

CSPI CENTER
FOR SCIENCE
IN THE
PUBLIC INTEREST

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Docket No. 01D-0493
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Enclosed please find the original and two copies of CSPI's comment on the Draft Guidance for Industry: Exemptions from the Warning Label Requirement for Juice - Recommendations for Effectively Achieving a 5-Log Reduction. Please file these comments under Docket No. 01D-0493. Thank you very much.

Sincerely,



Karen Egbert
Senior Staff Attorney, Food Safety

01D-0493

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February 19, 2002

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

Re: Draft Guidance For Industry: Exemptions from the Warning Label Requirement
For Juice – Recommendations for Effectively Achieving a 5-Log Reduction,
66 Fed. Reg. 65,978 (Dec. 21, 2001);
Docket No. 01D-0493

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On behalf of the Center for Science in the Public Interest (CSPI), we are writing to express our views on the recent draft guidance document, entitled “Exemptions from the Warning Label Requirement for Juice – Recommendations for Effectively Achieving a 5-Log Reduction” issued by the Center for Food Safety and Applied Nutrition, Office of Plant and Dairy Foods and Beverages 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 800,000 subscribers to its *Nutrition Action Healthletter*.

The draft document provides small and very small juice processors not yet subject to the juice Hazard Analysis and Critical Control Point (HACCP) rule with guidance on how to achieve the 5-log reduction performance standard necessary to attain an exemption from the label warning requirement. Although the draft guidance strengthens earlier guidance and is a substantial step in readying small and very small juice processors for full compliance with the juice HACCP rule by the applicable compliance deadlines (January 2003 for small processors and January 2004 for very small processors), it is deficient in one key respect.

The guidance should emphasize the need for juice processors to validate and verify through microbial testing that the intervention technologies they develop and use to achieve the 5-log reductions are truly effective in addressing microbial hazards. Adequate verification is a core HACCP principle.¹ In promulgating the final juice HACCP rule, FDA emphasized that the

¹ See FDA, *Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule*, 60 Fed. Reg. 65,129 (1995) (“verification is one of the seven commonly recognized HACCP principles”); USDA, Food Safety and Inspection Service, *Pathogen Reduction; Hazard Analysis and Critical Control Point*

5-log reduction requirement sets a goal for juice processors without mandating the specific intervention technologies they must use to achieve that goal and provides a mechanism for determining the equivalence of alternative strategies for controlling pathogens.² It is precisely because juice processors are provided with flexibility in choosing how to accomplish the pathogen-reduction goal that ongoing verification of their intervention processes through end-product microbial testing is necessary.

The mere fact that a treatment process has been scientifically validated to reduce pathogens alone does not assure that shortcomings in a particular facility's application of those processes are adequately identified and does not guarantee that those processes are actually working on a continuous basis to minimize identified microbiological risks – especially at plants using systems that are less well validated than pasteurization. While thermal pasteurization is an effective method for achieving the 5-log reduction, even facilities using pasteurization should verify that the system is functioning properly. Indeed, in promulgating the final juice HACCP rule, FDA itself recognized that “the effectiveness of pasteurization is dependent on implementation of an integrated system that validates and verifies the efficacy of the pasteurization process.” 66 Fed. Reg. 6137, 6145 (Jan 19, 2001). Moreover, there is no reason why citrus juice processors, who may employ surface treatments of fruit to contribute toward achieving the 5-log reduction, must sample their products to verify that the surface treatment is effective,³ while processors of non-citrus juices using different treatments on the extracted juice are not required to conduct testing to verify the effectiveness of their processes.⁴

Accordingly, the FDA should revise its guidance to encourage all juice processors to use regular end-product microbial testing as a tool to verify that their intervention technologies are achieving the 5-log reduction on a continuing basis. This testing should be conducted to affirm process control not lot-by-lot acceptance of the product and serve as an early warning system that any new hazards are properly identified and addressed, particularly where new machinery has been installed or process or product changes have been made. Such regular testing provides the greatest assurance that the risk of outbreaks from foods produced under HACCP systems is minimized.

For companies that are using pasteurization to meet the performance standard, verification testing could be conducted periodically, perhaps weekly or bi-weekly, until a record

(HACCP) Systems; Final Rule, 61 Fed. Reg. 38,817 (1996) (stating that “HACCP systems must be systematically verified”).

² 66 Fed. Reg. 6137, 6165 (Jan. 19, 2001).

³ 21 C.F.R. § 120.25 (requiring final product sampling for biotype I *Escherichia coli* each production day).

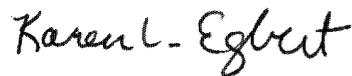
⁴ The fact that citrus processors may apply a surface treatment to achieve the 5-log reduction, while non-citrus fruit treatments must be applied to the expressed juice, does justify a difference in treatment between the two sets of processors since the effectiveness of any specific intervention treatment in reducing bacterial contamination cannot be judged on paper validation of the process alone.

of process control has been established. For companies using methods other than pasteurization to achieve the 5-log reduction, the FDA should encourage them to conduct daily testing of products – not to determine lot-by-lot acceptance of product but to demonstrate that the intervention system is working reliably, particularly when there has been a significant equipment, product, process or packaging change. Process verification through microbial testing is particularly important since FDA currently lacks the resources to conduct regular inspections of these facilities.

Finally, amending the guidance to recommend that processors conduct end-product testing will help assure that there has not been product re-contamination after application of the intervention treatment, particularly since studies on apples have suggested that microorganisms can be spread within processing areas and can accumulate on processing equipment.⁵

We appreciate the opportunity to comment on the draft guidance.

Sincerely,



Karen L. Egbert
Senior Food Safety Attorney

Caroline Smith DeWaal
Food Safety Director

⁵ See FDA, CFSAN, *Potential for Infiltration, Survival and Growth of Human Pathogens within Fruits and Vegetables* (Nov. 1999), at p. 4. Another study, conducted by the State of Maryland concluded that generic *E. coli* was introduced during in-plant processing, thus highlighting the importance of sanitation practices in juice product. *Id.* at 5.