

## **Review of Establishment Data Task FSIS Directive 5000.2**

### **Objectives**

Upon completion of this training module, Inspection Program Personnel (IPP) will be able to:

1. Explain the purpose of the Review of Establishment Data task.
2. Identify the kinds of monitoring and testing records that are subject to IPP review when performing the Review of Establishment Data task.
3. Describe how to assess the significance of information gathered during the Review of Establishment Data task.
4. Explain how to follow up on questions or concerns identified when performing the Review of Establishment Data task.
5. Explain how the Review of Establishment Data task is documented in PHIS.
6. Describe what is done if establishment management refuses access to records impacting its food safety system.

### **Introduction**

Establishments may conduct certain testing or monitoring activities that are not a part of their HACCP plans or Sanitation SOPs. For example, establishments may perform testing or monitoring activities as a part of a prerequisite program or conduct product testing to comply with certain specifications of its customers. Data generated by such activities may not even be referenced in a hazard analysis. Nonetheless, these activities may provide information relevant to the effectiveness of establishments' food safety systems. In other words, the data may raise questions or concerns about the adequacy of an establishment's hazard analysis.

Whenever the results of testing and monitoring activities provide information relevant to the adequacy of decisions made in a hazard analysis, FSIS considers records of these results to be supporting documentation for that hazard analysis. Such records must be maintained by the establishment and made available for FSIS review. A prudent establishment will consider the significance of this information with respect to the overall effectiveness of its food safety system, and respond to the results as necessary.

IPP should be aware of all monitoring and testing related to food safety conducted by an establishment, including monitoring and testing not referenced in the hazard analysis and not included as components of the establishment's

Sanitation SOPs or HACCP plan. FSIS Directive 5000.2 Rev. 2 specifies that at least once per week IPP are to review the results of any such monitoring and testing. In this training module we discuss the methodology for reviewing such data. The Review of Establishment Data task helps IPP gain a full understanding of the establishment's food safety system. Considering the significance of this information in the context of the establishment's food safety system may identify potential vulnerabilities that otherwise may not be recognized when performing other HACCP and sanitation inspection tasks.

## Records Subject to the Review of Establishment Data Task

The *Federal Meat Inspection Act* (Section 642) and the *Poultry Products Inspection Act* (Section 460(b)) both establish the legal authority for requiring establishments to maintain a broad range of records. In addition, the Acts provide FSIS the authority to access any required records as necessary. FSIS has made clear to the regulated industries that IPP have the authority to **access all establishment records that could disclose the existence of an insanitary condition** which needs to be addressed in an establishment's HACCP plan, Sanitation SOPs, or prerequisite programs.

The regulatory authority to have access to records, which may have some bearing on the hazard analysis, 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. Furthermore, establishments are required by 9 CFR 417.5(f) to make all records required by 9 CFR 417 available for official review.

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)). A hazard analysis (and any documentation supporting the decisions in that hazard analysis) is not intended to be a static document. At any time, additional information or data may call into question the adequacy of an establishment's hazard analysis. This information or data may not be specifically referenced in the hazard analysis or generated through implementation of the establishment's HACCP plan or Sanitation SOPs.

FSIS Directive 5000.2 specifies that IPP have access to any type of record maintained by the establishment if the record relates to the establishment maintaining its food safety system. Establishments must decide what type and frequency of testing is necessary to support the decisions made in its hazard analysis. Thus, the establishment decides which testing programs are necessary to ensure food safety and which testing programs are unrelated to food safety. **However, the establishment would have to explain to IPP why certain test records are not related to food safety and do not impact the hazard analysis.** If IPP learn of a testing program and have questions about whether

records of that testing program should be included in the Review of Establishment Data task, they should seek guidance from their supervisors and askFSIS.

NOTE: The Review of Establishment Data task targets records of monitoring and testing results that bear on food safety, not product quality concerns. Certain regulatory product quality concerns would be verified through non-food safety, other consumer protection (OCP) tasks instead of the Review of Establishment Data task.

Obviously, IPP should question why the results of any testing for pathogens conducted to meet purchase specifications or for other purposes would not affect the hazard analysis. It is not unusual, though, for many establishments to conduct testing of non-product contact surfaces or finished product for generic microbes such as aerobic plate counts (APCs), generic coliform bacteria, or other non-pathogenic microbes. Establishments may use such testing to provide information about product quality (e.g., shelf life) or to meet certain customer purchase specifications. Generally, such test results can also have implications for food safety. For example, if non-pathogen test results are used to ensure that the production process controls the overall level of microbes in the product, such test results may affect the hazard analysis, because the production process may be modified in response to microbial levels. In these situations, the test results should be made available to IPP for review. If purchase specifications call for testing of non-pathogens and the results are for information purposes only, those results would not affect the hazard analysis and generally would not have to be made available to IPP for review.

**EXAMPLE 1:**

One of the establishment's customers requires the establishment to conduct quantitative aerobic plate counts (APCs) on product contact surfaces during operations. The customer requires that the APC quantitative level not exceed a specified limit as an indication of the sanitary condition under which the product is produced. The establishment does not reference this testing program in its hazard analysis, and it is not a component of its HACCP plan or Sanitation SOPs. However, the results of this testing should be made available to IPP and included in their Review of Establishment Data task, because the establishment would be making a determination as to whether to adjust its process controls based on the results of the testing. This determination bears directly on the establishment's hazard analysis even if this testing program is not referenced in the hazard analysis. Alternatively, if the customer had not set a limit for the APC results that would cause rejection of the product, the testing would not bear on the determination of whether there is an insanitary condition and would not be subject to the Review of Establishment Data task.

For some tests, there may be no established industry-wide standards for what represents acceptable vs. unacceptable. ATP bioluminescence testing to assess

the cleanliness of surfaces is one example. Even when there are no industry standards for a particular test, if the test results are related to decisions in the food safety system, these results must be available to IPP for review. When reviewing the results of tests for which there are no industry standards, IPP would verify that an establishment is responding appropriately to its results based on the establishment's standards.

The types of records subject to the Review of Establishment Data task are not limited to records of microbial testing. For example, some establishments may include metal detection in their process to meet some customer purchase specification. The establishment's hazard analysis may reference preventive maintenance programs and visual checks for metal contamination as support for metal being not reasonably likely to occur, but not include the customer-required metal detection program as additional support. Nonetheless, the metal detection program has implications for food safety in such an establishment, and records associated with the metal detection program should be made available to IPP for review.

In addition to the results of any monitoring or test results, IPP also have access to any written procedures associated with those results. This would include information such as the methods of sample collection and analysis or the procedure for conducting some monitoring activity.

## **Performing the PHIS Review of Establishment Data Task**

At least once a week IPP should schedule and perform the PHIS Review of Establishment Data task. IPP review the results of any testing that the establishment has performed that may have an impact on the establishment's hazard analysis.

NOTE: Prior to the implementation of PHIS, reviews of establishment data were done during the performance of a HACCP 01 procedure. With the implementation of PHIS the HACCP 01 methodology was discontinued, and these reviews were defined as a specific PHIS task, the Review of Establishment Data task. FSIS Directive 5000.2 will be updated (from Revision 2 to Revision 3) to reflect this change.

### **Gathering Information**

When reviewing such monitoring and test results, inspection program personnel are to consider questions such as:

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

2. If the establishment uses the testing to reflect the effects of a prerequisite program do the results support the decision-making for the design of the program?
3. At what point in the process does the testing occur?
4. Does the establishment use the test results in a manner that checks the proper execution of some activity at the point in the process where the testing occurs?
5. Do the results indicate that a food safety concern may be developing?
6. Is the establishment reacting to the situation? If so, what is it doing?
7. Do results indicate that a potential food safety concern is decreasing?
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? For example, does a reduction in microbial counts coincide with a new cleaning regimen, or conversely, has there been an increase in microbial counts during a time when the establishment failed to adequately implement some Sanitation SOP activities?

### **Assessing Information**

A negative response to any of the questions above does not automatically mean there is a noncompliance or inadequate hazard analysis. IPP 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, IPP are not to write a noncompliance record on the basis of their review of these records. IPP should keep in mind that the Agency's policy is to encourage establishments to do testing and to address any problems that exist.

At weekly meetings with establishment management (see FSIS PHIS Directive 5000.1 & FSIS Directive 5010.1, Rev. 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 personnel are to raise concerns, through supervisory channels, to the District Office.

### **Documenting the Review of Establishment Data Task**

As part of documenting the weekly Memorandum of Interview (MOI), IPP are to indicate that they conducted the Review of Establishment Data task, and that they discussed, if indicated, any concerns with the establishment at the weekly meeting. In the MOI, IPP 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

Anytime IPP 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. Frontline Supervisors will periodically review the documentation above and raise any concerns with the in-plant team and, as necessary, the District Office. Based on the concerns raised by IPP 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.

Once IPP have conducted the Review of Establishment Data task, discussed any concerns with plant management, and included the items above in the MOI, they are to indicate within PHIS that the inspection task has been completed.

## **Refusal of Access to Records**

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.

The argument that the testing is a trade secret does not provide a basis not to share the information with FSIS. FSIS has authority and responsibility to protect trade secret information under the *Freedom of Information Act*. Such 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.

If the Inspection Program Personnel have questions about whether a particular type of data is available to the Agency, they are to advise their supervisor of the situation. As indicated above, an establishment is obligated to provide access to HACCP plans and other establishment data by 9 CFR 417.5(f). If an establishment refuses to provide access to its HACCP plan or other supporting documentation for review and recording of information into PHIS, IPP are to

record a noncompliance, citing 9 CFR 417.5(f). IPP are then to discuss this noncompliance with establishment management at the next weekly meeting, and document that fact and any establishment response in the MOI. If the establishment continues in its refusal, IPP are to immediately contact their Frontline Supervisor, who will in turn inform the District Manager (DM) of the establishment's refusal. The DM, or designee, will contact establishment management and discuss the issue. If the establishment continues to refuse, the DM will instruct IPP to take an official control action by withholding inspection as defined under 9 CFR 500.1(b). The DM will then document the incident in a letter to the establishment, officially informing it that FSIS has withheld inspection under 9 CFR 500.3(a)(6) because the establishment has interfered with an FSIS inspector performing his inspection duties. The DM will lift the withholding action when the establishment has provided its HACCP plan and supporting documentation to IPP.

**EXAMPLE 2:**

You are assigned to a large sliced deli meat establishment. While performing the Preoperational Review & Observation task in the post-lethality slicing and packaging room you observe QA personnel collecting environmental swabs in the area. Later, you proceed to the on-site microbiology laboratory to ask about the environmental swab sample collection observed earlier. The microbiologist explains that a customer requires quantitative tests for Aerobic Plate Counts as an indicator of adequate sanitation. He points to APC plates resting by the colony counter and incubator, and indicates that is what he's working on now. You request the APC records. The microbiologist states that you will have to see the plant manager about that. By this time, you must return to the inspection office to retrieve your agenda for the weekly meeting with plant management, which begins in a few minutes. You also decide to take a copy of FSIS Directive 5000.2 to the meeting. During the meeting, you provide a copy of the directive to the plant manager and summarize the directive's purpose. You discuss the observed environmental swabbing and discussion with the microbiologist today. You again request to review the APC test results. The manager informs you that these records are not subject to FSIS review because they were created solely to meet a client's purchase specifications and are not associated with the establishment's HACCP plan. You advise the manager that the records are subject to review by FSIS because the results reflect sanitary conditions within the post-lethality processing environment and would have bearing on decisions made in the hazard analysis at the slicing and packaging step of the process. You further explain that these records represent a form of supporting documentation required by 9 CFR 417.5(a)(1); therefore access must be granted in order to be in compliance with 9 CFR 417.5(f). The manager agrees to provide the APC records and sends the HACCP coordinator to retrieve the records from the microbiology lab so that you can review them and ask any additional questions during the meeting.