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

FSIS DIRECTIVE

5000.2
Revision 1

6/19/08

REVIEW OF ESTABLISHMENT TESTING DATA BY INSPECTION PROGRAM PERSONNEL

I. PURPOSE

The purpose of this directive is to clarify that inspection program personnel have access to a wide range of records under the Hazard Analysis and Critical Control (HACCP) regulations (9 CFR part 417), and that they are to use that access to review certain types of records on a regular basis.

NOTE: This directive does not address Sanitation Standard Operating Procedures (Sanitation SOPs) records verification. All instructions related to verification of Sanitation SOP records are addressed in FSIS Directive 5000.1, Chapter I.

II. CANCELLATION

FSIS Directive 5000.2, Review of Establishment Data by Inspection Program Personnel, dated 3/31/04

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to instruct inspection program personnel on how to document that they conducted the weekly record review and to provide additional information on how to review establishment records.

IV. REFERENCES

9 CFR part 417
FSIS Directive 5000.1

V. BACKGROUND

Under the HACCP regulations, an establishment is required to keep records related to the HACCP plan, including all decisionmaking documentation associated with its development and all records associated with its operation (i.e., monitoring, verification, and corrective action). To develop a HACCP plan, under 9 CFR 417.2(a)(1), an establishment is to have a written hazard analysis that reflects its determination of the food safety hazards that are reasonably likely to occur in the production process and to identify the preventive measures that the establishment will employ to control those hazards. The establishment develops a flow chart that lists the steps of each process and product flow in the establishment and that identifies the intended use or consumers of the finished product (9 CFR 417.2(a)(2)). In addition, under 9 CFR 417.5(a)(1), establishments are to maintain "…the written hazard analysis prescribed in 9 CFR 417.2(a) …, including all supporting documentation."

Given these regulatory requirements, the results of any testing that is performed by the establishment may have an impact on the establishment's hazard analysis, whether or not such testing is incorporated into an actual HACCP plan, referenced in a HACCP plan, or considered as a separate activity (e.g., a prerequisite program or testing related to ready-to-eat products). Therefore, records of the testing are subject to FSIS review and are to be available to FSIS personnel.

The activities in this directive are directly related to those found in FSIS Directive 5000.1, Chapter II - HACCP. Inspection program personnel are to verify the proper execution of an establishment's HACCP plans and any prerequisite programs as set out in FSIS Directive 5000.1. Examples of such test results include, but are not limited to, testing records, data, and supporting documentation associated with testing associated with prerequisite programs and good manufacturing procedures; and testing conducted for the establishment's business customers.

VI. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. Inspection program personnel are to be aware of any testing that is performed by the establishment that may have an impact on the establishment's hazard analysis and are to ask establishment management to make available for review the data that is generated by such testing so that it is available when inspection program personnel are verifying HACCP records.

B. At least once a week during the performance of an HACCP 01 procedure, inspection program personnel are to review the results of any testing that the establishment has performed.

C. When reviewing the test results, inspection program personnel should seek answers to questions such as:

1. is there documentation that supports the frequency of the testing that the establishment employs?

2. at what point in the process does the testing occur?

3. does establishment use the test results in a manner that checks the proper execution of the point in the process where the testing occurs?

4. are the results indicative that a food safety concern may be developing (e.g., over a month's time are there increasing numbers of *Listeria monocytogenes* or *Listeria* spp positives or *E. coli* O157:H7)?

5. is the establishment reacting to the situation? If so, what is it doing (e.g., taking corrective actions, reassessing its HACCP plan to determine whether a prerequisite is adequate, increasing the amount of testing)?

6. do results indicate that a potential food safety concern is decreasing (e.g., over one month's time, the number of positive results for *Listeria monocytogenes* or *Listeria* spp positives or *E. coli* O157:H7 decreased)?

7. if pathogen or indicator organism positive results have decreased, does the establishment plan to reduce testing frequencies? If so, how it will ensure that such modifications to its testing program will not affect the likelihood of finding pathogens?

8. are there operational results that correlate with the testing results (e.g., does an reduction in *Listeria* positive results coincide with a new cleaning regime; conversely, has the establishment not been performing some activities called for in its SSOP at the same time that there has been an increase in positive results in Listeria testing)?

NOTE: The purpose for the above questions is to help inspection program personnel gain a full understanding of the establishment's food safety system. A negative response to any of these questions does not automatically mean there is a noncompliance. Inspection program personnel are to consider all available information in order to make any determination regarding possible noncompliance and a possible trend of noncompliance in accordance with the instructions set out in FSIS Directive 5000.1.

D. At the weekly meeting, inspection program personnel are to raise any questions they have regarding any tests results that may have an impact on the establishment's hazard analysis. When necessary, inspection program are to raise concerns, through supervisory channels, to the District Office.

VII. DOCUMENTING THE REVIEW

A. Inspection program personnel are to document each week in a memorandum to the file that they conducted the records review, and that they discussed, if indicated, any concerns with the establishment at the weekly meeting. In the documentation, they are to:

1. briefly list what tests results they reviewed and for what time period;

2. describe the specific concerns, if any, that they discussed with the establishment;

3. state how the establishment responded.

B. If inspection program personnel have concerns about how an establishment responds to what was discussed at the weekly meeting, they are to raise those concerns through supervisory channels.

C. Front-line Supervisors are to periodically review the documentation above and raise any concerns with the in-plant team and, as necessary, the District Office.

VIII. DISTRICT OFFICE RESPONSIBILITIES

Based on the concerns raised by inspection program personnel through supervisory channels, District Offices may determine that an Enforcement Investigation Analysis Officer needs to conduct a food safety assessment to assess factors such as what the tests results reveal about food safety, and whether the design of testing, procedures or prerequisite programs are adequately supported by the decisions made in the hazard analysis.

Refer questions to the Policy Development Division at 1-800-233-3935.

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