

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2009D0347]

Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Availability

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons. This draft guidance is intended to cover the entire melon supply chain, both domestic firms and foreign firms exporting melons into the United States, to enhance the safety of melons by recommending practices to minimize microbial food safety hazards and to prevent microbial contamination. This draft guidance, when finalized, will supplement existing FDA guidances, including the 1998 Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, which applies to fresh produce commodities, and the 2008 Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, which applies to fresh-cut produce.

DATES:

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by [insert date 60 days after date of publication in the Federal Register].

ADDRESSES:

Submit written requests for single copies of the draft guidance to the Office of Food Safety (HFS317), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 3014362651. Submit written comments on the draft guidance to the Division of Dockets Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons. This draft guidance covers melons that are grown and harvested for fresh market (i.e., fresh, unprocessed form) or for fresh-cut/value-added products (i.e., minimally processed, such as trimmed, peeled, sliced or diced, and then bagged or prepackaged), cooled, shipped to retail, wholesale or for processing, and offered for sale to the consumer. The term melons as used in this draft guidance includes raw agricultural commodities and fresh-cut/value-added products derived from cantaloupe (also known as muskmelons), honeydew, watermelon, and variety melons (e.g., Canary, Crenshaw, and Galia). This draft guidance is based primarily on melon industry guidelines issued in 2005 (Ref. 1), along with agency experience and information from other recent public and private programs.

FDA is issuing this draft guidance as Level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the microbiological hazards presented by fresh and fresh-cut melons and the recommended control measures for such hazards in production and harvesting, postharvest operations, processing, distribution, and retail and food service handling of such produce. 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 35013520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish notice in the Federal Register soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collection of information in a future issue of the Federal Register.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this 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. The

draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>.

#### V. References

The following reference has been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

<EXTRACT>

1. Fleming, P., Pool, W., and Gorny, J., editors; Commodity Specific Food Safety Guidelines for the Melon Supply Chain (1st ed.); Produce Marketing Association and United Fresh Produce Association; November 7, 2005. Accessed online at <http://www.fda.gov/Food/FoodSafety/Product-Specific&fxsp0;Information/Fruits&fxsp0;Vegetables&fxsp0;Juices/Guidance&fxsp0;Compliance&fxsp0;Regulatory&fxsp0;Information/ucm168609.htm>.

</EXTRACT>

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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