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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
[Docket No. FDA-2010-N-0085]  
Preventive Controls for Fresh Produce; Request for Comments  
AGENCY: Food and Drug Administration, HHS.  
ACTION: Notice; request for comments.

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[Federal Register: February 23, 2010 (Volume 75, Number 35)] [Notices] [Page 8086-8087]  
From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr23fe10-89]

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to obtain information about current practices and conditions for the production and packing of fresh produce. FDA is establishing this docket in order to provide an opportunity for interested parties to provide information and share views that will inform the development of safety standards for fresh produce at the farm and packing house and strategies and cooperative efforts to ensure compliance.

DATES: Submit electronic or written comments by May 24, 2010.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>.  
Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-2024.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On March 19, 2009, President Barack Obama established a new Food Safety Working Group (FSWG), chaired by the Secretaries of the Department of Health and Human Services and the Department of Agriculture. In announcing creation of the FSWG, the President said the group would advise him on how to upgrade U.S. food safety laws for the 21st century, foster coordination of food safety efforts throughout the Government, and ensure laws are being adequately enforced to keep the American people safe from foodborne illness (Ref. 1).

On July 1, 2009, the FSWG recommended a new public health-focused approach to food safety based on three core principles: (1) Prioritizing prevention; (2) strengthening surveillance and enforcement; and (3) improving response and recovery (Ref. 1). The FSWG announced steps to be taken by FDA and other Federal agencies to achieve these goals.

With regard to fresh produce, the FSWG announced that FDA would issue "commodity-specific draft guidance on preventive controls that industry can implement to reduce the risk of microbial contamination in the production and distribution of tomatoes, melons, and leafy greens" (Ref. 1).

The FSWG also announced that FDA, over the next 2 years, would "seek public comment and work to require adoption of these approaches through regulation" (Ref. 1).

On August 3, 2009, FDA made available draft guidances to industry for leafy greens, melons, and tomatoes (Refs. 3 through 5). FDA is now establishing a docket in order to provide an opportunity for interested parties to provide information and share views that will inform the development of: (1) Safety standards for fresh produce at the farm and packing house and (2) strategies and cooperative efforts to ensure compliance.

## II. Request for Comments and Information

We are requesting comments that will inform the development of: (1) Safety standards for fresh produce at the farm and packing house and (2) strategies and cooperative efforts to ensure compliance. In particular, we welcome input on any of these general categories:

Role of the good agricultural practice guidelines entitled "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAPs Guide, Ref. 6);

- Standards for domestic and foreign growers and packers;
- Identification and prioritization of risk factors;
- Environmental assessment of hazards and possible pathways of contamination;
- The impact of scale of growing operations on the nature and degree of possible food safety hazards;
- Methods to tailor preventive controls to particular hazards and conditions affecting an operation;
- Possible approaches to tailoring preventive controls to the scale of an operation so that the controls achieve an appropriate level of food safety protection and are feasible for a wide range of large and small operations;
- Coordination of produce food safety practices and sustainable and/or organic production methods;
- Coordination of produce food safety practices and environmental and/or conservation goals or practices;
- Coordination of produce food safety practices and Federal, State, local and tribal government statutes and regulations;
- Microbial testing;
- Post-harvest operations and the role of the current good manufacturing practices in 21 CFR part 110;
- Records and other documentation that would be useful to industry and regulators in ensuring the safety of fresh produce; and
- Strategies to enhance compliance.

The agency will consider information submitted to the docket in developing safety standards for fresh produce. Comments previously submitted to the Division of Dockets Management for the following dockets will also be considered by FDA and do not need to be resubmitted:

- "Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Availability" (74 FR 38438, August 3, 2009; Docket No. FDA-2009-D-0346);

- ``Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons" (74 FR 38437, August 3, 2009; Docket No. FDA-2009-D-0347);
- ``Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Availability" (74 FR 38439, August 3, 2009; Docket No. FDA-2009-D-0348); and
- ``Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Request for Comments and for Scientific Data and Information" (73 FR 51306, September 2, 2008; Docket No. FDA-2008-N-0455).

### III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments regarding this docket. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. References

FDA has placed the following references on display in FDA's Division of Dockets Management (see ADDRESSES). You may see them between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.)

1. Food Safety Working Group, ``Food Safety Working Group: Key Findings" (July 1, 2009), Available at <http://www.foodsafetyworkinggroup.gov/ContentKeyFindings/HomeKeyFindings.htm>, Accessed and printed on January 11, 2010.
2. Food Safety Working Group, ``President's Food Safety Working Group: Delivering Results," Available at [http://www.foodsafetyworkinggroup.gov/FSWG\\_Fact\\_Sheet.pdf](http://www.foodsafetyworkinggroup.gov/FSWG_Fact_Sheet.pdf), Accessed and printed on January 11, 2010.
3. FDA, ``Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Availability" (74 FR 38438, August 3, 2009).
4. FDA, ``Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons" (74 FR 38437, August 3, 2009).
5. FDA, ``Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Availability" (74 FR 38439, August 3, 2009).
6. FDA, ``Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," October 26, 1998, Available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm>.

Dated: February 17, 2010.

Leslie Kux, Acting Assistant Commissioner for Policy.

[FR Doc. 2010-3409 Filed 2-18-10; 11:15 am]