

REGULATORY PROCESS REVIEW

Objectives

After completion of this module, the participant will be able to:

1. Explain the regulatory process, including the definition of the four components, and identify key parts of each component.
2. Identify the four questions to consider when determining whether to document noncompliance when there is failure to meet HACCP regulatory requirements.
3. Given a scenario, use the regulatory process to determine whether a food safety system is inadequate.
4. State two instances when a verification plan is prepared.
5. State how to verify the requirements of 9 CFR 418.3 for maintaining written recall procedures.

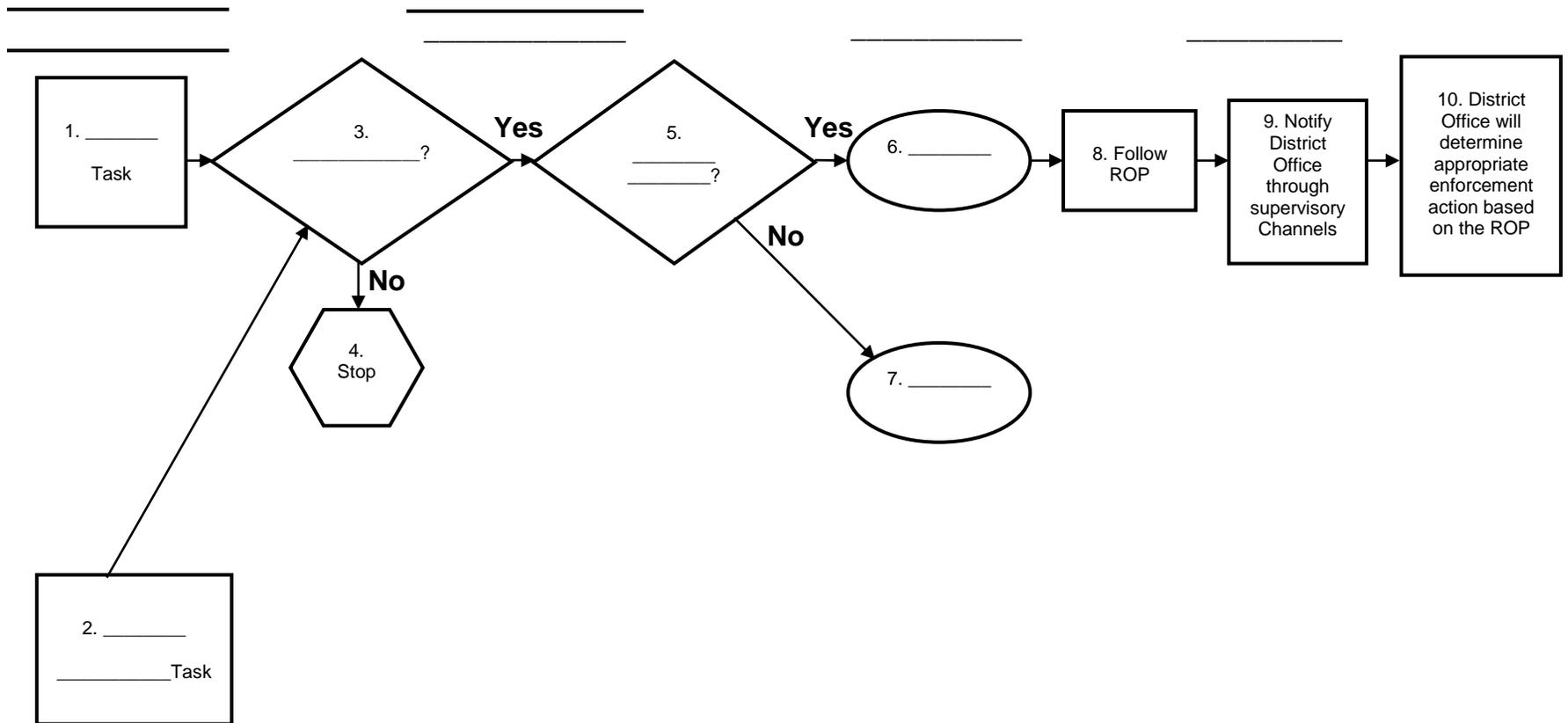
Regulatory Process

The HACCP system, referenced in 9 CFR 417.4, is defined in 9 CFR 417.1 as “the HACCP plan in operation, including the HACCP plan itself”. The HACCP plan in operation includes the:

- hazard analysis,
- HACCP plan,
- supporting documentation including prerequisite programs used to make decisions in the hazard analysis, and
- HACCP records generated on an ongoing basis.

IPP must focus on the overall effectiveness of the establishment’s HACCP system.

Active Learning Activity: Consider what you've already learned about the **Regulatory Process** and work with your neighbors to complete the diagram.



The diagram on the previous page shows the **HACCP Regulatory Process**, which includes the following four components:

- **Inspection Methodology**
 - Performing HACCP inspection tasks
 - Verifying specific HACCP regulatory requirements during the performance of the HACCP inspection task
- **Decision-making (GAD)**
 - Gathering information, making observations, reviewing documentation, assessing the gathered information and arriving at a supportable compliance or noncompliance determination.
- **Documentation**
 - Entering HACCP inspection task results (observations and determinations) in PHIS
 - Documenting noncompliance on a Noncompliance Record
 - Associating noncompliance from the same cause
- **Enforcement**
 - Following the Rules of Practice (ROP)
 - Providing the establishment with due process

FSIS Responsibilities

FSIS responsibilities for verifying an establishment's food safety system are outlined in **FSIS Directive 5000.1 and 5000.6**. You are responsible for understanding and properly performing the HACCP inspection tasks in the Public Health Information System (PHIS) as described in these Directives.

Inspection Methodology

IPP perform two HACCP inspection tasks to verify that establishments are complying with 9 CFR Part 417. The Hazard Analysis Verification (HAV) task directs the IPP to review the establishment's hazard analyses for one HACCP plan, prerequisite programs, and other supporting documentation. The HACCP verification task focuses the attention of the IPP on the execution or implementation of the establishment's HACCP plans, prerequisite programs and other supporting programs. Both of the HACCP verification tasks can be performed as a routine or directed task. Each HACCP task has two verification components:

- **A recordkeeping component, and**
- **A review and observation component**

IPP use either component or a combination of the components to verify regulatory compliance.

Regulatory Decision-Making- A Thought Process

When IPP perform both of the HACCP inspection tasks, they need to use the regulatory thought process described below.

Gather, Assess, and Determine or GAD

IPP are to **gather** all available information to help them determine regulatory compliance by:

- Reviewing establishment hazard analyses, HACCP plans, prerequisite programs and other supporting documentation
- Reviewing establishment records documenting the implementation of HACCP plans, prerequisite programs and other supporting programs or procedures
- Observing establishment employees implementing each HACCP plan, prerequisite program or other supporting program or procedure, and
- Observe product and occasionally take measurements as specified in the establishment HACCP plans, prerequisite programs, or other supporting programs or procedures.

IPP are to **assess** the significance and meaning of information gathered by:

- Comparing the information gathered to HACCP regulatory requirements
- Considering what each piece of information, either taken separately or with other findings, says about how the HACCP system is functioning to ensure that products are not adulterated
- Considering the information in the context of past findings to identify any patterns or trends, e.g., Is this an isolated or recurring problem? Are conditions getting worse? Is the establishment responding effectively and in a timely manner to problems?

IPP are to **determine** whether the information supports a finding of regulatory compliance by considering the following questions:

- Has adulterated product been produced or shipped?
- Is the HACCP system effectively controlling the relevant food safety hazards?
- Has the establishment failed to meet one or more HACCP regulatory requirements?

HACCP noncompliance is the failure to meet any of the HACCP regulatory requirements of 9 CFR Part 417. If a HACCP noncompliance occurs, the establishment is expected to take immediate and further planned actions or come back into compliance.

Before IPP determine whether or not they should document the failure to meet the HACCP regulatory requirements as a noncompliance, they should consider the following questions:

1. Has the establishment already identified the failure to meet regulatory requirements or deviation from a critical limit?
Note: A deviation from a critical limit is the failure to meet the applicable value established for the CCP.
2. If product is involved, has the establishment ensured product safety?
3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken corrective actions to address the deviation in accordance with 9 CFR 417.3?
4. Is a trend developing (i.e., has the establishment carried out the actions in 1 through 3 above for similar situations)?

Note: When answering these questions, it may be necessary for the IPP to gather additional information, e.g., records.

If the answer is “**yes**” to questions **1, 2, and 3** and “**no**” to **question 4**, then there is no noncompliance because the establishment has already identified and addressed the situation. IPP document compliance with the applicable regulations in PHIS. Because the establishment’s response provided the further planned actions and preventive measures for the noncompliance or deviation, not writing an NR does not adversely affect an IPP’s ability to track developing trends. However, an establishment’s failure to follow through on further planned actions and preventive measures could lead to recurring noncompliances and would warrant NRs in recurring situations.

If the answer is “**no**” to **questions 1, or 2, or 3**, or “**yes**” to **question 4**, then a noncompliance exists. IPP document noncompliance in PHIS and generate an NR.

Note: If IPP are uncertain whether the information supports a particular compliance determination, they are to discuss the issue with their supervisor. Once a sound determination has been made, IPP are to document their determination in accordance with FSIS Directive 5000.1.

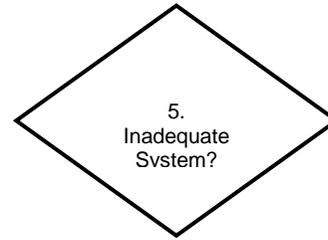
Noncompliance as it Relates to the HACCP System

While any noncompliance is important and must be properly documented, the purpose of the HACCP verification task is more than just to identify isolated instances of noncompliance. IPP must also consider what their findings, whether positive, negative, or inconclusive, suggest about the overall effectiveness of the establishment's HACCP system. When IPP have concerns about the ability of the establishment's HACCP system to produce safe products, they are to discuss those concerns with their supervisor.

It is important that IPP **consider each piece of information in the context of the HACCP system** and the potential for product adulteration. The following questions will help IPP to consider the significance of each finding for the HACCP system:

- **Is this piece of information part of a pattern?** For example, suppose the establishment skipped a measurement for a prerequisite program. Is this an isolated incident or has the establishment regularly failed to implement their prerequisite programs?
- **Is there other information to indicate that the HACCP system is working or is not working?** For example, an establishment's prerequisite program specifies product will be received with supplier certificates of analysis (COA) and periodically tested. If the establishment failed to receive a COA for a particular product, how did they respond on whether or not to use the product?
- **Does the information seem to agree with the other available information about the food safety system?** For example, the establishment uses a prerequisite program to prevent a hazard in incoming products, and the records appear to show that a particular hazard is being prevented. However, the establishment's testing of finished product for the particular hazard finds positive results.
- **Do these results support each other or is there an apparent contradiction?** For example, an establishment that uses a prerequisite program to prevent *E. coli* O157:H7 in incoming beef has certificates of analysis and verification test results on incoming trim that appear to indicate that the hazard is not reasonably likely to occur, but the establishment gets a positive test result on a finished product lot. The finished product test result calls into question the effectiveness of the prerequisite program as means of supporting the decision that *E. coli* O157:H7 is not reasonably likely to occur.

Inadequate System Determination



If noncompliance is found, you need to determine if it indicates an **inadequate system**.

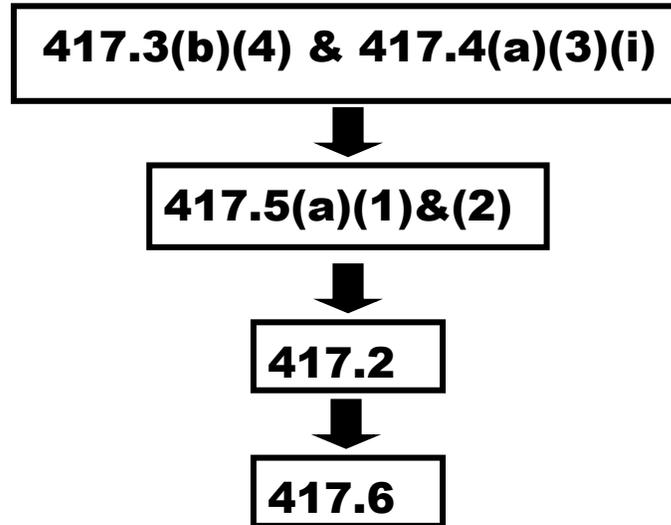
Sec. 417.6 - Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

- (a) The HACCP plan in operation does not meet the requirements set forth in this part;*
- (b) Establishment personnel are not performing tasks specified in the HACCP plan;*
- (c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;*
- (d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or*
- (e) Adulterated product is produced or shipped.*

To determine whether an establishment's HACCP system is adequate, you must consider more than the HACCP plan. Consider all available evidence, including the hazard analysis, supporting documentation, and other parts of the system (SSOP, in-plant testing programs, etc.). Depending on the problems identified, the establishment may need to reassess the hazard analysis and HACCP plan. For example, if an establishment has not identified *E. coli* O157:H7 as a food safety hazard reasonably likely to occur in its process, is testing outside the HACCP plan or SSOP, and gets a positive result, then a reassessment of its HACCP plan and hazard analysis is required by 9 CFR 417.4(a)(3). The establishment must support the decisions made during the reassessment as specified in 417.5(a)(1)&(2).

If the establishment did not reassess its HACCP plan and hazard analysis as required by 417.3(b)(4) and 417.4(a)(3)(i) or does not have supporting documentation required by 417.5(a)(1)&(2), you cannot determine that the HACCP system is meeting the requirements of 417.2, therefore the HACCP system may be determined to be inadequate as described in 417.6.



To determine if there is an inadequate system you need to answer the following:

1. Does the HACCP plan meet the regulatory requirements of Part 417?

If the establishment is not implementing all or some of its program, it has not met regulatory requirements. For example, if an establishment is not maintaining **any** records associated with its HACCP plan, the establishment is not monitoring critical limits at any CCP, the establishment did not reassess the HACCP plan when required, or the establishment did not modify its HACCP plan when it no longer met the requirements---then the establishment has not met the regulatory requirements. Therefore, you are unable to determine whether or not the establishment is producing un-adulterated product, and, therefore the HACCP system is inadequate. In these cases, the HACCP system would be considered inadequate because it did not meet the regulatory requirements of Part 417.

- If the answer is **no** to question 1, this may be indicative of an **inadequate system**.

2. Was adulterated product produced or shipped?

If the HACCP system did not prevent the production and distribution of adulterated product, it is an inadequate system. If you determine that the establishment failed to meet a critical limit for a CCP and did not take the corrective actions as per Section 417.3 of the Federal regulations, and the establishment has performed its pre-shipment review, the HACCP system is inadequate.

- If the answer is **yes** to question 2, this may be indicative of an **inadequate system**.

3. Is there a trend in establishment noncompliance?

You should observe trends in the regulations cited on NRs when determining whether an establishment's HACCP system is inadequate. If two or more NRs have the same regulations cited and if descriptions of noncompliances indicate that similar problems are recurring, there may be a trend indicating the HACCP system is inadequate.

There is no specific number of incidents which determine a trend. Because there will be a variety of processing environments and HACCP plans, FSIS cannot establish that a specific number of the same or similar incidents of noncompliance necessarily support an inadequate system. Therefore, you must thoroughly analyze and document noncompliance trends that may support a determination. When reviewing a possible trend in noncompliance, you must closely review the descriptions of noncompliance contained in Block 10 of the NR form. You should not solely rely on the number of linked noncompliances. Only through careful analysis of the regulations cited and the written descriptions of noncompliance can you determine whether there is a trend indicating that a HACCP system may be inadequate.

- If the answer is **yes** to question 3, this may be indicative of an **inadequate system**.

Action to Take If an Inadequate System Exists

If you determine that an **inadequate system** exists, then you must take action.

- You would notify the District Office.
- If you determine that adulterated product has been produced and shipped, you would take an immediate withholding action, according to the Rules of Practice.

The main point to remember is to contact the District Office, via supervisory channels, if you believe an inadequate system exists.

Documentation

Completing a Noncompliance Record (NR)

When documenting noncompliance on a Noncompliance Record (NR), do the following.

- Identify each noncompliance.
- Be specific and thorough, including time and location.
- Explain that establishment management has received notification.

- State any regulatory control actions you took.

If you need further information about completing the NR, please consult FSIS PHIS Directive 5000.1 and the PHIS User Guide.

Documenting a Trend

Throughout this course you have learned that when you observe noncompliance, you document noncompliance, and when there is a trend in noncompliance that is from the same cause you associate the noncompliances. Documenting and associating noncompliance are key concepts that must be carried out in your daily duties so that the agency is able to provide establishments with due process and to take enforcement action when necessary.

When you determine that the establishment does not meet one or more regulatory requirements, document your findings on an NR. If the establishment has produced and shipped unsafe food, initiate the appropriate enforcement actions described in §500.3. If you have documented multiple or recurring noncompliances, request that the DO issue an NOIE (Notice of Intended Enforcement Action) to the establishment as per §500.4. If you decide to request an NOIE it should come as no surprise. By the time you have made this decision, you should have been discussing the trend in noncompliance with the establishment during weekly meetings and you should have been keeping your frontline supervisor apprised of what was happening. Everyone (the establishment, your frontline supervisor, and the DO) should be expecting the request for the NOIE.

Enforcement

Follow Rules of Practice

Recall that the Rules of Practice (ROP) in 9 CFR 500 provide establishments with due process. They also describe how the Agency progresses with further enforcement actions and under what circumstances.

When a noncompliance determination is made, it may be necessary to take an **enforcement action** to prevent adulterated product from being produced and shipped. In accordance with the rules of practice, this enforcement action could be one of three types.

1. A “**regulatory control action**,” is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

2. A “**withholding action**,” is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.
3. A “**suspension**,” is an interruption in the assignment of program employees to all or part of an establishment.

Withholding actions affect whether the mark of inspection may be applied, while suspensions affect whether inspection verification activities will be performed.

Regulatory Control Actions

FSIS may take a regulatory control action if there are: (1) *insanitary conditions or practices*; (2) *product adulteration or misbranding*; (3) *conditions that preclude FSIS from determining that product is not adulterated or not misbranded*; or (4) *inhumane handling or slaughtering of livestock*.

A regulatory control action permits IPP to identify regulatory noncompliance and prevent the movement of the product involved or use of the equipment or facility involved until the noncompliance has been corrected. IPP are not required to give the establishment prior notification that they are about to execute a regulatory control action.

If there is SPS noncompliance without direct product contamination or adulteration, but there is an imminent probability that the noncompliance will result in product contamination or adulteration if not addressed immediately, you will take a regulatory control action such as retaining product or rejecting the equipment or room with a tag, and then complete an NR. Regulatory control actions should remain in effect until the establishment has brought itself back into compliance with regulations.

If there is SPS or SSOP noncompliance with direct product contamination or adulteration, you will verify that the establishment addresses the noncompliance by meeting the requirements of either Part 416 or Part 417. You will write an NR using the appropriate SSOP regulations or the appropriate HACCP regulations. You will verify that the establishment implements corrective actions, including product control actions that meet the requirements of §416.15. The establishment may need to re-evaluate the effectiveness of its procedures in its SSOP and modify them if they are no longer effective in preventing direct contamination or adulteration of product.

If the direct product contamination poses a food safety hazard, you will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of §417.3(b). These corrective actions include a reassessment to determine whether the unforeseen hazard should be incorporated into the HACCP plan. Regulatory control actions are not frequently

used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

Examples of common regulatory control actions related to slaughter would be stopping a line or retaining a carcass as a result of a slaughter food safety standard finding.

Withholding Action Without Prior Notice

There may be instances when it is necessary for you to take immediate enforcement actions to prevent imminent threat to public health, without giving the establishment prior notice. For example, if the establishment produced and shipped adulterated product, you would need to take an immediate withholding action. In these situations, first take the immediate withholding action, and then as soon as possible notify the District Office and your supervisor. For further information, refer to the Rules of Practice module.

Withholding and Suspension Actions With Prior Notification

Keep in mind that some withholding and suspension actions require prior notification according to the rules of practice. The most common withholding or suspension actions related to HACCP noncompliance are those in which the HACCP system is found inadequate due to **multiple or recurring noncompliances**. Withholding or suspending inspection for this cause does require prior notification to the establishment. The prior notice is in the form of a written Notice of Intended Enforcement Action (NOIE). Remember that a suspension may only be issued by a District Manager or higher FSIS official.

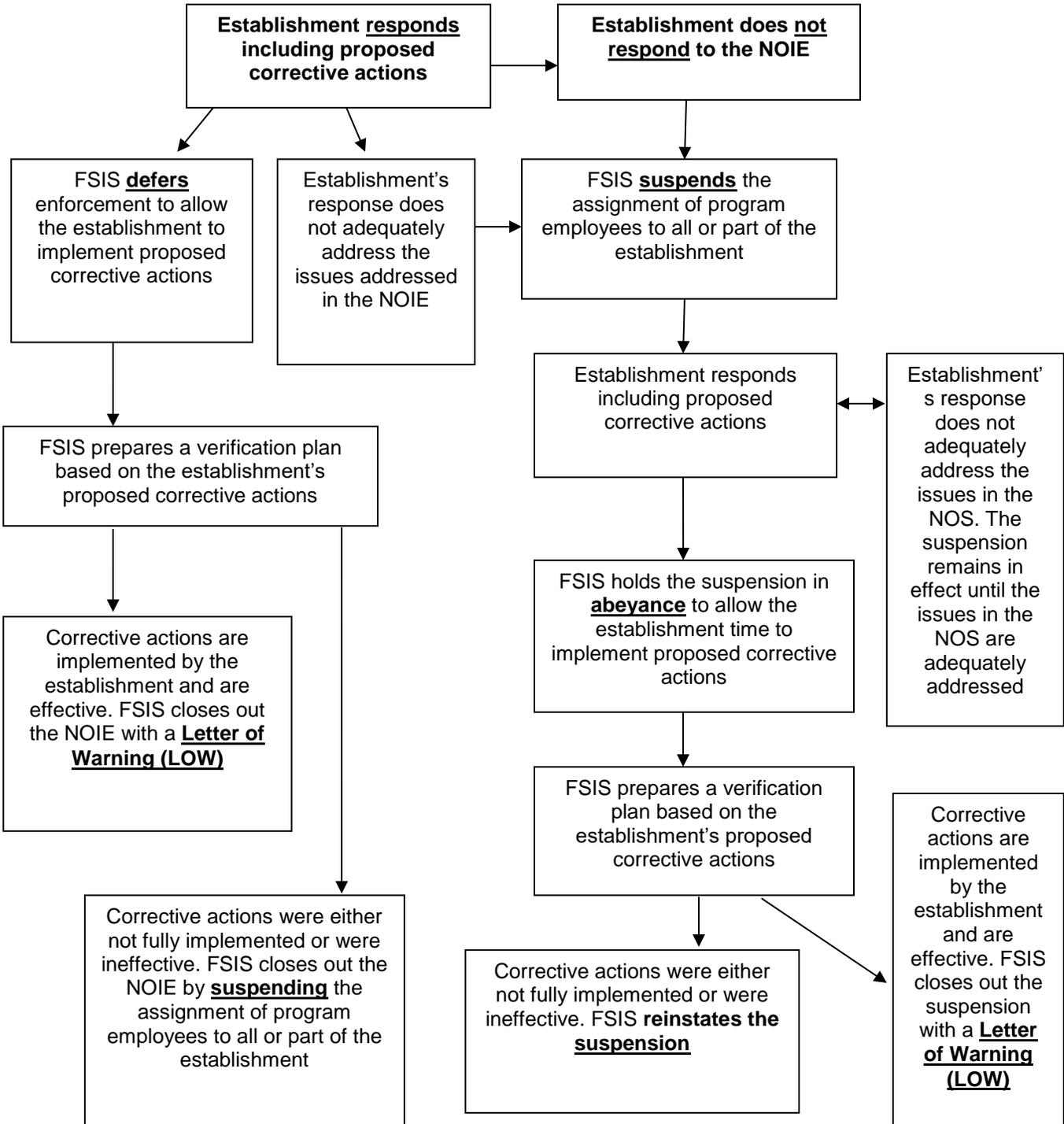
Notify the District Office

If you determine that an inadequate system may exist, you should notify the District Office. Provide the DO with all of the information about the situation. You should request that a Notice of Intended Enforcement be issued to the establishment. The DO will provide direction about further actions you need to take. The DO may assign an EIAO to evaluate the establishment's HACCP system.

District Office Determines Enforcement Action

After evaluating all of the facts of the case, the District Office will determine the appropriate enforcement action based upon the rules of practice.

Notice of Intended Enforcement Action
Establishment has 3 business days to respond



Verification Plan

When FSIS **defers** an enforcement action or holds a suspension in **abeyance**, FSIS allows the establishment time to implement their proposed corrective actions. A verification plan (VP) is developed by the EIAO with input from the in-plant inspection team and the Frontline Supervisor. The VP captures all of the corrective actions the establishment stated they would do, and the VP provides a systematic means for FSIS to verify that an establishment is effectively implementing the corrective measures that were proffered to FSIS.

A VP:

- Describes the verification activities to be performed by inspection personnel based on the establishment's corrective measures,
- Lists the procedures for each verification activity, and
- Identifies the regulatory citation for each verification activity.

IPP schedule and perform directed verification activities identified in the VP. On a weekly basis, the in-plant team reports, via e-mail to the District Office, the results of the activities conducted under the VP. The in-plant inspection team has the flexibility to increase the frequency of the verification activities based on its findings. Any failure to meet the conditions of the proposed corrective measures would support FSIS imposing further enforcement actions.

Recalls

Recalls are initiated when there is evidence of adulterated or misbranded product in commerce, for example, when a positive pathogen sample result is obtained for product that the establishment has shipped. FSIS Directive 8080.1, Rev. 7, Recall of Meat and Poultry Products, details all verification requirements for recalls.

Establishment Recall Requirements

On May 8, 2012, FSIS published the final rule "Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments" (77 FR 26929). The rule requires official establishments to:

1. Notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat or poultry product received by or originating from the official establishment has entered commerce (9 CFR 418.2);

2. Prepare and maintain written procedures for the recall of all meat and poultry products produced and shipped by the establishment (9 CFR 418.3); and
3. Prepare written recall procedures as required by 9 CFR 418.3 before being granted Federal inspection (9 CFR 304.3(a) and 381.22(a))

9 CFR 418.2 - Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

Establishments must notify the District Office that an adulterated or misbranded meat or poultry product received by or originating from the official establishment has entered commerce. Official establishments are to provide the DO with the type, amount, origin, and destination of the adulterated or misbranded product.

1. Product is in commerce if it is out of the producing establishment's direct control and is in distribution (e.g., in a warehouse, distribution center, retail facility, restaurant, or other institution).
2. The 24-hour period begins when an establishment has reason to believe that a product in commerce is adulterated or misbranded under the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). For example, product would be adulterated if the final results of a laboratory analysis show that raw ground beef contains *E. coli* O157:H7, or if product contains an allergen that is not declared on the product label.
3. There may be situations in which laboratory results are not available, but based on epidemiological evidence, there may be a probability of harm from consuming the product. Under these circumstances, official establishments are to consider the strength of the epidemiological evidence to determine whether there is reason to believe that the product is adulterated or misbranded.

The DO is to notify the Recall Management and Technical Analysis Division (RMTAD) as soon as possible after notification. If establishments contact other FSIS personnel, those employees are to contact RMTAD promptly through supervisory channels.

The DO and possibly the RMTAD evaluate each situation on a case-by-case basis (see FSIS Directive 8080.1, Rev. 7, Recall of Meat and Poultry Products). The RMTAD is notified immediately if product has left the establishment's control, and they coordinate any recall activities.

More or less product may be determined to be "affected product" based on all considered factors (e.g., whether some or all products produced under the same or a substantially similar HACCP plan have been affected, what pathogens are involved, whether there have been any other incidents of contamination in the establishment associated with the pathogen, and whether there have been persistent and recurring noncompliances in the establishment). The RMTAD is notified so a press release can be issued and effectiveness checks can be performed.

The establishment is expected to perform a voluntary recall of any unsafe product in commerce. If the establishment does not voluntarily recall product, the DO will coordinate actions to detain or seize affected product.

9 CFR 418.3 - Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

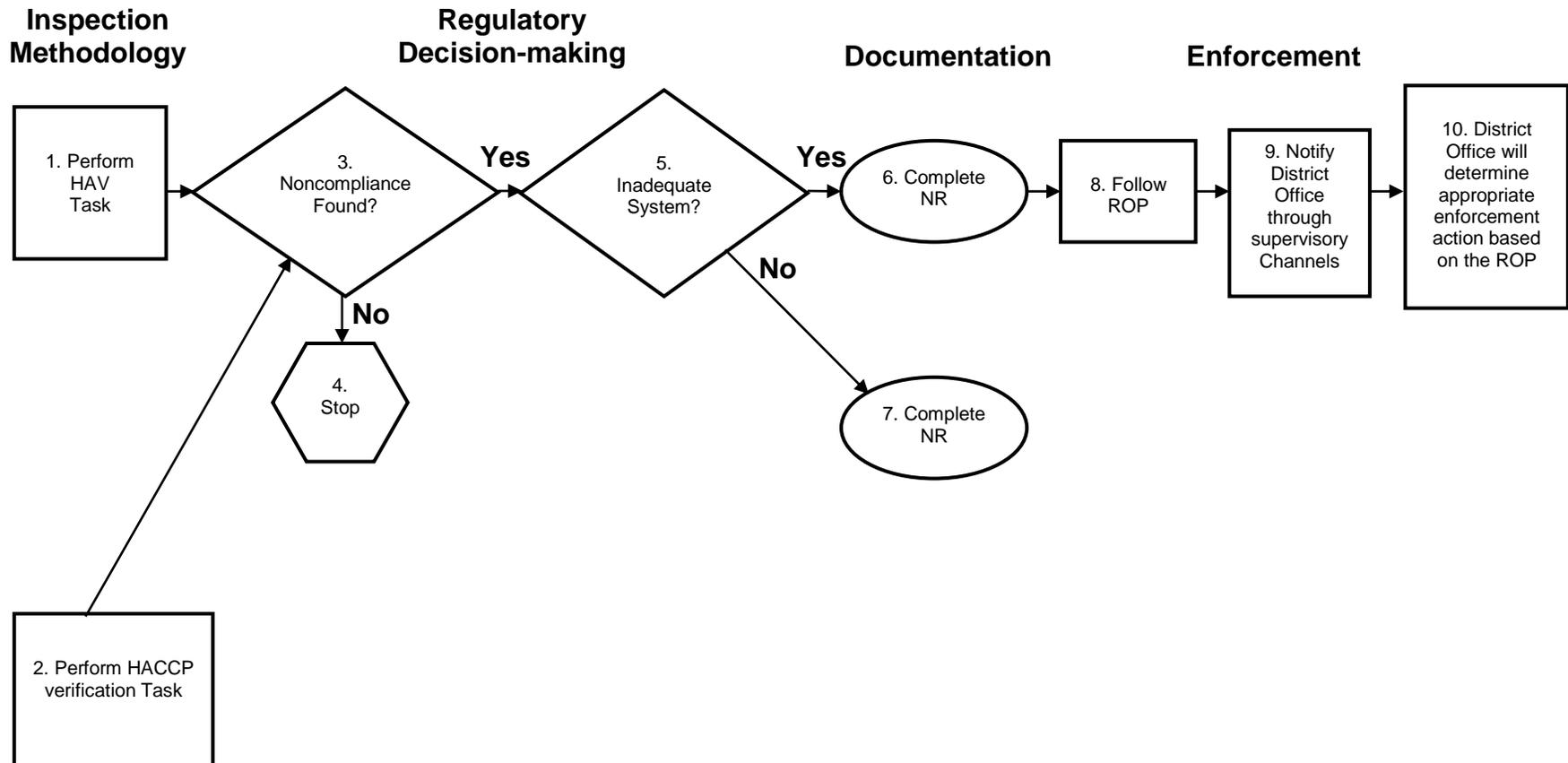
Meat and poultry establishments must have written procedures for the recall of any meat or poultry product produced and shipped by the official establishment. FSIS Directive 5000.8, Verifying Compliance with Requirements for Written Recall Procedures, dated 12/18/2013, outlines the details of how to verify the requirements of 9 CFR 418.3.

FSIS Verification

At least once a year, IPP are to perform a directed Other Inspection Requirements task to verify that establishments have written recall procedures.

If IPP determine that the establishment has written recall procedures, they are to document in PHIS that they performed the task, and that the establishment complies with 9 CFR 418.3. If IPP determine that the establishment does not have written recall procedures, they are to document the noncompliance in PHIS on a noncompliance record, citing 9 CFR 418.3.

HACCP Regulatory Process



Workshop: Regulatory Review

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. You are the IIC at a small establishment that produces frozen spaghetti and tomato sauce with meat entrees and frozen non-amenable spaghetti entrees made with a lobster cheese sauce. You are performing Pre-Operational Sanitation Review and Observation Task.

a. The regulation sections that you are verifying regulatory compliance with are?

You observe various product contact surfaces in the formulation area. You see that some of the blending equipment appears to have product residue from the previous day's production. You inspect the interior surfaces of the blenders and find residue. You see what appears to be cheese sauce residue in several areas, and you see what appears to be tomato sauce residue in several other areas. You check the production records from the previous day and determine that the establishment produced lobster cheese spaghetti in the morning and tomato sauce with meat spaghetti in the afternoon. The label of the spaghetti containing meat does not list any lobster (crustacean) or milk ingredients.

b. Are the conditions you observed creating an insanitary condition?

c. Can the conditions you observed lead to contaminated product?

d. Is there a food safety hazard associated with the contamination you observed?

e. You take official control of the blenders by placing a U.S. reject tag on them. What regulations give you the authority to take this action?

f. What statutes give you the authority to take this action? Explain in your own words the reasoning behind this authority.

g. What actions would you take next?

You review the HACCP plan and hazard analysis. The establishment found that food allergens were potential food safety hazards, but determined that they were not likely to occur in this process because the establishment has a food allergen control program which prevents the hazard.

h. Which corrective action regulation would apply in this situation?

As part of a Directed Fully Cooked but Not Shelf Stable HACCP Verification Task, you review the establishment's food allergen control program. You find that the establishment lists several daily in-plant checks and verification activities and the associated documentation that will be kept. You request recent records and your review reveals that the food allergen control program verification activities are not being done at the frequency listed in the program. Records are also not available for some of the days.

i. Could this indicate an inadequate system?

j. How would you document what you have found? What regulations would you use?

k. What actions would you take next?

2. While performing a Fully Cooked Not Shelf Stable HACCP verification task in a ready-to-eat product operation to verify the HACCP regulatory requirements, you review the establishment's HACCP plan. During this review, you notice that the establishment has documented a reassessment of its HACCP plan. You go to establishment management and ask what event triggered the reassessment. The establishment manager indicates that the reassessment was performed in response to a positive *Listeria monocytogenes* result from its microbiological testing of the finished ready-to-eat ham lunchmeat. This microbiological testing program is not referenced in the establishment's HACCP plan. *Listeria monocytogenes* testing is performed as a verification requirement for their

customer. You request the establishment to provide the results of their microbiological testing of the finished ham lunchmeat. The establishment provides this data to you. You observe that the last sample analyzed was found to be positive for *Listeria monocytogenes*. You request information about corrective actions taken and are shown an unforeseen hazard log that documents that the establishment segregated and held affected product. The establishment also has records to show that it performed a review to determine the acceptability of affected product, and took action to ensure that no product injurious to health entered commerce by denaturing and disposing of the adulterated product. Documentation that the product was denatured and disposed of in a landfill is provided. The log further shows that a reassessment was performed, and the establishment determined that this was not a hazard reasonably likely to occur in its process. It made no alterations to the hazard analysis or the HACCP plan. The basis for this decision is documented as: "It is the only positive ever received. We apply a full lethality treatment and apply our Sanitation Standard Operating Procedures daily. The application of our Sanitation Standard Operating Procedures daily should continue to be sufficient in the future. This result is a fluke. No changes to the HACCP plan are necessary at this point." When you ask for support for the decision that the hazard is still not reasonably likely to occur, the establishment manager says "the result was a fluke" and we documented that on the corrective action log. As part of the Fully Cooked Not Shelf Stable HACCP Verification Task on this specific production, you verify that all HACCP requirements, including pre-shipment review, were met for all CCPs, other than what is described above.

a. Has the establishment supported its decision about the results of the reassessment?

b. What are the 4 questions you would seek answers to as you gather information to determine whether or not to document this as a noncompliance, and what conclusion would you make?

Remember the 4 questions from the HACCP Regulatory Process presentation. If the system is working, you may not document some noncompliances.

c. What regulations need to be considered?

d. Is there a noncompliance? Please explain your answer.

e. If you determine that a noncompliance should be documented, what regulation would you cite?

f. What are the questions you would seek answers to as you gather information to determine whether or not there is an inadequate system, and what conclusion would you make?

Is there an indication of an inadequate system?

g. If you determine that you would document an NR, please complete blocks 6, 8, 9, and 10 **only** on the next page.

Appendix 1

FSIS Directives and Notices

FSIS Directive 5000.1, Verifying an Establishment's Food Safety System

FSIS Directive 5000.6, Performance of the Hazard Analysis Verification (HAV) Task

FSIS Directive 5000.8 Verifying Compliance with Requirements for Written Recall Procedures

FSIS Directive 8080.1, Recall of Meat and Poultry Products.

Appendix 2

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 417--HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Sec.

- 417.1 Definitions.
- 417.2 Hazard Analysis and HACCP plan.
- 417.3 Corrective actions.
- 417.4 Validation, Verification, Reassessment.
- 417.5 Records.
- 417.6 Inadequate HACCP Systems.
- 417.7 Training.
- 417.8 Agency verification.

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.

Source: 61 FR 38868, July 25, 1996, unless otherwise noted.

Sec. 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action - Procedures to be followed when a deviation occurs.

Critical control point - A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit- The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard- Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System- The HACCP plan in operation, including the HACCP plan itself.

Hazard - SEE Food Safety Hazard.

Preventive measure - Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument - An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official-The individual with overall authority on-site or a higher level official of the establishment.

Sec. 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. 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, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls. (2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified. (3) Food safety hazards might be expected to arise from the following:

- (i) Natural toxins;
- (ii) Microbiological contamination;
- (iii) Chemical contamination;
- (iv) Pesticides;
- (v) Drug residues;
- (vi) Zoonotic diseases;
- (vii) Decomposition;
- (viii) Parasites;
- (ix) Unapproved use of direct or indirect food or color additives; and
- (x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

- (i) Slaughter--all species.
- (ii) Raw product--ground.
- (iii) Raw product--not ground.
- (iv) Thermally processed--commercially sterile.
- (v) Not heat treated--shelf stable.
- (vi) Heat treated--shelf stable.
- (vii) Fully cooked--not shelf stable.
- (viii) Heat treated but not fully cooked--not shelf stable.
- (ix) Product with secondary inhibitors--not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under Sec. 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

Sec. 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the

corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

- (1) The cause of the deviation is identified and eliminated;
- (2) The CCP will be under control after the corrective action is taken;
- (3) Measures to prevent recurrence are established; and
- (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

- (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
- (2) Perform a review to determine the acceptability of the affected product for distribution;
- (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
- (4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with Sec. 417.4(a)(2)(iii) and the recordkeeping requirements of Sec. 417.5 of this part.

Sec. 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

- (i) The calibration of process-monitoring instruments;
- (ii) Direct observations of monitoring activities and corrective actions; and
- (iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. (i) Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of 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. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Sec. 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decision-making documents associated with the selection and development of CCP and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

Sec. 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

- (a) The HACCP plan in operation does not meet the requirements set forth in this part;
- (b) Establishment personnel are not performing tasks specified in the HACCP plan;
- (c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;
- (d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or
- (e) Adulterated product is produced or shipped.

Sec. 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Sec. 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

- (a) Reviewing the HACCP plan;
- (b) Reviewing the CCP records;
- (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

- (d) Reviewing the critical limits;
 - (e) Reviewing other records pertaining to the HACCP plan or system;
 - (f) Direct observation or measurement at a CCP;
 - (g) Sample collection and analysis to determine the product meets all safety standards;
- and
- (h) On-site observations and record review.

PART 418—RECALLS

Sec. 418.1 [Reserved]

Sec. 418.2 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

Sec. 418.3 Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

Sec. 418.4 Records.

All records, including records documenting procedures required by this part, must be available for official review and copying.