

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P-0009]

DMB

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Certifier D. Hawkins

Draft Guidance for Industry: Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices." This draft guidance document is intended to provide processors of juice concentrates and certain shelf stable juice products with recommendations for the use of appropriate control measures to ensure that juice concentrates and certain shelf stable juices do not become contaminated or recontaminated with microbial pathogens during bulk transport.

DATES: Submit written or electronic comments concerning the draft guidance by *[insert date 60 days after date of publication in the Federal Register]* to ensure adequate consideration in the preparation of the final guidance document. Comments on this guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Amy Green (see **FOR FURTHER INFORMATION CONTACT**). See **SUPPLEMENTARY INFORMATION** section for electronic access to this draft guidance.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers

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Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Amy Green, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2025, FAX 301-436-2651.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed the draft guidance document to provide processors of juice concentrates and certain shelf stable juice products with recommendations for the use of appropriate control measures to help ensure that juice concentrates and certain shelf stable juice products do not become contaminated or recontaminated with microbial pathogens during bulk transport. The draft guidance recommends control measures for several transport modalities, including: (1) Multiuse or reusable containers (e.g., tankers, reusable drums without liners, and reusable totes without liners) and (2) single-use sanitary containers or liners (e.g., single-use sanitary totes, single-use sanitary drums, bag-in-box containers, totes with single-use sanitary liners, and drums with single-use sanitary liners). The draft document describes five major areas of concern with bulk transport systems, special considerations for tankers, and provides examples of a cleaning and sanitizing protocol for a tanker, control measures that might be used in loading and unloading a tanker, and critical control points a producer might use to include bulk transport in its hazard analysis critical control point (HACCP) plan.

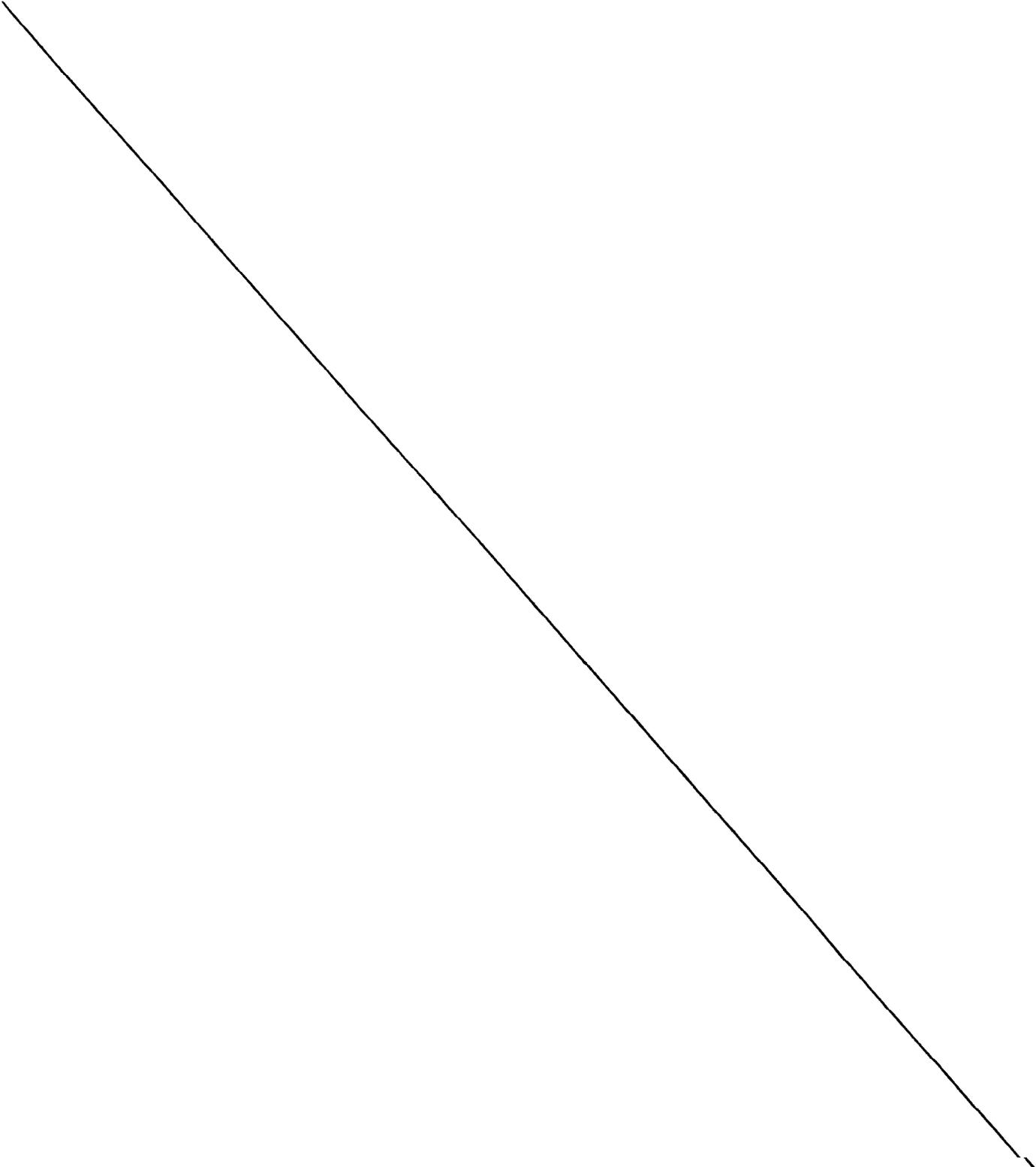
This draft guidance is partly in response to a citizen petition submitted by certain representatives of the juice industry asking that FDA: (1) Amend 21 CFR 120.24(c) to exempt processors of juice concentrate and certain shelf stable juice products from the “single facility requirement” and (2) delay the effective date of the “single facility requirement” until the agency has disposed of the citizen petition. The petitioners contend that transportation hazards, which the “single facility requirement” was designed to address, could be adequately addressed as part of a processor’s HACCP plan. This draft guidance provides recommendations that producers and users of juice concentrates and certain shelf stable juice products can use to prevent, reduce to acceptable levels, or eliminate the risk of contamination or recontamination of these products with microbial pathogens during bulk transport and thus satisfy the conditions under which FDA will consider the exercise of enforcement discretion.

The draft guidance entitled “Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices” is being issued as a level 1 draft guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This draft guidance represents the agency’s current thinking on this subject. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one

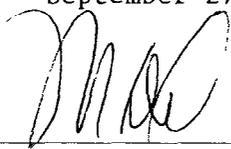
copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.cfsan.fda.gov/~dms/guidance.html>.

Dated: 9/27/02
September 27, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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