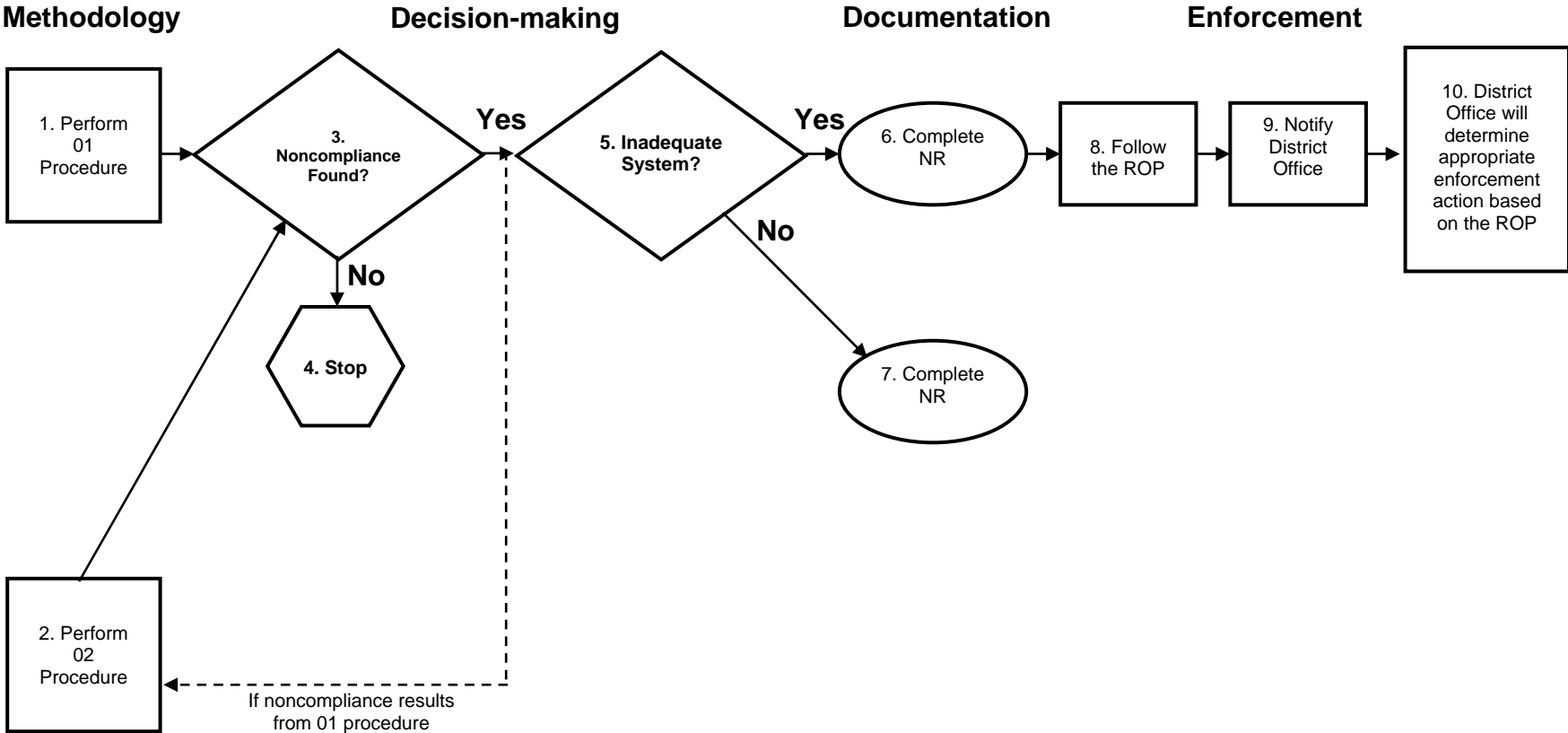


### Regulatory Process for HACCP 01 and 02 Procedures in 03B - J



## HACCP: NRTE/RTE Decision-Making, Documentation and Enforcement

### Decision-making

Next in the regulatory process is decision-making. In the decision-making thought process, you will determine whether or not the establishment is in compliance with the regulatory requirements. If noncompliance exists, then you will determine whether an inadequate system exists.

### Noncompliance and Deviation Definitions

A **HACCP noncompliance** is the failure to meet **any** of the regulatory requirements of 9 CFR Part 417: monitoring, verification, recordkeeping, corrective actions, and reassessment. If a HACCP noncompliance occurs, the establishment is **expected** to take immediate and further planned actions.

A **deviation from a critical limit** is the failure to meet the applicable value determined by the plant for a CCP. If a deviation from a critical limit occurs, the plant is **required** to take corrective actions in accordance with 9 CFR 417.3(a).

### Noncompliance Determination

Some failures to meet the regulatory requirements should not be documented on an NR. Before deciding to document noncompliance, consider the following questions:

1. Has the establishment already identified the failure to meet regulatory requirements or the deviation from a critical limit?
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 and preventive measures to address the deviation or unforeseen hazard in 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)?

If the answer is **yes** to **questions 1, 2, and 3** and **no** to **question 4**, then there is **no noncompliance that you would document**, because the establishment has already identified and addressed the situation.

Not writing an NR will not adversely affect your ability to track developing trends for deviations because the establishment must provide corrective actions. In other words, you can use plant records to support your decision that a trend is developing.

When the plant finds, documents, and satisfactorily handles a deviation or a HACCP noncompliance (e.g., a missed verification), you may decide not to write an NR for that incident. If you notice that the plant is having multiple deviations or routinely missing verification checks, you may use the plant's records to support your determination of a trend. Issue an NR to document your findings stating that the plant's corrective and preventive measures or immediate and further planned actions are not working and a trend is developing. State that failure to correct the situation could result in further enforcement actions.

If the answer is **no** to **questions 1, 2, or 3**, or **yes** to **question 4**, then there is a **noncompliance that you would document**.

### ***Examples of Noncompliance Determinations***

The following scenarios use monitoring as the example. The methodology applies to problems with verification, recordkeeping, corrective actions, and reassessment as well.

#### ***Situation 1***

While performing a records review for a HACCP 01 procedure, you find that a plant employee missed a 9:00 a.m. monitoring check. You also find that the plant found the error during its records verification, demonstrated product safety with other records, and took immediate and further planned actions for the noncompliance by retraining the employee. You looked at previous NRs and determined that the plant had not missed a monitoring check in over three months.

#### ***Outcome***

In this situation no NR is necessary even though there was a missed monitoring check, and you mark the HACCP 01 procedure as performed. However, if you found that adequate further planned actions were **not** in place, and that the missed monitoring check and correction had occurred several times within the month, you may determine that a trend for monitoring noncompliance has developed. In this case, issue an NR and discuss this trend with plant management during the weekly meeting.

### ***Situation 2***

While performing a HACCP 01 procedure using records review, you find that a plant employee missed a 9:00 a.m. monitoring check and there is no indication that the plant identified the missed monitoring check. You write an NR for the 01 procedure. When you perform the HACCP 02 procedure, you find that the product was shipped without a pre-shipment review.

#### *Outcome*

In this situation you write another NR, but for the 02 procedure this time, that explains this noncompliance. Next, you determine whether the plant can provide other documentation that establishes product safety. If the plant cannot demonstrate product safety, take action per Part 500.

### ***Situation 3***

While performing the recordkeeping component of the HACCP 01 procedure, you see that a plant employee recorded a deviation from a critical limit on the monitoring record. You verify that the corrective actions taken by the plant met the requirements of §417.3(a).

#### *Outcome*

There is no regulatory noncompliance, and an NR is not issued.

### ***Situation 4***

While performing a HACCP 02 procedure using records review for a single lot of product, you see in the records that a plant employee missed a monitoring check at 10:00 a.m., and there was a deviation from a critical limit at 11:00 a.m. You continue reviewing the records and find that at pre-shipment review the plant identified the deviation and took the proper §417.3(a) corrective and preventive measures but failed to address the missed monitoring check.

#### *Outcome*

In this situation, write an NR for the missed monitoring check and determine whether the plant can demonstrate product safety. If so, no other action is necessary. If the plant cannot support product safety, take action per Part 500.

## Basic Noncompliance

For meat or poultry establishments coming under inspection and establishments that have developed a **new** HACCP plan not yet in operation, there is noncompliance with the design or basic regulatory requirements for the HACCP plan if you make a check mark on the HACCP System—Basic Compliance Checklist (FSIS Form 5000-1) while performing procedure 03A01. In those cases,

- Enter the “m” noncompliance result code for the unscheduled 03A01 procedure on the PS and issue the NR
- The plant is not permitted to start production of products under the noncompliant HACCP plan.
- Notify the District Office.
- Attach the completed FSIS 5000-1 to the NR and file them in the government office.

If the plant **completely revises its HACCP plan**, it is essentially a new plan. However, since the plant has been producing products covered under the plan, you do not stop the plant from using the revised plan if you find noncompliance with the HACCP plan design or basic regulatory requirements. Issue an NR and contact the DO.

**Note:** The regulations require that the *records* be kept for a specific amount of time, but there is no such regulation specific to the HACCP plan. A prudent plant would keep the old plan for the same amount of time [§417.5(e)] that it keeps the records associated with it.

If a plant has been **operating under a given HACCP plan for some time**, and you find noncompliance with a HACCP plan design or basic requirements during performance of your other verification duties, you must first determine product safety. If food safety is *not* jeopardized, issue an NR under the HACCP procedure code that you were performing when you found the noncompliance (not under procedure 03A01) and contact the DO for further instruction.

## RTE Product Sample Noncompliance

When RTE product or food contact surface sample results are positive for a pathogen, establishments are required to take corrective actions and to make a proper disposition of the affected product. Your actions will depend on whether the sample was collected by FSIS or by the establishment.

If any RTE product sample **collected by FSIS** (after pre-shipment review) tests positive for a pathogen of public health concern, product in the sampled lot is adulterated. You are to issue an NR under the appropriate HACCP 03 ISP code, using the “verification” noncompliance classification (trend) indicator and citing 9 CFR 417.4(a) and 301.2 or 381.1. In block 10, document:

- Sample collection date
- Product name
- Production or lot code
- Organism or toxin found
- Sample request form number
- Whether the plant shipped product from the sampled lot

If an **establishment’s product or food contact surface sample** result is positive for *L. monocytogenes*, you **should not** issue an NR unless the establishment failed to hold the affected product and did not implement corrective actions, which includes properly disposing of the sampled product lot.

A positive RTE product sample (FSIS or the establishment) result for a pathogen of public health concern is a food safety hazard regardless of what type of program the establishment is using to address the pathogen. The product represented by the sample is adulterated. If a post-lethality exposed RTE food contact surface sample (FSIS or establishment) tests positive for *L. monocytogenes*, the product passing over the surface is adulterated unless a validated post-lethality treatment was applied to it.

In all cases stated above, the plant must meet the corrective action requirements in the HACCP regulations, 9 CFR 417.3. The establishment must meet 9 CFR 417.3(a) when the pathogen is addressed in the HACCP plan. If the pathogen is prevented through the Sanitation SOP, then the establishment must implement the corrective action in 9 CFR 417.3(b) and also implement the corrective action requirements for SSOP in 9 CFR 416.15. If the pathogen is prevented through a prerequisite program that is used to support the decision that a hazard is not likely to occur at a particular point in a process, then the establishment must implement the corrective action in 9 CFR 417.3(b) which includes a reassessment and comply with 417.4(a)(3), because there is a change in the process that affects the hazard analysis.

In each situation, you will need to review all information available to determine whether the establishment has implemented all appropriate corrective actions.

When an FSIS sample result is positive for a pathogen, perform the HACCP 02 procedure by reviewing the product records for the specific production represented by the sample, and perform procedures 01B01 and 01C01 on the plant's SSOP records covering the time period from when the sampled product was produced to the present. Whenever a sample is positive for a microbiological hazard, there are possible sanitation problems in the establishment.

If the plant does not initiate appropriate control of affected product, then you take a regulatory control action by retaining the product. If any affected product has left the plant, and it is no longer under the plant's control, notify the DO. Inform the DO of the amount of affected product that has left the establishment's control. The DO will relay the information to the RMS (Recall Management Staff). RMS will request that plant management recall the affected product.

The DO coordinates the scheduling of intensified verification testing through OCIO-DSMD to verify the establishment's corrective and preventive measures. This sampling might not be initiated until the corrective and preventive measures have been put in place.

<b>FSIS Documentation and Enforcement Actions for Positive <u>Product</u> or <u>Food Contact Surface</u> Samples and the Plant has a Sanitation Program to Control <i>L. monocytogenes</i></b>		
<b>If plant addresses this in its...</b>	<b>FSIS Sample</b>	<b>Plant Sample AND Plant Does Not Perform Corrective Actions</b>
HACCP	Issue NR – under appropriate HACCP 01 procedure; Noncompliance indicator: Verification; Cite §417.4 and §301.2/381.1 Verify plant's corrective actions; Perform procedures 01B01, 01C01 and HACCP 02	Issue NR – under appropriate HACCP 01 procedure; Noncompliance indicator: Corrective Action; Cite §417.3(a); Verify plant's corrective actions; Perform HACCP 02 procedure
SSOP	Issue NR – under appropriate HACCP 01 procedure; Noncompliance indicator: Verification; Cite §417.5(a)(1), §416.14, and §301.2/381.1; Verify plant's corrective actions; Perform procedures 01B01, 01C01 and HACCP 02	Issue NR – under appropriate HACCP 01 procedure; Noncompliance indicator: Corrective Action; Cite §417.3(b) and §416.15; Verify plant's corrective actions and reassessment; Perform HACCP 02 procedure
Prerequisite program	Issue NR – under appropriate HACCP 01 procedure; Noncompliance indicator: Recordkeeping; Cite §417.5(a)(1), and 301.2/381.1; Verify plant's corrective actions and reassessment; Perform procedures 01B01, 01C01 and HACCP 02	Issue NR – under appropriate HACCP 01 procedure Noncompliance indicator: Recordkeeping; Cite §417.3(b) and 417.5(a)(1); Verify plant's corrective actions and reassessment; Perform HACCP 02 procedure



## Inadequate System Determination

Before completing your decision-making process, you should consider whether or not the noncompliance indicates an inadequate HACCP 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 the adequacy of the plant's HACCP system, you must look beyond just the actual written HACCP plan. All available evidence and supporting documentation must be taken into account. You should have intimate knowledge of the plant's process capabilities and use this knowledge to assist you in your determination. You should evaluate other systems within the plant (SSOP, in-plant testing programs like environmental testing or end-product testing, etc.).

Depending on the problems identified, the establishment may need to reassess the HACCP plan. For example, if an establishment has not identified *L. monocytogenes* as a food safety hazard likely to occur in its process and is testing outside the HACCP plan or SSOP and gets a positive result, a reassessment of its HACCP plan and hazard analysis is required in 9 CFR 417.3(b)(4) and 417.4(a)(3). The establishment is required to support the decisions made during the reassessment as specified in §417.5(a)(1) and (2).

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

Remember at the beginning of the verification methodology you were told not to be afraid to ask very **specific** questions when you are trying to determine food safety. That thought process is something you should continue throughout your verification of the HACCP regulatory requirements. For example, construction could impact on the presence of *L. monocytogenes* and should be closely assessed. Ask what measures the plant will take to prevent product contamination. Ask if the plant will do environmental testing during the construction project, and if so, what will the plant do if the results indicate any

significant microflora changes during that time. Ask if the plant will implement any additional sanitation procedures during the construction project, and if it will do any testing to determine the effectiveness of these special procedures. Be curious and always look a step beyond what you know to be sure that you understand all aspects of the plant environment and production practices that have an impact on the safety of the products produced.

Documentation, both by the plant and by you, is vital to the success of the HACCP system. It is difficult to determine system adequacy without documentation. Likewise, if you are trying to initiate an enforcement action based on trends in noncompliance or a series of problems, and you do not have the NRs or other documents, you may not be able to support that enforcement action. To show a trend, you need to have linked NRs.

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

### **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 that the establishment is not producing 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(a) of the 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 noncompliance when determining whether an establishment's HACCP system is inadequate. If two or more NRs have descriptions of noncompliance indicating that similar problems are recurring, there may be a trend indicating the HACCP system is inadequate.

**There is no specific number of incidents which determines 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 supports an inadequate system. Therefore, you must thoroughly analyze and document noncompliance trends that may support a determination. When reviewing a possible trend in incidents of noncompliance, you must closely review the descriptions of noncompliance contained in Block 10 of the NR. You should not solely rely on the number of documented noncompliance classification indicators. Only through careful analysis of 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 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 if you believe an inadequate system exists. We will cover these enforcement actions in more detail in later in this section.

## Documentation

There are several responsibilities related to documentation that you must perform. They include (1) **updating the plant profile** with the appropriate HACCP processing categories that apply to the product produced by the establishment, (2) **documenting the procedures you perform** on the Procedure Schedule, and (3) **documenting all regulatory noncompliance**.

### ***(1) Updating the Plant Profile with the appropriate processing category***

When a plant begins operations or adds a new product, the Plant Profile must be developed or updated to show the processing categories that apply to the product produced by the establishment. Your responsibility is to determine the most likely HACCP processing category for the product and enter that category into PBIS for the system to schedule inspection procedures for you to perform. You can look at the processing procedure used to produce the finished product, product standards (if applicable), and labeling to assist you in determining the processing category. The process categories for the NRTE/RTE products are:

- Fully cooked – not shelf stable (03G)
- Heat treated but not fully cooked – not shelf stable (03H)
- Products with secondary inhibitors – not shelf stable (03I).

Select the appropriate processing category and complete the related electronic form in PBIS. This information is used to schedule inspection procedures for the establishment.

### ***(2) Documenting procedures performed on the Procedure Schedule***

For each procedure scheduled, you must indicate whether it is performed or not performed on the Procedure Schedule.

Only document scheduled procedures as “not performed”. It is not appropriate to list an unscheduled procedure as “not performed”. If you begin an unscheduled HACCP 02 procedure, do not enter anything into PBIS until the 02 procedure is completed. When you complete the 02 procedure you started, document it on the procedure schedule (PS). If an 02 procedure is on the PS that day, you may chose to use it as the procedure to enter into PBIS for the 02 procedure you just completed. However, you may also elect to perform (or start) the 02 procedure that is on the PS on a different specific production. In this case, the 02 procedure you completed is recorded as an unscheduled procedure. If there is no 02 procedure on the PS the day you complete an 02 procedure that you had previous started, you always enter it as an unscheduled procedure.

Here's an example of documenting an HACCP 02 procedure for a RTE product. Let's say you have 03G01 scheduled today. You select the semi-dry, keep refrigerated salami. While performing your 01 procedure, you discovered a noncompliance that triggered you to perform the 03G02. The specific production for the salami is only about two-thirds of the way through the entire process. You start the 02 procedure today, but since you won't be able to complete it today and the 03G02 was not scheduled to be performed (this procedure was triggered due to noncompliance for the 03G01 procedure), do not record anything for this 02 procedure on the PBIS Procedure Schedule (PS). At the end of next week, when the pre-shipment review is completed for that specific production, you need to record on the PS that you completed this 03G02 procedure. If there is an 03G02 procedure already scheduled on the PS the day you complete the 03G02, you may choose to use the 02 procedure on the schedule to document the completion of the 03G02 you started last week. Document it according to your findings of compliance/noncompliance. However, you may also elect to perform the 03G02 procedure on the PS on a **different** specific production. If you choose not to use the 03G02 on the PS to document the completion of the 03G02 procedure you had already started, or an 03G02 procedure is not on the PS for the day you complete the procedure you started the week before, then document 03G02 as unscheduled on the PS.

### ***(3) Documenting noncompliance***

To get to this step, you gathered information by seeking the answers to your questions and assessed the information so that you are now able to make a sound decision regarding compliance.

When you perform a HACCP procedure and determine that there is regulatory compliance, document the procedure as "performed" on the PS.

When you determine that the plant does **not** meet a regulatory requirement, you record the noncompliance on the PS, and you also document the noncompliance on the FSIS Form 5400- 4, Noncompliance Record (NR). An NR is issued for all noncompliance found by in-plant inspection personnel.

The NR is the basis for further enforcement actions that the Agency may take against an establishment. NRs are legal documents and it is vital that you write each finding in a clear and concise manner.

When documenting noncompliance on an NR, do the following.

- Identify each noncompliance.
- Be specific and thorough, including time, location, and the effect on the product.

- Explain that plant management has received notification.
- State any regulatory control actions you took.

If you need further information about completing the NR, consult FSIS Directive 5000.1, Rev. 2.

### **Noncompliance Classification (Trend) Indicators**

There are four noncompliance classification (trend) indicators used to document noncompliance with the HACCP regulatory requirements. Only one indicator is used for each NR issued.

1. Monitoring
2. Verification
3. Corrective Action
4. Recordkeeping

Notice that these correlate to the five HACCP regulatory requirements with the exception of reassessment. Reassessment noncompliance is documented under corrective action, verification, or the recordkeeping noncompliance indicator depending on the circumstances.

For example, if the plant did not reassess due to an unforeseen hazard, then use the *corrective action* indicator because reassessment is part of the regulatory requirements in §417.3(b). However, if the plant performed the reassessment as per §417.3(b)(4), but did not document it as part of the corrective action record, then the *recordkeeping* indicator is used. The recordkeeping indicator is also used when the plant performed the annual reassessment but did not document it (sign and date). If the plant did not reassess due to a change in the process that affected the hazard analysis or altered the HACCP plan, then use the *verification* indicator.

There is no indicator for noncompliance found while performing the 03A01 procedure. Noncompliance result code "M" is entered on the procedure schedule so that an NR can be completed.

#### *Monitoring Noncompliance Indicator*

Use the monitoring indicator when you determine that there is noncompliance with the monitoring requirement. Select this indicator when

- The plant is not monitoring the critical limit at the frequency stated in the HACCP plan.

- The plant is not monitoring the critical limit using the procedures described in the HACCP plan.
- You find a deviation from the critical limit that the plant has no way of detecting. (For example, you verified the monitoring requirement by taking a cooked product temperature of patties coming out of the cooking unit. You find that the critical limit is not met.)
- If you find a noncompliance that is attributed to an unforeseen hazard, document the noncompliance under HACCP monitoring, because the plant was not monitoring sufficiently to discover such a hazard on its own (monitoring was not sufficient to demonstrate process control).

#### *Verification Noncompliance Indicator*

Use the verification indicator when the plant is not conducting the verification activities

- As described in the HACCP plan, or
- At the frequencies described in the HACCP plan.

You also use the verification indicator when a RTE product sample is positive for a pathogen or a food contact surface sample is positive for LM.

#### *Corrective Action Noncompliance Indicator*

The corrective action indicator is used when a deviation or an unforeseen hazard occurs, and the plant's corrective action does not meet the regulatory requirements. For example, you use the corrective action indicator if the corrective actions taken in response to a deviation from a critical limit did not

- Appropriately address, identify and eliminate the cause of the deviation.
- Include measures to ensure that the CCP is under control.
- Include measures to prevent the deviation or unforeseen hazard from recurring.
- Include appropriate disposition of the product.

**Note:** For this indicator, only document a plant's failure to meet the corrective action requirements of 9 CFR 417.3. If the plant finds the deviation or

unforeseen hazard and takes the corrective action necessary to meet the regulatory requirements, there is no noncompliance.

### *Recordkeeping Noncompliance Indicator*

Use the recordkeeping indicator when the

- Monitoring records do not include the actual times, temperatures, or other quantifiable values; the calibration of process-monitoring instruments; corrective actions; verification procedures and results; product identity; signature or initials of the person making the entry; or the date the record is made.
- Plant does not have the decision-making documents associated with selecting and developing CCPs and critical limits, or documents supporting both the monitoring and verification procedures and frequencies.
- Plant did not conduct the pre-shipment review.
- Plant is not retaining HACCP records for the required length of time.

### **Linking NRs**

The purpose of linking NRs is to notify the establishment that its further planned actions are ineffective in preventing the noncompliance from recurring and that, if the trend continues, the repetitive noncompliance would support an enforcement action under the rules of practice. You should be linking NRs together only when the noncompliances are from the **same cause**.

**Good judgment** is necessary when determining which NRs to link together. Remember to follow the thought process, gather information by asking questions, assess the information, and make a sound, supportable conclusion. Some factors to consider are:

1. How much time has elapsed since the previous NR was written?
2. Was this noncompliance from the same cause as the previous NR?
3. Were the establishment's further planned actions implemented?
4. Were the establishment's further planned actions effective in reducing the frequency of these noncompliances?
5. Is the establishment continuing to implement better further planned actions?



6. Are there NRs over the past three months that should be linked to other NRs?
7. Do the NRs establish that there is a persistent problem in the plant's approach to addressing noncompliances (e.g., the establishment's procedures led to repeated noncompliances)?

The answers you obtain from these questions will help you make an informed decision about linking NRs. If you need clarification, contact your supervisor or PDD.

### How to link NRs

When you link one NR to another, you should document:

- The previous NR number and date.
- The further planned action that was ineffective in preventing recurrence of the noncompliance.
- Any discussion with plant management, during the weekly meeting, concerning the trend.
- A statement in Block 10 of the NR that continued failure to meet regulatory requirements can lead to enforcement actions as described in 9 CFR 500.4.

NRs should be linked **as they are issued**. For example, the plant has missed performing a verification procedure. You document this on an NR. A week or so later, the plant again misses a verification procedure. You refer to the first missed verification procedure (linking) in block 10 of the NR by listing the previous NR number and date. If this happens again a short time later, you reference the second NR on this current NR. Therefore, the first NR (first of the trend) is referenced on the second NR; the second NR is referenced on the third NR, and so on. Each NR is a link, and your linking forms a chain of documentation for noncompliance from the same cause. You should document the specific further planned actions that were not implemented or were ineffective in preventing recurrence of the noncompliance.

## Enforcement

When performing procedure 03A01, you take a withholding action when you determine that the HACCP plan is not in compliance with the design or basic regulatory requirements

- If the establishment coming under federal inspection
- If the HACCP plan was developed for a **new** processing category or
- If the HACCP plan was developed for a **new** product.

You do not permit the plant to operate under the noncompliant HACCP plan until the plant corrects the noncompliance.

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

When you determine that the plant does not meet one or more regulatory requirements, document your findings on an NR. If the plant 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.

In other situations, you may take a regulatory control action to prevent shipment of adulterated products. Keep your supervisor informed of any developing trends of noncompliance.

**Note:** 30-day letters are not an enforcement strategy. Do not confuse it with an NOIE, which is part of an enforcement strategy.

## Recalls

Recalls are initiated when there is evidence of unsafe or adulterated product in commerce, for example, when a positive pathogen sample result is obtained for product that the establishment has shipped. The DO and possibly the Recall Management Staff (RMS) evaluate each situation on a case-by-case basis. 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 plant associated with the pathogen, and whether there have been persistent and recurring noncompliances in the plant).

The RMS is notified immediately if product has left the establishment's control, and they coordinate any recall activities. You must determine the status of the products that were produced under the same HACCP plan in the same time frame as the sampled lot and report this back to the DO. The DO notifies the RMS (see FSIS Directive 8080.1, Rev. 4, Recall of Meat and Poultry Products). The RMS 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.

## **Summary for NRTE/RTE HACCP**

The HACCP regulations require that establishments conduct a hazard analysis to determine if there are any food safety hazards that are reasonably likely to occur in the production of meat and poultry food products and to develop critical control points to control those identified hazards.

The culmination of the plant's work (flow chart, hazard analysis, scientific support, critical control points, critical limits, etc.) is the HACCP plan. The plan contains CCPs with procedures and frequencies for monitoring the critical limits that have been established for each hazard identified as reasonably likely to occur. The HACCP plan also contains procedures and frequencies for verifying that the plan is functioning as intended. The HACCP plan identifies records that will be used to document the monitoring of critical limits and to document corrective actions if there is a deviation from a critical limit.

Establishments must be able to support the decisions they made during the hazard analyses and development of the HACCP plans, when setting critical limits and when determining monitoring and verification frequencies. Anytime you have question about the contents of the HACCP plan you may want to review the decision-making documents that the establishment has to support the hazard analysis and the HACCP plan. If you need help in determining whether scientific or technical supporting documentation is valid, you may contact the Technical Service Center.

The processing categories group similar products together based on processing techniques and labeling. Because the steps vary in producing the NRTE/RTE products, the hazards will also vary. Each plant is responsible for producing

product in accordance with §417.2 - 417.7. You are responsible for verifying that the plant is meeting the regulatory requirements.

The Regulatory Process for HACCP is consistent for each processing category in which you are verifying compliance. Understanding your role in properly performing verifications of the plant's monitoring, verification, recordkeeping, corrective actions, and reassessment is vital to accomplishing the Agency's mission of ensuring a safe, wholesome, unadulterated food supply to consumers.

HACCP documentation is important. You use plant documentation to make decisions about noncompliances, deviations, and the adequacy of the plant's HACCP system. The Agency relies on you for the initial documentation to support FSIS decisions regarding enforcement within the plant environment.

Do not be afraid to ask very **specific** questions when you are trying to determine food safety. You are in the plant to enforce the regulations that protect the public health. Be curious and always look a step beyond what you already know to be sure you understand all aspects of the plant environment and production practices that have an impact on the safety of the products produced. Often, the answers you receive will lead you to ask even more questions. You are better equipped to make sound decisions when you have all the answers to your questions. If you exclude some key questions, you may not be obtaining all the information needed for the Agency to properly assess the plant's food safety systems.

As you go about verifying the plant's compliance with regulatory requirements, think of the questions you would ask to aid you in making your determinations. What answers are you seeking and why? These are key factors in a sound decision-making process. The HACCP regulations are the Agency's design and your daily in-plant performance is the application of that design.



3. You are a GS-9, who has begun a new assignment in a facility that produces fully cooked chicken nuggets. Upon your arrival at the plant you took a tour of the facility and observed that the company uses a continuous oven to cook the product. You also noted that upon exiting the oven, the cooked nuggets immediately enter a spiral freezer and are quick frozen within 20 minutes.

Later in the day, as part of your familiarization with the company and its processes, the company QC Supervisor, Mr. J. Dough, conducted an awareness meeting with you where he described the plant operations, the hazard analysis, and the HACCP plan. He informed you that the company has identified one CCP, for lethality, at the cooking step in the hazard analysis. You noted that the company did address the stabilization (cooling) of the cooked chicken nuggets, but had determined that there was not a hazard that was reasonably likely to occur associated with that step in the process. The company's decision was based on the fact that the company is utilizing a quick freezing process. You asked Mr. Dough if the company has any documentation on file that supports that decision. He told you that he doesn't have any documents because everybody knows that the product is frozen so fast that no bacteria could grow.

As a critical thinker, how would you proceed?

Give examples of the type of documentation you might expect to see as decision-making documentation in the company files related to stabilization.

Is there a noncompliance?

If so, what information would you enter in blocks 6-10 on FSIS Form 5400-4, Noncompliance Record? If an NR is needed, complete the next page with as much information as possible.

The request for this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE <b>NONCOMPLIANCE RECORD</b>		TYPE OF NONCOMPLIANCE <input type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection	
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.	
4. TO (Name and Title)		5. PERSONNEL NOTIFIED	
6. RELEVANT REGULATION(S)			
7. SECTION/PAGE OF EST. PRODEDURE PLAN			
	HACCP	SSOP	OTHER
8. ISP CODE		9. NONCOMPLIANCE CLASSIFICATION INDICATORS	
10. DESCRIPTION OF NONCOMPLIANCE:			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.</i>			
12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):			
13. PLANT MANAGEMENT RESPONSE: (Further planned action(s)):			
<b>This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</b>			
14. SIGNATURE OF PLANT MANAGEMENT			15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			17. DATE

**Workshop** 

***Documentation and Enforcement – RTE Product Sampling***

From Est. 38, on February 10, you received a positive *L. monocytogenes* result from a sample of frankfurters you submitted.

What questions would you seek answers to? What actions would you take? If an NR is needed, list all of the information that you would need to include on the NR.



## References

Modified Atmosphere Packaging Fact Book by Li Xiong, Department of Food Science, Pennsylvania State University,  
<http://www.msu.edu/~xiongli/Project/FDS455/FDS455.html>

National Advisory Committee on Microbiological Criteria for Foods, 1998. Hazard analysis and critical control point principles and application guidelines. *Journal of Food Protection*, 61:762.

Stevenson, K.E., & Bernard, D.T., 1999. *HACCP: A systematic approach to food safety, a comprehensive manual for developing and implementing a hazard analysis and critical control point plan*. The Food Processors Institute.

**Regulations**

**Sec. 318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef products.**

- (a) Cooked beef, roast beef, and cooked corned beef products must be produced using processes ensuring that the products meet the following performance standards:
  - (1) Lethality. A 6.5-log<sub>10</sub> reduction of Salmonella or an alternative lethality that achieves an equivalent probability that no viable Salmonella organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.
  - (2) Stabilization. There can be no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than 1-log<sub>10</sub> multiplication of Clostridium perfringens within the product.

**Sec. 318.23 Heat-processing and stabilization requirements for uncured meat patties.**

- (a) Definitions. For purposes of this section, the following definitions shall apply:
  - (1) Patty. A shaped and formed, comminuted, flattened cake of meat food product.
  - (2) Comminuted. A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.
  - (3) Partially-cooked patties. Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.
  - (4) Char-marked patties. Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.
- (b) Heat-processing procedures for fully-cooked patties. (1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

Permitted Heat-Processing Temperature/Time Combinations for Fully-Cooked Patties

Minimum internal temperature at the center of each patty (Degrees)		Minimum holding time after required internal temperature is reached (Time)	
Fahrenheit	Or centigrade	Minutes	Or seconds
151.....	66.1.....	.68	41
152.....	66.7.....	.54	32
153.....	67.2.....	.43	26
154.....	67.8.....	.34	20
155.....	68.3.....	.27	16
156.....	68.9.....	.22	13
157 (and up).....	69.4 (and up)	.17	10

(2) The official establishment shall measure the holding time and temperature of at least one fully-cooked patty from each production line each hour of production to assure control of the heat process. The temperature measuring device shall be accurate within 1 degree F.

(3) Requirements for handling heating deviations. (i) If for any reason a heating deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized FSIS program employee, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence.

(ii) In addition, in the case of a heating deviation, the official establishment may reprocess the affected product, using one of the methods in paragraph (b)(1) in this section; use the affected product as an ingredient in another product processed to one of the temperature and time combinations in paragraph (b)(1) in this section, provided this does not violate the final product's standard of composition, upset the order of predominance of ingredients, or perceptibly affect the normal product characteristics; or relabel the affected product as a partially-cooked patty product, if it meets the stabilization requirements in paragraph (c) of this section.

(c) Stabilization. (1) Fully cooked, partially cooked, and char-marked meat patties must be produced using processes ensuring no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1 log<sub>10</sub> multiplication of *Clostridium perfringens*, within the product.

(2) For each meat patty product produced using a stabilization process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in Sec. 301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(3) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

(4) Partially cooked patties must bear the labeling statement "Partially cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 degrees F)." The labeling statement must be adjacent to the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(5) Char-marked patties must bear the labeling statement "Uncooked, Char-marked: For Safety, Cook Until Well Done (Internal Meat Temperature 160 degrees F)." The labeling statement shall be adjacent to the product name, at least one-half the size of the largest letter in the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

**Sec. 381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips.**

(a) Fully cooked poultry products must be produced using processes ensuring that the products meet the following performance standards:

(1) Lethality. A 7-log<sub>10</sub> reduction of Salmonella or an alternative lethality that achieves an equivalent probability that no viable Salmonella organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved

throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) Stabilization. There can be no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than a 1 log<sub>10</sub> multiplication of Clostridium perfringens within the product.

(b) Partially cooked poultry breakfast strips must be produced using processes ensuring that the products meet the performance standard listed in paragraph (a)(2) of this section. Labeling for these products must comply with Sec. 381.125. In addition, the statement "Partially Cooked: For Safety, Cook Until Well Done" must appear on the principal display panel in letters no smaller than 1/2 the size of the largest letter in the product name. Detailed cooking instructions shall be provided on the immediate container of the products.

(c) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in Sec. 381.1(b). Each process schedule

must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(d) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

## **Part 417--Hazard Analysis And Critical Control Point (HACCP) Systems**

### **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 CCPs, 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. 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.

(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 decisionmaking documents associated with the selection and development of CCPs 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 CCPs 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.