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

FSIS DIRECTIVE

5000.6
Rev. 2

06/29/18

PERFORMANCE OF THE HAZARD ANALYSIS VERIFICATION TASK

I. PURPOSE

This directive provides inspection program personnel (IPP) instructions for performing the Hazard Analysis Verification (HAV) task. This directive also identifies circumstances that will require IPP to conduct a directed HAV task for a specific product or processing category and provides instructions for IPP to perform such directed HAV tasks. This directive is being revised to provide updated instructions on assessing compliance with Hazard Analysis Critical Control Point (HACCP) systems validation regulatory requirements and to provide additional instructions to IPP when trends are identified during an analysis of HAV task data.

KEY POINTS:

- *Provides instructions to IPP on the performance of the HAV task*
- *Provides instructions to IPP on verifying the use and implementation of prerequisite programs*
- *Provides updated guidance for verifying compliance with validation regulatory requirements*

II. CANCELLATION

FSIS Directive 5000.6 Rev. 1, *Performance of the Hazard Analysis Verification (HAV) Task* 4/4/14

III. BACKGROUND

A. IPP verify that the development and implementation of an establishment's HACCP system meets the five regulatory requirements (i.e., monitoring, verification, corrective actions, recordkeeping, and reassessment) addressed in 9 CFR Part 417 by conducting the HAV task.

B. The purpose of conducting the HAV task is more than simply identifying isolated cases of noncompliance. IPP are to consider what their HAV task findings show about the overall effectiveness of the establishment's food safety system. The HAV task is not a Food Safety Assessment (FSA) or HACCP Implementation Task. IPP are to conduct the HAV task to verify that an establishment has performed and documented a hazard analysis that meets applicable regulatory requirements and has addressed all relevant food safety hazards associated with the establishment's processes and products, and the intended uses for those products in accordance with 9 CFR 417.2(a). IPP are to identify obvious cases of noncompliance and other issues of concern that may require further consideration or investigation by an Enforcement Investigations and Analysis Officer (EIAO).

C. Prerequisite programs provide the basic environmental and operational conditions that are necessary for safe food production. Prerequisite programs are procedures that may be used to support a decision

that a hazard is not reasonably likely to occur (NRLTO). Sanitation SOPs and Good Manufacturing Practices (GMPs) are some examples of prerequisite programs. Several Federal Register (FR) documents attest to the importance of prerequisite programs and the Agency's expectations when establishments use these programs specifically to address specific pathogens of concern including: the FR of October 7, 2002 (67 FR 62325) that describes the use of prerequisite programs to address *E. coli* O157:H7; and the FR of June 6, 2003 (68 FR 34224) that describes the use of prerequisite programs to address *Listeria monocytogenes* (Lm).

IV. SCHEDULING OF HAV TASKS

A. Routine HAV tasks are generated by the Public Health Information System (PHIS) on a quarterly basis for verifying whether the establishment meets the regulatory requirements for a specific HACCP plan.

B. The routine quarterly HAV task can be performed at any time during the three month window. If IPP are unable to complete the task on the scheduled day, they can move the task to a future date during the three month window. Once the HAV task has been opened it can be completed over multiple days.

C. In the following situations, IPP are to verify that the establishment meets the regulatory requirements in 9 CFR Part 417 using a routine HAV task if the task is still available on the establishment task list. If the routine HAV task is no longer available because it was recently performed, IPP are to schedule a directed HAV task.

1. Changes that could affect the hazard analysis or require altering the HACCP plan, such as an unforeseen hazard or a new or revised policy.

2. Addition or removal of a critical control point (CCP) or other control measure based on the establishment's determination related to whether a food safety hazard is reasonably likely to occur (RLTO).

D. If IPP determine there is new information related to the establishment profile during the performance of the HAV task, they are to incorporate that information into the establishment profile during the performance of the next Update Establishment Profile task as addressed in FSIS Directive 5300.1 *Managing the Establishment Profile in the Public Health Information System.*

NOTE: If IPP determine the new information related to the establishment profile directly impacts sampling eligibility, such as product volume information, they are to update the establishment profile immediately and not wait until performing the next Update Establishment Profile task.

V. PERFORMING THE HAV TASK

A. Once per quarter, IPP are to review the hazard analysis of one HACCP plan in accordance with the instructions below, paying particular attention to any changes made since the previous review of that hazard analysis.

NOTE: See FSIS PHIS Directive 13,000.1, *Scheduling In-plant Inspection Tasks in the Public Health Information System,* for instructions on using the PHIS tasks calendar to schedule inspection tasks.

1. In establishments that have one HACCP plan, IPP are to conduct the HAV task on that HACCP plan each quarter.

2. In establishments that have one or more HACCP plans, IPP are to select one HACCP plan to review using the priority rankings in Table 1 below, with the Slaughter HACCP Category having the highest priority. IPP are to select a different HACCP plan each quarter until all the HACCP plans have been reviewed. In the event an establishment has more than one HACCP plan in a processing category (e.g., Poultry Slaughter HACCP, Livestock Slaughter HACCP), IPP are to

select one of the HACCP plans in that processing category for that quarter and then select a different HACCP plan in that processing category during the next quarterly routine HAV task. After all HACCP plans in that HACCP processing category have been reviewed, IPP are to select a HACCP plan from the processing category with the next highest ranking.

Table 1: HAV HACCP Category Priority Ranking*
1. Slaughter
2. Raw/Non-Intact
3. Raw/Intact
4. Fully Cooked/Not Shelf Stable Post-lethality Exposed
5. Not Heat Treated/Shelf Stable
6. Heat Treated/Not Fully Cooked/Not Shelf Stable
7. Secondary Inhibitors
8. Heat Treated/Shelf Stable
9. Full Cooked/Not Shelf Stable Not Post-lethality Exposed
10. Thermally Processed

*The rankings are based on review of published information regarding the relative risks of meat and poultry products

NOTE: If the establishment produces product that does not have a HACCP plan because of its ability to support that there is not a food safety hazard that is RLTO, IPP are to conduct the HAV task on the hazard analysis that is specific to the product.

B. If the establishment has just completed the 90-day initial validation period, IPP are to perform the quarterly HAV task using Table 1 to select the recently validated HACCP plan with the highest priority ranking. Likewise, when determining that the establishment has validated a HACCP plan since the performance of the last HAV task, IPP are to conduct the quarterly HAV task on that validated HACCP plan even if it is lower in priority ranking than an existing HACCP plan.

NOTE: IPP are not to schedule and perform a separate directed HAV task to verify regulatory compliance with a recently validated HACCP plan unless instructed.

EXAMPLE: *An establishment plans to produce beef ravioli and has recently completed the 90-day initial validation for a Heat Treated/ Not Fully Cooked/ Not Shelf Stable HACCP plan. They also have Raw/Intact and Raw/Non-Intact HACCP plans. IPP are to perform the routine quarterly HAV task on the Heat-Treated HACCP plan, and then verify regulatory compliance with one of the other HACCP plans during the next quarterly HAV task.*

C. If the HAV task is scheduled during the 90-day conditional grant time frame, IPP are to conduct the HAV task when instructed by the District Manager (DM) as indicated in FSIS Directive 5220.1, *Granting or Refusing Inspection; Voluntary Withdrawing or Suspending Inspection; and Reinstating Inspection under PHIS*, Section V.N. If the DM informs IPP through supervisory channels, not to conduct the HAV task, IPP are to mark the HAV task as not performed with the justification, "Supervisory instruction." IPP are to then schedule the HAV task during the next quarter after the completion of the 90-day conditional grant/initial validation period.

D. If there are multiple IPP in an establishment, the first level supervisor is to coordinate the work between the available IPP so that the HAV task is assigned to only one of the IPP in a given quarter. In two-shift establishments, the routine HAV task will show up on the PHIS task list for both shifts each quarter. The first level supervisor is to coordinate the work between the two shifts so that the routine HAV task is only performed on one of the shifts during a given quarter. IPP not scheduled to perform the HAV task in each quarter are to schedule and then mark the HAV task as "not performed" with the justification

"task assigned to another inspector." The supervisor is to ensure that, over time, all inspectors have equal opportunities to perform the HAV task.

E. IPP are to add directed HAV tasks to the PHIS task list as advised by their supervisor or District Office personnel.

F. When IPP are notified that an FSA has been scheduled at the establishment, and the routine HAV task appears on the establishment's task list after the FSA has been scheduled or during the FSA, IPP are to wait until the FSA is completed to conduct the HAV task.

G. When performing any HAV task, IPP are to use the methodology described in Steps 1-8 below and consider how their findings may affect the food safety system. When IPP are uncertain about the adequacy of the establishment's hazard analysis, they are to discuss their concerns with their supervisor.

NOTE: In addition, supplemental guidance is provided to IPP for performing the HAV task in Attachment 1, **Summary of IPP Instructions (Steps 1-8) for Performing Hazard Analysis Verification (HAV) Tasks** and Attachment 2, **IPP Workflow and Decision Tree for Use When Conducting HAV Tasks**.

STEP 1- REVIEWING THE ESTABLISHMENT'S FLOWCHART

A. IPP are to become familiar with the production steps and product flow within the establishment by observing operations. If they have questions about the process steps and product flow, IPP are to ask establishment management for assistance in understanding these.

B. IPP are to compare the establishment's flowchart to the actual production process to determine whether the flowchart accurately describes the steps of each process and the product flow within the establishment (9 CFR 417.2(a)(2)). If the establishment handles rework and returned product, IPP are to verify whether these functions are reflected on the flow chart.

C. IPP are to refer to the *Meat and Poultry Hazards and Controls Guide* (HCG) when reviewing an establishment's flowchart. The establishment's process may not include all the steps listed in the HCG, but reviewing the process steps in the HCG may help IPP identify any steps in the establishment's process that are not in the flowchart. For additional information concerning the HCG, see Attachment 4.

D. The establishment may have a single flowchart that shows the entire production process or may have multiple flow charts that show each part of the process. In some establishments, the flowchart may be part of the HACCP plan, while in others it may be a separate document. All of these approaches to presenting the flow chart are acceptable.

E. There is no required format or specified structure of the flow chart, and FSIS does not dictate the level of detail that must be in a flow chart. It is up to the establishment to determine the format it wishes to use to ensure that the flow chart contains the information required for the entire production process (9 CFR 417.2(a)(2)). Likewise, it is up to the establishment to decide which activities represent a "step" in its operation and to identify the essential steps. IPP are to be aware that an "essential step" is a point or activity in an operation within the production process that is critical to the proper production of the finished product. Each step must be included on the flow chart, however, multiple activities can be incorporated into one step.

EXAMPLE: *An establishment may perform several different activities when processing raw, non-intact products (e.g., cutting, needle tenderizing, injecting, and tumbling). The establishment can group all of these activities into the single step of "processing" on the flowchart, as long as the hazard analysis addresses all the potential hazards associated with each activity.*

G. Questions that IPP are to ask regarding the flow chart include, but are not limited to, the following:

1. Do the steps identified by the establishment reflect the actual production process? If not, the flow chart does not comply with 9 CFR 417.2(a)(2).

2. Does the flowchart, or hazard analysis, identify the intended use or consumers of each product, and is the identified intended use consistent with the actual production process? If not, noncompliance with 9 CFR 417.2(a)(2) exists.

NOTE: Instructions for documenting noncompliance are addressed in Section V, Step 8 of this directive.

STEP 2- REVIEWING THE HAZARD ANALYSIS

A. FSIS does not dictate the level of detail that must be in a hazard analysis and there is no required format or specified structure for the hazard analysis; however, IPP are to verify that the hazard analysis contains the required information for the entire production process. For instance, the establishment may have decided to incorporate several production activities into one step in the operation. The hazard analysis must document the operations considered at each step of the process and the establishment must consider all the food safety hazards associated with all the activities conducted at that step in order to meet the requirement of 9 CFR 417.2(a).

B. IPP are to review the information for each process step in the HCG and compare it to the establishment's hazard analysis for that step. IPP are to consider the verification questions from the HCG and their knowledge of the actual establishment process to assess whether the establishment's hazard analysis has considered the appropriate hazards for each step in its production process.

NOTE: While reviewing the hazard analysis, IPP are to be aware that if an establishment identifies a biological food safety hazard that is RLTO in its operation, neither 9 CFR 417.2(a)(1) nor 9 CFR 417.2(c)(1) requires the establishment to identify (list) each microbial food safety hazard by name (e.g., *E.coli* O157:H7, *Salmonella Enteritidis*) in the hazard analysis and HACCP plan. For additional information regarding listing pathogens by name in the hazard analysis, IPP are to refer to Attachment 3.

C. Questions that IPP are to ask regarding the hazard analysis include, but are not limited to, the following:

1. Does the hazard analysis reflect all the steps in the flowchart and the actual production process? If not, it does not comply with 9 CFR 417.2(a)(1).

2. Has the establishment determined whether certain hazards are not reasonably likely to occur (NRLTO) because of the intended use of the product?

    a. If so, does the establishment have documentation (e.g., labeling records, shipping invoices, letter of intent from receiving establishments or other records) to support the intended use (9 CFR 417.5(a)(1))?

    b. If not, the establishment does not comply with 9 CFR 417.2(a)(2).

D. IPP are to consider general questions such as those provided below and those found in the HCG when evaluating the hazard analysis:

1. Has the establishment addressed this process step in the hazard analysis?

2. Does the establishment have a prerequisite program that addresses this step?

3. Has the establishment identified any hazards associated with this step?

4. Is this process step a CCP?

5. Is the establishment following all procedures identified in the hazard analysis?

6. Does the establishment maintain records associated with this process step?

7. Do the establishment's records contain information that indicates a reassessment of the hazard analysis or HACCP plan is necessary (e.g., CCP deviations, positive pathogen results, repeated sanitary dressing failures)?

8. Are the records made available to FSIS?

E. IPP are to verify that the establishment has at least one CCP for each hazard that is identified as being RLTO in the process and support for any decision that applicable hazards are NRLTO. When the establishment uses a prerequisite program such as a Sanitation SOP, GMPs, or purchase specifications to support the determination that a hazard is NRLTO, IPP are to verify that the establishment implements the prerequisite program effectively and achieves the expected results to support its decision (See Step 4 for additional guidance on reviewing prerequisite programs). For each food safety hazard identified in the hazard analysis, IPP are to ask the following questions:

1. Does the establishment consider the identified food safety hazard to be NRLTO in the production process? If so, does the establishment maintain support (e.g., a prerequisite or other supporting documentation) for this decision? If not, noncompliance with 9 CFR 417.5(a)(1) exists.

2. Does the establishment consider the identified food safety hazard to be RLTO in the production process? If so, does the establishment include one or more CCPs to control the hazard in the HACCP plan associated with that product? If not, noncompliance with 9 CFR 417.2(c)(2) exists.

F. If IPP are uncertain whether the establishment has considered the appropriate hazards at each process step, they are to contact their supervisor for assistance in order to determine whether noncompliance with 9 CFR 417.2(a)(1) exists.

STEP 3- REVIEWING SUPPORT FOR CCPs AND CRITICAL LIMITS

A. During the HAV task, IPP are to review the establishment's records to verify that the establishment has evidence to support the development of CCPs, critical limits (CLs), monitoring, and verification procedures.

B. IPP are to verify that the establishment maintains supporting documentation for its decisions at each CCP, including modifications to a CCP (e.g., after a reassessment). 9 CFR 417.5(a)(2) requires that the establishment maintain the following types of supporting documentation for the HACCP plan:

1. Decision making documents associated with the selection and development of CCPs and CLs;

2. Documents supporting the selection of monitoring procedures and associated frequencies; and

3. Documents supporting the selection of verification procedures and associated frequencies.

EXAMPLE: *Establishment A has an antimicrobial intervention CCP in its process for which it identifies the concentration of the intervention solution as the CL. The establishment maintains the following supporting documents to meet the requirement of 9 CFR 417.5(a)(2):*

1. *A decision memo that describes how establishment management selected the CCP based on a particular scientific article that addresses the establishment's particular hazard and product.*

2. *A copy of the referenced scientific article.*

3. *A document from the test kit manufacturer that describes a method for monitoring the concentration of the antimicrobial solution to support the establishment's monitoring procedure.*

4. *A written decision document to monitor the CL once per day because the establishment mixes the antimicrobial solution daily.*

5. *A written decision document stating that the establishment will verify that it maintains the necessary minimum concentration of antimicrobial weekly because historical records show consistent control of this CCP.*

NOTE: The documents listed are examples of supporting documentation an establishment may have on file to meet validation requirements discussed in Step 6 below and Attachment 4 of this directive.

C. If the establishment does not have documentation to support the development of CCPs, CLs, monitoring, or verification procedures and associated frequencies, noncompliance with 9 CFR 417.5(a)(2) exists.

D. IPP are not tasked with determining the adequacy of the documentation; however, if they have concerns about the documentation, they are to discuss the issue with their supervisor prior to making a compliance determination.

STEP 4- REVIEWING NRLTO DECISIONS INCLUDING PREREQUISITE PROGRAMS

A. A prerequisite program's purpose is not to control a food safety hazard that was identified in the hazard analysis as being RLTO, but instead, its purpose is to prevent the hazard from becoming RLTO. An establishment can determine, through its hazard analysis, that a food safety hazard is NRLTO because data collected from the implementation of a prerequisite program supports that that program is preventing the hazard from occurring. IPP are to be aware that when a prerequisite program is used to support decisions in the hazard analysis, it is supporting documentation in accordance with 9 CFR 417.5(a)(1), and any records associated with the prerequisite program must be available for FSIS review. Based on the information they gather from the records review and observations, IPP are to consider whether the establishment is implementing the prerequisite program or other control measures in a manner that supports the relevant hazard analysis decisions.

B. IPP are to be aware that the regulations in 9 CFR 417 do not include specific requirements (e.g., monitoring, recordkeeping, corrective actions) for prerequisite programs. However, without maintaining some level of documentation that demonstrates that the prerequisite program has been implemented effectively and serves its intended purpose, it may be difficult for establishments to support a decision that a food safety hazard is NRLTO or to comply with the requirements of 9 CFR 417.5(a)(1).

C. IPP are to consider the following questions when reviewing documentation used to support a prerequisite program and the decision that a hazard is NRLTO:

1. Is the program written, and if so, does it describe procedures implemented by the establishment to support that a hazard is NRLTO?

2. Does the program describe the records that the establishment keeps to show the program is implemented as written?

3. Does the establishment maintain records showing that the implementation of the prerequisite program continually supports that a hazard is prevented from becoming RLTO?

4. Does the program describe activities the establishment conducts if it fails to implement the program, or if it finds that implementation of the program failed to prevent a hazard from becoming RLTO?

D. If the establishment's prerequisite program is not designed in the manner defined by the criteria in paragraph C above, it is likely that the establishment has not met the requirements of 9 CFR 417.5(a)(1). IPP are to contact their supervisor for assistance if they have concerns about whether the prerequisite program is designed to prevent the relevant hazard.

E. One or more of the following findings are evidence that the establishment has not met the requirements of 9 CFR 417.5(a)(1):

1. The establishment employees are not implementing the procedures in the prerequisite program sufficiently to prevent the relevant hazard.

2. The prerequisite program records indicate that there have been consistent or repeated failures to implement the procedures in the prerequisite program, resulting in a lack of support that the relevant hazard is NRLTO.

NOTE: Establishments are not required to maintain records for prerequisite programs. In situations where the prerequisite program does not generate records, IPP are to determine compliance by observing whether the establishment implements the prerequisite program sufficient to prevent the hazard from being RLTO.

F. In general, the failure to comply with one aspect of the prerequisite program may not result in direct product contamination or adulteration; however, the safety of the product or the adequacy of the food safety system may need further evaluation by a supervisor or EIAO.

EXAMPLE: *Establishment A implements a prerequisite program to maintain raw product coolers below 35 degrees Fahrenheit (F) to prevent the identified hazard (pathogen growth) from being RLTO. On two separate days last week, the employee recording the cooler temperature records did not record information specified in the written program. This minor failure to follow the program would not represent a failure to support the hazard analysis as long as there is no reason to believe that the 35 degree F temperature was not maintained. Therefore, the establishment is in compliance with 9 CFR 417.5(a)(1).*

G. In contrast, repeated failure to implement procedures in a prerequisite program, or evidence that the program is not effectively preventing the hazard, is an indication that the establishment does not have adequate support for the relevant decisions in its hazard analysis. Failure to support hazard analysis decisions is cause for IPP to document noncompliance with 9 CFR 417.5(a)(1) and may be grounds for an enforcement action.

EXAMPLE: *Establishment B implements a prerequisite program of purchase specifications to support that the hazard of E. coli O157:H7 is NRLTO in received beef trimmings. The prerequisite program states that Establishment B will receive a Certificate of Analysis (COA) for each lot of trimmings as one way to demonstrate that the hazard is NRLTO. IPP observe that the establishment does not have a COA for the lot of trimmings they are grinding. This finding would call into question the establishment's decision that E. coli O157:H7 is NRLTO. Therefore, the finding would represent noncompliance with 9 CFR 417.5(a)(1) because the establishment does not have the records specified in the prerequisite program to support that the hazard of E. coli O157:H7 is NRLTO.*

H. If an establishment does not effectively design or inconsistently implements its prerequisite program and the applicable hazard occurs, the prerequisite program provides ineffective support that the hazard is NRLTO and there is noncompliance with 9 CFR 417.5(a)(1).

I. In addition, 9 CFR 417.2(a)(1) states a food safety hazard that is reasonably likely to occur is one for

which a prudent establishment would establish controls because it historically has occurred. For instance, if an establishment produces a product associated with an outbreak or illness, or has had multiple positive sample results for a pathogen of public health concern, and they have not addressed those hazards in its HACCP plan, IPP are to verify that the establishment takes appropriate corrective actions in response to an unforeseen hazard as per 9 CFR 417.3(b). When the establishment or FSIS determines the prerequisite program has failed to prevent the applicable hazard from occurring, to maintain an adequate HACCP system, the establishment will usually have to address the pathogen in its HACCP plan, rather than through a prerequisite program.

J. Certain prerequisite programs address specific issues, such as Sanitation SOPs or pest control programs and are managed as facility-wide programs rather than being process or product specific. IPP are to verify whether those issues are being addressed as part of their routine verification activities.

K. If IPP are uncertain whether the implementation and records of a prerequisite program support the hazard analysis decisions, they are to discuss the issue with their supervisor.

STEP 5- REVIEWING OTHER SUPPORTING DOCUMENTATION

A. IPP are to verify that the establishment maintains copies of all the documents referenced in the hazard analysis that are designated as support for the decisions regarding the prevention or elimination of food safety hazards or their reduction to an acceptable level. In many cases, this supporting documentation will take the form of scientific documents, establishment historical records, or other establishment generated data. Questions that IPP are to consider in regard to supporting documentation include, but are not limited to:

1. If establishment records or data are being used, does the establishment include a decision document that explains why the data or records support its decision?

2. If a scientific document is being used, is the establishment following the criteria addressed in the document?

3. If multiple records are being used to support a single outcome (e.g., multiple slaughter interventions used to support a specific log reduction), is the establishment able to explain how the documents support the outcome (e.g., decision document)?

B. If the establishment does not maintain copies of the documents referenced in the hazard analysis, it does not comply with 9 CFR 417.5(a)(1).

C. If IPP have concerns that the documents referenced in the hazard analysis do not support the relevant decisions, they are to discuss the issue with their supervisors.

STEP 6- VERIFY ESTABLISHMENT HACCP SYSTEM VALIDATION

A. 9 CFR 417.4 requires that each establishment validate the adequacy of its HACCP system in controlling the food safety hazards identified in its hazard analysis.

B. Under 9 CFR 417.4(a)(1), establishments are required to assemble two types of supporting documentation to demonstrate a HACCP system has been validated:

1. The scientific or technical support for the HACCP system design (design), and

2. The in-plant implementation (validation) data (execution).

C. When verifying that establishments meet validation requirements, IPP are to review the scientific and technical support and the documents associated with the effectiveness of the HACCP plan in operation in-plant (i.e., in-plant validation data). IPP are to verify that the establishment maintains both types of validation documents. If the establishment does not make documents or data available to IPP to demonstrate both parts of validation, there is noncompliance with 9 CFR 417.5(a)(1).

D. When IPP review the establishment's scientific or technical support, they are to verify the establishment maintains references and copies of relevant portions of text from the scientific or technical support to address the effectiveness of the CCPs and prerequisite programs that support decisions in the hazard analysis.

E. If the establishment does not maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to support decisions in the hazard analysis there is noncompliance with 9 CFR 417.5(a)(1). When determining noncompliance, IPP are to be aware:

1. The establishment must have scientific or technical support for CCPs and prerequisite programs that support decisions in the hazard analysis because these programs are considered part of the HACCP system and, therefore, must be validated.

2. Establishments may use more than one scientific or technical support document to support the effectiveness of an intervention in its HACCP system.

F. If while reviewing the scientific or technical support, IPP have a concern about a technical aspect of the documentation, they are to contact their supervisor. The following are examples IPP may identify regarding scientific or technical support that could warrant a discussion with their supervisor:

1. The scientific or technical support documentation is for a product that is different from the product that the establishment produces. In general, the establishment should be using scientific or technical support that is related to the product produced or provide support for why research with a different product applies to the product in question. For example, documentation that shows a process achieves a 5-log reduction of *E. coli* O157:H7 in apple cider would not be sufficient scientific support for the reduction of *E. coli* O157:H7 in a beef product without additional justification. In addition, documentation that shows a process achieves a 1-log reduction in *Salmonella* in poultry would not be sufficient scientific support for the reduction of *Salmonella* in beef without additional justification. However, research for an intervention's effectiveness on one species of mammalian livestock (i.e., cattle, swine, sheep, goats) can be applied to another mammalian livestock species without additional support and research for an intervention's effectiveness on one species of poultry (i.e., chickens, turkeys, ducks, geese, ratites, and squabs) can be applied to another species of poultry without additional support.

2. The establishment does not have additional scientific or technical support demonstrating the effectiveness of an intervention under specified critical operational parameters in addition to a No Objection Letter or application from FSIS Directive 7120.1,*Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products* when the No Objection Letters and FSIS Directive 7120.1 do not contain this information.

NOTE: Critical operational parameters are the specific conditions that the intervention or treatment must operate under for effectiveness. Such parameters include, but are not limited to, pH, concentration, time, temperature, humidity, dwell time, water activity, pressure or other equipment settings.

3. The scientific or technical support documentation contains expert opinion from a processing authority without any reference to scientific principles or peer-reviewed data. The documentation should contain reference to scientific principles or peer-reviewed data in addition to the processing authority's opinion to ensure that the decision is science-based.

4. The scientific or technical support documentation specifies the log reduction or prevention achieved by the process but does not include information on the critical operational parameters, such as pH, pressure, contact time, temperature, or relative humidity, critical to achieving that reduction. That information should be included in order for the process to be considered validated, and so that the establishment can implement the process consistent with the support.

5. The establishment's CCPs, prerequisite programs, or other programs do not incorporate the critical operational parameters described in the supporting documentation, and the establishment does not maintain additional data to support the adequacy of the measures that incorporate different parameters. Establishments should be using the same critical operational parameters as those in the scientific or technical support. However, some minor differences may be acceptable, and establishments may be able to provide additional data to support different parameters.

G. When IPP review the records that document initial in-plant validation, they are to verify that the establishment maintains its in-plant validation data for the life of the HACCP system.

NOTE: IPP are to be aware that establishments are to maintain the original in-plant validation data for the life of the HACCP system (not just an analysis or summary of the data). In addition, if establishments make changes to the HACCP system and determine as part of reassessment that in-plant validation data should be gathered to demonstrate the modified system is being implemented effectively, that new data is to be kept for the life of the HACCP system.

H. If the establishment does not maintain in-plant validation data, there is noncompliance with 9 CFR 417.4(a)(1). When determining noncompliance, IPP are to be aware that FSIS does not require establishments to collect in-plant microbiological data provided that the establishment has adequate scientific or technical support, is following the parameters in the scientific or technical support, and has in-plant validation data demonstrating that it can meet the critical parameters during operation.

I. If, while reviewing the in-plant validation data, IPP have a concern about a technical aspect of the documentation, they are to contact their supervisor. The following are examples of issues IPP may identify regarding in-plant validation data that could warrant a discussion with their supervisor:

1. The in-plant validation data was collected from HACCP records or other data collected or maintained by the establishment as part of its HACCP system, and the records do not include all critical operational parameters. IPP are to be aware that establishments that did not keep their in-plant validation data from when their HACCP systems were first implemented were given time by FSIS (until January 4, 2016 at large establishments and April 4, 2016 at small and very small establishments) to collect in-plant validation data from HACCP records, provided the data included all critical operational parameters, or the establishment provided additional support that all critical operational parameters are being implemented. An establishment may use data from records generated as part of the HACCP system in place of their original in-plant validation data provided it has support for its monitoring procedures and frequencies per 9 CFR 417.5(a)(2) and there is no evidence that the monitoring procedures and frequencies are insufficient to monitor the CLs and identify deviations. IPP are also to be aware that although FSIS recommends establishments gather in-plant validation data at an increased frequency compared to the frequency listed in the HACCP plan or prerequisite program, there is no requirement that an establishment do so.

2. The documentation does not contain in-plant validation data for at least one product per HACCP category and the establishment does not have support for why less data is sufficient. 9 CFR 417.2(b)(1) contains a list of HACCP processing categories. Depending on the HACCP category, products, and the frequency with which they are produced, establishments may be able to support collecting in-plant validation data for at least one product in some but not all the HACCP categories used.

3. The documentation contains in-plant validation data from fewer than the total number of production days the establishment operated within its 90-calendar day validation period. For large establishments, 90 calendar days equates to approximately 60 production days. For small and very small establishments, 90-calendar days may equate to a minimum level of records from 13 production days. IPP are to be aware that establishments may be able to provide support for why gathering records from less days than the total number of production days it operated, within a 90-calendar day period, is sufficient (e.g., by providing a written justification that explains how the records it did gather demonstrate the system is validated).

NOTE: The documentation for in-plant validation from small and very small establishments may also contain data from greater than 90 calendar days if a request is granted in writing by the DO for additional calendar days to gather records to cover at least 13 production days.

J. IPP are to contact their supervisor for assistance if he or she have any other concerns regarding the establishment's scientific or technical support or in-plant validation data not covered in this notice.

STEP 7- VERIFYING THE REASSESSMENT REQUIREMENTS

A. A reassessment of the HACCP system and/or HACCP plan must be conducted under the following conditions:

1. In an establishment that has a HACCP plan, reassessment of the HACCP system, including the hazard analysis and any prerequisite programs, is required:

    a. At least annually;

    b. Whenever changes occur that could affect the hazard analysis or require modification of the HACCP plan (9 CFR 417.4(a)(3));

    c. As part of the corrective actions when an unforeseen hazard has occurred (9 CFR 417.3(b)(4)); or

    d. When otherwise directed by the Agency based on the regulations (e.g., in a FR notice).

2. Establishments that do not have a HACCP plan because they determined that no hazards are reasonably likely to occur must reassess their hazard analysis whenever any changes occur that could affect the hazard analysis (9 CFR 417.4(b)).

NOTE: Changes that may affect the hazard analysis or require modification of the HACCP plan include, but are not limited to, changes in raw materials, product formulation, slaughter or processing methods or systems, production volume, personnel, packaging, finished product distribution systems, or the intended use or consumers of the finished product. In addition, violative sample results for residues or pathogens and outbreak information could also affect the hazard analysis and require modifications to the HACCP system, including the HACCP plan.

B. IPP are to review establishment records and ask establishment management about reassessments conducted since the previous HAV task. IPP are also to consider whether there have been any changes within the establishment that could affect the hazard analysis (including prerequisite programs) or present the need to modify the HACCP plan. IPP are also to consider whether any unforeseen hazards have occurred since the last HAV task that would have required reassessment.

C. One or more of the following findings provides evidence that the establishment does not comply with 9 CFR 417.4(a):

1. In an establishment that has a HACCP plan (9 CFR 417.4(a)(3)(i)):

a. Changes that could affect the hazard analysis or HACCP plan or unforeseen hazards have occurred, but the establishment has not performed a reassessment; or if the reassessment was performed but not documented it does not comply with 9 CFR 417.4(a)(3)(ii);

b. The establishment did not perform a reassessment at least once in the previous calendar year (i.e. the 12-month period ending on the previous December 31st); or if the reassessment was performed but not documented it does not comply with 9 CFR 417.4(a)(3)(ii); or

c. The reassessment was not performed by an individual trained in accordance with 9 CFR 417.7.

2. If an establishment does not have a HACCP plan because the hazard analysis shows that no food safety hazard is RLTO, the following findings may be evidence that the establishment does not comply with 9 CFR 417.4(b):

a. Changes that could affect the hazard analysis have occurred, but the establishment has not performed a reassessment;

b. The reassessment was performed by an individual not trained in accordance with 9 CFR 417.7; or

c. The reassessment is not documented in accordance with 9 CFR 417.4(a)(3)(ii).

STEP 8- DOCUMENTING HAV TASK RESULTS IN PHIS

A. While performing the HAV task, if IPP do not identify noncompliance and find no evidence of potential problems in the food safety system, they are to document the results of the HAV task in PHIS and indicate compliance with each of the regulatory requirements that were verified.

B. If IPP identify noncompliance, they are to document the noncompliance in accordance with FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System,* and, as needed, discuss the noncompliance with their supervisor to determine whether additional action is necessary. If IPP are unable to determine whether their findings represent regulatory noncompliance, they are to discuss the issue with their supervisor before making a determination.

NOTE: While performing the HAV task, if IPP observe noncompliance with a different regulation (e.g. Sanitation SOP, HACCP recordkeeping verification), IPP are to document the noncompliance using the appropriate verification task.

C. If IPP have questions regarding whether the establishment is implementing the prerequisite program as described or maintains sufficient records to support its decisions, IPP are to discuss their concerns with their supervisor. The supervisor may determine that it is necessary to request the assistance of an EIAO, who may conclude that the prerequisite program is not capable of supporting the decisions made in the hazard analysis. If the supervisor or EIAO determines the implementation of the prerequisite program no longer supports the decisions made in the hazard analysis, IPP are to do the following:

1. Document an Noncompliance Record (NR) as set out in FSIS Directive 5000.1, citing 9 CFR 417.5(a)(1); and

2. Verify that the establishment conducts the following activities:

a. Reassesses its hazard analysis as required in 9 CFR 417.4(b) or 9 CFR 417.4(a)(3)(i)

because the decisions made in the hazard analysis may no longer be supported as per 9 CFR 417.5(a)(1); and

b. Provides data supporting the decisions made during this reassessment as required in 9 CFR 417.5(a)(1).

D. If IPP determine that the failure to implement a prerequisite program results in a hazard being RLTO, or that an unforeseen hazard has occurred, they are to:

1. Describe those findings in a NR citing 9 CFR 417.5(a)(1);

2. Verify that the establishment performs and documents corrective actions in accordance with 9 CFR 417.3(b), including controlling the affected product;

2. Retain affected product if the establishment does not have other information to demonstrate that product is not adulterated; and

3. Seek guidance through supervisory channels regarding what additional actions may be necessary.

VI. SUPERVISORY PERSONNEL RESPONSIBILITIES

A. PHIS training emphasizes that while performing the HAV task, if IPP have a question or concern they should seek assistance from their supervisor. The supervisor plays a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority and Agency policy, and that IPP duties are performed in accordance with prescribed inspection methods and procedures addressed in this directive.

B. If IPP have obtained additional information from askFSIS or other resources, supervisors are to be actively engaged with IPP in reviewing the information and assist IPP in their process to make a final decision of compliance or noncompliance.

C. If IPP have concerns with prerequisite programs or scientific support for the hazard analysis or the in-plant validation data, supervisors need to address these questions and concerns. If needed, the supervisor is to ask the DO to assign an EIAO to review the prerequisite program or scientific support.

D. Supervisors are to keep track of when HAV tasks are scheduled by their IPP to ensure that these tasks are performed in a timely and complete manner.

E. Supervisors are to ensure that IPP understand and apply the Gather, Assess, Determine (GAD) process that is presented within the Inspection Methods training, and that IPP are:

1. Correctly applying the inspection methodology;

2. Making informed decisions;

3. Properly documenting findings; and

4. Taking the appropriate enforcement actions as instructed in this directive.

VII. DATA ANALYSIS

The Office of Policy and Program Development (OPPD) will assess PHIS data concerning completion of the HAV task and documentation of noncompliance annually. The data will be compared to the previous fiscal year analysis results and used to determine if there is a need for revisions to Agency policy. When necessary, OPPD will request the Office of Data Integration and Food Protection (ODIFP) to assist in

reviewing PHIS data on verification activities to determine whether the findings suggest potential improvements can be made in verification procedures or instructions to IPP.

VIII. QUESTIONS

Refer questions regarding validation to the Risk, Innovations, and Management Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question using the 'Submit a Question' tab, enter the following information in the fields provided:

Subject Field:	Enter **Directive 5000.6.**
Question Field:	Enter your question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Validation** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) or International** from the drop-down menu.

Refer questions regarding this directive to the Policy Development Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question using the 'Submit a Question' tab, enter the following information in the fields provided:

Subject Field:	Enter **Directive 5000.6.**
Question Field:	Enter your question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **HACCP** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) or International** from the drop-down menu.

When all fields are complete, press **Continue.**

Roberta J Wagner

Assistant Administrator
Office of Policy and Program Development

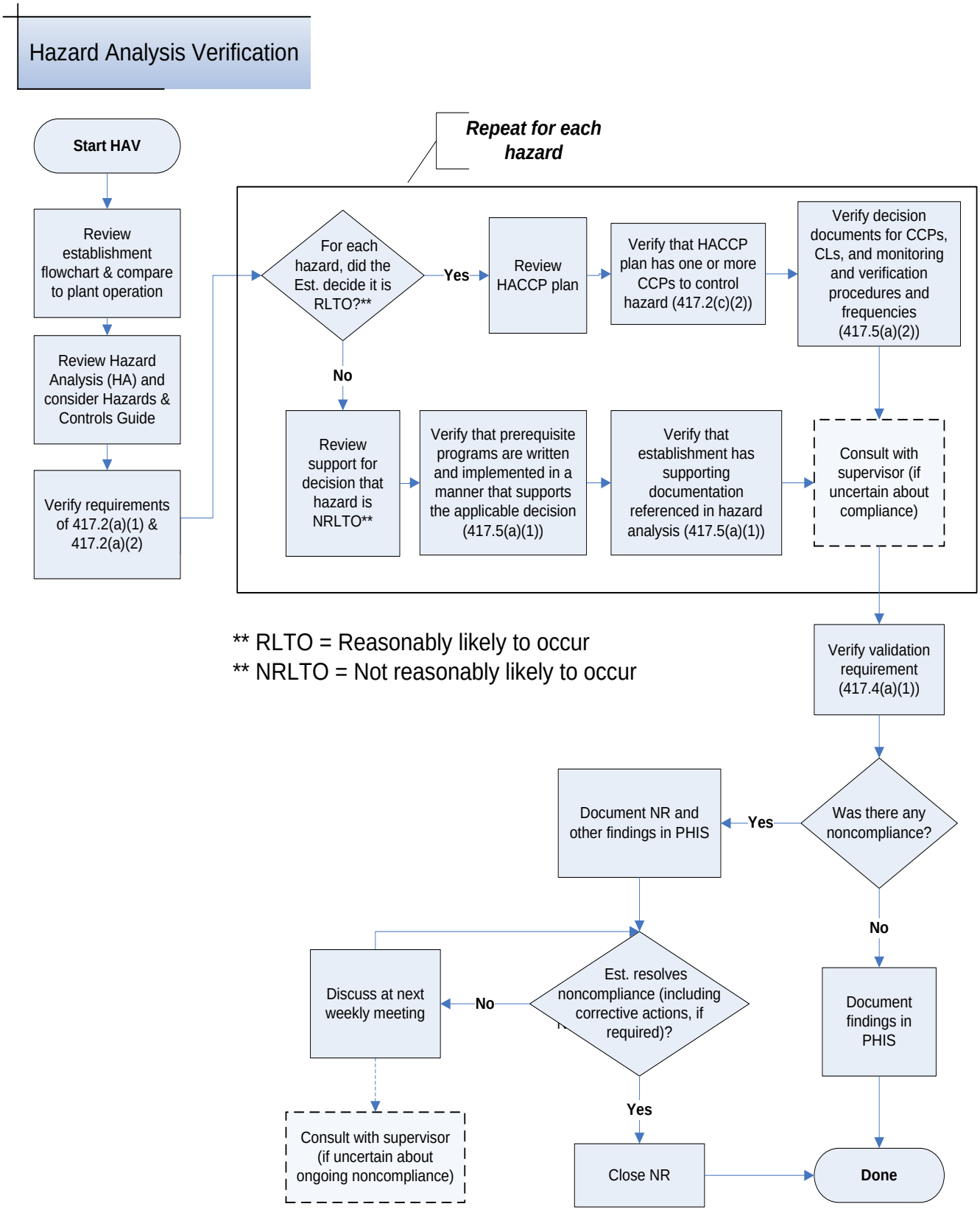
ATTACHMENT 1

A. Summary of IPP Instructions (Step 1-8) for Performing Hazard Analysis Verification (HAV) Tasks Flow: Refer to applicable sections of this directive for additional information about each step.

Step:	Description:	Verification Questions:	Reg. citation
Step 1	Review flowchart and compare to production process.	• Does the flowchart represent the actual production process?	417.2(a)(2)
Step 2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry HCG.	• Does the flowchart or hazard analysis identify the intended use or consumers of the product? • Does the hazard analysis appear to consider the relevant food safety hazards for the establishment's process, product, and intended use? • For each hazard, does the establishment consider it RLTO or NRLTO?	417.2(a)(2) 417.2(a)(1)
Step 3	For each hazard the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. *If no hazards are reasonably likely to occur, skip to Step 4.*	• Does the establishment have one or more CCPs to control the hazard in each product or process where it is reasonably likely to occur? • Does the establishment have information to support the CCPs, CLs, monitoring, and verification procedures?	417.2(c)(2) 417.5(a)(2)
Step 4	For each hazard the establishment considers NRLTO, determine what evidence the establishment uses to support the decision, including prerequisite programs and other supporting programs (e.g. written programs, records, and employee activities).	• Does the establishment prevent the hazard by implementing a prerequisite or other supporting program (SSOP, GMP, SOP, etc.)? – *proceed to Step 5.* • Does the establishment support the decision with other documentation besides a prerequisite or other supporting program? – *proceed to Step 6.* • Does the written program appear to be designed to prevent the relevant hazard? • Do the records and your observations indicate the program is consistently being implemented as written? • Do the records and your observations indicate that the	417.5(a)(1)

		program prevents the relevant hazard on an ongoing basis?	
Step 5	Review other supporting documentation.	• Does the establishment have copies of the documents referenced in the hazard analysis? • Do the documents appear to apply to the current establishment process?	417.5(a)(1)
Step 6	Review establishment validation documents, including scientific supporting documents and validation data.	• Does the establishment maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to support decisions in the hazard analysis? • Does the establishment maintain in-plant validation data for the life of the plan?	417.4(a)(1)
Step 7	Verify reassessment requirements. Check most recent signature date for each HACCP plan.	• Has the establishment reassessed at least once in the most recent calendar year? • Has the establishment reassessed, if necessary, in response to any changes that could affect the hazard analysis? • Has the establishment reassessed, if necessary, in response to any unforeseen hazard? • Has the establishment documented the results of the reassessment?	417.4(a)(3) 417.3(b) 417.4(a)(3)(ii)
Step 8	Document your findings.	• No problems detected – document HAV results in PHIS. • Clear case of noncompliance – document HAV results on NR in PHIS and notify your supervisor. • Concerns about the establishment HACCP system – discuss situation with your supervisor for assistance in determining how to proceed. Document HAV results in PHIS.	

ATTACHMENT 2: IPP Workflow and Decision Tree for Use When Conducting HAV Tasks



ATTACHMENT 3- LISTING PATHOGENS BY NAME IN THE HAZARD ANALYSIS AND HACCP PLAN

If an establishment determines that biological hazards are RLTO in that specific process, the establishment may simply state “pathogens” in the hazard analysis and HACCP plan in order to meet the intent of 9 CFR 417.2 (a)(1) and 417.2(c)(1). However, in accordance with 9 CFR 417.5(a)(1) and (2) and 417.4(a), the supporting documents and decision making documents associated with the selection and development of the CCPs and CLs must be sufficient to demonstrate the biological food safety hazards associated with the process are controlled. The supporting documents must also demonstrate that the establishment representative who conducted the hazard analysis actually considered which microbial pathogens were specific to the process in order to support that the design of the HACCP system is sound and effective in controlling the pathogens of concern.

IPP need to be aware that specific pathogens of concern are associated with the production of certain products (e.g., *E. coli* O157:H7 in a ground beef operation or *Listeria monocytogenes* in ready-to-eat products). In establishments that only identify “pathogens” in their hazard analysis and HACCP plan for biological food safety hazards, IPP are to review the establishment’s supporting and decision-making documents to determine whether the establishment’s HACCP system is sufficiently designed to control the specific pathogens associated with its process in accordance with 9 CFR 417.5(a)(1) and (2) and 417.4(a).

If IPP have concerns about the supporting documentation, they are to seek input from their immediate supervisor or request the assistance of an EIAO.

ATTACHMENT 4 – USING THE HCG AS A REFERENCE

A. The HCG is not a regulatory document. Therefore, establishments are not required to use the criteria identified in the HCG when identifying steps in their operations. Differences between the HCG and an establishment's hazard analysis are not sufficient to support findings of noncompliance with 9 CFR 417.2(a)(1). However, IPP are to use the HCG as a reference to help them assess whether an establishment has considered the potential hazards associated with a particular production process. The HCG contains information about the processing steps that are frequently associated with particular product types and addresses hazards that have typically, or historically, been associated with each of these steps. IPP are to use the HCG as a helpful reference.

B. IPP are to refer to the HCG when they verify whether the establishment's flow chart and hazard analysis meet regulatory requirements and to determine whether the establishment considered all the possible hazards for each process step.

C. The information and suggested verification questions in each section of the HCG will assist IPP when gathering information, assessing the information, and determining compliance during the HAV task.

D. IPP are to use the HCG when considering the following matters:

1. Does the establishment's flow chart and hazard analysis include all the applicable steps for the types of products that it produces?

2. Has the establishment considered the hazards that would typically be associated with the steps in its production process?

3. Has the establishment implemented measures to prevent or control the identified hazards at the relevant points in the process?

E. Because of differences in establishment processes and products, some of the information in the HCG may not apply to all establishments. If IPP have concerns about how the information in the HCG applies to a particular establishment's hazard analysis, they are to discuss the issue with their supervisor.