

November 4, 2002

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

**Re: Draft Guidance For Industry: Juice HACCP Hazards and Controls  
Guidance, First Edition, 67 Fed. Reg. 57,829 (Sept. 12, 2002)  
Docket No. 02D-0333**

Dear Dockets Management Branch,

On behalf of the Center for Science in the Public Interest (CSPI), we are writing to express our views on the recent draft guidance document, entitled "Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidance" announced by the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (FDA). CSPI is a non-profit public health group that focuses primarily on nutrition and food-safety issues and is supported principally by approximately 700,000 subscribers to its *Nutrition Action Healthletter*.

The draft guidance represents a significant step in assuring that consumers are protected from food-borne (microbial, chemical, and physical) hazards in juice. Below we provide some additional suggestions to strengthen the guidance.

#### ***Definition of Verification***

The definition should be expanded to state specifically that verification should include a testing regime for the most resistant pathogen reasonably likely to present a hazard in the juice. While the guidance emphasizes the importance of ongoing verification that the HACCP system is working properly to control the identified hazards, it also should identify ongoing microbial testing as an important step for in-depth verification.

#### ***Verification of Control Measures for Biological Hazards***

Under the juice HACCP, the control measure chosen to achieve the 5-log reduction for

**02D-0333**

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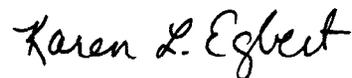
the pertinent microorganism must consistently achieve that reduction.<sup>1</sup> To determine whether the control measure is working consistently to achieve the 5-log reduction, the guidance should emphasize the importance of regular verification testing. While testing of finished product for generic *E. coli* is required by regulation, the guidance should be more specific in identifying the factors that might justify more frequent testing.

For producers of citrus juice who meet the 5-log reduction by surface treatment of the fruit, additional requirements apply. Under the HACCP regulations, a single *E. coli* positive during verification testing will require the facility to review its monitoring records for the control measures used to attain the 5-log pathogen reduction standard and correct those conditions and practices.<sup>2</sup> In implementing this provision, the guidance does not, however, identify any period of time FDA believes is reasonable for a facility to complete that review or correct the relevant conditions and practices. The guidance would be strengthened considerably if FDA defined the maximum amount of time within which it expects the review to be completed.

The draft guidance also provides that if a second positive result is found within seven consecutive tests, the control measures are deemed inadequate and the facility must start “immediate” corrective action (section 3.2). The guidance should define the timing for conducting the consecutive testing as well as what constitutes “immediate” corrective action. In addition, FDA should identify the time limit within which that corrective action should be completed.

We appreciate the opportunity to comment on the draft guidance.

Sincerely,



Karen L. Egbert  
Senior Food Safety Attorney

Caroline Smith DeWaal  
Director, Food Safety Project

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<sup>1</sup> Draft Guidance at p. 20.

<sup>2</sup> Draft Guidance at p. 23.

117 10 11

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Dear Sir or Madam:

Enclosed please find the original and three copies of CSPI's comments on the Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidance. Please file these comments under Docket No. 02D-0333. Thank you very much.

Sincerely,



Karen Egbert  
Senior Staff Attorney, Food Safety