

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. 02D-0384]

Guidance for Industry: Standardized Training Curriculum for Application of Hazard Analysis Critical Control Point Principles to Juice Processing; Availability
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing" (the guidance). The guidance advises juice processors of FDA's view that the 1st Edition of the Juice Hazard Analysis Critical Control Point (HACCP) Training Curriculum of the Juice HACCP Alliance (the standardized curriculum) is adequate for use in training individuals to meet the requirements of the juice HACCP regulation. The guidance also advises processors and educators on how the requirements of the juice HACCP regulation may be met using the standardized curriculum or alternative curricula for training individuals and on how they can view, download, or purchase the standardized curriculum.

DATES: You may submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (CFSAN) (see **FOR FURTHER INFORMATION CONTACT**). Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/comments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-2022, FAX: 301-436-2651, e-mail: mkashtoc@cfstan.fda.gov.

SUPPLEMENTARY INFORMATION:
I. Background

FDA's juice HACCP regulation in part 120 (21 CFR part 120) includes in § 120.13 a requirement that individuals who perform certain specified functions, e.g., developing the hazard analysis or the HACCP plan, "shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions." The guidance advises juice processors of FDA's view that the 1st Edition of the Juice HACCP Training Curriculum of the Juice HACCP Alliance (coordinated through the efforts of the National Center for Food Safety and Technology at the Illinois Institute of Technology) (the standardized curriculum) is adequate for use in training individuals to meet the requirements of the juice HACCP regulation. This guidance also advises processors and educators on how the requirements of the juice HACCP regulation may be met using the standardized curriculum or alternative curricula for training individuals and on how they can view, download, or purchase the standardized curriculum.

The guidance document is a level 1 guidance issued consistent with FDA's good guidance practices regulation (21 CFR 10.115) relating to the development, issuance, and use of guidance documents.

In the **Federal Register** of October 7, 2002 (67 FR 62489), FDA announced the availability of a draft guidance document entitled "Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing." The agency solicited public comment on the draft guidance document. FDA did not receive any comments and is finalizing the draft guidance document without revision.

This guidance represents the agency's current thinking on curricula for training juice processing personnel in the application of HACCP principles to juice processing. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the guidance document. Submit a single copy of electronic comments or two paper

copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

A copy of the guidance document is available on the Internet at <http://www.cfsan.fda.gov/guidance.html>.

Dated: June 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: July 16, 2003, 9 a.m.-5 p.m. July 17, 2003, 8:30 a.m.-3 p.m.

Place: The Latham Hotel, 3000 M Street, NW., Washington, DC 20007, (202) 726-5000.

Status: The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs which are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start initiative and infant mortality objectives from *Healthy People 2010*.

Agenda: Topics that will be discussed include the following: Low-Birth Weight and Preterm Birth; Birth Defects and Other Neonatal Conditions; and the Healthy Start Program. Agenda items are subject to change as priorities are further determined.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-2170.