

**Guidance to Minimize Food Safety Hazards for Fresh-cut Fruits and Vegetables**  
**Responses to OMB Comments of August 20, 2007**

- Please explain the incremental difference between what the fresh-cut industry is currently doing and what would be done if it consistently began to follow this draft guidance.

***Response:*** *Based upon our discussions with fresh-cut produce processors and our review of the comments received, it is our understanding that many existing processors already follow the strategies suggested in the guidance document. Such processors are aware that produce may be contaminated with pathogens during harvest and processing and they understandably are interested in minimizing microbial food hazards in their fresh-cut products. Specifically, existing firms in the fresh-cut produce industry already make use of Current Good Manufacturing Practices (CGMP)-related activities and other appropriate handling and processing practices, traceback procedures, and Hazard Analysis and Critical Control Point (HACCP) principles and plans.*

*We estimate that most of the burden of this guidance will fall on the new firms entering the industry, and that about 10 new firms are entering the fresh-cut produce industry each year.*

*The International Fresh-Cut Produce Association's (IFPA) written comments to the draft fresh-cut guidance (published in March 2006) were, as a rule, very specific to each section of the guidance. IFPA also provided more general recommendations, such as using a HACCP based system, establishing recall and traceback procedures, and confirming that CGMPs are mandatory for all fresh-cut processors.*

*IFPA's comments indicated to us that the industry already follows much of what is recommended in the guidance. Similarly, Mr. Hank Giclas of the Western Growers Association, in an interview with the press, noted that the industry already is carrying out most of the guidance's recommendations. In discussions at meetings with industry and in tours of fresh-cut facilities, we have gotten further confirmation that much of the industry is following the recommendations set down in the fresh-cut guidance.*

*It is worth noting that we also received a couple of comments that requested stronger language for some recommendations, including the application of pest control chemicals and the handling of wash water antimicrobial chemicals.*

- Where applicable, please compare these provisions to the following: GMPs, BT Act, HACCP, GAPS guide, IFCPA guidelines. I am particularly interested in the following areas: personnel health and hygiene, building and equipment, sanitation operations, training, Standard Operating Procedures (SOPs) plan, Sanitation Standard Operating Procedures (SSOPs) plan, documentation and recordkeeping. This could be a brief document done in a table/chart form.

***Response:*** *We have compared the recommendations of the Fresh Cut Guidance to the requested provisions. The information is set out in the table below:*

	<i>Fresh Cut Guidance</i>	<i>GMPs</i>	<i>BT Act</i>	<i>HACCP</i>	<i>GAPS guide</i> (covers growing, harvesting, packing and transport of fresh produce, the steps before fresh-cut processing)	<i>IFPA guidelines</i>
personnel health and hygiene	Recommended	Required	N/A	Required	Recommended	Recommended
building and equipment	Recommended	Required	Required	Required	Recommended (for packing facilities)	Recommended
sanitation operations	Recommended	Required	N/A	Required	Recommended	Recommended
training	Recommended	Recommended(“should” receive appropriate training)	N/A	Required	Recommended	Recommended
SOPs plan	Recommended	Quality control operation required, a planned and systematic procedure—required (use of SOP and SSOP language started in the HACCP regs)	N/A	Required	Not mentioned	Recommended
SSOPs plan	Recommended	See above	N/A	Required	N/A	Recommended
documentation	Recommended	Not yet required or mentioned, under consideration in GMP modernization effort	Required	Required	Recommended	Recommended
recordkeeping	Same	See above	Required	Required	Recommended	Recommended

- Please send a copy of any comments from International Fresh-Cut Produce Association.

**Response:** *The comments have been sent with this memorandum.*

- How will these guidelines be used in enforcement actions by FDA? By states? By others?

**Response:** *As is the case with all of FDA's guidance documents, per our good guidance practices regulations (GGPs), this guidance represents FDA's current thinking on the microbiological hazards presented by most fresh-cut fruits and vegetables and the recommended control measures for such hazards in the processing 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, thus this guidance cannot be used as a standard against which an enforcement action may be taken. Therefore, firms are free to adopt as many or as few of the guidance's recommendations as they choose.*

*In contrast, failure to comply with FDA's regulations may be cited during an FDA plant inspection and could lead to an enforcement action. For example, maintaining the sanitary condition of the facility or excluding persons with wounds or infections from contact with the food, food-contact surfaces or and packaging are required components of FDA's Current Good Manufacturing Practices (CGMPs), found in 21 CFR part 110. These provisions are discussed in the guidance to show the operation of a comprehensive approach to minimizing microbial food hazards.*

- By states? By others?

**Response:**

*As stated above, FDA's guidance documents are not legally binding. We do not expect this guidance to be used in state enforcement actions. We are not certain what "others" you are referring to.*

- Please revise the front page of the guidance document to include the standard PRA burden statement.

**Response:** *Agreed. The "draft final" guidance document announced in the Federal Register Notice of Availability does not display the standard PRA burden statement, in accordance with the Standard Operating Procedures (SOPs) issued by FDA's Office of Chief Counsel. When published on our website, the front page of the final guidance document will include the standard PRA burden statement.*