I. Introduction

The purpose of this document is to provide guidance to growers on how to evaluate the safety of flood-affected food crops for human consumption. This guidance applies to all food crops. Specifically, this document provides guidance on:

- safety of food crops when flood waters contacted the edible portions of the crops;
- safety of food crops when flood waters did NOT contact the edible portions of the crops;
- assessment of flood-affected fields before replanting; and
additional controls to avoid cross-contamination after flooding.

Assuring the safety of flood-affected food crops for human consumption is the responsibility of the growers that produce and market these crops. The recommendations in this guidance do not change the applicability of other federal or state regulations or the grower’s responsibility to comply with those regulations.

This guidance restates existing FDA positions, as described in FDA documents, on the safety of flood-affected food crops, and includes additional information to help growers assess the safety of food from flood-affected crops for human consumption. These FDA documents include: Draft Guidance to Minimize Microbial Food Safety Hazards of Leafy Greens (Ref. 1); A Notice from the Food and Drug Administration to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters for Food Products About the Safety of Food Affected by Hurricane, Flooding, and Power Outages (Ref. 2); and Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce (Ref. 3).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Background

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 (Ref. 1).

Flooding events can present a potentially hazardous public health risk. In some areas, crops may be submerged in flood water which may have been exposed to sewage, chemicals, heavy metals, pathogenic microorganisms or other contaminants. Even if the crop is not completely submerged, there may still be microbial contamination of the edible portion of the crop. There is also the potential for plants to take up chemical contaminants. In addition to the direct presence of contaminants noted above, mold and toxins may develop in the crops as a result of exposure to the water (Ref. 2).

III. Evaluating the Safety of Food from Flood-affected Crops

A. Safety of food crops when flood waters contacted the edible portions of the crops

If the edible portion of a crop is exposed to flood waters, it is considered adulterated under section 402(a)(4) (21 U.S.C. 342(a)(4)) of the Federal Food, Drug, and Cosmetic Act and should not enter human food channels. There is no practical method of reconditioning the edible portion of a crop that will provide a reasonable assurance of human food safety. Therefore, the FDA recommends that these crops be disposed of in a manner that ensures they are kept separate from crops that have not been flood damaged to avoid adulterating "clean" crops (Ref. 1, 2, 3).

Section A applies to ALL food crops, including:

- Surface crops such as leafy greens, tomatoes, string beans, berries, and corn;
- Underground crops, such as peanuts, potatoes, carrots, and garlic[2];
- Crops with a hard outer skin or shell, such as watermelon and winter squash[3];
- Grains, nuts, corns, and similar products stored in bulk[4];
- Others.

B. Safety of food crops when flood waters did NOT contact the edible portions of the crops

For crops that were in or near flooded areas but where flood waters did NOT contact the edible portions of the crops the growers should evaluate the safety of the crops for human consumption on a case-by-case basis for possible adulteration (Ref. 2). We encourage growers to work with state regulators and local FDA offices to assess their unique situations and to take into consideration all possible types and routes of contamination from flood waters in determining whether a particular crop is adulterated.

Factors to consider in terms of evaluation may include:

- Assessment of flood waters
  Flood waters may have been exposed to sewage, chemicals, heavy metals, pathogenic microorganisms or other contaminants (Ref. 2). In addition, there might have been localized catastrophes such as petroleum leak, chemical spills or other disasters due to flooding. Therefore, knowledge of the sources of flood waters and any possible upstream contributors of human pathogens and/or chemical contaminants will help evaluate the likelihood of crop contamination by flood waters (Ref. 2).
- Type of crop and stage of growth (Ref. 2, 8)
The likelihood of contamination may be low if:

- The edible portion of the crop has developed after the flood water receded, or
- The lowest edible portion of the crop was above the floodwaters level with minimum risk of contamination due to splashing; and
- The crop can be harvested without cross-contamination from nearby environment, including flooded soil and flooded portion of the crop.

The likelihood for crops to absorb or internalize potential contaminants from flood waters and/or flooded soil

Although limited information is available regarding the likelihood and the extent for food crops to internalize potential contaminants from flood waters and/or flooded soil, research on plant uptake of contaminants from soil suggests that uptake is likely and the rate of uptake can vary depending on many factors, including contaminant type, plant species, and soil conditions (Ref. 9, 10, 11).

The degree and duration of crop exposure to flood waters and related conditions

The potential impact of flooding on food crops is likely to be dependent on the degree and duration of crop exposure to flood waters. For example:

- The volumes of flood waters (how deep) and/or how long the flood waters were present in the field before receding.
- How quickly the field began to dry out after flood waters receded, taking into consideration soil type, topography and drainage.
- Whether conditions existed that exposed the crop to prolonged periods of moisture and stress which could foster fungal growth, and possibly, development of mycotoxins (Ref. 2).

**Testing:**

FDA recommends that, depending on the results of the assessment described above under section B, the growers consider testing any one or more of the following contaminants, as needed, to determine the suitability for human food use. Sampling should be representative of the crop being evaluated and testing appropriate for the specific crop and flood situation (see below). FDA recommends that growers discuss their testing plans with state and local FDA regulators and technical specialists for case-specific evaluations.

**Contaminants:**

- Mycotoxins, including: aflatoxin, fumonisin, vomitoxin (DON), ochratoxin, and patulin. Analytical testing methods for these mycotoxins can be found in FDA's Food Compliance Program 7307.001, Mycotoxins in Domestic and Imported Foods (http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073294.pdf).

  - Aflatoxin
    - CPG Sec. 555.400 Foods - Adulteration with Aflatoxin (http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074555.htm)
    - CPG Sec. 570.200 Brazil Nuts - Adulteration with Aflatoxin (http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074594.htm)
    - CPG Sec. 570.375 Aflatoxin in Peanuts and Peanut Products (http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074598.htm)
    - CPG Sec. 570.500 Pistachio Nuts - Aflatoxin Adulteration (http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074601.htm)
  
  - Fumonisin
  
  - Vomitoxin (DON)
    - Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat
Products for Human Consumption and Grains and Grain By-Products used for Animal Feed
(http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments /NaturalToxins/ucm120184.htm9)

- Patulin
  - Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice Products
    (http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/NaturalToxins /ucm212520.htm10)

- Heavy metals, including: cadmium, mercury, lead, and arsenic. Analytical testing methods for heavy metals can be found in FDA's Elemental Analysis Manual (EAM) for Food and Related Products
  (http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ElementalAnalysisManualEAM /default.htm11).

- Microbiological hazards of significant public health impact including human pathogens (e.g., Salmonella, E. Coli O157:H7, other Shiga toxin-producing E. coli, Clostridium perfringens), viruses (e.g., Hepatitis A), and parasite (e.g., Cryptosporidium, Giardia). These microbiological hazards should be absent in food crops. Preferred laboratory procedures for microbiological analysis of foods can be found in the FDA's Bacteriological Analytical Manual (BAM)
  (http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM /default.htm12).

- Pesticides. Analytical testing methods for pesticides can be found in FDA's Pesticide Analytical Manual (PAM)
  (http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/PesticideAnalysisManualPAM /default.htm13).

- Polychlorinated Biphenyls (PCBs).
  For total PCB analysis, FDA recommends methods described in Volume 1 of FDA's Pesticide Analytical Manual (PAM), Chapter 3, Chapter 5, and Appendix I

- Other contaminants as appropriate to the specific flood and crop situation. For example, if it is known that a significant amount of petroleum was present in flood water due to a localized catastrophe, the grower may consider testing the crop for any possible petroleum contamination.

Additional information about FDA’s policies on food contaminants and adulteration are available at FDA’s website:

- Food Contaminants & Adulteration (http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration /default.htm16)
- Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed
  (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments /ChemicalContaminantsandPesticides/ucm077969.htm18)

IV. Assessment of Flood-affected Fields before Replanting

FDA recommends not replanting in flooded fields if flood waters have not receded and the soil has not sufficiently dried. In the Draft Guidance to Industry to Minimize Microbial Food Safety Hazards of Leafy Greens (Ref. 1), FDA recommends the following assessment for formerly flooded production ground:

- Assessing field history and crop selection.
- Determining the time interval between the flooding event, crop planting, and crop harvest.
- Determining the source of flood waters (e.g., drainage canal, river, or irrigation canal) and whether there are significant upstream potential contributors of human pathogens.
- Allowing soils to dry sufficiently and be reworked prior to subsequently planting crops on formerly flooded production ground.
- Sampling previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms. Note: Microbial soil sampling can provide valuable information regarding relative risks, but sampling by itself does not guarantee that all raw agricultural commodities grown within the formerly flooded production area are free of the presence of human pathogens.
The waiting period before growers can replant depends on conditions such as temperature, weather, and soil type. Currently, FDA has not completed studies to determine the length of waiting time that is generally considered safe for replanting. State, industry, and university extension specialists have recommended a 30-60 day waiting period and/or soil testing prior to replanting to (Ref. 12, 13, 14, 15). While this time period is generally considered sufficient for fecal contamination to decline, chemical contaminations, if present, may continue to remain in the flood-affected soil (Ref. 12).

V. Additional Controls to Avoid Cross-contamination after Flooding

- **Segregate flood-affected crops from crops not affected.** FDA recommends that for crops that are adulterated by flood waters, the crops should be disposed of in a manner to ensure that they do not contaminate unaffected crops during harvesting, storage or distribution (Ref. 1). For flood-affected crops for which the growers have not yet determined whether they have been contaminated (i.e., the edible portion of crops are not exposed to flood waters), FDA recommends that growers clearly identify and sufficiently segregate these crops to prevent them from contaminating non-flood-affected crops and from entering the food supply inadvertently, pending determination of their disposition.

- **Prevent cross-contamination.** Growers should follow FDA’s *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (Ref. 5) to avoid possible cross-contamination after flooding. Farm equipment should not be used in a non-flooded field after use in a field that was flooded unless the equipment has been cleaned and sanitized first. Workers should wear protective clothing such as rubber boots and rubber gloves when working in fields that were flooded. Protective clothing should be discarded or thoroughly cleaned and disinfected after use.

- **A 30-feet buffer zone is generally recommended** between flooded areas of fields and areas to be harvested for human consumption. This distance is to accommodate a generous turning radius for farm equipment to prevent cross contamination between the flooded and non-flooded fields (Ref. 13, 14).

- **Check your well.** If the well head is under flood water, there is a potential for contamination and the well water quality should be tested before using. Growers may want to have their well examined by a water quality expert. Programs available from County Extension Offices, and state and local Public Health and Environmental Protection Agencies may help growers determine the condition of their wells (Ref. 5).

VI. Additional Resources

As of October 12, 2011, FDA had verified the Web site address for the additional resources it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site resources after October 12, 2011.


- Extension Disaster Education Network (EDEN). *Agriculture issues after a flood*. Available online at [http://eden.lsu.edu/Topics/Hazards/Floods/Pages/AgricultureIssuesAfterFlood.aspx](http://eden.lsu.edu/Topics/Hazards/Floods/Pages/AgricultureIssuesAfterFlood.aspx).


VII. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of October 12, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after October 12, 2011.


2. FDA. 2009b. A Notice from the Food and Drug Administration to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products About the Safety of Food Affected by Hurricanes, Flooding, and Power Outages.


[1] This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] Even though, visually, the underground crops may appear normal after the flood water recedes, they are still at risk for contamination by human pathogens and chemical contaminants because the edible portions of the underground crops may have contacted the flood waters that seeped into the soil. In addition, since the soil has been contaminated by the flood waters, FDA does not believe it is possible to harvest the underground crops without the additional risk of contamination from the flood-affected soil. Therefore, underground crops which have been in soil covered by flood water are adulterated.

[3] Although the surface of these crops is not typically eaten, the potential extent or type of contamination (e.g., chemical or microbial) makes the efficacy of washing in rendering the food safe, even with chlorinated water, too uncertain. As mentioned in existing FDA documents and guidance (Ref. 4, 5, 6), surface contaminants can be moved to the edible part of the commodity as the product is cut/prepared for consumption. Contaminants present in flood water can also be internalized into the edible portion of the commodity through bruised or damaged areas, which may not always be visually apparent.

[4] In addition to risk posed by microbial and chemical contaminants in flood water, these products are especially susceptible to fungal growth and possible mycotoxin development (Ref. 7).

[5] For example, in one study, the accumulation of cadmium (Cd) in plants grown in contaminated soil was shown to be generally the highest for leafy vegetables, moderate for root vegetables, and the lowest for legumes (Ref. 9). However, even for low accumulation legume plants (e.g., peas, beans), significantly higher levels of cadmium (Cd) were detected in the crops that were grown in contaminated soil when compared to those that were grown in non-contaminated soil (Ref. 9). Root vegetables such as carrots and onions also showed substantial uptake of lead (Pb) from the contaminated soil (Ref. 9).