

harvesting, packing, processing, and distribution of tomatoes, along with retail and food service preparation. Such tomatoes may be grown and harvested either from an open field or a greenhouse; they may be packed or repacked either for the fresh market or for “fresh-cut/value-added processing” (i.e., minimally processed, such as by slicing or dicing, and then bagged or prepackaged); and then shipped either to food service operations or retail establishments where they are offered for sale to the consumer. The use of the term “tomatoes” in this document includes raw agricultural commodities and fresh-cut/value-added products. This draft guidance is based primarily on tomato industry guidelines issued in July 2008 (Ref. 1), along with agency experience and information from other recent public and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FDA is issuing this draft guidance as Level 1 draft guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on the microbiological hazards that may result in contamination of fresh and fresh-cut tomatoes and the recommended control measures for such hazards in the growing, harvesting, packing, processing, and distribution of tomatoes, along with retail and food service preparation. 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. 3501–3520), 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.

1. North American Tomato Trade Workgroup and United Fresh Produce Association. “Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain.” 2d ed., July 2008. Accessed online at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/GuidanceComplianceRegulatoryInformation/ucm171695.htm>.

Dated: July 28, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2009–D–0348]

### Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; 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 Leafy Greens.” This draft guidance is intended to cover the entire

leafy greens supply chain, both domestic firms and foreign firms exporting leafy greens products into the United States, to enhance the safety of leafy greens 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 October 2, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Food Safety (HFS–317), 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 301–436–2651. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), 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:** Amy Green, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2025.

### 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 Leafy Greens.” This draft guidance covers leafy greens that are grown and harvested then packed or cooled for fresh market or for “fresh-cut/value-added processing” (i.e., minimally processed, such as chopped or shredded, moved through a series of washes, and then bagged or prepackaged), shipped to food service or retail establishments, and offered for

sale to the consumer. The term “leafy greens” as used in this draft guidance includes raw agricultural commodities and fresh-cut/value-added products. Examples of leafy greens include iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula, and chard. Leafy greens do not include herbs such as cilantro and parsley.

This draft guidance is based primarily on leafy greens industry guidelines issued in 2006 (Ref. 1), along with agency experience and information from other recent public and private programs. The leafy greens industry has since updated and supplemented its 2006 guidelines with additional recommendations on the production and harvest of leafy greens that include quantitative metrics and measures to assist industry in implementing the guidelines (Ref. 2). This draft guidance does not include these more specific and quantitative metrics and measures. We are considering the extent to which more specific measures, including metrics, should be utilized to help verify the implementation and efficacy of the Federal recommendations and industry practices. We are also evaluating the extent to which metrics can be applied to diverse geographic areas within the United States and internationally. FDA invites comment on whether such information should be incorporated into the guidance, when finalized.

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 leafy greens products 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. 3501–3520), 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

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## V. References

The following references have 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.

1. Gorny, J., et al., editors, “Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain” (1st ed.); International Fresh-cut Produce Association, Produce Marketing Association, United Fresh Fruit and Vegetable Association, Western Growers Association; April 25, 2006. Accessed online at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/GuidanceComplianceRegulatoryInformation/ucm168630.htm>.

2. See “Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens”; Produce Marketing Association, United Fresh Fruit and Vegetable Association, and Western Growers Association; last revised June 13, 2008. Accessed online at <http://www.caleafygreens.ca.gov/trade/documents/LGMAAcceptedGAPs06.13.08.pdf>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to

the Web site after this document publishes in the **Federal Register**.)

Dated: July 28, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Treatment of Cancer Using Metal Coordinating Compounds That Kill Multi-Drug Resistant Cancer Cells

*Description of Invention:* One of the major hindrances to successful cancer chemotherapy is the development of multi-drug resistance (MDR) in cancer cells. MDR is frequently caused by the increased expression or activity of ABC transporter proteins in response to the toxic agents used in chemotherapy. Research has generally been directed to overcoming MDR by inhibiting the activity of ABC transporters. However, compounds that inhibit ABC transporter activity often elicit strong and undesirable side-effects, restricting their usefulness as therapeutics.

In an alternative approach to reducing the debilitating effects of MDR during cancer therapy, scientists at the NIH have identified a family of compounds