

# Guidance for Industry

## Exemptions from the Warning Label Requirement for Juice – Recommendations for Effectively Achieving a 5-Log Reduction

### *DRAFT GUIDANCE*

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U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

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GDLI

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## Exemptions from the Warning Label Requirement for Juice --Recommendations for Effectively Achieving a 5-Log Reduction

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The Office of Plant and Dairy Foods and Beverages in the Center for Food Safety and Applied Nutrition has prepared this guidance. This guidance represents the agency's current thinking on reducing microbial food safety hazards in juice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. This guidance document supercedes "Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide," September 18, 1998, <http://www.cfsan.fda.gov/~dms/juicguid.html>.

#### **Background**

In the Federal Register of July 8, 1998 (63 FR 37030), the Food and Drug Administration (FDA) published a final rule requiring a warning label on any juice that has not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present (the "juice labeling rule"). In this guidance document, juice is any juice or juice ingredient in a beverage, as defined by 21 CFR 120.1(a). Under 21 CFR 101.17(g), any juice or juice ingredient that is not processed to reduce pathogens by 100,000-fold (i.e., attain a 5-log reduction in the pertinent microorganism) must bear a warning label. Because labeling may have limited effectiveness (i.e., it must be read and be understood), the warning label was intended to provide a measure of public safety until final Hazard Analysis and Critical Control Point (HACCP) regulations for juice could be established and implemented.

In the Federal Register of January 19, 2001 (66 FR 6138), FDA published a final rule requiring the application of HACCP principles to the processing of any juice or juice ingredient in a beverage (the "juice HACCP rule"). Juice produced in a retail establishment, i.e., a facility that produces juice that is only sold directly to consumers, is exempt from the HACCP requirements. Like the juice labeling rule, the juice HACCP rule utilizes the standard of a 5-log reduction in the pertinent microorganism. Specifically, under § 120.24(a), juice processors must establish control measures that will produce such a reduction.

After the publication of the juice labeling rule, FDA's scientific understanding of how to attain effectively a 5-log reduction evolved, as discussed in the preamble and as reflected in the requirements of the juice HACCP rule.

## **Purpose of this Guidance**

The purpose of this draft guidance document is to provide guidance to those juice processors not yet subject to the juice HACCP rule (e.g., small and very small processors who are not subject to the juice HACCP rule until January 21, 2003 and January 20, 2004, respectively) who are performing a 5-log reduction to attain exemption from the label warning requirement. This draft guidance document also provides guidance to processors at retail who are not subject to the juice HACCP rule and who are performing a 5-log reduction to attain exemption from the warning label requirement. FDA encourages those processors to operate consistently with this draft guidance in terms of 5-log reduction treatments because this draft guidance is based upon FDA's current scientific knowledge. The previous 5-log reduction guidance in the juice labeling rule and FDA's guidance document, "Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide" (the "small entity compliance guide") (Ref. 1), are superseded in part by this guidance because these documents no longer reflect FDA's current thinking.

## **FDA Recommendations**

FDA's current scientific understanding of how to attain effectively a 5-log reduction is based on information obtained from public meetings, discussions, comments to the juice HACCP proposed rule (63 FR 20450), and recommendations from the National Advisory Committee on Microbiological Criteria for Food (NACMCF) (Refs. 2 and 3). To assist juice processors in attaining a 5-log reduction consistent with current scientific knowledge, Table 1 compares FDA's previous and current recommendations for achieving the 5-log reduction. The following questions and answers provide additional guidance for current recommendations for the 5-log reduction:

*Question:* When in the process should the 5-log reduction treatment be applied?

*Answer:* Based upon current scientific understanding, FDA recommends that the 5-log pathogen reduction and final product packaging occur under one firm's control, in a single production facility that is operating under current Good Manufacturing Practices (CGMPs) and immediately before or immediately after packing. This recommendation is for both citrus and non-citrus juices. Thus, good agricultural practices (GAPs) and CGMPs at the farming and harvesting stages are encouraged but should not be counted towards the 5-log reduction. The basis for this recommendation is discussed in more detail in the juice HACCP rule (66 FR 6138 at 6166).

*Question:* What should be treated?

*Answer:* FDA recommends that juice processors use treatments that directly contact all pathogens that may be present in or on the fruit or vegetables being processed. For most products, this means that the treatments should be performed on the juice after it is expressed. For citrus juices only, effective surface treatment of the citrus fruit may constitute direct contact with all pathogens, and thus, processors may consider counting such treatment toward the 5-log reduction. If surface treatments are used on citrus fruits to achieve the 5-log reduction, FDA

recommends that the treatment be applied to undamaged tree-picked fruit (USDA choice or higher quality) that has been cleaned. The basis for this recommendation is discussed in more detail in the juice HACCP rule (66 FR 6138 at 6171).

### **Summary**

Processors who do not treat their juice to achieve the 5-log reduction should continue to comply with the juice labeling rule. However, based upon FDA's current knowledge, processing juice in accordance with the recommendations in the small entity compliance guide for the juice labeling rule may not reduce pathogens to an acceptable level. Therefore, juice processors claiming exemption from the warning label requirement on the basis of the 5-log reduction provision of 21 CFR 101.17(g)(7) should consider the principles in this guidance. FDA plans to publish two additional guidance documents, "Guidance for Industry: Juice HACCP Hazards and Control Guide" and "The Juice HACCP Regulation: Questions and Answers", that will provide additional information on the juice HACCP rule, including assistance in achieving a 5-log reduction. Both documents will be available electronically.

**Table 1:  
Comparison of FDA's Previous and Current  
Recommendations for 5-Log Reduction**

Previous Guidance	Current 5-Log Guidance (Draft)
5-log reduction must occur in target pathogen for a period of at least as long as the shelf-life of the product stored under normal or moderate abuse conditions (juice labeling rule, 21 CFR 101.17(g)(7)(i)).	No change (juice HACCP rule, 21 CFR 120.24(a)).
5-log reduction may include measures taken during farming, harvesting, or processing over which the processor has control and which are effective (Small Entity Compliance Guide).	<p>5-log reduction and final packaging should occur under one firm's control and within a single production facility. Any reduction of pathogens based upon the application of GAPs and CGMPs in farming and harvesting is encouraged but should not be counted towards 5-log reduction (see 21 CFR 120.24(b) and (c)).</p> <p>Once the juice HACCP rule is effective, juice processors subject to the rule must perform 5-log reduction treatments in the final packaging facility (juice HACCP rule, 21 CFR 120.24(b) and (c)).</p>
5-log reduction may be cumulative (Small Entity Compliance Guide).	No change (preamble to the juice HACCP final rule).

<p>No prior guidance.</p>	<p>5-log reduction should use treatments that directly contact all pathogens that may be present. For citrus fruit, surface treatment may be counted toward 5-log reduction following cleaning and culling. For non-citrus fruit, treatment should be applied to the expressed juice (see 21 CFR 120.24(b)).</p> <p>Once the juice HACCP rule is effective, juice processors subject to the rule must use a treatment that directly contacts all pathogens (juice HACCP rule, 21 CFR 120.24(b)).</p>
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## References

1. FDA, DHHS, "Guidance for Industry: Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide," September 18, 1998.
2. FSIS, USDA, "National Advisory Committee on Microbiological Criteria for Food, 64 FR 63281-63282, November 19, 1999.
3. NACMCF, "National Advisory Committee on Microbiological Criteria for Food, Meeting on Fresh Citrus Juice; Transcript of Proceedings," December 8 to 9, 1999, public meeting.