

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

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# FSIS NOTICE

66-12

10/24/12

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## ACTIONS TO TAKE WHEN AN ESTABLISHMENT SUBSTANTIALLY OR TEMPORARILY ALTERS ITS *SALMONELLA* CONTROL PROCESS

### I. PURPOSE

Notice 42-11 was issued in August 2011 to provide inspection program personnel (IPP) with instruction on how to request expedited scheduling of FSIS *Salmonella* verification sampling when an establishment has substantially altered its food safety system or temporarily changed its process without validation of the HACCP plan. This notice provides IPP with new examples of situations where requesting an expedited verification set is warranted and with updated instructions so that appropriate requests are made.

### II. BACKGROUND

Following a *Salmonella* verification set, an establishment may make substantial changes to its food safety system, such as removing chlorine-based compounds from the process or substituting other antimicrobial chemicals. Such changes are acceptable if validated; however, in some cases, Agency testing might be warranted to verify that the food produced by the modified system is safe. Alternatively, an establishment may temporarily change its food safety process during FSIS *Salmonella* verification sampling, then return to pre-sampling conditions once FSIS sampling is completed. Based on the evaluation of data collected since the implementation of notice 42-11, such temporary or unvalidated changes are not reported very frequently. This fact could be because such changes are not a common industry practice. Alternately, the infrequent reporting may be because IPP remain unaware of the need to look for and report such changes or do not understand what to look for and assess in the documentation.

### III. ESTABLISHMENT'S USE OF AN ALTERNATIVE ANTIMICROBIAL PROCESS DURING OR AFTER AN FSIS *SALMONELLA* SAMPLE SET

A. Based on requirements in 9 CFR 417.2(a) and 9 CFR 417.5(a)(1), IPP are to verify whether changes to a food safety system are consistently accompanied by HACCP supporting documentation, including during and after FSIS *Salmonella* verification testing. In addition, IPP are to determine whether an establishment altered its food safety system to coincide with the FSIS *Salmonella* verification sample set. The Public Health Veterinarian (PHV) is to file in the government office, or by means of PHIS, a Memorandum of Interview (MOI) detailing any changes or modifications that an establishment makes in its process when FSIS conducts a *Salmonella* verification sample set. The PHV is to present the information to the establishment management for discussion at the next weekly meeting (see [FSIS Directive 5010.1, Food Safety Related Topics For Discussion During Weekly Meetings](#), [FSIS Directive 5000.1, Verifying an Establishment's Food Safety System](#), and [FSIS PHIS Directive 5000.1](#)).

B. Examples of changes typically covered by this notice include, but are not limited to (see Sections D-H for specific instructions and actions to take):

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**DISTRIBUTION:** Electronic

**NOTICE EXPIRES:** 11/1/13

**OPI:** OPPD

1. Temporarily changing antimicrobials used in a poultry chiller only during a *Salmonella/Campylobacter* verification set, such as replacing chlorine with peroxyacetic acid (PAA).
2. Substantially increasing levels of antimicrobials above normal operating parameters only during a *Salmonella/Campylobacter* verification set. This type of change includes increasing to the upper bounds of levels within a validated system if the establishment routinely operates at the lower bounds. For example, if the establishment's validated range of chlorine in potable water measured at the chiller fresh water intake is 20-50 ppm, it routinely maintains a level of 20 ppm but increases the level to 50 ppm only during the set.
3. Permanent replacement of systemic hyper-chlorinated water with non-chlorine-based antimicrobials since the last *Salmonella/Campylobacter* verification set without proper validation.

**NOTE:** For instructions on follow-up actions to take in response to the situations described in these examples, see paragraphs G. and H. below.

C. Examples of changes typically NOT covered by this notice include, but are not limited to:

1. Replacing equipment that will be operated in the same manner as old equipment. For example, replacing one poultry immersion chiller with another without changing antimicrobial or product temperature parameters.
2. Permanently adding or removing antimicrobials at various steps in the process if the changes have been properly reflected in the establishment's food safety system with appropriate supporting documentation.

D. If temporary changes, modifications, or inconsistencies in an establishment's production practices that coincide with the FSIS sample set are confirmed through documentation and discussions, the PHV is to inform the District Office (DO) through the supervisory chain. At the same time, the PHV is to submit the information through [askFSIS](#) directly to the *Salmonella* and *Campylobacter* Coordination Group (SCCG) and to request the scheduling of an additional *Salmonella/Campylobacter* verification set for the establishment.

The scheduling request is to be routed through the following askFSIS queue:

- Product (General Inspection Policy)
  - Category (Sampling)
    - Sub-category (Request Expedited Salmonella Verification Set)

The PHV is to include the following information in the request:

1. Subject line: "Request Expedited Salmonella Verification Set";
2. Message text: the establishment name and number; and
3. A detailed summary of PHV and Frontline Supervisor (FLS) observations that might support the request for additional *Salmonella* verification sampling.

**NOTE:** This queue is ONLY for requests for expedited sets covered by this Notice. See Section V below regarding how to submit questions related to this notice or *Salmonella* sampling.

After review of the submitted information, the SCCG will send a reply, usually within 30 days through normal askFSIS incident response procedures, stating whether an additional *Salmonella* verification set will be initiated for the establishment.

E. If the request for additional scheduling occurs when a *Salmonella* verification set is still in progress, the current set will be carried to completion with the potential for another full set to follow. Higher priority for set scheduling will be given to establishments that do not collect daily *Salmonella* and other public health-related data, while lower priority will go to establishments demonstrating ongoing process control under the *Salmonella* Initiative Program (see [FSIS Directive 5020.1, Verification of Salmonella Initiative Program](#)).

F. If the establishment is not participating in SIP, IPP are to review the establishment's microbial testing data (see [FSIS Dir. 5000.2, Review of Establishment Testing Data By Inspection Program Personnel](#) and [FSIS Notice 61-11, Reviewing Establishment Salmonella Control Programs for Raw Classes of Meat and Poultry Product](#)) and then to compare recent production period data to the results from the beginning of the *Salmonella* verification set. Differing results may be related to variability in interventions being used by the establishment.

G. The PHV is to review the establishment's supporting documentation and to issue an NR if the interventions are not implemented in a manner that is consistent with their supporting documentation. For example, the establishment's food safety system might ordinarily rely on the direct application of a particular pathogen reduction treatment system, but the establishment varies the concentration without accompanying support in order to accommodate a specific purchase specification (e.g., export), or when FSIS verification sampling is conducted.

H. If IPP and the FLS have evidence that the establishment changes to an unsupported alternative process when FSIS is not collecting samples, or continues to have noncompliances associated with unsupported decisions, the DO is to consider scheduling a for-cause Food Safety Assessment (FSA). The FSA is to be used to determine whether the hazard analysis and supporting documentation associated with the alternative or modified process demonstrates that the process will prevent or control *Salmonella* in a manner that is at least as protective as the process used during FSIS *Salmonella* verification testing.

#### IV. DATA ANALYSIS

The Office of Policy and Program Development (OPPD) will review IPP requests submitted to the askFSIS "Request *Salmonella* Verification Set" queue and assess the overall scope and prevalence of the issue and evaluate the need for updated instructions to the field or changes in policy.

#### V. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Division through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

- Subject Field: Enter **FSIS Notice 66-12** or **Salmonella Verification**
- Question Field: Enter your question with as much detail as possible.
- Product Field: In the drop-down menu select **General Inspection Policy**
- Category Field: In the drop-down menu select **Sampling**
- Policy Arena: Select **Domestic (U.S.) Only** or **International (Import/Export)** from the drop-down menu.
- Sub-category: **(Request Salmonella Verification Set)**

When all fields are complete, press the **Submit** button.

A handwritten signature in black ink, reading "Rachel A. Edelstein". The signature is written in a cursive style with a large initial 'R' and 'E'.

Assistant Administrator  
Office of Policy and Program Development