PHIS Q&A – July 14, 2011 Industry Meeting

Construction

1. **What is considered a construction project? New equipment - remodeling - erecting new building. What is the difference between construction and a project? Is this a RTE focus vs. raw meat and poultry?**

   FSIS Inspection Program Personnel (IPP) are to capture large scale construction projects that alter normal production routines in areas where food is processed or held. During these projects, establishments take special precautions to protect product. Particular attention is focused upon projects within the ready-to-eat (RTE) processing environment.

   General, routine plant maintenance projects would not be recorded, but those that potentially impact food safety and may result in product contamination or adulteration would need to be noted (e.g., removal of drop ceilings, replacement/modification of RTE slicers).

Pre-requisite Programs

2. **What are the decision requirements that an IPP would use to write an NR when completing HAV of pre-requisite program(s)?**

   IPP would determine noncompliance with 9 CFR 417.5(a) (1) when the prerequisite program does not support the applicable decision in the hazard analysis, either because the prerequisite program design does not support the decision or because the establishment implementation is not sufficient to support the decision.

3. **If a prerequisite program does not have one or more of the requested features (i.e. verification procedures), can the inspector leave the field blank, and what would be the regulatory actions taken?**

   Failure of the prerequisite program to have one of the requested features would not necessarily be noncompliance. However, if a prerequisite program has all the requested features, it will be easier to verify that it meets the requirement of 9 CFR 417.5(a) (1) to support the applicable hazard analysis decisions.

4. **Establishments have many pre-requisite programs. Which pre-requisite programs do the IPP review?**

   During the HAV, IPP will specifically review any prerequisite programs that support specific decisions in the hazard analysis or that generally contribute to the sanitary conditions that allow the HACCP plan to operate successfully.

Hazard Analysis

5. Can we get a list of the pre-populated "Hazard" selections under the Biological, Chemical and Physical categories?

Hazard Selections Available in PHIS

Hazard Type	Hazard Category
Biological	Campylobacter
Biological	E.coliO157:H7
Biological	E.coliO157:H7, Lm
Biological	E.coliO157:H7, Salmonella
Biological	E.coliO157:H7, Salmonella, Lm
Biological	General Pathogens
Biological	Listeria monocytogenes
Biological	Other Biological
Biological	Other Pathogens
Biological	Salmonella
Biological	Specified Risk Material
Biological	Spore Forming Pathogens
Chemical	Allergens
Chemical	Chemical Contamination
Chemical	Other Chemical
Physical	Bone
Physical	Foreign Material
Physical	Metal
Physical	Other Physical
Physical	Specified Risk Material

6. If we reassess and modify our Hazard Analysis will the facility be required to notify the IPP?

PHIS has not changed the current regulatory requirements regarding notification. It is not required to notify IPP when hazard analysis or HACCP plans are reassessed or modified. However, when hazard analyses or HACCP plans are modified, they must be re-signed and dated in accordance with 9 CFR 417.2(d).

7. We consider blueprints to be confidential. Does the agency still plan to load this info into the PHIS system?

Blueprints are not required to be submitted when requesting a Grant of Inspection. However, if the establishment uses blueprints or other drawings to define the boundaries

and other features of the official premises of the establishment it is required to submit these to the DM during the grant approval process. In addition, if the establishment provides them to inspection personnel in an electronic format, IPP will upload them in the establishment profile. FSIS will not require establishments to provide them electronically for upload. It should be noted that FSIS personnel will treat all proprietary and confidential information in PHIS appropriately and protect it from accidental or intentional disclosure.

8. Who does the HAV in a large slaughter facility?

Any inspector, level 9 independently, level 8 with supervisory support, etc and it is the responsibility of supervisors to assign work to inspection personnel. Any inspection personnel trained to perform an HAV could have the task assigned.

9. It is my understanding that USDA will be entering each process step of the hazard analysis. If the process step has no hazards considered will supporting documentation be required to support that decision?

PHIS has not changed the HACCP regulatory requirements to support decisions made in the hazard analysis. If an establishment concludes that there are no hazards at a particular step but FSIS has reason to believe that one or more hazards would be associated with that step, FSIS will require that the establishment have support for the decision. However, there are many process steps which are generally recognized as not having associated hazards. Establishments are not necessarily required to provide supporting documentation for such conclusions, though if questions arise, establishment personnel should be prepared to describe the thought process.

10. How is a HAV different than a FSA?

The HAV is intended to give IPP a thought process and conceptual framework to help them identify significant problems with an establishment's hazard analysis decisions to help FSIS more quickly identify those situations where an establishment may be at risk of producing adulterated products. The FSA will continue to be a more in-depth assessment intended to yield a definitive evaluation of the scientific validity of an establishment's entire food safety system.

11. If during a HACCP reassessment, the facility decides to remove a CCP from a process; will the inspector have capability to remove a CCP from the profile? A "Delete" button did not show in the screen shots.

Recent revisions to the HACCP page of the profile provide the ability to delete a CCP.

12. Can the inspector cite more than one regulation per NR?

Yes, when an inspector observes noncompliance with more than one regulatory requirement during a verification task, he or she is to cite each noncompliant regulation.

Note that in PHIS, these may be documented on a single noncompliance form or on separate noncompliance forms, all within a single "Noncompliance Record" associated with a single verification task. Separate noncompliance forms within one NR will be designated by a sequential digit after the NR number (e.g. "/1," "/2," and so on).

13. If an NR has non-compliance in multiple regulations, will it just count as 1 NR, or will it count under each of the multiple non-compliant regulations?

With respect to the use of non-compliance data in the Public Health Decision Criteria, FSIS is continuing to calculate a non-compliance rate at the "task-level" (i.e. counting a non-compliant task once). Going forward, FSIS believes that it may be more effective to consider specific instances of noncompliance with a regulation (especially regulations of public health significance) than to simply count NR documents when assessing an establishment's performance. Therefore, FSIS intends to analyze non-compliances at the "regulation-level" (i.e. multiple NRs) as more data is collected in PHIS. This analysis may result in future changes to our decision criteria methodology. Any changes to that methodology will be communicated prior to implementation.

14. How do IPP handle facilities that use a Listeria Control program based off the Sentinal program that includes a short-term "CCP" for certain phases of their Listeria control program?

IPP would verify that an establishment is performing the *Listeria* program as written. It seems like a "temporary CCP" would actually be more like a corrective action the establishment would implement for a period of time in response to findings that meet certain action thresholds in their *Listeria* program. If so, IPP would not record it as a CCP in the PHIS profile HACCP information. FSIS will evaluate specific situations as they arise and provide appropriate instructions to IPP as necessary.

15. How will corporate oversight, domestic, import and export, of multiple facilities be handled?

The answer to this question will be addressed at the meeting.

16. Our IIC stated that he will be responsible for reviewing every document generated thru a pre-requisite program and entering those data/results into PHIS. Do you believe this to be an accurate statement?

This statement is not completely accurate. IPP will not be required to enter data/results of prerequisite programs in PHIS. However, IPP are responsible for periodically reviewing the data/results of prerequisite programs as part of their verification duties and recording the results of those verifications (compliant/noncompliant) in PHIS.

17. Even though askFSIS indicates that establishments should not change their HACCP plans based on PHIS implementation, some locations have been threatened with

additional regulatory scrutiny (i.e. an FSA & ultimately an NOIE). Why might this be?

The HACCP regulations provide the establishment the responsibility to make decisions regarding their HACCP plans, including when the hazard analysis or HACCP plan need to be modified. While performing verification procedures under PHIS, inspection personnel may find situations that indicate the hazard analysis or HACCP plan may need to be modified. They will communicate this to their supervisor. If the supervisor and the District Manager (DM) decide additional information is needed to make a final decision regarding regulatory noncompliance, the DM may assign an EIAO to perform a FSA.

18. **Should we expect the IIC to be primarily charged with PHIS "data entry" or will that task be shared between inspection personnel?**

    All off-line inspection personnel charged with verification duties will participate in recording their findings in PHIS. EIAOs and some other district office staff will also have roles that will include recording certain information in PHIS.

19. **What type of positive pathogen findings may trigger a HAV? Are these establishment lab results, or the Agency's lab results? Direct product? Non-Contact surfaces? Environmental surfaces?**

    Detailed information about the decision criteria used to schedule for cause Food Safety Assessments (FSAs) and increased HAV tasks are described in the "Data-Driven Inspection for Processing and Slaughter Establishments - Public Health Decision Criteria," which was posted on the Agency's website in September 2010 and is available at http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010_Public_Health_Decsion_Criteria_Report.pdf. FSIS may change the criteria as data suggests what is most effective at protecting public health.

20. **Does a GFSI third party type audit hold any weight in the PHIS System?**

    Third-party audits will continued to be considered as a form of support or verification for the applicable food safety decisions and evaluated on their particular merits in each situation, as they are now.

Non-compliance Records (FSIS Form 5400-4)

21. **It is our understanding that under the PHIS system noncompliance records for a facility will be entered into PHIS using an interview style format and the FSIS form 5400-4 will be generated based on the inspector's responses to interview questions. Currently we track our noncompliance records internally and would like to update our tracking system to conform to the format of the FSIS form 5400-1. After reviewing the form we have the following questions concerning data that may appear on the form:**

1) **Section 6 relevant regulations**

Is selection/inclusion of a regulation dependant on or restricted by the inspector's responses to interview questions or previously selected regulations. If there is a dependency can you provide a brief explanation?

Inspectors will indicate which regulatory requirements were verified (both compliant and noncompliant) during a verification task as part of the results for that task. Only those regulations identified as having been verified would be available to select as noncompliant, as supported by the observations.

2) Section 8 inspection types
Is there a predetermined list that the inspector chooses from or is this free form text? If there is a predetermined list of selections, can these be provided?

See Table 1 below.

3) Section 9 Verification Activity
Is there a relationship between selected/available options in Section 9 verification activity and Section 8 inspection types. If yes, can available verification activities for each inspection type be provided?

There is no relationship. For any verification task, the inspector is required to indicate whether he or she performed that task by review and observation (observing employees, conditions, operations in the establishment or conducting hands-on verification); record keeping (review of establishment records); or both. The selection made by the inspector when documenting the results of the inspection task is automatically documented on the NR.

4) Section 10 description of noncompliance record
Is the description completely free-form text or is any part auto-populated. If any portion is auto-populated can an explanation of where and how be provided?

The description of noncompliance is a free-form text field in which inspection personnel are to document their observations that support the finding of noncompliance and their actions in responding to the finding.

22. Does FSIS have a plan yet to provide industry with access to our own data?

In the fall of 2011, FSIS plans to begin an industry pilot to test the system before launching PHIS to the industry as a whole. The pilot will include 5 large, 5 small, and 5 very small establishments.

Table 1: Dictionary of Inspection Tasks in PHIS

Inspection Task Code	Inspection Task Name	Inspection Task Description
01B01	Pre-Op SSOP Record Review	Pre-operational Sanitation SOP verification by review of establishment records

Inspection Task Code	Inspection Task Name	Inspection Task Description
01B01_I	Pre-Op SSOP Record Review (Import)	Pre-Op Sanitation SOP Verification by review of import establishment records
01B02	Pre-Op SSOP Review and Observation	Review the establishment's SSOP and become familiar with the procedures
01B02_I	Pre-Op SSOP Review and Observation (Import)	Review the import shment's SSOP and become familiar with the procedures
01C01	Operational SSOP Record Review	Verify operational SSOP records
01C01_I	Operational SSOP Record Review (Import)	Verify operational SSOP records
01C02	Operational SSOP Review and Observation	Verification of the establishment's operational SSOP
01C02_I	Operational SSOP Review and Observation (Import)	Verification of the import establishment's operational SSOP
01D01	SPS Verification	Verification of the sanitation performance standards
01D01_I	SPS Verification (Import)	Verification of the sanitation performance standards
01D02	Beef Sanitary Dressing	Verify Sanitary Dressing in Livestock Slaughter Establishments
01D03	Poultry Sanitary Dressing	Verification of sanitary dressing in poultry slaughter
01D04	SPS Verification (V)	Verification of sanitation performance standards in voluntary facilities
01E01	Generic E. coli Verification	Verify the establishment's generic E. coli program.
03A02	Hazard Analysis Verification	Hazard Analysis Verification for all HACCP categories
03A03	Directed Hazard Analysis Verification	Directed HAV procedure is initiated if a public health based threshold has been exceeded (e.g., positive pathogen test results, trend of food safety NCs, or other information that requires follow-up).
03A04	Review of Establishment Data	Weekly review of establishment data per Directive 5000.2
03B02	Raw Non-Intact HACCP	HACCP verification for raw non-intact products.
03C02	Raw Intact HACCP	Verify all 5 HACCP regulatory requirements at all CCPs for specific production
03D02	Thermally Processed-Commercially Sterile HACCP	Verification of the 318.300,Subpart G, 381.300, Subpart X; Canning and Canned Products regulatory requirements and HACCP regulatory requirements.
03E02	Not Heat Treated-Shelf Stable HACCP	Verification of HACCP regulatory requirements through the use of review and observation and recordkeeping components
03F02	Heat Treated-Shelf Stable HACCP	Verification of all five HACCP regulatory requirements through the review and observation and recordkeeping components.
03G02	Fully Cooked-Not Shelf Stable HACCP	Verification of all 5 HACCP regulatory requirements through review and observation and recordkeeping components.

Table 1 (cont): Dictionary of Inspection Tasks in PHIS

Inspection Task Code	Inspection Task Name	Inspection Task Description
03H02	Heat Treated-Not Fully Cooked-Not Shelf Stable HACCP	Verification of all 5 HACCP regulatory requirements through use of review/observation and recordkeeping components.
03I02	Secondary Inhibitors-Not Shelf Stable HACCP	Verification of all 5 HACCP regulatory requirements through the use of review/observation and recordkeeping components.
03J02	Slaughter HACCP	Verification of all 5 HACCP regulatory requirements through the review/observation and recordkeeping components.
03J03	Livestock Zero Tolerance Verification	Verification of zero tolerance for feces, milk, ingesta on livestock carcasses
03J04	Poultry Zero Tolerance Verification	Verification of zero tolerance for feces on poultry carcasses entering chilling system.
04A01	Percent Yield/Shrink	Verify certain products that have a specified %Yield/Shrink as part of their Standard of Identity are met and not misbranded.
04A02	X Percent (%) Solution	Verify products that contain Percent (%) Added Solution meet regulatory standards and are not misbranded.
04A03	MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS	Verify Mechanically Separated, Partially Defatted, and Advanced Meat Recovery Products meet regulatory requirements.
04A04	Batter/Breading	Verify batter and breading of applicable products meets regulatory requirements and product is not misbranded.
04A05	Livestock Finished Product Standards	Verify Livestock products are wholesome and not adulterated.
04A06	Poultry Finished Product Standards	Verify poultry products are produced in a safe, wholesome manner and not misbranded.
04B01	Labeling - Product Standards	[No Description]
04B02	Child Nutrition/Grade Labeling/Declared Count/Vignette	[No Description]
04B03	Labeling - Net Weights	[No Description]
04B03_I	Labeling (Scale Calibration) (Import)	Verify scale calibration and acceptability.
04B04	General Labeling	[No Description]
04B04_I	General Labeling (Import)	Monitoring the stamping/marking of US Inspected and Passed cartons, containers, etc.
04B05	General Labeling (V)	Duplicate of General labeling (04B04) for voluntary facilities.
04B05_I	General Labeling (Pre-Stamp) (Import)	Monitoring of pre-stamped lots and program
04C02	Livestock Humane Handling	[No Description]
04C05	Poultry Good Commercial Practices	[No Description]
05A03	Salmonella Verification Sampling	Directed requests to collect Salmonella verification samples.
05A04	Microbiological Sampling	Directed collection of microbiological samples
05B01	Economic Verification Sampling	Directed sampling for economic wholesomeness issues

Table 1 (cont): Dictionary of Inspection Tasks in PHIS

Inspection Task Code	Inspection Task Name	Inspection Task Description
05C01	Directed Residue Sampling	Task for directed residue sampling for NRP
06A01	Export Certification	Verification of information provided on FSIS Form 9060-1, labeling of shipping containers, and export marks.
06A02	Export Certification (V)	Document export certification at voluntary facility
06B01	Custom Exempt	Verify that custom exempt operations in official establishments meet regulatory requirements and do not impact inspected products or operations.
06B02	Retail Exempt	Verify that retail exempt operations do not interfere with inspected products/operations
06D02	Other Inspection Requirements	Verify other inspection requirements
07B01	Update Establishment Profile	Review and update establishment profile to reflect current establishment operations.
07B01_I	Update Establishment Profile (Import)	Review Establishment Profile and make any needed corrections to reflect current operations. Please refer to FSIS Directive 5300.1 for instructions on the PHIS establishment profile.
07C01	Meeting with Establishment Management	Meet with establishment management
08A11	2011 Food Defense Survey	Record performance of 2011 Food defense survey (note only some establishments in PHIS at this point)
08A11_V	2011 Food Defense Survey (V)	Record performance of 2011 food defense survey (note not all establishments in PHIS at this time)
08S14	Food Defense - Water Systems	Verify establishment measures to protect water systems
08S14_I	Food Defense - Water Systems (Import)	Observe the security of the establishment's water systems, especially well water and ice storage facilities. Pay special attention to water used in defrost tanks and for cleaning and disinfecting.
08S15	Food Defense - Processing/Manufacturing	Verify food defense for processing and manufacturing areas
08S15_I	Food Defense - Reinspection/Staging Area (Import)	Observe import reinspection areas where exposed products are being handled. Observe whether the establishment has procedures in place to prevent deliberate contamination.
08S16	Food Defense - Storage Areas	Verify access/tampering in storage areas
08S16_I	Food Defense - Storage Areas (Import)	Observe products in cold and dry storage areas for evidence of tampering; Pay special attention to bulk products, such as combo bins of meat trim and poultry parts.
08S17	Food Defense - Shipping and Receiving	Verify food defense in shipping and receiving areas
08S17_I	Food Defense - Shipping and Receiving (Import)	Observe loading dock areas and vehicular traffic in and out of the establishment.
08S18	Food Defense - Water Systems (V)	Food defense verification of water systems for voluntary facilities.

Table 1 (cont): Dictionary of Inspection Tasks in PHIS

Inspection Task Code	Inspection Task Name	Inspection Task Description
08S19	Food Defense - Processing; Manufacturing (V)	Food defense verification in processing and manufacturing areas for ID warehouses
08S20	Food Defense - Storage Areas (V)	Verify food defense in storage areas in ID warehouses.
08S21	Food Defense - Shipping and Receiving (V)	Verify food defense for shipping and receiving in ID warehouses.

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