

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

5000.7

11/9/18

VERIFICATION OF ADEQUATE CONTROLS AT ESTABLISHMENTS IN AREAS AFFECTED BY NATURAL DISASTER

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) assigned to establishments in areas affected by a natural disaster, such as hurricanes, tornadoes, floods, earthquakes, or wildfires. IPP are to inform affected establishments that they are required to reassess their HACCP plans, and are to verify that establishments take appropriate actions to produce wholesome and unadulterated product.

KEY POINTS:

- *Verification of HACCP reassessment records after a natural disaster*
- *Verification of Sanitation SOP and sanitation performance standards*
- *Establishments with ready-to-eat (RTE) meat or poultry products may trigger Agency risk-based sampling*

II. BACKGROUND

A. Review of FSIS data and published research indicates the potential for an increase in *Salmonella* incidence in regulated food products following flood events. In addition, FSIS's recent review of noncompliance records has shown a spiked increase in sanitation and HACCP noncompliance 1-90 days after heavy rain periods.

B. Under the regulations, every establishment is to reassess the adequacy of its HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. A hurricane, tornado, flood, earthquake, wildfire or other natural disaster is a "change" that could affect the hazard analysis or alter the HACCP plan. If an establishment's hazard analysis documents that a hazard is not reasonably likely to occur based on a prerequisite program, the reassessment of the HACCP plan is to also include consideration of whether that prerequisite program needs modification to mitigate any effects caused by the natural disaster in affected areas.

III. COMMUNICATION WITH ESTABLISHMENT MANAGEMENT

IPP assigned to establishments in areas affected by natural disasters are to inform establishment management that:

1. Under the regulations (9 CFR 417.4), the establishment is required to reassess its HACCP plans, in light of the natural disaster, to determine whether the HACCP plans, including supporting prerequisite programs, are still effective or need to be changed to address new hazards, such as higher levels of pathogens or sanitation issues;
2. IPP verification activities will gather information to determine whether the establishment's Sanitation SOPs and any cleaning and related monitoring are adequate to address any additional sanitation problems related to the natural disaster;
3. IPP verification activities will include a review of the establishment's testing data to identify any adverse trends that may indicate problems with microbial contamination; and
4. In establishments producing ready-to-eat (RTE) products that were affected by service failures based on flooding, prolonged electric service failure, and boil water orders, or physical damage to production areas (as opposed to closure for non-facility reasons such as road conditions or employee absences), FSIS may schedule intensified verification testing (IVT) for *Listeria monocytogenes* to verify restoration of sanitary conditions upon re-starting operations.

IV. IPP RESPONSIBILITIES

A. IPP are to determine whether the establishment has conducted or intends to conduct a reassessment of its HACCP plans. If the establishment has conducted a reassessment, IPP are to verify that the establishment documented the reasons for any changes to the HACCP plan or reasons for not changing the HACCP plan (9 CFR 417.4(a)(3)(ii)).

NOTE: IPP are to add the appropriate directed HACCP verification task to the Task Calendar with the "Reason" selected "As Instructed in Policy Issuance".

B. IPP are to verify that establishments maintain sanitary conditions in accordance with the sanitation performance standards (9 CFR 416.1-416.6) and Sanitation SOP requirements (9 CFR 416.11-416.17) by following the instructions in [FSIS Directive 5000.1](#), *Verifying an Establishment's Food Safety System*.

C. IPP in establishments that produce RTE products are to alert the District Office (DO) through their supervisory chain if those establishments were directly affected by flooding, electrical service failure, boil water orders, or physical damage to production areas of the facility.

D. IPP are to review establishment testing data following the instructions in [FSIS Directive 5000.2](#), *Review of Establishment Data by Inspection Program Personnel*, and determine whether any adverse trends exist indicating any contamination problems.

1. IPP in slaughter establishments in the affected areas are to pay particular attention to any trends in establishment sampling results (e.g., *Salmonella*, generic *E. coli*) that may indicate increasing contamination of carcasses with microbial pathogens;
2. IPP are to be aware that these trends may become apparent up to 3 months or more after the natural disaster;
3. IPP are to document any adverse trends observed or identified during the performance of their verification activities and discuss during the weekly meeting with establishment employees. Adverse trends may or may not be related to natural disasters; and

4. Additionally, if IPP identify such trends, they are to alert the DO through their supervisory chain and share a copy of the weekly meeting documenting the discussion with the establishment.

E. IPP are to add a directed “Review of Establishment Data” task with the “Reason” selected “As Instructed in Policy Issuance.”

F. When IPP determine that the establishment has not reassessed its HACCP plans or if IPP have any enforcement related questions, they are to contact their immediate supervisor.

G. If IPP are unsure if a trend is emerging they are to consult their immediate supervisor.

V. DO RESPONSIBILITIES

A. DO personnel are to:

1. Initiate “for cause” intensified verification testing (IVT) in RTE establishments that are directly affected by hurricanes, tornadoes, floods, earthquakes, wildfires, prolonged electric service failure, boil water orders, or other impacts from natural disasters following the instructions in [FSIS Directive 10,300.1](#) *Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria monocytogenes*;
2. Prioritize RTE establishments using Alternative 3 (9 CFR 430.4(b)(3), use of sanitation procedures only, to prevent *Listeria* contamination and then prioritize RTE establishments producing shelf-stable products;
3. Follow [FSIS Directive 5100.4](#) *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*; and
4. Indicate in the PHIS tool that the IVT is being scheduled for the PHRE or FSA in accordance with FSIS Directive 5000.7.

B. DO personnel are to assign appropriate personnel to verify HACCP reassessment and subsequent actions by establishments where establishment or FSIS sampling results indicate a trend of increasing contamination with microbial pathogens in the period following a natural disaster.

VI. QUESTIONS

Refer questions regarding this notice and EIAO methodology or sampling to the Office of Policy and Program Development through [askFSIS](#). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided.

Subject Field: Enter **Directive 5000.7**
Question Field: **Enter your question with as much detail as possible.**
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select from the drop-down menu **Regulations/Agency Issuances** or **EIAO Methodology or Sampling**.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**

A handwritten signature in black ink that reads "Subrata J. Wagner". The signature is written in a cursive style with a large, stylized initial 'S'.

Assistant Administrator
Office of Policy and Program Development