Metal) (Part IV.C.1.31 and 1.32)** - The guidance states that a processor that packs in glass will conclude that glass fragments in juice are hazards that are reasonably likely to occur. The same suggestion is made for metal fragments. NJPA believes it is

important for the guidance document to accommodate determinations for processing operations where glass and metal fragments are not hazards reasonably likely to occur. Prerequisite programs (to include but not limited to filters, screens, glass breakage policies, equipment inspections, monitoring verification, validation and consumer comment reviews)) can establish that glass and metal hazards are *not* reasonably likely to occur. Also, certain extraction technologies (other than pin point) use plastic components so metal fragments from that source would not be reasonably likely to occur. When such determinations can be documented and justified, the guidance should be broad enough to recognize these determinations.

- **Control of Pathogens and Allergens Arising from Food Contact Surfaces** (Part IV.C. 3.4) – The guidance should account for determinations by some processing operations with rigorous SSOPs, that contamination of juice with pathogens or residues of food allergens from contact surfaces will *not* be reasonably likely occur. The guidance document suggests control as a CCP. Without a stronger case, NJPA suggests that such control may not need to be handled as a CCP but could be provided for in prerequisite programs and rigorous SSOPs.
- **Pinpoint Extraction-** The apparent endorsement of “pinpoint extraction” in the document is not necessary and implies the exclusion of other extraction technology. The guidance document should not prescribe or recommend pinpoint extraction and references should be removed. Technologies to achieve the 5-log reduction should be left to the processor and any examples should feature alternate extraction methods.
- **Control measures for Biological Hazards** (Part IV.B. 1.1) - NJPA suggests that *Listeria monocytogenes* not be positioned as the “default” pertinent microorganism for juices that have not been associated with illness outbreaks associated with *L. monocytogenes*. Testing other microorganisms should be recognized. The use of *L. monocytogenes* may be problematic, since NJPA is unaware of data for very many minor juices supporting 5-log reduction treatments where *L. monocytogenes* was the target pathogen. Processors packing multiple juices should be allowed the flexibility to target other pertinent microorganisms that are equally appropriate.
- **Allergens and Food Intolerance substances Added to Juice as Ingredients** (Part IV.C.1.23)- NJPA believes that controls to ensure that proper labels are used should be considered as part of the processor’s hazard analysis (rather than part of the HACCP plan as provided in the guidance). In recognition of the fact that beyond the 8 food allergens listed in section 1.22, virtually every food or ingredient can cause an allergic reaction in someone, NJPA suggests that the short list of intolerance/sensitive ingredients in 1.23 be struck. Those ingredients, as

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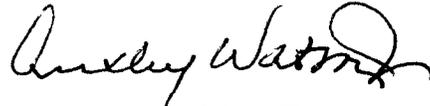
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well as others, when present in juice, must be declared on the product label and the list is not necessary.

Thank you for giving NJPA the opportunity to comment. If you have questions or if we can help you in any way, please do not hesitate to contact us.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ansley Watson, Jr.", written in a cursive style.

ANSLEY WATSON, JR.  
Executive Director