

Empire State Fruit & Vegetable Expo January 25, 2012

FDA Guidance on Fresh Produce and Flooded Fields

Michelle A. Smith, Ph.D.
Senior Policy Analyst
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
michelle.smith@fda.hhs.gov



Overview

- Guidance
 - What it is and what it isn't
- Flood guidance
 - Objectives of the flood guidance
 - Specific recommendations
 - Obtaining copies
 - Submitting comments



Guidance

- Guidance represents FDA's current thinking, intended to be a “living” doc.
- It does not bind FDA or the public, **recommendations NOT requirements**
- An alternative approach may be used if it satisfies the requirements of the applicable statutes and regulations



Hazards

Flooding events can present a potentially hazardous public health risk

- Flood waters may have been exposed to:
 - sewage
 - chemicals (e.g., heavy metals, PCBs, petroleum)
 - pathogenic microorganisms or
 - other contaminants
- In addition, mold and toxins may develop in crops as a result of exposure to the water



Flooding

- Flooding is the flowing or overflowing of a field with water outside a grower's control
- Pooled water (e.g., after rainfall) that is not reasonably likely to cause contamination of the edible portions of fresh produce is NOT considered flooding



Previous Flood Guidance

Notice from FDA to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters for Food Products About the Safety of Food Affected by Hurricane, Flooding, and Power Outages (Hurricanes Katrina & Isabelle)

Other Guidance re: Flooding

- Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce
- Draft Guidance to Minimize Microbial Food Safety Hazards of Leafy Greens



Highlights of Earlier Guidance

- If the edible portion of a crop is exposed to flood waters, it is considered adulterated and should not enter human food channels
- No practical method of reconditioning that will provide a reasonable assurance of food safety
- Crops where the edible portion has NOT come in contact with flood waters, may need to be evaluated on a case-by-case basis
 - Factors for consideration



2011 Hurricane Irene (and then Lee)

New situations, new questions and new information needs:

- What about...
 - areas where fields were flooded quickly and then the water subsided very quickly?
 - root crops and winter squash which are often peeled and cooked?
 - testing?
- Any science to support these guidelines would be much appreciated.



Economic & Personal Impact

September 27, 2011, FDA Letter to State Agricultural Departments/Agencies identifying Federal guidance and other available information concerning disposition of food from crops affected by flood waters

We stand ready to continue to engage and assist in your recovery efforts, and regret the significant impact that Hurricane Irene has had on the northeastern states.

Sincerely,



Michael M. Landa
Acting Director
Center for Food Safety
and Applied Nutrition



In Response to Questions

- Revisited existing FDA guidance
- Looked at guidance from others
- Looked at existing science
 - Balance providing specific recommendations & determining where science is sufficient to support them
- Elaborate on considerations for case-by-case assessments



Notice of Availability

October 24, 2011

Guidance for Industry on Evaluating the Safety of Flood-Affected Food Crops for Human Consumption

- Implemented without prior public comment because the guidance deals with highly time sensitive, public health issues
- Remains subject to comment in accordance with our GMPs regulation

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm274683.htm>



Overarching

- Growers are responsible to ensure the safety of the flood-affected food crops
- The guidance is intended to provide growers information on how to evaluate the safety of flood-affected food crops for human consumption



Specifically, the guidance addresses:

- (1) Safety of food crops when flood waters contacted the edible portions of the crops,
- (2) Safety of food crops when flood waters did not contact the edible portions of the crops,
- (3) Assessment of flood-affected fields before replanting, and
- (4) Additional controls to avoid cross-contamination after flooding



When Flood Waters Contact the Edible Portions of the Crop

- If the edible portion of a crop is exposed to flood waters, it is considered adulterated under the Act and should not enter human food channels
- No practical method of reconditioning the edible portion of a crop that will provide a reasonable assurance of food safety
- Dispose of these crops in a manner that ensures they are kept separate from crops that have not been flood damaged to avoid adulterating "clean" crops
- Applies to ALL food crops



When Flood Waters Did NOT Contact the Edible Portions of the Crop

- Evaluate the safety of the crops for human consumption on a case-by-case basis for possible adulteration
- Work with state & local agencies & local FDA offices to assess your unique situation and to consider all possible types and routes of contamination from flood waters in determining whether a particular crop is adulterated



Factors to Consider

- - Assessment of flood waters & potential exposure to contaminants
- - Type of crop and stage of growth
- - Likelihood for crops to absorb or internalize potential contaminants from flood waters and/or flooded soil
- - Degree and duration of crop exposure to flood waters



Testing

- Depending on the results of the assessment, consider testing one or more contaminants, as needed, to determine the suitability for human food use
- Sampling - representative of the crop being evaluated
- Testing - appropriate for the specific crop and flood situation
- Discuss testing plans with state and local FDA regulators & technical specialists for case-specific evaluations



Potential Contaminants

- **Mycotoxins** (e.g., aflatoxin, fumonisin, vomitoxin, ochratoxin & patulin)
- **Heavy metals** (e.g., cadmium, mercury, lead & arsenic)
- **Microbiological hazards** (e.g., *Salmonella*, *E. Coli* O157:H7, Hepatitis A, *Cryptosporidium* & *Giardia*)
- **Pesticides**
- **Polychlorinated Biphenyls (PCBs)**
- **Other contaminants** (e.g., petroleum)



Assessing Flood-affected Fields Before Replanting

- Field history and crop selection
- Time* between the flood event, planting & harvest
- Source of flood waters (e.g., drainage canal, river, or irrigation canal) & potential contributors of human pathogens
- Allowing soils to dry & be reworked prior to planting
- Sampling soil for pathogens or indicator organisms. Note: Can provide valuable information re relative risks, but not a guarantee

* Others rec 30-60 day wait and/or soil testing



Additional Controls

- Segregate flood-affected crops from crops not affected
- Prevent cross-contamination
- A 30-foot buffer zone is generally recommended between flooded areas of fields and areas to be harvested for human consumption
- Check your well



Copies of Flood Guidance

From the internet:

- <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or
- <http://www.regulations.gov>.



Copies of Flood Guidance

Written requests for single copies:

Division of Plant and Dairy Food Safety
Center for Food Safety and Applied
Nutrition (HFS-317)
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Include a self-addressed adhesive label to assist us in
processing your request



How to Comment

Docket No. FDA–2011–D–0733

- **Written comments:**

Division of Dockets Management (HFA–305),
Food and Drug Administration,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

- **Electronic submissions:**

<http://www.regulations.gov>

Include Docket Number above!



For More Information

Yinqing Ma

Center for Food Safety and Applied Nutrition

Office of Food Safety

Food and Drug Administration

5100 Paint Branch Pkwy

College Park, MD, 20740

Yinqing.ma@fda.hhs.gov

240-402-2479

