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

FSIS DIRECTIVE

5000.2
Revision 2

12/4/08

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.

II. CANCELLATION

FSIS Directive 5000.2, Revision 1, Review of Establishment Data by Inspection Program Personnel, dated 6/19/08

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to clarify what records inspection program personnel are to review and how they are to document the review. Specifically, FSIS has attached a question and answer that explains what data are available to the Agency.

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 that 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 in assessing a prerequisite program, 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 that could bear on the hazard analysis.

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 that may have an impact on the establishment's hazard analysis.

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

NOTE: Inspection program personnel are not to request that the establishment provide a written response to these questions.

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

2. If the testing is used by the establishment to reflect the effects of a prerequisite program do the results support the decision-making for the design of the program? (also see FSIS Directive 5000.1, Chapter II).

3. At what point in the process does the testing occur?

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

5. 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)?

6. 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)?

7. 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)?

8. 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?

9. 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 as to whether there is a basis for concern about how the establishment is implementing its system, or about how it is reacting to the results of its testing. However, inspection program personnel are not to write a noncompliance record on the basis of their review of the records (see VI D). Inspection program personnel should keep in mind that the Agency's policy is to encourage establishments to do testing and to and address any problems that exist.

D. At the weekly meeting as set out in FSIS Directive 5000.1, 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.

NOTE: At establishments where there is more than one shift, the notes from the weekly meeting are to be available to inspection program personnel on each shift. It is not required for each shift to hold the weekly meeting that is set out in FSIS Directive 5000.1.

VII. DOCUMENTING THE REVIEW

A. Inspection program personnel are to document each week in the weekly memorandum to the file as described in FSIS Directive 5000.1 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, or questions about whether a particular type of data is available to the Agency, they are to raise those concerns or questions through supervisory channels.

C. Frontline 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 regarding this directive to the Policy Development Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

Attachment 1

QUESTION AND ANSWER

Background: In the wake of the reissuance of FSIS Directive 5000.2, industry has raised questions as to exactly what establishment testing data need to be made available to FSIS inspection program personnel. Inspection program personnel have reported that establishments have refused to give them access to the results of equipment swab tests, microbiological testing of marinade solutions that are to be reused, and *Salmonella* testing. Establishments have refused to give access to these testing results on the grounds that the results are trade secrets, the testing is done for customers who do not want the results shared with the Agency, and the Agency is only entitled access to records upon which the establishment affirmatively relies.

Question: What testing records need to be made available to FSIS personnel?

Answer: The Agency has made clear that it has access to all establishment testing records that could disclose the existence of an insanitary condition that needs to be addressed in an establishment's HACCP plan, Sanitation Standard Operating Procedure, or prerequisite programs. This authority to have access to these records derives directly from 9 CFR 417.5(a)(1), which states that an establishment must maintain the written hazard analysis prescribed in 9 CFR 417.2(a) and all supporting documentation. See also 21 U.S.C. 642. The purpose of a hazard analysis is to identify all relevant hazards and to determine which are reasonably likely to occur in the production process (9 CFR 417.2(a)(1)). Significantly, the hazard analysis is not intended to be a static document. Under 9 CFR 417.4(a)(3), establishments are to reassess their HACCP plans *whenever* any changes occur that could affect the hazard analysis.

Thus, whenever an establishment does any testing that could reveal that an insanitary condition exists or is developing; that bears on the likelihood of a hazard developing; or that indicates that sanitary conditions exist, under 9 CFR 417.5(a)(1), FSIS has access to the record of the results of that testing. Access is necessary so that FSIS can verify the on-going adequacy of the establishment's hazard analysis.

For example, if a purchaser requires that a supplier conduct qualitative and quantitative tests for aerobic plate counts (APC), and the purchaser requires that the APC quantitative level not exceed a specified boundary as an indication of the sanitary condition under which the product is produced, the results of such testing must be available to FSIS. The supplier would be making a determination as to whether to adjust its process controls based on the results of the testing, and this determination bears directly on the establishment's hazard analysis. In contrast, in this example, if the purchaser does not set a boundary for APC, and there is no quantitative level for APC that would cause rejection of the product, the testing would not bear on the determination of whether there is an insanitary condition.

The argument that the testing is a trade secret does not provide a basis not to share the information with FSIS. FSIS has authority to protect trade secret information under the

Freedom of Information Act. This authority is meaningless unless the Agency has access to such information. The fact that a customer does not want the information shared with the Agency is irrelevant. The Agency's HACCP regulations have the force and effect of law and thus must be followed by the establishment. Finally, in some circumstances, the establishment clearly relies on the testing that it does. Failing to do so could cause the establishment to miss a significant problem in its HACCP system and thus to produce product under insanitary conditions that may render the product injurious to health. Consequently, establishments pay close attention to the results of the testing in which FSIS has an interest.

For all the foregoing reasons, FSIS has access to the results of all testing done by an establishment that could disclose the existence of a condition that needs to be addressed in the establishment's HACCP system.