



November 9, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

(Electronic copies to: <http://www.regulations.gov>)

**Re: Comments on Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens;
Docket No. FDA-2009-D-0348**

Dear Sir or Madam:

The Food Marketing Institute¹ (FMI) is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on the notice of the *Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens*. 74 Fed. Reg. 38439 (Aug. 3, 2009); 74 Fed. Reg. 42311 (Aug. 21, 2009). We wish to commend FDA for providing draft guidance on three commodities: melons, tomatoes and leafy greens. We agree with FDA's approach, which is based on science and does not favor any particular set of standards or criteria set by a State or other entity, and which can be applied to the respective commodities regardless of where they are grown, processed or handled. Furthermore, we agree with FDA's reliance on the recommendations in the FDA Food Code as the basis for draft guidance for handling these commodities in retail food stores.

We are submitting comments on one Section of the guidance for leafy greens: Part IX. Retail and Foodservice, Section C – Leafy Greens Re-Crisping. Although we are in general agreement with this section, we feel that the section needs to include the option of using approved antimicrobial agents as a way to minimize microbial risks. Furthermore, we suggest FDA refer to the use of “potable water” rather than “tap water” in this part of the guidance. Therefore, we recommend that you amend this section as follows:

¹ FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

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C. Leafy Greens Re-Crisping

Leafy greens such as lettuce may be re-cripsed by placing the whole or fresh-cut product in containers with potable water. The small amounts of chlorine normally present in potable water may be quickly inactivated by the organic load presented by leafy greens. This may increase the potential for leafy greens cross contamination particularly if additional leafy greens are added to the re-cripsing container (Ref. [25](#)).

FDA recommends:

- Reducing the potential for water and utensils to contaminate leafy greens when re-cripsing leafy greens by cleaning and sanitizing the sink or container before re-cripsing leafy greens.
- When water soaking is the preferred method for re-cripsing leafy greens, incorporate at least one alternative below in addition to using potable water:
 - * Change the water at a frequency sufficient to ensure that it is of appropriate microbial quality for its intended use.
 - * Allow for antimicrobial agents (as per 21 CFR 173.315) in the water to further minimize the potential for cross-contamination. Depending on the type and level of antimicrobial used, an additional potable water rinse may be necessary.
- Alternatively, use running water to re-crips leafy greens as needed, in lieu of re-cripsing by water soaking.

We believe that the changes recommended above will ensure re-cripsing practices that minimize the risk of contamination, while providing for alternatives consistent with the FDA Food Code and the Code of Federal Regulations.

Thank you for the opportunity to comment on this Notice. If we may be of further assistance, please do not hesitate to call on us.

Sincerely,



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Food Safety Programs

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