Jump to: HACCP Image Model (Clickable)

HACCP

Regulatory Process
For
HACCP-Based Inspection

Reference Guide

January 1998

United States Department of Agriculture

Food Safety and Inspection Service • Human Resource Development Staff

HACCP

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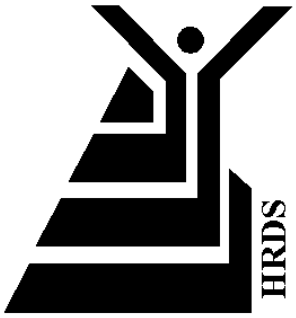

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HACCP Seven Principles

Principle 1 Conduct a Hazard Analysis

Principle 2 Identify Critical Control Points

Principle 3 Establish Critical Limits for Each Critical Control Point

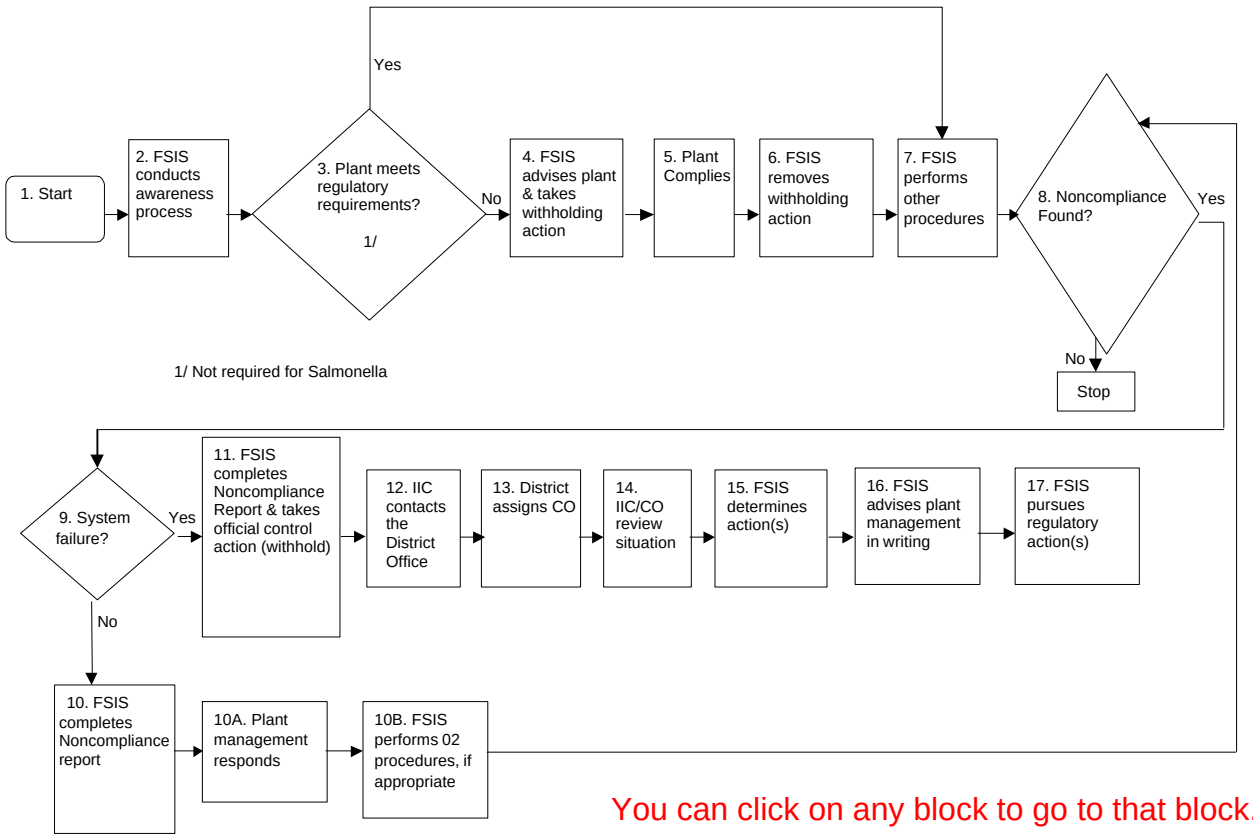
Principle 4 Establish Monitoring Procedures

Principle 5 Establish Corrective Actions

Principle 6 Establish Recordkeeping Procedures

Principle 7 Establish Verification Procedures

Regulatory Process For HACCP- Based Inspection



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Contents

Regulatory Process For HACCP-Based Inspection

Note: The "blocks" listed below and illustrated in the flow diagram on the preceding page represent steps in the regulatory process. Each "block" discussion addresses the decisions and actions required by the FSIS inspector at that step of the process. When applicable, sections from the Pathogen Reduction/HACCP final rule and other regulatory references are noted.

Contents

Block 1—Start

Preamble to Pathogen Reduction/HACCP Final Rule

This final rule published in the July 25, 1996 *Federal Register* requires that federally inspected establishments implement HACCP systems to address hazards that are reasonably likely to occur in their operations. The HACCP systems mandated by this final rule focus on attributes affecting product safety, not those affecting economic adulteration or quality. On the effective dates of this final rule, FSIS will begin verifying HACCP system operations as part of its inspection program.

The HACCP regulations set forth in Title 9 of the Code of Federal Regulations (CFR) part 417 and related provisions set forth in 9 CFR parts 304, 327, and 381 will be applicable as follows:

1. In large establishments, defined as all establishments with 500 or more employees, on January 26, 1998.

2. In smaller establishments, defined as all establishments with 10 or more employees but fewer than 500, on January 25, 1999.

3. In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than $2.5 million, on January 25, 2000.

Inspection Under HACCP

HACCP-oriented food safety inspection changes the approach of FSIS to overseeing the safety of meat and poultry products. Under this new approach, FSIS will rely less on after-the-fact detection of product and process defects and more on verifying the effectiveness of processes and process controls designed to ensure food safety. FSIS will restructure its inspection procedures to determine that production systems prevent the production of unsafe meat and poultry products. FSIS will carry out various activities to ensure that industry HACCP systems meet the requirements of this rule, and are functioning as designed.

The establishment must comply with all regulatory requirements. The establishment must develop written plans/procedures for HACCP, SSOP, and *E. coli* testing. Any time inspection personnel determine that regulatory requirements have not been met, the noncompliance will be documented and appropriate enforcement action will be taken. Upon initiation, inspection personnel verify that the plan or procedure is apparently responding to all regulatory requirements. If a required feature is not included in the plan or procedure, the nonconformance is documented and enforcement action is taken. Additional verification activities and noncompliance documentation are used to

Block 1—Start

determine whether there has been a system failure. Enforcement is the action taken by inspection personnel when a failure has occurred.

Actions

Block I

Preparation is essential for success. Before performing any task for regulatory enforcement of part 417 or other regulatory requirements, FSIS inspection program personnel must ensure that they:

1. know the regulatory requirements for HACCP

2. have the equipment, supplies, and references needed to perform and document their inspection findings

Decisions

Model

Once prepared, FSIS inspection program personnel will proceed to:

Block 2	if the task is conducting awareness process of a HACCP plan
Block 7	if the task is to perform other procedures

The color Cyan around any block means it is clickable.

Block 2—FSIS Conducts Awareness Process

Before performing basic compliance/noncompliance procedures, it is essential that inspection program and plant personnel understand the HACCP plan of the plant. To accomplish such understanding, the Inspector in Charge (IIC) should hold an awareness meeting between inspection program personnel and plant personnel.

First, the IIC will decide who will be involved in the meeting. Key management personnel responsible for development and maintenance of the company's HACCP plan and inspection program personnel performing HACCP inspection procedures should participate in this meeting.

Second, the IIC will determine how much time will be needed for the meeting. The amount of time will vary according to the plant size and complexity of the plans. One to four days may be needed for meetings in large plants. From four hours to one day may be all that is needed in small and very small plants.

The IIC might request an opportunity to review the HACCP plan before the awareness meeting to help decide how much time will be needed for the meeting. An outline can be made for the items to be discussed. As the SSOP plan, however, the HACCP plan is property of the establishment.

Because HACCP plans are plant-specific, inspection program personnel cannot effectively perform HACCP procedures until they understand the plan. The awareness meeting provides an opportunity for inspection program personnel to familiarize themselves with the plan. They can also learn about the plan in operation, such as where the HACCP records are kept, how to gain access to the computer, and where the CCPs are located.

Block 2

Upon completing the Awareness meeting, proceed to:

Block 3 Plant Meets Regulatory Requirements?

Model

Block 3—Plant Meets Regulatory Requirements?

Regulations–Sec. 417.2 Hazard Analysis and HACCP Plan

(a) Hazard analysis

(1) Every official establishment shall conduct, or have conducted, 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 in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards may be expected 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

(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

Block 3—Plant Meets Regulatory Requirements?

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 the Federal meat and poultry inspection regulations.

(c) 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

(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 section 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 the Federal meat and poultry inspection regulations, to be followed in response to any deviation from a critical limit at a critical control point

(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 the Federal meat and poultry inspection regulations.

(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

(iii) At least annually, upon reassessment, as required under Section 417.4(a)(3) of the Federal regulations.

(e) Pursuant to Title 21 of the U.S. Code of Federal Regulations, 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 the regulations may render the products produced under those conditions adulterated.

Section 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 the Federal regulations, which could include adapting a generic model that is appropriate for the specific product

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

(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.

Block 3—Plant Meets Regulatory Requirements?

Actions

Block 3

When the HACCP system regulations first apply to an establishment and, as appropriate, thereafter, inspection program personnel will perform Inspection System Procedure (ISP) 03A01 to determine whether an establishment has apparently complied with the requirements. (See the basic compliance checklist, FSIS Form 5000.1-1.)

Basic compliance checks–ISP procedures 01A01, 03A01, 05A01–focus on whether an establishment has failed to institute the system features required by FSIS regulations: i.e. either the establishment does not have a required plan or procedures or recordkeeping (for example, when an establishment does not have written SSOPs or written procedures for collecting samples for *E. coli* testing) or, what the establishment has clearly does not meet regulatory requirements (for example, when the SSOPs of an establishment do not identify which procedures are pre-operational procedures; or, when a HACCP plan does not list the critical limits to be met at each critical control point or does not identify the corrective action to be taken in response to a deviation from a critical limit at a critical control point).

When performing the basic compliance/noncompliance procedure, inspection program personnel are to use the basic compliance checklist to ensure compliance with the regulatory requirements. The regulatory requirements are included on the checklist in FSIS Directive 5000.1 II.B.

Decisions

After FSIS inspection program personnel establish whether a plant meets regulatory requirements, they should proceed to:

Block 7 if the plant plan meets regulatory requirements; or

Block 4 if one or more regulatory requirements have not been met.

Block 4—FSIS Takes Withholding Action

Finding noncompliance with requirements(s) in and of itself supports the withholding of inspection to prevent the production of products until the failure is remedied.

If noncompliance with requirements involves only a failure that the responsible establishment official can resolve effectively and immediately (for example, if the responsible establishment official did not sign or date the HACCP plan when required), before taking corrective steps, inspection program personnel are to provide establishment management with an opportunity to bring the establishment into compliance as set forth in FSIS Directive 5000.1 II.C.

Actions

Block 4

Any time noncompliance is found while performing the basic compliance procedure, it should be completely described on a Noncompliance Record (NR) FSIS Form 5400-4.

An IIC who determines that an establishment has failed to meet one or more of the requirements should take the following steps:

1. Advise establishment management orally of the findings on which the intended action is based and (as soon as possible and by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance findings(s)

2. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or “inspected for wholesomeness”

   Identify all possibly adulterated livestock or poultry products as “U.S. Retained”

3. Notify the District Office of the actions(s) taken and, if the establishment does not initiate action immediately to bring itself into compliance:

   a. the District Manager (DM), who will assign a Compliance Officer (CO) and,

   b. in conjunction with the CO, develop a case file and take further action as appropriate.

Block 4—FSIS Takes Withholding Action

Decisions

FSIS will continue to withhold marks of inspection until the plant meets the regulatory requirements. FSIS inspection program personnel must determine when requirements have been met. After FSIS inspection program personnel establish that requirements have been met, they should proceed to:

Block 5	Plant Complies	Model

Block 5—Plant Complies

Actions

Block 5

No further action is required by FSIS in this block. The withholding action imposed under Block 4 remains in effect until the plant complies with the HACCP regulations.

Decisions

If or when the noncompliance is corrected, FSIS inspection program personnel will proceed to:

Block 6	FSIS Removes Withholding Action	Model

Block 6—FSIS Removes Withholding Action

Establishment is allowed to resume operation.

Actions

Block 6

When the plant is in compliance with HACCP regulatory requirements, FSIS will remove the withholding action and allow the plant to resume operations and proceed to:

Block 7 FSIS Performs Other Procedures

Model

Block 7—FSIS Performs Other Procedures

FSIS Directive 5000.1 Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations

III. COMPLIANCE/NONCOMPLIANCE--OTHER REQUIREMENTS

A. General

Inspection program personnel will perform procedures (ISP procedures 03B01 and 02 through 03J01 and 02) to verify the adequacy of an establishment's HACCP plan(s) by making determinations about compliance with regulatory requirements.

PBIS will schedule procedures, selecting either--

- a procedure for reviewing features of a HACCP plan in operation (for example, correlating records with random observation or measurement at a CCP), or
- a procedure for reviewing implementation of a HACCP plan for a particular product.

The objective of these activities is to determine whether, as documented in its records (§ 417.5), the establishment is complying with the requirements for implementation of a HACCP plan, including monitoring, verification, and corrective action requirements (§§ 417.2(c)(4) and (c)(6), 417.3, 417.4(a), and 417.5 and § 304.3(c) or § 381.22(c)), so that FSIS can make determinations about HACCP system adequacy (§ 417.6), including whether the system prevents the distribution of adulterated products that may endanger public health.

In addition, for products covered by Salmonella performance standards (§§ 310.25(b)(1) and 381.94(b)(1)), noncompliance with the standard may constitute failure to maintain an adequate HACCP plan, which would result in the suspension of inspection services (paragraph (b)(3)(iii) of § 310.25 or § 381.94). (The DO will provide further information and instructions on a case-by-case basis.) Similarly, finding Listeria monocytogenes in a ready-to-eat product or residues of an animal drug that are not within an applicable tolerance established under the Federal Food, Drug, and Cosmetic Act is evidence that a HACCP plan may be inadequate and, therefore, should be reassessed.

Block 7—FSIS Performs Other Procedures

B. Requirements

The particular ISP procedure may focus on one or more of the requirements addressed in this Paragraph III.B.

1. Establishment monitoring

a. The establishment is monitoring CCP's to ensure compliance with critical limits (§ 417.2(c)(4)).

b. Establishment records documenting the monitoring of CCP's include the recording of actual values (in terms of observations and times, temperatures, and/or other quantifiable limits in the HACCP plan) (§§ 417.2(c)(6) and 417.5(a)(3)).

2. Establishment verification

a. The establishment is verifying the implementation of its HACCP plan(s) by performing verification activities (§§ 417.2(c)(7) and 417.4(a)(2)).

b. Establishment records documenting verification activities include:

- but are not limited to, the calibration of process-monitoring instruments, direct observations of monitoring activities and corrective actions, and the review of records generated and maintained in accordance with §417.5(a)(3).

- the review, prior to shipping product, of the records associated with the production of that product to ensure completeness. Where practicable, this review will be conducted, dated, and signed by an individual who did not produce the record(s).

(§§ 417.4(a)(2) and 417.5(c))

Block 7—FSIS Performs Other Procedures

c. If an establishment that slaughters cattle, swine, chickens, or turkeys has substituted an alternative frequency for the frequency of sampling for E. coli specified in § 310.25(a)(2)(iii) or § 381.94(a)(2)(iii), the alternative is an integral part of the establishment's verification procedures (paragraph (a)(2)(iv) of § 310.25 or § 381.94; see Part Four, Paragraph III.B.1.d.).

3. Deviations from critical limits

a. Corrective actions

(1) The HACCP plan assigns responsibility for taking corrective action (by, for example, specifying the establishment personnel who will perform various activities) (§ 417.3(a)).

(2) In response to a deviation from a critical limit for which a HACCP plan identifies the corrective action to be taken, the establishment followed the corrective action procedure(s) in the plan (§§ 417.2(c)(5) and 417.3(a)).

(3) The establishment's records document corrective action taken in response to a deviation from a critical limit, including procedure(s) to--

- identify and eliminate the cause of the deviation,
- bring the CCP under control,
- establish measures to prevent recurrence, and
- prevent distribution of product adulterated as a result of the deviation.

(§§ 417.3(a) and (c) and 417.5(a)(3))

b. Unforeseen hazards. In response to a deviation from a critical limit that a HACCP plan does not cover with a specific corrective action, the establishment's records document procedures used to segregate and hold affected product, at least until the establishment--

- performed a review to determine the acceptability of affected product for distribution, and

Block 7—FSIS Performs Other Procedures

- o when necessary, took action to ensure that product adulterated as a result of the deviation would not be distributed

(§§ 417.3(b) and (c) and 417.5(a)(3))

4. Plan reassessment and modification

a. Reassessment

(1) If a deviation that is not covered by a corrective action specified in a HACCP plan occurred, or another unforeseen hazard arose, the establishment reassessed the HACCP plan (§ 417.3(b)(4)).

(2) If a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding the applicable performance standard (in Table 2 of § 310.25(b)(1) or § 381.94(b)(1)) on the second consecutive series of FSIS tests for that product, the establishment reassessed the HACCP plan for that product (paragraph (b)(3)(ii) of § 310.25 or § 381.94).

(3) If there was a change that could affect the hazard analysis or alter a HACCP plan, the establishment reassessed the HACCP plan (§ 417.4(a)(3)).

b. Modification. If a plan reassessment revealed that a HACCP plan no longer meets the requirements in § 417.2(c), the establishment modified the HACCP plan (§ 417.4(a)(3)).

c. Training. The individual who performed the reassessment or modification of a HACCP plan meets the training requirements in § 417.7(b) (§§ 417.3(b)(4), 417.4(a)(3), and 417.7(a)(2)).

5. Records

a. HACCP plan support. Establishment records--

- o document the decisionmaking associated with the selection and development of CCP's and critical limits, including references to the basis (scientific or technical and/or regulation(s)) for each, and

Block 7—FSIS Performs Other Procedures

- o support the monitoring and verification procedures that the establishment has selected and the frequency with which the establishment conducts those procedures

(§ 417.5(a)(2))

b. Product identification. Establishment records document slaughter production lot, product code(s), product name, or other identifier (§ 417.5(a)(3)).

c. Authentication. Each entry on a record maintained under a HACCP plan--

- o is made at the time the specific event occurs,
- o includes the date and time that the entry was recorded, and
- o is signed or initialed by the establishment employee who made the entry

(§ 417.5(b))

(Note: Any other record required by § 417.5(a)(3) must include the date on which the record was made.)

d. Data integrity. The establishment has implemented controls to ensure data integrity for HACCP plan records maintained on computers (if any) (§ 417.5(d)).

e. Records review. Prior to shipping a product for distribution, the establishment's review of the records associated with the product's production (to ensure completeness) includes--

- o a determination that all critical limits were met, and
- o when appropriate, a determination that the establishment took corrective action(s), including the proper disposition of product

(§ 417.5(c))

Block 7—FSIS Performs Other Procedures

(Note: Where practicable, an individual who did not produce the records must conduct, date, and sign this review.)

f. Retention and availability

(1) The establishment retains records required by § 417.5(a)(3) for at least the following period(s):

- o 1 year for slaughter activities and for refrigerated product;
- o 2 years for product that is frozen, preserved, or shelf-stable

(§ 417.5(e)(1)).

(2) Records required by § 417.5(a)(3):

- o are on-site for at least 6 months, and
- o are available within 24 hours of an FSIS employee's request if stored off-site after 6 months

(§ 417.5(e)(2))

(Remember, the specific retention period and location requirements do not apply until the date on which an establishment must comply with the HACCP system regulations.)

Block 7—FSIS Performs Other Procedures

Actions

Block 7

Inspection program personnel will perform procedures (ISP procedures 03B01 and 02 through 03J01 and 02) to verify the adequacy of an establishment's HACCP plan(s) by making determinations about compliance with regulatory requirements.

PBIS will schedule procedures, selecting either--

- o a procedure for reviewing features of a HACCP plan in operation (for example, correlating records with random observation or measurement at a CCP), or

- o a procedure for reviewing implementation of a HACCP plan for a particular product.

The objective of these activities is to determine whether, as documented in its records (§ 417.5), the establishment is complying with the requirements for implementation of a HACCP plan, including monitoring, verification, and corrective action requirements (§§ 417.2(c)(4) and (c)(6), 417.3, 417.4(a), and 417.5 and § 304.3(c) or § 381.22(c)), so that FSIS can make determinations about HACCP system adequacy (§ 417.6), including whether the system prevents the distribution of adulterated products that may endanger public health.

In addition, for products covered by Salmonella performance standards (§§ 310.25(b)(1) and 381.94(b)(1)), noncompliance with the standard may constitute failure to maintain an adequate HACCP plan, which would result in the suspension of inspection services (paragraph (b)(3)(iii) of § 310.25 or § 381.94). (The DO will provide further information and instructions on a case-by-case basis.) Similarly, finding Listeria monocytogenes in a ready-to-eat product or residues of an animal drug that are not within an applicable tolerance established under the Federal Food, Drug, and Cosmetic Act is evidence that a HACCP plan may be inadequate and, therefore, should be reassessed.

Block 7—FSIS Performs Other Procedures

Decisions

Whenever inspection program personnel perform a procedure in the Inspection System Procedure (ISP) guide, whether scheduled or unscheduled, they either do or do not find noncompliance with one or more regulatory requirements.

Upon completion of an inspection procedure(s), FSIS inspectors will proceed to:

Block 8	determine whether a noncompliance exists

[Note: Further discussion regarding procedures 01 and 02 may be found under Block 10B, page 28, of this document.]

Model

Block 8—Noncompliance Found?

Noncompliance is the failure to meet any HACCP requirement. To determine noncompliance, inspection program personnel should use what is known to them as a fact and what is reasonable to assume. In making a determination, inspection program personnel must assess their observations, analyze the facts, and decide which performance standards or regulatory requirements apply.

Actions

Block 8

Model

Decisions

Upon completion of an inspection procedure(s), FSIS inspectors will proceed to:

Block 9	if a noncompliance is found to determine whether a System Failure exists, or
Stop	when noncompliance with regulatory requirements is not found, the procedure is recorded as "performed" on the Procedure Schedule (PS). FSIS sampling is recorded as "performed" as well.

Block 9—System Failure?

1. Has the establishment met the basic regulatory requirements? That is, if the establishment is not implementing all or some of its program, it has not met the basic 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 meets the requirements---then the establishment has not met the regulatory requirements. Therefore, inspection program personnel are unable to make the determination 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 for not meeting the Basic regulatory requirements. This noncompliance would be documented under the Basic procedure code 03A01.

   The determination of an inadequate system in this case could be accomplished by performing the 01 or 02 procedure.

2. Was adulterated product produced or shipped?

   The IIC has determined that the HACCP system did not prevent the production and distribution of adulterated product. 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. If inspection program personnel are able to make this determination, and the establishment has performed its pre-shipment review, then the HACCP system is inadequate.

   The determination of an inadequate system in this case could only be accomplished by performing the 02 procedure. It should be kept in mind that inspection program personnel could have performed the 02 procedure in response to noncompliance found during the 01 procedure.

Block 9—System Failure?

3. Is there a trend in establishment noncompliance?

   Inspection program personnel should observe trends in the noncompliance classification indicators marked on NRs when determining whether an establishment's HACCP system is inadequate. If two or more NR's have the same noncompliance classification indicators marked and if descriptions of noncompliance indicate that similar problems are recurring, there may be a trend indicating the HACCP system is inadequate. Because there will be a great 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, inspection program personnel must thoroughly analyze and document noncompliance trends that may support a determination.

   When reviewing a possible trend in incidents of noncompliance, inspection program personnel must closely review the descriptions of noncompliance contained in Block 10 of the NR form. Inspection program personnel should not solely rely on the number of marked noncompliance classification indicators. Only through careful analysis of written descriptions of noncompliance can inspection program personnel determine whether there is a trend indicating that a HACCP system may be inadequate.

   To adequately identify and track trends, inspection program personnel should document incidents of noncompliance, even if found and corrected by the establishment at a later step in the process. For example, if inspection program personnel observe that a designated establishment employee has failed to monitor a critical limit as specified within a HACCP plan, the incidence of noncompliance should be documented in an NR, even if the establishment also has discovered and corrected this noncompliance during verification.

4. Did the establishment review the records associated with production of the product? This review should have included determination that all critical limits were met and, if appropriate, corrective actions were taken, including proper disposition of product.

   If the establishment has not performed the pre-shipment review, then it has not met the regulatory requirements Section (417.5(c)of the Federal regulations). In such cases, inspection program personnel are unable to make the determination that the establishment is not producing adulterated product, and therefore the HACCP system is inadequate.

   The determination of an inadequate system in this case could only be accomplished by performing the 02 procedure.

Block 9—System Failure?

Actions

Block 9

When noncompliance with requirements is found, FSIS inspection program personnel will proceed to:

Block 10	in situations where noncompliance has been determined but there is not a system failure; or
Block 11	if the IIC has documented that a HACCP system did not prevent the production and distribution of adulterated product
Model	the violations include failures to comply with requirements for monitoring for CCP's, to respond to deviations from critical limits, and to document verification and review of production records.

Block 10—FSIS Completes Noncompliance Report

Recording Noncompliance

All noncompliance will be documented on a Noncompliance Record (NR) with NR Continuation Sheet(s) attached as appropriate. The most appropriate trend indicator will be marked on the NR.

Describing the Noncompliance

Noncompliance must be accurately described in Block 10 of the NR. The NR is an official record used by the inspector to document noncompliance. All information related to the noncompliance must be included when describing the noncompliance. Because NRs may be used to support an enforcement action, they must be written in a manner that will allow anyone reading the narrative to accurately visualize the noncompliance. If additional space is needed to describe a noncompliance, an NR Continuation Sheet should be used, and a notation to that effect should be made in Block 10. NR Continuation sheets should be attached, as appropriate.

Supporting Information

When documenting noncompliance, it is important to reference supporting documentation. The regulatory requirement that was not met must always be cited (for example, Section 417.3). The documentation should include the page and/or part number of the establishment's HACCP plan when the plan requirements are not met. The date and the name and/or number of the plant record must always be cited when describing any noncompliance connected with HACCP records. To adequately identify trends in noncompliance, it is important that the description include the date and number of related NRs. Also, it should be noted what corrective actions were taken in response to the related incidences of noncompliance and whether or not the failure of those corrective actions contributed to the current noncompliance.

A Noncompliance Record, FSIS Form 5400.5-4, serves as FSIS official record of noncompliance with one or more regulatory requirements. (As stated on the NR: "This document serves as written notification of your failure to comply with regulatory requirement(s), which could result in additional regulatory and administrative action.")

Block 10—FSIS Completes Noncompliance Report

Actions

Block 10

If the inspector is not able to determine that there is a system failure, the enforcement action is taken in accordance with Part Three of FSIS Directive 5000.1 III.C. 2. The inspector should:

- take official control action as appropriate
- advise establishment management by providing a copy of the NR that documents the noncompliance finding(s) as soon as possible and no later than the end of the tour of duty and give management an opportunity to respond
- complete documentation of establishment action(s) to bring the establishment into compliance (see FSIS Directive 5400.5)
- notify the DO if the establishment does not bring itself into compliance

Until an establishment is in compliance with the regulatory requirements(s) that resulted in issuance of an NR, the NR is "open". Inspection program personnel should review the file of "open" NRs daily

Inspection program personnel who find noncompliance with one or more regulatory requirements should also (1) categorize the noncompliance by marking the appropriate PS and NR indicator, and (2) document followup and their findings, using an NR.

It is the purpose of trend indicators to improve the ability of FSIS to evaluate establishment performance and process control by providing information on trends in noncompliance. FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance. Inspection program personnel must mark the indicator that best describes the noncompliance

Decisions

FSIS inspector completes NR for noncompliance and proceeds to:

Block 10A Plant Management Responds

Model

Block 10A—Plant Management Responds

Actions

Provide establishment management with an opportunity to respond to the NR, either orally or in writing. Block 12 of the NR–immediate action(s)–is used to show action the establishment is taking to correct the noncompliance that resulted in issuance of the NR, including appropriate product disposition. Block 13–further planned action(s)–is used to show action the establishment plans to take to bring itself into compliance with regulatory requirements; such action should include measures to prevent recurrence.

Inspection program personnel need to determine that the immediate and further planned actions bring the establishment back into compliance with regulatory requirements. **Official control action will be maintained if the inspector cannot determine from the identified actions that the plant is in compliance with regulatory requirements.**

When an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an NR, inspection program personnel should file the NR as "closed"

Block 10A.

Model

Decisions

FSIS proceeds to:

Block 10B.	FSIS Performs 02 Procedure, if appropriate.

Block 10B—FSIS Performs 02 Procedure, If Appropriate

Procedures 01 and 02

Because some of the requirements have records associated with them, both the 01 and 02 procedures have two components–**review and observation** and **recordkeeping review**. Both the 01 and 02 procedures can be used to verify each of the five features of HACCP systems. The method used to perform the procedure is **one** difference between them.

The 01 procedure is used to review at **random** the HACCP plan features in operation. Using the review and observation or recordkeeping component, any combination of the requirements can be randomly verified. It would be equally appropriate to focus on one feature specifically while performing the 01 procedure. For example, an inspector may decide to observe a plant employee measuring a critical limit and recording the result. The inspector may then measure the critical limit and compare his or her finding with the limit that the employee recorded. The inspector may also review CCP records for a different lot or lots of product or calibration records before considering the procedure complete.

The 02 procedure is used to **verify all requirements.** The 02 procedure focuses on the system in operation by making determinations about whether the establishment is following the HACCP plan: establishment personnel perform tasks in the plan, corrective actions are taken, and pre-shipment review prevents distribution of adulterated product for a given lot or shipment. For 02, inspection program personnel can use review and observation or recordkeeping review.

It is important to point out that because the 01 procedure is **random**, it is performed to determine whether the plant meets the HACCP regulatory requirements. Because the 02 procedure applies to an entire given lot or shipment, inspection program personnel are additionally determining whether the HACCP system worked.

In this procedure while the product is being produced, the inspector will verify each CCP, each CCP verification activity performed, the corrective action (if any) taken in response to a deviation, any reassessment conducted in response to a deviation, and the pre-shipment review for that specific production lot. The 02 procedure is not considered complete until after the inspector has verified the establishment's pre-shipment review. Therefore, performing the 02 procedure may be time-consuming, depending on the process.

If, while performing the 01 procedure, inspection program personnel determine noncompliance with the HACCP regulatory requirements, inspection program personnel should further verify whether the plan prevented adulterated product from being shipped. To make such verification, inspection program personnel will perform an 02 procedure **any time** noncompliance is found on an 01

Block 10B—FSIS Performs 02 Procedure, If Appropriate

procedure. When performing the 02 procedure, inspection program personnel should focus on very specific parts of the requirements.

Actions

Block 10B

Model

Decisions

If an 02 procedure is performed, proceed to:

Block 8 to determine whether a Noncompliance exists.

Block 11—FSIS Completes Noncompliance Report and Takes Official Control Action (Withhold)

Recording Noncompliance

All noncompliance will be documented on an NR with NR Continuation Sheet(s) attached, as appropriate. The most appropriate trend indicator will be marked on the NR.

Describing the Noncompliance

Noncompliance must be accurately described in block 10 of the NR. The NR is an official record used by the inspector to document noncompliance. All information related to the noncompliance must be included when describing the noncompliance. Because NRs may be used to support an enforcement action, they must be written in a manner that will allow anyone reading the narrative to accurately visualize the noncompliance. If additional space is needed to describe a noncompliance, an NR Continuation Sheet should be used, and a notation to that effect should be made in block 10. NR Continuation sheet(s) should be attached, as appropriate.

Supporting Information

When documenting noncompliance, it is important to reference supporting documentation. The regulatory requirement that was not met should always be cited (for example, Section 417.3). The page and/or part number of the establishment's HACCP plan must be included when the plan requirements are not met. The date and the name and/or number of the plant record must always be cited when describing any noncompliance connected with HACCP records. To adequately identify trends in noncompliance, it is important that the description include the date and number of related NRs. Also, it should be noted what corrective actions were taken in response to the related incidences of noncompliance and whether or not the failure of those corrective actions is responsible for the current noncompliance.

Block 11—FSIS Completes Noncompliance Report and Takes Official Control Action (Withhold)

Actions

Finding noncompliance with requirements(s) in and of itself supports the withholding of inspection to prevent the production of products until the failure is remedied.

1. Establishment management should be advised orally of the findings on which the intended action is based

2. a. The inspector should refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness"

   b. All possibly adulterated livestock or poultry products must be identified as "U.S. Retained"

Decisions

FSIS inspector completes NR for system failure and proceeds to:

Model

Block 12	IIC contacts the District Office.

Block 12—IIC Contacts the District Office

It is important to reiterate that inspection program personnel are to contact the **District Office** in cases of a withholding action due to a system failure.

Actions

Block 12

Notify the DO of actions taken.

Decisions

FSIS inspector proceeds to:

Block 13 District assigns CO

Model

Block 13—District Assigns CO

Actions

Block 13

The DM will assign a CO, who will visit the establishment and initiate a case file.

Decisions

Go To Block 14	IIC/CO review situation	Model

Block 14—IIC/CO Review Situation

Actions

Block 14

When inspection program personnel have documented noncompliance or linkages between several noncompliances that demonstrate a systems failure for HACCP, a Compliance Officer will visit the plant and establish a case file. To ensure that this occurs, inspection program personnel will call the District Office. The District Office will contact a Compliance Officer, who will visit the plant as soon as possible.

Once the Compliance Officer arrives at the plant, he or she will review the Noncompliance Record files to develop a case history. This history will aid the District Manager in deciding whether to either sustain current action or take further regulatory action.

When the Agency proceeds with regulatory action, the case file is presented as official evidence. All documentation must be written so that legal authorities can understand the seriousness of the noncompliance. Because documentation must support regulatory actions, documentation is important. The Compliance Officer will go through documentation looking for linkages or recurring noncompliance to prove that the plant does not have proper control over its processes. The Compliance Officer will stress these points in the case file.

In addition to the documents, the Compliance Officer will take a statement from the inspector. This is important because it establishes the inspector as a field expert. It allows the thought process to be captured in writing for legal authorities to review and understand without interviewing the inspector at the time of the review. The statement also demonstrates that inspection program personnel are working within the scope of their employment if later indemnification occurs. It should be kept in mind that the Compliance Officer needs the help of inspection program personnel to build a case.

Go To Block 15 FSIS Determines Action(s)

Block 15—FSIS Determines Action(s)

Actions

Block 15

Suspension and withdrawal actions are subject to Department and Agency supplementary guidelines and rules of practice. Inspection program personnel will receive specific instructions on appropriate in-plant controls on a case-by-case basis from the District Office.

Decisions

Go To Block 16 FSIS advises plant management in writing

Model

Block 16—FSIS Advises Plant in Writing

Actions

Block 16

The DM notifies the plant of the enforcement actions from this point.

Decisions

Go To Block 17	FSIS pursues regulatory action(s)	Model

Block 17—FSIS Pursues Regulatory Action(s)

Actions

Block 17

Regulatory actions are subject to Department and Agency rules of practice. Inspection program personnel will receive specific instructions on appropriate in-plant controls on a case-by-case basis from the District Office.

Model

Other Consumer Protection

At this time, regulatory requirements for other consumer protection activities such as misbranding or economic adulteration have not changed. The Deficiency Classification Guide will no longer be used in establishments subject to the Pathogen Reduction/HACCP regulations. The Compliance/Noncompliance Determination Guide covers all areas of FSIS regulatory responsibility. FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance.

Industry must prevent contamination and adulteration and comply with other FSIS regulations. When contamination or adulteration occurs, the establishment management has the responsibility to bring the establishment into compliance by controlling the immediate situation and preventing recurrence of the problem. Actions that do not accomplish both are inadequate. Adulterated or misbranded product must not be produced but, if contamination or adulteration occurs, corrective actions must be taken to prevent the product from being distributed and preventive measures must be taken to prevent recurrence.

FSIS will continue to have responsibility for ensuring that adulterated product does not enter commerce, even if such adulterated product is not a food safety hazard. For example, if product identified as "Bologna", made with beef and chicken, is being labeled as "Beef Bologna", inspection program personnel would initiate official control actions, document the noncompliance on an NR, and mark the "Misbranding" trend indicator on the Procedure Schedule (PS) and the Noncompliance Record. In other situations, official control actions might not be necessary, but the noncompliance would still be recorded on an NR and given to management as notification of the failure to comply with regulatory requirements. For example, if unused equipment and supplies were stored on the ground outside the plant and a mouse is seen running under the equipment, the "outside premises" trend indicator would be marked on the PS and NR. The noncompliance would be documented on the NR and given to plant management as notification of failure to meet regulatory requirements. The establishment is responsible for bringing itself into compliance with regulatory requirements. The establishment actions should address proper product disposition and measures to prevent recurrence. Documentation of recurring or repeated noncompliance with regulatory requirements may be used as a basis for further FSIS actions.

Regulatory Process For **Other** Consumer Protection Activities